

DISTRIBUTIVE JUSTICE IN PHARMACEUTICAL TORTS: JUSTICE WHERE JUSTICE IS DUE?

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I

INTRODUCTION

Ongoing tort reform efforts attest to the significant burden that medical liability imposes on the health care system.¹ General attempts to curb excesses can narrow socioeconomic disparities, but as Clark Havighurst and Barak Richman observe, such measures may leave intact some of the regressive characteristics of the framework they supplant.² Therefore, it seems appropriate to question whether tort law offers a proper platform for distributive justice. Would restrictions or other changes in medical liability unduly sacrifice individual justice for corporate justice? Would solutions outside tort law enhance distributive justice as—or perhaps more—effectively, while still giving each person his or her due?

To help resolve these questions, this article continues where Havighurst and Richman left off with medical malpractice. Part II revisits their suggested reforms to show how a tort-centered approach might aggravate socioeconomic disparities without dramatically leveling the playing field. Parts III through V of the article explain why pharmaceutical litigation again teaches that discretion may be the better part of valor when it comes to amending tort law for the sake of distributive justice. Although it is difficult to determine how the billions of dollars in products liability translate in terms of additional burdens on the health care system, further scrutiny is warranted before overarching pronouncements are made about the progressive or regressive tendencies of medical torts, considering the sheer scale of mass pharmaceutical litigation. Accordingly, Part III first discusses how traditional perceptions of class actions

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* Associate, Williams & Connolly, L.L.P. I am extremely grateful to Clark Havighurst and Barak Richman for their tutelage and for the opportunity to comment on their important and provocative article.

1. See, e.g., Help Efficient, Accessible, Low Cost, Timely Healthcare (HEALTH) Act of 2005, H.R. 5, 109th Cong. (2005) (as passed by H.R., July 29, 2005).

2. Clark C. Havighurst & Barak D. Richman, *Distributive Injustice(s) in American Health Care*, 69 LAW & CONTEMP. PROBS. 7, 71 (Autumn 2006) (discussing the capitation of non-economic damages). Capping non-economic damages still allows wealthier plaintiffs to collect more, as economic-damages calculations take into account a plaintiff's lost future income. E.g., RESTATEMENT (SECOND) OF TORTS §906(b) cmt. b (1965) (detailing calculation of damages based on lost future income).

and market forces create the expectation that—economic damages aside—pharmaceutical torts afford average Americans a relatively fair opportunity for restitution. Part IV surveys major pharmaceutical products liability cases from the past two to three decades to illustrate how overriding concerns for individual justice render class actions inert as a vehicle for distributive justice. Part V highlights important differences between individually adjudicated, plaintiff-by-plaintiff drug liability cases and ordinary, patient-by-patient medical malpractice litigation that help preserve mass pharmaceutical actions. To capture some of the divergent influences on distributive justice, Part VI explores the downstream effects of drug liability and the litigation process itself. The article concludes that, until empirical evidence clarifies the net distributive impact of pharmaceutical torts, the capacity for tort reform to rectify distributive injustices in health care will remain far from obvious.³

II

MEDICAL MALPRACTICE

Beginning first in the medical malpractice context, Havighurst and Richman note that defensive medicine and liability insurance exacerbate distributive injustices in health care.⁴ Wealthier patients receive more care and siphon more money from the malpractice insurance pool because of their greater propensity and capacity to sue.⁵ Litigious inclinations aside, higher-income patients also command a disproportionate share of the liability funds because of higher economic damage assessments.⁶ Thus, the fallout from malpractice claims (defensive medicine and the passing of liability costs onto patients) and the adjudication process itself (income-based compensation) exert regressive effects.

Recognizing both these facets of malpractice suits, Havighurst and Richman propose solutions that address each in turn.⁷ Their plea for freedom to negotiate care could substantially decrease the estimated \$70–\$126 billion spent on defensive medicine per year.⁸ However, less affluent patients may suffer a

3. My analysis focuses on the fairness of the judicial remedy itself, due to the lack of empirical evidence on the secondary consequences of pharmaceutical products liability and to the attention this topic has already received from others. Concentrating on the litigation mechanics also seems reasonable since part of the goal is to shed light on whether legislators can make refinements in the tort system that would achieve greater equity without trampling upon individual justice. Although the ramifications of liability are invariably tied to the legal standards and proceedings themselves, reforms outside of tort law may better address those issues while leaving room for important changes within tort law itself.

4. Havighurst & Richman, *supra* note 2, at 64–71.

5. *Id.* at 70.

6. For an explanation, see the text *supra* at note 2.

7. Havighurst & Richman, *supra* note 2, *passim*.

8. JUDYTH PENDELL, AEI-BROOKINGS JOINT CENTER FOR REGULATORY STUDIES, *THE ADVERSE SIDE EFFECTS OF PHARMACEUTICAL LITIGATION 2–3* (2003) (citing Alex Azar, *Liability and Patient Health*, Transcript of Conference Sponsored by AEI-Brookings Joint Center and Common Good, March 4, 2003).

severe disadvantage with regard to information. “Care by contract” may prompt them to forego services that preserve health and save money in the long run.⁹ The state of affairs might thereby transform from one in which less wealthy patients pay for care they do not want, to one where they want—or need—care that they can even less afford.¹⁰ Although Havighurst and Richman might thus support a certain baseline level of preventive medicine, it is unclear that broadly defined regulations could satisfactorily accomplish this objective. Practice guidelines are just “guidelines” precisely because patient circumstances vary tremendously.¹¹ Just as lawmakers cannot fashion rules for every situation, practice guidelines and regulations cannot replace individualized evaluation of medical need.

It is this need for personalized assessment that has helped reserve a place for medical malpractice suits. Some sort of third-party, case-by-case determination seems necessary before officially branding providers as charlatans.¹² Subsequently, eliminating a cause of action for failure to provide care may simply substitute one form of third-party review for another. Without the tort option, some sort of independent examination might still be warranted to keep providers accountable. Whether or not a “guilty” finding imposes a financial penalty, providers would still have incentive to practice defensive medicine. As Havighurst and Richman themselves maintain, the reputational and emotional toll alone could drive such behavior.¹³

The Congressional Budget Office (CBO) has similarly hypothesized that so-called defensive medicine is motivated by desire for profit and possible benefit to patients.¹⁴ Poorer patients, as Havighurst and Richman point out, may not as readily challenge authority figures,¹⁵ perhaps including when providers urge them to purchase more care. Consequently, the freedom-of-contract approach may not significantly rein in the waste associated with defensive or profit-oriented medicine, though a non-judicial process might lower administrative costs.

Meanwhile, Havighurst and Richman’s proposal to cap economic damages might help equalize the prospective compensation for richer versus poorer

9. By “care by contract,” I am referring to Havighurst and Richman’s proposal to allow patients to negotiate and contract for their own particularized care. They argue that regulatory minimums, purchasing agents, and other protective mechanisms may ameliorate informational disparities (see Havighurst & Richman, *supra* note 2, at 80), but these devices may not supplant the need for adjudication. See text, *infra*.

10. The current state of affairs already features both elements, but the health of the less wealthy could get worse if they select their own health care.

11. Part IV *infra* illustrates the degree to which patient circumstances may vary on a single health parameter, let alone in terms of an individual’s overall medical picture.

12. Independent determination appears necessary so that a patient might have a fighting chance for redress or vindication while helping ensure that physicians are not falsely accused of providing substandard care.

13. Havighurst & Richman, *supra* note 2, at 65.

14. CONG. BUDGET OFFICE, LIMITING TORT LIABILITY FOR MEDICAL MALPRACTICE 6 (2004) [hereinafter LIMITING TORT LIABILITY].

15. Havighurst & Richman, *supra* note 2, at 70.

plaintiffs, but it would not equalize their respective tendencies to sue. Moreover, although malpractice awards can amount to billions in the aggregate,¹⁶ profit-induced medicine appears to impose a much greater financial burden on society as a whole than litigation.¹⁷ Hence, capping economic damages might sacrifice individual justice (the wealthy do not recoup their losses) without substantially improving socioeconomic disparities. If so, answers outside the tort system may more appropriately and effectively address distributive injustices.¹⁸ For example, some of the economic solutions that Havighurst and Richman advocate¹⁹ would more directly combat profit-driven care.

III

PHARMACEUTICAL TORTS

A. Importance of Pharmaceutical Liability

Medical malpractice represents just one category of medical torts. Another major component is pharmaceutical litigation. To put matters in perspective, in 2002, malpractice payments totaled approximately \$24 billion.²⁰ Analysts project that the ongoing Vioxx litigation alone will cost Merck anywhere from \$8 to as much as \$50 billion (spread over several years).²¹ As mentioned, evaluating the health care repercussions of such liability requires further empirical research, but the magnitude of liability itself merits closer scrutiny of the litigation mechanics. Indeed, the conventional thinking that Havighurst and Richman allude to—that tort law permits ordinary Americans to obtain justice from the wealthy and powerful²²—may seem especially compelling when applied to litigation where thousands of average citizens gain billions of dollars in restitution.²³

16. In 2002, malpractice payments amounted to an estimated \$24 billion. LIMITING TORT LIABILITY, *supra* note 14, at 6.

17. See PENDELL, *supra* note 8, at 2–3 (estimating that profit-motivated care raises health care costs by \$70-\$126 billion per year).

18. Certainly, the malpractice system is far from perfect. For instance, it sometimes penalizes physicians who committed no wrong while leaving negligent physicians unpunished. See JOINT ECON. COMM., THE PERVERSE NATURE OF THE MEDICAL LIABILITY SYSTEM, REP. 109-2, at 1 (2005), available at <http://www.house.gov/jec/publications/109/03-21-05.pdf>. Such flaws could affect distributive justice, but reform efforts should more directly target socioeconomic disparities.

19. For example, they advocate competition among insurance plans that would maximize the per-dollar value of premium payments. Havighurst & Richman, *supra* note 2, at 16.

20. LIMITING TORT LIABILITY, *supra* note 14, at 6.

21. Heather Won Tesoriero, *Defending Multiple Vioxx Cases Is Costly Burden for Merck*, WALL ST. J., Jan. 26, 2006, at B1; Matthew Herper, *Vioxx Liability Could Force Biotechs to Merge*, FORBES, Sept. 14, 2005.

22. Havighurst & Richman, *supra* note 2, at 64.

23. For example, plaintiffs in the Fen-Phen/Redux diet drug litigation stand to share \$22 billion in settlement and other payouts. Robert Lenzner & Michael Maiello, *The \$22 Billion Gold Rush*, FORBES, Apr. 10, 2006. By some estimates, however, seventy percent of the awards go to patients who “aren’t sick and don’t deserve it.” *Id.*

B. Traditional Role of Class Actions

To appreciate the distributive justice implications of pharmaceutical torts, it is necessary to begin with a brief description of the problems with medical malpractice. As Havighurst and Richman observe, the limitations may be several-fold.²⁴ First, plaintiffs' attorneys are often more willing to accept cases with higher returns. Lower-income patients may thus find it more difficult to obtain representation because they command lower economic damages. Second, wealthier patients may have a greater capacity to discover that they have fallen victim to malpractice. As a result, they may seek legal recourse more frequently than their less affluent counterparts. Third, richer patients may have more confidence in their prospects of prevailing against wealthy and powerful caregivers and institutions. Again, this would increase the likelihood of suits by higher-income individuals.

These barriers to access are of course neither new nor unique to medical malpractice. It is with these concerns in mind, as well as those of administrative efficiency, that class actions evolved as a judicial remedy. The aggregation of individual claims provides plaintiffs' attorneys with the financial incentive to *solicit* plaintiffs regardless of their income. The more plaintiffs that attorneys recruit, the larger the size of the pot—all with minimal extra “overhead” for representing additional clients.²⁵ Such “strength in numbers” may also encourage ordinary citizens to participate in litigation against otherwise daunting adversaries. Class actions thereby help overcome the usual impediments to justice for the common citizen.

C. Class Actions for Pharmaceutical Products Liability

With prescription drug liability, class action becomes a distinct theoretical possibility. First, pharmaceutical companies are lucrative targets²⁶ for both the plaintiffs' bar and patients who may already bear grudges against “big corporations” (and perhaps the drug industry in particular). Second, as Part V outlines in greater detail, the search for pharmaceutical plaintiffs is far easier than the search for malpractice victims. Television and other advertisements by plaintiffs' attorneys need only identify a drug by name, and most patients who have taken the medication will recognize whether they are potential plaintiffs.²⁷

24. Havighurst & Richman, *supra* note 2, at 64–71.

25. Myron S. Greenberg & Megan A. Blazina, *What Mediators Need To Know About Class Actions: A Basic Primer*, 27 *HAMLIN L. REV.* 191, 203 (2004).

26. The allure of the industry's deep pockets is what ensures that even individual plaintiffs' cases will proceed without class actions. See Part V, *infra*. Indeed, twenty-seven percent of patients in a Harris Poll conducted at the behest of the U.S. Chamber of Commerce indicated that they would likely join a suit even if they had not experienced side effects from a drug. INSTITUTE FOR LEGAL REFORM, U.S. CHAMBER OF COMMERCE, PHARMACEUTICAL LIABILITY STUDY: REPORT ON FINDINGS 45 (2003), available at http://www.instituteforlegalreform.org/resources/PharmaceuticalLiabilityStudy_report.pdf [hereinafter PHARMACEUTICAL LIABILITY STUDY].

27. See U.S. GEN. ACCOUNTING OFFICE, GAO/AIMD-95-169, MEDICAL LIABILITY: IMPACT ON HOSPITAL AND PHYSICIAN COSTS EXTENDS BEYOND INSURANCE 16 (1995), available at <http://www.gao.gov/archive/1995/ai95169.pdf> (noting that most pharmaceutical litigation has involved

Last but not least, Rule 23(a) of the Federal Rules of Civil Procedure, which serves as the model for many state equivalents, stipulates that any class must be “so numerous that joinder of all members is impracticable”²⁸ The sheer number of plaintiffs involved in pharmaceutical torts will usually satisfy this “numerosity” prerequisite for class actions, in addition to providing financial incentive by aggregating claims. In the Vioxx litigation, for example, there are currently 14,200 lawsuits.²⁹

The threshold inquiry here, of course, is whether most plaintiffs in a would-be pharmaceutical class action do in fact hail from modest socioeconomic backgrounds. That question is most pertinent with respect to distributive justice, especially if, as Havighurst and Richman insist, wealthier patients consume more health care,³⁰ including prescription drugs. After all, consider the situations in which *pharmaceutical* torts typically arise. Standard failure to provide arguably “medically necessary” drugs would fall under the rubric of medical malpractice or insurance coverage claims.³¹ In contrast, pharmaceutical litigation occurs when previously unknown side effects begin to emerge with these medications. This was the case with Rezulin, a supplementary treatment for adult-onset diabetes that is associated with liver abnormalities.³² In these types of circumstances, socioeconomic bias may rear its ugly head, whether it is in the form of caregivers providing more care to wealthier patients (even when the medical community itself views the care as necessary),³³ or the inability of poorer patients to navigate the health care system. Both would increase the ratio of richer to poorer plaintiffs.

Similarly, the other prototypical scenario for liability claims occurs when elective medications allegedly cause injury. The building legal battle over hormone therapy, and whether it increases the risk of breast cancer,³⁴ falls in this category. Hormone therapy helps prevent osteoporosis and alleviates postmenopausal symptoms such as hot flashes and vaginal discomfort by replacing the hormones that a woman loses when she enters menopause. Although postmenopausal symptoms can severely affect functional capacity (by disrupting sleep and concentration, for example), physicians opting not to prescribe hormone therapy will not thereby jeopardize a woman’s health so

brand-name medications). See Part V, *infra*, for a discussion of how brand-name recognition facilitates the search for potential plaintiffs.

28. FED. R. CIV. P. 23(a)(1).

29. Heather Won Tesoriero, *Merck Is Victorious in New Orleans Vioxx Trial*, WALL ST. J., Sept. 27, 2006, at A13 [hereinafter *Vioxx Trial*].

30. Havighurst & Richman, *supra* note 2, at 42.

31. See, e.g., CAL. CIV. CODE § 3428 (West 2000) (outlining the liability of insurance plans for failure to provide “medically necessary” health care).

32. *In re Rezulin Prods. Liab. Lit.*, 210 F.R.D. 61 (S.D.N.Y. 2002).

33. Steven M. Asch et al., *Measuring Underuse of Necessary Care Among Elderly Medicare Beneficiaries Using Inpatient and Outpatient Claims*, 284 JAMA 2325 (2000) (finding that low-income beneficiaries were less likely to receive necessary care for seventeen health indicators).

34. Molly Selvin, *Hormone Suits Face Hurdle as Drugs Keep FDA Backing*, L.A. TIMES, Nov. 7, 2005, at C1.

long as the woman uses other medications or interventions for osteoporosis prevention. Therefore, with hormone therapy, physicians may use the intervention more frequently—as defensive medicine—with more affluent and medically savvy patients seeking additional care. Indeed, the Food and Drug Administration (FDA) approved Prempro (one of many hormone therapy regimens) only for postmenopausal symptoms and osteoporosis prevention, but available data support possible cardiovascular protection if women start taking the medication right around menopause.³⁵ Again, such “off-label” benefits may prompt greater consumption by wealthier, more knowledgeable patients and correspondingly skew the plaintiff pool.

In short, it seems that whether the drugs are essential or elective, higher-income patients may consume disproportionately more and thereby overrepresent the plaintiff population in pharmaceutical torts. So could a class action truly champion the less affluent? Without sufficient demographic information, the answer must come by inference. Fortunately, however, market forces may still render it a foregone conclusion. Specifically, the profit motive (and philanthropy, depending on whom one asks) drives the pharmaceutical industry toward prevalent diseases or conditions. The more widespread the problem, the larger the market to which a company can sell a product and recoup its extraordinary financial investment in discovering and launching the drug.³⁶ Take hormone therapy for example. *Every* woman will enter menopause as long as she lives to her fifties. Likewise, Rezulin targeted the obesity and diabetes epidemic in this country,³⁷ as did Baycol (an anti-cholesterol medication associated with muscle damage) and Fen-Phen and Redux (diet drugs associated with high blood pressure in the pulmonary arteries and heart valve injury, respectively). The anti-depressant Paxil was another heavy hitter until reports of suicide and homicide ushered the drug into courtrooms, and the list continues with Vioxx (arthritis/pain), Celebrex (same), Norplant (contraception), and Propulsid (heartburn and gastro-esophageal reflux).³⁸ These medications spawned the bulk of pharmaceutical tort litigation in recent years.³⁹ The mind-numbing number of eligible and actual patients for

35. See, e.g., Francine Grodstein, JoAnn E. Manson & Meir J. Stampfer, *Hormone Therapy and Coronary Heart Disease: The Role of Time Since Menopause and Age at Hormone Initiation*, 15 J. WOMEN'S HEALTH 35, 35 (2006) (“Women beginning [hormone therapy] near menopause had a significantly reduced risk of [coronary heart disease].”).

36. Joseph A. DiMasi, Ronald W. Hansen & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 151 (2003) (estimating the cost of developing and marketing one drug at \$802 million).

37. See Press Release, Centers for Disease Control and Prevention, *Obesity Epidemic Increases Dramatically in the United States: CDC Director Calls for National Prevention Effort* (Oct. 26, 1999), available at <http://www.cdc.gov/od/oc/media/pressrel/r991026.htm>.

38. See, e.g., Stephanie Saul, *Senators Ask Drug Giant To Explain Grants to Doctors*, N.Y. TIMES, July 6, 2005, at C3 (reporting that Johnson & Johnson paid \$90 million to settle Propulsid lawsuits); Gardiner Harris, *Spitzer Sues a Drug Maker, Saying It Hid Negative Data*, N.Y. TIMES, June 3, 2004, at A1 (discussing litigation over Paxil).

39. Russell G. Thornton, *Defending Claims Related to Prescribing Drugs or Using Medical Devices*, 15 BAYLOR UNIV. MED. CENTER PROC. 102, 102 (2002).

these products practically dictates that a representative majority of plaintiffs are from modest backgrounds, notwithstanding any socioeconomic biases in health care delivery.

In fact, short of lowering prices, the industry combats barriers to access on both the consumer and the provider ends. On the patient end, direct-to-consumer (DTC) advertising informs individuals of their candidacy for a medication and encourages them to talk to their doctors.⁴⁰ As for physicians, pharmaceutical companies sponsor continuing medical education and visit their offices to discuss how a product may improve the health of their patients. While the precise effect of these promotional and educational campaigns remains difficult to quantify, that companies spend millions of dollars on such efforts attests to their efficacy—both in terms of generating profit and ensuring that patients receive important medical interventions. In 2004, for instance, the industry spent more than \$4 billion on DTC advertising.⁴¹ Whether such expenditures are justified from a liability standpoint is for juries to decide—is it all about profit, or do the dollar amounts also reflect how strongly a company believes its product will better patients' lives? The relevant point here is that market maximization and advertising by the pharmaceutical industry, behaviors that are often criticized, may not only attenuate socioeconomic disparities by increasing consumption by the less affluent, but also assure that a class action would recruit far greater numbers of modest-income plaintiffs.

IV

PHARMACEUTICAL CLASS ACTIONS IN PRACTICE

A. Overall Result

Despite the virtual guarantee of legions of average- to lower-income plaintiffs, however, class actions have not lived up to their promise in pharmaceutical torts. Plaintiffs must satisfy four requirements for a suit to proceed as a class action:

- (1) the class is so numerous that joinder of all members is impracticable, (2) there are questions of law and fact common to the class, (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class, and (4) the representative parties will fairly and adequately protect the interests of the class.⁴²

But, as one court recently observed, “[t]o date, no [federal] Court of Appeals decision has approved class certification of an action involving prescription drugs.”⁴³ In fact, in the past twenty-five years, all eleven federal circuits have

40. Joel S. Weissman et al., *Physicians Report on Patient Encounters Involving Direct-to-Consumer Advertising*, 2004 HEALTH AFF. (WEB EXCLUSIVES) W4-219.

41. Betsy Querna, *The Big Pill Pitch: Drug Companies Are Marketing Directly to Patients. Is This Empowering or Perilous?*, U.S. NEWS & WORLD REP., June 6, 2005, at 52.

42. FED. R. CIV. P. 23(a).

43. *In re Baycol Prods. Liab. Lit.*, 218 F.R.D. 197, 204 (D. Minn. 2003).

denied class certification in over forty prescription drug and medical device cases.⁴⁴

Such uniformity of precedent underscores the intent of the judicial system—to secure justice for *individual* parties, or to remedy shared grievances, not necessarily to promote *distributive* justice across broad socioeconomic groups. The following section illustrates why courts appropriately deny class certification on Rule 23(a) grounds to safeguard party interests, notwithstanding any regressive implications. As mentioned, the purpose here is to help determine whether reforms in the pharmaceutical tort adjudication process are a logical platform for distributive justice. The Rule 23(a) analysis indicates that the class action framework, arguably the most pertinent locus of inquiry because of its ability to rally the masses, does not avail itself as a promising candidate for change. The highly personalized nature of pharmaceutical litigation, as magnified through class certification review, encapsulates and highlights the problem with converting the justice system into a distributive justice system for health care.

B. Rule 23(a) Factors

1. Commonality of Facts

In most pharmaceutical torts, facts are highly individualized. Hundreds to thousands of putative class members took different doses of a product for different periods of time, whereas available scientific data may only suggest risk of a complication after certain durations of use or dose exposures. With the hormone therapy litigation, for instance, the seminal study that launched the litigation was the Women's Health Initiative (WHI) trial.⁴⁵ The study reported an increased risk of breast cancer in women taking combination estrogen and progestin hormone therapy, but only after an average of five years on therapy, and only among women who had used hormone therapy prior to enrolling in the study.⁴⁶ Furthermore, given that the hormone therapy formulation in the

44. Wyeth's Opposition to Motion for Class Certification at 1 n.2, In re Prempro Prods. Liab. Lit., No. 4:03CV1507 WRW (E.D. Ark. May 13, 2005) (citing federal and state cases) (on file with author).

45. Writing Group for the Women's Health Initiative Investigators, *Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women: Principle Results from the Women's Health Initiative Randomized Controlled Trial*, 288 JAMA 321 (2002). This was the first of several reports on the findings from the Women's Health Initiative trial. See also Dan Lynch, *Wyeth Fights Class Action Status for Prempro Suit in Miami*, DAILY BUS. REV., March 24, 2005, available at <http://www.law.com/jsp/article.jsp?id=1111572312001> (tracing the origins of the hormone therapy litigation to the Women's Health Initiative study).

46. Rowan T. Chlebowski et al., *Influence of Estrogen Plus Progestin on Breast Cancer and Mammography in Healthy Postmenopausal Women: The Women's Health Initiative Randomized Trial*, 289 JAMA 3243, 3248 (2003) (indicating in Table 2 that breast cancer risk increased to a statistically significant degree, *i.e.*, in a manner consistent with a true rather than a chance finding, only in women who 1) had been taking estrogen plus progestin during the trial for five years and 2) had taken hormone therapy prior to enrolling in the study). In Table 2, the ninety-five percent confidence intervals (95% CI) for the listed hazard ratios (HR) include 1.0 until year five. For example, the 0.60 HR in the bottom left corner of the table is associated with a 95% CI of 0.29-1.23, so the 95% CI includes 1.0 (the

WHI study contained 0.625 mg of conjugated equine estrogen (CEE) and 2.5 mg of progestin, but lower doses of hormone therapy are also available, how the findings of the WHI trial translate to plaintiffs who used lower dosages is less clear.⁴⁷ Even among class representatives, there were women who took other combination hormone therapies that varied in terms of dose as well as composition.⁴⁸ Finally, each plaintiff has a unique medical history and hence individual levels of risk. For example, women who have a history of breast cancer in their family, give birth to their first child after the age of thirty, or start menstruating before the age of twelve are at greater risk of developing breast cancer regardless of hormone therapy use.⁴⁹

All the foregoing variables address only causation, but the story becomes even more complex when a court considers other elements of plaintiffs' complaints, such as deceptive advertising, failure to warn, and detrimental reliance. Again, with the hormone therapy litigation, even if plaintiffs concentrated their attack on one manufacturer, in lieu of other makers of hormone therapy, each plaintiff would have seen only selected bits from a vast array of television, periodical, and other advertisements over the past decade that the product has been on the market—or none at all. Likewise, as science has evolved, so have the FDA-approved warnings that accompany the medication.⁵⁰

Lastly, with prescription drugs, the learned intermediary rule comes to bear. Unlike other products about which consumers can make decisions entirely on their own, access to prescription drugs must be through a learned intermediary—a physician. Under the learned intermediary doctrine, a manufacturer's duty to warn about a drug's risks runs to physicians, not to patients.⁵¹ A plaintiff therefore must show that in his or her own particular case “the inadequacy of the manufacturer's warning affected [the physician's] use of the product.”⁵² In other words, the plaintiff has to demonstrate that but for the company's alleged failure to warn, his or her physician would not have

low end of the confidence interval is 0.29 while the high end surpasses 1.0 to reach 1.23). *Id.* HRs are not increased to a statistically significant degree unless the low ends of their 95% CI exceed 1.0.

47. See DEP'T OF HEALTH & HUMAN SERV., NAT'L INST. OF HEALTH, NAT'L INST. ON AGING, UNDERSTANDING THE WOMEN'S HEALTH INITIATIVE STUDY OF USING ESTROGEN ALONE 1 (2004) (“Does using a different estrogen and/or progestin or another dose change the risk?”).

48. For example, some women took CEE versus other estrogens; the variance was similar with different progestins/progesterone. Wyeth's Opposition to Motion for Class Certification, *supra* note 44, at 13–14. Their durations of therapy also ranged from six months to more than eight years. *Id.* at 13.

49. American Cancer Society, Detailed Guide: Breast Cancer, http://www.cancer.org/docroot/CRI/content/CRI_2_4_2X_What_are_the_risk_factors_for_breast_cancer_5.asp (last visited June 18, 2006).

50. Since 1995 the Prempro labeling alone has changed nine times.

51. See *In re Norplant Contraceptive Prods. Liab. Lit.* 215 F. Supp. 2d 795, 803 (E.D. Tex. 2002) (“The learned intermediary doctrine provides an exception to the general rule imposing a duty on manufacturers to warn consumers about the risks of their products.”); see also *E.R. Squibb & Sons Inc. v. Farnes*, 697 So. 2d 825, 827 (Fla. 1997) (“Florida law requires that the manufacturer provide an adequate warning only to the physician, or ‘learned intermediary.’”).

52. *Alexander v. Danek Med. Inc.*, 37 F. Supp. 2d 1346, 1350 (M.D. Fla. 1999).

prescribed the medication in question. This burden of proof is already very individualistic based on personal medical history alone; physicians have to weigh a given patient's needs and risks to ascertain whether a drug would be appropriate. The learned intermediary rule complicates the picture by expanding the inquiry to include what any single prescriber knew about a drug, and upon which source(s) of information he or she relied. Physicians obtain drug information from myriad sources besides manufacturer labeling, including journal articles, textbooks, continuing medical education, and peer discussions, and each will put more or less stock in certain references.

In short, individual facts will generally overwhelm any commonalities between cases. This is true even when plaintiffs seek to certify a medical-monitoring subclass, as they frequently do in pharmaceutical torts. Plaintiffs in a would-be medical-monitoring subclass are patients who have consumed a product, but who have not developed the disease or complication purportedly connected with the product.⁵³ The essence of their grievance is that a drug elevated their risk of a bad outcome. They demand extra medical surveillance so that any allegedly product-related problems can be detected and managed swiftly. For instance, plaintiffs in the hormone therapy litigation unsuccessfully sought breast cancer screening beyond routine mammography.⁵⁴ Medical-monitoring claims may circumvent some of the case-by-case scrutiny necessary to assess causality in patients with manifest injuries, but plaintiffs must nevertheless establish that some sort of surveillance program beyond the standard of care can more readily detect a disease or condition. As the court in *Perez v. Metabolife International, Inc.* found, "This element demands individualized rulings, because many of the individuals would normally be recommended to undergo exactly the same diagnostic screenings and tests based on risk factors other than [a product's] use."⁵⁵

Returning to the hormone therapy example, even if such medications added to a woman's risk of breast cancer, her other combined risk factors—age at first menstruation, body weight, history of childbirth, genetic predisposition to breast cancer, and even alcohol intake—have largely predetermined the level of screening she should receive. Thus a physician must carefully evaluate whether an individual patient should undergo additional monitoring based on his or her own medical history. For most women, routine mammographies suffice.⁵⁶ To require more than annual mammography, a court, with assistance from medical

53. *Wyeth Inc. v. Gottlieb*, 930 So. 2d 635, 638 (Fla. Dist. Ct. App. 2006) (citing the trial court's definition of a medical-monitoring subclass to include asymptomatic women taking hormone therapy during a particular time period).

54. *Gottlieb v. Wyeth Inc.*, No. 02-18165 CA 32 (Fla. Cir. Ct. 2005), *rev'd*, *Wyeth Inc. v. Gottlieb*, 930 So. 2d 635 (Fla. Dist. Ct. App. 2006).

55. 218 F.R.D. 262, 272 (S.D. Fla. 2003).

56. Robert A. Smith et al., *American Cancer Society Guidelines for Breast Cancer Screening: Update 2003*, 53 CA: CANCER J. CLINICIANS 141, 143 (2003), available at <http://caonline.amcancersoc.org/cgi/content/abstract/53/3/141> (recommending earlier and more frequent mammographies for women at increased risk of breast cancer and noting that additional screening modalities are not justified by current evidence).

experts, would have to examine a woman's particular medical situation no less closely, particularly because extra testing can incur physical as well as pecuniary costs.⁵⁷

2. Commonality of Law

Courts have also denied class certification in mass pharmaceutical litigation because common issues of law do not predominate.⁵⁸ Choice-of-law rules mean that federal courts almost always apply the law of the state where a plaintiff resides and consumed a product.⁵⁹ Prescription drug liability cases involve patients from across the country. Hence, for nationwide or at least multistate pharmaceutical class actions, federal courts must discern and apply the laws of multiple jurisdictions. Not surprisingly, the laws of different states vary substantially. For example, some states do not recognize medical monitoring as a cause of action for uninjured plaintiffs (patients who have yet to develop the disease or condition associated with a product),⁶⁰ while others, such as Maryland, have yet to resolve the matter.⁶¹

If class certification were granted, such a disparate legal landscape would place a federal court in the difficult and inappropriate position of making state law and violating state sovereignty. As the *Rezulin* court observed,

Many states never have recognized a claim for medical monitoring, a circumstance that would force this Court into the undesirable position of attempting to predict how their courts of last resort would resolve that issue. Those states that have done so have adopted widely varying criteria for recovery. There simply is no justification for embarking on so complex a path.⁶²

57. For example, the screening itself may be invasive and therefore carry risks, such as the risk of infection with breast needle biopsies. In addition, a false positive—an assay registering positive for a disease or condition when the patient does not actually suffer from the disease or condition—can prompt further workup that subjects a patient to unwarranted and potentially hazardous procedures. With breast cancer, a false-positive biopsy can lead to excision of a lump, *i.e.*, extraneous surgery.

58. *See, e.g.*, *In re Rezulin Prods. Liab. Lit.*, 210 F.R.D. 61, 71 (S.D.N.Y. 2002) (“The Court finds that individual questions of fact and law predominate with respect to the alleged class, that the interest of members of the class in individually controlling the prosecution of claims is paramount and that very serious difficulties would be encountered in managing the putative class action were it certified. The Court therefore declines to certify the proposed class.”); *In re Baycol Prods. Liab. Lit.*, 218 F.R.D. 197, 208 (D. Minn. 2003) (“Differences in state law, no matter how slight, are important and must be determined prior to certification because such differences may swamp any common issues and defeat predominance.”) (internal quotations and citations omitted); *In re Propulsid Prods. Liab. Lit.*, 208 F.R.D. 133, 146 (E.D. La. 2002) (“The application of multiple state laws to a class makes manageability more difficult in both (b)(3) and (b)(2) class actions.”).

59. *See In re Rezulin Prods. Liab. Lit.*, 210 F.R.D. at 70 (“Critical liability questions therefore will presumptively be governed by the law of the states in which particular members of this million person putative class reside.”); *see also Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496 (1941) (holding that a district court presiding over a diversity-of-jurisdiction case must apply the choice-of-law principles of the forum state to determine what substantive law to apply).

60. *See, e.g.*, *Hinton ex rel. Hinton v. Monsanto Co.*, 813 So. 2d 827, 831–32 (Ala. 2001); *Henry v. Dow Chem. Co.*, 701 N.W.2d 684, 686 (Mich. 2005); *Badillo v. Am. Brands, Inc.*, 16 P.3d 435, 440 (Nev. 2001).

61. *Philip Morris Inc. v. Angeletti*, 752 A.2d 200, 251 (Md. 2000) (declining to decide whether medical monitoring should be recognized as a distinct cause of action under Maryland common law).

62. 210 F.R.D. at 74.

Similarly, with respect to actual injury claims, another court noted, “Some states do not recognize strict liability. Some have adopted *Restatement (Second) of Torts* § 402A. Among states that have adopted the Restatement, there are variations.”⁶³

3. Typicality

In general, the claims of putative class representatives are not typical of other class members. This finding seems inevitable in light of the attendant individual facts. Manufacturers have unique defenses on causation, learned intermediary, and other inquiries. Thus, resolving one representative’s dispute would not address the controversies inherent in another plaintiff’s case.

4. Adequacy

Moreover, the representative parties would not fairly and adequately protect the interests of the class. For one, each plaintiff will have incurred different injuries. Any disease or condition can be mild or severe, and it can affect patients medically, functionally, and socially to varying degrees. For instance, a heart attack, the prolonged deprivation of blood-borne oxygen to cardiac tissues, can result in mild cardiac impairment, can significantly limit physical activity and hence perhaps work capacity, or can kill a patient outright—either by itself, or in combination with other ailments or variables.

Furthermore, an adverse clinical outcome can occur through multiple mechanisms, some of which might bear a stronger connection to the medication in question. Revisiting the heart attack example, atherosclerotic buildup and narrowing of the arteries feeding the heart could lead to a cardiac event. Alternatively, cardiac arrhythmia (irregular electrical conductance in the heart) can trigger a sudden heart attack by affecting the organ’s ability to pump blood to its own tissues. Yet another mode of injury entails the rupture of an atherosclerotic plaque that can set off a rapid clotting reaction that occludes the blood supply to the heart. The latter two processes happen acutely, whereas narrowing the blood vessels supplying the heart takes place gradually. With Vioxx, these distinctions are crucial, since the data that instigated that litigation pertain to atherosclerotic rupture, not to atherosclerosis itself or to arrhythmia.⁶⁴ In addition, each injury pathway is influenced by a patient’s specific medical history. Consequently, it is unlikely that a given class representative will fairly and adequately safeguard just one other plaintiff’s interests, let alone those of hundreds or thousands of patients.

Similarly, with medical monitoring, it is problematic for plaintiffs to insist that they sustained the same injury. Indeed, plaintiffs’ attempts to certify a medical-monitoring subclass stem in part from the need to minimize the case-

63. *Castano v. Am. Tobacco Co.*, 84 F.3d 734, 743 n.15 (5th Cir. 1996) (citations omitted).

64. See Andrew Lawler, *Vioxx Verdict: Too Little or Too Much Science?*, 309 SCIENCE 1481, 1481 (2005) (pointing out that while some researchers believe Vioxx may accelerate clotting, “Vioxx or other COX-2 drugs have not been associated in any study with arrhythmia”).

by-case discrepancies that undermine class certification of claims for manifest diseases or conditions. To maintain this compartmentalization, however, plaintiffs must forfeit any future grievances they may have concerning a drug. In other words, should some of them eventually develop the affliction allegedly connected with a drug, they would be unable to seek compensation for the manifest injury itself. Otherwise, class members would not be cohesive. Some would essentially be suing over an elevated risk of an adverse event, while others would be suing for increased risk as well as for future complications.⁶⁵ Yet, because many states do not allow claim-splitting,⁶⁶ a medical-monitoring class cannot simply abandon any future restitution for concrete injury and still “fairly and adequately protect the interests of the class.”⁶⁷ As a matter of law, putative class representatives who surrender the claims of certain class members are inadequate for the purposes of Rule 23(a)(4).⁶⁸

C. Concluding Remarks on Pharmaceutical Tort Adjudication

On a final note, statewide class actions have failed at the certification stage on the same grounds—lack of commonality, typicality, and adequacy.⁶⁹ A court in Florida recently certified a medical-monitoring class, but the decision did not stand on appeal.⁷⁰ Again, overriding principles of equity and fairness on the individual level demand this result, despite issues of distributive justice. After all, although distributive justice affects individual justice,⁷¹ sacrificing individual justice for corporate justice merely replaces one insult with another.

Importantly, this is not to say that drug liability law offers little or no room for improvements that might affect distributive justice. For instance, the learned intermediary doctrine hinders the ability of pharmaceutical companies to make the sort of economizing decisions that Havighurst and Richman

65. And, of course, there would be no way to tell in advance which class members will or will not have problems down the road.

66. Claim-splitting occurs when a plaintiff petitions for one remedy in one suit (for example, medical monitoring) and later sues for other compensation (such as damages) over a related injury. See *In re Methyl Tertiary Butyl Ether (MTBE) Prods. Liab. Lit.*, 209 F.R.D. 323, 339 (S.D.N.Y. 2002) (noting that California, Florida, Illinois, and New York all prohibit claim-splitting).

67. FED. R. CIV. P. 23(a)(4).

68. *Thompson v. Am. Tobacco Co.*, 189 F.R.D. 544, 550–51 (D. Minn. 1999) (refusing to certify a medical-monitoring class because class representatives failed to assert claims for personal injury on behalf of absent class members). The court found that “the named Plaintiffs’ efforts to reserve personal injury and damage claims may, in fact, jeopardize the class members’ rights to bring such claims in a subsequent case. . . . Under Minnesota law *res judicata* principles apply ‘not only to every matter which was actually litigated, but also as to every matter which might have been litigated, therein.’ . . . This possible prejudice to class members is simply too great for the Court to conclude that the named Plaintiffs’ interests are aligned with those of the class.” *Id.* at 547–48 (citations omitted).

69. See, e.g., *Albertson v. Wyeth Inc.*, 2005 WL 1048779 (Pa. Com. Pl. April 26, 2005) (denying class certification).

70. *Wyeth Inc. v. Gottlieb*, 930 So. 2d 635, 638 (Fla. Dist. Ct. App. 2006).

71. Indeed, how can a person experience justice if he or she disproportionately shoulders society’s burdens?

advocate.⁷² To be precise, although the learned intermediary rule rightly recognizes that physicians function as gatekeepers for prescription medications, it limits a drug company's participation in "risk management." According to the FDA, risk management entails "a coordinated effort on the part of many partners in the public and private sectors," that is, government and the pharmaceutical industry, to "minimi[ze] the risks associated with use of medical products."⁷³ Experts believe success is predicated upon interventions extending beyond "the package insert and routine post-marketing surveillance" and requires "pharma companies to think through not only how a drug is supposed to be used—the indications, contraindications, precautions, and warnings—but also how it will be used or misused by prescribers, dispensers, and patients throughout its lifecycle."⁷⁴

In other words, it may not suffice for drug manufacturers to provide adequate data and warnings but ultimately defer to physician judgment in specific situations. Rather, the industry should "seek to *influence* the behavior of all the parties responsible for drug safety, particularly patients, physicians, pharmacists, and allied medical staff."⁷⁵ The dilemma is that if manufacturers attempt to influence prescriber behavior—not merely by disclosing the risks associated with a drug, but by affirmatively instructing physicians on when to use or not to use a drug—they may forfeit the protection of the learned intermediary doctrine. From a legal perspective, instead of exercising independent medical judgment, physicians would be relegated to mere vendors who follow industry instructions. If so, there would be no cognizable "learned intermediary." This hazard prevents the industry from urging physicians *not* to prescribe their products to patients with higher risk-benefit ratios, notwithstanding "doctor's intuition" or other idiosyncratic deviations that may or may not be valid for a specific patient. Such industry-driven, conservative prescribing practices could save on 1) potentially unwarranted consumption, 2) litigation expenses, and 3) liability costs that companies may pass on to consumers.⁷⁶

Nevertheless, the question is not whether drug liability standards are perfect, but whether these imperfections should command much attention in

72. Havighurst & Richman, *supra* note 2, at 75 n.200 (discussing, generally, the inability of providers to offer or encourage less health care).

73. U.S. Food & Drug Admin., Risk Management, <http://www.fda.gov/oc/mcclellan/riskmngt.html>.

74. *See, e.g.*, LOU MORRIS, THE RISK MANAGEMENT MANDATE, PHARMACEUTICAL EXECUTIVE 98, 100 (May 2004). Dr. Morris spent twenty-three years at the FDA and served as a member of the agency's Drug Safety and Risk Management Advisory Committee.

75. *Id.* at 100 (emphasis added).

76. Although it seems self-evident that greater caution in drug use would reduce unnecessary consumption and help prevent lawsuits, data are scarce on whether pharmaceutical companies pass litigation costs on to consumers. Nevertheless, the dearth of evidence has not halted speculation to that effect. *See, e.g.*, Scott Gottlieb, *More Drug Use Will Mean More Lawsuits*, AM. ENTERPRISE INST. ONLINE: ON THE ISSUES March 4, 2003, http://www.aei.org/publications/pubID.16306/pub_detail.asp ("Drugs can have unforeseen problems when administered to large and old populations, and the resulting lawsuits have been allowed to handcuff the pharmaceutical industry by limiting drug development and driving up drug prices.").

discussions about distributive justice. For example, with risk management, some might challenge whether a for-profit industry should be persuading physicians to practice medicine a certain way. Moreover, many physicians may not listen to manufacturers in the first place, either because they rely more on other sources of information, or because they simply distrust pharmaceutical companies. Amending the learned intermediary rule might thus accomplish very little. It may be better to concentrate on other means of physician education. The rationale for examining liability law is to see if the tort system should be a focus in efforts to eliminate socioeconomic disparities in health care. In light of the aforementioned medical—and legal—complexities inherent in pharmaceutical torts, it seems that overhauling class certification procedures and other laws pertinent to drug liability may unduly jeopardize individual justice without closing the gap between rich and poor. Indeed, as the next section explains, denial of class certification does not leave less-affluent pharmaceutical plaintiffs as desperate as their counterparts in medical malpractice.

V

DIFFERENCES BETWEEN MALPRACTICE AND PHARMACEUTICAL TORTS

A. Profit and Logistics

Class actions are not the primary drivers of mass pharmaceutical litigation.⁷⁷ Significant differences between medical malpractice suits and pharmaceutical torts help secure justice for the less wealthy in the drug liability context. First and foremost, pharmaceutical companies present attractive targets for plaintiffs and plaintiffs' attorneys alike. Not surprisingly then, lawsuits will fill court dockets regardless of class certification. Litigation has not ceased against Bayer over Baycol, for instance, and the cases against Merck continue to mount.⁷⁸ The sheer number of plaintiffs suggests that denial of class certification may dampen pharmaceutical mass torts only to a limited degree.

Also, in drug litigation, there is a tendency for plaintiffs' attorneys to proceed with more meritorious clients irrespective of the clients' wealth. With medical malpractice, because complaints normally involve an isolated occurrence or chain of events, even similar cases remain relatively separate from one another. Although the same sort of conduct might underlie several incidents, the cast of characters usually changes on both the plaintiff and the defendant sides.⁷⁹ Judicial resolution of one case may have some precedential value, but it would not influence successive disputes to the degree that a ruling

77. This is evident from the burgeoning products liability docket despite the near universal denial of class certification. *See text, infra.*

78. *Vioxx Trial*, *supra* note 29 (reporting that Merck faces 14,200 lawsuits).

79. *See, e.g., Daniel J. Penofsky, Gynecological Malpractice Litigation*, 64 Am. Jur. Trials 1 (2006) (summarizing malpractice cases that repeat themselves in the gynecological setting with different plaintiffs and defendants).

in a drug liability case would influence future contests over the same product. Plaintiffs' attorneys in pharmaceutical litigation will hence survey their pool of plaintiffs and put their best foot forward. As part of the selection process, plaintiffs' attorneys may even choose modest-income patients to win a jury's sympathy. For example, the first three Vioxx cases featured a Wal-Mart produce manager,⁸⁰ a postal worker,⁸¹ and a manager of a seafood wholesaler, respectively.⁸²

B. Advertising

Of course, what allows the marshaling of non-wealthy plaintiffs at the outset is advertising by both plaintiffs' attorneys and drug manufacturers. DTC marketing by pharmaceutical companies helps generate initial demand for a medication. A 2004 study by the FDA found "high levels of general awareness of DTC advertising."⁸³ Specifically, eighty-one percent of patients surveyed in 2002 recalled seeing or hearing a prescription drug advertisement.⁸⁴ Forty-three percent of the respondents sought more information on a drug after learning about it from DTC marketing, and eighteen percent reported that an advertisement prompted them to speak to a physician.⁸⁵ These figures do not indicate whether less-affluent patients initiated the bulk of the office inquiries, but drug manufacturers cannot afford to rely on consumption by wealthier patients alone. Through a combination of DTC marketing and providing information to prescribers, pharmaceutical companies sustain a sufficiently broad customer base.

In turn, such mass communication facilitates advertising by plaintiffs' attorneys. With the names of blockbuster medications firmly implanted in the American consciousness, plaintiffs' attorneys need only reference a drug for patients to recognize whether they might have a claim. To elaborate, the capacity to highlight a distinct opportunity for legal redress does not often exist for medical malpractice. General solicitations by plaintiffs' attorneys for "medical malpractice" or "negligent treatment" do not help patients ascertain whether they have suffered an injury. For example, a male patient may not realize that current screening guidelines recommend routine prostate exams

80. Kevin McCoy, *Merck to Face First Vioxx Trial Before Texas Jury Next Month*, USA TODAY, June 29, 2005, at 1B.

81. Marc Kaufman, *Merck Wins Vioxx Lawsuit: Firm Not Held Responsible for Heart Attack*, WASH. POST, Nov. 4, 2005, at D01.

82. Kevin McCoy, *Merck Faces First Hearing on Vioxx Today as Lawsuits Mount*, USA TODAY, Nov. 17, 2004, at 4B.

83. KATHRYN J. AIKIN ET AL., U.S. FOOD & DRUG ADMIN., PATIENT AND PHYSICIAN ATTITUDES AND BEHAVIORS ASSOCIATED WITH DTC PROMOTION OF PRESCRIPTION DRUGS—SUMMARY OF FDA SURVEY RESEARCH RESULTS 85 (2004).

84. *Id.* In 2002, 944 patients were surveyed, fifty-three percent of whom responded. *Id.* at 1.

85. *Id.* at 26.

starting at the age of fifty to help detect prostate cancer.⁸⁶ As Havighurst and Richman observe, this lack of knowledge disproportionately affects less-wealthy patients.⁸⁷ In contrast, it is much easier for any patient to know whether he or she has ever taken Vioxx and experienced a heart attack. Plaintiffs' attorneys only have to identify 1) the drug involved and 2) the alleged side effect.

Indeed, available data strongly suggest that the plaintiff bar's rallying cries do not fall on deaf ears, especially in tandem with the extensive media coverage that ordinarily surrounds products liability litigation. A 2003 Harris Interactive Poll conducted at the behest of the U.S. Chamber of Commerce Institute for Legal Reform revealed that eighty-six percent of 301 patients interviewed were aware of lawsuit advertisements concerning a particular drug.⁸⁸ Approximately one in five patients (twenty-one percent) had seen an advertisement for a medication they were taking.⁸⁹ If they were to see a lawsuit advertisement, nineteen percent would contact the sponsoring law firm.⁹⁰ Twenty-seven percent would join a suit even if they have not experienced any adverse reactions.⁹¹

V

DOWNSTREAM IMPACT

A. Patient and Physician Response

To be sure, pharmaceutical torts might exert regressive effects as well, albeit perhaps secondary to the actual litigation process and proceedings themselves. For instance, unwarranted fear sparked by news of litigation could prompt less-informed, maybe less-affluent patients to stop taking a medication even though the benefits exceed the risks.⁹² With drugs that need steady compliance for the best results, health considerations compound the injustice of decreased health care consumption by modest-income patients.

86. American Cancer Society, Overview: Prostate Cancer, How is Prostate Cancer Found, http://www.cancer.org/docroot/CRI/content/CRI_2_2_3X_How_is_prostate_cancer_found_36.asp?sitearea= (last visited Feb. 22, 2006).

87. See Havighurst & Richman, *supra* note 2, at 51 (noting that lack of information is precisely what allows providers to charge for more health care than less affluent patients would choose for themselves). The same informational disadvantage would cause less wealthy Americans not to notice standard care.

88. PHARMACEUTICAL LIABILITY STUDY, *supra* note 26, at 39.

89. *Id.* at 40.

90. *Id.* at 42.

91. *Id.* at 45.

92. Returning to the 2003 Harris Poll, twenty-five percent of patients would immediately stop taking a drug upon discovering that there is a lawsuit over the product. *Id.* at 42. Thirty-eight percent of the 201 physicians interviewed recalled patients who stopped taking medication despite the physicians' belief that the medication was appropriate. *Id.* at 26. Twenty-nine percent of prescribers also reported patients who declined treatment because of ongoing litigation. *Id.* at 27.

On the caregiver side, the threat of litigation could lead to “reverse defensive medicine”—where *less* care is delivered.⁹³ Offhand, it is unclear whether the rich or the poor would bear the brunt of such apprehension. Conventional wisdom might predict that physicians would not withhold treatment from more-affluent patients because they might be sued for refusing to administer care. Yet, the converse logic argues precisely the opposite. Physicians wary of legal problems might avoid giving a potentially litigation-prone drug to wealthier patients, in light of their greater purported predilection and capability to sue.

This lose-lose scenario raises further questions as to whether medical malpractice—in and of itself, or as a consequence of products liability—would increase or decrease the overall amount of care rendered. The bi-directionality of incentives might help to explain why the CBO could not confirm that various state restrictions on malpractice liability attenuated so-called “defensive medicine.”⁹⁴ If desire for profit and patient welfare are the main contributors to “extra” care, as the CBO proposes, then malpractice and pharmaceutical liability may not substantially increase net health care services, especially if physicians would offer more care in some situations but less in others.

Moreover, if malpractice concerns induce physicians to provide less care to higher-income patients, the adage that tort liability imposes regressive externalities on the health care system could prove false in two respects. First (and most obviously), because of litigation, higher-income patients, not the rest of America, might be the ones who receive less care. Second, the cloud of litigation could *reduce* health care services, not heap more care onto those who already consume too much. This can happen not just with prescription drugs, but with many other forms of medical interventions, including surgery.⁹⁵ Threat of litigation could actually decrease unnecessary care, saving on direct expenditures as well as morbidity costs.

Significantly, missed diagnoses are the leading cause of malpractice suits, comprising twenty-eight percent of total claims.⁹⁶ Nevertheless, even assuming that *all* such cases stem from omission of care or poor screening,⁹⁷ this twenty-eight percent or so of all malpractice suits 1) barely surpasses the twenty-seven percent due to surgical incompetence, impropriety, or post-operative complications, and 2) still falls well short of the combined number of lawsuits

93. The 2003 Harris Poll found that forty-three percent of physicians did not prescribe what they regarded as a clinically indicated drug due to worries that the medication might become embroiled in litigation. *Id.* at 23.

94. LIMITING TORT LIABILITY, *supra* note 13, at 5. Recall that the CBO attributes “defensive medicine” to profit motives and patient welfare. *Id.* at 6.

95. According to one study, “inappropriate or unnecessary surgeries” make up part of the twenty-seven percent of malpractice claims related to surgery. U.S. GEN. ACCOUNTING OFFICE, *supra* note 27, at 20–21.

96. *Id.*

97. This would exclude, for example, incompetence in reading X-rays and other possibilities.

that would not per se inspire more health care.⁹⁸ In short, risk of legal trouble may be greater with “improper” or “unnecessary” care and adverse reactions than with failure to provide care at all. The cumulative effect could be that “reverse defensive medicine”—withholding care that may cause litigation, either in the pharmaceutical, malpractice, or other contexts—outpaces extra care from traditional forms of defensive medicine. The question is whether reluctance to administer appropriate care might incur greater costs in the long run and whether the rich or the poor will suffer disproportionately as a result.

B. Industry Reaction

Manufacturer response to products liability could also have regressive repercussions, but the true overall effect is similarly unclear, even when litigation leads to concrete, identifiable changes in the industry. For instance, in the first half of 2005, drug advertising expenditures fell by 0.4% to \$2.25 billion as pharmaceutical companies cut back on DTC marketing in the face of “increased public and governmental scrutiny.”⁹⁹ How this might play out in distributive-justice terms depends in part on whether Americans were over-purchasing beforehand or consuming at medically commensurate levels—or maybe under-consuming. In addition, to some unknown degree, any savings that might be passed on to patients could be offset by the decrease in less-affluent plaintiffs. Recall that DTC promotion of medication use by the less wealthy simultaneously increases their participation in the legal process.

Likewise, with regard to drug prices, pharmaceutical companies could pass their losses and legal bills on to consumers.¹⁰⁰ On the other hand, liability encourages safety measures that reduce morbidity as well as future legal expenses. However, would circumstances differ appreciably without lawsuits? As with malpractice, there is reason to believe that reputation costs alone would deter manufacturers from endangering patient welfare. Also, all prescription medications must satisfy FDA safety standards before entering the stream of commerce. Given these circumstances, does products liability contribute dramatically to patient health?

Perhaps the more important issue is the availability of medications. The National Academy of Sciences at one point concluded that pharmaceutical torts chill innovation in areas such as contraception.¹⁰¹ Given that average- and lower-income patients represent the lion’s share of a drug market, reduced

98. That number consists of the twenty-seven percent due to surgery-associated disputes, the twenty-six percent from “improper treatment” allegations, and the nineteen percent alleging “adverse reactions” to anesthesia, injections, and other interventions. U.S. GEN. ACCOUNTING OFFICE, *supra* note 27, at 20–21.

99. TNS Media Intelligence, *U.S. Advertising Market Grows 4.5 Percent in First Half of 2005*, <http://www.tns-mi.com/news/09062005.htm> (last visited June 18, 2006). It does not seem far-fetched to presume that some of the scrutiny takes place in the courtroom.

100. See AIKIN ET AL., *supra* note 83.

101. NAT’L ACAD. OF SCIENCES, *DEVELOPING NEW CONTRACEPTIVES: OBSTACLES AND OPPORTUNITIES* 3–4 (1990).

production would translate into decreased consumption by the less affluent.¹⁰² However, others maintain that litigation does not suppress innovation and production, and that drug development decisions are predicated upon profitability and the size of the drug market.¹⁰³ Once again, therefore, the relevance of tort reform to distributive justice seems unsettled.

Of note, even if the drug pipeline continues unabated, litigation could still jeopardize patients, particularly the less educated and less wealthy. Many physicians, to say nothing of patients, believe that the scientific content in prescription drug labels has become needlessly complicated because of defensive behavior by pharmaceutical companies.¹⁰⁴ Of course, from the industry perspective, the hazards of allegedly incomplete labels are quite real. For example, in the hormone therapy litigation, plaintiffs have insinuated that FDA-approved warnings about breast cancer in general do not suffice as warnings about a rare subtype of breast cancer, even though physicians would not approach these tumors any differently and the cancer subtype has a better prognosis.¹⁰⁵ Such accusations may indeed inspire ever more detailed and complex drug labels that could prompt less-affluent, less-informed patients not to take clinically indicated medications, or to use them improperly. According to the FDA, approximately three hundred thousand preventable adverse events occur per year in the United States, many as a result of confusing medical information.¹⁰⁶

In response, the FDA recently promulgated new labeling rules that require manufacturers to highlight critical data in a concise manner while preempting

102. That is, if a product that targets a large segment of the population is never produced because of litigation concerns, most of the people deprived of the medication will be average Americans, not wealthy Americans. As Havighurst and Richman point out, more care is not necessarily better care, Havighurst & Richman, *supra* note 2, at 65 n.174 (noting that more care in the form of defensive medicine does not necessarily translate into better health outcomes), but the fact that certain socioeconomic groups may receive even less care than they might otherwise is still relevant to the issue of distributive justice.

103. 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, 417 (1996) (“In the pharmaceutical industry, little evidence exists showing a chilling effect on innovation, and some industry insiders have observed little effect of any kind from the threat of litigation. Potential profitability and the size of the drug market are the real sources of drug development decisions.”) (citations omitted). In other words, although litigation costs might reduce profitability, the decrease may be too inconsequential to keep a medication off the shelves.

104. PHARMACEUTICAL LIABILITY STUDY, *supra* note 26, at 20.

105. See, e.g., Fred Hutchinson Cancer Research Center, Breast Cancer, http://www.fhcr.org/research/diseases/breast_cancer/ (last visited Feb. 23, 2006) (qualifying the association between hormone therapy and lobular breast cancer—a rare variant of breast cancer—by noting that lobular cancers carry better prognoses). To date, no medical organization or society has advocated an approach for screening or treating lobular breast cancer that differs from the standard of care for breast cancer in general.

106. Press Release, U.S. Food and Drug Admin., FDA Announces New Prescription Drug Information Format to Improve Patient Safety (Jan. 18, 2006), <http://www.fda.gov/bbs/topics/news/2005/NEW01272.html>.

liability under state law for FDA-approved labels.¹⁰⁷ The preemption clause has drawn criticism from Democratic leaders who view the regulation as an unabashed attempt by the Republican administration to shield the pharmaceutical industry from liability.¹⁰⁸ Meanwhile, agency officials continue to insist, as they have across administration changes, that FDA review and approval of drug labels ensures the integrity of the information patients and physicians receive.¹⁰⁹ Thus, it seems policymakers concur that simpler, user-friendly labels will improve health care, but diverge as to whether patients injured by medications should recover damages if they can establish causation.¹¹⁰ That the crux of the disagreement concerns compensation for plaintiffs—and not the benefits of extra-judicial measures such as FDA oversight—serves as yet another reminder that tort litigation is first and foremost about individual justice, not distributive justice or other matters of public policy.

VI

CONCLUSION

To be sure, the foregoing discussion does not come close to a comprehensive overview of the possible ramifications of pharmaceutical products liability, let alone medical torts as a whole. Nonetheless, even this limited survey shows that tort law may not provide an effective or desirable means of rectifying socioeconomic disparities in health care.

As a final case in point, one of the current legal standards for proving that physician conduct or a particular drug or intervention caused a plaintiff's injury, the "substantial contributing factor" test,¹¹¹ may make it more difficult for less-affluent patients to prevail in court. Under this standard, a patient must demonstrate that, despite several other actual or potential contributors to his or her grievance, the alleged malpractice, medication, or intervention was a "substantial" causal link.¹¹² Modest-income patients may fight an uphill battle because, as Havighurst and Richman observe, they tend to receive less care and

107. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3933 (Jan. 24, 2006) (to be codified at C.F.T. pts. 201, 314 & 601).

108. FDA News, Democrats Consider Legislation to Halt Labeling Preemption, Jan. 23, 2006, http://www.fdanews.com/dailies/drugdaily/2_267/news/50910-1.html.

109. See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3934.

110. See Lisa Richwine (Reuters), *US FDA Limits Drug Liability in Label Revamp* (Jan. 19, 2006), available at <http://www.emedicine.com/news.asp?name=20060119rglt002.xml&page=all>. Expressing outrage over the preemption clause while acknowledging the benefits of the new labeling requirements, Senator Edward Kennedy said, "It's a typical abuse by the Bush Administration—take a regulation to improve the information that doctors and patients receive about prescription drugs and turn it into a protection against liability for the drug industry."

111. See RESTATEMENT (SECOND) OF TORTS § 431(a) (1965).

112. *Id.*

be in poorer health.¹¹³ They may hence have more risk factors that predispose them to the disease or condition that brought them to court.

Yet, altering the substantial contributing factor test would put the cart before the horse. The root of the problem is the poorer health of less-affluent patients. Unless and until that is remedied, the health disparity will persist irrespective of the likelihood for a legal victory. Moreover, the win would come at the cost of justice for the defendants. They may pay even though other variables caused the plaintiffs' maladies. This could itself exacerbate socioeconomic disparities if physicians and pharmaceutical companies pass these expenses on to patients.

Fundamentally then, Havighurst and Richman were correct in saying, "It is, of course, not obvious how a system that permits injured patients to recover large amounts of money from professionals and elite institutions might ultimately serve the interests of the latter groups,"¹¹⁴ or at least disproportionately burdens the less well off. However, the end result is not obvious for reasons that are beyond the scope of their article. First, the downstream implications of tort reform are unclear. For example, would curbing or even outright eliminating tort liability address "defensive medicine" if profit motives are the real culprit? Does litigation, or the threat thereof, significantly influence drug safety, or do reputational costs and FDA supervision sufficiently protect consumers? Havighurst and Richman are right to note that medical torts may be a non-trivial source of distributive injustice,¹¹⁵ but they themselves appropriately await additional empirical evidence before issuing a verdict.

Second, it is not obvious that amending the legal framework would appreciably level the playing field or bring about a more equitable state of affairs. The notoriety and financial allure of pharmaceutical torts helps lower- and average- income patients secure legal representation, and capping economic damages would not help less-wealthy malpractice victims recognize or pursue their claims. Adjusting the class certification procedure, income-based compensation, or other facets of adjudication may lead only to individual injustice—an ironic consequence when distributive justice is itself predicated on fairness to the individual. After all, distributive injustices are deplorable precisely because individuals shoulder a greater load than fairness would warrant.

Should a medical regime in which "you get what you pay for" entail that "you *don't* get what you sue for"? Unless further research yields compelling support for sacrificing individual merit for the common good, policymakers

113. Havighurst & Richman, *supra* note 2, at 42.

114. Havighurst & Richman, *supra* note 2, at 64.

115. See JOINT ECON. COMM., LIABILITY FOR MEDICAL MALPRACTICE: ISSUES AND EVIDENCE, REP., 108th Cong., at 6 (2003), available at <http://www.house.gov/jec/tort/05-06-03.pdf> (estimating that in 2001, malpractice added \$350 to the health insurance premiums paid by a family of four).

should look to extra-judicial solutions for socioeconomic disparities in health care instead of converting the justice system into a distributive justice system.