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ENHANCING DRUG EFFECTIVENESS AND EFFICACY THROUGH PERSONAL INJURY LITIGATION

*Anita Bernstein**

INTRODUCTION

Alarmists spent decades trumpeting the dire effects of personal injury litigation on the supply of useful prescription drugs.¹ Their cries used to draw attention with vivid and specific worries. Imagine a world with no vaccines, they fretted.² Now that pregnant women in the United States have lost their only drug for morning sickness, more losses are sure

* Sam Nunn Professor of Law, Emory, and Wallace Stevens Professor of Law, New York Law School. I appreciate the suggestions and support of Margaret Berger, Benjamin Zipursky, and Tony Sebok, as well as the careful attention I received from participants in a Public Law Theory seminar at Washington University School of Law.

¹ Although this paper discusses “prescription drugs,” a category that Congress legislated in the Food, Drug, and Cosmetic Act of 1938, *see infra* note 87 and accompanying text, much of its thesis extends also to over-the-counter drugs and medical devices.

² *See, e.g.*, American Medical Association, Proceedings of the House of Delegates, 138th Annual Meeting 79 (1988) (deeming liability a serious threat to vaccine innovation and supply); Paula Jacobi, *Pharmaceutical Tort Liability: A Justifiable Nemesis to Drug Innovation and Access?*, 38 JOHN MARSHALL L. REV. 987, 987 (2005) (quoting headlines about the alarm). Because the United States is the center of drug research, “the world” might not be hyperbole. *See* Victor E. Schwartz & Phil Goldberg, *A Prescription for Drug Liability and Regulation*, 58 OKLA. L. REV. 135, 141 (2005) (describing the vast American pharmaceutical industry with reference to the size and scope of FDA regulatory efforts).

to follow.³ Stifled innovation. Lost cures. Ill health.⁴

Legislators and judges responded to the alarm. Vaccines, the drug category whose supply was most dramatically threatened, gained protection through federal no-fault legislation in 1986.⁵ Twelve years later, Congress banned state-level personal injury litigation for harms attributed to implanted biomaterials.⁶ Several states enacted industry-friendly legislation insulating drug manufacturers from an array of claims.⁷ On the question of

³ MICHAEL D. GREEN, BENEDICTIN AND BIRTH DEFECTS: THE CHALLENGES OF MASS TOXIC SUBSTANCES LITIGATION 336 (1996) (noting that now that no such drug is available, an increased fraction of pregnant women have been hospitalized for severe morning sickness); Peter W. Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 333 n.196 (1985) (quoting from a *New York Times* editorial that lamented the downfall of this drug); Jacobi, *supra* note 2, at 991 (remarking that this withdrawal was "not an isolated failure").

⁴ For a sampling of these works, see William M. Brown, *Deja Vu All Over Again: The Exodus from Contraceptive Research and How to Reverse It*, 40 BRANDEIS L.J. 1 (2001); Deborah J. La Fetra, *Freedom, Responsibility, and Risk: Fundamental Principles Supporting Tort Reform*, 36 IND. L. REV. 645 (2003); Gregory C. Jackson, Comment, *Pharmaceutical Product Liability May Be Hazardous to Your Health: A No-Fault Alternative to Concurrent Regulation*, 42 AM. U. L. REV. 199 (1992); LOUIS LASAGNA, THE CHILLING EFFECT OF PRODUCT LIABILITY ON NEW DRUG DEVELOPMENT, in THE LIABILITY MAZE: THE IMPACT OF LIABILITY LAW ON SAFETY AND INNOVATION 334, 334-48 (Peter W. Huber & Robert E. Litan eds., 1991).

⁵ National Vaccine Injury Compensation Program, codified at 42 U.S.C. §§ 300aa-11 (2004).

⁶ Biomaterials Access Assurance Act of 1998, Pub. L. No. 105-230, § 1, 112 Stat. 1519 (codified at 21 U.S.C. §§ 1601-1606 (2004)).

⁷ One strong state law is Mich. Stat. Ann. § 600.2946 (5) (2006), which eliminates causes of action for defective warning or design when the product complained about is an FDA-approved drug. See Adam Cohen, *They Say We Have Too Many Lawsuits? Tell It to Jack Cline*, N.Y. TIMES, Jan. 14, 2007, Week in Rev., at 11 (declaring that the pharmaceutical lobby pushed this reform through the Michigan legislature). The statute survived a challenge based on state constitutional law. *Taylor v. Smithkline Beecham Corp.*, 658 N.W. 2d 127 (Mich. 2003). For examples of narrower legislation, see Cal. Health & Safety Code § 199.45(n)(3) (West Supp. 2003) (enacted 1986) (immunizing manufacturers, should any come to exist, from design and warning liability for HIV vaccines); Schwartz & Goldberg, *supra* note 2, at 176 n.262 (referring to state statutes providing that compliance with federal

whether its past approvals of warning language preempt personal injury actions, the Food and Drug Administration (FDA) came to invert its position, swiveling from support for liability as a source of safety to a stance that liability threatens supply,⁸ and began to file amicus briefs urging courts to dismiss these claims based on federal preemption.⁹ Some courts have agreed with its new posture.¹⁰

The initiative to shield prescription drugs from the ravages of liability developed as a corner of the tort reform battleground. When the plaintiffs' side of the struggle worked against this initiative through the 1980s and into the early years of the new century, they gave drugs a subordinate place in their fight against measures to limit liability. Prescription drugs never were prominent villains to the plaintiffs' bar. The trial lawyers who lobbied Congress to dampen federal tort reform and fought court-closing legislation in the statehouses attacked the insurance industry, environmental polluters, "corporate greed," and other perennials, but did not identify pharmaceuticals as especially deserving of liability as a sanction. The prescription drug business caught another break circa 1987, when militants decried regulatory policy as harmful to the health of HIV-infected patients.¹¹ These partisans of regulatory relief identified

regulations establishes a rebuttable presumption that any product, including a drug, is not defective).

⁸ Food and Drug Administration, Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 2924 (2006). See also DAVID G. OWEN, PRODUCTS LIABILITY LAW 909-10 (2005) (describing this shift).

⁹ See Amicus Brief of the United States, *Motus v. Pfizer, Inc.*, 358 F.3d 659 (9th Cir. 2004) (Nos. 02-55372, 02-55498), 2002 WL 32303084; Brief for Amicus Curiae the United States, *Colaccio v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006) (No. 05-5500), 2006 WL 1784525.

¹⁰ See *Goldych v. Eli Lilly & Co.*, No. 5:04-CV-1477(GLS GJD), 2006 U.S. Dist. Lexis 49616 (N.D.N.Y. July 19 2006); *Colaccio v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006).

¹¹ For a short history, see Matthew C. Lovell, *Second Thoughts: Do the FDA's Responses to a Fatal Drug Trial and the AIDS Activist Community's Doubts About Early Access to Drugs Hint at a Shift in Basic FDA Policy?*, 51 FOOD & DRUG L.J. 273, 277-78 (1996).

constraints on the prerogatives of industry as a problem rather than a solution. With their street-theater flair and dramatic diction—Silence=Death, Queer Nation, ACT UP (an acronym for AIDS Coalition to Unleash Power)—AIDS activists could not be dismissed as tools of the drug-corporate establishment, and added a little radical chic to an increasingly conservative consensus.

Over these decades, legal luck would occasionally falter for the industry. A portion of sales revenues returns to customers as compensation for their personal injuries. The diet drug phen-fen, for example, cost its manufacturer more than \$16 billion in payments for cardiac injuries.¹² Harms attributed to Zyprexa, a drug for schizophrenia and bipolar disorder, generated \$1.2 billion in settlement expenses by early 2007.¹³ Big Pharma suffered a blow in 2004 when Vioxx, a one-time market leader, became discredited and then went on to generate several multimillion-dollar jury verdicts against its manufacturer, as well as, alarm within the industry.¹⁴ Drug companies also have paid fines and civil penalties.¹⁵ To date, however, large setbacks for pharmaceuticals defendants remain rare and (in relation to profits and gross sales revenues for the industry) trivial.¹⁶

¹² Phen-fen's Hazards Emerge Anew, *Bus. Wire*, Mar. 22, 2004, available at www.lexisnexis.com.

¹³ Alex Berenson, *Lilly Settles with 18,000 Over Zyprexa*, *N.Y. TIMES*, Jan. 5, 2007, at C1.

¹⁴ *The Lessons of Merck's Bad Day in Court*, *THE ECONOMIST*, Aug. 27, 200, available at www.lexisnexis.com. When Vioxx lost its FDA approval, every major newspaper in the United States led with the story.

¹⁵ The most notorious example involves the epilepsy drug Neurontin. In 2004 its manufacturer, Parke Davis, pleaded guilty to two counts of violating the Food, Drug, and Cosmetic Act, and agreed to pay a \$240 million criminal fine, the second-largest criminal fine in a health-law prosecution, in addition to almost \$200 million more in civil penalties. *Drug Maker to Pay \$430 Million in Fines, Civil Damages*, *FDA CONSUMER*, July-Aug. 2004, available at http://www.fda.gov/fdac/features/2004/404_w1.html.

¹⁶ The California Attorney General noted in an editorial that in 2002 *Fortune* magazine had ranked the prescription drug industry as "No. 1 in return on revenues, return on assets and return on equity." Bill Lockyer, *Prescription Warning*, *SAN FRAN. CHRON.*, May 10, 2004, at B7.

More important, not since the litigation-hastened demise of the very dangerous Dalkon Shield intrauterine device in 1974¹⁷ has any pharmaceutical product demonstrated that personal-injury liability can be a source of social utility. Take Vioxx as exemplar of what personal-injury liability has not achieved. Plaintiffs' lawyers did not discover its dangers; the drug had already left the market before a jury verdict came in against it; increases in talk about improving drug safety policy also had predated liability for this drug; and personal-injury litigation did not generate information to benefit the consuming public.¹⁸ Drug industry leaders may well disapprove of personal-injury liability as practiced in the United States, and the threat of liability may still inhibit what they choose to do.¹⁹ But their business has not suffered much adversity in court.

As for law review commentary, writers divide unequally between the pro- and anti-liability camps—the former group “conservative” in the sense of defending a status quo and “liberal” or “progressive” in favoring plaintiffs over corporate defendants.²⁰ Its antagonists on the anti-liability side make

¹⁷ The great muckraking journalist Morton Mintz told a devastating story in *AT ANY COST: WOMEN, CORPORATE GREED, AND THE DALKON SHIELD* (1985). See also Kenneth J. Chesebro, *Galileo's Retort: Peter Huber's Junk Scholarship*, 42 AM. U. L. REV. 1637, 1677-79 (1993) (noting the information-extracting effects of litigation about this product). The Dalkon Shield was a medical device, not a drug; for liability purposes the two cannot always be treated alike. See Richard A. Nagareda, *FDA Preemption: When Tort Law Meets the Administrative State*, 1 J. TORT L. article 4, 36-37 (2006) (noting distinctions).

¹⁸ See Anita Bernstein & Joseph Bernstein, *An Information Prescription for Drug Regulation*, 54 BUFF. L. REV. 569 (2006).

¹⁹ On “the shadow of the law,” see Robert H. Mnookin & Lewis Kornhauser, *Bargaining in the Shadow of the Law: The Case of Divorce*, 88 YALE L.J. 950 (1979); as affecting this industry, see La Fetra, *supra* note 4, at 646-54 (arguing that drug innovation and development are deterred by “the prospect of liability”). But see GREEN, *supra* note 3, at 339-41 (arguing that fears of ruinous liability by drug manufacturers and their advocates are exaggerated).

²⁰ Defenses of prescription-drug liability include JOAN CLAYBROOK, *RETREAT FROM SAFETY: REAGAN'S ATTACK ON AMERICA'S HEALTH* (1984); THOMAS H. KOENIG & MICHAEL L. RUSTAD, *IN DEFENSE OF TORT LAW* 101

reform proposals; these commentators have offered a variety of ideas about how to quell overdeterrence.²¹ Some seek to rewrite negligence doctrine for prescription-drug cases.²² Others would exempt a particular sector of the drug industry from tort liability generally, on the ground that it is too vital to be put in jeopardy by jury adjudication.²³ Numerous writers argue for a regulatory compliance defense that would establish FDA approval of drug design or warning as a shield against liability.²⁴

(2001); Lucinda M. Finley, *Female Trouble: The Implications of Tort Reform for Women*, 64 TENN. L. REV. 847 (1997); and (more equivocally) Teresa Moran Schwartz, *Regulatory Standards and Products Liability: Striking the Right Balance Between the Two*, 30 U. MICH. J.L. REF. 431 (1997).

²¹ The suggestions surveyed in this paragraph address liability as a source of overdeterrence that harms the supply of prescription drugs. Another set of writings sites overdeterrence in the FDA itself, and argues that Congress or the FDA itself should loosen the agency's monopoly on drug regulation. See Elizabeth C. Price, *Teaching the Elephant to Dance: Privatizing the FDA Review Process*, 51 FOOD & DRUG L.J. 651 (1996) (making this argument and summarizing other versions of it); see also RICHARD A. EPSTEIN, *OVERDOSE: HOW EXCESSIVE GOVERNMENT REGULATION STIFLES PHARMACEUTICAL INNOVATION* (2006) (arguing that by imposing high costs of doing business, pharmaceutical regulation threatens the supply of new drugs). Other writers go beyond the supply problem and ascribe more ill effects to prescription-drug liability. See JUDYTH PENDELL, *THE ADVERSE SIDE EFFECTS OF PHARMACEUTICAL LITIGATION*, AEI-BROOKINGS JOINT CENTER FOR REGULATORY STUDIES, Sept. 2003, at 4-10 (summarizing a range of complaints about the harms of liability, including that warnings are now written with liability rather than therapeutic benefit in mind; patients refuse to take a prescribed drug when they have heard a report of lawsuits about it; and pharmacists over-warn patients).

²² Eleanor M. Fox & Michael Traynor, *Biotechnology for Human Life and Health—The Special Case for a Negligence-Only Rule to Promote Critical Innovation*, 6 HIGH TECH L.J. 1 (1991).

²³ See, e.g., Brown, *supra* note 4 (proposing no-fault scheme for injuries attributed to contraceptives); Dan L. Burk & Barbara Bozcar, *Biotechnology and Tort Liability: A Strategic Industry at Risk*, 55 U. PITT. L. REV. 791 (1994); H. William Smith III, Note, *Vaccinating AIDS Vaccine Manufacturers Against Product Liability*, 42 CASE W. RES. L. REV. 207 (1992).

²⁴ David S. Torborg, Comment, *Design Defect Liability and Prescription Drugs: Who's in Charge?*, 59 OHIO ST. L.J. 633 (1998) (advocating a regulatory compliance defense for design claims); W. Kip Viscusi et al.,

This above-mentioned "variety of ideas" is not varied: homogeneity and stasis characterize the literature about the consequences of liability. On the relation between personal-injury litigation and drug supply, the sounds of alarm already noted—early tocsins like *Vaccinelessness is coming!* and *What will happen to birth control?*—have softened into a more muted chorus, with almost all singers holding the same industry-protective hymnal. Reminiscent of the courts and legislatures they study, whose attitudes toward prescription-drug liability range from militant loathing to indifference, law review writers typically either condemn this corner of personal injury law or ignore it. For the condemning cohort, the task of maintaining criticism grows less urgent but does not end. Shifts of statutory law and judicial doctrine do not entirely eliminate the risk of personal injury litigation that faced drug manufacturers in the years before tort reform, and so it appears to commentators that the problem of personal injury lawsuits will always be with us. Stifled innovation, lost cures, and ill health are just what liability *does*. The lament has no terminus in sight, no reason to declare victory and celebrate its successes in altering liability law. As long as fears of ruinous litigation continue, says the consensus, the supply of drugs will remain compromised.

One may consider a contrary view on this issue—the quaint belief, associated with the long-departed Roger Traynor (1900–1983), who served as chief justice of the California Supreme Court in the middle of the twentieth century, that litigation seeking redress for the adverse effects of manufactured products has good effects on public welfare and safety²⁵—without

Detering Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Compliance Defense, 24 SETON HALL L. REV. 1437 (1994) (including both design and warning). For a judicious look at the proposal, see Michael D. Green, *Safety as an Element of Pharmaceutical Quality: The Respective Roles of Regulation and Tort Law*, 42 ST. LOUIS L.J. 163 (1998); for an exploration of alternatives to a regulatory compliance defense that would advance similar ends of uniformity, see David R. Geiger & Mark D. Rosen, *Rationalizing Product Liability for Prescription Drugs: Implied Preemption, Federal Common Law, and Other Paths to Uniform Pharmaceutical Safety Standards*, 45 DE PAUL L. REV. 395 (1996).

²⁵ *Greenman v. Yuba Power Products Co.*, 377 P.2d 897, 901 (Cal.

necessarily rejecting the chorus and its hymns. The posture that Americans suffer from drug-liability overdeterrence goes unchallenged in this Article.²⁶ The question that *will* get attention pertains to the other side in the balance. Personal-injury litigation causes harm to the drug industry and its customers, we shall agree. Does it, or can it, cause good results as well? Is there a socially useful role for prescription-drug liability?

In search of social utility—both as it exists at present and the incremental benefit that might result from law reform—this Article considers effectiveness, the neglected and under-theorized younger sibling of prescription drug safety.²⁷ It recommends that courts deem ineffectiveness an actionable injury. Courts already extend this recognition when they hear claims for deceptive practices based on inaccuracy in pharmaceutical labeling. Yet deception does not cover all the harm that ineffective drugs cause. An ineffective drug is also a source of bodily injury. One manageable way to acknowledge this physical harm would be to permit a plaintiff who suffered

1962); *Escola v. Coca Cola Bottling Co. of Fresno*, 150 P.2d 436, 462-64 (Cal. 1944) (Traynor, J., concurring); Roger J. Traynor, *The Ways and Means of Defective Products and Strict Liability*, 32 TENN. L. REV. 363, 375 (1965).

²⁶ The pro-liability literature, *see supra* note 20, works at a high level of generality: dangerous side effects, corporate venality, hurt victims, inadequate regulation. For a more pointed look at whether prescription-drug liability enhances the public good, *see* Paul Rheingold, *The MER/29 Story—An Instance of Successful Mass Disaster Litigation*, 56 CAL. L. REV. 116 (1968). Rheingold, a litigator representing plaintiffs, argues that the defendant corporation suffered when its stock price dived “disastrously,” *id.* at 143-44, and that concerted activity by the lawyers gave injured people more effective representation. *Id.* at 147. To this extent, the litigation was successful. But Rheingold found little or no improvements to the industry, regulators, or the furnishing of medical care.

²⁷ Safety is already covered in the pro-liability literature, which defends personal-injury chiefly litigation as a way to protect persons who consume prescription drugs from dangerous side effects. *See supra* note 20. Like the thesis expressed in this paper, these claims of safety-enhancing policy seek to do some of the work of the FDA. On effectiveness in contrast to efficacy, *see infra* Part I.B.

from a drug's lack of safety to recover—if and only if she can prove that the drug did not live up to the claims on its label—for its ineffectiveness as well.²⁸

As legal concepts, safety and effectiveness reside in statutory law: a manufacturer may not sell a drug in interstate commerce unless the federal government has deemed it safe (per New Deal legislation, enacted in 1938, which empowered the Food and Drug Administration to ban the sale of unsafe drugs) and also, since 1962, effective. Ex ante determinations of safety and effectiveness are the province of regulation rather than liability law, but courts recognize the concepts in personal injury litigation using their own vocabulary: drugs that are not “safe and effective” in regulatory jargon might also be defective products, unreasonably dangerous manufactured goods, the result of a breach of the seller's duty, and the instantiation of negligence or strict products liability.

Liability doctrine has long manifested awareness of its connection to drug safety. The first encyclopedic statement about prescription drug liability in the United States, *Restatement (Second) of Torts* § 402A comment *k*, published in 1965, declared that if the benefits of a prescription drug “outweigh its known risks, and if the manufacturer has provided suitable warnings and directions for use, the defendant's product will be deemed reasonably safe, and the plaintiff will not recover.”²⁹ Courts that accept this formulation not only immunize

²⁸ The exact nature of this recovery could take many forms. Time will need to pass before ineffectiveness becomes accepted among tort lawyers and judges as a source of physical injury. For beginning steps, this Article proposes expanding ineffectiveness as a constituent of current doctrine regarding defect and danger, and as it pertains to punitive damages. *See infra* Part III.

²⁹ *See* Joseph A. Page, *Generic Product Risks: The Case Against Comment k and for Strict Tort Liability*, 58 N.Y.U. L. REV. 853, 855 (1983) (offering this paraphrase). Comment *k* is notoriously hard to fathom. Aaron Twerski, a co-Reporter for the successor *Restatement*, used to tell his Products Liability students that anyone in the class who could explain it to him would get an A. Aaron D. Twerski, *From a Reporter's Perspective: A Proposed Agenda*, 10 TOURO L. REV. 5, 15-16 (1993).

prescription drugs from design-defect liability,³⁰ a stance for which some commentary criticizes them,³¹ but also equate design defect with lack of safety, omitting from consideration the other drug-approval criterion of effectiveness—a judicial omission about which commentary has been silent. The apt remark that prescription-drug liability in the United States is all about warning rather than design³² also presumes the ascendancy of safety over effectiveness, because the danger of harmful effects can be named in a warning much more clearly than the danger of futility.

In defending the manufacturer-friendly rule they wrote to govern liability for harms caused by prescription drugs, the reporters of *Restatement (Third) of Torts: Products Liability* claimed that the standard Traynorian rationales about deterrence and safety incentives do not apply to prescription drugs: unlike manufacturers of other types of goods, drug manufacturers cannot sell their products before they receive a government proclamation of safety and effectiveness, and they reap extraordinary profits when they can promote their goods as better than their competitors'. Thus these sellers already "face adequate incentives to innovate to make drugs better and safer independently of incentives supplied by tort law."³³ They will emphasize safety to hone their competitive edge, because "drugs that cause serious negative side-effects are especially vulnerable

³⁰ E.g., *Brown v. Superior Ct.*, 751 P.2d 470 (Cal. 1988). See also *Transue v. Aesthetech Corp.*, 341 F.3d 911, 916 (9th Cir. 2003) (applying Washington law); *Grundberg v. Upjohn Co.*, 813 P.2d 89, 95 (Utah 1991).

³¹ George W. Conk, *Is There a Design Defect in the Restatement (Third) of Torts: Products Liability?*, 109 YALE L.J. 1087, 1118-27 (2000); Richard L. Cupp, *Rethinking Conscious Design Liability for Prescription Drugs: The Restatement (Third) Standard Versus a Negligence Approach*, 63 GEO. WASH. L. REV. 76 (1994); Page, *supra* note 29, at 865-67.

³² Michael D. Green, *Prescription Drugs, Alternative Designs, and the Restatement (Third): Preliminary Reflections*, 30 SETON HALL L. REV. 207, 209 (1999). See also RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 cmt. d (1998) (calling warning "the major basis" of liability for prescription drugs and devices).

³³ James A. Henderson, Jr., & Aaron D. Twerski, *Drug Designs are Different*, 111 YALE L.J. 151, 179 (2001).

to new alternatives not protected by the patent system.”³⁴ Though mindful of effectiveness, this view of liability sees effectiveness as extrinsic to personal injury litigation.

This Article explores the contrary thesis that effectiveness is, and ought to be, central to personal injury litigation related to prescription drugs, particularly at a time when neither the market nor regulation is attaining this social good, its presence in a strongly worded statute notwithstanding.³⁵ Part I explores the rule—on the books now for 45 years yet still extraordinary—that those who would sell one particular product in interstate commerce must prove (by “substantial evidence,” no less) that their product is effective. Though extraordinary, this criterion for premarketing approval is fixed, very popular, and almost entirely devoid of controversy. It responds to an enormous problem: ineffective drugs fill a landscape of calamitous waste and harm.³⁶ Among those who suffer from this harm, the

³⁴ *Id.*

³⁵ For a remote yet pertinent analogy one might go back again to the middle of the twentieth century, *see supra* note 25 and accompanying text, when civil rights activists, led by Thurgood Marshall, resorted to the courts not because they wanted to build famous case precedents culminating in *Brown v. Board of Education* but because they saw no other cure for powerlessness, disenfranchisement, and lack of protection from the rule of law. Their celebrated “litigation strategy” was costly, fatiguing, dispiriting, and dangerous. JACK GREENBERG, *CRUSADERS IN THE COURTS: HOW A DEDICATED BAND OF LAWYERS FOUGHT FOR THE CIVIL RIGHTS MOVEMENT* 81 (1994). In raising the analogy, I wish to be clear that as a social problem, ineffectiveness in any consumer product, not just drugs, is inherently suited less to litigation than the reparative reach of markets, in which the public can abjure deleterious items, and regulation, which curbs their tendency to injure. Only because of the inadequacy of these measures in practice does this Article seek to enlist litigants and judges in the work of demonstrating in court the connection between drug ineffectiveness and lack of safety. On the relation between the roughly contemporaneous expansion of tort remedies and civil rights in the United States, *see* Anita Bernstein, *Muss es Sein? Not Necessarily, Says Tort Law*, 67 L. & CONTEMP. PROB. 7, 13 & n. 27 (2004) (citing Gary T. Schwartz, *The Beginning and the Possible End of the Rise of Modern Tort Law*, 26 GA. L. REV. 601, 610-12 (1992)).

³⁶ Maxwell J. Mehlman, *Health Care Cost Containment and Medical Technology: A Critique of Waste Theory*, 36 CASE W. RES. L. REV. 778,

Article focuses, at the end of Part I and in more detail in Part II, on consumers, a group that includes physicians, patients, and third-party payors. Once the contention about harm is established, it becomes proper to envision legal remedies for a wrong recognized in law. The proposals offered at the end of the Article pay heed to particular players while recognizing that many more are hurt by ineffective drugs, and many other remedies for this social ill might exist: Part III addresses trial judges presiding over actions brought by patients who attribute injury to the prescription drugs they took.³⁷

I. WHAT IS AN EFFECTIVE DRUG?

In 1962, the requirement that drugs be effective became federal law in Section 505 of the Food Drug Cosmetic Act, which directed the Secretary of what is now the Department of Health and Services—in practice, the FDA—to withhold approval of a new drug unless the government has “substantial evidence” of its effectiveness.³⁸ This directive raises several questions. First, what does the effectiveness criterion add to the older safety criterion for approval? Second, which effects are

784-98 (1986) (depicting “waste” in medical treatments, a category that includes ineffective drugs, as a problem too large to be solved).

³⁷ For another policy prescription aimed at judges but used for a different goal, see Schwartz, *supra* note 4, at 172 (offering a section of liability-limiting suggestions under the caption “How Courts Should Handle Prescription Drug Litigation”). Another complementary subject is consumer fraud litigation for deceptive claims of safety and effectiveness, a cause of action that one trio of defense lawyers has described as likely to grow more favored by the plaintiffs’ bar. Joseph J. Leghorn, Christopher Allen, Jr., and Tavares Brewington, *Defending an Emerging Threat: Consumer Fraud Class Action Suits in Pharmaceutical and Medical Device Products-Based Litigation*, 61 FOOD & DRUG L.J. 519 (2006). Consumer fraud claims are based on state deceptive-practices statutes, typically do not involve physically injured plaintiffs, and often include attempts to obtain class certification. See *id.* By contrast, this paper looks at effectiveness as a constituent of personal injury claims and focuses on common law doctrine. See *infra* part III. Hewing mostly to state tort law, I do not address class actions, an increasingly federalized domain.

³⁸ 21 U.S.C. § 355(d) (2004).

contemplated in the word “effective”? Third, what classes of consumers and which of their interests does the statute address?

A. An Extraordinary Mandate

Americans now take the rule for granted, but it remains remarkable that Congress chose to forbid the marketing of one particular ineffective product in interstate commerce. Regulation of consumer products typically seeks to avert acute danger rather than futility or failure. A banned substance in the United States is usually a hazardous substance, and at the time of the 1962 amendments, prescription drugs already had to be approved as safe before marketing. Effectiveness is not entirely alien to regulation, of course.³⁹ Nevertheless, in a market economy effectiveness normally emerges through manifested behaviors—customers choose; they buy; they come back to buy again—rather than, so to speak, by prescription.

Critics have long proposed that federal law jettison or restrict the effectiveness criterion for prescription-drug approval. Going beyond the libertarian premise that it is wrong to ban the sale of a thing not known to harm or endanger anyone, they invoke the public weal, contending that because manufacturers must produce substantial evidence of effectiveness before the FDA will approve their new-drug applications, it becomes plausible to surmise that useful therapies will fail the stringent test and remain off the market.⁴⁰ Moreover, drugs that really are effective—some powerful enough to save lives—cannot reach patients’ bodies until years of testing have gone by, and so the critique posits martyrdom: an unknown number (more than zero) of dead or very sick people would be alive or healthy today had

³⁹ Licensing to ensure professional competence, for example, might be seen not only to seek safety for clients but to help give clients satisfactory affirmative results.

⁴⁰ Economist Sam Peltzman published his estimates in several papers and SAM PELTZMAN, *REGULATION OF PHARMACEUTICAL INFORMATION: THE 1962 AMENDMENTS* (1974). He testified before Congress in 1973 that the nation was losing more than \$450 million per year in gross therapeutic benefits as a result of the effectiveness criterion. Price, *supra* note 21, at 654 n.21.

they received an effective treatment in time.⁴¹ Other commentary that might be labeled libertarian-contrarian suggests that requiring effectiveness as a condition of sale reduces the impact of placebos—and a placebo does have an effect of its own.⁴²

Contemporary political conditions keep these ideas for libertarian reform permanently outside the United States Code. Pharmaceutical companies have been working with, not just grumbling about, the effectiveness criterion for many years, and would not embrace the uncertainty of some unknown alternative standard. They also value the criterion as a barrier to competitors' entering their market.⁴³ Even if manufacturers were to endorse repeal, the public would resist it. "Safe and effective drugs" seems to be a winning slogan. The effectiveness criterion drew enthusiasm in 1962 that went beyond bipartisanship: a unanimous vote in Congress, hearty support from the consumer-minded President Kennedy, and no opposition from the industry.⁴⁴ Today the FDA takes its share of criticism but still enjoys strong approval ratings—more than two-thirds of

⁴¹ Daniel B. Klein & Alexander Tabarrok, *Who Certifies Off-Label?*, REGULATION MAGAZINE, Summer 2004, at 60, 63; see also Elizabeth A. Weeks, *Is It Worth the Trouble? The New Policy on Dissemination of Off-Label Drug Use Under the Food and Drug Administration Modernization Act of 1997*, 54 FOOD & DRUG L.J. 645, 662 (1999) (noting that the effectiveness mandate has added two years to the amount of time it takes the FDA to approve a new drug application).

⁴² One health-law scholar explores the placebo effect in the context of informed consent and concludes that it might be ethical to conceal from one's patient that a treatment is a placebo. Kathleen M. Boozang, *The Therapeutic Placebo: The Case for Patient Deception*, 54 FLA. L. REV. 687 (2002). The same reasoning supports a modification of the effectiveness criterion for drug approval. At present, the FDA interprets "substantial evidence" as requiring, as a condition for approval, that the manufacturer of a drug demonstrate clinical effects beyond what a placebo would achieve. See 21 C.F.R. 314.126(b)(2)(i.) (2006).

⁴³ Thanks to David Schoenbrod for telling me so.

⁴⁴ PHILIP J. HILTS, PROTECTING AMERICA'S HEALTH: THE FDA, BUSINESS, AND ONE HUNDRED YEARS OF REGULATION 161 (2003); MORTON MINTZ, THE THERAPEUTIC NIGHTMARE 44-54, 71 (1965).

Americans hold the agency and its work in high regard⁴⁵—in an era when both elites and ordinary citizens feel hostile or skeptical toward federal bureaucracies.⁴⁶

Judges have interpreted the effectiveness criterion for approval with some severity, holding that consumers have no right to partake of drugs not approved as effective. The most compelling category of plaintiffs to protest this stance would be terminally ill patients, who can credibly say they are about to die anyway and so should be allowed an unapproved drug for whatever effects (perhaps placebo effects) that it might offer.⁴⁷ Yet even plaintiffs in this sympathetic group, patients who wanted a nostrum to treat advanced cancer, were rebuffed in 1979 by a unanimous Supreme Court.⁴⁸ Recently the libertarian effort enjoyed a triumph in the Court of Appeals for the District of Columbia, which found that terminally ill patients had a constitutional right of access to a drug that had passed preliminary safety studies and had not yet been approved as effective.⁴⁹ However, the triumph was short-lived—the court

⁴⁵ Rita Rubin, *Can Americans Trust Their Medicine?*, USA TODAY, Dec. 20, 2004 at A1 (reporting on a survey taken in November 2004, a difficult time for drug manufacturers and regulators, suggesting 70 percent of Americans have confidence in the FDA); Hilts, *supra* note 44, at 235 (reporting consistency of this popularity and noting that in 1995 Newt Gingrich, then a member of Congress, went down after a misfired attack on the agency). A 1980s survey identified the FDA as the nation's second-most popular federal agency, behind the National Parks Service. Sharon Smith Holston, FDA Deputy Commissioner for External Affairs, *The Value of Patient's Perspective in FDA's Decision Process*, speech delivered Nov. 3, 1997, available at <http://www.fda.gov/oashi/cancer/value.html>.

⁴⁶ See THOMAS F. BURKE, *LAWYERS, LAWSUITS, AND LEGAL RIGHTS: THE BATTLE OVER LITIGATION IN AMERICAN SOCIETY* 13 (2002) (attributing American litigiousness in part to a national suspicion about bureaucratic power).

⁴⁷ One father of a young child who died of cancer after being denied an unapproved drug treatment makes a poignant case for expanded access in Michael E. Horwin, Comment, "*War on Cancer*": *Why Does the FDA Deny Access to Alternative Cancer Treatments?*, 38 CAL. W. L. REV. 189 (2001).

⁴⁸ *United States v. Rutherford*, 442 U.S. 544, 551 (1979). The drug these patients wanted was the notorious Laetrile.

⁴⁹ *Abigail Alliance for Better Access to Developmental Drugs v. Von*

vacated the judgment⁵⁰—and so, at least at the moment, the extraordinary mandate of satisfactory results before marketing remains in place as far as legislators, regulators, courts, the drug industry, and most of the American public are concerned.

The mandate suggests a next step for courts to take. Federal law proscribes the sale of ineffective drugs; courts interpreting this law declare that consumers have no right to ineffective drugs. From here, one may infer that when consumers receive drugs that, unknown to them, are ineffective, they have suffered an infringement of their rights. The Food, Drug, Cosmetic Act provides no private right of action for this injury, but furnishing redress to victims who already have other routes to the courts would honor their right to drug effectiveness.

B. Effectiveness versus Efficacy

It now becomes necessary to consider what “effective” means—and also what it might be mistaken to mean. Here we contrast effectiveness with efficacy; for this purpose the two nouns are not synonyms. This discussion postpones the concept of “comparative effectiveness” (also known by similar terms like “relative efficacy”), which is not present in the four corners of the statute.⁵¹

Congress wrote an implicit definition of the word “effective” in the 1962 amendments, declaring that the federal government must prohibit the sale of any drug if “there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.”⁵²

Eschenbach, 445 F.3d 470, 472, 500 (D.C. Cir. 2006). This action was financed by the Washington Legal Foundation. *Abigail Alliance* distinguished *Rutherford* on the ground that Laetrile had never received safety approval.

⁵⁰ *Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach*, No. 04-5350, 2006 U.S. App. LEXIS 28974, at *1 (D.C. Cir. Nov. 21, 2006). Additional litigation was pending when this Article went to press in the summer of 2007.

⁵¹ See *infra* note 59 and accompanying text.

⁵² 21 U.S.C. § 355(d) (2004).

This meaning of “effective” distinguishes effectiveness from efficacy.⁵³ Efficacy refers to the propensity of a drug to achieve intended, observable clinical improvement, with “improvement” in turn referring to metrics rather than a feeling of good health. An anti-hypertensive drug is efficacious if it lowers blood pressure, even if the patient has no consciousness of improvement, because (in most cases and *ceteris paribus*) the lowering of abnormally high blood pressure is a salubrious change.

Effectiveness, by contrast, refers to the fit between what happens to patients and what manufacturers promise on drug labels. An example of a drug that achieves efficacy but not effectiveness might be the anti-hypertensive mentioned above, when it functions to lower blood pressure but not by as many millimeters as its manufacturer asserts that it will. A drug called Lovenox, the top-seller in its category (low molecular weight heparins), provides an example of effectiveness that may or may not deliver efficacy. Lovenox, the trade name for enoxaparin, promises to reduce the incidence of deep-vein thrombosis. Approximately a third of the patients who experience deep-vein thrombosis go on to experience pulmonary embolism; approximately a third of the patients who experience pulmonary embolism die. For most patients, by this reckoning, Lovenox is an idle substance that does their mortality and morbidity prospects no good. But it does do what its label says it will do—reduce the incidence of deep-vein thrombosis—and so in 1993 it won its FDA-approved effectiveness wings.⁵⁴ In the vocabulary

⁵³ Jennifer Kulynych, *Will FDA Relinquish the “Gold Standard” for New Drug Approval? Redefining “Substantial Evidence” in the FDA Modernization Act of 1997*, 54 FOOD DRUG L.J. 127, 132-34 (1999). Although the words have different meanings, many people use them interchangeably. When the FDA studied drug effectiveness soon after the passage of the 1962 amendments, for example, it referred to its review as the Drug Efficacy Study Implementation, even though the object of the study was to see whether drugs lived up to the promises on their labels.

⁵⁴ See generally Bruce L. Davidson, *Controversies in Pulmonary Embolism and Deep Venous Thrombosis*, 60 AM. FAMILY PHYSICIAN 1269 (1999) (summarizing the history and uses of Lovenox in treating these conditions).

of another profession, efficacy invokes a tort-like failure to achieve improvement, while effectiveness, the codified criterion, is grounded in an implied-in-law contract between buyer and seller.

C. The Effectiveness Contract

Identifying the buyer is more complex than identifying the seller. We know the seller. Since most prescription drugs are carefully branded, at least during their period of patent life, identification issues found elsewhere in products liability conveniently disappear. Identifying the buyer—or, more precisely, the consumer—is more difficult; one cannot rest with the Uniform Commercial Code's definition of a buyer as "a person that buys or contracts to buy goods."⁵⁵ There are three categories of drug buyer in the United States, each with its own mix of expectations regarding effectiveness.⁵⁶

1. Three Types of Consumers

Physicians comprise one cohort of consumers. The Food, Drug, and Cosmetic Act of 1938 bestowed on them the prerogative to direct purchases of prescription drugs. Other people may swallow drugs or apply them to their bodies, while yet other people pay for them; but assent from a physician is necessary to the transaction. For decades, every drug manufacturer targeted virtually all of its advertising and promotion to this class of buyers, and today most of this promotional effort still goes to them.

Patients are the group is usually what commentators have in mind when they refer to "direct to consumer" marketing or advertising by drug manufacturers. It is patients who in physiological terms interact with, use up, or metabolize this product. The category of patients includes, at one end of a

⁵⁵ U.C.C. § 2-103(1)(a).

⁵⁶ This section summarizes a longer discussion in Bernstein & Bernstein, *supra* note 18.

spectrum, passive recipients (*e.g.*, children, emergency victims, unconscious and mentally incapacitated persons), who receive drug treatments without their consent, and, at the other end, highly informed patients who pick out the drug they want first and seek a prescription second. In the middle of the spectrum are adults with a say in their drug selection who, to varying degrees, depend on the advice and discretion of their physicians. As buyers, few patients pay the official, stated retail price of the prescription drugs they consume.

Third-party payors include governments (notably Medicaid at the state level, some federal programs like the Veterans Administration, and more recently Medicare), insurers, and some employers that administer health plans. It is they who best fit the U.C.C.'s "contracts to buy" definition of a buyer, as they do most of their drug purchasing in bulk and, unlike physicians and patients, are positioned to negotiate terms with the seller. Third-party payors use formularies as a principal cost-containment device.⁵⁷ Formularies, which in pharmacology are lists "of pharmaceutical substances along with their formulas, uses, and methods of preparations,"⁵⁸ are for third-party payors databases that tell them which drugs to prefer for the treatment of which conditions.

2. *Effectiveness as Consumers Seek It*

All three categories of consumers want prescription drugs to be both safe and effective; each has a slightly different set of desires. For physicians, safety is paramount. Their professional oath exhorts them to do no harm, rather than to achieve results.

⁵⁷ For an expression of squeamishness on this point from one formulary authority, see Association of Managed Care Pharmacies, Format for Voluntary Submissions iv (Apr. 2005), *available at* http://www.fmcenet.org/data/resource/Format~Version_2_1~Final_Final.pdf ("Users should always keep in mind that the Format [to be used by formulary writers] is not a cost-containment device but an analytic tool to improve the value of health care delivered.").

⁵⁸ THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE (4th ed. 2000).

Physicians value safety higher than effectiveness: in their perspective, futile treatments can be scrapped and supplanted in a trial-and-error effort, but dangerous effects can at best be mitigated, never undone. For patients, the two adjectives are of more equal weight. Since they are suffering from the vexations of a pathological condition more directly than physicians, they may value effectiveness more than safety.

Third-party payors introduce another priority to the mix: they are especially keen on *comparative effectiveness*.⁵⁹ Because they deal with large numbers of patients, they regard prescription drugs in the aggregate rather than as a tailored response by one provider to benefit one individual. In this respect this buyer-consumer is more like the seller than are the other two consumers. Both manufacturers and third-party payors, as businesses, focus on revenue: "sales" for the industry, "cost" for the payors. Both are relatively uninterested in limited-marked "boutique" products to treat rare conditions.⁶⁰

The action, as far as both manufacturers and third-party payors are concerned, is in products that reach millions of patients with chronic conditions: drugs to lower cholesterol and blood pressure and blood sugar; drugs for mental illnesses that are either very common (such as depression) or relatively common and very costly not to treat (schizophrenia, bipolar disorder); painkillers; asthma treatments; palliatives for gastric symptoms; and industry Holy Grails (an HIV vaccine, a drug that would safely let people eat whatever they want without gaining weight). For manufacturers, such drugs pour profits into their bottom line. For the third-party payor, they are what its physicians and patients feel entitled to receive and what it too sometimes has an incentive to want: a good drug can improve a payor's bottom line, perhaps by reducing hospital stays or permitting a patient to work more productively. The third-party payor knows it has to buy such drugs. But not all of them, as if

⁵⁹ Although "comparative efficacy" would be a more precise locution, see *supra* Part I.B., this Article uses "comparative effectiveness" because it is more familiar.

⁶⁰ See generally Bernstein & Bernstein, *supra* note 18 (elaborating on this discussion of expectations).

they were all exactly like others in their class. When good generic substitutes are available, a payor would prefer them to a patented product. When generics are unacceptable, or not available, the payor choosing among brands wants the best bang for its buck.

Everyone, to be sure—even manufacturers—welcomes safety, effectiveness, and comparative effectiveness; these three desires are noted not so much to separate each buyer from the other two as to introduce the third desideratum. Although comparative effectiveness is not mentioned as a criterion for approval in the Food, Drug, and Cosmetic Act, increasingly the federal and state governments have been pursuing it as policy.⁶¹ Times have changed since 1962: back when Congress passed the effectiveness amendments, far fewer drugs were available, and the rise of competitive markets to treat particular conditions had not yet been envisioned.⁶² In the twenty-first century, for example, a prescriber must strain to think of tricyclic drugs as “effective” for depression, notwithstanding their decades-old undisturbed approval under the effectiveness criterion, because competitor drugs, especially selective serotonin reuptake inhibitors, work so much better. This space in the effectiveness contract—between what regulators understand to be the law governing premarketing approval and the sets of expectations and entitlements that develop around a statute—is amenable to input from the courts.

Effectiveness as customers seek it, in sum, includes both halves of the effectiveness/efficacy division: customers want drugs to live up to the promises on their labels, and they want improved therapeutic outcomes. “Improved,” in their view, relates not only to a patient’s antecedent physiological state but also to what alternative treatments would deliver. Although judicial competence is more pertinent to the first desire (“effectiveness”) than the second (“efficacy”), judges can help

⁶¹ *Id.*

⁶² Robert D. Reischauer, *Prescription Drug Coverage and Medicare*, Sept. 28, 1999, available at <http://www.brookings.edu/views/testimony/reischauer/19990928.htm>.

to fulfill both.⁶³

C. The Judicial Role in Determining or Ensuring that Drugs are Effective

In contrast to its approach to safety,⁶⁴ the judiciary has delineated a narrow role for itself with respect to drug effectiveness. Judges interpreting state law governing personal-injury claims do not consider effectiveness, manifesting a belief that in their courtrooms litigants are entitled to drug safety but not the other criterion for drug approval. Judges interpreting federal statutes deal with effectiveness only as a matter of administrative law, reviewing agency actions.

1. Inside the Beltway

The unavailing claim in *United States v. Rutherford* by patients seeking access to a drug not approved⁶⁵ fits in a wider jurisprudence of federal courts disinclined to enforce the effectiveness mandate of Section 505. In its stated rights of action, the statute recognizes only a manufacturer's appeal from the denial of a new drug application:⁶⁶ following such a denial, a manufacturer will in some circumstances have a right to a hearing.⁶⁷ The court that holds appellate power over federal administrative decisions, the United States Court of Appeals for the District of Columbia, has expressed unwillingness to hear effectiveness-related claims from consumers.⁶⁸

⁶³ See *infra* Part II.A.

⁶⁴ See *supra* text accompanying notes 29-32.

⁶⁵ See *supra* note 48 and accompanying text.

⁶⁶ 21 U.S.C. § 355(h) (2004).

⁶⁷ *Weinberger v. Hynson, Westcott & Dunning*, 412 U.S. 609 (1973) (cautioning that in order to be entitled to a hearing, the manufacturer must have submitted evidence of effectiveness).

⁶⁸ *Cutler v. Hayes*, 818 F.2d 879, 889 (D.C. Cir. 1987) (holding that consumers have only very limited standing to compel the FDA to complete a mandated study of the effectiveness of over-the-counter drugs).

2. *Toward an Entitlement to Effectiveness, Enforced in Federal and State Courts*

Away from the regulatory-review docket of the D.C. Circuit, courts have not yet confronted the question of whether individuals who allege injuries that they attribute to prescription drugs may seek redress for ineffectiveness as well as lack of safety. Consumers who use state-level deceptive practices legislation to contend that promises of effects constituted deception have had mixed results in court.⁶⁹ The litigant envisioned in this Article is a different type of consumer, one bringing a tort-based claim of negligence or strict products liability against a drug manufacturer for physical injuries. Our plaintiff ascribes her injury to the deficient design or warning that the drug manufacturer chose.

Defects in warning and design equate to lack of safety; in our scenario, the plaintiff objects to lack of effectiveness as well. Although a litigant who suffered a physical injury from a drug is a patient rather than a physician or a third-party payor, this claim of injury necessarily includes harms to the other two types of consumer: a physician's opportunity to practice medicine satisfactorily is impaired by ineffective drugs, and any third party who bought this drug received poorer value than what it sought. The patient-plaintiff should not receive compensation for injuries to these consumers, of course; they are not present as parties. A judge should, however, remember the nonparties when reflecting on the overdeterrence chorus with which we began. As buyers who participate in sales of this same good, they too suffered the injury of ineffectiveness of which the plaintiff complains. If this type of litigation tends to ameliorate the harms of ineffective drugs, then these nonparties would benefit accordingly.

Our judge might raise doubts at this point. Does ineffectiveness really inflict personal injury? Even if it does, would recognition of an effectiveness-based claim in a personal

⁶⁹ See Leghorn et al., *supra* note 37 (summarizing results, from a manufacturer's perspective).

injury action usurp the functions of Congress and the FDA by arrogating to the judiciary a subject that Congress has claimed for itself and assigned to regulators? These questions are taken up in the next part. Part II answers the first with a resounding Yes—and this affirmative, a conclusion about gross rather than net injury, is undiminished by evidence that the effectiveness criterion hurts consumers;⁷⁰ regulation can do good and harm at the same time.⁷¹ Part III answers No to the second question, and recommends modifications of existing doctrine to articulate a role for courts in enforcing drug effectiveness.

II. SOME HARMS TO CONSUMERS CAUSED BY INEFFECTIVE, COMPARATIVELY INEFFECTIVE, AND INEFFICACIOUS DRUGS

Judicial clinging to metaphors of absence and inaction—the dog that didn't bark,⁷² the gun that didn't go off⁷³—to describe a drug that fails to achieve clinical improvement, or to honor the promises on its label, will leave undisturbed the current understanding about the incompetence of personal-injury law to enhance drug effectiveness. The conventional divide will endure. Product safety versus products liability, *ex ante* versus *ex post*,

⁷⁰ See *supra* note 41 and accompanying text.

⁷¹ Airline deregulation lowered prices and took away legroom. Professional monopolies protect clients and raise fees. Zoning laws make residences homier at the price of lost freedoms. Government-mandated disclosures to investors convey information and tedium in the same document.

⁷² In the famous colloquy between a Scotland Yard detective and Sherlock Holmes:

“Is there any other point to which you would wish to draw my attention?”

“To the curious incident of the dog in the night-time.”

“The dog did nothing in the night-time.”

“That was the curious incident.”

ARTHUR CONAN DOYLE, *SILVER BLAZE* (1892), available at <http://www.classic-literature.co.uk/silver-blaze/>.

⁷³ Celia Wren, *Chekhov's Plays*, COMMONWEAL, May 3, 1996, at 18 (referring to the famous dictum that “a gun hanging on the wall in the first act of a play must fire before the close of the final scene”).

regulation versus adjudication, prevention of harm versus remedy of harm: in this view, effectiveness and efficacy have no place in court. Regulators should continue to apply the statutory effectiveness criterion to new-drug applications, and when drugs prove unsafe in use—when they hurt someone—then liability will bring in its labels: defect, unreasonably dangerous, strict liability, negligence, failure to warn. “Ineffective,” as seen here, is not found in the liability lexicon.

This view is misguided: ineffectiveness, in this respect just like lack of safety, harms drug consumers. The stance that regulatory compliance does not immunize manufacturers from liability—still in place around the country except where the odd state legislature has installed a change—indicates that packaging their drugs consistent with FDA decrees for the label also should not give them immunity. Whether or not harms attributable to ineffectiveness ought to be actionable in the courts, they exist, and deserve consideration in any contemplation of the judicial role in remedying ineffectiveness.

A. Pathologies Unaddressed

The notion that drugs lacking in safety cause injury and drugs lacking in efficacy do nothing fails to reckon with the reason drugs are manufactured, prescribed, and ingested: to alter the body, pursuant to a determination that such an alteration is necessary to ameliorate or prevent a pathological state. Injury is the condition against which a drug acts. When the drug does not do what its label promises, or does not make the patient better off, then the patient suffers from, at a minimum, whatever remains of the underlying condition the drug was supposed to fix.⁷⁴ In this sense the drug is responsible for some portion of the patient’s injury, comparable to the way tort law holds some

⁷⁴ One litigant who before his death sought access to an unapproved drug, Joel Oppenheim, reported “dangerous and damaging” effects from approved, conventional treatments. *Abigail Alliance for Better Access to Developmental Drugs v. Van Eschenbach*, 469 F.3d 129, 134-35 (D.C. Cir. 2006); see also Horwin, *supra* note 47 (reporting the travails of the author’s son).

defendants responsible under negligence doctrine for physical injuries that they did not actively inflict if they had a duty to act affirmatively to protect or rescue plaintiffs and did not fulfill this duty.

To continue the analogy from negligence law, one exception to the common law rule of no duty to rescue another person arises from an undertaking. A defendant who ordinarily would have no obligation to benefit the plaintiff acquires this obligation through affirmative conduct, and becomes liable for injuries resulting from the failure to act.⁷⁵ Prevailing plaintiffs usually establish that “undertaking” defendants in effect fended off alternative sources of help, leaving them isolated and dependent on this solitary source of rescue. Because prescription drugs consumed by patients have prevailed in a competition, they too are not inert in the mode of a dog that doesn’t bark. Sellers put their products forward as interventions. They displaced at least one alternative—to do nothing—and for most medical conditions also prevailed over nonpatented treatments and competitor pharmaceuticals.

Here the gap between efficacy, or clinical improvement, and effectiveness, understood by American regulatory law to mean different enough from a placebo in response rates to support a promise on a label, becomes vivid. Few drugs are efficacious. When a senior executive of the biggest pharmaceuticals company in Britain said publicly in 2003 that “most prescription medicines do not work on most people who take them,”⁷⁶ his remark came across as both a “gaffe” and the telling of “an open secret.”⁷⁷ Drugs for Alzheimer’s disease work for fewer than one in three patients. Cancer drugs work for fewer than one out of four. Drugs for migraines, osteoporosis, and arthritis are more efficacious, working about half the time. The best antidepressant drugs help about two-thirds of patients, but some large fraction of the group that enjoys improvement, perhaps 30-

⁷⁵ See generally DAN B. DOBBS, *THE LAW OF TORTS* 860-69 (2001) (detailing this basis of liability for physical injury).

⁷⁶ Steve Connor, *Glaxo Chief: Our Drugs Do Not Work on Most Patients*, *THE INDEP.*, Dec. 8, 2003.

⁷⁷ *Id.*

50 percent, would have done as well with placebos.⁷⁸ Unsatisfactory compliance by patients accounts for some of the disappointing results, but experts ascribe more of the failure to genotypes: many patients do not benefit because they are physically incapable of responding to even “effective” drugs.⁷⁹

At first blush, this gloomy story about lack of efficacy in practice might support more despair than reformist energy. After all, if manufacturers, physicians, and patients, all amply motivated to sell and buy the best drugs, do not achieve improvement through pharmaceutical intervention, what can personal-injury doctrine do? Still, the efficacy record shows opportunity as well as failure. Judges who contribute to even small gains in drug efficacy would make relatively large changes to the policy landscape, because the quantity of actual clinical improvement is small. Improving effectiveness is only one step away, as the promise that a manufacturer wants most to make on its label is one of likely clinical improvement. Bringing efficacy and effectiveness into the personal-injury courtroom would also help to clarify and expound on the useful distinction between the two words. Efficacy may remain elusive, given the limitations of even a mighty industry, but effectiveness will get better after courts do more to encourage accuracy in labeling; and the need for accuracy holds promise for improving research and development.

B. Money Wasted

We return to cost-effectiveness and comparative effectiveness, concerns that preoccupy everyone who pays for prescription drugs, especially third-party payors. Most of the time, anyone buying medications will want to get the maximum clinical improvement for the minimum expenditure, or at least will consider cost as a variable.⁸⁰ This desire underlies

⁷⁸ Joe & Teresa Graedon, *Some Prescription Drugs Don't Work as Advertised*, AUGUSTA CHRON., Jan. 13, 2004, at D2.

⁷⁹ Connor, *supra* note 76.

⁸⁰ Commentators make this point while contending that the effectiveness criterion is obsolete in the managed-care era. See Note, *FDA Reform and the*

formularies, the drug-selecting apparatus already mentioned.⁸¹

The premise behind formularies is that a third-party payor will waste a significant amount of money if it does not consider cheaper alternatives to whichever drug that someone else who doesn't have to pay the price—a patient, a prescribing physician, a promotion-minded manufacturer—suggests to them that they buy.⁸² The premise appears sound. According to a 1998 study, physicians write 30 million prescriptions a year for ineffective drugs in Britain, wasting more than £100 million of National Health Service money.⁸³ No comparable “wastestimate” exists for the United States, which lacks a solitary payor comparable to the British NHS, but simple extrapolation from American drug futility generally—the high failure rate of drugs⁸⁴ multiplied by its much larger population—suggests a figure many times higher.⁸⁵

This aspect of harm receives only partial expression by plaintiffs in personal-injury litigation. Patients who ingest drugs without clinical improvement, along with their families, may

European Medicines Evaluation Agency, 108 HARV. L. REV. 2009, 2019-23 (1995) (arguing that in contrast to 1962, today managed-care organizations have incentives to enforce effectiveness); Henry I. Miller, *Vaccine Development a Casualty of Flawed Public Policy*, Hoover Institution Weekly Essays, May 5, 2003, available at <http://www.hoover.stanford.edu/pubaffairs/we/2003/miller05.html> (arguing that managed-care organizations will not support an ineffective vaccine).

⁸¹ See *supra* notes 57-58.

⁸² Ironically, third-party payors can achieve comparable waste by refusing to consider a more expensive drug. International donors operating in Africa have refused to buy an extremely effective antimalarial drug, artemisinin-combination therapy or ACT, because chloroquine-derived drugs are cheaper, even though evolution has now rendered chloroquine almost useless in combating malaria. Cynthia Scharf, Op-Ed, *There is a Drug that Works: A Matter of Money Against Malaria*, INT'L HERALD TRIB., July 21, 2004, at 8.

⁸³ *Millions Spent on 'Ineffective Drugs,'* BBC News, Oct. 27, 1998, available at <http://news.bbc.co.uk/2/hi/health/202251.stm>.

⁸⁴ See *supra* notes 76-79 and accompanying text.

⁸⁵ Britain does have a more lenient effectiveness criterion for premarketing approval, however. See *FDA Reform and the European Medicines Evaluation Agency*, *supra* note 80, at 2014.

feel cheated or that they have wasted their money, but most of the loss attributed to the waste is not theirs.⁸⁶ Furthermore, to the extent that ineffectiveness (and inefficacy) are the patients' own fault (they may have unreasonably failed to comply with a drug regimen, for example), they will seldom suffer a financial penalty in the way that contributory negligence reduces a plaintiff's compensation. Empowering plaintiffs to recover for drug ineffectiveness (or inefficacy), then, cannot restore the amount of money wasted on ineffective and inefficacious drugs. It would, however, force manufacturers to internalize part of the loss that they created.

C. *Unnecessary Toxic Effects*

In the 1938 Food, Drug, and Cosmetic Act—the first federal law that referred to limited-sale “prescription” drugs that only a physician could choose⁸⁷—Congress made safety a condition for approval by the FDA. The reason for this new safety mandate? *Lack* of safety, inherent in the category, and incapable of elimination: prescription drugs are those drugs with “toxicity or other potentiality for harmful effect” that renders them “not safe except under the supervision of a practitioner licensed by law.”⁸⁸ Further recognizing that danger is a *sine qua non* of all prescription drugs, the Food, Drug, and Cosmetic Act has never purported to define safety as an aspect of drugs, even though in 1962 Congress went on to say much about what it means for a drug to be effective. The Food and Drug Administration, moreover, *does* define safety in its regulation of other products. For example, food additives may not be sold unless regulators find “reasonable certainty that no harm will result” from their

⁸⁶ See *supra* Part I.C.1 (noting that few persons pay more than a token share of the stated retail price of prescription drugs they consume).

⁸⁷ The category of prescription drugs was formally codified later in the Durphy-Humphrey Amendment to the FDCA. Act of Oct. 25, 1951, 65 Stat. 648 (1951) (codified at 21 U.S.C. § 353(b) (2004)).

⁸⁸ Act of June 25, 1938, ch. 675, § 503, 52 Stat. 1051, codified at 21 U.S.C. § 353 (2004).

consumption.⁸⁹ Applied to prescription drugs, such a definition of safety would shipwreck the industry.

All prescription drugs are dangerous, then. The only way to regard them as "safe" is to take into account the good they do: their efficacy and effectiveness.⁹⁰ Seen this way, ineffective drugs are (once again) not an inert gun that didn't fire, but a source of statistically certain danger to patients without an offset of purposefully obtained therapeutic gain.

D. Emotional Distress

Just as commentary about the effect of liability on prescription drugs has been one-sided, focusing on overdeterrence to the exclusion of other policy consequences, the jurisprudence of the effectiveness criterion as a source of emotional distress has lamented only the dolor of drugs withheld from the market. In the literature on the effectiveness criterion, for example, AIDS activists are found sharing their grief and rage over lack of access to therapies.⁹¹ A father mourns his dead son, to whom the FDA said it would give a particular unapproved drug only after conventional treatment failed—too late.⁹²

Lack of efficacy and lack of effectiveness also cause emotional distress. Patients who take a drug that turns out, without warning, to lack efficacy have reason to lament lost opportunities. To some degree they share this unhappiness with medical providers and third-party payors. Whatever underlying pathologies called for clinical intervention have not gone away, and whatever hopeful comfort patients took from the prescribing of new drugs must end when they learn the truth about futility.

⁸⁹ 21 C.F.R. § 170.3(i) (2004).

⁹⁰ Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1764 (1996).

⁹¹ See Jay Branegan, *An Uproar Over AIDS Drugs*, TIME, Apr. 6, 1987; Holston, *supra* note 45 (recalling the "wrenching experience" of working inside the FDA in the 1980s when activists, in a "furious outburst," demanded "immediate access to unapproved therapies").

⁹² See *supra* note 47.

Because of this blow to their optimism, they are now worse off than they were back when they had only the pathological condition and no prescription-drug treatment history for it. Some patients have the temperament or circumstance (stoicism, religious faith, perversity) to ease this blow: but it appears reasonable to associate distress with disappointment on matters of one's health. We have noted that effectiveness, the fulfillment of promises made on a drug's label, sets up a contract-like relation between buyer (patient, physician, or third-party payor) and seller. Contract doctrine generally withholds redress for emotional distress, but recognizes that breached contracts can in fact cause this injury, and permits recovery when "the breach is of such a kind that serious emotional disturbance was a likely result."⁹³

Distress derived from inefficacy and ineffectiveness is manifest in case law, if one is willing to look for it. Although plaintiffs can seldom recover when unsafe drugs cause them emotional distress without objective symptoms of physical harm, the cases show that many patients attribute fear, anxiety, grief, and intense unhappiness to encounters they had with prescription drugs and their close analogue, prescription medical devices.⁹⁴ These emotions turn up in judicial opinions even though the safety-focused personal injury doctrine emphatically does not want to hear about them. Drug-effectiveness law wants to hear

⁹³ RESTATEMENT (SECOND) OF CONTRACTS § 353 (1981).

⁹⁴ For unsuccessful claims, see *Payton v. Abbott Labs*, 437 N.E. 2d 171 (Mass. 1982) (denying recovery to DES-exposed plaintiffs who had not yet developed adenosis or adenocarcinoma); *Friedman v. Merck & Co.*, 107 Cal. App. 4th 454 (2003) (denying recovery to a strict vegan who became distraught when he learned that, contrary to assurances, the tuberculosis test he had taken contained animal products). A rare success story for plaintiffs was litigation over a defective heart valve, recalled in 1985 because of its propensity to fracture. In 1993 the manufacturer, Shiley, paid confidential settlements to 260 plaintiffs for their emotional distress. See DAVID G. OWEN, JOHN E. MONTGOMERY, & MARY K. DAVIS, *PRODUCTS LIABILITY AND SAFETY: CASES AND MATERIALS* 682-83 (4th ed. 2004) (also citing *Bravman v. Baxter Healthcare Corp.*, 984 F.2d 71 (2d Cir. 1993), which allowed an emotional-distress claim over a different heart valve that made loud noise, audible at 30 feet).

them even less. A reversal of this stance would bring to case law extended accounts of regret, frustration, resentment, pessimism about the possibility of relief, and anxiety about lost opportunities that were always present, but suppressed under doctrine that refused to recognize them.

III. A PARTIAL CURE IN THE COURTS

What can courts do, in the context of personal injury litigation, to enforce a consumer entitlement to effectiveness as well as safety?⁹⁵ The suggestions offered here rest on Part I's understanding of effectiveness and the consumers who hold expectations about it. Like other discussions of drug effectiveness, they include references to efficacy and comparative effectiveness, yet also maintain the Food Drug and Cosmetic Act's implicit definition of effectiveness as living up to promises on a label.⁹⁶

At present, deceptive-practices statutes and common law fraud provide redress for those instances of ineffectiveness that reach the level of deceit, but do not explicitly connect ineffectiveness with physical injury. Subparts A and B below suggest ways for courts to recognize this connection. The implicit conception of standing used there (and also in Subpart C *infra*, which advocates robust punitive damages), envisions plaintiffs who already have good claims of failure to warn, or perhaps for design defect, against drug manufacturers: that is to say, they have suffered physical injuries suggesting that drugs lack safety. Claims of lack of effectiveness as well as of the more familiar safety claims become available in such actions,

⁹⁵ The focus on state law in this article, see *supra* note 37, does not neglect federal judges. Pursuant to diversity jurisdiction they hear drug injury cases, see *supra* note 10 (noting two FDA preemption cases in federal court interpreting Pennsylvania and New York Law), and for non-diversity cases, federal common law may be available, *Erie* notwithstanding. See Geiger & Rosen, *supra* note 24, at 422-27 (observing that federal common law "still flourishes" to implement federal statutes, and that the Food, Drug, and Cosmetic Act is well suited to this type of common law).

⁹⁶ See *supra* note 53 and accompanying text.

and thus amenable to adjudication, when judges accept any of the following shifts in doctrine.

*A. Mandate Information about the Comparative Record,
Using Failure to Warn Doctrine*

Because personal-injury liability for injuries caused by prescription drugs centers around failure to warn, anyone who seeks to change the outcomes of drug-liability litigation will begin with the law of warning. Products liability law relies on warning as a means to make users' encounters with products less dangerous. A manufacturer must use reasonable care in the design and fabrication of its products and then, to the extent foreseeable dangers remain, warn users. In principle, warnings, which can convey advice on how to use a product safely and whether to reject it altogether,⁹⁷ keep to a minimum the effects of dangers that cannot be eliminated through improved design.⁹⁸

Applied to cases where defendants sold their product with a warning—all personal-injury claims for drug-caused harms fall in this category, because FDA regulations look closely at packaging and compel sellers to submit proposed words for pre-clearance before marketing—doctrine focuses on its “adequacy” or “sufficiency.” The leading case on adequate warning, *Pavlidis v. Galveston Yacht Basin, Inc.*,⁹⁹ identifies an obligation of the seller to communicate to the consumer what he or she would reasonably want to know about risks. That for most prescription drugs manufacturers discharge their duty by warning a “learned intermediary” between them and the

⁹⁷ James A. Henderson, Jr. & Aaron D. Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn*, 65 N.Y.U. L. REV. 265, 285 (1991) (distinguishing between “risk reduction” and “informed choice” warnings).

⁹⁸ For a trenchant reminder to courts that, notwithstanding § 402A of the *Second Restatement*, warnings should insulate manufacturers from liability only when the dangers could not have been eliminated by reasonable redesign, see Howard Latin, “Good” Warnings, Bad Products, and Cognitive Limitations, 41 UCLA L. REV. 1193 (1994).

⁹⁹ 727 F.2d 330 (5th Cir. 1984).

patient—that is, the patient’s physician—does not alter the need for adequacy.

The current *Restatement* states the duty to warn concisely: “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 “prescribing and other health-care providers” or patients directly, depending on the context.¹⁰⁰ Because safety is a context-driven condition, bound up with effectiveness—even a small risk is too much when the drug is absolutely ineffective—and because no prescription drug is perfectly safe, this black-letter necessarily takes effectiveness into account. And whenever consumers have more than one treatment to choose from, effectiveness cannot be divorced from comparisons with the drug’s alternatives.

To put the point within traditional warning doctrine, a crucial element of an adequate warning is communication about the consequences of not heeding it. Warnings are messages about choice. The risk reduction category of warning says, “When you use our product, consider the following concurrent precaution, for the following reason.” Warnings in the other category, informed choice, give users what they need to know as they decide between abstention and engagement. Although an implicit comparator is present also in the risk reduction category, informed choice is the central reason to tell consumers about alternatives.

The FDA, acting perhaps out of its mistaken belief that drug regulators considering a new drug application have no authority under the Food, Drug, and Cosmetic Act to consider what comparators offer,¹⁰¹ has not ordered manufacturers to provide

¹⁰⁰ RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d) (1998).

¹⁰¹ Lars Noah, *Medicine’s Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community*, 44 ARIZ. L. REV. 373, 437 (2002) (noting FDA resistance to regulating drug comparisons). See also Mehlman, *supra* note 36, at 788 (observing that the FDA almost never withholds approval on the ground that a drug is inferior to “an alternative already on the market”).

this comparative information to consumers.¹⁰² The lost opportunity has led to a comprehensive and fundamental deprivation, so complete that reformers have had trouble imagining repair. In a moment of what he called “wishful thinking,”¹⁰³ physician-pharmacologist Jerry Avorn wrote two sentences that manufacturers could tack onto the label of most newly approved drugs, if they were inclined to tell the whole truth: “This new medication has not been shown to be any better than currently available products, and has a much more limited safety record. There is no evidence that its higher price is accompanied by any demonstrated therapeutic advantage.”¹⁰⁴

While regulatory politics in Washington prevent the FDA from demanding that much candor about the effectiveness of a drug before approval, judges who interpret and apply the common law duty to warn remain free to determine that silence about alternatives withholds from consumers information to which they are entitled. The law of preemption does not block this stance: most courts agree that the Food, Drug, and Cosmetic Act does not preempt claims against pharmaceutical manufacturers for warning defects in prescription drugs, and maintain that “drug labeling regulations generally impose only minimum standards—these regulatory provisions provide merely a safety floor—and state tort law beneficially supplements federal regulatory efforts to promote drug safety.”¹⁰⁵ Although the FDA announced in 2006 by preamble its view that agency approval of labeling preempts failure-to-warn claims,¹⁰⁶ this view is not entitled to deference from judges.¹⁰⁷ States may, if

¹⁰² Bernstein & Bernstein, *supra* note 18.

¹⁰³ JERRY AVORN, *POWERFUL MEDICINES* 365 (2004).

¹⁰⁴ *Id.*

¹⁰⁵ Owen, *supra* note 8, at 909.

¹⁰⁶ Food and Drug Administration, Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 2924 (2006).

¹⁰⁷ See *Perry v. Novartis Pharma. Corp.*, 456 F. Supp. 2d 678 (E.D. Pa. 2006) (so holding with respect to a suit in which the FDA had filed an amicus brief). See also Timothy Ardizzone, Comment, *The FDA: Advocate or Regulator of the Pharmaceutical Industry? The Attempted Preemption by*

they wish, enact statutes that impose a contrary pro-preemption stance.¹⁰⁸ The majority of them do not constrict their common law by this means. Courts construing the law of most states thus may deem a warning inadequate even if the FDA approved it. Congress and state legislatures, in sum, have given federal and state judges latitude to set warning standards high enough to include the comparative information that the FDA did not demand.

Regarding the content of this missing information about comparative treatments, the phrase “informed choice” continues instructive. Different consumers have differing needs to be informed about the relative merits of each drug. Recall the three categories of consumers: physicians, patients, third-party payors. Prescribing physicians cannot make informed treatment decisions without manufacturer-furnished information of how drugs compare to their patented competitors, to generics and other non-patented treatments, and to no treatment at all. Patients might for some drugs be entitled to information not mediated through their physicians, even though, as was mentioned, the learned intermediary doctrine is undisturbed by a judicial stance that manufacturers must provide information about comparative effectiveness; judges need not jettison this traditional protector of defense interests when they rule that the failure to provide comparative information can result in a warning defect. Indeed, the learned intermediary doctrine is worth remembering here: courts decided that warning physicians rather than the patient suffices to discharge the duty to warn not because patients are too stupid to follow directions but in recognition of the vast array of choices and tradeoffs that drugs present—an array that has become much more vast since courts formed the doctrine

the FDA of State Tort Claims for Failure to Warn on Pharmaceutical Labeling, 75 U. CIN. L. REV. 763, 780-86 (2006) (arguing that the FDA’s effort violates an executive order, reflects unsound policymaking, and is entitled to no *Chevron* deference because it is in effect an advisory opinion).

¹⁰⁸ See, e.g., Mich. Stat. Ann. § 600.2946 (5) (Michie 2007) (enacted 1995) (providing that, absent fraud or bribery, FDA approval preempts common law warning and design claims).

decades ago.¹⁰⁹

It also bears mention that under the law of informed consent, a physician must “inform the patient of a drug’s benefits and dangers (as well as the benefits and dangers of no treatment and alternative treatments).”¹¹⁰ If such information about how a drug performs is integral to the practice of medicine, then it is equally integral to the proper marketing of this type of product. Indeed, the medical-malpractice concept of informed consent relates closely to the products-liability concept of informed choice. *Restatement (Third) of Torts: Products Liability* co-reporter Aaron D. Twerski has argued in work co-authored with Neil B. Cohen that physicians should be obliged to tell their patients not only about alternative treatments but alternative providers.¹¹¹ In other words, when the physician or a managed-care defendant knows that other physicians have a better track record in performing the service in question, failure to so inform the patient is a violation of the duty to obtain informed consent. This contention, though still unfamiliar, has support in case law.¹¹²

By denying that patients need to receive direct warnings about most types of drugs, the learned intermediary doctrine opens several realistic avenues to encourage the furnishing of comparative information. The Avorn warning on a patient insert becomes less necessary when “learned intermediaries” possess basic data about the drug in its market. Just as physicians are

¹⁰⁹ RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 cmt. b (1998); *Larkin v. Pfizer, Inc.*, 153 S.W. 3d 758, 763-64 (Ky. 2004) (summarizing rationales for the doctrine).

¹¹⁰ Owen, *supra* note 8, at 608-09.

¹¹¹ Aaron D. Twerski & Neil B. Cohen, *The Second Revolution in Informed Consent: Comparing Physicians to Each Other*, 94 NW. U. L. REV. 1, 24 (1999); Aaron D. Twerski & Neil B. Cohen, *Comparing Medical Providers: A First Look at the New Era of Medical Statistics*, 58 BROOK. L. REV. 5, 13 (1992).

¹¹² *Johnson v. Kokemoor*, 545 N.W. 2d 495 (Wis. 1996) (holding, in an informed consent case, that comparative mortality and morbidity data about the surgeon-defendant were properly admitted at trial); *DeGennaro v. Tandon*, 873 A.2d 191 (Conn. App. 2005) (holding that the defendant had an obligation to disclose her relative lack of experience).

presumed to be learned about the patient's needs, so too might third-party payors be deemed the correct recipients of information about comparative effectiveness.

B. Fine-Tune § 6(c) of the Third Restatement

In their Section 6(c), about design-defect liability for prescription drugs, the reporters of *Restatement (Third) of Torts: Products Liability* wrote provocative new blackletter that did not pretend to restate what courts were doing, except in its bottom line on which side ought to prevail.¹¹³ Judges have always been hostile to claims that prescription drugs are defective in design, and the *Restatement* continues this posture of rejection. The novelty of the "unusual, to say the least"¹¹⁴ rule in § 6(c) is its unique rejectionist path: a drug is defective in design only if a reasonably informed health-care provider, "knowing of its foreseeable risks and therapeutic benefits, would not prescribe . . . [it to] any class of patients."¹¹⁵ Traditionally courts would reach the same answer with reference to the much-maligned comment *k* of the *Second Restatement*, which had deemed prescription drugs "unavoidably unsafe" and hence not defective as a matter of law.

The test for defectiveness that the *Third Restatement*, comment *k*, and the judicial consensus all reject for prescription drugs is the one that governs design-defect claims about products that are not prescription drugs: risk-utility balancing (at a macro level) or the possibility that a plaintiff can prevail by presenting a better alternative design. Neither of these analytic devices is available to plaintiffs in drug-design cases: a plaintiff cannot

¹¹³ While the *Restatement* was in draft form, one commentator observed that "no published decision proffers the 'reasonable physician' or 'reasonable health care provider' as a legal test for determining whether or not the drug or prescription device in question is unavoidably unsafe." Jeffrey D. Winchester, *Section 8(c) of the Proposed Restatement (Third) of Torts: Is It Really What the Doctor Ordered?*, 82 CORNELL L. REV. 644, 670-71 (1997).

¹¹⁴ Owen, *supra* note 8, at 556.

¹¹⁵ RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(c) (1998).

prevail by showing that a drug as designed does more harm than good in the aggregate. Nor can claimants bring to court proposed chemical reformulations that engineer out the dangers they have identified. "Drug designs are different," intoned the reporters.¹¹⁶ Indeed. Because physicians oversee distribution, this product—unlike most other products, which a user can buy and consume without pre-clearance—can go to individuals who can benefit from it and kept from those who would be hurt by its danger. Only when no benefited cohort exists is the design bad; almost every drug that injures a plaintiff could help heal another person, and so the failure lies not in design but in distribution.

So far, so good: yet a departure from risk-utility assessment this radical still favors pharmaceutical defendants in contrast to all other manufacturing defendants, and the fact that pharmaceutical defendants had to climb regulatory hurdles may not be enough reason to protect them this much. Courts enjoy a chance to modify the radicalism of § 6(c) by paying heed to the Traynorian heritage. Although the central "drugs are different" contention remains sound, when not construed carefully § 6(c) achieves little beyond protection for the industry via a slammed courthouse door.

A few suggestions pertinent to a *Restatement* § 6(c)-based motion for summary judgment in response to a design-defect claim:

(1) *Compel the manufacturer, rather than the plaintiff, to identify the § 6(c) "class of patients" in order to prevail on summary judgment.* The "class of patients" criterion of § 6(c) overtly states, in blackletter, the relevance of effectiveness to personal-injury litigation. Because effectiveness is so central to § 6(c), courts that accept this rule of this section can justifiably use the burden of production to help achieve it. In commentary, the *Restatement* implies that the plaintiff holds the obligation to persuade on the "no class of patients" point,¹¹⁷ but it is wrong

¹¹⁶ See *supra* note 33.

¹¹⁷ RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 (1998) cmt. f ("Given this very demanding objective standard, liability is likely to be imposed only under unusual circumstances. The court has the responsibility

to saddle a plaintiff with this burden after she has identified a flaw in the design of the drug, proposed the rudiments of a feasible alternative, and shown that the design caused her injury. Manufacturers instead should have to identify the class of patients that would benefit from its challenged design. Notwithstanding dicta in one case that rejected § 6(c) for its state (on the ground that it is "too strict"¹¹⁸), a mere assertion by "the defense's expert witness that the drug at issue had some benefit for any single class of people"¹¹⁹ should not suffice for summary judgment. Expert testimony on the point should be open to *Daubert* scrutiny.¹²⁰

The reasons to put this burden on defendants rather than on plaintiffs are comprehensive. Defendants will typically know who would benefit from their drugs as designed, whereas plaintiffs would have to go to expense and trouble to support their contention that no such class of patients exists. The defendant's task of identifying one benefited class is much easier than the plaintiff's task of showing that no such class exists. Imposing this cost on defendants would lower the cost of bringing valuable information to public light.

Second, consistent with other burden-shifting doctrines in tort law, this category of plaintiff has demonstrated her exceptional status among plaintiffs. She can benefit from the burden-shifting rule only after demonstrating that the product in question either fails in a macro-balance inquiry or should be replaced by a feasible alternative design.¹²¹

Perhaps the most salubrious effect of this rule is its

to determine when the plaintiff has introduced sufficient evidence so that reasonable persons could conclude that plaintiff has met this demanding standard.").

¹¹⁸ *Freeman v. Hoffman-LaRoche, Inc.*, 618 N.W. 2d 827, 840 (Neb. 2000).

¹¹⁹ *Id.*

¹²⁰ *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).

¹²¹ Cf. Susan Epstein, *Tort Reform to Ensure the Inclusion of Fertile Women in Early Phases of Commercial Drug Research*, 3 U. CHI. L. SCH. ROUNDTABLE 355 (1996) (defending a burden-shifting proposal to favor plaintiffs in litigation against drug manufacturers with reference to criteria courts have used to support this shift).

propensity to generate (not just reveal) more information. Scholars have shown that current law encourages a manufacturer of risky or toxic products to stick its corporate head in the sand, choosing lack of knowledge over knowledge in order to benefit from a lower standard of care.¹²² With the “class of patients” burden put on defendants, however, the manufacturer prospers by doing the post-marketing studies that the FDA does not now demand.¹²³ Even if the number of plaintiffs bringing design defect claims remains relatively low notwithstanding this easing of their obligations, manufacturers would, out of prudence, be prepared to describe the class of patients to whom a reasonable provider would prescribe their products. The preparation of such information offers social utility at a relatively cheap price.

(2) *Demand information about the § 6(c) “class of patients” beyond the fact that such a class exists.* Consumers would benefit from more information about which groups of patients benefit from a particular drug. The cohorts that pharmaceutical interventions address are not generally known. Which groups have relevant traits in common? Why are they well positioned to benefit from a particular drug? How did researchers learn about the effects on this group? Who isn’t benefiting? Litigation offers unique opportunities to enhance transparency about marketing practices. At present, manufacturers are prohibited from suggesting in their advertisements that physicians make therapeutic use of a drug for a purpose that the FDA has not approved, but if they stop short of overt advertisement, in practice they enjoy latitude to promote these unapproved

¹²² Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 CORNELL L. REV. 773 (1997). See also Margaret A. Berger, *Eliminating General Causation: Notes Toward a New Theory of Justice and Toxic Torts*, 97 COLUM. L. REV. 2117, 2138-39 (1997) (noting that even if a manufacturer can expect to be found liable for harm its toxic product caused, the costs of this liability are remote and contingent, whereas the cost of researching present dangers arrives immediately).

¹²³ Wagner, *supra* note 122, at 833-48. While this Article was going to press, the United States Senate passed a bill expanding FDA oversight over drugs post-approval. Commentators expressed confidence that the measure would become law. *Heading Toward Reform of the FDA*, N.Y. TIMES, May 11, 2007, at A26 (noting overwhelming 93-1 “veto-proof majority” vote).

applications.

Much discreet, unreviewable promoting takes place behind closed doors in medical offices. In one familiar scenario, an attractive young saleswoman working on commission, successor to the “detail man” of yore, totes sample pills and corporate-embossed trinkets (and often an expense account to pay for meals) when she visits a physician to suggest expanded patient demographics for her brand-name product.¹²⁴ Some observers who do not receive these freebies have wanted to know more about the promotional script, but their suggestions that the FDA (or another regulator like the Securities and Exchange Commission) monitor more closely what drug companies spend on promotions and what usages their agents recommend have not been heeded. Trial judges, who lack authority to produce the information-fostering rules that regulators have declined to write, can nevertheless encourage the production of information by reading § 6(c) as an expansive rather than a narrow standard. They can withhold summary judgment and send drug-design claims to the jury when a manufacturer does not furnish full information about the class of patients that benefit from the challenged design.

(3) *For § 6(c) purposes, courts should welcome evidence of “off-label” practices.* Continuing the expansiveness theme, “off-label” uses should be available to litigants and courts that seek

¹²⁴ One physician has confessed that he enjoys the company of “pharma babes” in his office:

On the record, most docs will say reps are just a minor distraction, that as professionals “we do our learning the old-fashioned way.” The cheap pens and pads adorned with logos and drug names and the occasional steak dinners are supposed to mean nothing to us. But 10 minutes of rapt attention from a smiling beauty is still 10 minutes more than usual. So what if she’s talking about nausea, vomiting, and diarrhea—we talk about that stuff too. . . . I eavesdropped on the medical marketing world when I repped medical devices for a summer job in college—the reps knew what suckers doctors were and taught me to take advantage of the fact. It hasn’t changed; just grab hold of that inflated medical ego and twist—over we go.

Scott Haig, *Attack of the Pharma Babes*, TIME, Jan. 2, 2007.

the class of patients to which a reasonably informed provider would give the drug as designed. “Off-label,” a bit of industry jargon, refers to uses and indications that are not named in the labeling and packaging that the FDA approves when it permits a manufacturer to market a prescription drug. Physicians who prescribe a pharmaceutical product to treat a condition are not bound by the indications for which the FDA approved the drug, and can dispense it to any patient.¹²⁵

One category of drug now used much more often off-label than on- is tricyclic antidepressants, mentioned above, one of the earliest FDA-approved treatments for depression. Providers now seldom dispense them for this purpose. The tricyclic design might now be defective in terms of its officially sanctioned purpose, then, because it is unsafe and ineffective when viewed in relation to alternatives for its approved use. Yet a reasonably informed provider would consider prescribing tricyclic antidepressants for several classes of patients—persons suffering from bulimia, cystitis, irritable bowel syndrome, even persistent hiccups¹²⁶—and so a plaintiff bringing a design-defect claim ought to lose with reference to these off-label uses.

More clarity in the law of evidence could bolster the off-label concept and make it cheaper to administer in court. For example, courts could recognize expertise in off-label dispensation as distinct from whether a reasonable physician would dispense a drug off-label to a particular patient and accordingly allow non-physician witnesses to testify, or perhaps be allowed to admit what is now characterized as hearsay, thereby lowering expert-witness costs for litigants. Live testimony might be required only in unusual circumstances. Like the other suggestions just made, this recognition of off-label prescribing furthers the goal of fostering information by encouraging candor and transparency about what prescribers are

¹²⁵ The exceptions among prescription drugs are “controlled substances” like opiates, whose distribution the Drug Enforcement Agency monitors closely, with an eye toward reducing the dangers of addiction. *See* 21 U.S.C. § 801 et seq. (2004).

¹²⁶ MARTINDALE: THE COMPLETE DRUG REFERENCE (33d ed.) (Sean Sweetman ed., 2002).

doing with this product.

For good or ill—probably, on the whole, for good—off-label uses of prescription drugs have begotten a trove of new therapies.¹²⁷ Cancer patients today are seldom restricted to the four corners of FDA-approved uses for a drug, especially when their physicians believe they are running out of time.¹²⁸ One famous prescription drug, Viagra, would not have been developed and patented as a treatment for erectile dysfunction if its manufacturer had not noted the side effect that subjects reported when they used an angina drug under study;¹²⁹ the cardiac use for which Pfizer intended to seek on-label approval never reached the market. American patients have been enlisted in a massive uncontrolled experiment in off-label dispensation that has helped and hurt them to an extent regulators do not measure. Evidence-law reform could encourage the publication of more off-label experience—both good and bad—and bring to light data that the industry possesses and now shares only selectively.

C. Punitive Damages and Effectiveness

In the hymnal that is the consensus about personal-injury law as over-deterring drug manufacturers from bringing products to the market, the song about the evil of punitive damages is particularly oft-sung. Many statutes, both proposed and enacted, that strive to improve either punitive damages law or pharmaceutical law or both eliminate this form of damages in actions for injury attributed to an FDA-approved drug.¹³⁰ The leading piece of decisional law on the poor fit between punitive

¹²⁷ See Klein & Tabarrok, *supra* note 41.

¹²⁸ Bernadette Tansey, *Why Doctors Prescribe Off Label*, S.F. CHRON., May 1, 2005, at A12.

¹²⁹ Klein & Tabarrok, *supra* note 41.

¹³⁰ See, e.g., Help Efficient, Accessible, Low-cost, Timely Healthcare (HEALTH) Act of 2003, H.R. 5, 108th Cong. (introduced 2003) at 7; Ariz. Rev. Stat. Ann. 12-701 (2004); Ohio Rev. Code Ann. 2307.80 (C)(1) (2005). New Jersey, N.J. Stat. Ann. 2A:58C-5(c) (West 1987); Oregon, Or. Rev. Stat. 30.927 (2000); Utah Code Ann. 78-18-2 (Michie 2004).

damages and products liability arose from litigation about a cholesterol-lowering drug.¹³¹

As with drug litigation generally, critics of liability cannot point to defeats in court as a reason for reform—only their lack of a guarantee that such defeats could never happen. One leading critic, Kip Viscusi, who concedes that courts almost never award punitive damages in personal-injury drug litigation unless a manufacturer has in effect lied to the FDA—withholding or rewriting material negative information about its product¹³²—nevertheless insists that the industry should receive more shelter from “litigation uncertainty” in the form of stringent punitive-damages reform.¹³³ Unless the industry badly needs more protection from the dreaded forces of overdeterrence (a need it has never demonstrated),¹³⁴ the opposite conclusion seems more warranted by the record, with its absence of actual awards for anything other than fraud on the regulatory authorities.

Adding effectiveness to the punitive damages matrix could raise the number of cases that impose punitive damages on drug manufacturers while remaining sensitive to the concern about over-detering product development. As practiced, punitive damages for this category of litigation identify the American public rather than individual litigants as the victims of wrongdoing.¹³⁵ The plaintiff’s role as private attorney general, doing the work of regulators, emerges more clearly than in

¹³¹ *Roginsky v. Richardson-Merrell, Inc.*, 378 F.2d 832, 832 (2d Cir. 1967) (Friendly, J.).

¹³² Viscusi, *supra* note 24, at 1476 n.41.

¹³³ *Id.* at 1476-77.

¹³⁴ JUDITH P. SWAZEY, *Prescription Drug Safety and Product Liability*, in *THE LIABILITY MAZE: THE IMPACT OF LIABILITY LAW ON SAFETY AND INNOVATION* 295-96 (Peter W. Huber & Robert E. Litan eds., 1991) (observing that drug manufacturers have the data to demonstrate the adverse effects of liability but have never used these facts to document the reform proposals they advocate).

¹³⁵ Here I am influenced by, but do not hew to, Catherine M. Sharkey, *Punitive Damages as Societal Damages*, 113 *YALE L.J.* 347, 389 (2003) (contemplating payouts to recipients who were not parties to originally filed claims).

personal injury litigation not involving regulated industries, where the particulars of the plaintiff create a basis for punishment. In drug litigation, by contrast, the plaintiff has helped the government do its safety work. Punitive damages for this type of injury serve to reward plaintiffs for detecting and then deterring misinformation about dangers that thwarted the FDA safety mission. Similarly, then, plaintiffs could be rewarded for detecting and deterring misinformation that thwarted the FDA effectiveness mission.

The suggestion here is that a subset of plaintiffs with good claims for drug-caused injury be allowed to collect punitive damages for the societal wrong of selling a prescription drug that is not effective, just as a subset now can collect such damages for the societal wrong of selling an unsafe prescription drug. Criteria for punitive damages would include an injury to the plaintiff caused by the drug, a showing that the drug was not effective and, again to retain a connection to current punitive-damages traditions, proof that in its FDA new drug application the manufacturer withheld or misstated information about this lack of effectiveness. Other restrictive criteria might be added, if these prove too generous to plaintiffs.

This approach to punitive damages requires a court to agree that consumers are injured by ineffectiveness; it must reject metaphors of unbarking dogs and non-firing guns.¹³⁶ Once courts recognize the reality of injury, they become freer to award punitive damages in the right measure. This opportunity grows particularly valuable in this post-*State Farm* era, now that the Supreme Court has repeatedly declared that punitive damages in an amount too many times larger than the compensatory award may violate a defendant's due process rights.¹³⁷ The baseline of safety-related harm is the value of physical injury that the plaintiff suffered, and courts in the future might well hold that a plaintiff bringing a safety-related claim may not collect more than a single-digit multiple of that

¹³⁶ See *supra* notes 72-73 and accompanying text.

¹³⁷ *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 424-45 (2003); *Cooper Indus., Inc. v. Leatherman Tool Group*, 532 U.S. 424, 441-42 (2001); *BMW of North America, Inc. v. Gore*, 517 U.S. 559, 581 (1996)

sum. Because ineffectiveness-related harm is less determinate—and affects third-party payors and physicians, not just patients—the maximum award for punitive damages can enlarge.¹³⁸

Steps toward expanding punitive damages should not be taken lightly: courts need to keep overdeterrence in mind. If drug manufacturers are now unduly threatened and hampered by liability, then more punitive damages for drug claims becomes a problem rather than a solution. Yet to a judge seeking to apply the law, principles of legislative supremacy are at least as worthy of attention as a lament about too much liability. At the state level, legislatures that have not banned punitive damages in drug cases have manifested a tacit choice to permit them.¹³⁹ The large majority of states that have not adopted a regulatory compliance defense have declared that FDA approval of a drug is a floor, or minimum, rather than an upper limit on liability. At the national level, Congress saw fit (in a unanimous vote) to prohibit the sale of any drug for which there is no substantial evidence of effectiveness, and has not amended the Food, Drug, and Cosmetic Act to discourage personal injury litigation with express preemption, a regulatory compliance defense, or a ban on punitive damages—all choices that it had the authority to make. It is reasonable to infer that legislatures support the expansion of punitive damages for deceiving the FDA on effectiveness.

As for the policy effects of punitive damages, judges should

¹³⁸ When this Article went to press, published case law in the wake of *Philip Morris USA v. Williams*, 127 S. Ct. 1057 (2007) had just barely begun to appear. In *Williams*, a 5-4 decision, the Supreme Court reversed a judgment of \$79 million in punitive damages on the ground that this sum had reflected recognition of injuries to persons who were not parties to the action. Much rides on whether *Williams* stands for the proposition that very large punitive damage awards violate the Due Process Clause simply by their size and indeterminacy. Should its reach prove more modest in operation, then the understanding of ineffectiveness as a distinct source of personal injury becomes vital for the force of this measure following its constitutionalization post-1996.

¹³⁹ See Schwartz & Goldberg, *supra* note 4, at 175-76 (pointing out, by naming only a few states, that the majority of United States legislatures do not single out drug cases as less deserving of punitive damages).

bear in mind the distinction between effectiveness and efficacy. Mere failure to attain clinical improvement in patients does not violate the post-1962 mandate that a drug must be effective. The job of a drug is to live up to the promises on its label. Telling the truth about what the drug will do, then, would insulate a manufacturer from punitive damages.

"No it won't," a spokesperson for the industry might retort. "One runaway jury misreading a label, and our multimillion-dollar investment in development is done for." Anti-liability partisans might envision a badly injured sympathetic plaintiff—perhaps a child injured in utero—serving as the compensatory base, with punitive damages fancifully extracted by misreading of a label.

Such worries lack foundation. Heart-tugging plaintiffs have enjoyed whatever powers they have held for years; they are unaddressed in this Article. The power identified by expanded liability comes from authoritative yet dishonest words. A plaintiff's lawyer could win punitive damages only by showing that promises about clinical effects were false by design. This verbal, text-based contention is rooted in contract, and breach of a written contract is inherently cooler, less manipulative, and less inflammatory than a claim of personal injury attributed to wrongful action.

CONCLUSION

After many years of criticism about its over-deterrent effects, prescription drug liability has become stagnant. Legislation, case law, and scholarship, all sharing their worry about reducing the supply of prescription drugs, dampened the fiery old conviction that products liability enhances consumer welfare. In a literature now deficient in balance, writers propose few suggestions for reform beyond liability-squelching.

The result is a sorry circle. Daunted by anti-liability rhetoric that is among other things an attack on their work product, judges feel they can achieve less through the imposition of liability. When courts do less with liability, liability comes to have fewer effects. When liability has fewer effects, it does less

observable good, and becomes both harder to embrace and easier to decry for its hypothetical power to wreck an industry. The circle is complete when these attacks daunt the judiciary. No surprise, then, that personal-injury liability for defective drugs has achieved little to improve welfare since the heady days when it blasted the Dalkon Shield out of the market and sent a strong consumer-protection message.

This outcome would be acceptable, even desirable, if liability really hurts rather than helps the public. Prescription-drug liability probably offers both overdeterrence and underdeterrence, however. Although the persons who manage manufacturers undoubtedly feel apprehensive about the possibility of paying ruinous damages to litigious victims,¹⁴⁰ and the industry has suffered unjustly on occasion in court,¹⁴¹ the pharmaceutical sector has also been prospering at the expense of consumers. Numerous commentators have decried them for producing and selling unsafe drugs. Less well-documented in the courts and in law reviews, but at the center of this Article, is the fact that this industry also produces and profits from ineffective and inefficacious drugs.

Lack of safety and lack of effectiveness both violate a popular, uncontroversial, established-for-decades statutory mandate. Regarding safety claims, participants in and observers of the drug-liability system accept that the Food and Drug

¹⁴⁰ See *supra* note 21.

¹⁴¹ Bendectin is widely believed to be a martyr drug. See generally GREEN, *supra* note 3 (describing Bendectin as a poster child of courts driving away a valuable drug). One critic of liability argues that two intrauterine devices, the Copper-7 and Lippes Loop, were also martyred following the well-deserved demise of the Dalkon Shield. PETER W. HUBER, *LIABILITY: THE LEGAL REVOLUTION AND ITS CONSEQUENCES* 41-42 (1988). In response to Huber in particular, defenders of liability have retorted that when the disappearance of a particular drug results from poor marketing, disappointing profits, or perhaps even a desire to flounce away from the market to express pique about the existence of liability, its manufacturer will naturally prefer to blame what it could not control. Jeff L. Lewin, *Calabresi's Revenge? Junk Science in the Work of Peter Huber*, 21 HOFSTRA L. REV. 283, 297 (1992) (reviewing Huber's *Galileo's Revenge*); Joseph A. Page, *Deforming Tort Reform*, 78 GEO. L.J. 649, 685-89 (1990) (reviewing Huber's *Liability*).

Administration will not detect every safety-related flaw in advance of approval, and they agree that litigation *ex post* functions as a means to remedy this deficiency (some like this litigation; some don't). The same reasoning suggests that litigation *ex post* is also a means (some will like this litigation; some won't) to remedy the deficiency in effectiveness.

True, the harm of an ineffective drug is harder to see than the harm of an unsafe one, and when harm is not seen, personal-injury litigation appears beside the point. It is not. Safety and effectiveness are related conditions that cannot be understood in isolation from each other. Lack of effectiveness is central to lack of safety. Without the possibility of good results, even small risks are unjustified. Without alignment between label-promises and outcomes, the perils of deceit, wrongfully gained revenue, and emotional distress loom large. Without therapeutic benefit from a product (putting aside for this purpose the small percentage of prescription drugs that give consumers things they do not need to sustain their life or health, such as sexual enhancements or new hair growth), a patient remains in danger. Lack of effectiveness in a drug causes plenty of harm. A subset of injured persons ought to find relief in the courts for this injury.

In conclusion, recall overdeterrence—both its reality and its specter. So long as legislators and commentators continue to site the problem of supply incentives at the heart of prescription-drug liability, judges cannot, and should not, abandon their present concern about over-wielding the liability sanction. Accordingly, the specific suggestions to them offered in this Article take only modest first steps.¹⁴² In the event of a future revised consensus that what vexes the prescription drug market is too little deterrence rather than too much—the belief that launched strict products liability around the time that the 1962 drug amendments were enacted—stronger reforms than those proposed here could be written: for example, courts could bolster the *qui tam* action to augment rewards for bringing

¹⁴² See *supra* n.28 and Part III.

ineffectiveness to public light,¹⁴³ and courts and legislatures could encourage class actions that allege deception by drug manufacturers.¹⁴⁴ Meanwhile, policy-minded judges mindful of the importance of supply must also bear in mind that each drug on the American market wrapped in false promises of therapeutic gain violates a law-based entitlement to effectiveness.¹⁴⁵ This wrong ought to imply a right.

¹⁴³ For example, federal courts could bolster the qui tam action by allowing a person who knows that an FDA-approved drug is not effective to invoke the False Claims Act, 31 U.S.C. § 3729(a) (2005). This statute allows for treble damages and provides that the initiator, called the realtor, collects between 15 and 30 percent of any recovery if the action succeeds. 31 U.S.C. § 3730(d)(1) (2005). Qui tam helped bring down overpromotion and other misconduct related to the epilepsy drug Neurontin. *See supra* note 15; Ralph F. Hall & Robert J. Berlin, *When You Have a Hammer Everything Looks Like a Nail: Misapplication of the False Claims Act to Off-Label Promotion*, 61 FOOD & DRUG L.J. 653, 662-63 (2006) (noting that the realtor, a physician named David Franklin, recovered \$27 million for his Neurontin work). For a qui tam reform proposal focusing on drug safety, *see* Catherine T. Struve, *The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation*, 5 YALE J. HEALTH POL'Y L. & ETHICS 587 (2005). State courts, for their part, could become more welcoming to deceptive-trade practices actions.

¹⁴⁴ *See supra* note 37 (observing that at present, many courts appear to favor discouragement).

¹⁴⁵ In addition to imposing an extraordinarily high effectiveness hurdle for new-drug approval, the 1962 amendments to the Food, Drug, and Cosmetic Act took an intolerant view of existing approved drugs. These drugs benefited surprisingly little from "grandfathering" or a presumption of effectiveness, and in the 1960s the FDA put them through controlled studies to see how well they measured up to the claims on their labels. *See supra* note 53; PETER BARTON HUTT & RICHARD MERRILL, FOOD AND DRUG LAW: CASES AND MATERIALS 478 (2d ed. 1991).

