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## Dangers in Prescription Drugs: Filling a Private Law Gap in the Healthcare Debate

David G. Owen

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## Article

### Dangers in Prescription Drugs: Filling a Private Law Gap in the Healthcare Debate

DAVID G. OWEN

*The healthcare debate raging in this nation largely ignores the role of private law in healthcare reform. One aspect of private law occasionally included in the discussion is how medical malpractice litigation may raise healthcare costs, by increasing the cost of liability insurance for medical providers and encouraging them to practice “defensive medicine.” Yet, another aspect of private law affecting health care in America remains outside the current debate—the responsibility of makers and sellers of prescription drugs for harm caused by the dangers such drugs contain.*

*Closing this gap in the healthcare debate, this Article proposes that the law ban design defect litigation against manufacturers of pharmaceuticals, and, further, that it abolish the “learned intermediary doctrine,” thereby imposing full-bodied duties on both manufacturers and pharmacists to warn consumers. These changes should promote the central goals of healthcare reform—maximizing consumer choice, increasing quality, and reducing costs of health care in America. While these proposals are bold, the current healthcare crisis demands bold solutions. Together, these reforms should motivate drug companies, pharmacists, and patients to partner together to reduce the harmful effects of unavoidable dangers in prescription drugs while exploiting the many benefits of pharmaceuticals for human health.*

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# Dangers in Prescription Drugs: Filling a Private Law Gap in the Healthcare Debate

DAVID G. OWEN\*

## I. INTRODUCTION

How America should reform its healthcare system is one of the most unsettled and contentious political issues in the nation today. Swirling within the debate are questions of how to cover millions of uninsured; how to maximize patient choice of physicians and treatments; how to improve the quality of care; how broadly to restructure the health delivery system; and how to limit the costs of, and fund, whatever newly constructed healthcare system emerges from the present debate. No matter how a person may view the myriad issues in this great American dialogue, one which surely will continue for years to come, observers generally agree that central objectives of any plan should include maximizing consumer choice and healthcare quality, and minimizing costs.<sup>1</sup>

When commentators critique the present system, and when they prescribe cures, they understandably focus most closely on healthcare providers—physicians, nurses, hospitals, and other persons and institutions who provide services to the sick, injured, and infirm<sup>2</sup>—and on those who fund the system—employers, insurers, and government.<sup>3</sup> While the present debate sometimes also focuses on the citizenry—patients, who are the consumers of healthcare products—conspicuously absent from such discussions is a consideration of the ability and responsibility of patients to participate in decisions concerning their own health care in order to protect themselves. Instead, patients too often are viewed as (and all too willing to play the role of) passive recipients of whatever health care the system may provide. Also missing from the debate is the role of those who make and sell healthcare products—manufacturers and pharmacists—and how their

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<sup>1</sup> See Tom Daschle, *Climbing the Hill on Health Care*, WALL ST. J., Sept. 3, 2009, at A17 (“The goal of meaningful health reform should be to expand coverage, reduce projected costs, improve health-system quality, and enhance health-care options for all Americans.”); see also Barack Obama, Op-Ed., *Why We Need Health Care Reform*, N.Y. TIMES, Aug. 16, 2009, at WK9; Ruth Mantell, *Meaningful Health-Care Reform Getting Closer: Outline of Changes Likely To Be Enacted Begins To Take Shape*, MARKETWATCH, Mar. 16, 2009, <http://www.marketwatch.com/story/health-care-reform-consensus-builds-around>; Uwe E. Reinhardt, *Lost in the Shuffle: The Overarching Goals of Health Reform*, N.Y. TIMES ECONOMIX, Aug. 7, 2009, <http://economix.blogs.nytimes.com/2009/08/07/lost-in-the-shuffle-the-overarching-goals-of-health-reform>.

<sup>2</sup> See Reinhardt, *supra* note 1.

<sup>3</sup> See Paul Krugman, Op-Ed., *Health Care Realities*, N.Y. TIMES, July 31, 2009, at A23.

behavior may exacerbate healthcare problems, how altering their behavior may improve healthcare choice and quality, and how these alterations may affect healthcare costs.

These gaps in the healthcare debate are part of a broader failure of the present national discussion to focus meaningfully on the role of private law in healthcare reform. One aspect of private law, which only recently has begun to be seriously considered an organic part of healthcare reform, is the role of medical malpractice litigation in raising the costs of health care as a whole.<sup>4</sup> The threat of expensive malpractice litigation, it is argued, increases costs by making liability insurance for medical providers more expensive and by encouraging providers to practice “defensive medicine,” such as ordering unnecessary tests and treatments to address even the tiniest doubts and aspects of a patient’s condition.<sup>5</sup> Tort reform issues of this type are important, but although they are beginning to receive some attention, that attention so far has been insufficient. Yet, there is another aspect of private law significantly affecting health care in America that has managed to remain almost entirely under the radar in the current debate—the responsibility of makers and sellers of prescription drugs for harm caused by dangers in such drugs. This is the aspect of private law that is the subject of this Article.

The Article begins to fill a gap in the present healthcare debate on the role of private law in addressing the problem of dangers in prescription drugs. Part II explores broadly how the American regulatory and medical systems work together to promote public health, and what role that leaves for private law. Part III then examines how products liability law has evolved with respect to responsibility for harm caused by the design of prescription drugs, and Part IV considers the evolving law shielding manufacturers and pharmacists from a duty to provide warnings directly to drug patients. Part V proposes that private law be reformed to ban design defect litigation against pharmaceutical manufacturers while expanding the duties of both manufacturers and pharmacists to warn consumers directly of drug dangers. The Article concludes that such reforms should increase healthcare choice and quality, while decreasing healthcare costs.

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<sup>4</sup> See Scott Horsley, *Could Lawsuit Curbs Pave Way for Health Care Deal?*, NPR, Sept. 2, 2009, <http://www.npr.org/templates/story/story.php?StoryId=112454986>; Barack Obama, *President Obama’s Health Care Speech to Congress*, N.Y. TIMES, Sept. 9, 2009, [http://www.nytimes.com/2009/09/10/us/politics/10obama.text.html?\\_r=1&ref=politics](http://www.nytimes.com/2009/09/10/us/politics/10obama.text.html?_r=1&ref=politics); Dionne Searcey & Jacob Goldstein, *For Health Care, Tangible & Unseen Costs*, WALL ST. J., Sept. 3, 2009, at A13.

<sup>5</sup> See Kimberley A. Strassel, *The President’s Tort Two-Step*, WALL ST. J., Sept. 11, 2009, at A17 (“Experts on left and right agree that defensive medicine—ordering tests and procedures solely to protect against Joe Lawyer—adds enormously to health costs.”); see also Searcey & Goldstein, *supra* note 4 (“This is defensive medicine—a careful, fretful approach to treating patients, in which doctors authorize tests in part to reduce the risk that they will be sued.”).

## II. PRESCRIPTION DRUGS, PRIVATE LAW, AND THE HEALTHCARE PROBLEM

No one should doubt that dangerous pharmaceuticals are a significant contributor to the current healthcare crisis, contributing extensively to human suffering and substantially increasing healthcare costs. Each year offers new examples of injuries and deaths caused by untoward dangers in prescription drugs. Prominent illustrations from recent years include Vioxx, a popular arthritis painkiller that more than doubled the risk of heart attacks and strokes,<sup>6</sup> a risk that lingered long after users stopped taking the drug;<sup>7</sup> “Phen-fen,” a diet drug that caused heart damage;<sup>8</sup> and Propulsid, a drug that reduced gastric acid but also threatened patients’ hearts.<sup>9</sup> Once information on these side-effects became known to the public, the manufacturers of each of these drugs stopped selling them and, eventually, paid millions or billions of dollars to settle claims for resulting injuries.<sup>10</sup> Merck, for example, having withdrawn the profitable Vioxx drug<sup>11</sup> from the market in 2004, settled nearly 50,000 Vioxx cases in late 2007 for \$4.85 billion.<sup>12</sup> In 2009, Eli Lilly agreed to plead guilty and pay \$1.415 billion in criminal and civil penalties for promoting its antipsychotic drug, Zyprexa, as suitable for uses not approved by the Food and Drug Administration (“FDA”).<sup>13</sup> These cases may be among the more prominent, but they represent just the tip of the iceberg of damage caused by prescription drugs.

Many have been frustrated in attempting to figure out just how principles of private law, products liability in particular, should be applied

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<sup>6</sup> See Parker Waichman Alonso LLP, *Yet Another Vioxx Settlement*, Aug. 4, 2009, <http://www.yourlawyer.com/articles/read/16836> [hereinafter *Vioxx Settlement*]; Official Vioxx Settlement, <http://www.officialvioxxsettlement.com> (last visited Sept. 3, 2009); see also Margaret Gilhooly, *Addressing Potential Drug Risks: The Limits of Testing, Risk Signals, Preemption, and the Drug Reform Legislation*, 59 S.C. L. REV. 347, 349–50 (2008) [hereinafter Gilhooly, *Addressing Risks*]; *Bextra Doubles Risk of Heart Attack and Stroke, Study Finds*, CONSUMER AFFAIRS, Nov. 11, 2004, [http://www.consumeraffairs.com/news04/vioxx\\_bextra2.html](http://www.consumeraffairs.com/news04/vioxx_bextra2.html) (stating that Bextra, another Cox-2 inhibitor, possibly shares the same risk as Vioxx).

<sup>7</sup> Steven Reinberg, *Vioxx’s Heart Risk Lingered Long After Use Ended*, U.S. NEWS & WORLD REP., Oct. 14, 2008, <http://health.usnews.com/articles/health/healthday/2008/10/14/vioxxs-heart-risk-lingered-long-after-use-ended.html>.

<sup>8</sup> Anita Bernstein & Joseph Bernstein, *An Information Prescription for Drug Regulation*, 54 BUFF. L. REV. 569, 578–79 (2006).

<sup>9</sup> *Id.* at 581–82.

<sup>10</sup> See *id.* at 582 (reporting that Johnson & Johnson paid \$90 million in 2004 to settle claims that Propulsid caused hundreds of deaths and many thousands of injuries); see also *id.* at 579 (reporting that, in 2004, Wyeth settled the Phen-fen class action for \$3.75 billion).

<sup>11</sup> Annual sales of Vioxx reportedly were \$2.5 billion. *Vioxx Settlement*, *supra* note 6.

<sup>12</sup> *Id.*

<sup>13</sup> This amount included a \$515 million criminal fine, the largest ever imposed on an individual corporation in the United States. Press Release, Dep’t of Justice, Eli Lilly and Company Agrees to Pay \$1.415 Billion to Resolve Allegations of Off-label Promotion of Zyprexa (Jan. 15, 2009), available at <http://www.justice.gov/opa/pr/2009/January/09-civ-038.html> [hereinafter DOJ Press Release, Jan. 15, 2009].

to prescription drugs. Whether and how prescription drugs should be treated differently from other products has consumed more time and effort, and resulted in the gnashing of more teeth, than about any other particularized issue in all of American products liability law.<sup>14</sup> In addition to featuring two prominent *Restatement* provisions—comment *k* to section 402A of the *Restatement (Second) of Torts* and section 6 of the *Restatement (Third) of Torts: Products Liability*—the drug liability story wends through two of the most important cases in modern products liability law history: *Feldman v. Lederle Laboratories*<sup>15</sup> and *Brown v. Superior Court*,<sup>16</sup> which together rescued American law from the great strict liability experiment of the 1960s and 1970s and returned principles of foreseeable risk and negligence as the bedrock of responsibility for manufacturers of pharmaceutical drugs.<sup>17</sup>

Drug liability law involves a vast range of complex products liability issues, including the battle for supremacy between consumer-oriented and manufacturer-oriented liability tests for establishing the defectiveness of a product's design; the never-ending struggle between negligence and strict liability; how design and warning defect notions fit together; the responsibility of manufacturers for harm from inherent dangers that are unforeseeable or otherwise unavoidable under the prevailing state of the art; the scope of a manufacturer's liability for prenatal harm; limitations on litigation by a manufacturer's compliance with federal agency regulations; the federal preemption doctrine; and, at bottom, whether prescription drugs in fact are sufficiently distinct from other types of products to be treated

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<sup>14</sup> For discussion of prescription drug liability, see Anita Bernstein, *Enhancing Drug Effectiveness and Efficacy Through Personal Injury Litigation*, 15 J. L. & POL'Y 1051, 1055–57 (2007) [hereinafter Bernstein, *Drug Effectiveness*]; Bernstein & Bernstein, *supra* note 8, at 573–74; George W. Conk, *The True Test: Alternative Safer Designs for Drugs and Medical Devices in a Patent-Constrained Market*, 49 UCLA L. REV. 737, 738–39 (2002) [hereinafter Conk, *True Test*]; George W. Conk, *Is There a Design Defect in the Restatement (Third) of Torts: Products Liability?*, 109 YALE L.J. 1087, 1087–89 (2000) [hereinafter Conk, *Design Defect*]; Richard L. Cupp, Jr., *The Continuing Search for Proper Perspective: Whose Reasonableness Should Be at Issue in a Prescription Product Design Defect Analysis?*, 30 SETON HALL L. REV. 233, 234 (1999); Margaret Gilhooly, *When Drugs Are Safe for Some but Not Others: The FDA Experience and Alternatives for Products Liability*, 36 HOUS. L. REV. 927, 929–30 (1999); Michael D. Green, *Prescription Drugs, Alternative Designs, and the Restatement (Third): Preliminary Reflections*, 30 SETON HALL L. REV. 207, 208–10 (1999); James A. Henderson, Jr. & Aaron D. Twerski, *Drug Designs Are Different*, 111 YALE L.J. 151, 151–53 (2001); Lars Noah, *This Is Your Products Liability Restatement on Drugs*, 74 BROOK. L. REV. 839 (2009); Victor E. Schwartz & Phil Goldberg, *A Prescription for Drug Liability and Regulation*, 58 OKLA. L. REV. 135, 136 (2005); Jane Stapleton, *Liability for Drugs in the U.S. and EU: Rhetoric and Reality*, 26 REV. LITIG. 991, 992 (2007). For a fuller collection of the literature, see DAVID G. OWEN, PRODUCTS LIABILITY LAW § 8.10 n.1 (2d ed. 2008).

<sup>15</sup> 479 A.2d 374, 382–83 (N.J. 1984).

<sup>16</sup> 751 P.2d 470, 482–83 (Cal. 1988).

<sup>17</sup> On the role of these two cases in the history of tort law, see David G. Owen, *Bending Nature, Bending Law*, 62 FLA. L. REV. (forthcoming 2010).

differently by the law.<sup>18</sup>

As with most other types of products, manufacturers of prescription pharmaceuticals presently are subject to liability on four separate grounds: for misrepresenting a drug's dangers and for selling drugs with defects in manufacture, design, or warnings. There is little debate about the first two grounds—all agree that manufacturers should bear the consequences of selling drugs that are said to be safe when the manufacturer knows they are not, and for selling drugs that are dangerously contaminated. In private law, the raging debates on drug products liability law concern responsibility for defects in a drug's formulation (“design”) and whether manufacturers and pharmacists should have a duty—like manufacturers and retailers of most other types of products—to warn consumers directly of whatever substantial, hidden dangers pharmaceuticals may contain. As will be explored below, the issue of design defectiveness is a troublesome but largely phantom issue in modern drug litigation, where, notwithstanding the availability of drug design liability, “the liability game is with the warnings candle, not with design.”<sup>19</sup> Yet American law needs to stomp out drug design litigation altogether, and to spread the light of the warnings candle, since present legal doctrine misguidedly shields both manufacturers and pharmacists from full responsibility to warn consumers of the many hazards that lurk within prescription pharmaceuticals.

#### A. *The Problem of Dangerous Drugs*

Prescription drugs are paradoxical: as one of the greatest triumphs of the twentieth century, their powerful chemicals and biologics save many millions of humans from suffering and death; yet, these same chemicals also *cause* great suffering and death.<sup>20</sup> All prescription drugs, that is, possess substantial costs as well as benefits. This is because most drug hazards are inherent and unavoidable. Normally, these dangers simply cannot be removed: the same chemical properties in drugs that can cause great harm to some are the very properties that are therapeutic to others.<sup>21</sup> Put another way, if a drug's chemical structure were altered to avoid some adverse health effect, that same change often would also reduce or eliminate the drug's health benefits. Thus, a drug's “design” normally cannot be changed to improve its safety.

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<sup>18</sup> These particular topics are all addressed in OWEN, *supra* note 14. This Article draws in part from various sections, particularly sections 8.10 and 9.6, of the forthcoming third edition of this treatise. DAVID G. OWEN, PRODUCTS LIABILITY LAW (3d ed. forthcoming).

<sup>19</sup> Green, *supra* note 14, at 209.

<sup>20</sup> “[Indeed,] all drugs do harm.” Bernstein & Bernstein, *supra* note 8, at 570.

<sup>21</sup> “Normally,” because the hazard in some drugs may be reduced or eliminated by changing the prescribed dosage, the active ingredients in combination drugs, or the inert ingredients used in a drug. Green, *supra* note 14, at 210–12. On inherent product hazards, see OWEN, *supra* note 14, §§ 6.2, 10.3.



Penicillin may be the classic example of a drug that, while highly beneficial to most people, can be hazardous, indeed lethal, to others.<sup>22</sup> But, other examples abound. Accutane is a good modern illustration of a drug that combines great benefits with great risks of harm: it is highly effective in treating the most severe cases of acne; yet, it is a virulent teratogen that can cause serious birth defects when given to pregnant women.<sup>23</sup> Surely the most compelling historical example of this phenomenon is thalidomide, another teratogen, prescribed widely as a sedative and for morning sickness throughout much of the world (but not the United States) during the 1950s and 1960s.<sup>24</sup> Despite the enormous toll of birth defects this drug then wreaked around the globe, the FDA approved thalidomide in 1998 for fighting leprosy.<sup>25</sup> These are only three illustrations, and the list of unavoidably unsafe drugs goes on and on.<sup>26</sup>

Outside of tort law, the American medico-legal systems address this conundrum—the bad-comes-with-the-good aspect of prescription drugs—in two basic ways.<sup>27</sup> First, prior to being allowed onto the market, prescription drugs must undergo rigorous chemical analysis, laboratory testing, and clinical trials, the results of which are closely scrutinized by

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<sup>22</sup> See WILLIAM L. PROSSER, HANDBOOK OF THE LAW OF TORTS § 99 (4th ed. 1971).

<sup>23</sup> See *Myers v. Hoffman-LaRoche, Inc.*, 170 P.3d 254, 256 (Ariz. Ct. App. 2007).

<sup>24</sup> Thalidomide caused severe limb deformities in children born to women who took the drug while pregnant. The FDA's protracted review of the drug barely saved most Americans from this terrible tragedy. See Joseph Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 HASTINGS L.J. 301, 313–14 (1992) (characterizing thalidomide as “one of the most potent human teratogens ever found”); see also Anita Bernstein, *Formed by Thalidomide: Mass Torts as a False Cure for Toxic Exposure*, 97 COLUM. L. REV. 2153, 2158 n.26 (1997).

<sup>25</sup> See Sheryl Gay Stolberg, *Thalidomide Approved To Treat Leprosy, with Other Uses Seen*, N.Y. TIMES, July 17, 1998, at A1.

<sup>26</sup> See PROSSER, *supra* note 22, § 99 (“The whole pharmacopeia is full of drugs which are not safe, and at present cannot be made safe.”).

<sup>27</sup> A third approach that lies outside the tort law system is the no-fault compensation system to compensate children suffering adverse reactions to vaccinations required by public health statutes. See National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1–300aa-34 (2006). Claims are made in the Court of Claims against the Secretary of Health and Human Services, including recovery for economic losses, pain and suffering (limited to \$250,000), and death (limited to \$250,000). *Id.* §§ 300aa-11(c), 300aa-15(c). A claimant may accept or reject the court's award; if it is rejected, the claimant may then (and only then) initiate a products liability action against the manufacturer. *Id.* § 300aa-22(b)(1). The Act, however, bars recovery in such actions for “side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.” *Id.* § 300aa-22.

For useful descriptions of the structure of the Act, see Okianer C. Dark, *Is the National Childhood Vaccine Injury Act of 1986 the Solution for the DTP Controversy?*, 19 U. TOL. L. REV. 799, 839–42 (1988); Lars Noah, *Triage in the Nation's Medicine Cabinet: The Puzzling Scarcity of Vaccines and Other Drugs*, 54 S.C. L. REV. 741, 761–62 (2002); Robert L. Rabin, *Some Thoughts on the Efficacy of a Mass Toxics Administrative Compensation Scheme*, 52 MD. L. REV. 951, 958–60 (1993); Derry Ridgway, *No-Fault Vaccine Insurance: Lessons from the National Vaccine Injury Compensation Program*, 24 J. HEALTH POL. POL'Y & L. 59, 62–64 (1999); Victor E. Schwartz & Liberty Mahshigian, *National Childhood Vaccine Injury Act of 1986: An Ad Hoc Remedy or a Window for the Future?*, 48 OHIO ST. L.J. 387, 389–91 (1987); Whitney S. Waldenberg & Sarah E. Wallace, *When Science Is Silent: Examining Compensation of Vaccine-Related Injuries When Scientific Evidence of Causation Is Inconclusive*, 42 WAKE FOREST L. REV. 303, 305–07 (2007).

the FDA, to assure both the safety and efficacy of all new drugs. Under the amended Food, Drug, and Cosmetic Act of 1938,<sup>28</sup> Congress has vested more regulatory power in the FDA to regulate drug safety than it has vested in other agencies to regulate the safety of other products, reflecting the special role of prescription drugs in preserving life and health together with the special dangers such drugs pose to life and health. A key function of the FDA is to help ensure that only drugs that, on balance, are beneficial to some class of patients ever reach the healthcare market.<sup>29</sup>

The second relevant feature of America's medico-legal system is that it positions experts in diagnosis and drug therapy—doctors and nurse practitioners—between beneficial yet dangerous prescription drugs, on the one hand, and the lay public who need drug therapy, on the other. The role of such healthcare professionals, such “learned intermediaries,” is to connect individual drugs with individual patients—to choose from among the panoply of available prescription drugs the one with the highest benefit-risk ratio for each particular patient's needs. That is, a doctor's role in drug therapy is to ensure that the right prescription medicine, in view of its particular benefits and risks, is assigned to the right patient, in view of that patient's special needs.<sup>30</sup>

#### B. *The Question for Private Law*

The question of interest here is what role, if any, does the medico-legal system leave for private law—the law of torts and products liability? Because the system just described breaks down in many ways in practice, American products liability law has assumed a vital role in compensating

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<sup>28</sup> 21 U.S.C. §§ 301–399 (2006); *see also id.* § 331(a) (prohibiting the sale of “any food, drug, device, or cosmetic that is adulterated or misbranded”); *id.* § 355(a) (requiring FDA approval prior to the marketing of any new drug).

<sup>29</sup> For discussion of the FDA and drug regulation, see Bernstein, *Drug Effectiveness*, *supra* note 14, at 1062–67; Bernstein & Bernstein, *supra* note 8, at 569–71; Daniel R. Cahoy, *Medical Product Information Incentives and the Transparency Paradox*, 82 IND. L.J. 623, 624–26 (2007); Richard A. Epstein, *Regulatory Paternalism in the Market for Drugs: Lessons from Vioxx and Celebrex*, 5 YALE J. HEALTH POL'Y L. & ETHICS 741, 748–49 (2005); Gilhooley, *Addressing Risks*, *supra* note 6, at 349–51; Michael D. Green, *Safety as an Element of Pharmaceutical Quality: The Respective Roles of Regulation and Tort Law*, 42 ST. LOUIS U. L.J. 163, 167–68 (1998); Marc T. Law, *How Do Regulators Regulate? Enforcement of the Pure Food and Drugs Act, 1907–38*, 22 J.L. ECON. & ORG. 459, 460–61 (2006); Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1753–54 (1996) [hereinafter Merrill, *Architecture*]; Richard A. Merrill, *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1, 8–11 (1973) [hereinafter Merrill, *Compensation*]; Teresa M. Schwartz, *Regulatory Standards and Products Liability: Striking the Right Balance Between the Two*, 30 U. MICH. J.L. REFORM 431, 445–46 (1997) [hereinafter Schwartz, *Striking the Right Balance*]; Teresa M. Schwartz, *The Role of Federal Safety Regulations in Products Liability Actions*, 41 VAND. L. REV. 1121, 1147–49 (1988) [hereinafter Schwartz, *Role of Federal Safety Regulations*]; 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, 594–97 (2005).

<sup>30</sup> *See infra* Part IV.D.1. (examining the “learned intermediary doctrine”).

persons harmed unnecessarily by defective drugs, and some role in promoting drug safety by deterring the sale of such unnecessarily dangerous drugs. The model of a perfect FDA, unfortunately, does not fit the real world closely. Legislative, budgetary, and political constraints mar the ideal of a regulatory body that optimally protects the public from exposure to defective drugs.<sup>31</sup> Nor, as most people painfully well know, do doctors typically match prescription drugs to patients in a manner that approaches optimality.<sup>32</sup> Thus, due to these and other shortcomings in the medico-legal structure for the production and distribution of prescription drugs in the United States, products liability law plays a significant role in compensating, and hopefully helping to protect, consumers of defective prescription drugs.

Because the answer to the question posed above is that American products liability law plays an important role when people suffer harm from prescription drugs, we must inquire into what that role is and what it should be. The following inquiry reveals that courts, commentators, and the Torts Restatements mostly agree that the American products liability system should place its primary emphasis on assuring that doctors and (indirectly) patients receive adequate warnings about drug dangers, and instructions on how to avoid them, and that judicial reevaluations of prescription drug designs should be limited. How these general propositions have evolved doctrinally in the Restatements and the courts is first explored, beginning with a consideration of a drug manufacturer's duty of safe design and followed by a consideration of the limited warning duties of both drug manufacturers and pharmacists. This Article then inquires into how current principles of responsibility for harm from prescription drugs might be reformed to better address the fundamental goals of America's healthcare system.

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<sup>31</sup> For discussion of weaknesses present in the FDA model, see George W. Conk, *Punctuated Equilibrium: Why Section 402A Flourished and the Third Restatement Languished*, 26 REV. LITIG. 799, 860–61 (2007); Margaret Gilhooley, *Vioxx's History and the Need for Better Procedures and Better Testing*, 37 SETON HALL L. REV. 941, 941–43 (2007) [hereinafter Gilhooley, *Vioxx's History*]; Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049, 2075–77 (2000); Schwartz, *Role of Federal Safety Regulations*, *supra* note 29, at 1154–58. Congress addressed some of the weaknesses in the Food and Drug Administration Amendments Act of 2007, which expanded agency oversight of drug safety and provided the agency with additional resources. See Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823, 825, 842 (2007); see also Morgan Weiland, *FDA: President Bush Signs FDA Legislation Expanding Drug Safety, Drug, Device Fees*, PRODUCT LIABILITY DAILY (BNA), Sept. 28, 2007, at D7.

<sup>32</sup> Apart from the increasingly limited time doctors devote to treating each patient, doctors typically receive woefully limited education on pharmaceuticals. See *infra* note 162 and accompanying text (noting that doctors typically know less than pharmacists about drugs); see also FRANK M. MCCLELLAN, *MEDICAL MALPRACTICE: LAW, TACTICS, AND ETHICS* 188–89 (1994) (discussing the limited knowledge and inadequate training of physicians in drug therapy); Green, *supra* note 14, at 229 n.67 (explaining how the “idealized role of the physician is not borne out in practice”).

### III. DESIGN DANGERS IN PHARMACEUTICAL DRUGS

Design defectiveness has never been a favored theory of recovery for drug injuries. While strict liability in tort generally got off the ground in America in the 1960s, and while design defect claims for most types of products became prevalent during the 1970s, American courts did not even begin imposing design defect liability on drug manufacturers until the 1980s and 1990s.<sup>33</sup> And even to the present, most courts in the United States are chary in allowing such claims, properly directing drug litigation away from design defect claims to warning claims.

#### A. *The Controversial Comment k*

An attempt to understand how the notion of a design defect fits together with prescription drugs in American products liability law ideally should begin with a study of the chemical properties, manufacturing techniques, marketing approaches, and therapeutic applications of this peculiar type of product. Yet, because time and space require that such deep explorations be left to specialized texts<sup>34</sup> and journal articles<sup>35</sup> on drugs, the best place to begin the inquiry here is with comment *k*, a controversial comment to section 402A of the *Restatement (Second) of Torts*. In a nutshell, comment *k* provides that manufacturers are not subject to strict liability in tort for harm caused by certain “unavoidably unsafe” but useful products, notably prescription drugs, on the basis that their inherent hazards cannot feasibly be designed away.<sup>36</sup> The Reporter for the

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<sup>33</sup> *Brochu v. Ortho Pharmaceutical Corp.* is widely thought to be the first prescription drug case in which a defective drug design claim figured prominently. See *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 655 (1st Cir. 1981) (holding that a manufacturer of oral contraceptives could be held liable for design defect inherent in high content of estrogen in a pill). A small number of earlier cases also involved challenges to drug designs. See *Tinnerholm v. Parke Davis & Co.*, 285 F. Supp. 432, 444–46 (S.D.N.Y. 1968) (ruling that an unstable pertussis vaccine that damaged an infant’s brain was unmerchantable), *aff’d as modified*, 411 F.2d 48, 53 (2d Cir. 1969); *Stromsodt v. Parke-Davis & Co.*, 257 F. Supp. 991, 994 (D.N.D. 1966) (holding that a defect in manufacturer’s drug caused damage to brain), *aff’d*, 411 F.2d 1390, 1402 (8th Cir. 1969).

<sup>34</sup> See 5 LOUIS R. FRUMER & MELVIN I. FRIEDMAN, PRODUCTS LIABILITY ch. 50 (Cary Stewart Sklaren ed., 2007) (examining drug litigation); see also 1 FRANK C. WOODSIDE, DRUG PRODUCT LIABILITY ch. 3 (2009) (examining principles of pharmacology).

<sup>35</sup> See *supra* note 14.

<sup>36</sup> In fact, this is the theme of three companion comments to section 402A: comments *i*, *j*, and *k*. RESTATEMENT (SECOND) OF TORTS § 402A cmts. i–k (1965); see also OWEN, *supra* note 14, § 6.2 (examining these three comments in depth). In full, comment *k* provides:

*k. Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same

*Second Restatement* who drafted comment *k*, William Prosser, justified this exemption in a famous quote:

The argument that industries producing potentially dangerous products should make good the harm, distribute it by liability insurance, and add the cost to the price of the product, encounters reason for pause, when we consider that two of the greatest medical boons to the human race, penicillin and cortisone, both have their dangerous side-effects, and that drug companies might well have been deterred from producing and selling them.<sup>37</sup>

Drugs, in short, are different.<sup>38</sup> As a result, most American courts agree that comment *k* properly exempts useful prescription drugs that are unavoidably unsafe from strict products liability,<sup>39</sup> assuming always that

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is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

<sup>37</sup> PROSSER, *supra* note 22, § 99.

<sup>38</sup> See Henderson & Twerski, *supra* note 14, at 153 (explaining that drugs are different from other products and should be treated differently under the *Restatement*); Daniel P. Richardson, Note, *The Lost Child of Products Liability: New Thoughts About Advertising and the Learned Intermediary Doctrine*, 27 VT. L. REV. 1017, 1049 (2003). Professor Michael Green has catalogued various ways in which drugs are different: (1) “they cannot be manipulated physically to provide marginally greater safety”; (2) they are harmful for some people while beneficial for others; (3) their adverse effects frequently are not discoverable through research and testing, such that these harmful effects are not revealed until they injure drug consumers; (4) they are subject to especially heavy regulatory oversight, much of it pre-market, by the FDA; (5) they have high social utility; and (6) learned intermediaries, i.e., doctors, stand between drug products and consumers, matching particular drugs to particular people. Green, *supra* note 14, at 209–11, 232. To these six claims of difference, a seventh might be added: (7) they are extremely costly to bring to market—each new brand name prescription drug on average costing roughly \$500 million for research, development, laboratory testing, clinical testing, FDA submission work, and production.

For information on the costs of getting a single new prescription pharmaceutical to market, see Lara J. Glasgow, *Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?*, 41 IDEA 227, 231 (2001) (listing an estimated cost of between \$250 and \$500 million based on the Federal Trade Commission’s Bureau of Economic Staff Reporting); Margaret Z. Johns, *Informed Consent: Requiring Doctors to Disclose Off-Label Prescriptions and Conflicts of Interest*, 58 HASTINGS L.J. 967, 973 (2007) (“The FDA approval process takes six to fifteen years and costs between \$100 million and \$880 million per drug.”); Justin C. Ward, Note, *Bayer v. Schein Pharmaceuticals—Best Mode Requirement—In Chemical Inventions: When Does “Carrying Out the Invention” Start? A Proposal for a Comprehensive Best Mode Compliance Test*, 3 CHI.-KENT J. INTELL. PROP. 120, 142 n.25 (2003) (estimating a cost of \$800 million).

<sup>39</sup> See 1 FRUMER & FRIEDMAN, *supra* note 34, § 8.07[3] (citing cases from thirty states and the District of Columbia applying comment *k*). A small number of courts have explicitly rejected comment

they are properly prepared and carry adequate warnings.<sup>40</sup>

In addition to disagreeing about comment *k*'s very premise—that prescription drug manufacturers should be protected from the rigors of strict liability—courts and commentators disagree about a number of other, important aspects of comment *k*, including (1) whether its application is confined to a limited class of drugs properly characterized as “unavoidably unsafe,” or whether it broadly applies to all prescription drugs; and (2) whether the exemption it affords from strict liability in tort applies as well to negligence. On the first question, the New Jersey Supreme Court in 1984 ruled in *Feldman v. Lederle Laboratories*<sup>41</sup> that only certain drugs qualify for comment *k*'s exemption from design defect liability—those proven on a case-by-case basis to be highly useful and unavoidably unsafe.<sup>42</sup> The year after *Feldman*, a California intermediate appellate court decided *Kearl v. Lederle Laboratories*,<sup>43</sup> in which it adopted and elaborated upon the *Feldman* approach, prescribing a detailed “mini-trial” necessary before a judge could qualify a drug for exemption from strict liability under comment *k*.<sup>44</sup> Soon thereafter, however, the California Supreme Court rejected the *Feldman-Kearl* approach in *Brown v. Superior Court*, interpreting comment *k* as embracing *all* prescription drugs within its unavoidably-unsafe safe harbor.<sup>45</sup> The *Brown* court reasoned that forcing drug manufacturers to litigate whether their drugs deserve design-defect exemption in every case would emasculate comment *k*'s objective of

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*k*. See, e.g., *Allison v. Merck & Co.*, 878 P.2d 948, 954 (Nev. 1994) (holding that comment *k* does not apply because the victim chose to be injected having known the potential consequences); *Collins v. Eli Lilly Co.*, 342 N.W.2d 37, 52 (Wis. 1984) (holding that comment *k* is too restrictive); see also *Shanks v. Upjohn Co.*, 835 P.2d 1189, 1197–98 (Alaska 1992) (refusing to adopt comment *k* but agreeing with its basic policy).

<sup>40</sup> See *supra* note 36 and accompanying text.

<sup>41</sup> 479 A.2d 374 (N.J. 1984).

<sup>42</sup> *Id.* at 382–83.

Comment *k* immunizes from strict liability the manufacturers of some products, including certain drugs, that are unavoidably unsafe. However, we see no reason to hold as a matter of law and policy that all prescription drugs that are unsafe are unavoidably so. Drugs, like any other products, may contain defects that could have been avoided by better manufacturing or design. Whether a drug is unavoidably unsafe should be decided on a case-by-case basis; we perceive no justification [in policy or under comment *k* for immunizing prescription drug manufacturers from their safe manufacturing, warning, and risk-utility design obligations under strict liability in tort.]

*Id.* at 383.

<sup>43</sup> 218 Cal. Rptr. 453 (Cal. Ct. App. 1985).

<sup>44</sup> Sitting in this phase of the trial without a jury, the judge would determine:

(1) whether, when distributed, the product was intended to confer an exceptionally important benefit that made its availability highly desirable; (2) whether the then-existing risk posed by the product both was “substantial” and “unavoidable”; and (3) whether the interest in availability (again measured as of the time of distribution) outweighs the interest in promoting enhanced accountability through strict liability design defect review.

*Id.* at 464; see also *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 840–41 (Neb. 2000).

<sup>45</sup> *Brown v. Superior Court*, 751 P.2d 470, 482 (Cal. 1988).

shielding prescription drug manufacturers *ex ante* from the risks of design defect litigation *ex post* in order to reduce the perils of “overdeterrence,” such as higher drug prices and fewer new drugs.<sup>46</sup> While a few courts have followed *Brown*’s general exemption of all prescription drugs from design defect liability,<sup>47</sup> most courts have taken the *Feldman-Kearl* case-by-case approach, reluctant to surrender judicial oversight of a drug manufacturer’s responsibility for safety in design.<sup>48</sup>

Another aspect of comment *k* that engenders some debate is whether comment *k*, assuming (as almost all courts do) that it exempts manufacturers of at least some drugs from strict liability in tort, should exempt them also from liability in *negligence* for defects in design.<sup>49</sup> The language of comment *k*, which should not be parsed as if it were a statute, does not address the question of a drug manufacturer’s liability in negligence for defects in design. After all, this provision is a comment to section 402A, which addresses a seller’s *strict* liability in tort—not negligence, which is a different topic the *Restatement* separately addresses in another section.<sup>50</sup> Apart from this quite obvious fact, the debate may be resolved quite simply: if the design of a drug is not defective for purposes of strict liability in tort, it cannot be negligent to sell it in that nondefective condition.<sup>51</sup>

While this kind of doctrinal, set-theory reasoning normally is sound, it falters somewhat in the special context of prescription drugs. Comment *k* exempts *all* prescription drugs from strict liability in tort, not because they all are truly nondefective, but because (1) *most* drugs are (due to market competition and oversight by the FDA); and (2) a protective umbrella

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<sup>46</sup> *Id.* at 479–80.

<sup>47</sup> For decisions supporting the exemption of all prescription drugs from liability, see *Transue v. Aesthetech Corp.*, 341 F.3d 911, 916 (9th Cir. 2003); *McKee v. Moore*, 648 P.2d 21, 24 (Okla. 1982); *Adams v. Wyeth*, No. 3452, 2005 WL 1528656, at \*3–4 (Phila. Ct. Com. Pl. June 13, 2005); *Grundberg v. Upjohn Co.*, 813 P.2d 89, 95 (Utah 1991).

<sup>48</sup> For decisions supporting a case-by-case approach, see *West v. Searle & Co.*, 806 S.W.2d 608, 612 (Ark. 1991); *Adams v. G.D. Searle & Co.*, 576 So. 2d 728, 731 (Fla. Dist. Ct. App. 1991); *Bryant v. Hoffmann-La Roche, Inc.*, 585 S.E.2d 723, 728 (Ga. Ct. App. 2003); *Toner v. Lederle Labs.*, 732 P.2d 297, 308 (Idaho 1987); *Glassman v. Wyeth Labs., Inc.*, 606 N.E.2d 338, 342 (Ill. App. Ct. 1992); *Savina v. Sterling Drug, Inc.*, 795 P.2d 915, 924 (Kan. 1990); *Bennett v. Madakasira*, 821 So. 2d 794, 809 (Miss. 2002); *Freeman*, 618 N.W.2d at 837; *Hill v. Wyeth, Inc.*, No. 4:03CV1526 JCH, 2007 WL 674251, at \*4–5 (E.D. Mo. Feb. 28, 2007); *White v. Wyeth Labs., Inc.*, 533 N.E.2d 748, 752 (Ohio 1988); *Castrignano v. E.R. Squibb & Sons, Inc.*, 546 A.2d 775, 781 (R.I. 1988).

<sup>49</sup> Most courts hold that negligence liability in fact applies to the design of drugs. See, e.g., *Toner*, 732 P.2d at 310; *Johnson v. Am. Cyanamid Co.*, 718 P.2d 1318, 1324–25 (Kan. 1986).

<sup>50</sup> The *Second Restatement* addresses a manufacturer’s negligent design of products in section 395, which makes no reference to liability for the sale of dangerous drugs. RESTATEMENT (SECOND) OF TORTS § 395 (1965).

<sup>51</sup> See PROSSER, *supra* note 22, § 99 (“Where only negligence liability is in question, the answer as to such products [inherently hazardous drugs] is usually a simple one. The utility and social value of the thing sold normally outweighs the known, and all the more so the unknown risk, and there is no negligence in selling it, provided always that proper warning and directions are given.”); see also OWEN, *supra* note 14, §§ 2.1, 5.9.

shielding all prescription drugs (including the defective ones) from strict liability avoids discouraging manufacturers from developing important new drugs (most of which *will* be nondefective) and from setting high drug prices. Thus, some prescription drugs probably *are* “defective” in design notwithstanding the comment *k* exemption, and the manufacturers of some of those defective drugs may well have been negligent in their development and sale.

Even if strict liability for design defects is allowed in prescription drug cases, its usefulness to consumers appears quite limited. Because the doctor is the “consumer” in such cases under the learned intermediary rule,<sup>52</sup> the consumer expectations test provides no relief to patients suffering foreseeable drug injuries if the manufacturer adequately warned doctors of that risk. And if the drug contains foreseeable dangers that doctors do not expect, failure-to-warn claims protect persons injured by such drugs. Finally, because almost all American jurisdictions now shield manufacturers from liability for dangers that are unforeseeable under the prevailing state of the art,<sup>53</sup> patients injured by an unforeseeable drug risk in most American courts have no claim under any liability test or theory.

Under a risk-utility test (whether based on “negligence,” “strict liability,” or simply “design defectiveness”),<sup>54</sup> a manufacturer is subject to liability for failing to adopt a particular design feature that would have prevented the plaintiff’s harm if the safety benefits of the untaken design feature were greater than its costs.<sup>55</sup> But this suggests that a drug can be re-engineered to eliminate a particular danger without sacrificing its health benefits, which normally is impossible since the hazards in most drugs, as mentioned earlier, are inherent and unavoidable.<sup>56</sup> This leaves only one narrow version of risk-benefit analysis available for properly assessing the defectiveness of a drug’s design: the approach adopted by the *Third Restatement*.

#### B. *The Third Restatement*

In 1998, the American Law Institute (“ALI”) promulgated a liability standard for defective drug designs that is unusual, to say the least. Section 6(c) of the *Restatement (Third) of Torts: Products Liability* (the “*Third Restatement*”) provides:

(c) A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are

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<sup>52</sup> See *infra* Part IV.D.1.

<sup>53</sup> See OWEN, *supra* note 14, § 10.4.

<sup>54</sup> *Id.* §§ 2.2, 5.7, 8.4.

<sup>55</sup> See *id.* §§ 8.4–5, 8.8.

<sup>56</sup> See *supra* Part II.A.



sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.<sup>57</sup>

The most important thing to note about this novel liability standard, which has been judicially applied,<sup>58</sup> is that it leaves a very small window for design defect claims for prescription drugs, a window so tiny that almost no drug claim could fit through it. Even thalidomide would not be captured by the *Third Restatement* test because of its value in treating leprosy. But thalidomide may prove the virtue of this test, rather than its frailty, for who reasonably can argue that lepers should be deprived of beneficial drug therapy because some doctors improperly give the drug to child-bearing women. In such a case, the defect, it would seem, would lie in the doctor rather than the drug. While not minimizing the tragedy of a child born deformed to a woman who was prescribed the drug improperly, perhaps tort (and possibly criminal) remedies against the prescribing doctor would be a better way to address the problem, rather than forcing the manufacturer and lepers to suffer from an untoward misuse of a pharmaceutical that is highly beneficial to at least one class of patients.

In a world in which the medico-legal scheme described earlier operates with perfection—where manufacturers carefully conduct, and act appropriately upon, drug-safety investigations; where a fully-funded, and politically neutral, FDA keeps drugs with foreseeable excess dangers from being sold; and where doctors perfectly match individual drugs to individual patients—the section 6(c) formulation of design defectiveness for drugs would appear ideal. The problem, of course, is that models of a perfect FDA and of perfect prescribing doctors are quite inaccurate. But the solution to imperfections in the medico-legal framework is not to allow juries to engage in risk-utility comparisons between different drugs used to treat the same condition.

Assume that three drugs, A, B, and C, each are used to fight lung infections, and that drug A causes drowsiness in some persons, drug B causes birth defects when given to some women, and drug C causes acne in some teenage boys. A doctor presumably would prescribe drug B or possibly C to an adult male truck driver, drug A or B to a teenage boy, and drug A or C to a woman capable of bearing children. Assuming that each

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<sup>57</sup> RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(c) (1998).

<sup>58</sup> See *Gebhardt v. Mentor Corp.*, 191 F.R.D. 180, 185 (D. Ariz. 1999) (granting summary judgment for manufacturer because plaintiff failed to prove that a reasonable healthcare provider would not have prescribed an Angelchik for any class of patients), *aff'd*, 15 F. App'x 540 (9th Cir. 2001); see also *Madsen v. Am. Home Prods. Corp.*, 477 F. Supp. 2d 1025, 1037 (E.D. Mo. 2007) (providing an example where the defendant's expert testified that "risks of obesity for some patients are greater than the risks of [dietary] medications").

drug bears proper warnings, surely the law should not allow juries to impose substantial economic costs on the manufacturer of any of these drugs because a prescribing doctor matches one drug to the wrong patient. Nor should these manufacturers have to litigate such cases of misprescription, over and over again in courtrooms around the nation, assuming further, of course that they fully and properly performed their investigation and reporting duties to the FDA. Nor should consumers be deprived of one or two of these drugs because the litigation costs (including occasional lost verdicts) prove too burdensome for manufacturers to keep them on the market, particularly when juries begin to classify one drug of the three as causing the least net harm to all these patient groups, considered as a whole.<sup>59</sup>

This latter example reveals the perils of using a global, macro-balance approach to risk-utility analysis.<sup>60</sup> Notwithstanding the frailties of doctors and the FDA, a drug's design should not be characterized as defective on the ground that its total harm to all users exceeds its total benefits to all users, assuming that the drug provides net benefits to any class of patients, and assuming further that the drug's excessive harm results from its improper use by doctors.<sup>61</sup> Applying such a macro-balance test to declare drug designs defective in such cases would be both "unfair and inefficient," in the words of the *Third Restatement* Reporters, because it "would require courts to deny classes of patients access to a particular drug that provides them unique benefits in order to protect other patients from the risks of misprescription by negligent physicians."<sup>62</sup>

Pointing to the weaknesses in the FDA and healthcare delivery systems, the natural profit motivations of drug manufacturers to skimp on product research and design,<sup>63</sup> a patent system that artificially protects

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<sup>59</sup> See *infra* text accompanying note 195.

<sup>60</sup> For a discussion of "macro-balancing" and "micro-balancing," see generally David G. Owen, *Toward a Proper Test for Design Defectiveness: "Micro-Balancing" Costs and Benefits*, 75 TEX. L. REV. 1661 (1997).

<sup>61</sup> This assumes that a manufacturer's sales representatives do not promote the drug for such improper use, in which case the manufacturer should be subject to liability. On the prevalence of such promotion, see Gardiner Harris, *Pfizer To Pay \$2.3 Billion To Settle Inquiry over Marketing Case*, N.Y. TIMES, Sept. 3, 2009, at B4; DOJ Press Release, Jan. 15, 2009, *supra* note 13. On the prevalence of off-label use by physicians, see Johns, *supra* note 38, at 968–69; Lars A. Noah, *Constraints on the Off-Label Uses of Prescription Drug Products*, 16 J. PROD. & TOXICS LIAB. 139, 139–41 (1994). On the ignorance of many doctors as to whether common drugs' uses are or are not off-label, see Kevin B. O'Reilly, *Physicians Know FDA-OK'd Uses for Drugs Half the Time*, AM. MED. NEWS, Sept. 7, 2009, at 21.

<sup>62</sup> Henderson & Twerski, *supra* note 14, at 152–53. For commentary that agrees that section 6(c) basically is sound, if in need of some improvement, see Bernstein, *Drug Effectiveness*, *supra* note 14, at 1088–94 (suggesting how courts may "modify the radicalism of § 6(c)"); Green, *supra* note 14, at 209.

<sup>63</sup> See Jeffrey D. Winchester, Note, *Section 8(c) of the Proposed Restatement (Third) of Torts: Is It Really What the Doctor Ordered?*, 82 CORNELL L. REV. 644, 692 (1997) ("[I]n light of the enormous amounts of money at stake in the global pharmaceutical industry, manufacturers are inevitably tempted to market products that are clearly less effective and more dangerous than others.").

manufacturers from competition, and the industry's temptation to over-promote its products,<sup>64</sup> some courts and commentators reject the *Third Restatement's* narrow definition of design defectiveness for drugs.<sup>65</sup> The argument for rejecting section 6(c) is the belief that drug designs should be subject to private law challenge on some basis or another—either by means of a normal risk-utility test (on proof of a safer alternative design) or a macro-balance test (on proof that a drug caused patients as a whole more harm than good). Yet, neither approach works well in most drug cases, as previously discussed. The first simply does not work because most drugs cannot be redesigned, since their hazards are inherent. As for the second test, it is true that any product that causes more harm than good is truly bad (“defective”) from a utilitarian point of view. And, if there were an effective way to identify such products, their manufacturers might fairly be required to pay for all the harm they cause, and such products normally should be banned.<sup>66</sup> As discussed above, however, particular classes of patients (e.g., lepers) deserve therapy from drugs, even if doctors sometimes do misuse those drugs on other classes of patients. Moreover, there is a devil residing in the process of distinguishing which drugs, on balance, have net value from those that produce net harm—and in the threat of repeated litigation over the ultimate social value of any type of drug that causes someone harm because it did not suit that patient.

So the *Third Restatement's* test for defective drug designs, though very narrow, and incomplete in failing to identify important exceptions,<sup>67</sup> seems basically correct. By putting most drugs beyond the reach of design defect litigation (under any liability theory), the *Third Restatement* properly pours most litigation concerning hazardous drugs into the defectiveness of their warnings and instructions,<sup>68</sup> to which the discussion now turns.

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<sup>64</sup> See Harris, *supra* note 61 (describing “the largest health care fraud settlement and the largest criminal fine of any kind ever” resulting from Pfizer’s illegal marketing of Bextra and other drugs).

<sup>65</sup> See Bryant v. Hoffmann-La Roche, Inc., 585 S.E.2d 723, 725–28 (Ga. Ct. App. 2003); Freeman v. Hoffman-La Roche, Inc., 618 N.W.2d 827, 839–40 (Neb. 2000); Conk, *True Test*, *supra* note 14, at 738–40; Conk, *Design Defect*, *supra* note 14, at 1088–89; Cupp, *supra* note 14, at 234; Richard L. Cupp, Jr., *Rethinking Conscious Design Liability for Prescription Drugs: The Restatement (Third) Standard Versus a Negligence Approach*, 63 GEO. WASH. L. REV. 76, 80 (1994); Jerry J. Phillips, *The Unreasonably Unsafe Product and Strict Liability*, 72 CHI.-KENT L. REV. 129, 130 (1996); Schwartz, *Striking the Right Balance*, *supra* note 29, at 459; Teresa M. Schwartz, *Prescription Products and the Proposed Restatement (Third)*, 61 TENN. L. REV. 1357, 1378–85 (1994) [hereinafter Schwartz, *Prescription Products*]; Dustin R. Marlowe, Note, *A Dose of Reality for Section 6(c) of the Restatement (Third) of Torts: Products Liability*, 39 GA. L. REV. 1445, 1446–48 (2005).

<sup>66</sup> See OWEN, *supra* note 14, § 10.3.

<sup>67</sup> For discussions of some exceptions to the *Third Restatement's* test, see William A. Dreier, *Manufacturers' Liability for Drugs and Medical Devices Under the Restatement (Third) of Torts: Products Liability*, 30 SETON HALL L. REV. 258, 262 (1999); Green, *supra* note 14, at 219–20.

<sup>68</sup> While section 6(c) might seemingly be improved by including a proviso that allows claims for a manufacturer's failure to meet its research and reporting responsibilities to the FDA, robust warning claim enforcement (without preemption interference) appears a better way for products liability law to perform its oversight of those responsibilities.

## IV. WARNING OF DANGERS IN PHARMACEUTICAL DRUGS

Warning issues in cases involving prescription drugs in many ways parallel those issues in other types of products liability cases. Yet, as seen in connection with design defectiveness,<sup>69</sup> prescription drugs raise a variety of special problems for products liability litigation. While design defectiveness is the most prevalent claim in most products liability cases,<sup>70</sup> warning claims dominate prescription drug litigation.<sup>71</sup>

Several important warning issues recur in cases involving drugs. One concerns the theories of liability applicable to this type of case. Another involves the regulatory backdrop to this area of the law, provided by the Federal Food, Drug, and Cosmetic Act of 1938, administered by the FDA. A further issue is whom a manufacturer of such products should warn—the doctor and the patient, or just the doctor. Whether a warning or instruction about a drug is “adequate” is usually the principal issue in this type of litigation. A final question is whether pharmacists should have a duty to warn patients about prescription drug risks at all, and, if so, what the scope of that duty should be. A wealth of information is available on each of these important issues,<sup>72</sup> and each is briefly considered here.

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<sup>69</sup> See *supra* Part III.

<sup>70</sup> See OWEN, *supra* note 14, § 1.3.

<sup>71</sup> “Failure to instruct or warn is the major basis of liability for manufacturers of prescription drugs and medical devices.” RESTATEMENT (THIRD) TORTS: PRODUCTS LIABILITY § 6 cmt. d (1998).

<sup>72</sup> See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d) (1998); 5 FRUMER & FRIEDMAN, *supra* note 34, §§ 50.01–.08 (providing an overview of drug litigation and liability issues); Bernstein, *Drug Effectiveness*, *supra* note 14, at 1052–53 (exploring drug ineffectiveness as a basis for liability); William A. Dreier, *Liability for Drug Advertising, Warnings, and Frauds*, 58 RUTGERS L. REV. 615, 616–17 (2006) (addressing state and federal control over consumer information in the pharmaceutical industry); Barry R. Furrow, *Enterprise Liability for Bad Outcomes from Drug Therapy: The Doctor, the Hospital, the Pharmacy, and the Drug Firm*, 44 DRAKE L. REV. 377, 378–79 (1996) (discussing the potential for danger with improperly prescribed drugs); Gilhooley, *Addressing Risks*, *supra* note 6, at 350 (examining the role of the FDA in addressing drug risks); Gilhooley, *Vioxx’s History*, *supra* note 31, at 942–43 (using the example of Vioxx to explore regulatory issues and the need for reform); M. Stuart Madden, *The Enduring Paradox of Products Liability Law Relating to Prescription Pharmaceuticals*, 21 PACE L. REV. 313, 314 (2001) (arguing that courts and legislatures have taken a protective approach to drug liability cases); James T. O’Reilly, *Pin the Tail on the Other Donkey: Allocating and Avoiding Injury Losses After Drug or Device Approval*, 62 FOOD & DRUG L.J. 559, 571–72 (2007) (exploring potential solutions for better protection of patients in drug liability cases); Schwartz & Goldberg, *supra* note 14, at 136–37 (discussing liability issues that arise when a class of patients experiences negative side effects despite full compliance with FDA regulations); Stapleton, *supra* note 14, at 993 (comparing prescription drug liability issues in the United States to the European Union); Charles J. Walsh & Alissa Pyrich, *Rationalizing the Regulation of Prescription Drugs and Medical Devices: Perspectives on Private Certification and Tort Reform*, 48 RUTGERS L. REV. 883, 931–49 (1996) (examining problems with the current drug regulation scheme); Schwartz, *Prescription Products*, *supra* note 65, at 1363–64, 1369–85 (reviewing proposed changes to drug liability in the Restatement (Third)); see generally Chester Chuang, Note, *Is There a Doctor in the House? Using Failure-To-Warn Liability To Enhance the Safety of Online Prescribing*, 75 N.Y.U. L. REV. 1452 (2000) (analyzing warning liability for online prescribing).

### A. *The Liability Theory Puzzle*

Settling on a proper theory of liability for inadequate warnings and instructions has been of greater interest in cases involving prescription drugs than any other type of product. Courts widely apply all three theories of liability to cases of this type—negligence, breach of the implied warranty of merchantability, and strict liability in tort<sup>73</sup>—as well as special warning liability provisions of state products liability statutes.<sup>74</sup> Courts have been drawn to negligence principles in warning cases more than in cases involving other types of defects,<sup>75</sup> and this has been especially true where prescription drugs are involved. Except for cases of contamination, drugs were largely exempted from strict liability in tort from the very start of modern products liability law in section 402A of the *Restatement (Second) of Torts*,<sup>76</sup> and courts have continued to apply negligence principles—and to reject true strict liability principles—in landmark prescription drug cases over the years.<sup>77</sup>

The reasons for preferring negligence principles to true strict liability in drug warning cases run broad and deep,<sup>78</sup> but they are worth summarizing here. First, banning foreseeability from the liability calculus—the principal way in which strict liability distinguishes itself from negligence—does violence to basic principles of justice and fair play.<sup>79</sup> Another reason for preferring negligence principles in this context has been the belief that the extra deterrent effect of strict liability is less necessary for products whose warnings must be specifically approved prior to marketing by the FDA,<sup>80</sup> as discussed below. A related reason is the

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<sup>73</sup> See *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 761 (Ky. 2004).

<sup>74</sup> See *Graham v. Am. Cyanamid Co.*, 350 F.3d 496, 513–14 (6th Cir. 2003) (addressing an Ohio statute that defines warning defects in negligence terms); *Perez v. Wyeth Labs. Inc.*, 734 A.2d 1245, 1263–64 (N.J. 1999) (holding that direct marketing to consumers creates a duty to warn of defects, as an exception to New Jersey’s codification of the learned intermediary doctrine).

<sup>75</sup> See OWEN, *supra* note 14, § 9.2.

<sup>76</sup> See RESTATEMENT (SECOND) OF TORTS § 402A cmts. j–k (1965); Madden, *supra* note 72, at 321–24.

<sup>77</sup> See *Brown v. Superior Court*, 751 P.2d 470, 477 (Cal. 1988) (rejecting strict liability and concluding that comment *k* is the appropriate test for determining responsibility for defectively designed drugs); *Feldman v. Lederle Labs.*, 479 A.2d 374, 386 (N.J. 1984) (finding that in warning cases, negligence and strict liability are “functional equivalents”); see also *Vassallo v. Baxter Healthcare Corp.*, 696 N.E.2d 909, 923–24 (Mass. 1998) (discussing the functional equivalency of negligence and strict liability in the case of breast implants). *But see* *Carlin v. Superior Court*, 920 P.2d 1347, 1350–51 (Cal. 1996) (holding that while “strict liability is to some extent a hybrid of traditional strict liability and negligence doctrine,” because a manufacturer’s “strict liability” duty to warn embraces only risks “known to the scientific community at the time” of manufacture, strict liability in tort and warranty nevertheless remain viable claims in drug warning cases).

<sup>78</sup> See OWEN, *supra* note 14, §§ 6.2, 10.3.

<sup>79</sup> See David G. Owen, *Figuring Foreseeability*, 44 WAKE FOREST L. REV. 1277 (2009); David G. Owen, *The Moral Foundations of Products Liability Law: Toward First Principles*, 68 NOTRE DAME L. REV. 427, 437, 448 (1993).

<sup>80</sup> See *Brown*, 751 P.2d at 482–83 (holding that defendant drug manufacturer could not be held strictly liable for injuries caused by a prescription drug “so long as the drug was properly prepared and

possibility that strict liability may result in *too much* deterrence, that pharmaceutical manufacturers may be discouraged from investing in new prescription drugs, already extremely expensive to develop and bring to market,<sup>81</sup> for fear of financial ruin if the new product possesses unexpected problems. For these and other reasons, while most courts in this context continue to apply “strict” liability by name to warning cases, the principles they in fact apply are nothing more than negligence. The *Third Restatement* follows this approach in limiting a manufacturer’s warning responsibility in prescription drug cases to a duty to provide “reasonable instructions or warnings regarding foreseeable risks of harm.”<sup>82</sup>

### B. Regulation by the FDA

Prescription drug litigation must be considered against the backdrop of the relatively strict regulation provided by the FDA.<sup>83</sup> The FDA regulates both the safety and effectiveness of prescription pharmaceuticals and certain medical devices.<sup>84</sup> In addition to ensuring that prescription drugs are safe and effective before they are sold in interstate commerce, the FDA approves all information a manufacturer plans to provide physicians on a drug’s recommended use, contraindications, risks, and side-effects. Underlying the regulatory scheme are two assumptions reflecting the special types of dangers that inhere in drugs classified as prescription pharmaceuticals. First is the belief that the risks in many drugs are so complex and dangerous that the FDA must determine their safety and effectiveness before they can be marketed at all. The second premise is that the potential risks of improperly using many drugs are so substantial as to require professional medical judgment and supervision by doctors and nurse practitioners, rendering such products available to consumers only through prescriptions written by such health professionals.

The principal federal statute regulating the quality of drugs is the Federal Food, Drug, and Cosmetic Act, originally enacted by Congress in 1938.<sup>85</sup> The Act’s key provisions prohibit the sale of “any food, drug,

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accompanied by warnings of its dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution”).

<sup>81</sup> See *supra* note 38.

<sup>82</sup> See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d) (1998).

<sup>83</sup> The FDA’s regulatory problems were previously noted. See Gilhooley, *Vioxx’s History*, *supra* note 31, at 960–61. Nevertheless, the FDA’s pre-marketing approval process for prescription drugs is rigorous, time-consuming, and expensive. See *supra* note 38; see also Schwartz & Goldberg, *supra* note 14, at 145 (explaining that the FDA monitors more than 10,000 drugs on the market and receives more than 400,000 problem reports in a year).

<sup>84</sup> “Drugs” over which the FDA has authority are defined in 21 U.S.C. § 321(g)(1)(C) (2006) as “articles (other than food) intended to affect the structure or any function of the body.” A “device” subject to regulation is defined in § 321(h)(3) as “an instrument, apparatus, implement, machine, contrivance, . . . or other similar or related article [that] is intended to affect the structure or any function of the body.” 21 U.S.C. § 321(h)(3) (2006).

<sup>85</sup> Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–392 (2006).

device, . . . or cosmetic that is adulterated or misbranded”<sup>86</sup> and require FDA approval of all new drugs prior to marketing.<sup>87</sup> The Act addresses warnings and instructions through its requirement that drug labels not be “misbranded.”<sup>88</sup> The Act requires manufacturers to provide adequate information on the purpose, proper dosage, and possible dangers to consumers for over-the-counter (“OTC”) drugs,<sup>89</sup> and to medical professionals for prescription drugs. A prescription drug is one that, “because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use,” is safe only when prescribed and used under the supervision of a licensed medical practitioner,<sup>90</sup> and such drugs must be labeled accordingly.<sup>91</sup> Labels for OTC drugs must state the drug’s active ingredients and “established name”;<sup>92</sup> must contain information on dosages, duration of use, directions for use, and warnings against dangerous uses;<sup>93</sup> and must describe the drug’s effectiveness, side-effects, and contraindications.<sup>94</sup>

### C. Adequacy

Principles of adequacy applicable to product warnings generally<sup>95</sup> apply as well to warnings required for prescription drugs, forming the center of a manufacturer’s duty to warn. Liability for failing to warn is premised on a defendant’s failure to provide users and consumers adequate information about a product danger or how to avoid it.<sup>96</sup> Many courts have stated what makes a warning “adequate.” A frequently cited formulation of adequacy is from *Pavlidis v. Galveston Yacht Basin, Inc.*,<sup>97</sup> where the court explained that, to be adequate, a warning

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<sup>86</sup> *Id.* § 331(a).

<sup>87</sup> *Id.* § 355(a). This requirement applies to “any new drug,” including over-the-counter drugs. *See, e.g., id.* § 321(g)(1) (defining the term “drug”).

<sup>88</sup> *Id.* §§ 352–353.

<sup>89</sup> The process by which a drug may be determined to be an OTC drug as opposed to a prescription drug is described in 21 C.F.R. § 330.10, which provides a detailed process for determining a drug’s safety and effectiveness that includes a benefit-to-risk ratio. *See* 21 C.F.R. § 330.10(a)(4)(iii); *see also* 21 C.F.R. § 330.10(a)(4)(vi) (“A drug shall be permitted for OTC sale and use by the laity unless, because of its toxicity or other potential for harmful effect or because of the method or collateral measures necessary to its use, it may safely be sold and used only under the supervision of a practitioner licensed by law to administer such drugs.”).

<sup>90</sup> 21 U.S.C. § 353(b)(1)(A)–(B).

<sup>91</sup> Prescription drugs must bear labels stating, “CAUTION: Federal law prohibits dispensing without prescription,” and must provide any special directions for use and cautionary statements contained in the prescription. *See id.* § 353(b)(2), (4).

<sup>92</sup> *Id.* § 352(e).

<sup>93</sup> *Id.* § 352(f).

<sup>94</sup> *Id.* § 352(n).

<sup>95</sup> *See OWEN, supra* note 14, § 9.3.

<sup>96</sup> *See id.*, §§ 9.2–9.3.

<sup>97</sup> 727 F.2d 330, 330, 338 (5th Cir. 1984).

must provide a complete disclosure of the existence and extent of the risk involved. A warning must (1) be designed so it can reasonably be expected to catch the attention of the consumer; (2) be comprehensible and give a fair indication of the specific risks involved with the product; and (3) be of an intensity justified by the magnitude of the risk.<sup>98</sup>

Another court aptly observed that a warning's adequacy depends on a balance of many factors, including

the severity of the danger; . . . the likelihood that the warning will catch the attention of those who will foreseeably use the product and convey the nature of the danger to them; . . . the intensity and form of the warning; . . . and the cost of improving the strength or mode of the warning.<sup>99</sup>

The *Third Restatement* notes that determining a warning's adequacy requires focusing on its "content and comprehensibility, intensity of expression, and the characteristics of expected user groups."<sup>100</sup>

More concisely, it might be said that to be adequate, a warning must provide a reasonable amount and type of information about a product's material risks and how to avoid them in a manner calculated to reach and be understood by those likely to need the information.<sup>101</sup> The adequacy of a warning is often bound up with the issue of who should be warned, so that a warning ordinarily will not be adequate unless it warns persons foreseeably threatened by a product hazard or others in the best position—such as doctors—to act on warnings to protect persons subject to the hazard.<sup>102</sup> Whether a manufacturer or other seller has provided sufficient information about a product's hazards is especially fact intensive, such that

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<sup>98</sup> *Id.* at 338 (internal citations omitted). Other courts still rely on this formulation. *See, e.g., Lewis v. Sea Ray Boats, Inc.*, 65 P.3d 245, 248 (Nev. 2003) (holding that in order for a product warning to be ruled adequate, the warning "must (1) be designed so it can reasonably be expected to catch the attention of the consumer; (2) be comprehensible and give a fair indication of the specific risks involved with the product; and (3) be of an intensity justified by the magnitude of the risk" (internal quotations and citations omitted)).

<sup>99</sup> *Bloxom v. Bloxom*, 512 So. 2d 839, 844 (La. 1987) (internal citations omitted); *see also Gray v. Badger Mining Corp.*, 676 N.W.2d 268, 274 (Minn. 2004) ("To be legally adequate, the warning should (1) attract the attention of those that the product could harm; (2) explain the mechanism and mode of injury; and (3) provide instructions on ways to safely use the product to avoid injury.").

<sup>100</sup> RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(c) cmt. i (1998).

<sup>101</sup> The first half of this formulation concerns the "substantive" adequacy of the warning's informational content, and the latter half concerns the "procedural" adequacy of the form of its conveyance. On this distinction, *see OWEN, supra* note 14, § 9.3.

<sup>102</sup> *See Anderson v. Hedstrom Corp.*, 76 F. Supp. 2d 422, 440 (S.D.N.Y. 1999) ("The factual determination of whether an adequate warning was given is often interwoven with the question of whether the defendant manufacturer has a duty to warn, and if so, *to whom that duty is owed.*" (emphasis added) (internal quotations and citations omitted)).



the adequacy of warnings and instructions normally, but not always,<sup>103</sup> is a factual question for the jury to decide.<sup>104</sup>

In the context of drug warnings, the manufacturer must convey all material information on possible risks to doctors, comprehensible to the general practitioner as well as to the specialist, or to consumers, comprehensible to them if the circumstances warrant.<sup>105</sup> For a drug warning to be “adequate,” it must describe the scope of the danger;<sup>106</sup> the effects of misuse, including the failure to follow instructions; and the physical aspects of the warning and broader method of conveyance must be likely to alert recipients to the danger.<sup>107</sup> Other aspects of a drug warning’s adequacy include such matters as the effect of a manufacturer’s “overpromotion” of a drug’s safety<sup>108</sup> and whether warnings should be

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<sup>103</sup> See *Austin v. Will-Burt Co.*, 361 F.3d 862, 869 (5th Cir. 2004) (finding that a warning may be adequate as a matter of law when it specifically warns against the very risk that causes a plaintiff’s harm); *Calhoun v. Hoffman-La Roche, Inc.*, 768 So. 2d 57, 61 (La. Ct. App. 2000) (holding that adequacy becomes a question of law when the warning is “accurate, clear, and unambiguous”); *Martin v. Hacker*, 628 N.E.2d 1308, 1312 (N.Y. 1993) (explaining that “whether a given warning is legally adequate or presents a factual question for a jury to decide requires a careful analysis of the warning’s language”); see also 2 LOUIS R. FRUMER & MELVIN I. FRIEDMAN, *PRODUCTS LIABILITY* § 12.03[1][b] (2009) (noting that “[c]ourts frequently state that the adequacy of warnings is a question for the trier of fact”).

<sup>104</sup> See *McNeil v. Wyeth*, 462 F.3d 364, 368 (5th Cir. 2006) (reasoning that when a risk described on a drug label is low enough to induce a doctor to undertake the risk, the court could not rule that “no reasonable jury could conclude that a warning was inadequate”); *Madsen v. Am. Home Prods. Corp.*, 477 F. Supp. 2d 1025, 1035 (E.D. Mo. 2007) (explaining that in a prescription drug liability case: “[A]n adequate warning is one reasonable under the circumstances. Specifically, the warning must: (1) indicate the scope of the danger; (2) communicate the extent or seriousness of the potential danger; (3) alert a reasonably prudent practitioner to the danger; and (4) be conveyed in a satisfactory manner.”).

<sup>105</sup> See *Perez v. Wyeth Labs. Inc.*, 734 A.2d 1245, 1257 (N.J. 1999) (holding that a warning must include all material risks, meaning those to which a reasonable patient would attach significance in deciding whether to take the drug); *Wagner v. Roche Labs.*, 671 N.E.2d 252, 256 (Ohio 1996) (finding that drug warnings were inadequate, meaning there was not a reasonable disclosure of “all risks inherent in the use of the drug of which the manufacturer, being held to the standards of an expert in the field, knew or should have known to exist”).

<sup>106</sup> See *Madsen*, 477 F. Supp. 2d at 1035; see also *Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 853 (10th Cir. 2003). Compare *Myers v. Hoffman-La Roche, Inc.*, 170 P.3d 254, 262–65 (Ariz. Ct. App. 2007) (refusing to hold Accutane warnings adequate as a matter of law under the learned intermediary doctrine on motion to dismiss), with *Gerber v. Hoffman-La Roche, Inc.*, 392 F. Supp. 2d 907, 917–19 (S.D. Tex. 2005) (holding that the Accutane package insert adequately warned dermatologists of the risk of birth defects when prescribed for pregnant women).

<sup>107</sup> See OWEN, *supra* note 14, § 9.3.

<sup>108</sup> As with other types of products, risks in pharmaceuticals must not be unduly downplayed, nor safety “overpromoted”; instead, a manufacturer’s communications to doctors must present a reasonably balanced portrayal of the effectiveness and dangers of a drug. See *Motus v. Pfizer, Inc.*, 196 F. Supp. 2d 984, 998 (C.D. Cal. 2001) (“An overpromotion theory is one way that a plaintiff in a failure-to-warn case can overcome the manufacturer’s argument either (1) that it provided adequate warnings or (2) that the doctor’s decision to prescribe a drug despite his awareness of its dangers was an intervening cause sufficient to vitiate the manufacturer’s liability.”), *aff’d*, 358 F.3d 659, 360–61 (9th Cir. 2004); see also *Ebel v. Eli Lilly & Co.*, 536 F. Supp. 2d 767, 775–76 (S.D. Tex. 2008) (noting that while overpromotion can include promotion of off-label use not approved by the FDA, there was insufficient proof thereof); *Madden*, *supra* note 72, at 330 (“An otherwise suitable warning may be vitiated by the conduct of the manufacturer or those acting at [its direction] . . . if they promote the product in such a

made in foreign languages.<sup>109</sup> The California Supreme Court addressed the latter issue in *Ramirez v. Plough, Inc.*,<sup>110</sup> where an infant contracted Reye's Syndrome after his Spanish-speaking mother gave him St. Joseph's Aspirin for Children to relieve his cold symptoms. The aspirin's label warned of the Reye's Syndrome risk in English but not in Spanish. Although the FDA specifically permitted English-only labeling, the plaintiff claimed that the label's failure to include a Spanish warning rendered it inadequate. The court reviewed a number of related factors: the web of rules on foreign-language labeling requirements in various other contexts adopted by the California legislature; the FDA's quite specific rules governing foreign-language labeling that permitted, but did not require, such labeling; and the multiplicity of health, social, cost, and practicability factors. Considering all these factors, the court concluded that foreign-language labeling requirements were better determined by legislatures and regulatory agencies than by the courts. Because other branches of government had determined that English-only warnings were sufficient, the court decided that it should apply the same rule to the case.<sup>111</sup>

An example of the adequacy issue at play in a normal prescription drug case is *Martin v. Hacker*,<sup>112</sup> in which a doctor treated the decedent, Mr. Martin, for hypertension (high blood pressure) with two drugs manufactured by the defendant, including Reserpine. Mr. Martin became severely depressed and fatally shot himself in the head, allegedly because of the Reserpine. The issue was whether the information provided by the manufacturer to physicians about the drug's risks was adequate as a matter of law. The package insert specified among the drug's "CONTRAINDICATIONS," "mental depression (especially with suicidal tendencies)"; and among its "WARNINGS," the package insert stated:

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fashion as to obscure or lessen the cautionary impact of the seller's warnings."); Janet Fairchild, Annotation, *Promotional Efforts Directed Toward Prescribing Physician as Affecting Prescription Drug Manufacturer's Liability for Product-Caused Injury*, 94 A.L.R.3d 1080, 1080 (1979). Compare *Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 655-56 (Cal. 1973) (finding overpromotion of Chloromycetin, a broad-spectrum antibiotic, downplaying the risk of fatal aplastic anemia), with *Spinden v. Johnson & Johnson*, 427 A.2d 597, 599 (N.J. Super. Ct. App. Div. 1981) (holding that *AMA Journal* ads did not amount to overpromotion).

<sup>109</sup> See Christopher S. Maciejewski, *The Dilemma Over Foreign-Language Labeling of Over-the-Counter Drugs*, 15 J. LEGAL MED. 129, 144-48 (1994).

<sup>110</sup> 863 P.2d 167 (Cal. 1993).

<sup>111</sup> *Id.* at 169-70, 174-76. Noting that the FDA stresses the importance of "uniformity in presentation and clarity of message," the court concluded:

To preserve that uniformity and clarity, to avoid adverse impacts upon the warning requirements mandated by the federal regulatory scheme, and in deference to the superior technical and procedural lawmaking resources of legislative and administrative bodies, we adopt the legislative/regulatory standard of care that mandates nonprescription drug package warnings in English only.

*Id.* at 177.

<sup>112</sup> 628 N.E.2d 1308 (N.Y. 1993).

Extreme caution should be exercised in treating patients with a history of mental depression. Discontinue the drug at first sign of despondency, early morning insomnia, loss of appetite, impotence, or self-deprecation. Drug-induced depression may persist for several months after drug withdrawal and may be severe enough to result in suicide.<sup>113</sup>

Carefully applying a full list of adequacy factors, the court concluded that the warning was commensurate with the risk, including possible adverse consequences of use (death from suicide was specifically mentioned); the insert's language was accurate, clear, direct, unequivocal, sufficiently forceful, complete, consistent, devoid of contradiction, and the information was current,<sup>114</sup> and, when read as a whole, the meaning conveyed about the possible consequences of taking the drug was unmistakable.<sup>115</sup> The court thus determined that the warnings were adequate as a matter of law.<sup>116</sup>

A recurring adequacy issue, sometimes dubbed "procedural adequacy," concerns the method by which the information is conveyed to the recipient.<sup>117</sup> There are several standard avenues of communication between drug companies and physicians for transmitting information about drugs, and a manufacturer must select the best methods reasonably available to convey important new information on drug dangers to doctors who need the information. The *Physician's Desk Reference* ("PDR"), updated periodically, contains copies of package inserts for many prescription drugs. Other sources of information that are more complete than the PDR are *Facts and Comparisons* (updated monthly), the annual United States Pharmacopeial Drug Information's ("USP DI") *Vol. 1: Drug Information for the Health Care Professional*, and *Vol. 2: Advice for the Patient—Drug Information in Lay Language*. Information on warnings and contraindications is readily available to physicians from these reference works, and the warnings in package inserts and the PDR ordinarily are adequate to alert physicians to drug hazards.

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<sup>113</sup> *Id.* at 1309–10.

<sup>114</sup> To be adequate, a warning must be timely. A long series of cases involving Aralen, a drug used in the treatment of rheumatoid arthritis and eventually linked to irreversible eye damage in some users, established certain principles. To be timely, a warning of side-effects must be made promptly upon discovery of the coexistence of the side-effect and use of the drug, even though a causal relationship has not been clearly proved. See *Basko v. Sterling Drug, Inc.*, 416 F.2d 417, 426 (2d Cir. 1969); *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 84–85 (8th Cir. 1966). Since the drug company is held to have the knowledge of an expert, to be timely, a warning must be given as soon as the risks are pointed out in reputable scientific journals. *Schenebeck v. Sterling Drug, Inc.*, 423 F.2d 919, 921–23 (8th Cir. 1970).

<sup>115</sup> *Martin*, 628 N.E.2d at 1312–15.

<sup>116</sup> *Id.* at 1315. But in this context, as in others, adequacy usually is a factual issue for the jury. See, e.g., *Anderson v. Hedstrom Corp.*, 76 F. Supp. 2d 422, 440 (S.D.N.Y. 1999).

<sup>117</sup> OWEN, *supra* note 14, § 9.3.

New developments, however, may render information in the *PDR* obsolete, and a manufacturer's failure promptly to update the medical profession may subject it to liability. If information is critical, the manufacturer may need to send "Dear Doctor" letters advising physicians individually of the new information.<sup>118</sup> The typically busy doctor, however, may not regularly consult the *PDR* or even routinely read "Dear Doctor" letters. If the need to warn is compelling enough, reasonable care may require a drug company to use its salespersons who regularly call on doctors ("drug reps," formerly called "detail men") to warn them personally of a particular risk.<sup>119</sup>

Unlike the controversial provision on design defects in prescription drugs discussed above,<sup>120</sup> the *Third Restatement* defines a manufacturer's responsibility for warning defects in prescription drugs in conventional negligence terms that give no cause to cavil. In section 6(d), the *Third Restatement* provides, "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" healthcare providers or patients, depending on the applicability of the learned intermediary doctrine,<sup>121</sup> as discussed below. Principles of adequacy are embraced by the requirement that warnings and instructions be "reasonable," and the limitation on responsibility to "foreseeable" risks reflects the now well-established principle, discussed above, that the law should not hold manufacturers of drugs or any other type of product responsible for harm that is unforeseeable or otherwise unavoidable under the prevailing state of the art, an important aspect of products liability law examined elsewhere in greater depth.<sup>122</sup>

#### D. *The Law's Duty Shield: Manufacturers*

##### 1. *The Doctor in the Middle: The "Learned Intermediary Doctrine"*

In addition to the required pre-market approval by the FDA, a

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<sup>118</sup> As to the standards of adequacy for such letters, see *Lawson v. G.D. Searle & Co.*, 356 N.E.2d 779, 783–84 (Ill. 1976).

<sup>119</sup> For an early, leading case that examines factors bearing on whether a company must warn doctors in this manner, see *Sterling Drug, Inc. v. Yarrow*, 408 F.2d 978, 991–92 (8th Cir. 1969) (explaining that the failure to use detail men to alert doctors of possible eye damage was unreasonable in light of the fact that the *PDR* and "Dear Doctor" letters might not warn fast enough).

The FDA now publishes and regularly updates comprehensive drug, biologic, medical device, and dietary supplement safety information on its MedWatch Safety Information and Adverse Event Reporting web site, available at <http://www.fda.gov/medwatch/SAFETY.htm>. See, e.g., Stephen E. Scheve & Andrew E. Costa, *The Learned Intermediary Doctrine After FDA's Drug Watch and PhRMA's Clinical Study Results Database*, 73 DEF. COUNS. J. 12, 12 (2006) (analyzing the implications of two online databases that publish comprehensive drug safety information).

<sup>120</sup> See *supra* Part II.

<sup>121</sup> RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d) (1998).

<sup>122</sup> See OWEN, *supra* note 14, § 10.3; Owen, *Bending Nature*, *supra* note 17.

prescription drug's warnings and instructions must be provided to health professionals—doctors and nurse practitioners—rather than directly to patients. Such “learned intermediaries” stand between the drug manufacturer and the patient, dispensing what medications and information they deem best. Thus, the learned intermediary doctrine is an exception to the general rule that manufacturers must take all reasonable steps to provide warnings directly to a product's ultimate user or consumer.<sup>123</sup> Under the learned intermediary doctrine, the prescription drug manufacturer's duty to inform consumers runs only indirectly through physicians, rather than directly to consumers.<sup>124</sup>

The basic rationale for the learned intermediary doctrine is quite powerful: medical professionals, and only medical professionals, have the requisite knowledge, training, and judgment to properly match particular drugs with distinctive benefits and dangers to particular patients with distinctive constitutions and medical conditions, and to properly monitor the results thereafter. If manufacturers fulfill their obligations to provide full and fair information to healthcare professionals, those professionals should be able to make intelligent, reasonably safe, and effective treatment decisions.<sup>125</sup> In turn, a prescribing doctor is obliged under the law of torts to inform the patient of a drug's benefits and risks (as well as the benefits and risks of no treatment and alternative treatments), and to monitor how

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<sup>123</sup> See *Vitanza v. Upjohn Co.*, 778 A.2d 829, 836–37 (Conn. 2001).

<sup>124</sup> For contextual analysis of this doctrine, see Richard C. Ausness, *Learned Intermediaries and Sophisticated Users: Encouraging the Use of Intermediaries To Transmit Product Safety Information*, 46 SYRACUSE L. REV. 1185, 1195–96 (1996); Pamela R. Ferguson, *Liability for Pharmaceutical Products: A Critique of the 'Learned Intermediary' Rule*, 12 OXFORD J. LEGAL STUD. 59, 66–68 (1992); Richard B. Goetz & Karen R. Growdon, *A Defense of the Learned Intermediary Doctrine*, 63 FOOD & DRUG L.J. 421, 422 (2008); Jeffrey W. Kemp & Lindsay Nicole Alleman, *The Bulk Supplier, Sophisticated User, and Learned Intermediary Doctrines Since the Adoption of the Restatement (Third) of Torts*, 26 REV. LITIG. 927, 947 (2007); Nancy K. Plant, *The Learned Intermediary Doctrine: Some New Medicine for an Old Ailment*, 81 IOWA L. REV. 1007, 1007 (1996); Susan Poser, *Unlabeled Drug Samples and the Learned Intermediary: The Case for Drug Company Liability Without Preemption*, 62 FOOD & DRUG L.J. 653, 656–58 (2007); Charles J. Walsh et al., *The Learned Intermediary Doctrine: The Correct Prescription for Drug Labeling*, 48 RUTGERS L. REV. 821, 844 (1996); see also Chuang, *supra* note 72, at 1463–76; Jennifer Girod, Note, *The Learned Intermediary Doctrine: An Efficient Protection for Patients, Past and Present*, 40 IND. L. REV. 397, 397 (2007).

<sup>125</sup> Judge Wisdom well explained the doctrine's rationale in *Reyes v. Wyeth Laboratories*: Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a “learned intermediary” between manufacturer and consumer.

498 F.2d 1264, 1276 (5th Cir. 1974); see also *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 763–64 (Ky. 2004).

the drug affects the patient.<sup>126</sup>

Sprouting in the 1960s,<sup>127</sup> and becoming firmly rooted in the early 1970s,<sup>128</sup> the learned intermediary doctrine is an established fixture in American products liability law, adopted now by courts in a large majority of states.<sup>129</sup> It may well be that the foundations of this doctrine are weakening,<sup>130</sup> but the rule was explicitly endorsed by the *Third Restatement* and appears quite firmly entrenched for now.<sup>131</sup> Because the doctrine defines the scope of a pharmaceutical manufacturer's duty to warn, application of the learned intermediary rule involves a question of law for the court, not a factual question of adequacy for a jury.<sup>132</sup>

<sup>126</sup> See FRANK M. McCLELLAN, *MEDICAL MALPRACTICE: LAW, TACTICS, AND ETHICS* 189, 199 (1994); see also DAN B. DOBBS, *DOBBS, LAW OF TORTS* § 250 (2000); W. PAGE KEETON ET AL., *PROSSER AND KEETON ON TORTS* § 32, at 189–93 (5th ed. 1984); George P. Smith, II, *The Vagaries of Informed Consent*, 1 IND. HEALTH L. REV. 109, 112 (2004).

<sup>127</sup> See *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121, 130 (9th Cir. 1968); *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966) (“[T]he purchaser’s doctor is a learned intermediary between the purchaser and the manufacturer. If the doctor is properly warned of the possibility of a side effect in some patients, and is advised of the symptoms normally accompanying the side effect, there is an excellent chance that injury to the patient can be avoided.”); *Stottlemire v. Cawood*, 213 F. Supp. 897, 898–99 (D.D.C. 1963); see also *Magee v. Wyeth Labs., Inc.*, 29 Cal. Rptr. 322, 327–28 (Cal. Ct. App. 1963) (“The rule seems settled that a person not reasonably expected to use the manufacturer’s drug (or product) is not one to whom the warranty runs, and that he who uses it in a manner contrary to adequate warnings given by the manufacturer is in the same status.”).

<sup>128</sup> See *Reyes*, 498 F.2d at 1276; *Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132, 142 (3d Cir. 1973); *Gravis v. Parke-Davis & Co.*, 502 S.W.2d 863, 870 (Tex. App. 1973) (“The entire system of drug distribution in America is set up so as to place the responsibility of distribution and use upon professional people. The laws and regulations prevent prescription type drugs from being purchased by individuals without the advice, guidance and consent of licensed physicians and pharmacists. These professionals are in the best position to evaluate the warnings put out by the drug industry.”); *Incollingo v. Ewing*, 282 A.2d 206, 220 (Pa. 1971).

<sup>129</sup> See, e.g., *Meridia Prods. Liab. Litig. v. Abbott Labs.*, 447 F.3d 861, 867 (6th Cir. 2006) (“[T]he vast majority of jurisdictions—45 out of 50 states—apply the learned intermediary doctrine to product liability claims.”); *Ehlis v. Shire Richwood, Inc.*, 367 F.3d 1013, 1017 (8th Cir. 2004) (“[T]he [learned intermediary] doctrine either applies or is recognized . . . in 48 states, the District of Columbia, and Puerto Rico.”) (quoting *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d 795, 806 (E.D. Tex. 2002)); *Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 852 (10th Cir. 2003) (stating that forty-four jurisdictions adhere to the doctrine (citing *Vitanza v. Upjohn Co.*, 778 A.2d 829, 838 n.11 (Conn. 2001)). But see *State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899 (W. Va. 2007) (rejecting the doctrine and asserting that twenty-two state high courts have not adopted the doctrine). A few states have adopted the doctrine by statute. E.g., MISS. CODE ANN. § 11-1-63(c)(ii) (2009); N.J. STAT. ANN. § 2A:58C-4 (2009); N.C. GEN. STAT. ANN. § 99B-5(c) (2009).

<sup>130</sup> See James Ottavio Castagnera & Richard Ryan Gerner, *The Gradual Enfeeblement of the Learned Intermediary Rule and the Argument in Favor of Abandoning It Entirely*, 36 TORT & INS. L.J. 119, 120 (2000) (describing a weakening of the rule due to “(1) the rise in consumer awareness, (2) the complexity of pharmaceutical products, (3) the development of clinical pharmacies that bring their own special expertise to bear on consumer and patient choices, and (4) the reduced time spent by patients in doctors’ offices”).

<sup>131</sup> See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d) (1998).

<sup>132</sup> See *Vitanza*, 778 A.2d at 840 (refusing to convert a claim—that a manufacturer, which provided adequate warnings of Ansaids’ risks to doctors, should have placed warnings on drug samples—into a factual question of adequacy for a jury).

## 2. Exceptions to the Doctrine

When prescription drugs are dispensed under circumstances where healthcare professionals foreseeably fail to render the type of individualized balancing of benefits and risks contemplated by the learned intermediary doctrine, drug manufacturers may have a duty to provide warnings directly to patients. That is, when the rationale for the learned intermediary doctrine falls away, the general rule—requiring manufacturers to warn consumers directly—logically should return. This commonsense principle has spawned the following three exceptions,<sup>133</sup> only the first of which has much support.

The most established exception to the learned intermediary rule is for mass immunization programs where no health professional mediates information about drug risks for the benefit of the patient.<sup>134</sup> Most courts confronted with the issue have thus refused to apply the learned intermediary rule to situations where patients are vaccinated in assembly-line fashion, often by persons other than physicians, with no opportunity for individualized medical assessments. When people line up like lemmings to receive a polio shot or flu vaccination at a school or other facility for mass distribution of a vaccine, the manufacturer must take all reasonable steps to ensure that each patient is directly provided warnings and instructions on risks the manufacturer should know the drug possesses.<sup>135</sup> As an exception to the learned intermediary rule, which itself is an exception to the manufacturer's general obligation to warn consumers directly, the mass immunization doctrine restores the manufacturer's duty to provide warnings (by leaflets or posters) directly to recipients of the vaccine. This true exception was applied in early cases to the polio

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<sup>133</sup> Some plaintiffs' lawyers and scholars argue for additional exceptions to the learned intermediary doctrine, and courts occasionally assert, in dictum, the existence of one or more such exceptions. See, e.g., *Vitanza*, 778 A.2d at 846–47 (listing six supposed exceptions, including “overpromoted drugs” and “drugs withdrawn from the market,” but rejecting plaintiff's request for a prescription drug sample exception); *In re Zyprexa Prod. Liab. Litig.*, 2009 WL 20004540 (E.D.N.Y. 2009) (Weinstein, J.) (citing dubious authority for the existence, “[i]n unusual cases,” of the overpromotion exception); Susan Poser, *Unlabeled Drug Samples and the Learned Intermediary: The Case for Drug Company Liability Without Preemption*, 62 FOOD & DRUG L.J. 653 (2007) (arguing for drug sample exception); Frank C. Woodside III & Margaret M. Maggio, *The Learned Intermediary Doctrine: Is It Eroding?*, 52 FED. LAW. 28, 31 (Nov./Dec. 2005) (noting that plaintiffs sometimes argue that overpromotion by detail reps undermines “the physician's ability to act as an intermediary and insist that, in this context, drug manufacturers have a duty to warn consumers directly”). To date, however, no courts appear to have formally adopted any exceptions other than the three discussed below.

<sup>134</sup> See Marc A. Franklin & Joseph E. Mais, Jr., *Tort Law and Mass Immunization Programs: Lessons from the Polio and Flu Episodes*, 65 CAL. L. REV. 754, 775 (1977) (questioning the usefulness of tort law in the mass immunization context).

<sup>135</sup> See *Petty v. United States*, 740 F.2d 1428, 1433–34 n.3 (8th Cir. 1984) (quoting the warning provided to patients regarding the Swine Flu vaccine, which noted possible side effects, including “fever, chills, headache, or muscle aches” and special precautions to be taken by those interested in receiving the vaccine, namely, “[c]hildren under a certain age should not routinely receive flu vaccine”).

vaccine,<sup>136</sup> and later to the Swine Flu vaccine.<sup>137</sup> Although a court has wavered here or there,<sup>138</sup> there is every reason to believe that courts will continue to require direct warnings to consumers in similar instances of mass immunization programs.

Another exception, sometimes mentioned, concerns birth control pills. In *MacDonald v. Ortho Pharmaceutical Corp.*,<sup>139</sup> the plaintiff suffered a stroke leaving her partially paralyzed after taking the defendant's birth control pills for an extended period of time, during which she had seen her physician once each year. The manufacturer provided information to consumers via a package insert that included a warning of the risks of blood clots but that did not specifically mention the possibility of strokes. After suffering a stroke, the plaintiff claimed that the manufacturer had a duty to provide full and adequate warnings directly to her, the patient, and not just to doctors. Although all but one of the fifteen prior reported judicial opinions had applied the learned intermediary doctrine to birth control pills, like other prescription drugs,<sup>140</sup> the *MacDonald* majority reinstated a jury verdict for the plaintiff, reasoning that oral contraceptives stand apart from other types of prescription medications because of the

heightened participation of patients in decisions relating to use of "the pill"; the substantial risks affiliated with the product's use; the feasibility of direct warnings by the manufacturer to the user; the limited participation of the physician (annual prescriptions); and the possibility that oral communications between physicians and consumers may be insufficient or too scanty standing alone fully to apprise consumers of the product's dangers at the time the initial selection of a contraceptive method is made as well as at subsequent points when alternative methods may be

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<sup>136</sup> See *Givens v. Lederle*, 556 F.2d 1341, 1345–46 (5th Cir. 1977); *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974) ("[T]he manufacturer of a prescription drug who knows or has reason to know that it will not be dispensed as such a drug must provide the consumer with adequate information so that he can balance the risks and benefits of a given medication himself."); *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121, 131 (9th Cir. 1968).

<sup>137</sup> See *Brazzell v. United States*, 788 F.2d 1352, 1358 (8th Cir. 1986) ("The only warning appellee was given . . . in no way warned of the possibility of prolonged, debilitating muscle pain."); *Petty*, 740 F.2d at 1437, 1440 (finding the given warning insufficient and affirming that the manufacturer has a duty to warn "the ultimate consumer in a mass-immunization case").

<sup>138</sup> Compare *Mazur v. Merck & Co., Inc.*, 964 F.2d 1348, 1350–51 (3d Cir. 1992) (concluding that the measles, mumps, and rubella vaccine maker satisfied its duty by providing information to the Center for Disease Control), with *Allison v. Merck & Co., Inc.*, 878 P.2d 948, 958–59 (Nev. 1994) (holding that the manufacturer of a vaccine for measles, mumps, and rubella could *not* delegate its duty to warn to the CDC whose information sheet made no mention of risks of blindness, deafness, and brain damage).

<sup>139</sup> 475 N.E.2d 65 (Mass. 1985).

<sup>140</sup> *Id.* at 65–68, 73.



considered.<sup>141</sup>

For these reasons, the court concluded that the learned intermediary doctrine should not apply to birth control pill manufacturers who therefore must provide warnings directly to ultimate users on the nature, gravity, and likelihood of foreseeable side-effects, and who must advise consumers to ask their doctors about any other matters about which they may be concerned.<sup>142</sup> The dissenting Justice, observing that manufacturers of prescription pharmaceuticals have a duty to provide full information on all material risks to prescribing physicians who, in turn, have a duty (under the informed consent doctrine, redressable in a malpractice action) to provide full information on all material risks to patients for whom they prescribe the drug, argued that this traditional division of responsibility best allocates risks and responsibilities among the parties.<sup>143</sup> While *MacDonald* is frequently cited as creating a new common law exception to the learned intermediary rule for birth control pills, only a small number of federal judges followed it, whereas other courts have uniformly rejected it and continue to apply the learned intermediary doctrine to birth control pills as other types of prescription pharmaceuticals.<sup>144</sup>

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<sup>141</sup> *Id.* at 70.

<sup>142</sup> *Id.*

<sup>143</sup> *Id.* at 74 (O'Connor, J., dissenting). Justice O'Connor wrote:

The rules place on drug manufacturers the duty to gather, compile, and provide to doctors data regarding the use of their drugs, tasks for which the manufacturers are best suited, and the rules place on doctors the burden of conveying those data to their patients in a useful and understandable manner, a task for which doctors are best suited. Doctors, unlike printed warnings, can tailor to the needs and abilities of an individual patient the information that that patient needs in order to make an informed decision whether to use a particular drug. Manufacturers are not in a position to give adequate advice directly to those consumers whose medical histories and physical conditions, perhaps unknown to the consumers, make them peculiarly susceptible to risk. Prescription drugs—including oral contraceptives—differ from other products because their dangers vary widely depending on characteristics of individual consumers.

*Id.*

<sup>144</sup> See *In re Norplant Contraceptive Prods. Liab. Litig.*, 955 F. Supp. 700, 704 (E.D. Tex. 1997) (indicating that “[o]nly a single jurisdiction, Massachusetts, recognizes an exception to the doctrine for prescription contraceptives”). Note, however, that an FDA regulation requires birth control manufacturers to provide warnings of dangers in lay language directly to users. See Patient Package Inserts for Oral Contraceptives, 21 C.F.R. § 310.501 (2009). This means that a negligence per se action may be available against such a manufacturer who fails to provide adequate risk information directly to users. But the violation-of-regulation approach was explicitly rejected in *Martin v. Ortho Pharmaceuticals, Corp.*, 661 N.E.2d 352, 353, 355–57 (Ill. 1996) (concerning the risk of birth limb reductions from pills used in the first trimester of pregnancy).

Consider also that the *MacDonald* exception might create an “over-warning” problem for birth control pills, detrimental to most women’s health. A Gallup poll in 1985 showed that “Americans greatly overestimate the risks and understate the effectiveness of birth control methods, particularly the pill, leaving them vulnerable to unintended pregnancies.” According to the American College of Obstetricians and Gynecologists, unwanted pregnancies and more than a million abortions each year needlessly threaten women’s lives. “The society’s survey found that people are particularly misinformed about the birth control pill, which the group said is the most effective and safest contraceptive for many women.” Three quarters of the women surveyed thought that the pill presents

A third exception, developed more recently, arose in response to direct-to-consumer advertising. It may be that the learned intermediary doctrine is out of touch with how modern medicine is practiced in a world where prescription drug manufacturers jump over health professionals to consumers via television and other mass advertising.<sup>145</sup> In *Perez v. Wyeth Laboratories*,<sup>146</sup> the plaintiffs experienced problems after being implanted with the Norplant contraceptive device. The plaintiffs sued Wyeth, which had properly warned doctors of possible complications, for failing to provide warnings directly to patients. The trial court granted summary judgment for the manufacturer, based on the learned intermediary doctrine as incorporated in a New Jersey statute, and the appellate division affirmed. In an important opinion, the New Jersey Supreme Court reversed, ruling that the learned intermediary doctrine should no longer insulate prescription drug manufacturers from their duty to warn consumers directly when they seek to influence a patient's choice of drugs through mass-marketing.<sup>147</sup>

The *Perez* court reasoned that the learned intermediary doctrine is based on outmoded images of health care from a time when doctors gave medical advice in their offices, made house calls on request, charged only small sums for their advice, and prescribed medicines compounded by a neighborhood pharmacist—all at a time when “the prevailing attitude of

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substantial health risks, despite the fact that the risk of death from taking the pill is about half the mother's risk of death from childbirth. *Pill Poll—National Survey Finds Many Have Bad Information*, STATE (Columbia, S.C.), Mar. 6, 1985, at 2A.

<sup>145</sup> See Richard C. Ausness, *Will More Aggressive Marketing Practices Lead to Greater Tort Liability for Prescription Drug Manufacturers?*, 37 WAKE FOREST L. REV. 97, 139 (2002); William A. Dreier, *Direct-to-Consumer Advertising Liability: An Empty Gift to Plaintiffs*, 30 SETON HALL L. REV. 806, 825 (2000); Timothy S. Hall, *Regulating Direct-to-Consumer Advertising with Tort Law: Is the Law Finally Catching Up with the Market?*, 31 W. NEW ENG. L. REV. 333, 348–52 (2009) [hereinafter Hall, *Regulating Consumer Advertising*]; Timothy S. Hall, *The Promise and Peril of Direct-to-Consumer Prescription Drug Promotion on the Internet*, 7 DEPAUL J. HEALTH CARE L. 1, 40–41 (2003) [hereinafter Hall, *DTC Prescription Drug Promotion*]; Justin L. Heather, *Liability for Direct-to-Consumer Advertising and Drug Information on the Internet*, 68 DEF. COUNS. J. 412, 420 (2001); Bradford B. Lear, *The Learned Intermediary Doctrine in the Age of Direct Consumer Advertising*, 65 MO. L. REV. 1101, 1116–17 (2000); Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141, 180 (1997); Scheve & Costa, *supra* note 119, at 21; Teresa M. Schwartz, *Consumer-Directed Prescription Drug Advertising and the Learned Intermediary Rule*, 46 FOOD DRUG COSM. L.J. 829, 848 (1991); Victor E. Schwartz et al., *Marketing Pharmaceutical Products in the Twenty-First Century: An Analysis of the Continued Viability of Traditional Principles of Law in the Age of Direct-to-Consumer Advertising*, 32 HARV. J.L. & PUB. POL'Y 333, 387 (2009); Paul F. Strain & Christina L. Gaarder, *Direct-to-Consumer Advertising and the Learned Intermediary Doctrine: Unsettling a Settled Question*, 30 U. BALT. L. REV. 377, 382, 387 (2001); Barbara J. Tyler & Robert A. Cooper, *Blinded by the Hype: Shifting the Burden When Manufacturers Engage in Direct to Consumer Advertising of Prescription Drugs*, 21 VT. L. REV. 1073, 1105 (1997); Jeffrey J. Wiseman, Note, *Another Factor in the “Decisional Calculus”: The Learned Intermediary Doctrine, the Physician-Patient Relationship, and Direct-to-Consumer Marketing*, 52 S.C. L. REV. 993, 1016–17 (2001).

<sup>146</sup> 734 A.2d 1245 (N.J. 1999).

<sup>147</sup> *Id.* at 1247–49, 1264 (citing N.J. STAT. ANN. § 2A:58C-4).

law and medicine was that the ‘doctor knows best.’<sup>148</sup> Sadly, this picture is radically different from the healthcare world that presently exists. Today, managed healthcare organizations are mammoth businesses, dispensing medical care and prescriptions impersonally, and medicines are sold in supermarket pharmacy departments and “often paid for by third-party providers.”<sup>149</sup> Against this backdrop, modern manufacturers of prescription drugs mass-market their wares directly “to consumers on the radio, television, the Internet, billboards on public transportation, and in magazines.”<sup>150</sup> The court observed that problems in these advertising practices are manifest, permitting manufacturers and advertisers to manipulate information on safety and effectiveness that, at best, presents a diluted picture of a product’s risks.<sup>151</sup>

Since *Perez*, several other courts have reconsidered the learned intermediary doctrine in light of direct-to-consumer advertising, the sale of prescription pharmaceuticals over the Internet from abroad, and the general depersonalization of healthcare delivery in the modern world. For eight years, all courts considering the issue rejected *Perez* and continued to apply the learned intermediary doctrine.<sup>152</sup> But in 2007, the West Virginia Supreme Court of Appeals, as a matter of first impression, refused to adopt the learned intermediary doctrine in *State ex rel. Johnson & Johnson Corp. v. Karl*.<sup>153</sup> While acknowledging that most states have adopted the doctrine, and that many lower court decisions have applied it, the majority opinion lists twenty-one states whose high courts have *not* adopted this special drug exception to the ordinary duty of manufacturers to provide warnings directly to consumers.<sup>154</sup> Agreeing with *Perez* that the learned intermediary doctrine is outmoded in the modern medical world, the *Karl* majority held that “manufacturers of prescription drugs are subject to the same duty to warn consumers about the risks of their products as other

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<sup>148</sup> *Id.* at 1246–47 (quoting *Logan v. Greenwich Hosp. Ass’n*, 465 A.2d 294, 299 (Conn. 1983)).

<sup>149</sup> *Id.* at 1247.

<sup>150</sup> *Id.*

<sup>151</sup> *Id.* at 1252–53 (citing Jon D. Hanson & Douglas A. Kysar, *Taking Behavioralism Seriously: Some Evidence of Market Manipulation*, 112 HARV. L. REV. 1420, 1456 (1999)).

<sup>152</sup> See, e.g., *In re Norplant Contraceptive Prods. Liab. Litig.*, 165 F.3d 374, 380 (5th Cir. 1999) (finding that the learned intermediary doctrine applies); *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1376–77 (S.D. Fla. 2007) (declining to adopt an exception to the learned intermediary doctrine); *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 547 n.30 (E.D. Pa. 2006) (stating that no state has followed New Jersey’s exception and that, unless the law changes, Pennsylvania also does not have such an exception), *aff’d*, 521 F.3d 253, 276 (3d Cir. 2008); *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 812 n.19 (N.D. Ohio 2004) (stating that “[t]he Court . . . could not apply *Perez*’s logic even if it desired to do so,” and if it did, the plaintiffs still would not succeed), *aff’d*, 447 F.3d 861 (6th Cir. 2006).

<sup>153</sup> 647 S.E.2d 899, 900–01 (W. Va. 2007).

<sup>154</sup> The court lists Arizona, Colorado, Idaho, Indiana, Iowa, Louisiana, Maine, Maryland, Michigan, Minnesota, Nevada, New Hampshire, New Mexico, North Dakota, Rhode Island, South Carolina, South Dakota, Vermont, West Virginia, Wisconsin, and Wyoming. *Id.* at 905.

manufacturers.”<sup>155</sup> Concurring, Justice Maynard observed that “[p]atients can read the labels, instructions and warnings, and if the manufacturer makes them clear enough, then patients can be proactive in working with their doctors to receive the best care.”<sup>156</sup>

Now that *Perez* is accompanied by *Karl*, it may well be that other jurisdictions will begin to rethink the logic of applying a rigid, paternalistic doctrine that developed under very different circumstances than exist today.<sup>157</sup> But two decisions do not make a trend, and it is still too early to know when other courts may begin to recognize the wisdom of broadening the duty of pharmaceutical manufacturers to share vital information about drug risks directly with consumers. In the meantime, it should be noted that only one of the three exceptions to the learned intermediary rule, the exception for mass immunization programs, is generally accepted, and it is even applied infrequently.<sup>158</sup> While the *Third Restatement* adopts the learned intermediary rule, it provides a general exception wide enough to accommodate all three exceptions,<sup>159</sup> and it specifically leaves open the question of whether a new exception should be created for drugs that are mass-marketed directly to consumers.<sup>160</sup>

#### E. *The Law's Duty Shield: Pharmacists*

Pharmacists dispense millions of drug prescriptions in America each day.<sup>161</sup> While doctors prescribe pharmaceutical drugs, they typically know much less about such drugs (which they normally study for only one to three semesters) than pharmacists who study all aspects of drug therapy for five to seven years.<sup>162</sup> For whatever reasons, many doctors order inappropriate prescription drugs for their patients, causing numerous patients to suffer adverse drug reactions—many of which could easily be prevented if patients received adequate drug warnings, which often they do

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<sup>155</sup> *Id.* at 914.

<sup>156</sup> *Id.* at 917, 919 (Maynard, J., concurring).

<sup>157</sup> See *Rimbert v. Eli Lilly & Co.*, 577 F. Supp. 2d 1174, 1219 (D.N.M. 2008) (predicting that New Mexico would not adopt the learned intermediary doctrine: “There is nothing inconsistent with a patient relying on his or her doctor, and reading warning labels. The informed consumer is likely to ask the physician more questions, and informed responses may increase reliance rather than decrease reliance. The warnings may make the relationship more dynamic rather than one-sided.”).

<sup>158</sup> See *Mazur v. Merck & Co.*, 742 F. Supp. 239, 253 (E.D. Pa. 1990) (noting that “[a]ll of the vaccine cases recognize the theoretical validity of the ‘mass immunization exception’ to the learned intermediary rule, but very few have found situations where its application is warranted”).

<sup>159</sup> The *Third Restatement* provides that a prescription drug or medical device is defective if the manufacturer fails to provide reasonable warnings of foreseeable risks to: (1) the doctor or other healthcare provider, or (2) the patient, if the manufacturer should know that healthcare providers are “not in a position to reduce the risks of harm in accordance with the instructions or warnings.” RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d) (1998).

<sup>160</sup> *Id.* at cmt. e.

<sup>161</sup> See Steven W. Huang, *The Omnibus Reconciliation Act of 1990: Redefining Pharmacists' Legal Responsibilities*, 24 AM. J.L. & MED. 417, 418 (1998).

<sup>162</sup> See *id.* at 440–41.

not. Studies show that a large proportion of drug prescriptions contain errors that result in adverse drug events,<sup>163</sup> and that most persons are inadequately warned, either by their doctors or pharmacists, of drug interactions and other hazards of prescription drugs.<sup>164</sup> These facts suggest that pharmacists should have a duty of reasonable care to warn patients of hazards in prescription drugs.<sup>165</sup>

Because pharmacists are more in the nature of service providers, like doctors, than retail merchants, like hatters, they are subject to liability for selling prescription drugs only in negligence, not strict liability.<sup>166</sup> In filling prescriptions, pharmacists are held to the highest standard of care, such that a pharmacist who makes a mistake in filling a prescription is almost certainly responsible for any resulting harm.<sup>167</sup> But pharmacists long have been held to have no duty, apart from not misrepresenting facts about a drug,<sup>168</sup> other than to dispense drugs accurately according to the terms of a valid prescription.<sup>169</sup> In particular, pharmacists simply have no general duty to warn patients—not even to pass along package inserts (intended for physicians) containing detailed warnings—of hazards or side-

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<sup>163</sup> See, e.g., Michele L. Hornish, *Just What the Doctor Ordered—Or Was It?: Missouri Pharmacists' Duty of Care in the 21st Century*, 65 MO. L. REV. 1075, 1076 (2000) (“[C]ourts have begun to recognize that pharmacists are the last chance that the system has to correct itself, and that pharmacists are experts in pharmaceutical science and should be treated as professionals.”).

<sup>164</sup> See Huang, *supra* note 161, at 419 (citing a survey that found that only forty-four percent of the respondents reported that their pharmacists warned them about drug interactions).

<sup>165</sup> See Kenneth R. Baker, *The OBRA 90 Mandate and Its Developing Impact on the Pharmacist's Standard of Care*, 44 DRAKE L. REV. 503, 518 (1996); David B. Brushwood, *The Pharmacist's Duty Under OBRA-90 Standards*, 18 J. LEGAL MED. 475, 494–97 (1997).

<sup>166</sup> See *Parker v. St. Vincent Hosp.*, 919 P.2d 1104, 1106, 1112 (N.M. Ct. App. 1996); *Madison v. Am. Home Prods. Corp.*, 595 S.E.2d 493, 494, 496 (S.C. 2004); *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 435 (Tenn. 1994); *Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 79 P.3d 922, 933 (Utah 2003); see also RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(e) (1998); Timothy E. Travers, Annotation, *Druggist's Civil Liability for Injuries Sustained as Result of Negligence in Incorrectly Filling Drug Prescriptions*, 3 A.L.R.4TH 270, 276 (1981). But see *Heredia v. Johnson*, 827 F. Supp. 1522, 1525 (D. Nev. 1993) (denying the defendant's motion for summary judgment with regard to the claim of strict liability); *Griffith v. Blatt*, 51 P.3d 1256, 1262 (Or. 2002) (finding that a pharmacist who sold prescription lotion was a “seller” under section 402A and, hence, possibly subject to strict liability in tort for failing to warn).

<sup>167</sup> See, e.g., *Marston v. Walgreen Co.*, 907 N.E.2d 851, 854 (Ill. App. Ct. 2009) (providing an example of filling a prescription for allopurinol with glipizide pills); *Troppe v. Scarf*, 187 N.W.2d 511, 513 (Mich. Ct. App. 1971) (finding negligence in filling a prescription for birth control pills with a tranquilizer, which resulted in an unwanted child); *Burke v. Bean*, 363 S.W.2d 366, 366–68 (Tex. App. 1962) (addressing the sale of Oxoralen capsules when Oxacholin tablets were prescribed).

<sup>168</sup> See, e.g., *Rite Aid Corp. v. Levy-Gray*, 894 A.2d 563, 579 (Md. 2006) (holding that the learned intermediary doctrine does not protect a pharmacy from breach of express warranty claims for incorrectly stating that a drug could be taken with food or milk if it upset the client's stomach).

<sup>169</sup> See, e.g., *Kampe v. Howard Stark Prof'l Pharmacy, Inc.*, 841 S.W.2d 223, 227 (Mo. Ct. App. 1992) (ruling that properly filling legal prescription fulfills the pharmacist's duty), *abrogated by Horner v. Spalitto*, 1 S.W.3d 519, 524 (Mo. Ct. App. 1999) (rejecting “the suggestion in *Kampe* that the only functions which a pharmacist must perform to fulfill his duty is to dispense drugs according to a physician's prescription”); see also Huang, *supra* note 161, at 417–18 (explaining that the law clearly provides that a pharmacist has a duty to properly dispense drugs, but that the law is ambiguous as to any further duty).

effects in prescription drugs that they dispense.<sup>170</sup> The pharmacist's immunity from a general duty to warn patients has been justified on a number of grounds, including the learned intermediary doctrine's placement of warning responsibilities solely on doctors and nurse practitioners who theoretically are aware of a patient's treatment needs as well as the benefits and dangers of particular prescription drugs;<sup>171</sup> the burdens on pharmacists of having to second-guess decisions of prescribing doctors; the confusion of patients receiving conflicting information from their doctors and pharmacists; and an assumption that doctors are simply better skilled than pharmacists at evaluating the possible consequences of prescription medications.<sup>172</sup>

But cracks are beginning to appear in the pharmacist's general immunity from a duty to warn, reflecting legislative requirements that pharmacists monitor and counsel their clients about prescription drugs,<sup>173</sup> a development that has stimulated increased education and professionalism in this field.<sup>174</sup> In a number of cases, courts have held that pharmacists may have a duty of reasonable care to warn in certain circumstances. First, pharmacists are subject to liability in negligence for failing to recognize a

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<sup>170</sup> See *In re Rezulin Prods. Liab. Litig.*, 133 F. Supp. 2d 272, 279, 294 (S.D.N.Y. 2001) (discussing numerous cases concerning diabetes medication and finding that there was no general duty to warn in Alabama, Mississippi, Louisiana, Texas, or West Virginia); *Deed v. Walgreen Co.*, 927 A.2d 1001, 1002–04 (Conn. Super. Ct. 2007) (finding that a pharmacy had no duty to warn when a customer died from acute toxicity resulting from 149 prescriptions filled according to physician directions in the year prior to her death); *Pysz v. Henry's Drug Store*, 457 So. 2d 561, 562 (Fla. Dist. Ct. App. 1984) (holding that it was the doctor's responsibility, not the pharmacist's, to warn plaintiff of addiction risk in Quaaludes dispensed for more than nine years); *Frye v. Medicare-Glaser Corp.*, 605 N.E.2d 557, 561 (Ill. 1992) (finding no duty to warn of the drug's interactions); *Stebbins v. Concord Wrigley Drugs, Inc.*, 416 N.W.2d 381, 385, 387–88 (Mich. Ct. App. 1987) (finding no duty to warn of drowsiness that caused car accident); *Moore v. Mem'l Hosp. of Gulfport*, 825 So. 2d 658, 661 (Miss. 2002) (ruling that a pharmacist was not liable for failing to warn a pregnant woman that Diovan was contraindicated for pregnancy where her child suffered kidney failure as a result); *Laws v. Johnson*, 799 S.W.2d 249, 253 (Tenn. Ct. App. 1990) (finding no liability for removing a package insert that warned of risk of heart attack); *Schaerrer*, 79 P.3d at 925 (holding that a pharmacist who compounded and sold Phen-fen without warning of risks was not liable for negligence); *McKee v. Am. Home Prods. Corp.*, 782 P.2d 1045, 1046–47 (Wash. 1989) (providing an example where pharmacists refilled potentially addictive amphetamine, prescribed as an appetite suppressant, for ten years without warning of addiction risk or passing on drug insert that warned about it).

<sup>171</sup> See *Springhill Hosps., Inc. v. Larrimore*, 5 So. 3d 513, 521 (Ala. 2008) (applying the learned intermediary doctrine to bar pharmacist liability for alleged negligence in filling a prescription that led to the death of a patient).

<sup>172</sup> See *Moore v. Wyeth-Ayerst Labs.*, 236 F. Supp. 2d 509, 512–13 (D. Md. 2002) (“[I]t is unwise to impose liability on a pharmacist for filling a prescription signed by the physician, because the physician is in a better position to evaluate the patient's medical needs.”); *Chamblin v. K-Mart Corp.*, 612 S.E.2d 25, 27 (Ga. Ct. App. 2005) (finding that the learned intermediary rule properly shields pharmacists from duty to warn of drug side-effects); *Moore*, 825 So. 2d at 666 (finding that the learned intermediary doctrine protects pharmacists); *Morgan v. Wal-Mart Stores, Inc.*, 30 S.W.3d 455, 469 (Tex. App. 2000) (concluding that the general no-duty rule should be retained); *Schaerrer*, 79 P.3d at 929 (noting that information may confuse consumers).

<sup>173</sup> See, e.g., *McKee v. Wal-Mart Stores, Inc.*, 964 So. 2d 1008, 1011 (La. Ct. App. 2007); Huang, *supra* note 161, at 433–34.

<sup>174</sup> See Huang, *supra* note 161, at 440.

clear and obvious error present on the face of a prescription.<sup>175</sup> So, if a prescription fails to state a medication's maximum dosage, it is patently defective on its face, and a pharmacist may be subject to liability in negligence for failing to check with the prescribing physician or inform the patient of this important dosage fact.<sup>176</sup> Further, a pharmacist may have a duty to warn a customer or contact the physician if the pharmacist knows a drug is contraindicated for the customer, as when a pharmacist knows a customer is an alcoholic,<sup>177</sup> has an allergy,<sup>178</sup> or is taking another, incompatible drug.<sup>179</sup> In addition, if a pharmacist undertakes to collect data on a client's allergies,<sup>180</sup> to monitor its client's prescriptions for drug interactions,<sup>181</sup> or, perhaps, to warn of side-effects,<sup>182</sup> it normally will be bound to perform that undertaking with reasonable care.<sup>183</sup> In these and other situations where a pharmacist has special knowledge of a risk to a particular client, courts have sometimes broken through the traditional immunity and held pharmacists to a duty of reasonable care to warn of the risk of addiction,<sup>184</sup> potential drug interactions,<sup>185</sup> and other adverse effects

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<sup>175</sup> See *Downing v. Hyland Pharmacy*, 194 P.3d 944, 949 (Utah 2008) (holding that the learned intermediary doctrine does not exempt a pharmacy from liability for filling a prescription for drugs withdrawn from the market by the FDA).

<sup>176</sup> See *Horner v. Spalitto*, 1 S.W.3d 519, 524 (Mo. Ct. App. 1999) (finding that a jury could conclude that the pharmacist failed to fulfill his duty by not informing the prescribing physician that he was prescribing the medication at a significantly higher dose than recommended); *Riff v. Morgan Pharmacy*, 508 A.2d 1247, 1249–50, 1253 (Pa. Super. Ct. 1986) (holding that the pharmacy failed to fulfill its duty by not supplementing inadequate instructions on a prescription).

<sup>177</sup> See *Hand v. Krakowski*, 453 N.Y.S.2d 121, 122–23 (N.Y. App. Div. 1982).

<sup>178</sup> See *Happel v. Wal-Mart Stores, Inc.*, 766 N.E.2d 1118, 1124 (Ill. 2002) (ruling that a pharmacy, because it undertook to compile plaintiff's allergies, had superior knowledge and a duty to exercise reasonable care to warn of foreseeable risk of allergic reaction).

<sup>179</sup> See *Brienze v. Casserly*, No. 01-1655-C, 2003 WL 23018810, at \*2 (Mass. Super. Ct. Dec. 19, 2003); cf. *Powers v. Thobhani*, 903 So. 2d 275, 277, 280 (Fla. Dist. Ct. App. 2005) (reversing summary judgment for a pharmacy in a case where the patient died from an overdose of OxyCodone and many other prescription narcotics for neck and back pain that the pharmacy repeatedly filled too closely in time).

<sup>180</sup> See *Happel*, 766 N.E.2d at 1121, 1124.

<sup>181</sup> See *Baker v. Arbor Drugs, Inc.*, 544 N.W.2d 727, 729, 731 (Mich. Ct. App. 1996) (“[D]efendant voluntarily assumed a duty of care when it implemented the Arbotech Plus system and then advertised that this system would detect harmful drug interactions for its customers.”).

<sup>182</sup> See *In re Propulsid Prods. Liab. Litig.*, No. MDL 1355, 2002 WL 1446714, at \*4 (E.D. La. July 2, 2002) (denying summary judgment when a pharmacy allegedly misrepresented the side-effects to a customer); *Cottam v. CVS Pharmacy*, 764 N.E.2d 814, 818–19, 823 (Mass. 2002) (holding that by providing a partial list of side-effects, reasonable care might require including impotency). *Contra Kasin v. Osco Drug, Inc.*, 728 N.E.2d 77, 81 (Ill. App. Ct. 2000) (finding that by listing some side-effects, pharmacy did not have duty to list them all).

<sup>183</sup> See RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL AND EMOTIONAL HARM § 43 (2010) (explaining liability for harm from negligent undertakings that increase risk or on which plaintiff relies).

<sup>184</sup> See *Lasley v. Shrake's Country Club Pharmacy, Inc.*, 880 P.2d 1129, 1134 (Ariz. Ct. App. 1994); *Hooks SuperX, Inc. v. McLaughlin*, 642 N.E.2d 514, 520–21 (Ind. 1994).

<sup>185</sup> See *Baker*, 544 N.W.2d at 732–33 (finding that a pharmacist assumed a duty to warn by advertising that its computerized drug detection system identified and prevented drug interactions); *Dooley v. Everett*, 805 S.W.2d 380, 382, 386 (Tenn. Ct. App. 1990) (determining that a disputed issue of fact exists whether pharmacy had a duty to warn of potential drug interactions).

of prescription drugs.<sup>186</sup>

How far these small cracks in the pharmacist's no-duty-to-warn wall eventually may propagate is impossible to say, and there clearly is no stampede to break down the pharmacist's virtual immunity from a warning obligation.<sup>187</sup> Yet, the pharmacy profession is changing in ways that suggest that these strategically positioned experts in prescription pharmaceuticals might properly be required to bear a greater responsibility for warning patients of the hazards of such medications.

#### V. REFORMING PRIVATE DRUG LAW TO IMPROVE THE PUBLIC HEALTH

Responsibility in private law for drug dangers has evolved reasonably over time, but it needs to be reformed. The major problem generating a need for reform is that the law on medical malpractice, federal preemption, and a variety of products liability law principles developed separately, under discrete doctrinal umbrellas, rather than together within a holistic public health perspective. That is, private law duties on drug designs and warnings have evolved with an insular tort law focus on how litigation has been thought to promote drug safety and on whom most fairly, in terms of fault, responsibility for drug injuries should be placed. Such conventional tort law perspectives surely are fundamentally sound, yet they are grounded in archaic visions of the evolving roles and relationships of the affected groups—drug manufacturers, doctors, pharmacists, and patients. Largely overlooked by the tort law litigation system—whose general principles of reparative justice evolve narrowly, slowly, and incrementally under the common law—are vital goals of the nation's public health system: consumer choice, quality health care, and cost containment.<sup>188</sup>

This section explores how private law might consider reforming three principles of products liability law with respect to dangerous prescription drugs: (1) the liability of prescription drug manufacturers for design defects; (2) the limited duty of prescription drug manufacturers to provide warnings only to healthcare providers, not directly to consumers; and (3) the absence of a duty of pharmacists to provide warnings to consumers. In examining the evolution of these principles of drug products liability law, this Article has revealed their respective weaknesses. For reasons explored

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<sup>186</sup> See *Guillory v. Dr. X*, 679 So. 2d 1004, 1010 (La. Ct. App. 1996) (finding that a pharmacist has a duty to fill a prescription correctly and to warn the patient or to notify the prescribing physician of an excessive dosage or of obvious inadequacies on the face of the prescription); see also *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 435 (Tenn. 1994) (finding that the duty to warn did not extend to patient's third-party relative).

<sup>187</sup> See *Deed v. Walgreen Co.*, 927 A.2d 1001, 1004 (Conn. Super. Ct. 2007) (holding that, under the learned intermediary doctrine, a pharmacist has no duty to warn customers); *Morgan v. Wal-Mart Stores, Inc.*, 30 S.W.3d 455, 467 (Tex. App. 2000) (providing a thorough review of a pharmacist's duty to warn and concluding that the general, no-duty rule should be retained).

<sup>188</sup> Broad, even universal, insurance coverage is another important healthcare goal, but it is largely unrelated to private law.



above, it is here proposed that prescription drug manufacturers be exempted from private law responsibility for design defects, and that manufacturers and pharmacists both be required to exercise reasonable care in warning and instructing consumers on prescription drug dangers and how to avoid them. This section sketches out how each of these reforms appears consistent with three principal goals of healthcare reform: maximizing consumer choice, improving healthcare quality, and containing costs. The preliminary analysis here is intended as a start to deeper inquiry into these and other private law reforms that may help resolve the healthcare crisis.

### A. Choice

Choice, a vital ingredient of human freedom, allows persons to exercise autonomy in making important decisions about their lives.<sup>189</sup> The design of a healthcare system in a free society thus should promote consumer choice as much as practicable. With respect to prescription drugs, this means making useful information meaningfully available to patients (as well as to their professional healthcare advisers) so that patients can make genuinely informed decisions, guided by their doctors, on which drugs (if any) to take to treat their particular conditions.<sup>190</sup> Focusing on this objective reveals a number of shortcomings in current principles of private drug law addressed by these three reforms.

#### 1. *Ban Liability for Defective Design*

The first reform proposal is to ban claims against drug manufacturers for defective design, a type of claim that a number of courts have allowed over the last couple of decades.<sup>191</sup> Courts that have allowed such claims, drawing from conventional tort law rationales, often reason that drug manufacturers should be subject to design defect claims to enhance the safety of drugs and provide compensatory relief to persons injured by drugs designed in an unnecessarily dangerous manner.<sup>192</sup> Yet, narrowly

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<sup>189</sup> See David G. Owen, *Philosophical Foundations of Fault in Tort Law*, in *PHILOSOPHICAL FOUNDATIONS OF TORT LAW* 201, 209 (David G. Owen ed., 1995) (“Autonomy entails the notion that a person may—indeed, must—make choices and then act upon those choices.”); Owen, *Figuring Foreseeability*, *supra* note 79 (explaining the relationship between autonomy and choice).

<sup>190</sup> See Oonagh Corrigan, *Empty Ethics: The Problem with Informed Consent*, 25 *SOC. HEALTH & ILLNESS* 768, 769–70 (2003) (noting that the underpinning of informed consent is that it will protect the autonomy of patients in making free and informed choices); Jessica J. Flinn, Comment, *Personalizing Informed Consent: The Challenge of Health Literacy*, 2 *ST. LOUIS U. J. HEALTH L. & POL’Y* 379–94 (2009) (recognizing the low “health literacy” of millions of Americans and adoption of the “reasonable patient” standard as the scope of a physician’s duty to inform in order to combat it).

<sup>191</sup> See *supra* note 48 and accompanying text (listing the courts that have accepted the *Feldman-Kearl* case-by-case approach to allowing prescription drug design defect liability claims).

<sup>192</sup> See *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 833–42 (Neb. 2000) (adopting a case-by-case application of comment *k* as an affirmative defense to a plaintiff’s design defect claim for prescription drugs).

focusing on traditional tort law goals—deterrence and compensation—misses altogether broader aspects of drug safety in the healthcare system. A normal design defect challenge to a drug’s design suggests that a drug (like any other type of product) could and should have been designed more safely some other way.<sup>193</sup> Apart from the important fact that most dangers in a drug are unavoidable attributes of the very chemicals that promote its cures,<sup>194</sup> design defect claims discourage manufacturers from developing and marketing new drugs that would provide new approaches to conditions for which another drug already may exist. This disincentive exists because conventional cost-benefit theory for design defectiveness suggests that only *one* design can optimally achieve a health or other benefit when balanced against competing safety and other costs.<sup>195</sup>

A look back at the earlier illustration involving three drugs for lung infections, each with differing side-effects,<sup>196</sup> illuminates this problem. It will be recalled that although each of these separate drugs for the same condition caused side-effects in some people, each provided effective treatment for others, so that each such drug was reasonably “designed.” Yet, if drug design defect litigation were generally allowed, once the first such drug was marketed, other drug manufacturers would have little incentive to spend the half billion dollars or so required to develop and market a new lung infection drug.<sup>197</sup> Consumer (and physician) choice would be materially enhanced if the other two drugs became available, but manufacturers would be gambling large to develop them at all, for it often is difficult to predict which among two or more drugs aimed at the same malady lay jurors ultimately may conclude has the best ratio of benefits to risks.

Thus, a robust design-defect litigation process would tend to drive all drugs competing for the treatment of each particular ailment, but one, from the market, notwithstanding the fact that a variety of drugs—each with slightly differing side-effects and benefits for different people—may enrich the pharmacopeia available to a population comprised of many millions of very different people. As for protecting the public from improperly designed drugs, the combination of vigorous FDA oversight, warning claims against manufacturers, and market incentives (consider the costs to

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<sup>193</sup> See Conk, *True Test*, *supra* note 14, at 738–39 (criticizing the exclusion of prescription drugs from the “general measure of product design defect—the reasonable alternative design test”); Conk, *Design Defect*, *supra* note 14, at 1089 (stating that the *Restatement (Third) of Torts*’s exemption of medical devices from the alternative-safer-design standard “reverses thirty-five years of safety-advancing products-liability law”).

<sup>194</sup> See *supra* Part III.A.

<sup>195</sup> See OWEN, *supra* note 14, § 8.5.

<sup>196</sup> See *supra* Part III.B.

<sup>197</sup> See *supra* note 38 and accompanying text (discussing the costs of bringing a new prescription drug to the market).

Merck of the Vioxx recall and imbroglio)<sup>198</sup> seems preferable to scattered juries empanelled in boxes of twelve for resolving the baskets of complex policy questions involved in determining what kinds of drugs (with what kinds of benefits, risks, and warnings) properly should be on the market. The issue here is about choice; the lung infection illustration above shows how drug availability and, thus, choice are restricted by private litigation into the defectiveness of drug designs. Banning drug design litigation altogether would remove this obstacle and thereby promote consumer choice.

## 2. *Expand Duties to Warn*

If drug manufacturers are protected from design defect litigation, which they should be, then they should also be required to disseminate information widely and effectively about whatever dangers their drugs may contain. Warnings of this type, of course, are vital to intelligent choice about the desirability of particular drugs. Current principles on warning “adequacy” are suited to the substantive aspect of this task.<sup>199</sup> But, as previously discussed, two limited-duty principles seriously obstruct the dissemination of warning information: liability shields protecting both drug manufacturers and pharmacists from providing warnings directly to patients.<sup>200</sup> Both types of healthcare providers are protected by the learned intermediary principle and its premise that only doctors (and nurse practitioners) should communicate directly with patients about the costs and benefits of particular drugs. Yet, manufacturers and pharmacists—not doctors—are the true experts on pharmaceuticals.<sup>201</sup> Making useful information about prescription drugs available to patients, the ultimate consumers, is necessary to maximizing choice, since uninformed choice is no choice at all.<sup>202</sup>

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<sup>198</sup> See *supra* notes 12–13 and accompanying text.

<sup>199</sup> This assumption is premised on the continued decline of the federal preemption doctrine as a bar to warning adequacy claims against drug manufacturers. See *Wyeth v. Levine*, 129 S. Ct. 1187, 1191 (2009) (holding that prior FDA approval of a drug label did not bar an inadequate warning claim); Memorandum for the Heads of Executive Departments and Agencies, 74 Fed. Reg. 24,693 (May 20, 2009) (restraining agencies from secreting preemption rulings in preambles to federal regulations and from asserting the preemptive effect of federal law without sufficient justification); see also Mary J. Davis, *The Battle over Implied Preemption: Products Liability and the FDA*, 48 B.C. L. REV. 1089, 1089–94 (2007).

<sup>200</sup> See *supra* Parts IV.D–E.

<sup>201</sup> See *The Pharmaceutical Research & Manufacturers of American Report, in THE PURSUIT OF HIGH PERFORMANCE THROUGH RESEARCH AND DEVELOPMENT: UNDERSTANDING PHARMACEUTICAL RESEARCH AND DEVELOPMENT COST DRIVERS 4–11* (2007), available at <http://www.phrma.org/files/Accenture%20R&D%20Report-2007.pdf> (noting the vast amounts of time and money spent by pharmaceutical companies on research and development); *supra* note 162 and accompanying text (noting the extensive training pharmacists receive in all aspects of drug therapy compared to the cursory training doctors receive).

<sup>202</sup> Owen, *Figuring Foreseeability*, *supra* note 79, at 1281–82.

To enhance choice, therefore, private law should abolish the learned intermediary rule. So doing would provide both manufacturers and pharmacists with duties to communicate useful cost-benefit information about drug dangers—effective, not vague boilerplate warnings—to consumers. Doctors (often, together with their health-education delegates) would retain their vital, professional duty to link appropriate drugs to appropriate patients, but drug manufacturers no longer would be allowed to entice consumers with television commercials—depicting happy and healthy people dancing in fields of flowers—only to shield themselves from a responsibility to warn behind the doctor’s white coat. And pharmacists would also be required to share their very substantial pharmacological expertise with the people they directly serve—a responsibility that this noble profession, marginalized so long by the learned intermediary doctrine, might enthusiastically embrace. Ultimately, abolishing the learned intermediary rule should increase the amount of information on drug dangers provided to consumers, improving their opportunity for an intelligent, final say on what types of dangerous pharmaceuticals, if any, they choose to consume.<sup>203</sup>

### B. *Quality*

In a truly liberal democracy, quality health care means the individualized health care chosen by each citizen, so that the very idea of quality, at a fundamental level, merges into choice. But there are also objective aspects to quality health care relevant to the private law prescription drug issues examined here. First, banning drug design litigation should increase the availability of drugs, as discussed above, thereby providing doctors (with patient input) with greater opportunities to make better matches of particular drugs to particular patients.<sup>204</sup> Drug therapy, therefore, should be improved by this change in private law.

The proposal to broaden duties to warn should also improve the quality of health care.<sup>205</sup> As manufacturers and pharmacists fulfill their new duties to provide consumers with effective information about various drug choices, informed consumers will be better positioned to help doctors decide, initially, which (if any) drugs are best suited to their particular conditions and constitutions. Moreover, once patients begin to take particular drugs, they will be better informed (by manufacturers, doctors,

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<sup>203</sup> Another important reform to private drug law, albeit outside the scope of this Article, is to lift some preemption restrictions to products liability actions imposed by the U.S. Supreme Court over the last couple of decades. See, e.g., *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 348 (2001) (prohibiting state law actions for fraud-on-the-FDA). President Obama recently reversed the Bush administration’s similarly restrictive preemption policies. See Memorandum for the Heads of Executive Departments and Agencies, *supra* note 199.

<sup>204</sup> See *supra* Part V.A.1.

<sup>205</sup> See *supra* Part V.A.2.

and pharmacists) on what warning signals to watch out for with respect to particular side-effects, allowing them to seek ameliorative care sooner than otherwise would be the case. Harm caused by drug side-effects should therefore be reduced.

### C. Cost

While choice and quality of health care are both quite likely to improve from the proposed reforms, it is more difficult to predict the net effects of such reforms on costs and cost containment in the healthcare system. Surely some costs will increase. First, if design litigation is banned, manufacturers should make larger investments in developing, manufacturing, and marketing new drugs, as previously postulated.<sup>206</sup> Yet, one might reasonably assume that manufacturers will assure that the benefits of drugs in which they invest will exceed their costs. Indeed, without the constant threat of unpredictable drug design litigation, the accuracy of a manufacturer's cost-benefit analyses of its drugs should be improved. In addition, increasing the warning responsibilities of manufacturers and pharmacists, and indirectly of doctors (who will have to spend more time answering questions posed by better-informed patients), will generate various direct information costs, and a surfeit of available information may result in "warnings pollution," which has costs of its own.<sup>207</sup>

Despite these cost increases, the reforms proposed here should decrease various other costs of the healthcare system. First, improvements in the quality of health care discussed above should enhance the health of the citizenry and thus lower the costs of health care overall.<sup>208</sup> For example, improving drug therapy by expanding the duties to warn should alleviate some conditions that otherwise would require more expensive surgical intervention. Moreover, fully informed patients should be less likely to agree to unnecessary drug treatments that some doctors may prescribe defensively to guard against malpractice litigation, since patients should not want to expose themselves to disclosed drug dangers unless they have reason to believe that the benefits of the proposed drug therapy outweigh the risks.

Other cost decreases may result from structural changes in how health information is delivered, changes that may be prompted by the proposals offered here. Presently, doctors and nurse practitioners are the only parties charged with providing information to patients, as previously discussed.<sup>209</sup>

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<sup>206</sup> Cf. *supra* notes 194–95 and accompanying text (explaining how design defect litigation discourages manufacturers from developing new drugs).

<sup>207</sup> See OWEN, *supra* note 14, § 9.3.

<sup>208</sup> See *supra* Part V.

<sup>209</sup> See *supra* Part IV.D.

Yet widening the duty to disseminate health information to manufacturers and pharmacists is likely to create a veritable revolution in how information is disseminated, as previously suggested.<sup>210</sup> For example, patient counseling on drug dangers by expert pharmacists is plainly cheaper than by physicians, whose time is typically more expensive and often better spent on the direct provision of health care. Another result of this information revolution may be to help doctors realize that they need to partner with professional health educators in healthcare delivery. Today, doctors as a practical matter fail to fulfill their informed consent responsibilities to inform patients fully and meaningfully on the costs and benefits of a proposed drug or other treatment, including alternative treatments, or no treatment at all.<sup>211</sup> Once healthcare consumers become routinely bombarded with information on the benefits and risks of various drug therapies by manufacturers and pharmacists (as well as by doctors), doctors may become overwhelmed with patient questions about the benefits and risks of drugs and alternative therapies. In such an environment, it seems likely that many doctors will choose to delegate considerable responsibility for information dissemination to professional health educators, whose time is less expensive than that of physicians. In this way, increased burdens from broader health information disclosure duties may prompt helpful structural changes in healthcare delivery that decrease the costs (and improve the quality) of information dissemination.

The doctrine of comparative fault may appropriately generate another cost saving. Once consumers become broadly informed of drug dangers under the reforms suggested here, they should be fully equipped to make intelligent decisions on their own drug therapies. If, with all this information, they fail to participate meaningfully in initial drug therapy decisions, or if they later fail adequately to monitor their conditions during therapy, responsibility for a harmful result that a cautious patient would have avoided should logically fall on the shoulders of the passively imprudent patient.<sup>212</sup> The careless patient in this scenario would appropriately be deprived of some or all legal relief against the drug manufacturer, the doctor, or the pharmacist, which would effectively remove these costs from the healthcare system.

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<sup>210</sup> See *id.*

<sup>211</sup> See Grant H. Morris, *Dissing Disclosure: Just What the Doctor Ordered*, 44 ARIZ. L. REV. 313, 313–17 (2002) (describing current practices relating to informed consent as “a charade, a symbolic but contentless formality”); Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899, 900–06 (1994) (examining the ineffectiveness of informed consent to health care and recommending its contextualized application).

<sup>212</sup> Although the patient’s worsened condition may generate additional healthcare needs, presumably this outcome would have been the same under the current private law regime.

## VI. CONCLUSION

Structural proposals for reforming the healthcare system presently at large appear to overlook important ways in which private law affects the system. Current law on responsibility for dangers from prescription drugs is antiquated by its narrow obsession with classic tort law goals to the exclusion of the broader needs of the healthcare system. It is here proposed to reform current law by banning design defect litigation against manufacturers of pharmaceuticals, and by abolishing the learned intermediary doctrine, the latter of which would impose full-bodied duties to warn consumers on both manufacturers and pharmacists. Consistent with traditional principles of private drug law, these reforms appear to promote central goals of healthcare reform—maximizing consumer choice, increasing quality, and reducing costs of health care in America. Each of these reform proposals is bold, yet the current healthcare crisis in this nation demands bold solutions. Private law should be flexible enough, perhaps with some legislative help, to shift its focus to provide appropriate incentives to drug companies, pharmacists, and patients to partner together to minimize harm from and maximize the benefits of the vast pharmacopeia of drugs.