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COMMENTS

THE INCREASING NECESSITY OF THE TORT SYSTEM IN EFFECTIVE DRUG REGULATION IN A CHANGING REGULATORY LANDSCAPE

ANNE ERIKSON HAFNER*

Plaintiffs injured by defective drugs have several types of tort remedies, the most effective being failure to warn and misrepresentation claims. While the Food and Drug Administration (FDA) fulfills its regulatory function by prescribing and supervising the drug approval process, it is the interplay of the regulatory and tort systems that strikes a necessary balance between developing innovative new drugs and protecting consumers from the enticement of profiteering drug companies. Pre-marketing approval of new drugs has always relied upon clinical trials performed solely by drug companies. Yet, in the past ten years, systemic changes have altered the drug regulation and enforcement landscape. These changes have increased the necessity of preserving traditional tort remedies against the drug manufacturers who control the manufacturing, testing, and approval process.

When defective drugs harm consumers, the options for compensation are already limited. While the FDA ultimately approves a drug for marketing, the Federal Tort Claims Act bars most claims against the agency incident to drug approval, absent egregious misconduct. Claims against drug manufacturers are already somewhat limited by the learned intermediary doctrine, which shifts liability for failure to warn from manufacturers to doctors. Meanwhile, regulatory compliance defenses for drug manufacturers proposed in a recent wave of state and federal tort reform measures would limit liability yet again. The result of these converging developments may be to leave the injured drug consumer remediless.

This Comment examines the role of the tort system in effective prescription drug regulation and enforcement, specifically in light of these recent legislative, regulatory, and administrative developments. Part I provides context for this discussion with a brief overview of current and proposed tort reform measures at their intersection with FDA regulation, which entails a brief discussion of FDA history, the current FDA regulatory process, and an overview of available common law tort claims currently available for injured drug consumers. This section also addresses three important changes to prescription drug regulation in recent years: the Prescription Drug User Fee Act of 1992, the 1997 FDA *Guidance for Industry*:

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Consumer-Directed Broadcast Advertisements, and the November 2001 Department of Health and Human Services (HHS) policy directive to the FDA.

Part II documents the positive and negative effects of these recent changes on the pharmaceutical industry, the FDA, and drug consumers. Notably, drug approval times have been shortened, and more new drugs make it to market than ever before. However, the expedited drug approval process has increased FDA research workload and contributed to more defective drugs also reaching consumers at a greater rate than ever before. Part II examines this data in the context of relaxed direct-to-consumer advertising regulation and enforcement. This relaxation has led to a drastic increase in expenditures by pharmaceutical companies on direct-to-consumer advertising. In effect, many of the drugs that are most heavily advertised post the largest profit margins. This Comment argues that regulation of advertising by the FDA has been inadequate, often leaving consumers with misperceptions of the efficacy of drugs advertised on television. When coupled with the increased likelihood that these drugs are defective, there is much cause for alarm.

Due in part to the recent scandals over Vioxx, Baycol, and Paxil, the FDA faces renewed criticism for its role in the approval and regulation of defective drugs. Part III examines the inadequacy of FDA oversight and the reasons why the tort system is necessary for effective drug regulation and enforcement despite the regulatory framework. Specifically, this section examines the role of traditional tort remedies as both a carrot and a stick in promoting good drug manufacturing practices, full disclosure of adverse drug reactions, and compliance with FDA advertising standards. Finally, Part IV revisits the regulatory compliance defense, and explains why the defense is dangerous to drug consumers in the current landscape.

I. THE DRUG REGULATION LANDSCAPE

A. *A Rising Tide of Tort Reform*

Publicity in recent years surrounding excessive jury verdicts and punitive damage awards has fueled a national outcry for state and federal tort reform. Several political organizations have led the charge to cap punitive damages in jury verdicts and otherwise “reform” plaintiffs’ actions in a variety of areas, including health care liability, products liability, and class action lawsuits.¹ Such efforts

1. See, e.g., Lawsuit Abuse Reform Coalition, <http://www.lawsuitabusereform.org> (last visited Sept. 21, 2006) (“a broad spectrum of American businesses fighting against lawsuit abuse”); American Tort Reform Association, <http://www.atra.org> (last visited Sept. 21, 2006) (calling for change through “health care liability reform, class action reform, promotion of jury service, abolition of the rule of joint and several liability, abolition of the collateral source rule, limits on punitive damages, limits on non-

recently resulted in the passage of the federal Class Action Fairness Act of 2005,² which provides for easier attainment of federal diversity jurisdiction for class action lawsuits and greater judicial oversight of settlement awards.³ Another tort reform bill, the Lawsuit Abuse Reduction Act,⁴ has moved out of committee and is due this term for a full vote in the House of Representatives. According to one proponent of the legislation, the bill aims to prevent lawsuits that “bankrupt individuals, ruin reputations, drive up insurance premiums, increase health care costs and put a drag on the economy.”⁵ As of this year, forty states have enacted joint and several liability reform legislation,⁶ thirty-two have enacted punitive damage award reform legislation, and sixteen have enacted product liability reform legislation.⁷

The regulatory compliance defense to manufacturer liability for defective drugs is one approach to tort reform particularly important to this discussion. Under this defense, legislation would “insulate manufacturers of pharmaceuticals approved by the FDA or manufacturers who comply with applicable FDA regulations from tort liability, or, alternatively, from liability for punitive damages.”⁸ In effect, depending on the form of regulatory compliance enacted by a particular state, drug manufacturers may be immune from liability unless fraud is proven. Even under a regulatory compliance defense that allows recovery but bars punitive damages, liability would be minimal.⁹ Although the details vary somewhat between jurisdictions, several states have enacted regulatory compliance

economic damages, production liability reform, appeal bond reform, sound science in the courtroom, and stopping regulation through litigation”).

2. Pub. L. No. 109-2, 119 Stat. 4 (2005) (codified in scattered sections of 28 U.S.C.).

3. Pub. L. No. 109-2, 119 Stat. 13 (to be codified at 28 U.S.C. § 1453). Easier attainment of federal diversity jurisdiction effectively prevents plaintiffs from forum-shopping, i.e., choosing to file lawsuits in jurisdictions that are traditionally more favorable to plaintiffs by lowering the threshold for qualification for trial in a federal court.

4. H.R. 420, 109th Cong. (2005).

5. 151 CONG. REC. H633-64 (daily ed. Feb. 16, 2005) (statement of Rep. Lamar Smith). The proposed legislation would allow judges to issue sanctions for the filing of frivolous lawsuits and restrict forum-shopping. *Id.* However, the Federal Rules of Civil Procedure already provide for sanctions where attorneys bring frivolous claims. FED. R. CIV. P. 11(b)(2).

6. Joint and several liability provides for recovery of the full amount of a damage award from one party alone, even if more than one party is found liable in a civil action. BARRON'S LAW DICTIONARY 255 (3d ed. 1991).

7. AM. TORT REFORM ASSOC., TORT REFORM RECORD: JULY 2005 2-3 (2005), http://www.atra.org/files.cgi/7927_Record7-05.pdf.

8. Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J.L. REFORM 461, 465 (1997).

9. *Id.* See generally Teresa Moran Schwartz, *Punitive Damages and Regulated Products*, 42 AM. U. L. REV. 1335 (1993) (discussing the effects of limiting punitive damage claims under regulatory compliance defense).

statutes.¹⁰ This momentum has also taken hold on the federal level, where a regulatory compliance statute was considered, though not enacted, by the 104th Congress.¹¹

While at first glance the theories and arguments supporting the statutory compliance defense may seem appealing, a complete analysis of the relationship between the FDA, the pharmaceutical industry, and the tort system renders a different conclusion—that tort remedies are necessary to effective drug regulation and enforcement in the United States. As such, we must preserve our common law tort remedies against pharmaceutical manufacturers for injuries caused by defective drugs.

B. Tort Recovery for Injured Drug Consumers Under Current Law

1. The Federal Tort Claims Act and FDA Liability

While the Federal Tort Claims Act (FTCA) exposes the federal government to being sued in several categories, it also functions as a shield from liability in most situations.¹² Most claims against government agencies fall within the “discretionary function” exception to the waiver of tort immunity under the FTCA.¹³ Under the discretionary function exception, government employees are immune from liability when acting within the discretionary function of their employment. As the Supreme Court explained, this exception aims to “prevent judicial ‘second-guessing’ of legislative and administrative decisions grounded in social, economic and political policy through the medium of an action in tort.”¹⁴ The Court later clarified the discretionary function as any government action involving “a matter of choice for the acting employee” where the choice is “based on considerations of public policy.”¹⁵

10. *E.g.*, MICH. COMP. LAWS ANN. § 600.2946(5) (West 2000) (exempting manufacturers from liability if approved by FDA, except for fraud or bribery); N.J. STAT. ANN. § 2A:58C-4 (West 2000) (creating rebuttable presumption that warning approved by FDA is adequate); N.D. CENT. CODE § 28-01.1-05(3) (1991) (creating rebuttable presumption that a product is not defective if it complies with FDA standards); OHIO REV. CODE ANN. § 2307.80(C) (LexisNexis 2005) (barring punitive damage recovery against manufacturer if in compliance with FDA); OR. REV. STAT. § 30.927 (2003) (barring punitive damages if drug approved by FDA, except where material information withheld); UTAH CODE ANN. § 78-18-2 (2002) (barring punitive damages if drug approved by FDA).

11. Common Sense Product Liability Reform Act of 1995, H.R. 956, 104th Cong. §§ 101, 105 (1995). Like many similar state statutes, the proposed legislation contained a scienter exception, under which drug companies may be held liable if they knowingly withheld information.

12. 28 U.S.C. § 2680(a) (2000).

13. *Id.*

14. *United States v. S.A. Empresa de Viacao Aerea Rio Grandense (Varig Airlines)*, 467 U.S. 797, 814 (1984).

15. Deborah F. Buckman, Annotation, *Liability of United States, Under Federal Tort Claims Act (28 U.S.C.A. §§ 1346, 2680), for Damages Caused by Ingestion or Administration of Government-*

Despite the broad protections of the discretionary function exception, courts have allowed for tort recovery for damages caused by government-approved medications and vaccines in several limited circumstances. First, the FTCA has provided for liability in failure to warn actions where the government has required or encouraged citizens to get a vaccine that later caused physical harm.¹⁶ For the most part, these cases have been limited to illness resulting from national vaccination programs, such as the National Swine Flu Vaccination Program.¹⁷ Second, where a government employee fails to follow protocol in his or her administration or manufacturing of a vaccine, or approval of a drug, the FTCA may allow for recovery.¹⁸ Such was the case in *Berkovitz v. United States*, where the Court recognized that because federal regulations require the FDA to examine products for compliance with regulatory standards, failure to examine would be actionable under the FTCA.¹⁹

Typically, however, decisions of drug approval fall within the discretionary function exception of the FTCA, in that FDA approval decisions are “plainly of the ‘nature and quality that Congress intended to shield from tort liability.’”²⁰ Even in the case of DES, where thousands of cancer cases were later linked to maternal use of the drug, the courts have continually found that the discretionary function exception applies to the drug approval process.²¹ Particularly where the drug approval occurs under the FDA’s general regulatory scheme, courts have recognized the need for discretion.²² Therefore, most drug approvals fall squarely

Approved Drugs, Vaccines, and Medications, 173 A.L.R. FED. 431, § 2[a] (2001) (citing *Berkovitz v. United States*, 486 U.S. 531 (1988)).

16. *See, e.g.*, *Cardillo v. United States*, 622 F. Supp. 1331, 1346-47 (D. Conn. 1984) (allowing recovery for damages caused by government Swine Flu inoculation program); *McDonald v. United States*, 555 F. Supp. 935, 974 (M.D. Pa. 1983) (allowing recovery for disease suffered as a result of Swine Flu inoculation). *But see, e.g.*, *Young v. United States*, 542 F. Supp. 1306, 1311-12 (S.D.N.Y. 1982) (finding no liability for Swine Flu inoculation where government shown to have adequately disclosed risks); *Saxe v. United States*, 577 F. Supp. 135, 147 (N.D. Ohio 1983) (allowing no recovery where damages were so rare as not to be “material” and therefore not necessary to disclose).

17. *See Buckman, supra* note 15, §§ 3-4.

18. *See, e.g.*, *Andrulonis v. United States*, 952 F.2d 652, 655 (2d Cir. 1991) (finding that the negligent administration of rabies vaccine did not involve conduct grounded in considerations of public policy, and thus the discretionary function exception was not applied); *Griffin v. United States*, 500 F.2d 1059, 1069 (3d Cir. 1974) (allowing for recovery where an injury was caused by improperly-released lot of vaccine).

19. 486 U.S. 531, 547 (1988).

20. *Bailey v. Eli Lilly Co., Inc.*, 607 F. Supp. 660, 663 (M.D. Pa. 1985) (noting that even if FDA had been negligent or intentional in its defective approval of a drug, the approval would still fall under the discretionary function exception to the FTCA).

21. *See, e.g.*, *Gray v. United States*, 445 F. Supp. 337, 340 (S.D. Tex. 1978) (holding that although FDA was given a broad statutory mandate to assure drug safety, the means of accomplishing that mandate are purely discretionary); *Forsyth v. Eli Lilly & Co.*, 904 F. Supp. 1153, 1160 (D. Haw. 1995) (finding discretionary function in the FDA’s approval of Prozac).

22. Drug approvals that have taken place under drug-specific regulations, such as the polio vaccine, may be more susceptible to FTCA liability because there is less room for discretion. *See*

within the discretionary function exception of the FTCA. As a result, unless a consumer can prove that an FDA employee deviated from regulatory guidelines in approving a drug, any claim against the FDA for negligent approval would most likely be barred.

2. Drug Companies and Tort Liability

The Food, Drug, and Cosmetic Act²³ does not provide for a private cause of action against pharmaceutical companies.²⁴ However, state common law tort remedies remain available for injured consumers. The most effective of these claims have been under theories of traditional negligence and the products liability claims of breach of implied warranty, failure to warn, and negligent and intentional misrepresentation. To prove negligence, plaintiffs must show they are owed a duty, that the duty was breached, a causal link between the breach and the resulting injury, and damage. To prove that a manufacturer breached a duty to a drug consumer, a plaintiff must show that the manufacturer did not meet the standard of care maintained by other industry participants. Under either traditional tort or products liability claims, compliance with FDA regulations is viewed as evidence of compliance with the applicable standard of care, but is not determinative of non-negligence.²⁵

According to the Third Restatement of Torts, “most product safety statutes establish a floor of safety below which product sellers fall only at their peril, but they leave open the question of whether a higher standard of product safety should be applied.”²⁶ Thus, in a claim for liability for design defect, the Restatement instructs that “a product’s noncompliance with an applicable product safety statute or administrative regulation renders the product defective with respect to the risks sought to be reduced by the statute or regulation.”²⁷ On the other hand, the Restatement also provides that compliance with administrative regulation should be considered when determining defectiveness but that it is not determinative of non-defectiveness.²⁸

Similar rules apply in failure to warn claims, where courts have recognized FDA approval of a particular drug manufacturing and labeling scheme as evidence that manufacturers have satisfied the standard of care in providing adequate

Forsyth, 904 F. Supp. at 1159 (distinguishing polio vaccination cases because of the intricate and detailed nature of polio vaccine development guidelines).

23. 21 U.S.C. §§ 301-397 (2000).

24. 2 JAMES T. O'REILLY, FOOD AND DRUG ADMINISTRATION 26-3 (2d ed. 2005); e.g., *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 544 (3d Cir. 1994) (affirming that the Food, Drug and Cosmetic Act does not confer a private right of action).

25. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4(b), § 4 cmt. e (1998).

26. *Id.*

27. *Id.* § 4(a).

28. *Id.* § 4(b).

warning. Thus, failure to comply with FDA-approved manufacturing and labeling requirements may establish both duty (under regulatory guidelines) and breach of duty (failure to comply with those regulatory guidelines) on the part of drug manufacturers. For instance, in *Benedi v. McNeil P.P.C., Inc.*, punitive damages were awarded for failure of a drug manufacturer to report adverse drug reactions as required by the FDA.²⁹ Consistently, the courts have been reluctant to recognize FDA approval as anything more than a necessary minimum standard of care requirement.³⁰

There are significant policy goals achieved by courts' refusals to accept regulatory compliance as determinative of standard of care in common law tort actions. By refusing to recognize compliance with regulation as determinative, courts encourage manufacturers to apply a higher standard of product safety than that mandated by regulation. Furthermore, the refusal to find minimal satisfaction of regulatory requirements as determinative preserves the role of the jury in rendering their own cost-benefit analyses and determining reasonableness.

3. *Doctors and Tort Liability*

The learned-intermediary doctrine shifts liability from drug manufacturers to doctors in failure to warn claims where manufacturers provided adequate drug warnings to the prescribing doctor.³¹ The doctrine provides an exception to the rule that a manufacturer has a duty to warn of known dangers associated with a prescription drug. This doctrine presumes that doctors are in the best position, after reading all manufacturer warnings, to determine whether a drug should be prescribed to a patient.³² While serving as a shield against drug industry liability, the doctrine also has the effect of increasing liability for doctors for failure to warn.³³

There are several scenarios under which courts may refuse to apply the learned-intermediary doctrine. First, if the FDA requires additional warnings from manufacturers directly to consumers, the courts are less likely to apply the doctrine

29. 66 F.3d 1378, 1389 (4th Cir. 1995).

30. See *Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 661 (Cal. 1973) (affirming that regulatory warnings establish a minimum standard of care); *Feldman v. Lederle Labs.*, 479 A.2d 374, 391 (N.J. 1984) (holding FDA regulations are minimal standards that do not destroy manufacturer's duty to warn of potential dangers); *Bristol-Meyers Co. v. Gonzales*, 548 S.W.2d 416, 423 (Tex. Civ. App. 1976) (rejecting the argument that standard of care is satisfied by mere FDA approval); *Edwards v. Basel Pharms.*, 933 P.2d 298, 303 (Okla. 1997) (finding that FDA-approved warnings are only the starting ground and are not conclusive).

31. See Diane Schmauder Kane, Annotation, *Construction and Application of Learned-Intermediary Doctrine*, 57 A.L.R. 5TH 1, §§ 25-26 (1998).

32. *Id.* The doctrine "shields a manufacturer from liability, notwithstanding an inadequate warning. . . ." *Id.* § 26[b].

33. See *id.* § 26.

where those warnings have not been made.³⁴ This outcome comports with the Restatement approach—that compliance with FDA regulations is evidence supporting but not determinative of compliance with the standard of care. Similarly, some California courts have held that continued over-promotion of drugs by manufacturers, even after the risks of a drug have been publicized, may destroy learned intermediary protections and render the manufacturer warnings inadequate despite doctor intermediation.³⁵

*C. The Food and Drug Administration:
History, Structure, & Approval Process*

1. *History and Recent Development.* The FDA has its roots in consumer protection. The FDA was created by the Pure Food and Drugs Act of 1906, partially due to public outcry from the publication of Upton Sinclair's *The Jungle*,³⁶ which exposed the poor safety and health conditions in the meat packing industry.³⁷ Consumer health concerns again helped drive an expansion of the FDA in 1938 to cover regulation and enforcement of the pre-market approval of safety in drug composition and labeling.³⁸ Later, the Kefauver-Harris Amendments of 1962 again expanded the FDA's authority over new drug approval procedures, in large part due to public reaction to widespread birth defects from maternal ingestion of thalidomide.³⁹ The 1962 Amendments mandated the establishment of drug efficacy before marketing, tightened FDA control of new, experimental, and prescription drugs, and required the submission of post-marketing reports of all

34. Such was the case in *Edwards*, where the court refused to apply the learned-intermediary doctrine because manufacturers failed to comply with FDA requirements that nicotine patches include warnings directly to consumers. 933 P.2d at 303.

35. See *Stevens*, 507 P.2d at 653, 661 (holding warnings inadequate where a drug manufacturer over-promoted its product even after it sent out warnings to physicians of potential associated risks).

36. UPTON SINCLAIR, *THE JUNGLE* (Viking Press 1946) (1905).

37. Pure Food & Drugs Act, Pub. L. No. 59-384, 34 Stat. 768 (1906) *repealed by* The Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-399 (2000)) and scattered sections of 28 U.S.C. (2000)); see U.S. FOOD & DRUG ADMIN., HISTORY OF THE FDA: THE PURE FOOD AND DRUGS ACT AND ITS ENFORCEMENT, <http://www.fda.gov/oc/history/historyoffda/section1.html> (last visited Sept. 21, 2006) [hereinafter HISTORY OF THE FDA].

38. Pub. L. No. 75-717, 52 Stat. 1040 (1962). A Tennessee drug company marketed an untested pediatric drug, Elixir Sulfanilamide, which was later shown to be a form of antifreeze. Over one-hundred people, mostly children, died as a result of ingesting the elixir. Following this crisis, the expansion of the Food and Drugs Act quickly passed through Congress. HISTORY OF THE FDA, *supra* note 37.

39. Pub. L. No. 87-781, 76 Stat. 780 (1938) (codified as amended in scattered sections of 21 U.S.C. (2000)). Under the original act, applications for new drug approval were submitted directly to the Secretary of Agriculture, and required reporting of investigative reports on drug safety, articles used in the components of the drug, a statement of drug composition, a description of methods used to manufacture, samples of the drug, and specimens of the labeling of such drug. Pub. L. No. 59-384, 34 Stat. 768 (1906).

adverse drug reactions by drug companies to the FDA.⁴⁰ Much of the drug approval process established by the 1962 Amendments still exists today. Although the FDA has been part of several other agencies throughout the years, since 1979 it has been under the charge of HHS.⁴¹

More recently, Congress enacted the 1992 Prescription Drug User Fee Act (PDUFA)⁴² in large part in response to demand from consumers and AIDS activists for earlier consumer access to groundbreaking new drugs.⁴³ The PDUFA provides for an accelerated drug approval process for both standard and priority drugs,⁴⁴ the additional cost of which is passed on to the manufacturer as a “user fee.”⁴⁵ Although the original act was set to expire in 1997, Congress renewed the user fee program for an additional five years through the Food and Drug Administration Modernization Act of 1997 (FDAMA) and also shortened goal times for drug approval.⁴⁶ In 2002, the user fee program was again extended for an additional five years.⁴⁷

Under the user fee system, participating pharmaceutical companies pay three types of fees that are collected for use in the human drug review process.⁴⁸ An application fee is paid to support the agency’s review process for new drug applications.⁴⁹ Annual fees are required to be paid for each facility in which drugs subject to PDUFA are manufactured (“establishment fees”) and for marketed drugs with no generic equivalent (“product fees”).⁵⁰ These fees contribute to the

40. Pub. L. No. 87-781, 76 Stat. 780-787; U.S. FOOD & DRUG ADMIN., FDA CONSUMER, THE STORY OF THE LAWS BEHIND THE LABELS, pt. 3, (1981), <http://www.cfsan.fda.gov/~lrd/histor1b.html>.

41. U.S. FOOD & DRUG ADMIN., FDA HISTORY: DESIGNATION AND LOCATION OF FDA IN FEDERAL GOVERNMENT, <http://www.fda.gov/opacom/morechoices/designat.html> (last visited Sept. 21, 2006).

42. Pub. L. No. 102-571, tit. 1, § 103, 106 Stat. 4491 (1992) (codified as amended at 21 U.S.C. § 379g (2000)).

43. Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1864-65 (1996). See generally U.S. GOV’T ACCOUNTABILITY OFFICE, FDA DRUG APPROVAL—A LENGTHY PROCESS THAT DELAYS THE AVAILABILITY OF IMPORTANT NEW DRUGS (1980) (providing an overview of—and the reasons for—the slow FDA drug approval process and discussing PDUFA).

44. “Standard drugs” are drugs for less-virulent illnesses and those that are similar to drugs already on the market; “priority drugs” are drugs that treat life-threatening illnesses and represent significant drug advances. Pub. L. No. 102-571, 106 Stat. 4491.

45. 106 Stat. at 4493-95. The additional costs now passed on to manufacturers include “expenses incurred in connection with the process for the review of human drug applications.” *Id.*

46. Pub. L. No. 105-115, tit. 1, § 103, 111 Stat. 2299 (1997) (codified at 21 U.S.C. § 379h (2000)).

47. Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, tit. V, subtitle A, 116 Stat. 594, 687-88 (2002) (codified in scattered sections of 21 U.S.C.).

48. U.S. GEN. ACCOUNTING OFFICE, REPORT TO THE CHAIRMAN, COMMISSION ON HEALTH, EDUCATION, LABOR, AND PENSIONS, U.S. SENATE, FOOD AND DRUG ADMINISTRATION: EFFECT OF USER FEES ON DRUG APPROVAL TIMES, WITHDRAWALS, AND OTHER AGENCY ACTIVITIES 6 (2002) [hereinafter EFFECT OF USER FEES ON DRUG APPROVAL TIMES].

49. *Id.*

50. *Id.*

increased drug review costs of meeting performance goals under newly mandated goal times.⁵¹

2. *The Current Scope and Structure of the FDA.* After years of evolution and revision, the current FDA has a wide range of responsibilities that continue to grow. These responsibilities include approving and regulating “all food except for meat and poultry, all prescription and non-prescription drugs; all blood products, vaccines, and tissues for transplantation; all medical equipment and all devices that emit radiation, including microwave ovens; all animal drugs and feeds; and even all cosmetics.”⁵² Purchases of FDA-regulated goods add up to almost \$1.5 trillion annually, or 20% of all consumer purchases.⁵³ Yet, the increase in FDA responsibilities is outpacing the FDA’s ability to fulfill effectively those responsibilities. According to the FDA website, “although FDA’s appropriations have increased in the past eight years, trends in a wide variety of external factors are generating workloads and public expectations that are poorly matched with FDA’s capacity to respond in a timely, adequate manner.”⁵⁴

The current FDA is a relatively small governmental agency charged with an enormous regulatory mandate. While over 10,000 people are employed by the FDA in various capacities,⁵⁵ the agency must monitor over 150,000 drugs and devices.⁵⁶ The FDA’s discretionary budget for FY 2006 stands at \$1.487 billion, with approximately \$300 million more collected in user fees from participating drug manufacturers.⁵⁷ To put the FDA’s budget limitations into perspective, the discretionary budgets of two other HHS sub-agencies dwarf the budget of the FDA; the Health Resources and Services Administration’s budget is \$5.982 billion,

51. The performance goals set in the 1992 PDUFA were further abbreviated in the 1997 FDAMA. Food and Drug Modernization Act of 1997, Pub. L. No. 105-115, tit. 1, § 101(4), 111 Stat. 2299 (1997) (codified as amended at 21 U.S.C. § 379h (2000)).

52. U.S. FOOD & DRUG ADMIN., THE NATION’S FOREMOST CONSUMER PROTECTION AGENCY: FDA’S GROWING RESPONSIBILITIES FOR THE YEAR 2001 AND BEYOND 2 (2001) [hereinafter FDA’S GROWING RESPONSIBILITIES].

53. U.S. FOOD & DRUG ADMIN., PERFORMANCE BUDGET OVERVIEW 1 (2006), available at <http://www.fda.gov/oc/oms/ofm/budget/2006/PDFs/consolidatedbudget.pdf>.

54. FDA’S GROWING RESPONSIBILITIES, *supra* note 52, at 5.

55. Eve. E. Slater, *Today’s FDA*, 352 N. ENG. J. MED. 293, 293 (2005) (citing FDA Budget Proposal for FY 2004).

56. U.S. FOOD & DRUG ADMIN., STRATEGIC ACTION PLAN: PROTECTING AND ADVANCING AMERICA’S HEALTH 9 (2003), available at <http://www.fda.gov/oc/mcclellan/FDAStrategicPlan.pdf>.

57. U.S. OFFICE OF MGMT. & BUDGET, BUDGET OF THE U.S. GOV’T., FISCAL YEAR 2006 148 (2005), available at <http://a255.g.akamaitech.net/7/255/2422/07feb2005/1415/www.gpoaccess.gov/usbudget/fy06/pdf/budget/hhs.pdf>; U.S. FOOD & DRUG ADMIN., PERFORMANCE BUDGET OVERVIEW 36 (2006), <http://www.fda.gov/oc/oms/ofm/budget/2006/PDFs/BnB1.pdf>.

while the discretionary budget of the National Institutes of Health is \$28.590 billion.⁵⁸

As part of the Department of Health and Human Services, the FDA is an agency in an executive department under the executive branch of government.⁵⁹ This means that positions at both FDA and HHS are filled through executive appointments, nominated by the President and confirmed by the Senate.⁶⁰ The effect of FDA being an executive agency is that persons filling high-ranking positions are subject to the changing political tide. Thus, each change in administration may result in the replacement of FDA officials with those who are more ideologically or politically compatible. Many of these newly-jobless, highly-specialized individuals eventually gravitate to the private pharmaceutical industry. And, when the shift occurs again, many go back to the FDA. This “revolving door” between government and industry raises concerns. First, agency officials may be positioning themselves for future work in the pharmaceutical industry when the administration inevitably changes again. Also, there may be increased cooperation between industry and regulatory officials, destroying some of the necessary tensions in the regulatory process.⁶¹

3. *The Current Drug Approval Process.* To initiate testing of a new drug, a manufacturer must submit an Investigational New Drug (IND) application for FDA review at least thirty days before an experiment is set to begin.⁶² Three separate phases of clinical trials take place in the IND phase: (1) limited human trials that establish physiological reactions to drugs, (2) limited human trials on patients with the condition the drug is designed to treat, in order to establish efficacy, and (3) expanded human trials of several thousand subjects, to produce data on potential side effects and risks.⁶³ Upon completion of the Phase III clinical trials, the significant benefits of a treatment must be shown among the patients who receive it.⁶⁴ Then, FDA officials meet with representatives from sponsoring companies in order to identify problems and areas that need further testing and research, as well

58. U.S. DEP'T OF HEALTH & HUMAN SERVS., MEETING PRESIDENTIAL GOALS 148 (2006), available at <http://a255.g.akamaitech.net/7/255/2422/07feb20051415/www.gpoaccess.gov/usbudget/fy06/pdf/budget/hhs.pdf>.

59. For an instructive HHS organizational chart, see U.S. Dep't of Health and Human Servs., Department of Health and Human Services Organizational Chart, <http://www.hhs.gov/about/orgchart.html>.

60. Slater, *supra* note 55, at 294.

61. See Editorial, *FDA's Revolving Door*, BALT. SUN, Nov. 27, 2005 at 22A.

62. See 21 C.F.R. §§ 312.20, 312.35 (2005); O'REILLY, *supra* note 24, at 13-85.

63. O'REILLY, *supra* note 24, at 13-86 to 13-87. In the limited human trial phase, scientists study absorption, elimination, metabolization, and toleration of the drug. In the second phase, which usually takes two years to complete, several hundred ill patients are administered the drug. In the last phase, taking between one and four years, hundreds of ill patients are administered the drug in an attempt to gauge appropriate dosage. *Id.*

64. *Id.* at 13-87.

as to review results.⁶⁵ If a drug passes the scientific review of IND test results, the New Drug Application (NDA) will be accepted by the FDA.⁶⁶ If an approval letter is issued, the drug may then be marketed, sometimes subject to additional post-marketing testing.⁶⁷

Notably, all clinical testing is conducted exclusively by the sponsoring pharmaceutical companies. Although the FDA may request additional research and testing from these companies, the FDA itself never conducts any clinical tests. While this fact alone is not conclusory of bias, it is important for a discussion of the regulatory process to understand that the scientific testing and reporting is being conducted by interested parties. The results of all clinical trials are required to be reported to the FDA; however, there is no legal requirement to disclose clinical trials to the public.⁶⁸ As a result, the public may often not be informed of negative clinical trial results that occur prior to drug approval.

4. *Post-Approval Regulatory Controls.*

i. *Adverse Drug Reaction Reports.* An important aspect of the FDA's post-marketing control over new drugs is the requirement of filing adverse drug reaction reports (ADRs).⁶⁹ The FDA requires that, within the first year of approval, drug manufacturers submit reports of adverse reactions within fifteen days, regardless of whether the reaction is presumed to have resulted from ingestion of the drug.⁷⁰ These reports must include both adverse reactions reported directly from consumers and those reported in medical journals.⁷¹ However, there is a severity threshold that must be met for mandatory reporting to be triggered. Manufacturers are only obligated to report "serious and unexpected" adverse reactions, which are limited to effects that are "fatal, life-threatening, or persistent."⁷² The determination of when an ADR is necessary must be made by the manufacturers themselves. Once an ADR is filed, manufacturers must submit follow-up reports to the FDA detailing actions that they have taken to further investigate and respond to the ADR.⁷³

65. *Id.* at 13-88; 21 C.F.R. §§ 314.102, 312.82 (2005).

66. O'REILLY, *supra* note 24, at 13-89 to 13-91. In addition, the FDA reviews promotional, labeling, and manufacturing information before an approval letter is sent out. *Id.* at 13-92 to 13-93.

67. *Id.* at 13-92.

68. Drummond Rennie, *Trial Registration: A Great Idea Switches From Ignored to Irresistible*, 292 JAMA 1359, 1359 (2004).

69. 21 C.F.R. § 314.80 (2005).

70. *Id.* §§ 314.80(a), 312.32.

71. *Id.* § 314.80(b).

72. *Id.* § 314.80(a); CTR. FOR DRUG EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., POSTMARKETING ADVERSE EXPERIENCE REPORTING OF HUMAN DRUG AND LICENSED BIOLOGICAL PRODUCTS: CLARIFICATION OF WHAT TO REPORT 2-3 (1997).

73. 21 C.F.R. §§ 314.80(b)-(d) (2005).

ii. *FDA Advertising Regulation & Enforcement.* In 1997, the FDA drafted extensive new regulations and guidance on prescription drug advertising that were finalized in 1999.⁷⁴ The FDA regulates three categories of advertising: (1) reminder advertisements, (2) help-seeking advertisements, and (3) product-claim or indication advertisements.⁷⁵ A reminder ad does not mention specific details of a drug, but simply introduces the name of the drug into the public sphere.⁷⁶ A help-seeking ad alerts consumers to see their doctor for help with a particular condition, but never names the drug specifically.⁷⁷ Product claim ads, on the other hand, both mention the name of the drug and the drug's indications.⁷⁸ As such, this last category of advertising is much more heavily regulated than the other two.

The regulations allow for the FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) to monitor product claim advertisements for truthfulness in statements of side effects, contraindications, and effectiveness; fair balancing between information of effectiveness and that of side effects and contraindications; disclosure of material consequences of the drug; and representations that a drug is safer than it has been proven in scientific testing.⁷⁹ If the DDMAC finds advertisements in violation of these regulations, either a warning letter or an untitled letter is sent to the pharmaceutical company, to which the company is required to respond in fourteen days by describing the remedial actions taken.⁸⁰

In November 2001, HHS changed its policy to require that all regulatory (either untitled or warning) letters first be submitted to the FDA's Office of the Chief Counsel for review before being sent to violating manufacturers.⁸¹ According to HHS, the policy was implemented "to ensure that all draft warning

74. *Id.* §§ 202, 202.1 (2005); U.S. FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., GUIDANCE FOR INDUSTRY: CONSUMER-DIRECTED BROADCAST ADVERTISEMENTS (1999) [hereinafter GUIDANCE FOR INDUSTRY].

75. Direct-to-Consumer Promotion: Public Hearing, 60 Fed. Reg. 42,581-83 (1999).

76. *Id.* at 42583.

77. *Id.* at 42582.

78. *Id.*

79. 21 C.F.R. §§ 202, 202.1(e)(5) (2005).

80. Untitled letters are sent in response to such violations as "overstating the effectiveness of the drug, suggesting a broader range of indicated uses than the drug has been approved for, and making misleading claims because of inadequate context or lack of balanced risk information." U.S. GOV'T ACCOUNTABILITY OFFICE, REPORT TO CONGRESSIONAL REQUESTERS, PRESCRIPTION DRUGS: FDA OVERSIGHT OF DIRECT-TO-CONSUMER ADVERTISING HAS LIMITATIONS 8 (2002) [hereinafter REPORT TO CONGRESSIONAL REQUESTERS]. Warning letters "advise a pharmaceutical firm that FDA may take further enforcement actions, such as seeking judicial remediation, without notifying the company, and generally ask the firm to conduct a new advertising campaign to correct inaccurate impressions left by the advertisement." *Id.* at 8-9.

81. *Id.* at 22.

and untitled letters from FDA were reviewed for ‘legal sufficiency and consistency with agency policy’⁸² before being sent out.

II. THE EFFECTS OF RECENT LEGISLATIVE, REGULATORY, AND ADMINISTRATIVE CHANGES AT THE FDA

A. Shortened Drug Approval Times Lead to an Increase in Drug Prescription

On its face, the accelerated approval process has been mutually beneficial for drug companies and the FDA—the FDA has quelled criticism for slow approval times, while drug manufacturers have gained approval for more drugs at faster rates. Between 1993 and 2001, the median approval time for standard drugs decreased from twenty-seven to fourteen months, while the median approval time for priority drugs was reduced from twenty-one to six months.⁸³ As critics of the slow approval process had hoped, a greater number of Americans are accessing pharmaceuticals under this new regulatory scheme. In 1992, when the original PDUFA was enacted, Americans received 1.9 billion prescriptions. Since then, that number has been steadily increasing, from 2.4 billion prescriptions in 1997 to 3.1 billion prescriptions in 2001.⁸⁴ These 3.1 billion prescriptions contributed to an increase of 16.9% in drug expenditures that year.⁸⁵

The pharmaceutical industry has applauded both the decreased approval times and increased prescription drug consumption. The industry adopts the position that increased prescription drug availability is a sign that “better and cost-effective new medicines [have] changed health care practice to focus more on prevention and treatment of a growing range of illnesses with pharmaceuticals.”⁸⁶ The industry advocates increased use of prescription drugs as beneficial to society as a whole, noting that “increased use of innovative drugs is saving lives and improving quality of life for patients by decreasing hospitalizations and surgeries, reducing medication side effects, and helping workers with illnesses be productive.”⁸⁷

Supporters of the user fee program and the expedited approval process claim that society is better off as a result of the recent regulatory changes. Yet while the

82. *Id.*

83. EFFECT OF USER FEES ON DRUG APPROVAL TIMES, *supra* note 48, at 9-10.

84. NAT'L INST. FOR HEALTH CARE MGMT., PRESCRIPTION DRUG EXPENDITURES IN 2001: ANOTHER YEAR OF ESCALATING COSTS 7 fig. 5 (2002), available at http://www.nihcm.org/finalweb/pg_publications_prescription.htm.

85. PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA (PHRMA), INCREASED USE OF MEDICINES IN HEALTH CARE 24 (2003), available at <http://www.phrma.org/publications/>.

86. *Id.*

87. *Id.*

goals of the legislation have been met, negative consequences of increased pharmaceutical use have surfaced. Upon examination, the negative consequences seem to outweigh the benefits of the legislation.

B. More Defective Drugs are Being Approved Than Ever Before

Although the user fee program has accomplished the goal of shortened approval times, there is evidence that the drugs being approved under the expedited process are not as safe as their predecessors. A recent Congressional analysis of FDA data found that, since the enactment of PDUFA, a higher percentage of drugs have been withdrawn from the market for safety-related reasons.⁸⁸ For the eight-year period before the original PDUFA was passed in 1992, and the eight-year period after its passage, defective drug removals increased from 3.1% to 3.47%.⁸⁹ This increase is even more apparent when we examine the figures after the issuance of the 1997 *Industry Guidance*; of drugs approved between 1997 and 2000, 5.34% have been withdrawn from the market for safety-related reasons.⁹⁰

1. Reasons for Increase in Defective Drug Withdrawals

i. Increased Reviewer Workload. There are many possible reasons for the increase in safety-related drug withdrawals. One reason may be the increased workload for individual drug reviewers post-PDUFA. User fees have been successful in expediting review of new drug applications.⁹¹ Yet the new goal times for approval decisions have effectively increased the workload of individual reviewers rather than driving creation of new reviewer positions.⁹² Because the FDA continually over-estimated the number of new drug submissions, and thus the amount it would collect in user fees for those submissions, it has been under-budgeted for the personnel required to meet expedited approval times.⁹³ Thus, it is not surprising that when compared to similar positions in similar agencies in the federal government—and to the federal government as a whole—attrition rates for FDA drug reviewers are noticeably higher.⁹⁴ Worse, the remaining reviewers may

88. EFFECT OF USER FEES ON DRUG APPROVAL TIMES, *supra* note 48, at 4.

89. *Id.*

90. *Id.* It should be noted that the FDA has challenged the findings of this report because of the implications of comparing the three year period from 1997-2000 with two eight year periods. *Id.*

91. Prescription Drug User Fee Act of 1992, H.R. 5952, 102d Cong. § 2 (1992).

92. EFFECT OF USER FEES ON DRUG APPROVAL TIMES, *supra* note 48, at 18-19. The performance goals established under PDUFA included review completion within ten months of 90% of all new drug applications. Pub. L. No. 105-115, tit. 1, § 101(4), 111 Stat. 2299 (1997) (codified as amended at 21 U.S.C. 379h (2000)).

93. EFFECT OF USER FEES ON DRUG APPROVAL TIMES, *supra* note 48, at 9.

94. *Id.* at 21-22 (citing study by Office of Personnel Management and FDA that compared FDA attrition rates to those of National Institutes of Health and Centers for Disease Control and Prevention).

be less trained than their predecessors—FDA reviewers report that they regularly forego training in order to meet PDUFA performance goals.⁹⁵

A 2003 report from HHS Office of the Inspector General also supports the conclusion that FDA reviewers have too heavy a workload to effectively assess new drug applications. After conducting a survey of FDA reviewers, the office reported that “workload pressures increasingly challenge the effectiveness of the review process.”⁹⁶ Some reviewer responses to specific questions were quite alarming. Among reviewers who worked at the FDA for five years or more, 40% indicated that the review process had worsened during their tenure in terms of allowing for “in-depth, science-based reviews.”⁹⁷ Fifty-eight percent of respondents indicated that the six months allotted for drug review under PDUFA was inadequate.⁹⁸ Other changes reported included decreased use of independent scientific Advisory Committees in determining drug approval, and insufficient time for raising scientific disputes within the approval process.⁹⁹

ii. Increased Manufacturer Control Over Approval Process. Another possible reason for this increase in defective drugs may be the reported increase in manufacturer control over the approval process. Elizabeth Barbehenn, a former FDA pharmacologist who left her drug review job in 1998 after thirteen years, reported significant changes in the structure of the approval process pre- and post-PDUFA.¹⁰⁰ Barbehenn commented in the *New England Journal of Medicine* that after PDUFA was passed, “she was allowed to communicate only indirectly, through a supervisor, with scientists at the companies whose drugs she was reviewing.”¹⁰¹ According to Barbehenn, the drug approval process has become “driven by what industry wants.”¹⁰² In the same article, a current FDA reviewer confirmed that “it is very, very clear that the emphasis now is getting drugs approved,” rather than the former goal of establishing drug safety.¹⁰³

In response to these reports, the FDA suggested several possible reasons for the increase in safety-related drug removals. First, FDA officials concede that clinical trials on a few thousand patients are inadequate to detect all of a drug’s adverse side effects.¹⁰⁴ Also, officials explain that the increase in overall consumption of medication increases the probability of negligent prescription and

95. *Id.* at 23.

96. OFFICE OF THE INSPECTOR GEN., U.S. DEP’T OF HEALTH & HUMAN SERVS., FDA’S REVIEW PROCESS FOR NEW DRUG APPLICATIONS: A MANAGEMENT REVIEW, at ii (2003).

97. *Id.* at 6.

98. *Id.* at 10.

99. *Id.* at 3.

100. Susan Okie, *What Ails the FDA?*, 352 NEW ENG. J. MED. 1063, 1064 (2005).

101. *Id.*

102. *Id.*

103. *Id.*

104. EFFECT OF USER FEES ON DRUG APPROVAL TIMES, *supra* note 48, at 26.

adverse effects.¹⁰⁵ According to Dr. Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research, "[I]t is very likely that the newer classes of drugs in general are safer than older drugs, but you have to recognize that many more people are taking medicines now than used to."¹⁰⁶

The revolving door of FDA regulators and industry may be enabling increased industry control over the approval process. For example, Daniel E. Troy, chief counsel for the FDA from 2001-2004, previously represented pharmaceutical companies against increased FDA regulation in his private law practice.¹⁰⁷ By 2001, the former industry advocate was now shaping policy. As chief counsel for the FDA, Troy advocated for spread of the regulatory compliance defense in a 2003 address to pharmaceutical industry lawyers.¹⁰⁸ It is also Troy's former office of chief counsel through which regulatory letters for advertising violations are reviewed, purportedly for "legal sufficiency and consistency with agency policy."¹⁰⁹ The revolving door of regulators and industry raises important implications about the purity of the drug approval, regulation, and enforcement process as a whole.

*C. Direct-to-Consumer Advertising—And Industry Profits—
Are Increasing Exponentially, While More Consumers are Harmed*

Another possible, yet not widely examined, reason for the increase in unsafe drugs being removed from the market may be the changes in advertising regulation and enforcement. The FDA's 1999 *Guidance for Industry* has caused a drastic increase in direct-to-consumer (DTC) advertising from the pharmaceutical industry. Prior to the issuance of this new regulatory guidance, pharmaceutical companies were required to provide all side-effects and risks of a drug during a broadcast advertisement.¹¹⁰ This mandatory disclosure standard made broadcast advertisements ineffective and unattractive to pharmaceutical companies, often requiring more air-time for warnings than for true advertisement. Under the post-1999 regime, pharmaceutical companies can now satisfy the regulatory requirements by only disclosing the *major* side effects of drugs (either in audio or

105. *Id.*

106. Alex Berenson, *Trial Lawyers Are Now Focusing on Lawsuits Against Drug Makers*, N.Y. TIMES, May 18, 2003, at 1.

107. Anne C. Mulkern, *Watchdogs or lap dogs? When Advocates Become Regulators*, DENVER POST, May 23, 2004, at A-01. The new head counsel of the FDA is Sheldon Bradshaw, who took over the position in April 2005. According to at least one commentator, Bradshaw "has continued to intervene on behalf of drug companies in private civil lawsuits" and has kept many industry-friendly policies in place. Lily Henning, *Is FDA's New Chief Counsel Change in Name Only?*, LEGAL TIMES, Sept. 20, 2005, available at <http://www.law.com/jsp/ihc/PubArticleIHC.jsp?id=1127133334301>.

108. *Id.*

109. REPORT TO CONGRESSIONAL REQUESTERS, *supra* note 80, at 22.

110. *Id.* at 8.

visual format), and by “making adequate provision . . . for dissemination of the approved or permitted package labeling in connection with the broadcast presentation.”¹¹¹ According to the FDA *Guidance for Industry*, the “adequate provision” requirement is satisfied by providing full disclosure of information through toll-free telephone recordings, direct mailings, and direction to websites.¹¹²

The *Guidance for Industry* expanded the boundaries of permissible pharmaceutical advertising to a degree much more favorable to drug manufacturers. As a result of the relaxed requirements, pharmaceutical advertising expenditures have increased dramatically since the draft *Guidance* was issued in 1997.¹¹³ The pharmaceutical industry has seized this opportunity to directly inform consumers about new—and now more readily available—drugs. According to one Congressional report, spending by the pharmaceutical industry on DTC advertising from 1997 to 2001 increased by 145%, from \$1.1 billion to \$2.7 billion.¹¹⁴

1. Increased Advertising Affects Consumer Choice. Significantly, this increase in spending on advertising has had a major effect on which drugs consumers are prescribed. Between 1999 and 2000, there was a 25% increase in prescriptions for the most heavily advertised drugs, while those drugs that were not heavily advertised experienced only a 4% increase.¹¹⁵ Estimates indicate that roughly 8.5 million consumers per year specifically request and are prescribed drugs from their doctors as a result of DTC advertising.¹¹⁶

Other studies have also confirmed that DTC advertising has a direct impact on individual patient prescription of the advertised drug. In 2004, the FDA’s Center for Drug Evaluation and Research (CDER) conducted a survey of both patients and physicians regarding the impact of DTC advertising.¹¹⁷ Thirty-nine percent of patients who asked their doctors about availability of prescriptions for a condition requested a specific brand.¹¹⁸ In response, half of those patients reported that doctors prescribed the specific brand about which they inquired.¹¹⁹ Even more alarming, 41% of all participating physicians indicated that their patient was confused about the effectiveness of the drug because of the DTC advertisement.¹²⁰

111. 21 C.F.R. §§ 202, 202.1(e)(1) (2005); GUIDANCE FOR INDUSTRY, *supra* note 74, at 2.

112. REPORT TO CONGRESSIONAL REQUESTERS, *supra* note 80, at 2-3.

113. *Id.* at 3.

114. *Id.* at 3, 9.

115. *Id.* at 3.

116. *Id.* at 4.

117. CTR. FOR DRUG EVALUATION & RESEARCH, U.S. DEPT. OF HEALTH & HUMAN SERVS., PATIENT AND PHYSICIAN ATTITUDES AND BEHAVIORS ASSOCIATED WITH DTC PROMOTION OF PRESCRIPTION DRUGS: SUMMARY OF FDA SURVEY RESEARCH RESULTS 2 (2004), available at <http://www.fda.gov/cder/ddmac/Final%20Report/FRFinalExSu1119042.pdf>.

118. *Id.* at 4.

119. *Id.*

120. *Id.* at 6-7.

Finally, a majority (65%) of physicians reported that their patients confused the relative risks and benefits of DTC-advertised drugs, and an even greater proportion (75%) report that these advertisements led patients to over-estimate the efficacy of these drugs.¹²¹

2. *Increased Advertising Leads to Increased Profits.* The increase in DTC advertising has been extremely beneficial for the pharmaceutical industry. In 2000, the most heavily advertised drug in the DTC market was Vioxx (rofecoxib), the anti-inflammatory drug manufactured by Merck.¹²² According to the National Institute for Healthcare Management, Merck spent \$160.8 million promoting the drug through various media outlets that year, part of the company's one-year 117% increase in DTC advertising.¹²³ As a result, retail sales of Vioxx *quadrupled* from \$329.5 million in 1999 to \$1.5 billion in 2000.¹²⁴ Merck was not the only company to reap huge profits from advertising investments. Pfizer increased its total spending on DTC advertising by 98.5% between 1999 and 2000, and spent \$58.2 million on DTC advertising for the cholesterol reducer Lipitor in 2000.¹²⁵ By the end of that year, Pfizer experienced a 38.8% increase in sales of Lipitor.¹²⁶

3. *While Profits and Ads Are On the Rise, Enforcement Proves Ineffective.* While drug industry advertising has multiplied exponentially, the 2001 HHS changes to regulatory enforcement procedures have dramatically increased the amount of time between the observation of a violation and the issuance of a regulatory letter to the offending corporation. Prior to the policy change, letters were issued within several days of receipt of notice of a violation.¹²⁷ After the policy change, a Congressional report concluded that the Office of the Chief Counsel's "reviews of draft regulatory letters from FDA have taken so long that misleading advertisements may have completed their broadcast life cycle before FDA issued the letters."¹²⁸ In other words, most ads have already stopped airing by the time that regulatory letters are received.

The result of the HHS policy change is that the time it takes between manufacturer violation and FDA reprimand renders any enforcement completely ineffective. Worse, this policy seems part of a larger initiative to increase industry profits while decreasing industry liability. As previously noted, all regulatory

121. *Id.* at 8.

122. NAT'L INST. FOR HEALTHCARE MGMT, PRESCRIPTION DRUGS AND MASS MEDIA ADVERTISING 6 (2000), *available at* <http://www.nihcm.org/finalweb/DTCbrief.pdf>.

123. *Id.* at 2, 10 fig.6.

124. *Id.* at 4 fig.4, 9 fig.5.

125. *Id.* at 9 fig.5, 10 fig.6.

126. *Id.* at 9 fig.5. Sales of Lipitor amounted to over \$1.03 billion in 2000. Pfizer, Inc., 2004 Financial Report 1 (Feb. 24, 2005).

127. REPORT TO CONGRESSIONAL REQUESTERS, *supra* note 80, at 22.

128. *Id.* at 23. A 2002 sampling of regulatory-letter turnaround time from OCC showed a range of between thirteen and seventy-eight days. *Id.*

letters must now be reviewed by the FDA's office of chief legal counsel. This is the same office that continues to implement many of the policies instituted under former chief counsel—and former pharmaceutical industry advocate—Daniel Troy.¹²⁹ According to a recent letter from Rep. Henry Waxman to HHS Secretary Tommy Thompson, “This . . . may be a welcome development for the drug industry, but it poses serious dangers to public health.”¹³⁰

In the regulation of drug advertising, time is truly of the essence. Because just one commercial may trigger consumers to seek a particular prescription drug, any misrepresentation is only magnified by an ad's increased air time. Even when pharmaceutical companies receive warning letters, some drugs continue to be marketed with aggressive and misleading advertisements. The Government Accountability Office reported to Congress that “FDA's oversight has not prevented some pharmaceutical companies from repeatedly disseminating new misleading advertisements for the same drug . . .”¹³¹ To put it simply, the profit incentives of drug companies often far outweigh the costs of a regulatory letter's being issued, particularly when the offending ad may have already run its broadcast life by the time the letter is issued.

i. The Worst Regulatory Offenders Often Reap the Greatest Profits. Some of the most egregious examples of advertising violations are ads for the most lucrative drugs. One of the worst examples of repeated disregard for the FDA's regulatory enforcement has been from Pfizer. Between 1998 and 2002, the FDA issued four regulatory letters to Pfizer for producing misleading ads for its blockbuster cholesterol-lowering drug Lipitor.¹³² The FDA continually charged that Pfizer misrepresented the severity of side effects, the overall safety of the drug, and the effectiveness of Lipitor as compared to other similar products.¹³³ As a result, Pfizer was required to pull the misleading ad from the broadcast market. Even so, the public witnessed days and weeks of advertising in which it was exposed to misleading statements of Lipitor's efficacy. Yet the benefits to Pfizer that run from deceptive over-promotion of Lipitor tremendously outweigh the FDA's effective slap on the wrist; Pfizer posted 2004 revenues for Lipitor in excess of \$10.8 billion.¹³⁴

129. Mulkern, *supra* note 107; Henning, *supra* note 107.

130. Mulkern, *supra* note 107.

131. REPORT TO CONGRESSIONAL REQUESTERS, *supra* note 80, at 4.

132. *Id.* at 21.

133. Letter from Joan Hankin, Consumer Protection Analyst, Division of Drug Marketing, Advertising, and Communications, U.S. Dept. of Health & Human Servs., to Christopher A. Graham, Director, Worldwide Regulatory Strategy, Pfizer (Aug. 12, 2002), available at <http://www.fda.gov/cder/warn/2002/10939.pdf>.

134. PFIZER, 2004 FINANCIAL REPORT I (2004), available at http://www.pfizer.com/pfizer/annualreport/2004/financial/index_financial.jsp.

ii. *Sometimes, the Worst Offenders of Advertising Regulation are Selling Dangerous Drugs.* Vioxx is the best, and perhaps the most egregious, example of a pharmaceutical manufacturer's misleading the public through over-promotion of a dangerous drug. Unfortunately, Vioxx also serves as an example of the inadequacy of the FDA in enforcing advertising regulations. As noted above, Merck relied successfully upon DTC advertising in its promotion of its new anti-inflammatory drug Vioxx following FDA approval in 1999. When Vioxx was voluntarily withdrawn from the market on September 30, 2004, due to increased risks of myocardial infarction (heart attack) and strokes, annual profits from sales of Vioxx exceeded \$2.5 billion per year.¹³⁵

The most disturbing aspect of this particular case is that the FDA was aware that Vioxx caused an increase in heart attacks and stroke, and unsuccessfully reprimanded Merck for advertising exactly the opposite conclusion. In 2001, Merck received a warning letter about making false and misleading advertising claims that Vioxx did *not* increase incidence of myocardial infarction and stroke. The FDA warning letter to Merck states:

You have engaged in a promotional campaign for Vioxx that minimizes the potentially serious cardiovascular findings that were observed in the Vioxx Gastrointestinal Outcomes Research (VIGOR) study, and thus, misrepresents the safety profile for Vioxx. Specifically, your promotional campaign discounts the fact that in the VIGOR study, *patients on Vioxx were observed to have a four to five fold increase in myocardial infarctions (MIs) compared to patients on the comparator non-steroidal anti-inflammatory drug (NSAID), Naprosyn (naproxen).*¹³⁶

The warning letter references an earlier regulatory letter sent to Merck for the exact same violation the previous year. As the warning letter later confirms, Merck's "misrepresentation of the safety profile for Vioxx is particularly troublesome because we have previously, in an untitled letter, objected to promotional materials that have also misrepresented Vioxx's safety profile."¹³⁷

By the time that Vioxx was withdrawn from the market in 2004, three years after this warning letter was issued, tens of millions of patients were taking rofecoxib. During Vioxx's time on the market, Merck aggressively defended

135. Eric J. Topol, *Failing the Public Health – Rofecoxib, Merck, and the FDA*, 351 NEW ENG. J. MED. 1707, 1707 (2004).

136. Letter from Thomas W. Abrams, Director, Division of Drug Marketing, Advertising, and Communications, U.S. Dept. of Health & Human Servs., to Raymond V. Gilmartin, President and CEO, Merck & Co., Inc. (Sept. 17, 2001), available at <http://www.fda.gov/cder/warn/2001/9456.pdf> (emphasis added).

137. *Id.* at 2.

numerous independent studies questioning the safety of Vioxx.¹³⁸ According to one doctor and commentator, “Sadly, it is clear to me that Merck’s commercial interest in rofecoxib sales exceeded its concern about the drug’s potential cardiovascular toxicity.”¹³⁹ Apparently, Merck had notice both from the FDA and from independent researchers that Vioxx was dangerous, but continued to aggressively market the drug despite these warnings and attempts at regulation.

Such egregious disregard for FDA advertising regulations has prompted legislators in both houses of Congress to introduce legislation that would amend the Internal Revenue Service Code to limit each manufacturer’s tax deductions for prescription drug advertising to the level of research and development expenditures.¹⁴⁰ Other legislators have suggested reducing deduction amounts to half of expenditures on research and development,¹⁴¹ and even complete revocation of tax deductions for DTC advertising.¹⁴² Yet at least one recent Supreme Court case has brought the constitutionality of such advertising restrictions into question.

4. *Constitutional Barriers to Advertising Regulation.* We are currently the only country, aside from New Zealand, that allows DTC advertising.¹⁴³ While it is tempting to argue that tougher or even prohibitory regulations would solve the DTC problem altogether, the Supreme Court recognizes direct limitations on this type of commercial speech as a violation of the First Amendment.¹⁴⁴ In *Thompson v. Western States Medical Center*, the FDA argued in defense of its regulatory ban on the advertising of compound pharmaceutical products.¹⁴⁵ A majority of the Court reasoned that prohibiting advertising of compound drugs would prevent useful speech. The Court also argued that it was not the least restrictive means of accomplishing the goal of protecting public health.¹⁴⁶ Under *Thompson*, even proposed indirect limitations may be struck down as unconstitutional.¹⁴⁷

138. Topol, *supra* note 135, at 1707. These aggressive defenses included Merck’s press release entitled “Merck Reconfirms Favorable Cardiovascular Safety of Vioxx” and several papers written by Merck employees and published in medical literature. Further, Merck sponsored numerous educational symposiums at national meetings “in an effort to debunk the concern about adverse cardiovascular effects.” *Id.*

139. *Id.* at 1708.

140. Fair Advertising and Increased Research (FAIR) Act, H.R. 4821, 107th Cong. § 2801 (2002); S. 2486, 107th Cong. § 2801 (2002); Francis B. Palumbo & C. Daniel Mullins, *The Development of Direct-to-Consumer Prescription Drug Advertising Regulation*, 57 FOOD & DRUG L.J. 423, 434 (2002).

141. Prescription Affordability and Medicine Safety Act of 2002, H.R. 5350, 107th Cong. § 2801(a).

142. Say No to Drug Ads Act, H.R. 5105, 107th Cong. § 2801 (2002); 148 CONG. REC. 4552 (July 11, 2002).

143. Palumbo & Mullins, *supra* note 140, at 431.

144. *Thompson v. Western States Medical Center*, 535 U.S. 357, 366-68, 377 (2002).

145. Palumbo & Mullins, *supra* note 140, at 441.

146. *Thompson*, 535 U.S. at 374-76.

147. *See* Palumbo & Mullins, *supra* note 140, at 442.

Although recent legislative, regulatory, and administrative changes at the FDA have decreased drug approval times, the American public is suffering the consequences of these industry-friendly developments. The convergence of expedited approval processes, relaxed advertising regulations, and decreased regulatory enforcement has led to a noticeable increase in consumption of prescription drugs—and industry profits. Unfortunately, statistics also show that more of these new drugs are unsafe for consumers. In many circumstances, it is the most heavily advertised and profitable drugs that are the most harmful. These developments add an increased urgency to the preservation of tort remedies against drug manufacturers.

III. THE ROLE OF THE TORT SYSTEM IN DRUG INDUSTRY REGULATION AND ENFORCEMENT IS ESSENTIAL TO CONSUMER PROTECTION IN THE TRANSFORMED REGULATORY LANDSCAPE

As pharmaceutical sales and drug availability are on the rise, the FDA faces new criticism arising from several well-publicized withdrawals of FDA-approved drugs.¹⁴⁸ Although some problems with the drug approval process existed long before the most recent legislative and regulatory changes, these developments have only magnified previous criticism. As a result, there is increasing public concern that consumers are not adequately protected from harmful drugs.

Like the FDA, the tort system provides an incentive to produce safe drugs and regulatory enforcement when drugs are proven unsafe. The tort system currently works along with the FDA to compensate drug consumers where regulation has failed. In fact, the evidentiary basis for many tort actions is often provided by FDA regulation and enforcement proceedings. Tort remedies offer the benefit of sending a clear message to pharmaceutical companies that liability may exist where they choose to value profits over consumer safety.

A. Tort Claims Provide Remedies Where FDA Approves Defective Drugs

1. The Scope of the Defective Drug Approval Problem

During the entire pre-marketing drug approval process, all clinical testing is performed either by pharmaceutical company employees or by independent researchers paid by the pharmaceutical company that sponsors the drug.¹⁴⁹ In

148. See discussion *supra* part II(C)(3)(ii) and accompanying notes; discussion *infra* part III (A)(2)(ii) and accompanying notes.

149. See Green, *supra* note 8, at 481 (noting that “FDA’s approval of a drug, which includes a determination of the appropriate labeling (i.e., warnings) is wholly dependant on testing performed and reported by the sponsoring manufacturer.”).

effect, all proof of drug safety and efficacy required under the 1962 Kefauver-Harris Amendments is demonstrated by the pharmaceutical companies themselves.¹⁵⁰ While the FDA reviews these applications, and occasionally requests additional information during their review, FDA researchers do not perform any independent testing. Most importantly, negative scientific findings at any phase of the clinical trial are under the control of the drug company, and very likely may not be publicized when the drug makes it to market. In fact, even though negative results are included in new drug applications, the FDA is under no legal obligation to report such findings to the public.¹⁵¹

The pre-marketing drug approval process has proven seriously inadequate in making preliminary determinations of the efficacy and safety of pharmaceuticals. A 1990 study by the General Accountability Office (GAO) reviewed all approved prescription drugs between 1976 and 1985 for incidents of adverse reaction.¹⁵² The GAO reported that over 50% of all prescription drugs approved by the FDA had serious risks that failed to be exposed in the new drug application phase.¹⁵³ While it is inevitable that some defective drugs may slip through the FDA approval process, the current influx of defective drugs under the existing regulatory landscape makes tort remedies more necessary than ever before.

2. *Examples of Successful Tort Intervention*

i. *Pediatric Use of Paxil*. While the use of selective serotonin reuptake inhibitors (SSRIs) to treat pediatric depression was approved by the FDA, it was not until tort claims were initiated that dangers were exposed to consumers. In the first quarter of 2004, GlaxoSmithKline made \$533 million in profits from sales of one version of the SSRI paroxetine, also known as Paxil.¹⁵⁴ Unbeknownst to consumers were results from two 1998 clinical trials indicating not only that Paxil was ineffective for treating pediatric depression but that incidents of suicidal tendencies among trial participants administered the drug were 3.2 times higher than those for patients given a placebo.¹⁵⁵ While the FDA received the results of

150. 21 U.S.C. § 355(b)(1)(A) (2000).

151. See Rennie, *supra* note 68, at 1359 (noting that negative trial results reported to FDA “disappear without a trace” because FDA has no mandate to disseminate this negative information).

152. U.S. GOV'T ACCOUNTABILITY OFFICE, FDA DRUG REVIEW: POSTAPPROVAL RISKS 1976-85 3 (1990), available at <http://161.203.16.4/d24t8/141456.pdf>. GAO conducted this review to determine the “frequency and seriousness of the additional risks linked to these drugs after their initial approval.” *Id.* at 3. Additional adverse effects were indicated by subsequent removal from the market or revision in labeling. *Id.* at 11.

153. *Id.* at 51.

154. Rennie, *supra* note 68, at 1360.

155. *Id.* at 1359; Wayne Kondro & Barbara Sibbald, *Pharmaceutical Industry: Drug Company Experts Advised Staff to Withhold Data About SSRI Use in Children*, 170 CAN. MED. ASS'N J. 783, 783 (2004).

these studies during the pre-marketing approval process, Paxil was nevertheless approved for consumption in children with major depressive disorder.¹⁵⁶

Apparently, GlaxoSmithKline officials were aware of the dangers in pediatric consumption of Paxil as early as 1998. GlaxoSmithKline internal memos, released in 2004 by the Canadian Medical Association, concluded that “[i]t would be commercially unacceptable to include a statement that efficacy had not been demonstrated, as this would undermine the profile of paroxetine.”¹⁵⁷ Furthermore, company researchers recommended that they “effectively manage the dissemination of these data in order to minimize any potential negative commercial impact.”¹⁵⁸ Although these actions are alarming, they are not illegal: so long as negative test results are disclosed to the FDA, there is no legal obligation to make these results public. In effect, GlaxoSmithKline’s regulatory obligation was fulfilled simply by reporting the results of this trial to the FDA. If the regulatory compliance defense were available, GlaxoSmithKline would be immune from—or liable for significantly less—damages. In an action for failure to warn or intentional misrepresentation, however, GlaxoSmithKline may not prove so lucky.

In fact, several such actions have been filed against GlaxoSmithKline. As a result of this data being released, New York’s Attorney General Eliot Spitzer filed suit against the company, alleging that “GlaxoSmithKline deprived physicians of the information needed to evaluate the risks and benefits of prescribing paroxetine for children and adolescents with MDD [major depressive disorder].”¹⁵⁹ The legal basis for Spitzer’s claim was intentional misrepresentation in “playing down negative pediatric test information.”¹⁶⁰ GlaxoSmithKline eventually settled the suit for \$2.5 million,¹⁶¹ a settlement that also included disclosure of previously unpublished negative study results for public review.¹⁶²

The filing of this lawsuit drew increased attention to the problem of unpublicized clinical trials. Almost immediately after Spitzer filed suit against GlaxoSmithKline, the American Medical Association (AMA) called for creation of a federal database to which researchers would be required to submit clinical trial information before, during, and after drug approval by the FDA.¹⁶³ The AMA’s

156. Paxil was approved by the FDA on December 29, 1992. U.S. FOOD & DRUG ADMIN., QUESTIONS & ANSWERS ON PAXIL, available at <http://www.fda.gov/cder/drug/infopage/paroxetine/paxilq&a.htm> (last visited Sept. 21, 2006).

157. Kondro & Sibbald, *supra* note 155, at 783.

158. *Id.*

159. Rennie, *supra* note 68, at 1360.

160. Barry Meier, *Medical Editors Likely to Call for Registration of Drug Tests at Outset*, N.Y. TIMES, Sept. 8, 2004, at C1.

161. For perspective, it is important to consider the earlier figure of \$533 million in profits from *one quarter* of Paxil sales in 2004. Rennie, *supra* note 68, at 1360; Alex Berenson, *Despite Vow, Drug Makers Still Withhold Data*, N.Y. TIMES, May 31, 2005, at A1.

162. Berenson, *supra* note 161, at A2.

163. Meier, *supra* note 160.

response was followed by widespread calls for fundamental change to the clinical trial reporting system among medical professionals, medical journals, and Congress.¹⁶⁴ The FDA responded to this outcry by holding public hearings, and eventually conceded that children taking SSRIs are 1.78 times more likely to commit suicide than those not taking the drug. As a result, the FDA began including “black box” warnings that suicidal tendencies may occur in higher rates in juveniles taking SSRIs.¹⁶⁵

This is just one example of where the FDA drug approval scheme inadequately protected American consumers from harm. While both GlaxoSmithKline and the FDA complied with their regulatory duties, consumers still have been injured by SSRIs. Here, the tort system served an integral function. Aside from drawing widespread public attention and debate, the tort system drove disclosure of potential harmful side effects. Particularly in failure to warn claims, disclosing much and disclosing early may insulate drug manufacturers from liability. In effect, the increased threat of tort litigation functions to increase dissemination of potential risks *before* consumers are harmed.

*B. Tort Claims Provide Remedies for Non-Compliance with
Post-Marketing Regulation*

1. Scope of the Non-Compliance in Post-Marketing Reporting Problem

i. Inadequate Enforcement of Adverse Drug Reaction Reports. According to a recent study reported in the *Journal of the American Medical Association*, over 770,000 deaths each year are a result of adverse drug reactions in patients.¹⁶⁶ A 2000 report from the FDA indicates that only 10% of doctors make adverse drug reaction reports at all.¹⁶⁷ At least one commentator suggests that our system of adverse drug reaction reporting from pharmaceutical manufacturers only identifies 10% of actual adverse reactions that occur in patients.¹⁶⁸ While a drug cannot be marketed until it passes through the pre-market regulatory process, post-market compliance is not examined until non-compliance is suggested.¹⁶⁹ This means that until the scientific community or the public suggest otherwise, compliance with the

164. *Id.*

165. Jonathon Mahler, *The Antidepressant Dilemma*, N. Y. TIMES, Nov. 21, 2004, at 8.

166. AGENCY FOR HEALTH RESEARCH & QUALITY, U.S. DEP'T OF HEALTH & HUMAN SERVS., REDUCING AND PREVENTING ADVERSE DRUG EVENTS TO DECREASE HOSPITAL COSTS 1 (2001), available at <http://www.ahrq.gov/qual/aderia/aderia.htm>.

167. See U.S. GEN. ACCOUNTING OFFICE, Adverse Events: Surveillance Systems for Adverse Events and Medical Errors: Statement of Janet Heinrich 3 (2000), available at <http://www.gao.gov/archive/2000/he00061t.pdf>.

168. Denise Grady, *Study Finds New Drugs May Carry Extra Hazards*, N.Y. TIMES, May 1, 2002, at A20.

169. See Green, *supra* note 8, at 476.

ADR system is presumed. This downstream regulatory control has proven to be ineffective at ensuring adequate adverse reaction reporting. Under this regulatory scheme, it often takes public outcry over drug injuries for a drug to be pulled from the market.

The initial problem with the current ADR system is that it relies upon voluntary submission of information to drug companies by doctors and patients.¹⁷⁰ Under the current system, patients report the occurrence of an adverse event either to their doctor, the manufacturer, or the FDA.¹⁷¹ After patients report adverse drug reactions to doctors, the reporting by the doctor to the drug manufacturer is also strictly voluntary.¹⁷² For both doctors and lay patients, it is often difficult to separate adverse reactions from effects of the underlying disease. As a result, many adverse reactions may go unreported.

A second obstacle to an effective ADR reporting system is the failure of drug companies to report adverse drug reactions to the FDA once they are informed. According to Professor Michael D. Green, co-reporter of the *Third Restatement of Torts*, “[T]he marketing and profit incentives for a pharmaceutical manufacturer are contrary to thorough and accurate gathering and reporting of ADRs.”¹⁷³ Simply, the profit goals of drug companies may undermine their credibility as an important link in the reporting system. Unfortunately, these conflicts of regulatory and fiduciary interests often result in a failure to warn consumers of potential injuries. For example, Professor Green described how one drug manufacturer in the Bendectin litigation¹⁷⁴ “persuaded doctors who called to report birth defects associated with maternal use of [Bendectin] to characterize their calls as ‘inquiries’ rather than reports” so as to circumvent the ADR process.¹⁷⁵

Even when the FDA has access to ADRs, it often fails to adequately assess the information and disseminate warnings to the medical community. The AMA recently reported significant failures by the FDA to synthesize reports of dangerous adverse drug interactions that were already in their databases.¹⁷⁶ According to the AMA, it was not until researchers from the sponsoring company analyzed the data

170. O'REILLY, *supra* note 24, at 13-209 to 13-210 (“Drug sponsors must file the reports; others are encouraged to do so.”).

171. *Id.*; 21 C.F.R. § 314.80(b) (2005).

172. O'REILLY, *supra* note 24, at 13-209. As of 1990, less than 10% of doctors participated in adverse reaction reporting. Green, *supra* note 8, at 55.

173. Green, *supra* note 8, at 499.

174. Bendectin was a drug approved by the FDA and used by pregnant women in the later 1970s and early 1980s to curb the effects of morning sickness. See generally MICHAEL D. GREEN, BENDECTIN AND BIRTH DEFECTS: THE CHALLENGES OF MASS TOXIC SUBSTANCES LITIGATION 331 (1996).

175. Green, *supra* note 8, at 499 n.140, (citing *id.* at 129). Worse, the offending drug company also was revealed to have denied the existence of birth defects in other pregnant women taking Bendectin. *Id.*

176. Bruce M. Psaty et al., *Potential for Conflict of Interest in the Evaluation of Suspected Adverse Drug Reactions: Use of Cerivastatin and Risk of Rhabdomyolysis*, 292 JAMA 2622, 2622-31 (2004).

themselves (three years after initial approval) that the dangerous drug interaction became clear.¹⁷⁷ Eve E. Slater, former HHS Assistant Secretary for Health, attributes this failure to adequately analyze adverse reaction data to the lack of a centralized system of ADR collection and analysis.¹⁷⁸ Currently, ADR data is located in separate databases of pre-approved clinical trials, post-approval FDA information, medical literature, and post-approval data of drug sponsors.

ii. *Inadequate Enforcement of Post-Marketing Research.* Many drug companies commit themselves to extensive post-marketing research in exchange for drug approval under the “priority drug” framework of the user fee program. Under the accelerated drug approval scheme for priority drugs, a lower threshold of clinical testing is required for approval for drug marketing. Yet approval under this accelerated scheme is predicated upon the performance of post-marketing tests in order to flesh out potential reactions and side effects that the accelerated process left undiscovered. Unfortunately, these post-marketing tests are often not completed. A recent FDA report indicated that “of the more than 1300 post-marketing studies to which drug companies have committed themselves, 65% have not been started.”¹⁷⁹

2. Tort Litigation Provides Remedies for Post-Marketing Regulatory Non-Compliance

The FDA mandates reporting of serious adverse effects within fifteen calendar days, followed by investigation into these adverse reactions.¹⁸⁰ At worst, failure to comply with procedures may subject a manufacturer to an FDA regulatory enforcement case.¹⁸¹ In effect, many pharmaceutical companies may fail to report adverse reactions to the FDA because reporting would potentially cause profitable drugs to be pulled from the market.¹⁸² Under a cost-benefit analysis, the profit of keeping a drug on the market for even a few more days often far outweighs the cost of a regulatory enforcement action. However, there is no private cause of action available to plaintiffs against drug manufacturers who fail to file ADRs in a timely manner.¹⁸³

177. *Id.* at 2622.

178. Slater, *supra* note 55, at 295.

179. Okie, *supra* note 100, at 1065.

180. 21 C.F.R. §§ 314.80(c)(1)(i)–(ii) (2005); Expedited Safety Reporting Requirements for Human Drug and Biological Products, 62 Fed. Reg. 52237, 52240-41 (Oct. 7, 1997).

181. O'REILLY, *supra* note 24, at 13-207, § 13:26.

182. See GREEN, *supra* note 174, at 55 (“Reporting by manufacturers to the FDA, despite the legal requirement, has been less than perfect.”).

183. See *Munson v. Eli Lilly & Co.*, Civil No. 4-86-607 (D. Minn., Nov. 25, 1987). However, recent legislation has been introduced that would create civil and criminal penalties for manufacturers failing to report adverse reactions to the FDA. Pharmaceutical Research & Manufacturer Accountability Act of 2005 (PHRMA) H.R. 870, 109th Cong. (proposing provisions that would fine pharmaceutical

In several egregious examples, tort remedies continue to provide enforcement and regulation where FDA measures were inadequate to enforce ADR reporting. In *Benedi v. McNeil-P.P.C., Inc.*, the Fourth Circuit held that punitive damages were reasonable against a pharmaceutical manufacturer that withheld ADRs from the FDA regarding the toxic effects of mixing Tylenol and alcohol.¹⁸⁴ The plaintiff suffered severe liver injury and transplant as a result of ingesting Tylenol in addition to his nightly three glasses of wine.¹⁸⁵ According to expert testimony, by the end of 1992 the manufacturer received more than sixty adverse reaction reports of the possible mixing between acetaminophine and alcohol.¹⁸⁶ In addition, numerous scientific studies were cited in support of the finding of a connection between the two.¹⁸⁷ Although the FDA convened a panel to research the correlation as early as 1972, it concluded that no warning label alerting consumers to the risk was necessary because the risk was only associated with consumers who were chronic alcohol abusers.¹⁸⁸

A more recent case has prompted some members of Congress to propose criminal penalties for failure to report ADRs. In the Baycol litigation,¹⁸⁹ plaintiffs alleged that Bayer failed to investigate reports of connections between the diabetes drug and a rare muscular disorder. During one trial, a note from an official at Bayer was introduced into evidence. The note read, "If the [FDA] asks for bad news, we have to give, but if we don't have it, then we can't give it to them."¹⁹⁰ After revealing that company executives deliberately avoided investigating or reporting this adverse drug reaction, Bayer settled with a group of plaintiffs for over \$1.1 billion in products liability actions.¹⁹¹

The public outcry over failure to report adverse drug experiences led members of Congress to introduce criminal and civil penalties for withholding evidence of adverse effects from the FDA. The Pharmaceutical Research and Manufacturer's Accountability Act of 2005 was introduced in the House of Representatives in 2005 by Rep. Stark of California.¹⁹² The Act called for criminal penalties for industry executives of up to twenty years in jail and fines not to exceed \$2 million for knowingly concealing adverse drug experiences.¹⁹³ The Act

CEOs up to \$2 million for withholding adverse reactions, and imposing minimum prison terms of twenty years).

184. 66 F.3d 1378, 1389 (4th Cir. 1995).

185. *Id.* at 1381.

186. *Id.* at 1382.

187. *Id.*

188. *Id.*

189. *In re Baycol Prods. Litigation*, 321 F. Supp. 2d 1118 (D. Minn. 2004).

190. Berenson, *supra* note 106, at 2.

191. O'REILLY, *supra* note 24, at 13-212 (citing Dietra Henderson, *FDA Reviews When Bayer Revealed Drug Risks*, CIN. ENQUIRER, Nov. 28, 2004).

192. H.R. 870, 109th Cong. (2005).

193. *Id.* § 2(a).

also provided for fines of up to \$5 million per month for failure to complete post-marketing reports in a timely manner.¹⁹⁴

In addition to compensating injured consumers, tort litigation over failure to make adverse reaction reports has prompted public outcry and legislative response. For pharmaceutical companies, the incentives to avoid filing adverse reaction reports far outweigh the benefits of making such reports to the FDA. Strengthening FDA regulatory and enforcement procedures may be effective at cutting down on this abuse. Yet the threat of punitive damages from thousands of litigants forces drug manufacturers to consider these litigation costs when deciding whether to investigate and report ADRs.

*C. Inadequate FDA Enforcement of Advertising Regulation and
Potential Recovery in Tort*

The FDA's 1999 promulgation of the *Guidance for Industry* on DTC broadcast advertisements, in combination with the 2001 HHS change in regulatory letter policy, has effectively given the pharmaceutical industry free reign to continually broadcast a strain of advertising that is extremely effective—and often misleading. Consumption of heavily advertised drugs has been increasing drastically since the draft *Guidelines for Industry* were issued in 1997.¹⁹⁵ By 2003, the pharmaceutical industry was spending over \$2.7 billion on advertising directly to consumers.¹⁹⁶

While numerous studies have shown that DTC advertising is extremely lucrative for drug companies,¹⁹⁷ they have reported that it confuses drug consumers and increases pressure on doctors to prescribe these high-profile drugs.¹⁹⁸ The pharmaceutical industry continues to take the likely position that these ads are educating the public as to the health benefits of prescription drugs.¹⁹⁹ The American College of Physicians has rejected this reasoning and concluded that “though information may be put forth in drug advertisements to educate, these ads

194. *Id.* § 2(j).

195. REPORT TO CONGRESSIONAL REQUESTERS, *supra* note 80, at 11-14.

196. O'REILLY, *supra* note 24, at 15-63, §15:15.

197. REPORT TO CONGRESSIONAL REQUESTERS, *supra* note 80, at 12 (noting that in 2000, twenty-two of the fifty drugs with the highest DTC spending were among the top fifty in sales).

198. Tamar V. Terzian, *Direct to Consumer Prescription Drug Advertising*, 25 AM. J.L. & MED. 149, 158, 159 (1999) (stating that 39% of physicians find that DTC ads cause patients to reach incorrect conclusions); CTR. FOR DRUG EVALUATION & RESEARCH, U.S. DEP'T OF HEALTH & HUMAN SERVS., PATIENT AND PHYSICIAN ATTITUDES AND BEHAVIORS ASSOCIATED WITH DTC PROMOTION OF PRESCRIPTION DRUGS—SUMMARY OF FDA SURVEY RESEARCH RESULTS 8 (2004) [hereinafter PATIENT AND PHYSICIAN ATTITUDES ABOUT DTC ADVERTISING]; REPORT TO CONGRESSIONAL REQUESTERS, *supra* note 80, at 16.

199. PHRMA, *supra* note 85, at 28.

are primarily calculated to encourage increased consumption of the advertised product.²⁰⁰

1. Inadequate FDA Enforcement of Regulations

The advertising that has spawned such industry growth has gone largely unregulated. One reason has been the 2001 HHS changes to FDA policy, which have impeded the regulatory letter system to a point where advertisements have often ended before warning letters are issued.²⁰¹ In some instances, the excessive lag time that now exists between the observation of a misleading advertisement and the issuance of a regulatory letter has been as great as seventy-eight days.²⁰² During this delay, hundreds of thousands of potential consumers are exposed to misleading advertising that will inevitably lead some to request that very drug from their doctors.

Yet the problem is not only that misleading advertisements are reaching consumers, but that the misleading advertisements reaching consumers are for drugs of questionable safety. Under the current system, even when regulatory letters are issued in a timely manner, pharmaceutical companies are not deterred from making the same misleading claims in later advertisements.²⁰³ The FDA has been unwilling and unable to enforce DTC advertising regulations that might have prevented consumer harms from drugs like Vioxx and Paxil.

2. Potential Tort Actions

i. Destruction of the Learned Intermediary Doctrine for Over-Promotion.

Yet again, where regulatory enforcement measures are inadequate, tort remedies may provide a limitation on the over-promotion of drugs. The *Third Restatement of Torts* suggests that when a physician has a diminished role in the decision-making of drug prescription, an additional manufacturer warning may be necessary.²⁰⁴ Several cases and commentators have suggested an outright exception from traditional learned intermediary protection from manufacturer liability where manufacturers have participated in DTC advertising.²⁰⁵ According

200. AMER. COLL. OF PHYSICIANS, DIRECT TO CONSUMER ADVERTISING FOR PRESCRIPTION DRUGS 2 (1998), available at <http://www.acponline.org/hpp/pospaper/dtcads.htm>.

201. REPORT TO CONGRESSIONAL REQUESTERS, *supra* note 80, at 22-23.

202. *Id.* at 23.

203. *Id.* at 21.

204. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d) (1998) (“A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to . . . the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.”).

205. *Perez v. Wyeth Laboratories, Inc.*, 734 A.2d 1245, 1257 (1999) (holding that direct to consumer advertising voids the previous shield under the learned intermediary doctrine); *Vitanza v.*

to this argument, the manufacturer's over-promotion of a drug would destroy learned intermediary protection because it effectively hinders the physician's ability to exercise professional discretion due to the eagerness of the patient to be prescribed the advertised drug.²⁰⁶

California courts have applied this logic in cases of drug manufacturers' advertising products directly to physicians. As early as 1964, the California Court of Appeals held that where a pharmaceutical company vigorously and successfully promoted its drug to the medical profession, the company was liable for failure to warn, despite providing warnings to doctors of the dangers of the drug.²⁰⁷ In 1973, a California district court held that the over-promotion of an antibiotic to doctors, even in light of warnings, was enough to defeat the application of the learned intermediary doctrine.²⁰⁸ Other courts have held that whether pharmaceutical manufacturers' over-promotion of a drug eroded the effectiveness of warnings is a question of fact for the jury, and does not invoke learned intermediary immunity.²⁰⁹

While previously applied in the context of manufacturer to physician advertising,²¹⁰ the argument that over-promotion destroys learned intermediary immunity may work in the field of DTC advertising as well. There is powerful evidence supporting such an argument. First, an FDA survey has shown that, of 39% of respondents who inquired about a drug they had seen in a DTC advertisement, almost half were prescribed that drug by their doctor.²¹¹ The GAO

Upjohn, 214 F.3d 73, 78 (1999) (finding that application of learned intermediary doctrine in light of DTC advertising is a matter of unsettled law); e.g., Mitchell S. Berger, *A Tale of Six Implants: The Perez v. Wyeth Laboratories Norplant Case and the Applicability of the Learned Intermediary Doctrine to Direct-to-Consumer Drug Promotion*, 55 FOOD & DRUG L.J. 525, 574 (2000); Sheryl Calabro, *Breaking the Shield of the Learned Intermediary Doctrine: Placing the Blame Where it Belongs*, 25 CARDOZO L. REV. 2241, 2313-15 (2004); Bradford B. Lear, *The Learned Intermediary Doctrine in the Age of Direct Consumer Advertising*, 65 MO. L. REV. 1101, 1114-16 (2000).

206. See Kane, *supra* note 31, at 102 (describing the logic of over-promotion in destroying learned intermediary protections).

207. Love v. Wolf, 226 Cal. App. 2d 378, 402 (1964).

208. Stevens v. Parke, Davis & Co., 507 P.2d 653, 662 (1973) (finding that even though warning letters were distributed to doctors, the pharmaceutical company continued to distribute calendars and giveaways, and place advertisements for the antibiotic in magazines).

209. Salmon v. Parke, Davis & Co., 520 F.2d 1359, 1363 (4th Cir. 1975); see Kane, *supra* note 31, at 104.

210. Application of the theory under the original theory of manufacturer-to-physician advertising would be a possibility as well. In fact, the GAO reports that in 2001, most advertising money coming from drug companies went to advertising aimed at physicians. REPORT TO CONGRESSIONAL REQUESTERS, *supra* note 80, at 3 (reporting that over 80% of promotional spending was aimed at physicians in 2001). In order to minimize the length of this discussion, I have not addressed the impact of alarming statistics of industry influence on physicians in drug prescription. It is noteworthy that one recent survey reported that 61% of doctors responded that they had accepted free meals and tickets for entertainment or travel from pharmaceutical companies. KAISER FAMILY FOUND., NAT'L SURVEY OF PHYSICIANS: PART II: DOCTORS AND PRESCRIPTION DRUGS, at chart 2 (2002).

211. PATIENT AND PHYSICIAN ATTITUDES ABOUT DTC ADVERTISING, *supra* note 198, at 4.

estimates that “about 8.5 million consumers received a prescription after viewing a DTC advertisement and asking their physician for the drug in 2000.”²¹² This data indicates that drug consumers may be empowered through DTC advertising to seek specific drugs from their doctors, which minimizes the role of the doctor in the decision-making.

ii. Misrepresentation Claims. Drug companies that are subject to FDA regulatory letters may be exposed to liability for intentional misrepresentation. To establish a prima facie case of negligent misrepresentation, a plaintiff must show that (1) the defendant made a false representation, concealment, or non-disclosure, (2) the defendant had knowledge of the misrepresentation, (3) the defendant intended to defraud or induce reliance, (4) the plaintiff justifiably relied on defendant’s misrepresentation, and (5) damage resulted to the plaintiff.²¹³

Counsel for injured consumers could build a case around publicly available information, even without the benefit of discovery. For instance, the FDA posts all regulatory and warning letters that it issues to drug manufacturers on its website, as well as responses to those letters.²¹⁴ These letters describe, often in scientific detail, why the FDA finds an advertisement to be false or misleading.²¹⁵ Thus, the FDA’s determination of misrepresentation may satisfy the first element of a prima facie case. The second and third elements would most likely also be satisfied by the regulatory letter, particularly where the same misleading advertising tactics are later used again. In fact, the primary purpose in drug advertising is to induce consumers to purchase and use the drug. Because the drug companies themselves conducted the clinical trials, these regulatory letters could establish that drug companies knew the risks of taking a drug but advertised to the contrary.

The fourth element of justifiable reliance could be proven by testimony of the plaintiff that she sought the medication from her doctor after seeing the ad on television. This testimony could also be buttressed by statistical reports that high percentages of consumers who see DTC ads later ask their doctor for those drugs. The final damage element could be proven by testimony from the plaintiff’s personal physician, in combination with reports from the clinical trials that this type of physical harm is precisely the type of injury that was seen in the clinical trials.

The combination of an accelerated drug approval framework with relaxed advertising regulations has created a tremendous boom in the pharmaceutical industry during the past seven years. The FDA has failed in effectively regulating

212. REPORT TO CONGRESSIONAL REQUESTERS, *supra* note 80, at 16.

213. RESTATEMENT (SECOND) OF TORTS §§ 525-31 (1977).

214. See U.S. Food & Drug Admin., Warning Letters and Notice of Violation Letters to Pharmaceutical Companies, <http://www.fda.gov/cder/warn/index.htm> (last visited Sept. 21, 2006) (providing links to warning letters and notice of violation letters, sorted by year).

215. See, e.g., Letter to Merck, *supra* note 136.

the expedited approval process, post-marketing reporting system, and enforcement of advertising. As a result, the pharmaceutical industry has effective control over the entire drug approval process, from submission of the IND to DTC advertising. Worse, the revolving door of the pharmaceutical industry and the FDA has turned a formerly adversarial system of drug regulation into a collusive, profit-driven apparatus. Faced with an ineffective and inefficient system of FDA regulation, tort remedies are more necessary to consumer protection than ever before.

IV. THE REGULATORY COMPLIANCE DEFENSE REVISITED

Proponents typically advance the regulatory compliance defense as part of broader tort reform measures aimed at capping damage awards, limiting products liability actions, and removing cases from the province of the jury. The regulatory compliance defense is generally proposed either as a total immunity for pharmaceutical manufacturers from product liability for compliance with FDA regulations or, alternatively, as an immunity from punitive damage awards for regulatory compliance.²¹⁶ It is important to note that proponents of the defense do not advocate that mere FDA approval should immunize manufacturers from liability; rather, the defense focuses on compliance with FDA regulatory standards as basis for immunity.²¹⁷

There are several reasons why the regulatory compliance defense, though initially attractive, would prove detrimental to public health. First, the defense would insulate drug manufacturers from liability, although they are in the best position to make products safer. Because all clinical trials are performed under the control of a sponsoring drug company, and most adverse reaction reports are filed through drug companies, the companies themselves have control over safety in testing and reporting. Under the common law tort system, pharmaceutical companies are encouraged to go beyond the minimal safety and warning requirements of the FDA because regulatory compliance does not presume satisfaction of the standard of care. Rather, complying with FDA standards is treated as evidence of compliance with a standard of care, but is not determinative of satisfaction of that standard of care. As a result, the regulatory compliance defense would destroy much of the incentive for pharmaceutical companies to develop safe and effective drugs and to warn consumers in a timely manner when defects are later uncovered.

It is important to understand that drug companies participating in egregious behavior may be shielded from liability under the regulatory compliance defense. For example, Merck complied with all regulatory requirements in gaining approval

216. See Green, *supra* note 8, at 465.

217. *Id.* at 481.

of Vioxx in 1999. In addition, Merck complied with all regulatory requirements by withdrawing the offending Vioxx ads after warning letters were issued in 2002. Thus, Merck's liability would have been limited (or totally eliminated) under the regulatory compliance defense. The same is true of the use of Paxil to treat pediatric depression. Notably, GlaxoSmithKline was under no regulatory or statutory requirement to release the results of clinical studies showing increased incidence of suicide in pediatric depression patients. Worse, the results of those clinical trials were submitted to the FDA in the initial application process. Thus, GlaxoSmithKline also complied with its regulatory obligations. In both cases, the regulatory compliance defense would shield these manufacturers from liability.

Also, the regulatory compliance defense may leave large numbers of injured consumers with inadequate remedies—or even completely remediless. Under the FTCA, the FDA is almost always immune from liability for approval of defective drugs. If the regulatory compliance defense were enacted, medical malpractice actions against prescribing physicians would be the only remaining remedy for injured drug consumers. Yet doctors are liable under the Learned Intermediary Doctrine in only limited cases, where physicians failed to warn patients adequately of known side effects of a drug. Where a pharmaceutical company has failed to perform clinical testing adequately or failed to warn of adverse reactions, doctors should not—and most probably would not—be held liable.

Third, because pharmaceutical companies are profiting from the development and sale of new drugs, they should also be held responsible where consumers are injured as a result of their unsafe products and intense marketing campaigns. Drastic increases in pharmaceutical sales have also significantly increased industry profits. While some industry critics complain that the costs of tort litigation are stifling research and development, one industry group reports “dramatic growth in research and development” between 1990 and 2002—from \$8 million to \$32 million.²¹⁸ Because these companies are reaping the benefits of decreased regulation, pharmaceutical companies should be the party that absorbs the loss when the regulations fail to protect the public.

Liability Insurance and Punitive Damages. It is important to briefly note the role of the insurance industry when discussing the costs of liability. It is true that all drug companies own liability insurance, and thus do not directly pay the costs of compensating injured drug consumers. However, liability insurance rates are based on premiums that drug companies are responsible for paying. Where liability costs increase, those premiums will inevitably rise as well. Likewise, a clean safety record and fewer tort actions may reduce insurance premiums for drug

218. PHARMACEUTICAL RESEARCH & MANUFACTURERS ASS'N (PHRMA), PHARMACEUTICAL INDUSTRY PROFILE: 2003, DRAMATIC GROWTH OF RESEARCH AND DEVELOPMENT 10-11 (2004), available at <http://www.phrma.org/publications/publications/profile02/2003%20CHAPTER%202.pdf>.

companies. As a result, drug companies do feel the effect of tort litigation (or lack thereof), despite having liability insurance.

Even under a form of the regulatory compliance defense that only shields manufacturers from punitive damages, consumers may still be left remediless. In many states, compensatory damage awards are statutorily capped.²¹⁹ This enables drug companies to estimate more easily a maximum cost for consumer injury when performing a cost-benefit analysis of the potential profits from a drug versus the potential liability cost of potential injured consumers. Because damages are capped in many jurisdictions, compensatory damages for injured drug consumers would almost always be outweighed by high potential profit margins.

V. CONCLUSION

The FDA will inevitably make errors in the regulation and enforcement process. As Richard Merrill, future Chief Counsel of the FDA, remarked in 1973, “[T]he conclusion is inescapable that the [FDA] occasionally makes wrong choices, even when all of the facts are before it.”²²⁰ One reason for these wrong choices is that the entire clinical testing process has always been controlled by the sponsoring manufacturer. This was true even in 1962, when regulation of the much smaller drug approval process first became part of the FDA’s mandate.²²¹ In fact, it would be virtually impossible for the process to happen any other way. Yet we continue to ask more of our FDA. In the past fifteen years, reviewer workload has increased, while time frames for decisions on drug approval have drastically decreased.²²² As the FDA’s responsibilities continue to outpace its funding and manpower, there is a growing likelihood that defective drugs will continue to make it to market. As a result, drug consumers will continue to be harmed.

Where FDA regulation and enforcement fail, we cannot depend on the pharmaceutical industry to self-regulate. As corporate entities, it is the goal of drug companies to earn profits for their shareholders. In fact, corporations have a fiduciary duty to make sound financial decisions that maximize profits. Inevitably, conflicts of interest arise between making profits and ensuring a safe product. This is where tort remedies are most necessary to the preservation of public health and safety. Tort remedies ensure that, while earning profits for their shareholders, drug

219. According to the American Tort Reform Association, thirty-two states have enacted some punitive damage reform measures, and twenty three states have enacted non-economic damage reform. Of these reform measures, the most common is damage caps. AMERICAN TORT REFORM ASSOC. (ATRA), *THE TORT REFORM RECORD 1* (2005), available at http://www.atra.org/files.cgi/7990_Record_12-31-05.pdf.

220. Richard A. Merrill, *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1, 16 (1973).

221. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (codified as amended in scattered section of 21 U.S.C. (2000)).

222. EFFECT OF USER FEES ON DRUG APPROVAL TIMES, *supra* note 48, at 18-19.

companies fulfill their duties to adequately test drugs, effectively warn consumers of potential dangers, and accurately represent the risks and benefits of their drugs. Importantly, our current tort system encourages manufacturing and selling drugs for the safest use possible, rather than satisfying minimal safety requirements.

In today's regulatory landscape, new drugs are reaching consumers faster than ever before, while regulation protecting them from deceptive advertising is rarely enforced. Tort litigation provides essential remedies for consumers, and incentives for manufacturers, to ensure consumer safety to the greatest extent possible. Yet the increasing need for consumer protection has been met by a decline in both regulation and enforcement. Now more than ever, drug consumers need tort remedies when injured by harmful drugs.