This Is Your Products Liability Restatement on Drugs

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[I]ll health offers adventure; no one has a better chance to live dangerously than the ill who must take their medicine.
–Roger Traynor[1]

I. INTRODUCTION

Lawsuits against the manufacturers of drugs and medical devices have become increasingly important in the last few decades, both in their volume and in the conceptual challenges that they have presented,[2] and courts have created a variety of special rules to accommodate products liability litigation against the sellers of medical technologies.[3] The work of the American Law Institute (ALI) has played an important role in this process, though so far the special provisions of the *Products Liability Restatement* applicable to prescription drugs and devices have had little discernable impact. These provisions have, however, provoked a great deal of scholarly commentary, and the few courts to consider the issue have uncritically relied upon the published critiques. As explained at length herein, I find little merit in most of these negative assessments, though I point out a number of flaws, ambiguities, and arguable inconsistencies in the new *Restatement*'s special provisions that seemingly no one else has identified.

This Article attempts to offer a comprehensive evaluation of the various facets of the *Products Liability Restatement* that relate to medical technologies, and it does so from a perspective rooted in the regulatory as opposed to the doctrinal challenges posed by these products. Part II addresses production defects, focusing on the heated debate over what

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[1] Roger J. Traynor, *The Ways and Meanings of Defective Products and Strict Liability*, 32 TENN. L. REV. 363, 368 (1965).

[2] *See* Alex Berenson, *Drug Industry Braces for New Suits over Even More of Its Products*, N.Y. TIMES, Apr. 22, 2006, at C1 ("As Merck reels from 11,500 suits over Vioxx, its arthritis drug, the rest of the industry is girding for challenges over another half a dozen widely used [and still marketed] medications [including Seroquel, Ortho–Evra, Prempro, and Fosamax] that plaintiffs' lawyers say have hidden and severe side effects or were improperly marketed."); *id.* ("Eli Lilly agreed to spend $700 million to settle 8,000 lawsuits over Zyprexa . . . . Wyeth has spent $15 billion since 1998 to resolve lawsuits over its fen-phen diet-drug combination . . . ."); Lisa Girion, *State Vioxx Trial Is Set as Drug Suits Boom; An Explosion in Litigation Spurs Calls for Legal Reform and Regulatory Changes*, L.A. TIMES, June 27, 2006, at C1 (calling "the pharmaceutical industry the nation's No. 1 target of product liability lawsuits," adding that "[m]ore than 71,000 drug lawsuits have been filed in federal courts since 2001 and . . . now account for more than a third of all product liability filings"); Julie Schmit, *More Drugs Get Slapped with Lawsuits*, USA TODAY, Aug. 23, 2006, at 3B.

[3] *See* LARS NOAH, LAW, MEDICINE, AND MEDICAL TECHNOLOGY chs. 5–8 (2d ed. 2007); M. Stuart Madden, *The Enduring Paradox of Products Liability Law Relating to Prescription Pharmaceuticals*, 21 PACE L. REV. 313 (2001) (describing at length some of the older case law). Classic treatments of the subject include Richard A. Merrill, *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1, 29–50, 87–120 (1973), and Paul D. Rheingold, *Products Liability—The Ethical Drug Manufacturer's Liability*, 18 RUTGERS L. REV. 947, 970–1018 (1964).

standards to use in deciding whether a prescription drug suffers from a defective design. Part III considers defects related to the information that accompanies prescription drugs, especially those advertised directly to consumers. Finally, Part IV touches on some of the peculiar issues raised by investigational products, generic drugs, prescription medical devices, and the duties of non-manufacturing sellers.

II. FLAWS IN PRODUCTION

A product must have some sort of defect before an injured consumer may recover damages from the manufacturer or other member of the chain of distribution. This Part discusses, in turn, manufacturing and design defect claims against pharmaceutical manufacturers. It reviews several case studies that other commentators have offered, concluding that the most important potential design feature relates to the manner in which sellers restrict access to pharmaceutical products.

A. Manufacturing Defects

The *Products Liability Restatement* uses the same standard to define manufacturing defects in prescription drug and medical device cases as it does for other consumer goods.[4] Thus, if a product falls out of specifications for any reason, then it has a defect (a true strict liability standard).[5] Manufacturing defect claims involving pharmaceuticals, such as instances of product contamination, generally pose few difficulties for courts.[6] As with other types of consumer goods, however, plaintiffs may have to rely on circumstantial evidence of such flaws, seeking an inference of defectiveness from the occurrence of an obvious malfunction.[7] Although patients injured by medical devices may rely on a product malfunction approach,[8] injuries associated with drug products

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[4] *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(b)(1) (1998) (cross-referencing § 2(a), which provides that a product "contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product").

[5] *See, e.g.*, Transue v. Aesthetech Corp., 341 F.3d 911, 917–20 (9th Cir. 2003) (holding that the trial judge erred in failing to use a strict liability instruction on a manufacturing defect claim involving silicone-gel breast implants); *id.* at 919 (quoting *Products Liability Restatement* § 6 comment c as further support).

[6] *See, e.g.*, *In re* Copley Pharm., Inc., "Albuterol" Prods. Liab. Litig., 158 F.R.D. 485, 487–88 (D. Wyo. 1994) (certifying a class action on behalf of patients who were injured by bacterial contamination of four batches of a bronchodilator drug later recalled by the manufacturer); *see also* Martin v. Am. Med. Sys., Inc., 116 F.3d 102, 103, 105 (4th Cir. 1997) (allowing a patient to pursue a breach of express warranty claim for an implant that was not sterile); Ferren v. Richards Mfg. Co., 733 F.2d 526, 527–28, 530–31 (8th Cir. 1984) (affirming judgment for plaintiff where metal defect in hip implant caused injury). *But cf. infra* notes 332–334 and accompanying text (discussing questions about the line between manufacturing and design defects in connection with tainted blood products and contaminated heparin).

[7] *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 3 & cmt. b (1998).

[8] *See, e.g.*, McCorvey v. Baxter Healthcare Corp., 298 F.3d 1253, 1258–60 (11th Cir. 2002) (balloon catheter burst); Oja v. Howmedica, Inc., 111 F.3d 782, 792–93 (10th Cir. 1997)

rarely lend themselves to this sort of an analysis: given the variability in patient response and the inevitably of unexpected adverse events, a seemingly inexplicable failure of a metabolized chemical hardly bespeaks some deviation from the manufacturer's specifications.

B. Design Defects

As for claims of defective designs in pharmaceuticals, section 6(c) of the *Products Liability Restatement* provides as follows:

> A prescription drug . . . is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug . . . are 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 . . . for any class of patients.[9]

As elaborated in the accompanying comment, this language sought to create a "very demanding objective standard, [and] liability is likely to be imposed only under unusual circumstances."[10] As the Reporters' notes explained, "[s]ection 6(c) is a significant departure from the general defective design rules . . . , in recognition of the unique characteristics of prescription drugs."[11]

In adopting section 402A of the *Restatement (Second) of Torts* more than thirty years earlier, the ALI had attempted to address these issues in comment k ("unavoidably unsafe products"),[12] which generated much confusion among courts and commentators.[13] In resolving design

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(reversing a directed verdict against a plaintiff's manufacturing defect claim involving a hip implant); Parkinson v. Guidant Corp., 315 F. Supp. 2d 741, 750–51 (W.D. Pa. 2004) (allowing plaintiff to request *res ipsa loquitur* instruction to provide inference of manufacturing defect where a guidewire fractured during angioplasty); *cf.* Fane v. Zimmer, Inc., 927 F.2d 124, 129–32 (2d Cir. 1991) (affirming a directed verdict for manufacturer where a metal brace may have broken because of patient misuse); Mozes v. Medtronic, Inc., 14 F. Supp. 2d 1124, 1128–29 (D. Minn. 1998) (rejecting *res ipsa loquitur* where a manufacturer of pacemaker leads offered numerous post-sale explanations for failure); Fulton v. Pfizer Hosp. Prods. Group, Inc., 872 S.W.2d 908, 910–12 (Tenn. Ct. App. 1993) (reversing judgment for a plaintiff because no evidence supported the inference that some manufacturing defect caused the pegs in a knee replacement to shear off).

[9] RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(c) (1998) (omitting parallel references to "medical device").

[10] *Id.* cmt. f ("[A]s long as a given drug . . . provides net benefits for a class of patients, it should be available to them, accompanied by appropriate warnings and instructions. Learned intermediaries must generally be relied upon to see that the right drugs . . . reach the right patients.").

[11] *Id.*

[12] *See* RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965). As the Reporter later explained:

> 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.

WILLIAM L. PROSSER, HANDBOOK OF THE LAW OF TORTS 661 (4th ed. 1971) (footnotes omitted).

[13] *Compare* Hackett v. G.D. Searle & Co., 246 F. Supp. 2d 591, 595 (W.D. Tex. 2002) (exempting all FDA-approved prescription drugs from design defect scrutiny), Grundberg v. Upjohn

defect claims against prescription (Rx) drug manufacturers, a few courts preferred to apply the warranty-inspired consumer expectations approach,[14] which the *Products Liability Restatement* rejects as a freestanding test for any products other than foods.[15] Other courts employed a risk-utility standard in such cases,[16] which section 2(b) of the new *Restatement* endorses for all other types of consumer goods, including nonprescription drugs.[17]

One year before getting underway with work on the *Products Liability Restatement*, the future Reporters summarized the problems with trying to make sense of comment k: "Case law that is unintelligible cannot be intelligently restated. There is a need in this area to clarify the issues and to provide direction to the courts as to how this very special

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Co., 813 P.2d 89, 92–99 (Utah 1991) (same), and Young v. Key Pharm., Inc., 922 P.2d 59, 64–65 (Wash. 1996) (plurality), *with* Shanks v. Upjohn Co., 835 P.2d 1189, 1197–98 (Alaska 1992) (declining to adopt comment k). *See generally* Richard C. Ausness, *Unavoidably Unsafe Products and Strict Products Liability: What Liability Rule Should Be Applied to the Sellers of Pharmaceutical Products?*, 78 KY. L.J. 705 (1990); Victor E. Schwartz, *Unavoidably Unsafe Products: Clarifying the Meaning and Policy Behind Comment k*, 42 WASH. & LEE L. REV. 1139 (1985).

[14] *See, e.g.*, Allison v. Merck & Co., 878 P.2d 948, 951–56, 961 (Nev. 1994) (plurality) (rejecting comment k in a case where a vaccine allegedly caused encephalitis, opting instead for the consumer expectations test or a product malfunction theory); *cf.* Castrignano v. E.R. Squibb & Sons, Inc., 546 A.2d 775, 780–82 (R.I. 1988) (treating comment k as an affirmative defense that allows the manufacturer to respond to a consumer expectations based design defect claim with risk-utility balancing). *But see* Brown v. Superior Court, 751 P.2d 470, 477–78 (Cal. 1988) (explaining that the consumer expectations test has no place in cases involving Rx drugs).

[15] *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(b) & cmts. f–h (1998); *id.* § 7. Because the Reporters put so much emphasis on differential marketing to justify section 6(c), one should note that physicians may "prescribe" nutritional (non-drug) products to treat patients with special dietary needs. *See* 21 U.S.C. § 360ee(b)(3) (2006) (defining "medical food" as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation"); 21 C.F.R. § 101.9(j)(8) (2008) (elaborating on the definition); Symposium, *Medical Foods: Their Past, Present, and Future Regulation*, 44 FOOD DRUG COSM. L.J. 461 (1989); *cf.* Lambert v. Yellowley, 272 U.S. 581, 589–97 (1926) (upholding a Prohibition-era federal law that allowed for the medicinal use of certain liquors only when prescribed by a physician who had a special permit and only in strictly limited quantities).

[16] *See, e.g.*, Doe v. Solvay Pharm., Inc., 350 F. Supp. 2d 257, 266–68 (D. Me. 2004) (quoting *Products Liability Restatement* § 6, but retaining a risk-utility standard); *Shanks*, 835 P.2d at 1196–97; Savina v. Sterling Drug, Inc., 795 P.2d 915, 925–27 (Kan. 1990).

[17] *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(b) & cmt. k (1998). Some courts have used the consumer expectations test in such cases. *See* Green v. Smith & Nephew AHP, Inc., 629 N.W.2d 727, 741–55 (Wis. 2001) (rejecting the risk-utility standard on a design defect claim against the seller of latex gloves used by health care workers, and holding that the defendant would face liability even if it could not have known of the risk of allergic reactions at the time of sale); *see also* West v. Johnson & Johnson Prods., Inc., 220 Cal. Rptr. 437, 458 (Ct. App. 1985) (allowing a plaintiff to use the consumer expectations test in a design defect claim against the manufacturer of a tampon that caused toxic shock syndrome). In jurisdictions that continue to use both tests for design defect, some courts allow plaintiffs to use a risk-utility standard because otherwise an adequate warning might defeat a design claim based on consumer expectations. *See* Reece v. Good Samaritan Hosp., 953 P.2d 117, 122–23 (Wash. Ct. App. 1998); *cf.* Haddix v. Playtex Fam. Prods. Corp., 138 F.3d 681, 684–86 (7th Cir. 1998) (affirming summary judgment for a tampon manufacturer because the plaintiff could not opt to use the risk-utility test for such a simple product and her design defect claim failed under the consumer expectations test where the labeling included a clear warning of the risk of toxic shock syndrome).

genre of cases can be sensibly approached."[18] Instead of asking whether a reasonable alternative design (RAD) exists, the new test asks whether a fully-informed health care provider would ever select the product for any class of patients. Although a good deal clearer than its predecessor, section 6(c) of the *Products Liability Restatement* has proven to be no less controversial or subject to misunderstanding.[19]

Insofar as the availability of safer substitutes undoubtedly would impact a reasonable physician's decision, section 6(c) does not differ so terribly from the risk-utility test of section 2(b).[20] In a subsequent article, the Reporters clarified that RADs would remain relevant in this limited fashion.[21] They clearly meant, however, to avoid a test that focused on

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[18] James A. Henderson, Jr. & Aaron D. Twerski, *A Proposed Revision of Section 402A of the* Restatement (Second) of Torts, 77 CORNELL L. REV. 1512, 1545 (1992); *see also id.* at 1537 ("[Comment k] is poorly drafted and inter[n]ally inconsistent. . . . To draw on comment *k* as authority to resolve problems that no one even contemplated at the time of its adoption is sheer foolishness.").

[19] *See* George W. Conk, Essay, *Is There a Design Defect in the* Restatement (Third) of Torts: Products Liability*?*, 109 YALE L.J. 1087, 1089 (2000) (arguing that section 6(c) "demands less than reasonable care from manufacturers of drugs" and that "the rule will create a dangerous chasm in the tort law and ultimately will undermine the credibility of the ALI"); *id.* at 1106 (complaining that "the ALI adopted section 6(c) without benefit either of floor debate or of a solid bedrock of judicial decisions"); 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, 91–110 (1994); William A. Dreier, *Manufacturers' Liability for Drug and Medical Devices Under the* Restatement (Third) of Torts: Products Liability, 30 SETON HALL L. REV. 258 (1999); Teresa Moran Schwartz, *Prescription Products and the Proposed* Restatement (Third), 61 TENN. L. REV. 1357, 1365–68, 1378–85 (1994); 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 (2005); 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 (1997); *see also* Frank J. Vandall, *The American Law Institute Is Dead in the Water*, 26 HOFSTRA L. REV. 801, 809–10 (1998) (complaining that section 6(c) "reads as if it were written by a lobbyist for the pharmaceutical companies"). This generally unflattering reception generated a pair of responses penned by the Reporters. *See* James A. Henderson, Jr., *Prescription Drug Design Liability Under the Proposed* Restatement (Third) of Torts*: A Reporter's Perspective*, 48 RUTGERS L. REV. 471 (1996); James A. Henderson, Jr. & Aaron D. Twerski, Essay, *Drug Designs* Are *Different*, 111 YALE L.J. 151, 180 (2001) (noting that section 6 "has become a lightning rod for criticism"); *id.* ("[W]e plead guilty to the charge that we did not restate existing case law. One could hardly be expected to restate gibberish. Instead, we opted for a fresh look at the question of design liability for prescription products . . . ."); *see also* Michael D. Green, *Prescription Drugs, Alternative Designs, and the* Restatement (Third)*: Preliminary Reflections*, 30 SETON HALL L. REV. 207 (1999) (staking out a middle ground in the debate).

[20] In this sense, it also might align closely with the older case-by-case approach to deciding whether to apply section 402A comment k (or, for that matter, the retention of negligence claims for design defect in jurisdictions applying comment k across the board). *See, e.g.*, Toner v. Lederle Labs., 732 P.2d 297, 306–11 (Idaho 1987). It might even align with the older consumer expectations test, at least insofar as the question gets asked from the perspective of a fully-informed health care professional. *See Shanks*, 835 P.2d at 1195; *see also* Henderson & Twerski, *supra* note 19, at 177–78 ("[A] patient *never* actually expects to suffer a devastating side-effect from taking a drug that is supposed to be beneficial. . . . [and,] assuming adequate warnings have been given, a reasonable, intelligent prescribing physician *always* expects that, over the run of patients, warned-against side-effects will occur.").

[21] *See* Henderson & Twerski, *supra* note 19, at 155 (conceding that "some of the relevant language in both the blackletter of, and comments for, section 6(c) is ambiguous"); *id.* at 155–56 ("Obviously, such a reasonable provider should consider available alternative drugs in deciding which drug, if any, to prescribe. Indeed, that may be said to be the essence of the healer's craft—assessing and comparing all available courses of medical treatment."); *id.* at 152 ("Plaintiffs may

the availability of hypothetical RADs in part because full substitutability seemed far harder to predict in this context: the Reporters insisted that a purported RAD serve all potential classes of patients, and they rejected any reference to Rx drugs that had not yet received approval from the Food and Drug Administration (FDA).[22]

Taking a cue from the medical profession promised a firmer basis for making such tricky judgments,[23] especially when coupled with an assumption of full information.[24] The Reporters had in mind an aspirational rather than simply a custom-based standard,[25] even though,

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establish defectiveness by showing that safer alternative drugs were available on the market that reasonable health care providers would have prescribed in place of a defendant's drug for all classes of patients."). In his rejoinder to their response to his essay, Mr. Conk cried foul. *See* George W. Conk, *The True Test: Alternative Safer Designs for Drugs and Medical Devices in a Patent–Constrained Market*, 49 UCLA L. REV. 737, 739 (2002) (expressing "surpris[e]" at the "new, expansive construction of the rule"); *id.* at 740 (observing that no one else previously had interpreted section 6(c) in this way); *id.* at 744–45 ("If both prescription drugs and medical devices were intended to be vetted for defective design by comparison to other products on the market—why doesn't the Restatement say so plainly? A blackletter rule that leads careful observers to conclude that the Restatement rejects such analysis is defective . . . ."). Even before I read their dueling essays, this point struck me as fairly obvious: after all, two of the three decisions cited in the accompanying Reporters' notes had engaged in precisely such a comparison (before finding that the purportedly safer available alternatives failed to serve the needs of all classes of patients), though the third decision (and the only one finding a defective design) had not done so. *See infra* Part II.C.1. Moreover, an article published in 1994 had seen this type of RAD analysis as one possible interpretation. *See, e.g.*, Schwartz, *supra* note 19, at 1383 (doubting, however, that the Reporters had intended such a broad reading of the proposed standard that eventually became section 6(c)).

[22] *See* Henderson & Twerski, *supra* note 19, at 158. This led one persistent critic to assail their "endorsement of custom" as satisfying the industry's standard of care. *See* Conk, *supra* note 21, at 746; *see also id.* at 746–49; *id.* at 751 (objecting to section 6(c)'s "cramped approach" to design defects); *id.* at 753–54 (arguing that a malpractice-inspired "lower standard is inconsistent with the thrust of modern products liability law"); *id.* at 755 ("The new Restatement's lax standard for prescription drug and medical device design liability requires less than reasonable care."). Mr. Conk preferred a test allowing a plaintiff to base a design defect claim on expert testimony that a "postulated alternative has a reasonably good chance of withstanding FDA review." *Id.* at 761.

[23] Commentators who worry about this approach leave me perplexed. *See, e.g.*, Schwartz, *supra* note 19, at 1382 ("Clearly, medical practice should not be the basis for determining the safety of pharmaceutical products."). Clearly, she would prefer that juries make these judgments without taking any cue from medical professionals (or regulatory officials)! *See id.* at 1383 ("[I]t would seem more straightforward and less confusing to ask [the fact finder] whether a reasonable manufacturer . . . would have put the product on the market. This approach, at least, would reduce the risk of the medical custom becoming the liability standard for design claims." (footnote omitted)).

[24] If the labeling fails to fully inform physicians, then the plaintiff will have an inadequate warning claim. *See* Henderson, *supra* note 19, at 493 ("[M]assive misprescription of drugs and medical devices almost certainly must be caused by defendants' providing inadequate warnings to medical care providers."); *see also id.* at 483 (arguing that, under such circumstances, there should be "joint responsibility of the prescribing physicians, for misprescribing obsolete drugs, and of the drug industry for continuing to promote the prescription and consumption of such drugs"). Allowing a design defect claim under this standard would serve no independent purpose. *See id.* at 493 (challenging critics "to try to compose a list of reported decisions in which defective design is the only basis for liability, not undercut by failure to warn"); *see also* Henderson & Twerski, *supra* note 19, at 171; *cf.* Neade v. Portes, 739 N.E.2d 496, 500–03 (Ill. 2000) (dismissing claims for breach of fiduciary duty as duplicative of malpractice claims).

[25] *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(c) cmt. f (1998) ("That some individual providers do, in fact, prescribe defendant's product does not in itself suffice to defeat the plaintiff's claim. Evidence regarding the actual conduct of health-care providers, while relevant and admissible, is not necessarily controlling."). Thus, the mere fact of widespread (and perhaps

in practice, a fully-informed health care provider represents a largely unattainable ideal.[26] In cases involving genuinely—and, if properly labeled, unabashedly—worthless and dangerous drugs,[27] plaintiffs should have no particular difficulty finding qualified experts willing to testify that no reasonable physician would have used such a drug in any class of patients,[28] which, apart from a malpractice claim against the prescribing physician, would provide the basis for a design defect claim unless the manufacturer nonetheless managed to identify such a class.[29]

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misinformed usage) would not defeat testimony from an expert for the plaintiff that these patterns reflected irrational prescribing. *Cf.* Philip G. Peters, Jr., *The Role of the Jury in Modern Malpractice Law*, 87 IOWA L. REV. 909, 912–21 (2002) (describing the shift away from a custom-based standard of care); *id.* at 958–61, 966–69 (applauding the movement to a reasonable physician standard). *See generally* Symposium, *Empirical Approaches to Proving the Standard of Care in Medical Malpractice Cases*, 37 WAKE FOREST L. REV. 663 (2002).

[26] *See* Lars Noah, *Medicine's Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community*, 44 ARIZ. L. REV. 373, 376, 381–84, 391–95, 402–06, 421–22, 432–33, 438–40, 465 (2002); *see also* Karen E. Lasser et al., *Adherence to Black Box Warnings for Prescription Medications in Outpatients*, 166 ARCHIVES INTERNAL MED. 338, 342 (2006); Andrea Petersen, *How Drug Alerts Trickle Down to Your Doctor: Amid Flurry of Red Flags About Serious Side Effects, Prescribing Turns Trickier*, WALL ST. J., Sept. 15, 2004, at D4 ("[R]esearch underscores how difficult it is for doctors to stay on top of the mass of drug information, and decide how or whether to act. The number of drugs has exploded in recent years, so there are simply more side effects and potential drug-to-drug interactions to keep track of."); Jonathan D. Rockoff, *Doctors Buried by Drug Data; Volume of Advisors from the FDA Has Some Seeking Clarity from Private Sources*, BALT. SUN, Apr. 7, 2006, at D1.

[27] *See* Harvey L. Kaplan et al., *Third Restatement: New Prescription for Makers of Drugs and Medical Devices*, 61 DEF. COUNS. J. 64, 73 (1994); Aaron D. Twerski, *From a Reporter's Perspective: A Proposed Agenda*, 10 TOURO L. REV. 5, 17–18 (1993) (explaining that in the case of drugs with "no social utility for even a discreet group of patients[,] . . . the manufacturer clearly would have a duty to warn that the drug simply does not function or does not have a particularly good use"). Of course, it seems entirely implausible that the labeling for an FDA-approved drug would ever contraindicate use in all potential classes of patients.

[28] In recent years, and putting aside the regular condemnations from Ralph Nader's associates, *see, e.g.*, Marilyn Chase, *Consumer Crusader Sidney Wolfe, M.D., Causes Pain to FDA, AMA and the Health Industry*, WALL ST. J., Apr. 7, 1992, at A18, a number of prominent physicians have assailed drug approval decisions by the FDA, *see, e.g.*, Diedtra Henderson, *Watchdog Draws Growls in Return: Cardiologist–FDA Adviser Says His Goal Is Drug Safety; Critics Say He's Bucking to Run Agency*, BOSTON GLOBE, June 5, 2007, at C1 (discussing Dr. Steven Nissen from the Cleveland Clinic). Indeed, it has become increasingly fashionable to berate the FDA and the drug industry in the pages of leading medical journals. *See, e.g.*, Eric J. Topol, *Failing the Public Health—Rofecoxib, Merck, and the FDA*, 351 NEW ENG. J. MED. 1707 (2004); *see also* Linda A. Johnson, *Doctors Fed up with Drugmakers' Tactics*, STAR-LEDGER (NEWARK), Sept. 11, 2008, at Bus.26 ("Just about every segment of the medical community is piling on the pharmaceutical industry these days . . . . Recent articles and editorials in major medical journals blast the industry."); Karl Stark, *JAMA Articles Say Merck Used Vioxx Ghostwriters*, PHILA. INQUIRER, Apr. 16, 2008, at C1 (describing a pair of articles published in the *Journal of the American Medical Association* that lambasted Merck's research, adding, however, that "[s]everal of the JAMA authors had consulted for plaintiffs' attorneys").

[29] *See* Madsen v. Am. Home Prods. Corp., 477 F. Supp. 2d 1025, 1034, 1037 (E.D. Mo. 2007) (assuming that, because the Iowa Supreme Court previously had adopted *Products Liability Restatement* §§ 1–2, it would use section 6 to resolve informational and design defect claims against the manufacturer of fenfluramine and dexfenfluramine, and granting the defendant summary judgment on the design defect claim in light of uncontested testimony that some physicians would have continued prescribing these withdrawn diet drugs to some of their obese patients even after learning of the risk of valvular heart disease); Savina v. Sterling Drug, Inc., 795 P.2d 915, 926 (Kan. 1990) ("Although Pantopaque was preferred by some radiologists for limited situations, the testimony of the experts established that Amipaque, containing metrizamide, was the preferred contrast agent at the time of plaintiff's myelogram. Later, preference for metrizamide was replaced

By asking what a reasonable physician would select, the test presumably did not mean fully-informed only about the risks and benefits of the particular drug; instead, it imagined an expert with knowledge about the peculiar needs of the patient as well as perspective about the entire range of (drug and non-drug) options available for treatment.[30] Thus, section 6(c) has less to do with reasonable alternative designs than with the broader (though related) question of substitutability.[31] Indeed, manufacturers might fare better under section 2(b) in cases where fully-informed physicians would prefer a surgical procedure over a prescription product with a challenged but unalterable design.[32] So far, however, courts generally have not embraced this new approach.

After noting that no precedent existed to support what it called the "reasonable physician test" for judging design defect claims, the Nebraska Supreme Court offered a number of reasons for rejecting section 6(c) based on criticisms that had appeared in the academic literature: it is difficult to apply (and premised on a misapprehension of what influences prescribing decisions), unjustifiably protects less essential drugs (including merely "cosmetic" drugs such as Accutane®), and would deny plaintiffs recovery even in cases where a RAD existed.[33]

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by other water-soluble contrast agents."); *id.* at 927 ("[T]he testimony of all the radiologists indicates that, although Pantopaque may be utilized for some limited situations, the preferred contrast agent at the time of plaintiff's myelogram was Amipaque. Thus, Pantopaque was not an alternative product that would have as effectively accomplished the full and intended purpose of metrizamide."); *cf.* Sita v. Danek Med., Inc., 43 F. Supp. 2d 245, 256 & n.9 (E.D.N.Y. 1999) (noting that a manufacturer of pedicle screws used in spinal fixation had compiled supportive testimony from 270 surgeons).

[30] *See* James A. Henderson, Jr. & John A. Siliciano, *Universal Health Care and the Continued Reliance on Custom in Determining Medical Malpractice*, 79 CORNELL L. REV. 1382, 1390 & n.32 (1994) (noting the proliferation of therapeutic options); Amy L. Wax, *Technology Assessment and the Doctor–Patient Relationship*, 82 VA. L. REV. 1641, 1651 (1996).

[31] On the difficulties in defining substitutability (and how that concept differs from the idea of a safer alternative design), see Richard L. Cupp, Jr., *Defining the Boundaries of "Alternative Design" Under the* Restatement (Third) of Torts*: The Nature and Role of Substitute Products in Design Defect Analysis*, 63 TENN. L. REV. 329 (1996).

[32] *See* Violette v. Smith & Nephew Dyonics, Inc., 62 F.3d 8, 13–14 (1st Cir. 1995) (upholding a jury verdict that found an endoscopic device intended for the treatment of carpal tunnel syndrome defectively designed because a clearly safer surgical procedure existed); Hill v. Searle Labs., 884 F.2d 1064, 1069–70 (8th Cir. 1989) (rejecting comment k defense for intrauterine device (IUD) because safer non-IUD options existed to achieve contraception); *see also* Lars Noah, *Assisted Reproductive Technologies and the Pitfalls of Unregulated Biomedical Innovation*, 55 FLA. L. REV. 603, 648 (2003) (suggesting that a "plaintiff might argue that—in light of the current state of the art—the older fertility drugs are defectively designed insofar as the risk of multifetal pregnancy now outweighs their limited benefits when compared with alternative, safer ARTs" including procedures such as in vitro fertilization).

[33] *See* Freeman v. Hoffman–La Roche, Inc., 618 N.W.2d 827, 839–40 (Neb. 2000); *see also id.* at 840 (instead applying the consumer expectations test, but allowing the manufacturer to respond by reference to risk-utility factors). Separately, and after an even more conclusory analysis, the court also rejected section 9 (relating to non-fraudulent misrepresentation), *see id.* at 844–45, but it adopted section 6(d) (the learned intermediary rule for defining the scope of the duty to warn for prescription products), *see id.* at 842, which is discussed more fully below in Part III. For more on the drug Accutane, see *infra* Part II.C.5.

In 2003, an intermediate appellate court in Georgia likewise rejected the approach endorsed by the *Products Liability Restatement*:

> [Section] 6(c) has been criticized for its failure to reflect existing case law, its lack of flexibility with regard to drugs involving differing benefits and risks, its unprecedented application of a reasonable physician standard, and the fact that a consumer's claim could easily be defeated by expert opinion that the drug had some use for someone, despite potentially harmful effects on a large class of individuals.[34]

The track record in medical device cases looks about the same so far.[35]

To be sure, the older case law provided little direct support for the standard announced in section 6(c). Even so, as elaborated in the sections that follow, the substantive objections do not withstand close scrutiny: courts can manage any asserted difficulties (which seem no greater than problems one might encounter, for example, in resolving medical malpractice claims); adequately labeled prescription products leave contested questions of utility in the proper hands (namely, physicians and patients rather than judges and jurors); and, given unpredictable variability in patient response, it makes no sense to say that a RAD exists for a drug if a fully-informed health care professional would select it for some patients. In fact, if section 6(c) suffers from any flaws, I argue below that it may offer incomplete protection against inappropriate claims of defective design.

1. MUDs and Child's Play

Section 6(c) shares important similarities with another contentious pocket of design defect scrutiny. Although elsewhere the *Products Liability Restatement* rejected the proposition that some types of products (e.g., cigarettes and handguns) may create such a high risk of injury and have so little social utility that they should be regarded as defective even without proof of a RAD,[36] the Reporters conceded that

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[34] Bryant v. Hoffman–La Roche, Inc., 585 S.E.2d 723, 727 (Ga. Ct. App. 2003); *see also id.* at 728 (instead adopting comment k as an affirmative defense); *id.* at 730 (concluding that the manufacturer had failed to establish that the drug's utility outweighed its risks); *cf. id.* at 731–34 (Andrews, J., concurring) (advocating adoption of section 6(c)). If the court had decided otherwise, one wonders how the standard might have operated in that case because the drug was withdrawn less than one year after approval: Posicor® (mibefradil), a calcium channel blocker (used to treat angina and hypertension), caused serious interactions with several other commonly prescribed drugs (including beta blockers, another class of antihypertensives) though seemed to be relatively safe and effective when reserved for patients not taking other drugs. *See* Robert Langreth, *Recall of a Popular Roche Drug Raises Questions on Testing, Approval Process*, WALL ST. J., June 10, 1998, at B16. It sounds to me like a failure-to-warn claim at most.

[35] *See infra* notes 326–328 and accompanying text.

[36] *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. d (1998). For proponents of such a view, see Carl T. Bogus, *War on the Common Law: The Struggle at the Center of Products Liability*, 60 MO. L. REV. 1, 59 (1995); Ellen Wertheimer, *The Smoke Gets in Their Eyes: Product Category Liability and Alternative Feasible Designs in the Third* Restatement, 61 TENN. L. REV. 1429 (1994). *See generally* Symposium, *Generic Products Liability*, 72 CHI.–KENT L. REV. 1 (1996).

some products, such as toy guns that shoot hard rubber pellets, may suffer from a "manifestly unreasonable" design (MUD) if courts defined the relevant product category (and substitutes) too narrowly.[37] In short, if no parent in their right mind would purchase such a product, then a jury could conclude that the manufacturer should not have made it available in the first place (in effect, to protect children against the foolishness of their parents and their own lack of judgment).[38]

Because prescription drugs often represent a class onto themselves without clear substitutes,[39] and because their purchase requires assent from a person more sophisticated than the end user, section 6(c) created a similar standard for judging design defects.[40]

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[37] *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. e (1998) ("The court would declare the product design to be defective and not reasonably safe because the extremely high degree of danger posed by its use or consumption so substantially outweighs its negligible social utility that no rational, reasonable person, fully aware of the relevant facts, would choose to use, or to allow children to use, the product."); *see also* Michael J. Tõke, Note, *Categorical Liability for Manifestly Unreasonable Designs: Why the Comment d Caveat Should Be Removed from the* Restatement (Third), 81 CORNELL L. REV. 1181, 1201–02 (1996) (describing this concession as a response to objections lodged by members of the plaintiffs' bar); *id.* at 1222–24 (warning that this exception to the design defect standard might swallow the rule).

[38] *See* Model Uniform Product Liability Act, 44 Fed. Reg. 62,714, 62,727–28 (Oct. 31, 1979) ("An example [of a case where liability should attach even without a RAD] is a product seller who markets a toy that is highly dangerous to children."); *see also* Metzgar v. Playskool Inc., 30 F.3d 459, 462–65 & n.6 (3d Cir. 1994) (allowing a design defect claim where a toddler choked on a small toy). *See generally* April A. Caso, Note, *Unreasonably Dangerous Products from a Child's Perspective: A Proposal for a Reasonable Child Consumer Expectation Test*, 20 RUTGERS L.J. 433 (1989); Sonja A. Soehnel, Annotation, *Products Liability: Toys and Games*, 95 A.L.R.3d 390 (1979 & Supp. 2008). I want to thank my newborn daughter Sigrid for inspiring this line of thought.

[39] *See* Frank R. Lichtenberg & Tomas J. Philipson, *The Dual Effects of Intellectual Property Regulations: Within– and Between–Patent Competition in the U.S. Pharmaceuticals Industry*, 45 J.L. & ECON. 643, 651–52 (2002) (identifying "five levels of the drug classification hierarchy" in descending order of specificity: class, subclass, drug, subdrug, and drug product); *id*. at 652 ("For economic purposes, subdrugs may be close but not perfect substitutes, but drug products within the same subdrug are certainly close to perfect substitutes."); *see also id*. at 655 ("Drugs are a very useful product market to study in this respect because the disease categories in which so-called therapeutic competition occurs are relatively well defined compared to other markets."); *id*. at 668–71 tbl.A1 (listing more than 150 recognized classes). Only generic versions of brand-name drugs serve as true substitutes, but they raise entirely separate liability issues discussed below in Part IV.B. In the context of insurance coverage for drugs, debates have arisen about therapeutic interchange or substitutability. *See* Council on Ethical & Judicial Aff., AMA, *Managed Care Cost Containment Involving Prescription Drugs*, 53 FOOD & DRUG L.J. 25, 25 (1998) ("The needs of specific patients may be ignored in this framework because approved drugs are selected on the basis of average patient outcome, not individual effectiveness."); Donald P. Hay & Linda K. Hay, *Diagnosing and Treating Depression in a Managed Care World*, 42 ST. LOUIS U. L.J. 55, 57–58 (1998) (criticizing formularies for excluding new generations of costly antidepressant drugs that pose fewer risks for some patients); Milt Freudenheim, *Not Quite What Doctor Ordered; Drug Substitutions Add to Discord over Managed Care*, N.Y. TIMES, Oct. 8, 1996, at D1. Antitrust issues also may turn on drug substitutability. *See* Eric L. Cramer & Daniel Berger, *The Superiority of Direct Proof of Monopoly Power and Anticompetitive Effects in Antitrust Cases Involving Delayed Entry of Generic Drugs*, 39 U.S.F. L. REV. 81, 117–18, 126–34 (2004); *id.* at 129 ("[D]ifferent drug molecules within the same therapeutic class, despite possible therapeutic similarities, tend not to be close economic substitutes for purposes of defining relevant markets in delayed generic entry cases."); *id.* at 113 (conceding that a broader product market definition may be appropriate in merger cases); M. Howard Morse, *Product Market Definition in the Pharmaceutical Industry*, 71 ANTITRUST L.J. 633, 639–40, 643–52, 659–70, 676 (2003).

[40] *See* Conk, *supra* note 19, at 1102, 1118–19; Victor E. Schwartz & Phil Goldberg, *A Prescription for Drug Liability and Regulation*, 58 OKLA. L. REV. 135, 153–54 (2005) (suggesting

Although paternalism in medicine has acquired a bad reputation, patients seek out professional assistance precisely because they lack the expertise to make such choices unaided.[41] The parallel to products that children may use also helps to explain other aspects of the special provisions governing design and informational defect claims involving prescription products.[42] Similarly, section 2(b) imagines that the utility of some products may outweigh their risk only when used by a subset of potential consumers (e.g., adults or experts), which then requires that labeling define the appropriate subset.[43] In short, rather than the "unprecedented"

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by way of illustration that the COX-2 inhibitors Vioxx® and Celebrex® "are each unique products, not alternative designs of each other"); *id.* at 154 n.137 (drawing a parallel to the MUD test); *see also* Green, *supra* note 19, at 227–28, 231; *id.* at 227 (noting "a certain irony" that section 6(c) "permits categorical liability (condemnation of a drug as not worthy of being on the market)" given the "pitched battle over categorical liability" with regard to other products). For a critique (purportedly grounded in "feminist theory") that completely missed this parallel, see Dolly M. Trompeter, Comment, *Sex, Drugs, and the* Restatement (Third) of Torts, *Section 6(c): Why Comment e Is the Answer to the Woman Question*, 48 AM. U. L. REV. 1139, 1151–52, 1171–76 (1999) (advocating extension of the MUD standard to prescription products).

[41] *See* Mark A. Hall, *The Legal and Historical Foundations of Patients as Medical Consumers*, 96 GEO. L.J. 583, 584–85, 596–97 (2008); Carl E. Schneider, *After Autonomy*, 41 WAKE FOREST L. REV. 411, 436–38 (2006) (explaining that many patients do not want to make decisions about their medical care); *id.* at 417–25, 432–36 (discussing the impossibility of truly informed consent); *id.* at 440 (concluding that "the central bioethical enterprise of confiding decisions to patients in some strong sense is doomed"); Jan Hoffman, *Awash in Information: Patients Face a Lonely, Uncertain Road*, N.Y. TIMES, Aug. 14, 2005, § 1, at 1; *see also* Ezekiel J. Emanuel & Linda L. Emanuel, *Four Models of the Physician-Patient Relationship*, 267 JAMA 2221, 2226 (1992) ("Many have attacked physicians as paternalistic, urging the empowerment of patients to control their own care. . . . This model embodies a defective conception of patient autonomy, and it reduces the physician's role to that of a technologist."); *id.* (advocating instead a "deliberative" model).

[42] *See infra* notes 194, 280–282 and accompanying text. Just as physicians choose treatments for use by their patients, parents must select products for their young children and then supervise the safe use of these products. Although the Reporters thought that the opportunity to engage in "differential marketing" (to ensure distribution only to appropriate users) was unique to prescription drugs and devices, *see* Henderson & Twerski, *supra* note 19, at 170–71, toys share similarities in this regard. If some toys (e.g., those with small pieces that can create a choking hazard) pose excessive dangers to one class of youngsters but not to another, then they must carry clear instructions and warnings (e.g., "not appropriate for children less than three years old"). *See* Lars Noah, *The Imperative to Warn: Disentangling the "Right to Know" from the "Need to Know" About Consumer Product Hazards*, 11 YALE J. ON REG. 293, 333 (1994). In short, instructions and warnings directed to parents help to ensure that the right toys get to the right children.

[43] *See, e.g.*, Hernandez v. Tokai Corp., 2 S.W.3d 251, 260 (Tex. 1999) ("Products liability law does not force experienced carpenters to use only nail guns that are safe for the garage workshop. . . . To make such products safe for the least apt, and unintended, user would hold other users hostage to the lowest common denominator."); *see also* Ruiz–Guzman v. Amvac Chem. Corp., 7 P.3d 795, 796 n.2 (Wash. 2000) (noting that manufacturers of "restricted use" pesticides can only distribute these through licensed dealers for use by certified applicators); *id.* at 797 (explaining that the manufacturer of Phosdrin, an organophosphate pesticide, had created additional restrictions in advance of its proposed use in apple orchards); *id.* at 803–04 (extending § 402A comment k to such products, but only if their utility to society greatly outweighed their risks). *See generally* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2, cmts. f–g, i & *l* (1998). In short, although risk will outweigh utility in many (e.g., inexpert) users, such a product would not fail the test for design defect simply because safer substitutes exist for most (but not all) uses. Instead, the issue becomes one of clear labeling and perhaps limited channels for marketing. *Cf.* Barnes v. Litton Indus. Prods., Inc., 555 F.2d 1184, 1185–88 & n.1 (4th Cir. 1977) (imposing a duty to warn against the misuse of a prescription product by laypersons even though the label had indicated "For Professional Dental Use Only"); *infra* Part II.D (discussing access restrictions). One critic of section 6(c) argued, however, that prescription products are not different from other consumer goods with designs that might

(even "radical") new test assailed by critics, section 6(c) announces a blended standard drawn from entirely familiar tests for judging design defects in other contexts.

Some commentators have criticized section 6(c) for insulating both lifesaving and lifestyle (read "trivial") prescription products,[44] but they make the same mistake as those who would call lawfully marketed products that appeal to some (wrong-headed?) consumers defectively designed even in the absence of a RAD (and in the face of an adequate warning).[45] One central objection to the recognition of a broader form of "product category" liability is that it would allow courts to decide that lawfully marketed products should not be available to consumers. Of course, a jury verdict does not amount to an injunction against further sales of a product,[46] and defenders of a more expansive standard of liability for design defects would say that it simply amounts to an obligation to pay for harm caused (and to spread those costs among all users who may derive utility from the product).[47] If nothing else has

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appeal to one class of buyers while posing a risk of harm to another class. *See* Cupp, *supra* note 19, at 99–101 (discussing crashworthiness features of automobiles that particular users do not need and might prefer not to pay for); *see also* Green, *supra* note 19, at 215–16 (elaborating on this parallel). One difference, of course, lies in the fact that physicians control access to products in a way structured to help ensure that the right drugs get to the right patients.

[44] *See, e.g.*, 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, 252–54 (1999) (focusing on "cosmetic" uses such as treating baldness); *id.* at 257 ("[W]hen seeking to structure some well-deserved protection for extremely useful drugs, courts should note that prescription products are not all created equal, and that uses of prescription products are not all created equal."); *see also* Green, *supra* note 19, at 214 ("[T]he vast majority of new drugs provide little therapeutic advantage. . . . Rogaine may be near and dear to the hearts of some, but it is not the social-welfare equivalent of antibiotics."); *infra* note 343 (citing commentators who object to special protections for cosmetic devices such as silicone-gel breast implants). In contrast, as one commentator argued, "it is unexplained why such useful products as microchips, personal computers, telephones, trains, planes, and automobiles should always come in second to medical products in the calculus of social good." Conk, *supra* note 19, at 1127 ("[W]hy should things that we hope will bring us pleasure be subject to a more stringent standard of products liability than products that we hope will restore or maintain our health?"). For more on the lifestyle drug point, see *infra* notes 105–119 and accompanying text.

[45] *See* James A. Henderson, Jr. & Aaron D. Twerski, *Closing the American Products Liability Frontier: The Rejection of Liability Without Defect*, 66 N.Y.U. L. REV. 1263 (1991); Töke, *supra* note 37, at 1205–24. Of course, for those who criticize the MUD standard as anemic and would prefer a broader form of product category liability, *see supra* note 36, restricting design defect scrutiny for prescription products would have to find justification elsewhere. For the record, I have expressed similar qualms about agencies reaching beyond the limits of their delegated authority in pursuit of well-intentioned public health crusades. *See* Lars Noah, *Regulating Cigarettes: (Non)sense and Sensibility*, 22 S. ILL. U. L.J. 677, 689–90 (1998); *see also* Lars Noah, *Interpreting Agency Enabling Acts: Misplaced Metaphors in Administrative Law*, 41 WM. & MARY L. REV. 1463, 1476–80, 1488, 1529–30 (2000).

[46] *Cf. In re* Paxil Litig., No. CV 01-07937 MRP, 2002 WL 31375497, at *1 (C.D. Cal. 2002) (declining to issue a preliminary injunction in a class action lawsuit brought on behalf of users of an antidepressant who requested an order barring the manufacturer from claiming in television ads that the drug was not habit-forming); Bernhardt v. Pfizer, Inc., 2000 WL 1738645, at *1 (S.D.N.Y. 2000) (refusing to issue an injunction ordering a drug manufacturer to notify physicians and patients about the results of a study finding that its antihypertensive agent worked less well than diuretics because this presented an issue for the FDA to resolve).

[47] *See, e.g.*, Conk, *supra* note 21, at 783. A few commentators have gone still further, disputing the proposition that prescription pharmaceuticals differ fundamentally from other products

emerged from the otherwise confused preemption jurisprudence of the last fifteen years, however, the Supreme Court has left little doubt about the potential regulatory effect of tort judgments.[48]

A conclusion that a prescription drug has a design defect may well amount to a command that would deprive other patients of access to the product.[49] If a manufacturer has provided an adequate warning to the health care providers responsible for selecting an intervention for a particular patient, a jury generally would have no basis for deciding that a drug had no legitimate use in any class of patients, even if a physician may have erred in selecting it for the plaintiff.[50] As it did in recognizing MUDs in only the narrowest of circumstances, the *Products Liability Restatement* crafted a design defect standard for prescription products to guard against the risk of such judicial tunnel-vision.[51]

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and favoring the imposition of tort liability even on such high utility products (and even for entirely unknowable risks), which would mean a rule of absolute liability on sellers of all consumer products, dispensing with any need to establish a defect (though retaining a comparative negligence defense for instances of consumer misuse). *See* 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, 415–33 (1996) (emphasizing both compensatory and deterrence rationales); Elizabeth C. Price, *Toward a Unified Theory of Products Liability: Reviving the Causative Concept of Legal Fault*, 61 TENN. L. REV. 1277, 1329–37, 1353–55 (1994); Ellen Wertheimer, *Unavoidably Unsafe Products: A Modest Proposal*, 72 CHI.–KENT L. REV. 189, 217 (1996) (emphasizing fairness and cost-spreading rationales); *id.* at 200–06 (discussing vaccines); *id.* at 207 n.58 (prescription drugs); *id.* at 197 n.29 (unknowable risks).

[48] *See* Riegel v. Medtronic, Inc., 128 S. Ct. 999, 1007–10 (2008); Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 347–53 (2001) (holding that fraud-on-the-FDA claim involving medical device review was impliedly preempted); *see also* R.F. v. Abbott Labs., 745 A.2d 1174, 1192–94 (N.J. 2000); Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934–36 (Jan. 24, 2006) (codified at 21 C.F.R. pts. 201, 314, 601) (announcing administrative preemption of failure-to-warn claims involving Rx drugs); Lars Noah, *Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability*, 88 GEO. L.J. 2147, 2159 (2000); *cf.* Levine v. Wyeth, 944 A.2d 179, 184 (Vt. 2006) (rejecting implied preemption defense), *cert. granted*, 128 S. Ct. 1118 (U.S. Jan. 18, 2008) (No. 06–1249).

[49] *See* Henderson & Twerski, *supra* note 19, at 169 n.78.

[50] *Cf.* Swayze v. McNeil Labs., Inc., 807 F.2d 464, 468, 471–72 (5th Cir. 1987) (rejecting the plaintiff's claim that, if the manufacturer could not reduce the risk that health care professionals would act negligently and administer excessive doses of fentanyl, it should have withdrawn the drug from the market). In fact, when enhanced warnings fail to alter dangerous prescribing behavior (as happens far too often), pharmaceutical manufacturers may withdraw from the market products that continue to have legitimate uses. *See* Noah, *supra* note 26, at 438–40; *see also* Karen E. Lasser et al., *Timing of New Black Box Warnings and Withdrawals for Prescription Medications*, 287 JAMA 2215 (2002) (explaining that the use of such warnings may not save a drug from eventual withdrawal).

[51] *See* Henderson, *supra* note 19, at 493–94 (explaining that, "if a drug truly is the only one that can help a class of patients who otherwise are going to suffer serious medical injury, it would be unacceptable to deny them the drug just because doctors are misprescribing it to patients who should not be taking it," and calling this a matter "of interpersonal fairness"); Henderson & Twerski, *supra* note 19, at 152–53 (defending their "refusal to sacrifice the welfare of one class of patients to enhance the welfare of another"); Noah, *supra* note 48, at 2163; Winchester, *supra* note 19, at 657 ("One could easily imagine that a jury, faced with the tragic facts of the case before it, could be convinced that the act of marketing an injury-causing drug was inherently unreasonable, simply because the drug did indeed cause the injury its maker knew would occur in a certain percentage of the people who took it."); *see also* Lars Noah, *Civil Jury Nullification*, 86 IOWA L. REV. 1601, 1609, 1656–57 (2001). In this sense, we have the book-end to the longstanding idea that strict liability focuses on the nature of the product rather than the conduct of the seller (*see* Barker v.

When risks come to light after approval, some courts have allowed design defect claims framed by asking whether a reasonable drug manufacturer would have continued selling the product.[52] A few critics of section 6(c) have expressed a preference for this standard,[53] in part out of a concern that physicians often continue prescribing obsolete drugs because the FDA can withdraw a product only under the rarest of circumstances.[54] This represents a serious misapprehension of the relevant legislation and agency practice. The statutory provision that they cite relates only to the power to withdraw a license summarily,[55] while the immediately preceding clause of that subsection broadly authorizes withdrawal on any of a number of grounds but entitles the license holder to a hearing.[56] Moreover, the FDA has the leverage to order nominally "voluntary" withdrawals, thereby avoiding the need to

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Lull Eng'g Co., 573 P.2d 443, 447 (Cal. 1978); RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 1 cmt. a (1998)): it makes no more sense to say that a product was defectively designed for this particular user. *Cf.* Simeon v. Doe, 618 So. 2d 848, 851 (La. 1993) (suggesting that, in allergic reaction cases, the "'defect' is really found in the person rather than the product").

[52] *See, e.g.*, Feldman v. Lederle Labs., 479 A.2d 374, 385 (N.J. 1984); *see also* Tobin v. Astra Pharm. Prods., Inc., 993 F.2d 528, 536–37, 540 (6th Cir. 1993) (same, but not involving postapproval discovery of risks).

[53] *See, e.g.*, Conk, *supra* note 19, at 1119–27; *id.* at 1126 ("Harm preventable by reasonable care or by reliance on practical, feasible, and available alternative designs is not 'unavoidable,' and manufacturers should be held responsible for failing to prevent such harms."); Conk, *supra* note 21, at 752 ("[T]he designer-manufacturer is in a position to make choices from a superior vantage point."); *id.* at 761, 787–88; Cupp, *supra* note 44, at 241 ("The reasonable manufacturer test utilizes a broader perspective and is flexible enough to recognize that, even if there is a class of persons for whom the drug is acceptable when taken as designed, the manufacturer still might be unreasonable in marketing the drug if its social costs outweigh its benefits."); *id.* at 257 ("The broad perspective of the reasonable manufacturer test is needed to provide at least some tort accountability for defective prescription-product designs."); Teresa Moran Schwartz, *The Impact of the New Products Liability Restatement on Prescription Products*, 50 FOOD & DRUG L.J. 399, 409 (1995); *id.* at 407 (calling an earlier version of section 6(c) "a kind of 'super' negligence standard that imposes liability only where . . . the drug or device should not have been on the market at all"); Winchester, *supra* note 19, at 663, 670–88, 693; *see also* Green, *supra* note 19, at 224–32 (agreeing with section 6(c)'s prohibition on "interdrug" risk-utility comparisons, but concluding that, "[t]o the extent that drugs can be manipulated to make them safer [e.g., changing combinations of ingredients or dosage], the case for an exemption from tort liability is hard to justify, even with FDA regulatory oversight"). Predicting the consequences of tweaking an existing drug product (to create a hypothesized superior version) may, however, pose greater difficulties than making comparisons among arguable therapeutic substitutes already approved for marketing. *See infra* Part II.B.3.

[54] *See* Cupp, *supra* note 44, at 236 n.17 ("The inferior drug may continue to be prescribed because statutorily a drug may only be removed from the market when there is an 'imminent hazard to the public health.'" (citing Schwartz, *supra* note 19, at 1382)).

[55] *See* 21 U.S.C. § 355(e) (2006) (entitling the manufacturer to an "expedited hearing" after withdrawal); 21 C.F.R. § 2.5 (2008) (defining "imminent hazard"); *see also* Forsham v. Califano, 442 F. Supp. 203, 207–10 (D.D.C. 1977) (sustaining the FDA's first and only attempted exercise of this authority).

[56] *See* Warner–Lambert Co. v. Heckler, 787 F.2d 147, 150–51 (3d Cir. 1986). The agency may utilize a summary judgment procedure to deny hearing requests when it withdraws approval, *see* Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 620–22 (1973), and reviewing courts show tremendous deference to the FDA, *see* Schering Corp. v. FDA, 51 F.3d 390, 399–400 (3d Cir. 1995).

abide by any procedural niceties,[57] and it has done so recently to remove prescription drugs once safer substitutes became available.[58]

Although a reasonable manufacturer test sounds like the other side of the same coin as the reasonable physician test,[59] it may not provide a suitable safeguard for patient welfare. On the one hand, some manufacturers may persist in marketing drugs past the point of genuine obsolescence;[60] on the other hand, overly conscientious pharmaceutical manufacturers may remove drugs from the marketplace even though reasonable physicians would have continued prescribing them for a subset of patients.[61] Once serious risks with an approved drug become

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[57] *See* Lars Noah, *The Little Agency That Could (Act with Indifference to Constitutional and Statutory Strictures)*, 93 CORNELL L. REV. 901, 906–10 & n.40, 913–14 & n.73 (2008).

[58] *See, e.g.*, Denise Grady, *Doctors Call for Caution on Two More Diabetes Drugs*, N.Y. TIMES, May 20, 2000, at A10 (Rezulin®); Gardiner Harris, *Studies Lead to Withdrawal of Drug for Bowel Ailment*, N.Y. TIMES, Mar. 31, 2007, at A12 (Zelnorm®); *Parkinson's Drug Pulled off the Market*, WASH. POST, Mar. 30, 2007, at A8 (reporting that the FDA requested the withdrawal of pergolide, a dopamine agonist, because it had been associated with heart valve damage since 2002 and "[t]here are other drugs in the same class that can be substituted"); *see also* Conk, *supra* note 21, at 754 ("The FDA may . . . withdraw permission to market because a new drug comes on the market that is of superior safety.").

[59] *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 Reporters' Notes, cmt. f (1998) ("[W]hen a drug or device provides no net benefits to any ascertainable patient class—when reasonably informed medical providers would not prescribe the drug and *no reasonable, informed manufacturer would place it on the market*—then the product design is defective and the manufacturer should be liable for the harm caused by selling it." (emphasis added)). *But cf.* Ray v. BIC Corp., 925 S.W.2d 527, 530–31 (Tenn. 1996) (rejecting suggestions that the consumer expectation test and prudent manufacturer test of design defect represented two sides of the same coin). The Reporters subsequently explained that their choice of perspective "was made to objectify the test and to cleanse it from any sense of partisanship. Reasonable health-care providers have no stake whatsoever in whether a drug should remain on the market." Henderson & Twerski, *supra* note 19, at 155–56 n.18 (adding that use of a reasonable manufacturer standard typically would give plaintiffs less protection).

[60] *See, e.g.*, FDA, Notice, Sandoz Pharmaceuticals Corp.; Bromocriptine Mesylate (Parlodel) for the Prevention of Physiological Lactation; Opportunity for a Hearing on a Proposal to Withdraw Approval of the Indication, 59 Fed. Reg. 43,347, 43,348 (Aug. 23, 1994) (recounting the manufacturer's decade-long pattern of resisting agency requests to modify labeling for the drug); *see also id.* at 43,351 ("In light of the limited benefit of using bromocriptine for the prevention of lactation, and the effectiveness and lack of serious adverse effects of conservative treatments such as . . . mild analgesics, the risk that bromocriptine may cause a serious adverse effect in a postpartum woman is unacceptable."); *cf.* Glastetter v. Novartis Pharm. Corp., 252 F.3d 986, 991 (8th Cir. 2001) ("The FDA's 1994 decision that Parlodel can cause strokes is unreliable proof of medical causation in the present case because the FDA employs a reduced standard (vis-a-vis tort liability) for gauging causation when it decides to rescind drug approval."). In the end, Sandoz did not request a hearing to challenge the agency's proposal to withdraw this indication. *See* FDA, Notice, Sandoz Pharmaceuticals Corp.; Bromociptine Mesylate (Parlodel); Withdrawal of Approval of the Indication for the Prevention of Physiological Lactation, 60 Fed. Reg. 3404 (Jan. 17, 1995); *see also* Kuhn v. Sandoz Pharm. Corp., 14 P.3d 1170, 1174–75 (Kan. 2000) (summarizing the FDA's negotiations with the manufacturer); Rick Weiss, *Drug Will No Longer Be Sold to Stop Breast Milk*, WASH. POST, Aug. 23, 1994, at F7 (explaining that emerging tort litigation and a petition filed by Public Citizen had prompted the FDA's action and the manufacturer's decision, noting one specialist's complaint that the withdrawal represented "another victory of legal intimidation over sound medical judgment"). Parlodel continues to have appropriate uses in other classes of patients, including those with Parkinson's disease, so it would not face design defect claims under section 6(c), though plaintiffs might well pursue informational defect claims.

[61] *See supra* note 50. Some commentators point to the withdrawn analgesic Vioxx® (rofecoxib) as an example of a defectively designed drug. Although informational defect claims may well have merit in this case, it makes no sense to call the product defective in any other sense.

known, risk-averse firms may not see much countervailing revenue in continuing to serve a narrow patient population,[62] and patients deprived of a drug from which they derived therapeutic benefits would have no claim for continued access.[63] Thus, framing the question from the perspective (or through the lens) of a reasonable health care provider better guards against the twin dangers of tunnel-vision (risk-utility judged solely from a plaintiff's perspective) and preference aggregation (risk-utility evaluated from a societal perspective),[64] both of which might unduly sacrifice the needs of a minority of patients for whom the risk-utility balance differs from either the particular victim or the norm.

2. Snowflakes (and Cost–Consciousness) in Medical Practice

Section 6(c) appropriately recognizes the variability in patient response and the inadvisability of considering a particular product design as the best choice for treating a condition in every case.[65] When it comes

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See Richard A. Epstein, *Regulatory Paternalism in the Market for Drugs: Lessons from Vioxx and Celebrex*, 5 YALE J. HEALTH POL'Y L. & ETHICS 741, 751–54 (2005); *id.* at 768 ("Vioxx is better in some circumstances and worse in others. The only case in which the FDA should urge the ban is when some other drug *dominates* Vioxx on all relevant dimensions."); Marc Kaufman, *FDA Panel Opens Door for Return of Vioxx: Many Advisers Urge New Restrictions on Painkillers*, WASH. POST, Feb. 19, 2005, at A1; *see also* Stephanie Saul, *Pfizer in $894 Million Drug Settlement*, N.Y. TIMES, Oct. 18, 2008, at B2 (Bextra and Celebrex). For the latest on this unfolding litigation, see Heather Won Tesoriero, *Vioxx Rulings Raise Bar for Suits Against Drug Firms—Decisions by Courts in Texas, New Jersey Boost Merck's Strategy in Liability Cases*, WALL ST. J., May 30, 2008, at B1.

[62] *See* Henderson, *supra* note 19, at 487–88 ("[T]he manufacturer's perspective may invite a more global, and inappropriate, netting out of costs and benefits over different classes of patients."); *cf.* Lars Noah, *Triage in the Nation's Medicine Cabinet: The Puzzling Scarcity of Vaccines and Other Drugs*, 54 S.C. L. REV. 741, 747, 751–53, 758–61 (2003) (making a similar point in connection with vaccines). In unusual cases, physicians have taken the lead in resisting FDA efforts to restrict the use of an approved drug. *See, e.g.*, Bradley v. Weinberger, 483 F.2d 410, 411–15 & n.1 (1st Cir. 1973) (oral hypoglycemics).

[63] Courts have rejected such claims when brought by subjects enrolled in halted clinical trials of investigational drugs. *See, e.g.*, Abney v. Amgen, Inc., 443 F.3d 540, 550–53 (6th Cir. 2006); *cf.* Dahl v. HEM Pharm. Corp., 7 F.3d 1399, 1404–05 (9th Cir. 1993) (holding that the plaintiffs had a contract claim entitling them to an additional one-year supply); Michael M. Grynbaum, *Judge Orders Drug Maker to Provide Experimental Treatment to Terminally Ill Teenager*, N.Y. TIMES, Aug. 21, 2008, at C3.

[64] Selecting the correct frame of reference can make a tremendous difference in avoiding simple mistakes. *See, e.g.*, Lars Noah, *An Inventory of Mathematical Blunders in Applying the Loss-of-a-Chance Doctrine*, 24 REV. LITIG. 369, 393–404 (2005) (arguing that courts resolving these medical malpractice claims should convert estimated reductions in the odds of survival into relative risk figures); *cf.* Marcantonio v. Moen, 937 A.2d 861, 875–76 (Md. Ct. Spec. App. 2007) (citing this article but still entirely missing the point), *rev'd*, 959 A.2d 764, 776 (Md. 2008) (getting the result right but for the wrong reason by focusing only on the antecedent chance of survival); *id.* at 881–85 (Meredith, J., dissenting) (getting it right).

[65] *See* Green, *supra* note 19, at 230–31; Henderson & Twerski, *supra* note 19, at 168–72; *id.* at 180 ("To deny one group of patients a beneficial drug merely because adequately—warned physicians may misprescribe the same drug for another group of patients would be unfair and inefficient . . . ."); *see also* Williams v. Ciba–Geigy Corp., 686 F. Supp. 573, 577 (W.D. La.) ("Rather than simply permitting juries to apply, haphazardly and case-by-case, the risk-utility test whenever harm results, the court must require, as a part of the plaintiff's burden of producing evidence, an articulable basis for disregarding the FDA's determination that the drug should be available."), *aff'd mem.*, 864 F.2d 789 (5th Cir. 1988); *id.* at 578 ("The consequences of the

to pharmaceutical interventions, one size does not fit all.[66] The requirements of patients vary widely, depending on factors such as the nature of their symptoms, progression of the underlying disease, presence of any concurrent conditions or use of other medications, and sensitivity to (or tolerance of) specific side effects. For example, differences in metabolic patterns depending on age, gender, and ethnic background may indicate selection of a drug for some patients even if its risk-utility balance is less favorable for most other persons in the population.[67]

Physicians frequently must try different medications at different dosages until they find the one that seems to work best in a particular patient, and they may have to try various combinations.[68] In some cases, a patient proves to be refractory to the "drug of choice" but responds well to a second- or third-line (often more dangerous) therapeutic agent.[69]

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nonavailability of Tegretol for those patients who suffer serious seizures, which can be fatal if not controlled, but who cannot take other anticonvulsants [because they "do not respond to, or are endangered by, more conventional anticonvulsants"], would be grave indeed.").

[66] *See* John C. Ballin, Editorial, *Who Makes the Therapeutic Decisions?*, 242 JAMA 2875, 2875 (1979) ("As every physician recognizes, a drug may be the agent of choice for the majority of patients, but it is not necessarily the best therapy for all patients. Individual pharmacologic responses and idiosyncracies require that a variety of similar agents be available."); Benjamin Freedman et al., *Placebo Orthodoxy in Clinical Research I: Empirical and Methodological Myths*, 24 J.L. MED. & ETHICS 243, 247 (1996) ("To paraphrase Abraham Lincoln, when it comes to drugs, you can treat all of the people some of the time, and some of the people all of the time, but you cannot treat all of the people all of the time."); *see also id.* ("Side-effects are found in some who take a drug, but not in others; and even when the side-effects in two patients are by objective measure equivalent, one may find those side-effects tolerable and the other not. Heterogeneity of response is, in short, an unavoidable fact about drugs and disease . . . ."); Scott Sasjack, *Demanding Individually Safe Drugs Today: Overcoming the Cross-labeling Legal Hurdle to Pharmacogenomics*, 34 AM. J.L. & MED. 7, 8 (2008) ("[E]fficacy rates for drugs used to treat most diseases typically range between 50% and 75%."). Thus, the FDA does not seek to approve only the single "best" drug to treat a particular condition. *See* Einer Elhauge, *The Limited Regulatory Potential of Medical Technology Assessment*, 82 VA. L. REV. 1525, 1593 (1996); Maxwell J. Mehlman, *Health Care Cost Containment and Medical Technology: A Critique of Waste Theory*, 36 CASE W. RES. L. REV. 778, 787–88 (1986) (explaining that the FDA "has occasionally, albeit rarely, denied approval to market a drug on the basis that it was less safe or less effective than an alternative already on the market").

[67] *See* Grant R. Wilkinson, *Drug Metabolism and Variability Among Patients in Drug Response*, 352 NEW ENG. J. MED. 2211, 2211 (2005); *infra* Part IV.D.2 (discussing pharmacogenomics); *see also* Mark A. Hall, *The Defensive Effect of Medical Practice Policies in Malpractice Litigation*, LAW & CONTEMP. PROBS., Spring 1991, at 119, 144 (referring to the "snowflake" theory, which posits that no two patients are exactly alike).

[68] *See* Leila Abboud, *Drug Cocktails Hit Psychiatry*, WALL ST. J., Aug. 10, 2004, at D1 (drawing a parallel to the treatment of cancer and HIV).

[69] *See* Robert M. Temple, *Commentary on "The Architecture of Government Regulation of Medical Products,"* 82 VA. L. REV. 1877, 1888 (1996) ("In some cases, a relatively toxic drug will be identified as a 'second-line,' a drug to be used only in people who cannot tolerate, or do not respond to, safer agents."); Chris Adams, *Trial Judge: At FDA, Approving Cancer Treatments Can Be an Ordeal*, WALL ST. J., Dec. 11, 2002, at A1 (reporting that, after initially rejecting Eloxatin® as a "first line" therapy for colorectal cancer patients because the manufacturer had not shown extended survival, the FDA approved the drug as a "second line" treatment based on a trial demonstrating tumor shrinkage in 9% of patients who had not responded to chemotherapy); Andrew Pollack, *After a Long Struggle, Cancer Drug Wins Approval*, N.Y. TIMES, May 14, 2003, at C1 (reporting that the FDA approved Velcade® for multiple myeloma patients who have relapsed after trying at least two other treatments).

This may happen, for instance, when a patient encounters a resistant strain of a common infectious agent.[70] These characteristics make pharmaceutical products fundamentally unlike most consumer goods, which anyone equipped with basic information could select and use successfully to achieve the product's intended purpose.

In theory, of course, there always might be at least one hypothetical patient who does not tolerate or mysteriously fails to respond to every other alternative treatment in whom a reasonable physician—at a loss for any other ideas—would try a particular drug.[71] The Reporters had made it clear, however, that this possibility would not suffice to demonstrate the existence of a class of patients for whom physicians appropriately might select a drug.[72] Labeling helps in this connection: indications (and contraindications) may specify those subpopulations of patients with a condition in whom use of the drug would (or would not) be appropriate.[73] Occasionally after drug withdrawal, the FDA permits continued use by an even more narrowly defined class of patients.[74] Finally, courts could take a cue from the

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[70] *See, e.g.*, Gardiner Harris, *F.D.A. Warns of Liver Failure After Antibiotic*, N.Y. TIMES, June 30, 2006, at A14; *see also* Alexandra Calmy et al., Letter, *First-line and Second-line Antiretroviral Therapy*, 364 LANCET 329, 329 (2004).

[71] *See, e.g.*, Denise Grady, *A Daring Treatment, a Little Girl's Survival*, N.Y. TIMES, Mar. 18, 2008, at F5 (describing the apparently successful use of Celebrex and thalidomide with low-dose chemotherapy in treating a child's otherwise incurable brain tumor). Separately, a surprising number of physicians report prescribing obviously ineffective (and largely benign) drugs to treat nonserious conditions in certain kinds of patients. *See* Gardiner Harris, *Study Finds Many Doctors Often Give Placebos*, N.Y. TIMES, Oct. 24, 2008, at A12.

[72] *See* Henderson, *supra* note 19, at 477 (explaining that the test "refers to more than a single patient, although the number necessary to constitute a class is not specified" (footnote omitted)); *see also* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. f (1998) ("That some individual providers do, in fact, prescribe defendant's product does not in itself suffice to defeat the plaintiff's claim. Evidence regarding the actual conduct of health-care providers, while relevant and admissible, is not necessarily controlling."). The "respectable minority" rule in medical malpractice poses similar difficulties. *See* Noah, *supra* note 26, at 458 & nn.382–83.

[73] *See* Richardson v. Miller, 44 S.W.3d 1, 8 n.2, 16–17 (Tenn. Ct. App. 2000). When clinical trials produce equivocal results, sponsors may engage in statistical analyses designed to stratify the subject population in the hopes of identifying some subset in which the investigational product worked without causing unacceptable side effects. *See* Jennifer Kulynych, *Will FDA Relinquish the "Gold Standard" for New Drug Approval? Redefining "Substantial Evidence" in the FDA Modernization Act of 1997*, 54 FOOD & DRUG L.J. 127, 141–43 (1999) (discussing "post hoc subgroup analysis" and the FDA's reluctance to consider it as proof of effectiveness); Aldo P. Maggioni et al., *FDA and CPMP Rulings on Subgroup Analyses*, 107 CARDIOLOGY 97, 98–101 (2007) (explaining that labeling may describe the results of such analyses); Salim Yusuf et al., *Analysis and Interpretation of Treatment Effects in Subgroups of Patients in Randomized Clinical Trials*, 266 JAMA 93, 94 (1991) ("[T]rials adequate for detecting an overall treatment effect cannot be expected to detect effects within even relatively large subgroups . . . .").

[74] *See, e.g.*, Forsham v. Califano, 442 F. Supp. 203, 205 (D.D.C. 1977) (upholding the FDA's decision to withdraw phenformin, but allowing continued distribution to the limited class of diabetic patients for whom this oral hypoglycemic drug offered a greater therapeutic benefit than any alternative treatments); *see also* David A. Kessler, *Regulating the Prescribing of Human Drugs for Nonapproved Uses Under the Food, Drug, and Cosmetic Act*, 15 HARV. J. ON LEGIS. 693, 737 (1978) ("Withdrawal of a drug that has value to a certain patient population because the drug may be misused by a larger population in effect imposes an unfair hardship on those patients who could use the drug safely and profitably."); Francesca Lunzer Kritz, *FDA to Weigh New Controls on Problematic Drugs: Lotronex Will Be First for Consideration by New Panel*, WASH. POST, Apr. 16,

FDA's orphan drug regulations, which require that manufacturers identify a "medically plausible" subset of patients with a relatively common condition if they seek the incentives available for products designed to treat "rare" diseases.[75]

In contrast to the multi-factor test of section 2(b) of the *Products Liability Restatement*, section 6(c), with its inquiry limited to "therapeutic benefits" and using a physician-based frame of reference, may fail to protect legitimate design choices and prescribing decisions. In particular, it may undervalue matters of patient convenience, even though in practice this may have genuine public health consequences.[76] For instance, simplified dosing or delivery may improve patient compliance with prescribed treatment.[77] Changes in dosage forms may, however, present trade-offs between safety, efficacy, and convenience. In the early 1970s, scientists found that oral contraceptives containing high doses of estrogen posed a greater risk of cerebral thrombosis, and, even though it now appears that lower-dose versions did not work quite as well,[78] at the time it seemed that high-dose products offered no

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2002, at F1 (Propulsid®); Francesca Lunzer Kritz, *Still Irritable, Still Waiting: After Return to Market, Lotronex Can Be Hard to Get*, WASH. POST, Feb. 11, 2003, at F1; Andrew Pollack, *F.D.A. Restricts Access to Cancer Drug, Citing Ineffectiveness*, N.Y. TIMES, June 18, 2005, at C2 (reporting that patients who had benefitted from Iressa® could continue to use it and that the sponsor could continue enrolling subjects in clinical trials); *Some Women Can Get Zelnorm Again*, L.A. TIMES, July 28, 2007, at A13.

[75] *See* 21 C.F.R. § 316.20(b)(6) (2008); *see also* Marlene E. Haffner, *Orphan Products—Ten Years Later and Then Some*, 49 FOOD & DRUG L.J. 593, 596–98 (1994) (discussing the "salami slicing" problem, and explaining that "characteristics of the therapy (e.g., toxicity that limits the use of a drug)" may provide the basis for a medically plausible subset of patients, for instance if there is a drug with a property that "limits its use in some way to certain individuals"). Instead, one commentator has looked to the orphan drug regulations for entirely different purposes. *See* Conk, *supra* note 19, at 1107 n.86 (suggesting that these rules contemplate that different manufacturers could design competing versions of the "same" drug). Regulations that define notions of sameness in functional terms (and for purposes of awarding market exclusivity for orphan indications to sponsors of drugs no longer protected by patent), in this or any number of other FDA-related contexts (e.g., paper NDAs and generic bioequivalence), tell us nothing about whether it makes sense to imagine redesigning an approved drug.

[76] *See* Amy Dockster Marcus, *The Real Drug Problem: Forgetting to Take Them*, WALL ST. J., Oct. 21, 2003, at D1; Andrew Pollack, *Take Your Pills, All Your Pills; Drug Makers Nag Patients to Stay the Course*, N.Y. TIMES, Mar. 11, 2006, at C1; *cf.* Hill v. Searle Labs., 884 F.2d 1064, 1070–71 (8th Cir. 1989) (distinguishing, in a contraceptive failure-to-warn case, between "convenience or cost" and "medical necessity").

[77] *See* Justin Gillis, *FDA Approves Inhalable Insulin*, WASH. POST, Jan. 28, 2006, at A1 (explaining that the agency's "decision confronts millions of Americans—diabetics make up 7 percent of the population—with a complicated new strategic problem, requiring them to figure out how much long-range risk they're willing to incur for the convenience, and possibly greater disease control, of using inhaled insulin"); Ranit Mishori, *Special Delivery; Coming Soon: New Ways to Take Drugs, Without Needles or Pills*, WASH. POST, Feb. 8, 2005, at F1; Shankar Vedantam, *Implants May Reshape Schizophrenia Treatment; New Techniques Raise Fears of Coercion*, WASH. POST, Nov. 16, 2002, at A1 (reporting that long-acting antipsychotics delivered by injection could reduce problems with patient non-compliance); *see also* Mary Duffy, *Patch Raises New Hope for Beating Depression*, N.Y. TIMES, Dec. 3, 2002, at F7 (explaining that alternatives to oral formulations avoid the digestive track, which may allow for lower dosages and fewer side effects).

[78] *See* Anna Wilde Mathews, *FDA Mulls Birth–Control Standards*, WALL ST. J., Jan. 19, 2007, at B5; *see also* Michael Mason, *Pressing to Look Closer at Blood Clots and the Pill*, N.Y.

advantage in preventing pregnancy. Nonetheless, doctors sometimes prescribed the higher-dose versions to patients who suffered "break-through bleeding" when using the lower-dose products, a bothersome side effect that may reduce patient compliance with daily dosing directions and, thereby, reduce effectiveness in practice.[79]

Moreover, in judging the design of older prescription drugs, the reasonable physician standard (and section 6(c)'s emphasis on "*therapeutic* benefits") might make manufacturers more vulnerable to defect claims than the risk-utility test that governs other consumer products and takes cost into account.[80] Consider this the flipside of the more typical cost-related criticism of section 6(c),[81] with a few commentators worrying that the sole supplier of a prescription drug would have no incentive (at least not mediated by the tort system) to adopt an even slightly more costly but much improved design insofar as reasonable physicians would have no choice but to continue demanding the cheaper and more dangerous product in the absence of substitutes.[82] Such a scenario would, of course, provide a golden opportunity for a

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TIMES, Feb. 13, 2007, at F5 (reporting that "third-generation" low-dose contraceptives also may pose heightened risks).

[79] Courts typically, and I think inappropriately, left an analysis of this trade-off to juries. *See* Brochu v. Ortho Pharm. Corp., 642 F.2d 652, 654–55 & n.4 (1st Cir. 1981); Ortho Pharm. Corp. v. Heath, 722 P.2d 410, 414–16 (Colo. 1986); Glassman v. Wyeth Labs., Inc., 606 N.E.2d 338, 340–41, 343 (Ill. App. Ct. 1992). Nowadays some products halt the menstrual cycle altogether. *See* Shari Roan, *Now, a Birth Control Bonanza*, L.A. TIMES, July 10, 2006, at F1 (describing continuous dosing schedules and implants having the same effect); *see also* Anne Marie Chaker, *Doctors Back off Birth–Control Patch*, WALL ST. J., Nov. 22, 2005, at D1 (reporting that the FDA has added a warning about elevated estrogen levels associated with a once-a-week transdermal product); Dawn Fallik, *Experts: Patches + Heat = Danger*, PHILA. INQUIRER, Mar. 5, 2006, at A18 (describing some of the resulting litigation).

[80] *See, e.g.*, Banks v. ICI Am., Inc., 450 S.E.2d 671, 675 n.6 (Ga. 1994). If the reasonable physician standard governed design defect claims against automobile manufacturers, would vehicles that sacrificed some amount of passenger safety for greater affordability (or merely aesthetics) get driven from the marketplace? *Cf.* Linegar v. Armour of Am., Inc., 909 F.2d 1150, 1154 (8th Cir. 1990) ("A manufacturer is not obliged to market only one version of a product, that being the very safest design possible. If that were so, automobile manufacturers could not offer consumers sports cars, convertibles, jeeps, or compact cars."); *id.* at 1154–55 (explaining the lower cost and other utilities of less-protective bullet proof vests).

[81] *See* Cupp, *supra* note 19, at 103 ("Failing to make a design alteration that would save the lives of ninety percent of a prescription product's users but not affect the other ten percent would apparently be justified if the alternative design would raise the product's price by one pe[n]ny."). Putting aside the obvious implausibility of the one cent differential (and the assumption that competitors would not respond to such an obvious opportunity to capture a large share of this market), this hypothetical incorrectly assumes that one can predict that the redesign would not sacrifice any therapeutic utility to the ten percent of patients who benefit from the existing design. *Cf. infra* note 102 and accompanying text (discussing adverse consequences of attempts to reduce OxyContin's abuse potential). Furthermore, as argued in the text, added expense may excuse a failure to adopt a safer alternative design under section 2(b) but play essentially no role under section 6(c).

[82] *See, e.g.*, Dreier, *supra* note 19, at 261–62 (suggesting that the duty to test might take care of this problem); Winchester, *supra* note 19, at 686 ("[W]hat about the case in which there is only one drug available on the market for an identifiable group of patients, yet . . . the manufacturer had in fact determined how to make the product safer, but decided not to?"); *id.* at 685–88 (suggesting that adoption of a reasonable manufacturer standard might obviate this problem).

competitor to enter this market.[83] One commentator responded by emphasizing that the patent system creates barriers to entry,[84] but those relate primarily to delayed price competition from generic ("knock off") versions rather than genuinely safer alternative designs.[85]

Imagine a new biotechnology drug that is safer and more effective in every type of patient with a certain condition, but it costs $50,000 annually as compared to $500 for the old standby;[86] from a purely medical standpoint, no reasonable physician would prescribe the older product,[87] at least not unless affordability got factored into the equation.[88] With time, older medical technologies will fade from the

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[83] *See* Henderson & Twerski, *supra* note 19, at 179; *infra* note 85; *see also* Matt Richtel, *Warding off Diseases, Many Vaccines at a Time*, N.Y. TIMES, May 16, 2007, at H5 (describing "a broad renaissance in vaccine research and development"); Daniel Costello, *Vaccine Industry Is Being Revived*, L.A. TIMES, Jan. 28, 2007, at A1 (same).

[84] *See* Conk, *supra* note 21, at 757–61; *id.* at 787 ("The patent system's limits on competitive development of safer and more effective designs makes the tort system's functions of deterrence and compensation of particular importance in regard to the designs of drugs . . . ."). For a more detailed response to this point, see *infra* notes 176–181 and accompanying text.

[85] *See* Lichtenberg & Philipson, *supra* note 39, at 644 ("A patent protects an innovator only from others who produce the same product, but it does not protect him from others who produce better products under new patents."); *id.* at 651 ("[W]ithin-patent competition after patent expiration is from so-called generic manufacturers and between-patent competition is from so-called brand-name manufacturers engaging in therapeutic competition within a given disease class."); *id.* at 646–47 ("[C]reative destruction through between-patent competition accounts for at least as much erosion of innovator returns as within-patent competition caused by patent expiration, and often considerably more."); Kevin Outterson, *The Vanishing Public Domain: Antibiotic Resistance, Pharmaceutical Innovation and Intellectual Property Law*, 67 U. PITT. L. REV. 67, 95 n.159 (2005) ("Within a particular class, many drugs may reach the market, very frequently with different patent holders."); *id.* at 95 n.162 ("The average time before a second member of a therapeutic class is marketed is about 1.2 years.").

[86] *See* Denise Gellene, *New Cancer Drugs Are Driving up Cost of Care*, L.A. TIMES, May 14, 2005, at C1 (reporting that the switch from standard chemotherapy agents to "targeted" drugs has, for instance, doubled the average life expectancy of patients with inoperable colon cancer (to 22 months), while treatment costs increased 500-fold (to $250,000)); Rachel Zimmerman, *Drug Slows a Deadly Cancer, Study Finds, but Price Is Steep*, WALL ST. J., June 16, 2005, at D2 (reporting that Velcade®, a newly approved proteasome inhibitor that costs more than $45,000 for a nine month course of treatment, allowed multiple myeloma patients to live an average of three months longer than those given the standard treatment of dexamethasone, a generic corticosteroid that costs $170 and causes fewer serious side effects); *see also* Thomas H. Lee & Ezekiel J. Emanuel, *Tier 4 Drugs and the Fraying of the Social Compact*, 359 NEW ENG. J. MED. 333 (2008); Deborah Schrag, *The Price Tag on Progress: Chemotherapy for Colorectal Cancer*, 351 NEW ENG. J. MED. 317 (2004); Marilyn Chase, *Cancer Tab: Pricey Drugs Put Squeeze on Doctors*, WALL ST. J., July 8, 2008, at A1.

[87] Unlike some other industries (e.g., consumer electronics), technological advance in medicine brings with it increasing rather than declining costs. *See* David M. Kent et al., *New and Dis-improved: On the Evaluation and Use of Less Effective, Less Expensive Medical Interventions*, 24 MED. DECISION MAKING 281, 282 (2004) ("Although lower quality, lower cost products are ubiquitous in most consumer markets, barriers remain for . . . cost-saving medical technologies."); *id.* at 285 ("Clinical medicine is perhaps unique as a consumer market for the absence of innovations promoted for being less costly, albeit less effective, than the best standard.").

[88] *Cf.* Savina v. Sterling Drug, Inc., 795 P.2d 915, 924 (Kan. 1990) (explaining that other courts included cost as a risk-utility factor in resolving pharmaceutical design defect claims); Peter D. Jacobson & C. John Rosenquist, *The Use of Low–Osmolar Contrast Agents: Technological Change and Defensive Medicine*, 21 J. HEALTH POL. POL'Y & L. 243, 250–54 (1996); Laura Landro, *The Informed Patient: Weighing Which Babies Get a Costly Drug—Small Numbers Who Benefit May Not Justify $6,000 Price of Preventive RSV Therapy*, WALL ST. J., Apr. 16, 2008, at D1 (Synagis®). Perhaps physicians would worry that some patients would not comply with a treatment

scene, but manufacturers may persist in marketing them, especially if cost-conscious purchasers continue to demand "safe enough" prescription drugs.[89] Section 6(c) appropriately discourages the continued marketing of genuinely obsolete prescription products that pose undue risks to patients when the FDA has not acted to withdraw these products,[90] but it also should incorporate section 2(b)'s willingness to factor affordability and convenience into the equation.

3. Myths About Designer (and "Lifestyle") Drugs

Section 6(c) recognizes that pharmaceuticals are not designed in the same sense as other consumer goods; instead, new drugs are discovered.[91] The advent of new techniques of "rational drug design,"[92] which some commentators point to when disputing the supposed distinctiveness of pharmaceutical products,[93] will not fundamentally

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regimen because of the expense. *Cf.* Cupp, *supra* note 44, at 237 (suggesting "that physicians are acting reasonably in prescribing the cheaper Proscar to the subclass planning to cut the pills to use safely for baldness"). For the most part, however, they know little about the prices of drugs or how these may impact their patients. *See* Michael E. Ernst et al., *Prescription Medication Costs: A Study of Physician Familiarity*, 9 ARCHIVES FAM. MED. 1002, 1004–06 (2000); Alex D. Federman, Editorial, *Don't Ask, Don't Tell: The Status of Doctor–Patient Communication About Health Care Costs*, 164 ARCHIVES INTERNAL MED. 1723 (2004).

[89] *See supra* note 39 (discussing restricted formularies); *see also* Scott Gottlieb, Op-Ed, *Congress Wants to Restrict Drug Access*, WALL ST. J., Jan. 20, 2009, at A15. Thus, an insurer might defend a policy that covered only generic drugs in the sense that it ensured payment for the state-of-the-art as it had existed approximately one decade earlier (and as it still exists in many industrialized countries where price controls have slowed the introduction of expensive innovations). *Cf.* Outterson, *supra* note 85, at 73 ("Rich consumers pay for and receive the latest innovations (2005 medicine), while the poor might well be satisfied with the less effective, but much less expensive, 1991 all-generic pharmacopoeia."); Daniel Yi, *Savings Ahead in Generic Medicines: Patents Are Expiring on Four Big Brand Names*, L.A. TIMES, July 15, 2006, at A1.

[90] *See* Conk, *supra* note 21, at 749–50 (conceding that section 6(c) would impose liability on a prescription product if it "became obsolete as a result of other subsequently developed and approved drugs of superior safety and equivalent efficacy that have entered the market, without the challenged drug being removed from the marketplace" (footnote omitted)). For instance, the approval of recombinant growth hormone (rhGH) entirely displaced the form derived from cadavers, which suppliers had withdrawn after reports that it transmitted Creutzfeldt–Jakob disease. *See* Lars Noah, *Managing Biotechnology's [R]evolution: Has Guarded Enthusiasm Become Benign Neglect?*, 11 VA. J.L. & TECH. 4, 21 (2006).

[91] Even today, drug discovery depends to a large extent on dumb luck. *See* Thomas M. Burton, *Flop Factor: By Learning from Failures, Lilly Keeps Drug Pipeline Full*, WALL ST. J., Apr. 21, 2004, at A1; Gina Kolata, *Drugs That Deliver More Than Originally Promised*, N.Y. TIMES, Apr. 5, 1998, § 4, at 3; Peter Landers, *Stalking Cholesterol: How One Scientist Intrigued by Molds Found First Statin*, WALL ST. J., Jan. 9, 2006, at A1.

[92] Green, *supra* note 19, at 200; *see also* Naomi Aoki, *Inventing Designer Drugs: By Moving to Cambridge, Novartis Bets $4 Billion It Can Revamp the Science of the Pharmaceutical Industry*, BOSTON GLOBE, Apr. 13, 2003, at D1; Denise Grady & Lawrence K. Altman, *Experimental Drug May Fight SARS, Researchers Say*, N.Y. TIMES, May 14, 2003, at A6.

[93] *See, e.g.*, Green, *supra* note 19, at 220; *id.* at 213 (conceding that this remains "generally more theoretical than contemporaneously real," but predicting that it will become more significant in the future); *see also* Conk, *supra* note 19, at 1107 (arguing that a RAD-based standard "could prove increasingly useful as genetic engineering and microbiology advance and the range of design choices for pharmaceutical product designers becomes broader and less opaque"); Conk, *supra* note 21, at 756 (same). Advances in genetics may, instead, make pharmaceutical cases even more challenging to resolve under existing products liability doctrine. *See infra* Part IV.D.2.

change things anytime soon.[94] A pharmaceutical manufacturer cannot market a theoretical redesign until it discovers this allegedly superior drug, subjects it to the full battery of preclinical and clinical testing over a period of several years, and then patiently waits for the FDA's blessing.[95] Hypothesized redesigns have unpredictable safety and efficacy profiles, which makes it impossible for an expert to predict whether it would pass muster with the FDA.[96]

In some cases, a design defect may relate to the proportions of (or interactions between) ingredients used in a combination drug product rather than the design of the separately approved chemicals themselves.[97]

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[94] *See* Peter Landers, *Human Element: Drug Industry's Big Push into Technology Falls Short*, Wall St. J., Feb. 24, 2004, at A1 (reporting that combinatorial chemistry and high-throughput screening have not panned out); *see also* John Markoff, *Herculean Device for Molecular Mysteries*, N.Y. TIMES, July 8, 2008, at F2 ("Experimentation in the use of supercomputers to model molecular interactions has been going on for more than a decade, but the field is still largely in its infancy."). Even if improved genetic information and enhanced computing power allow for greater initial precision in the identification of promising agents, testing in animals and humans will have to continue for the foreseeable future. *See* Helen M. Berman & Rochelle C. Dreyfuss, *Reflections on the Science and Law of Structural Biology, Genomics, and Drug Development*, 53 UCLA L. REV. 871, 883–86 (2006).

[95] *See* Ackley v. Wyeth Labs., Inc., 919 F.2d 397, 398–404 (6th Cir. 1990); *id.* at 401 ("Without an FDA license to produce another design, Wyeth was legally prohibited from distributing either a fractionated cell or an acellular [pertussis] vaccine . . . ."); Pease v. Am. Cyanamid Co., 795 F. Supp. 755, 757, 760 (D. Md. 1992) (explaining that the FDA did not approve an acellular version until 1991, and then only as a booster because of doubts about its effectiveness in infants); Jones v. Lederle Labs., 785 F. Supp. 1123, 1127–28 (E.D.N.Y.) (granting a JNOV to the manufacturer), *aff'd*, 982 F.2d 63, 64 (2d Cir. 1992); White v. Wyeth Labs., Inc., 533 N.E.2d 748, 753 (Ohio 1988) (describing evidence concerning the relative safety and effectiveness of alternative vaccine designs as "speculative at best"); *see also* Henderson & Twerski, *supra* note 19, at 175 ("[A]s long as marketing of such safer drugs requires FDA approval, in-court replication of the formal approval process will continue to exceed the limits of adjudication."). *But see* Graham v. Wyeth Labs., 666 F. Supp. 1483, 1496–98 (D. Kan. 1987); Toner v. Lederle Labs., 732 P.2d 297, 308 (Idaho 1987).

[96] *See* Stephanie Saul, *Drug Makers Race to Cash in on Fight Against Fat*, N.Y. TIMES, Apr. 3, 2005, § 1, at 1; *see also* **Error! Main Document Only.**Robert J. Mayer, Editorial, *Targeted Therapy for Advanced Colorectal Cancer—More Is Not Always Better*, 360 NEW ENG. J. MED. 623 (2009) (describing entirely unexpected efficacy problems encountered when using a pair of approved drugs in combination). If any such experts actually existed, then they could make a killing in the stock market! *Cf.* John Russell, *Which Way, FDA?: Is Lilly's Promising Blood Thinner Effient Destined to Move Ahead with FDA Approval Next Week, or Could It Stall Because of Concerns over Its Health Risks?*, INDIANAPOLIS STAR, Sept. 21, 2008, at Bus. 1 (reporting disagreement among investment analysts, even after the completion of all testing, about the approval odds for prasugrel as the deadline neared for a final agency decision); Jeanne Whalen, *FDA Setback for New Drug from Roche*, WALL ST. J., Sept. 19, 2008, at B10 (actrema).

[97] *See, e.g.*, Ezagui v. Dow Chem. Corp., 598 F.2d 727, 731–32 (2d Cir. 1979) (alleged defect related to the use of a different inactive ingredient that caused endotoxins to leak from the pertussis component of a combination vaccine); *id.* at 733–36 (finding sufficient evidence in the record to present a jury question); *see also* Green, *supra* note 19, at 211–12, 219 (using other illustrations to make these points). Along similar lines, consider the following hypothetical:

> Suppose the vaccine causes a mild auto-immune reaction—a rash that lasts for a week—in one out of a million persons who take the vaccine. The side effect can be eliminated by changing one of the inert ingredients with which the vaccine is coated to another inert ingredient, no more expensive and equally adept at serving its purpose. The vaccine is defectively designed despite its enormous social utility.

Michael D. Green, *The Schizophrenia of Risk–Benefit Analysis in Design Defect Litigation*, 48 VAND. L. REV. 609, 619 (1995) ("Risk-benefit operates at the margin—the utility of the existing design compared to the alternative—not at the level of the entire product."); *see also* Green, *supra*

Design issues also may relate to fixed dosage levels.[98] Even minor changes in formulation (e.g., different inactive ingredients) would, however, require the submission of a new drug approval (NDA) supplement to the FDA with supporting data to demonstrate bioavailability of the active ingredient.[99] For instance, OxyContin® caused deaths among abusers who had managed to defeat the delayed-release mechanism by crushing or dissolving the pills.[100] After the filing of several lawsuits, the manufacturer announced plans to add an ingredient that could deactivate the oxycodone when crushed, but the changed formulation would have to await FDA approval.[101] In fact, these reformulation efforts have encountered roadblocks.[102]

Apart from laboring under misimpressions about the ease of redesigning prescription drugs, critics of efforts to constrain design defect scrutiny point out that pharmaceutical products do not all have equally high utility. In making product approval decisions, the FDA routinely struggles with such questions.[103] Obviously, the agency will

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note 19, at 225 ("At the margin, we should always be willing to examine whether we can improve the overall benefit-to-risk ratio of a product."). In support of the argument that design defects may relate to the relative portions of different active ingredients in combination drugs, critics often cite *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652 (1st Cir. 1981), but the claims against the manufacturer of the oral contraceptive at issue in that case had more to do with the risks and benefits of just one of the active ingredients as compared to lower-dose versions used in competing products, *see id.* at 654–55 & nn.1&4.

[98] *See* Green, *supra* note 19, at 212–13; *see also* Suz Redfearn, *Low–Dose Hormone Approved*, WASH. POST, Mar. 25, 2003, at F1 (reporting that the manufacturer of Prempro® had responded to new risk information by securing approval for a lower-dose (and presumably safer) version, and noting a similar response many years earlier by sellers of oral contraceptives); Andrew Schneider, *Banned Pesticide Allowed as Medicine: U.S. Bars Lindane, Except to Treat Lice*, BALT. SUN, Aug. 14, 2006, at 1A (reporting that the FDA sought to limit the number of doses dispensed at a time). Changes in dosing instructions, however, relate more to questions of labeling than design. *Cf.* Abigail Zuger, *Caution: That Dose May Be Too High*, N.Y. TIMES, Sept. 17, 2002, at F1 (reporting that manufacturers often reduce recommended dosages in response to postapproval safety concerns).

[99] *See* 21 C.F.R. § 314.70 (2008) (distinguishing—for purpose of requiring NDA supplements—between "major," "moderate," and "minor" changes); *see also* Mead Johnson Pharm. Group v. Bowen, 838 F.2d 1332, 1334–35 & n.2 (D.C. Cir. 1988) (explaining that lower-level agency reviewers have the authority to approve NDA supplements but not NDAs). Perhaps hypothetical redesigns that would require only an NDA supplement (especially for changes that did not qualify as "major") might provide fair game for design defect claims while those that would require the filing of a new (full blown) NDA should remain off limits.

[100] *See* Barry Meier, *U.S. Asks Painkiller Maker to Help Curb Wide Abuse*, N.Y. TIMES, May 1, 2001, at A16. OxyContin is an extended-release formulation of oxycodone, a synthetic form of morphine effective in relieving severe or chronic pain such as that experienced by cancer patients.

[101] *See* Lars Noah, *Challenges in the Federal Regulation of Pain Management Technologies*, 31 J.L. MED. & ETHICS 55, 62 (2003) (discussing the use of naltrexone); *see also* Sandra Blakeslee, *Drug Makers Hope to Kill the Kick in Pain Relief*, N.Y. TIMES, Apr. 20, 2004, at F1 (reporting that another approach involves adding a chemical irritant such as capsaicin).

[102] *See* Andrew Pollack, *Company Said to Develop Substitute for Painkiller*, N.Y. TIMES, Nov. 5, 2003, at C4; *see also* Marc Kaufman, *Drug Firms Trying to Make Painkillers Less Abusable*, WASH. POST, June 14, 2004, at A7 (reporting that "some combination drugs that might reduce the abuse potential of painkillers are also likely to reduce their effectiveness").

[103] *See, e.g.*, E.R. Squibb & Sons, Inc. v. Bowen, 870 F.2d 678, 681–86 (D.C. Cir. 1989) (upholding the FDA's decision to withdraw approval of drugs where the agency found no "medical significance" to the use of antifungal ingredients intended to reduce candidal overgrowth after a

tolerate substantial risks for drugs that may save lives,[104] while products that treat minor conditions or offer only symptomatic relief will not get approved unless fairly benign.[105] Between these two extremes lie difficult and increasingly contested judgments about the nature of the condition intended for treatment,[106] as illustrated by recent debates over the use of psychotropic drugs,[107] stimulants in children with behavioral

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course of antibiotics); Warner–Lambert Co. v. Heckler, 787 F.2d 147, 154–56 (3d Cir. 1986) (rejecting the plaintiff's claim that "'effectiveness' as used in the Act means only that the drug will have the effect the manufacturer claims for it," and concluding that the demonstration of effectiveness must include evidence of a therapeutic level of action compared with placebo); *see also* Rob Stein, *Medication Under a Microscope: Studies Raise Questions About Drugs' Efficacy Against Disease*, WASH. POST, Feb. 19, 2008, at A2. FDA regulations define "effectiveness" in terms of "clinically significant" outcomes. *See* 21 C.F.R. § 330.10(a)(4)(ii) (2008) (nonprescription drugs); *id.* § 601.25(d)(2) (biologics); *id.* § 860.7(e)(1) (devices).

[104] *See* Temple, *supra* note 69, at 1888 ("For serious diseases, especially those poorly treated by available therapy, considerable toxicity is acceptable, and labeling is used to attempt to guide physicians in detecting and mitigating harm."); Ron Winslow, *What Makes a Drug Too Risky? There's No Easy Answer*, WALL ST. J., Feb. 16, 2005, at B1. In reviewing high priority (potentially lifesaving) drugs, the agency has become more willing to accept "surrogate markers" for clinical endpoints. *See* 21 C.F.R. §§ 314.510, 601.41. For example, in the case of new cancer treatments, tumor shrinkage might substitute for evidence of extended survival times. *See* Anna Wilde Mathews, *Are Long Trials Always Needed for New Drugs?*, WALL ST. J., Apr. 26, 2004, at B1; *cf.* Andrew Pollack, *F.D.A. Restricts Access to Cancer Drug, Citing Ineffectiveness*, N.Y. TIMES, June 18, 2005, at C2 (reporting that the FDA approved Iressa® for lung cancer based on a fairly small clinical trial that showed tumor shrinkage in 10% of patients who had not responded to chemotherapy but rescinded its approval two years later after the sponsor submitted postapproval clinical trials that showed no improvement in survival).

[105] *See* Scott Allen, *In Fat War, Doctors Have Few Weapons*, BOSTON GLOBE, Apr. 1, 2004, at A1 (reporting that, according to some critics, FDA reviewers "subject weight-loss drugs to tougher safety standards than other drugs because they do not regard obesity as a true disease"); Laura Johannes & Steve Stecklow, *Dire Warnings About Obesity Rely on Slippery Statistic*, WALL ST. J., Feb. 9, 1998, at B1 ("[T]he FDA's bar for approving new drugs is lower for disease treatments than for other problems, such as baldness or skin wrinkles. The agency is less likely to approve a drug for a nondisease condition when it is shown to have serious side effects—such as those that diet drugs produce."); *see also* Christopher Rowland, *FDA Chief Looks to Speed Diabetes, Obesity Drugs*, BOSTON GLOBE, June 4, 2003, at A1; Rob Stein, *Is Obesity a Disease?: Insurance, Drug Access May Hinge on Answer*, WASH. POST, Nov. 10, 2003, at A1.

[106] *See* Lars Noah, *Pigeonholing Illness: Medical Diagnosis as a Legal Construct*, 50 HASTINGS L.J. 241, 259–63, 290–92 (1999). Thus, commentators have criticized the drug industry for promoting the medicalization of normal or relatively minor conditions. *See* Ray Moynihan et al., *Selling Sickness: The Pharmaceutical Industry and Disease Mongering*, 324 BRIT. MED. J. 886 (2002); Rob Stein, *Marketing the Illness and the Cure? Drug Ads May Sell People on the Idea That They Are Sick*, WASH. POST, May 30, 2006, at A3; Fiona Walsh, *Glaxo Denies Pushing "Lifestyle" Treatments*, GUARDIAN (LONDON), Apr. 28, 2006, at 28 (GSK "defended itself against accusations that it is turning healthy people into patients by 'disease mongering' and pushing 'lifestyle' treatments for little-known ailments [e.g., restless leg syndrome]. Studies published in a respected medical journal . . . accused the big pharmaceutical companies of 'medicalising' problems such as high cholesterol and sexual dysfunction."); *see also* Marc Kaufman, *Hormone Replacement Gets New Scrutiny: Finding of Increased Risks Prompts Federal Effort*, WASH. POST, Aug. 14, 2002, at A1 (reporting that "federal officials want to explore whether hormone therapies and their producers have encouraged women to believe menopause is a condition to be treated, rather than an inevitable and natural set of changes to be managed," noting "the FDA's discomfort with the way that hormone treatments have been widely presented as an antidote to menopause").

[107] *See* Colleen Cebuliak, *Life as a Blonde: The Use of Prozac in the '90s*, 33 ALTA. L. REV. 611 (1995) (discussing emotional enhancement and cosmetic pharmacology); Jeff Donn, *Are We Taking Too Many Drugs?*, NEWSDAY, Apr. 19, 2005, at B13 ("[T]he Centers for Disease Control voiced concern about huge off-label growth of antidepressants to treat such loosely defined syndromes as compulsion, panic or anxiety and PMS. Drug makers, doctors and patients have all

disorders,[108] the abortifacient drug Mifeprex® (mifepristone),[109] and the vaccine Gardasil® (designed to prevent a sexually transmitted disease, human papillomavirus (HPV), linked to cervical cancer).[110]

Some commentators would hold manufacturers of "lifestyle" drugs to a higher standard. One laundry list of such products included treatments for erectile dysfunction (ED), arthritis, obesity, and urinary incontinence,[111] but it failed to explain the reasons for lumping these disparate drugs together: was it that they offered primarily symptomatic relief (or targeted a mere risk factor[112]) and required chronic use? Aside from problems of recreational abuse, are powerful analgesics properly

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been quick to medicate some conditions once accepted simply as part of the human condition."); Shankar Vedantam, *Drug Ads Hyping Anxiety Make Some Uneasy*, WASH. POST, July 16, 2001, at A1 (describing the successful marketing of Paxil® (paroxetine), and noting that "pharmaceutical companies, traditionally in the business of finding new drugs for existing disorders, are increasingly in the business of seeking new disorders for existing drugs"); *see also* Lars Noah, *Comfortably Numb: Medicalizing (and Mitigating) Pain-and-Suffering Damages*, 42 U. MICH. J.L. REFORM 431, 463–64 (2009)

[108] *See* Gardiner Harris, *F.D.A. Strengthens Warnings on Stimulants' Risks*, N.Y. TIMES, Aug. 22, 2006, at A14; Shankar Vedantam, *Warning Urged for ADHD Drugs: Panel Cites Risks, Fears of Overuse*, WASH. POST, Feb. 10, 2006, at A1 ("About 10 percent of 10-year-old American boys are taking such medications, and there have been recent sharp increases in the number of adults taking them."); *see also* Gardiner Harris, *Use of Antipsychotics in Children Is Criticized*, N.Y. TIMES, Nov. 19, 2008, at A20.

[109] *See* Lars Noah, *A Miscarriage in the Drug Approval Process?: Mifepristone Embroils the FDA in Abortion Politics*, 36 WAKE FOREST L. REV. 571, 593 (2001) ("Some opponents have suggested that the agency might . . . recast mifepristone's intended use in terminating pregnancy as a risk to the fetus rather than (or perhaps in addition to) a benefit to the mother, which might then justify summary withdrawal of the drug as an imminent hazard to public health."); *see also id.* at 580 ("[T]he clinical utility of a drug that can terminate pregnancy must lie in the fact that it provides a safer (or more convenient) alternative to a surgical abortion."); *id.* at 581–82 (questioning the product's eligibility for accelerated FDA approval as a treatment for "serious illness").

[110] *See* Charlotte J. Haug, Editorial, *Human Papillomavirus Vaccination: Reasons for Caution*, 359 NEW ENG. J. MED. 861, 861–62 (2008); Sylvia Law, *Human Papillomavirus Vaccination, Private Choice, and Public Health*, 41 U.C. DAVIS L. REV. 1731, 1733–42, 1755–64 (2008); *see also* Note, *Toward a Twenty-first Century* Jacobson v. Massachusetts, 121 HARV. L. REV. 1820, 1838–41 (2008) (suggesting a distinction, for purposes of evaluating the constitutionality of compulsory immunization programs, between "medically necessary" vaccines, which offer the only real means of protection against infectious diseases, and "practically necessary" vaccines that protect, for instance, against STDs (e.g., HPV and hepatitis B), which could be avoided through other means).

[111] *See* Joseph Weber & Amy Barrett, *The New Era of Lifestyle Drugs: Viagra and Other Blockbusters Are Transforming the $300 Billion Industry*, BUS. WK., May 11, 1998, at 92; *see also* David Gilbert et al., *Lifestyle Medicines*, 321 BRIT. MED. J. 1341, 1342 (2000) (offering a similar list, and focusing on payment issues); Cindy Parks Thomas, *Incentive–Based Formularies*, 349 NEW ENG. J. MED. 2186, 2188 (2003) ("Some insurers have created a fourth, 'lifestyle,' tier for more discretionary or 'cosmetic' drugs . . . .").

[112] What once qualified as mere risk factors may, over time, get recharacterized as diseases in their own right, as in the case of hypertension. *See, e.g.*, Denise Grady, *As Silent Killer Returns, Doctors Rethink Tactics to Lower Blood Pressure*, N.Y. TIMES, July 14, 1998, at F1 (reporting that "it is not known whether all drugs that lower blood pressure also protect against heart attack and stroke"). Thereupon, physicians began diagnosing patients with pre-hypertension. *See* Elizabeth Agnvall, *Making Us (Nearly) Sick: A Majority of Americans Are Now Considered to Have at Least One "Pre–Disease" or "Borderline" Condition. Is This Any Way to Treat Us?*, WASH. POST, Feb. 10, 2004, at F1; *see also* January W. Payne, *Forever Pregnant—Guidelines: Treat Nearly All Women as Pre–Pregnant*, WASH. POST, May 16, 2006, at F1.

dismissed as merely "lifestyle" drugs? Contraceptives sometimes get trivialized in this fashion.[113]

Even if not elevated to the vaunted status of a genuine "disease," bothersome conditions (e.g., irritable bowel syndrome) and disfiguring ailments (e.g., cystic acne) undoubtedly have adverse effects on the sufferers' quality of life, which can take an emotional and financial toll on them.[114] If not unduly dangerous, the FDA does permit marketing of prescription products that presumably everyone would label as "lifestyle" drugs (e.g., wrinkle reducers),[115] though even unmistakably cosmetic products such as Botox® may have secondary therapeutic uses.[116] In the final analysis, all drugs are, to one degree or another, lifestyle drugs.[117]

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[113] *See, e.g.*, Hill v. Searle Labs., 884 F.2d 1064, 1069–70 & n.9 (8th Cir. 1989) (finding that IUDs do not serve an "exceptional social need" in part because many alternative forms of contraception exist, including abstention); *see also* MacDonald v. Ortho Pharm. Corp., 475 N.E.2d 65, 69–70 (Mass. 1985) (emphasizing the elective nature of contraceptives). *But see* Kociemba v. G.D. Searle & Co., 680 F. Supp. 1293, 1305–06 (D. Minn. 1988) (disagreeing). Contraceptives may, however, have unmistakable medical justifications, *see* Steven R. Bayer & Alan H. DeCherney, *Clinical Manifestations and Treatment of Dysfunctional Uterine Bleeding*, 269 JAMA 1823, 1826–28 (1993), including for women in whom pregnancy would present dangers to themselves or their children (indeed, the labeling for prescription drugs that treat other conditions may insist that patients use contraceptives in order to guard against the risk of birth defects).

[114] *See, e.g.*, Denise Grady, *F.D.A. Pulls a Drug, and Patients Despair*, N.Y. TIMES, Jan. 30, 2001, at F1 (reporting that those who favored withdrawing Lotronex® (alosetron), a drug indicated for use in patients with irritable bowel syndrome, had argued that its risks of severe constipation or ischemic colitis were unacceptable because it only treated a non-life-threatening condition, while the majority of patients on the drug who had suffered no serious side effects protested the withdrawal because the drug had helped them to cope with a condition that significantly interfered with their daily life activities).

[115] *See* Natasha Singer, *Injecting Silicone, and Risk*, N.Y. TIMES, Jan. 26, 2006, at G1.

[116] *See* Lisa Girion, *Concern Raised on Botox Safety*, L.A. TIMES, Feb. 9, 2008, at C1; Rhonda L. Rundle, *Botox Use on Migraines Gains Support*, WALL ST. J., Sept. 12, 2008, at B3; Shankar Vedantam, *Botox Appears to Ease Depression Symptoms*, WASH. POST, May 21, 2006, at A9; *see also* Liz Kowalczyk, *Doctors Seek a Viagra Variant for Lung Ailment*, BOSTON GLOBE, Aug. 3, 2001, at A1 (reporting that physicians have used the ED drug sildenafil to treat pulmonary hypertension in infants); Donald G. McNeil, Jr., *Cosmetic Saves a Cure for Sleeping Sickness*, N.Y. TIMES, Feb. 9, 2001, at A1.

[117] *Cf.* Anita Bernstein & Joseph Bernstein, *An Information Prescription for Drug Regulation*, 54 BUFF. L. REV. 569, 608–11 (2006) (conceding that "lifestyle" drugs lie along a continuum, though suggesting a distinction based on the exercise of patient choice). A similarly vague dividing line exists with regard to medical procedures, treating "elective" surgeries as non-essential (or, at least, non-emergency). *See* FDA, General and Plastic Surgery Devices; Effective Date of Requirement for Premarket Approval of Silicone Inflatable Breast Prosthesis, 58 Fed. Reg. 3436, 3439 (Jan. 8, 1993) ("Whether performed for reconstruction or augmentation purposes, breast implantation is a discretionary elective surgical procedure performed for its psychological benefits."); *see also* Zalazar v. Vercimak, 633 N.E.2d 1223, 1225–27 (Ill. App. Ct. 1993) (adopting a subjective standard of decision causation for informed consent claims involving elective cosmetic surgery); Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899, 955 (1994) (proposing a heightened consent duty in the case of elective treatments); *cf.* Whitlock v. Duke Univ., 637 F. Supp. 1463, 1470–71 (M.D.N.C. 1986) (concluding that the degree of required risk disclosure is higher in the context of non-therapeutic research), *aff'd*, 829 F.2d 1340 (4th Cir. 1987). *But see* Pauscher v. Iowa Methodist Med. Ctr., 408 N.W.2d 355, 359–61 (Iowa 1987) (declining to draw such a distinction). Even so, unmistakably lifesaving procedures technically also should qualify as elective insofar as respect for autonomy means that patients have a right to decline treatment. *See* Dan W. Brock & Steven A. Wartman, *When Competent Patients Make Irrational Choices*, 322 NEW ENG. J. MED. 1595 (1990).

In theory, section 6(c)'s reference to "therapeutic benefits" and use of a physician-based standard might expose "lifestyle" drugs to unforgiving design defect scrutiny.[118] Although it appears that the Reporters meant to include even "cosmetic" products that required the intervention of a health care provider,[119] courts may refuse to credit these separately published glosses on the blackletter formulation. If taken at face value, section 6(c) could have the effect of delegating judgments about the utilities of prescription products to reasonable physicians whose professional training presumably would give us a far narrower range of legitimate clinical endpoints, which would make some pharmaceutical manufacturers more vulnerable to design defect claims than they would have been under the more flexible and consumer-oriented standard of section 2(b).

Aside from questions about the special utility of prescription drugs, some commentators have argued that, unlike other consumer goods, these products rarely cause third-party effects,[120] but this claim of

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[118] *See* Henderson, *supra* note 19, at 492 ("[W]hen defendant's drug is the only one of its kind on the market and serves what members of the medical profession ostensibly believe to be a useful purpose, plaintiff should not reach the trier of fact."). A subsequent article co-authored by one of the Reporters (but unrelated to section 6) repeatedly drew a distinction between "lifestyle" and "therapeutic" drugs. *See* Margaret A. Berger & Aaron D. Twerski, *Uncertainty and Informed Choice: Unmasking* Daubert, 104 MICH. L. REV. 257, 259, 272, 288 & n.148 (2005) [hereinafter *Informed Choice*]; *id.* at 279 (imagining a drug that "has little therapeutic value and provides only aesthetic or palliative relief"); *see also id.* at 269–70 (using Parlodel, which allegedly "created gratuitous risk with very little benefit" in lactation suppression, especially compared to the use of OTC analgesics for this same purpose, to justify the recognition of a new type of failure-to-warn claim that would not require proof of causation); *cf.* David E. Bernstein, Correspondence, *Learning the Wrong Lessons from "An American Tragedy": A Critique of the Berger–Twerski Informed Choice Proposal*, 104 MICH. L. REV. 1961, 1967–68 (2006) (disputing their suggestion that the morning sickness remedy Bendectin qualified as a lifestyle drug, explaining that, in severe cases, it could reduce dehydration and the accompanying need for hospitalization and risks of fetal harm). Their rejoinder never attempted to respond to the point that Bendectin served genuine therapeutic purposes, opting instead for rhetorical flourishes to underscore their thesis. *See* Margaret A. Berger & Aaron D. Twerski, Correspondence, *From the Wrong End of the Telescope: A Response to Professor David Bernstein*, 104 MICH. L. REV. 1983, 1989 (2006) ("When one seeks to huckster drugs as if they were M&M's, brutal honesty is called for."); *id.* at 1992 (referring to decisions "to imbibe non-therapeutic drugs," as if these amounted to alcoholic beverages); *see also id.* at 1991–92 (suggesting that Vioxx "offer[ed] little or no therapeutic benefits").

[119] *See* Henderson, *supra* note 19, at 484–86 (discussing a hypothetical choice between different breast implant designs, and arguing that fully-informed patients should be allowed to opt for a riskier version on aesthetic grounds); Henderson & Twerski, *supra* note 19, at 176–77 (noting that "there exists a class of patients who benefit emotionally and psychologically," even if not physically, from such products, and recognizing that "prescription drugs and devices [with] aesthetic properties can have profoundly beneficial effects on an individual's psychic well-being"); *cf.* Savina v. Sterling Drug, Inc., 795 P.2d 915, 927 (Kan. 1990) ("The policy considerations underlying strict liability and Comment *k* would apply to a diagnostic drug as well as to a drug used for treatment."). It remains unclear how they would evaluate secondary utilities such as convenience and cost that seemingly have no therapeutic benefit broadly conceived. *See supra* notes 76–90 and accompanying text.

[120] *See* Green, *supra* note 19, at 216 ("Only in the rarest situation is there any potential for third-party effects from drugs."); Henderson, *supra* note 19, at 494 (referring to "the substantial absence of third-party effects"); *see also id.* at 480–81 ("[W]hen negative third party effects are minimal, courts should hesitate before imposing the added costs of greater safety on users or consumers who do not volunteer to pay for additional safeguards when choosing which product

distinctiveness strikes me as clearly incorrect. It disregards, for instance, recurring litigation over birth defects (including cases where the drug has no intended use related to pregnancy),[121] sedation (as it relates to automobile accidents and the like),[122] and psychosis.[123] It also seemingly disregards claims related to abuse and diversion.[124] Finally, though not so far as I know litigated, efficacy failures may permit contagious diseases to spread to others,[125] pharmaceuticals may cause harm to health care workers,[126] and medical technologies may have deleterious environmental consequences.[127] Prescription products have many

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designs to buy in the marketplace." (footnote omitted)); Henderson & Twerski, *supra* note 19, at 177 (noting that cosmetic drugs and devices "rarely have adverse third-party effects").

[121] *See infra* Part II.C.2 (thalidomide and methotrexate); *infra* Part II.C.5 (isotretinoin); *infra* notes 313–314 and accompanying text (diethylstilbestrol); *see also* David B. Brushwood, *Drug Induced Birth Defects: Difficult Decisions and Shared Responsibilities*, 91 W. VA. L. REV. 51 (1988).

[122] *See, e.g.*, McKenzie v. Hawai'i Permanente Med. Group, Inc., 47 P.3d 1209, 1210–11, 1218–22 (Haw. 2002); Coombes v. Florio, 877 N.E.2d 567, 572–75 (Mass. 2007) (plurality) (addressing the duty of physicians to warn in such cases); Osborne v. United States, 567 S.E.2d 677, 679 (W. Va. 2002); *see also* Stephanie Saul, *Some Sleeping Pill Users Range Far Beyond Bed*, N.Y. TIMES, Mar. 8, 2006, at C1 (reporting that Ambien® has been linked to sleepwalking and impaired driving).

[123] *See, e.g.*, Potter v. Eli Lilly & Co., 926 S.W.2d 449, 451 (Ky. 1996) (Prozac®), *abrogated on other grounds by* Hoskins v. Maricle, 150 S.W.3d 1 (Ky. 2004); Rimbert v. Eli Lilly & Co., 577 F. Supp. 2d 1174, 1234 (D.N.M. 2008) (same); Upjohn Co. v. Freeman, 885 S.W.2d 538, 540, 548–50 (Tex. Ct. App. 1994) (reversing a judgment for plaintiffs in a Halcion® psychosis case); Emily Heller, *Drug Maker Hit with $8M Verdict: Jury Finds Maker of Paxil Mainly Responsible for Multiple Shooting Deaths*, NAT'L L.J., June 25, 2001, at A5.

[124] *See, e.g.*, Erony v. Alza Corp., 913 F. Supp. 195, 197 (S.D.N.Y. 1995) (allowing an inadequate warning claim to proceed on behalf of a teenager who died after sucking on his father's discarded Duragesic® patches); *see also* Joseph B. Prater, Comment, *West Virginia's Painful Settlement: How the OxyContin Phenomenon and Unconventional Theories of Tort Liability May Make Pharmaceutical Companies Liable for Black Markets*, 100 NW. U. L. REV. 1409 (2006); *cf.* Gipson v. Kasey, 150 P.3d 228, 229, 233–34 (Ariz. 2007) (holding that a patient who gave away oxycodone owed a duty to others injured by misuse). On this score, the Reporters only imagined a minor possibility that friends or family of patients would borrow their unused prescription drugs. *See* Henderson & Twerski, *supra* note 19, at 171 n.81.

[125] *Cf.* Dave Murphy, *92 Patients Told of Possible Exposure to TB: Medical Devices in Hospital Surgeries Weren't Sterilized*, S.F. CHRON., Feb. 11, 2005, at B4 (reporting that a sterilizing device had failed to function). The flipside of this argument appears frequently (as justifying limits on liability in order to reduce disincentives to R&D): vaccines and antibiotics, for example, resemble public goods because, when they work, both the patient and third parties benefit; conversely, when antibiotics are used inappropriately, the patient derives no benefit and third parties eventually may suffer harm due to the emergence of bacterial resistance. *See* David Brown, *Drug–Resistant Cases of TB in U.S. Increase*, WASH. POST, Mar. 24, 2006, at A10; Justin Gillis & Ceci Connolly, *Emphasis on Cipro Worries Officials*, WASH. POST, Oct. 19, 2001, at A17 (reporting that drug-resistant bacteria contribute to 70,000 deaths each year in the United States); Anita Manning, *"Superbugs" Spread Fear Far and Wide: Drug–Resistant Staph Infections No Longer Threaten Just Hospital Patients*, USA TODAY, May 11, 2006, at 1A (reporting outbreaks of community-acquired methicillin-resistant staph aureus (MRSA)); *see also* Outterson, *supra* note 85, at 67–68, 73–86, 94–114, 119–123 (elaborating on problems of resistance to antibiotics and antivirals, and discussing various proposed solutions).

[126] *See* Jim Morris, *What If the Cure Is Also a Cause?: The Same Chemo Drugs That Save Some Cancer Patients' Lives Put Health Workers at Risk*, WASH. POST, Feb. 15, 2005, at F1.

[127] *See* Christopher T. Nidel, *Regulating the Fate of Pharmaceutical Drugs: A New Prescription for the Environment*, 58 FOOD & DRUG L.J. 81 (2003); Martha Mendoza, *Drugs Found in More Cities' Water*, ORLANDO SENT., Sept. 12, 2008, at A12; Frank D. Roylance, *"Rescue"*

distinctive characteristics, but an absence of third-party effects is not one of them.

C. Case Studies

The operation of section 6(c) becomes more concrete when applied to particular fact patterns, real or imagined (as I note repeatedly below, these turn out to be far more imagined than real, but that alone does not defeat the effort to draw relevant insights from these case studies).[128] The sections that follow discuss various illustrations offered by both proponents and critics: ritodrine, thalidomide, finasteride, polio vaccines, and isotretinoin. In the subpart that follows immediately after these case studies, I draw some broader lessons and suggest a centrally important design feature of pharmaceutical products that has escaped the attention of commentators.

1. Ritodrine

The Reporters offered an illustration of a successful design defect claim under section 6(c),[129] which they had based on the decision *Tobin v. Astra Pharmaceutical Products, Inc.*[130] Commentators have debated whether or not *Tobin*'s holding aligns with section 6(c), but nearly everyone has taken the opinion at face value.[131] In fact, the court's

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Inhaler Costs to Climb: Supplies Tighten Ahead of Ban of Ozone–Destroying CFC Propellants in Devices, BALT. SUN, Feb. 19, 2006, at 1A.

[128] Pure hypotheticals offered by critics of section 6(c) suffer from acontextuality. *See, e.g.*, Cupp, *supra* note 19, at 100 n.147 (imagining a drug that provides "a slight benefit to" 10% of users, while causing a lethal allergic reaction in the other 90%, and that it was not possible to specify the subgroup of users for whom the drug worked without harm); *id.* at 97 (arguing, even more implausibly, that, "if the prescription product could reasonably be prescribed to a single person—even if it were fatal as to all other persons to whom it is prescribed—the product would be immune from design liability"). In terminally-ill patients who have exhausted alternative treatments, I would expect reasonable physicians (and their desperate patients) to opt for a 10% chance of slight benefit even in the face of a 90% chance of death; while, in non-serious conditions (or life-threatening conditions amenable to other treatments), I trust that no reasonable health care provider supplied with an adequate warning would use such a product (in the highly unlikely event that the FDA would have allowed its marketing in the first place). *See id.* at 100 n.147 (conceding as much). In a subsequent article, this same commentator offered a different hypothetical based only loosely on reality. *See* Cupp, *supra* note 44, at 234–38 (discussing finasteride); *id.* at 237 n.26 (conceding the hypothetical nature of the facts presented); *see also infra* Part II.C.3 (critiquing this case study).

[129] *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. f & illus. 1 (1998).

[130] 993 F.2d 528 (6th Cir. 1993).

[131] Strangely, a feminist critique of section 6(c) dismissed *Tobin* as atypical because it seemed to involve a drug marketed without having secured FDA approval. *See* Trompeter, *supra* note 40, at 1154–55; *see also id.* at 1156 (suggesting that the case really involved a product malfunction, which would allow an inference of a manufacturing defect, even though from all appearances the drug had worked to halt the plaintiff's premature labor). Contrary to this commentator's interpretation, *see id.* ("Thus, section 6(c) is a 'super' res ipsa loquitur standard, forcing the plaintiff to shoulder the difficult burden of establishing *comprehensive* product failure not just for her, but for every class of users."); *id.* at 1172 (reiterating that "inefficacy is the basis of liability"), effective drugs could fail the test if equally effective interventions posed lower risks in all classes of patients. She also badly misunderstood the one judicial opinion that offered the clearest

analysis in that case seemed emblematic of precisely the sort of mischief that the Reporters had sought to guard against,[132] and it also poses important questions about the operation of their blackletter formulation.

In *Tobin*, a woman pregnant with twins received a prescription for Yutopar® (ritodrine) to prevent premature labor. She developed serious cardiac problems while taking the drug and, after a successful delivery, required a heart transplant. The plaintiff prevailed at trial on her design defect and failure-to-warn claims, after her experts identified numerous methodological flaws in the clinical trials submitted to the FDA, which members of the agency's advisory committee also had criticized. The federal appellate court in *Tobin* affirmed, concluding that, notwithstanding the fact of FDA approval (or any evidence of fraud in securing that approval or contrary postapproval data),[133] the jury could have concluded that the manufacturer should never have marketed the drug because it had no good evidence of effectiveness in improving neonatal outcomes, though the court did concede that the drug appeared to reduce the need for maternal hospitalization.[134] In short, if the jury found that the drug lacked all utility (because it simply did not work), then any risk would render it defectively designed. The drug's labeling

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support for the protective standard announced in section 6(c). *See id.* at 1159–60 (focusing on language in *Williams v. Ciba–Geigy Corp.*, 686 F. Supp. 573 (W.D. La.), *aff'd*, 864 F.2d 789 (5th Cir. 1988), that discussed matters of safety, entirely ignoring other language in the opinion that explained, even if the risk were higher than established, the anticonvulsant would have been appropriate for epileptics unresponsive to other less dangerous drugs and was the only treatment available for patients with trigeminal neuralgia); *see also* Cupp, *supra* note 44, at 242 (making the same mistake).

[132] *See* Henderson, *supra* note 19, at 492 (conceding that section 6(c) "allows courts to second-guess the FDA on the . . . question of whether a drug approved by the FDA and marketed by a defendant should *not* have been approved and marketed," though trusting that that would occur "only in relatively rare cases"); Henderson & Twerski, *supra* note 19, at 174 ("By countenancing a finding that a defendant's drug is, essentially, worthless, section 6(c) tacitly assumes that the FDA will occasionally approve (or fail to order withdrawal of) a drug that should not be allowed on the market."). I fail to see how this involves any less an exercise in "rank speculation" than trying to decide whether the FDA might approve a hypothesized alternative design, *id.* at 167; *see also id.* at 162–164; indeed, absent some confession of error by the agency, *cf. supra* note 60 (discussing the FDA's decision to withdraw bromocriptine for the suppression of lactation based on postapproval risk information and reconsideration of its relative efficacy), it seems even less appropriate to invite a jury to engage in this sort of reassessment, *see* Green, *supra* note 19, at 231 ("The FDA performs a risk-benefit analysis when it approves a new drug and, as long as the FDA is provided accurate and complete study data from the drug's sponsor, only a regulatory skeptic or a jury exalter would suggest that such a determination be reconsidered de novo in a civil case."); *see also id.* at 222–23, 232 (explaining the importance of insisting on full regulatory compliance and not simply the fact of agency approval); *cf.* Kaplan et al., *supra* note 27, at 70–75 (favoring the complete elimination of design defect claims).

[133] Even skeptics of a regulatory compliance defense seem to concede that it ought to cover those rare cases where plaintiffs allege defectiveness at the time of FDA approval without suggesting that the manufacturer misled the agency. *See* Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J.L. REFORM 461, 477–78, 495 (1997); *see also id.* at 490–92 (explaining the difficulties that courts would encounter if asked to revisit approval decisions that plaintiffs allege the applicant tainted by some violation of agency requirements); *id.* at 472–73, 495–96 (explaining that most cases involve risks discovered after approval and, for that reason, should proceed as failure-to-warn rather than design defect claims).

[134] *See Tobin*, 993 F.2d at 537–40 & n.8.

had contraindicated its use in patients with pre-existing cardiac disease (which, it turns out, this patient had, though her doctors did not know that at the time), but the court concluded that the drug also should not have been available for use in any other types of patients.

Tobin suffers from numerous shortcomings. First, the court allowed the jury to conclude (with the assistance, of course, of the parties' experts) that the FDA should have accepted neither a surrogate marker (i.e., gestational age) for a clinical end-point (i.e., neonatal health), nor a sub-group analysis of clinical trials that the agency's advisory committee had viewed as methodologically flawed.[135] Second, the court failed to consider the fact that the FDA had not approved any other tocolytic agents as of 1993 or that neonatal intensive care was more primitive when it approved ritodrine in 1980.[136] Third, the court marginalized ritodrine's evident effectiveness in reducing the need for repeated hospitalizations during pregnancy.[137] In effect, it turned a complex risk-utility judgment, using data from less than ideal clinical trials, into a no-brainer by allowing the jury to conclude that the drug was totally ineffective.[138] In short, *Tobin* offers a poor illustration of section 6(c)'s intended scope and operation.

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[135] The court gave exaggerated significance to the comments of the advisory committee, disregarding the fact that the FDA had undertaken a lengthy internal review (and had no obligation to abide by the committee's recommendations) and that the committee had in the end recommended approval. In 1992, based on newly published research, another FDA advisory committee concluded that oral ritodrine lacked effectiveness at current dosages. *See* F–D–C REP. ("The Pink Sheet"), Nov. 2, 1992, at 4; *see also* Kenneth J. Leveno & F. Gary Cunningham, Editorial, *β–Adrenergic Agonists for Preterm Labor*, 327 NEW ENG. J. MED. 349, 349–51 (1992). The drug remains available in the United States, though only in an injectable form (oral dosage forms are still marketed in Canada).

[136] *Cf.* Niels H. Lauersen et al., *Inhibition of Premature Labor: A Multicenter Comparison of Ritodrine and Ethanol*, 127 AM. J. OBSTET. & GYNECOL. 837, 844–45 (1977); Sandra G. Boodman, *Labor Drug Assailed: Article Challenges Mag Sulfate Use*, WASH. POST, Oct. 10, 2006, at F1. The court noted that extended bed rest worked in half of all preterm labor cases. *See Tobin*, 993 F.2d at 540 n.9. In fact, no research supports this still widespread assumption. *See* Valerie Ulene, *Downside of Bed Rest Often Gets Overlooked*, L.A. TIMES, Nov. 5, 2007, at F3.

[137] The court's evident indifference to the drug's ability to reduce the need for maternal hospitalization reinforces previously discussed questions about section 6(c)'s emphasis on "therapeutic benefits." *See supra* notes 76–90 and accompanying text.

[138] Thus, I disagree with one commentator's recent claim that judges resolving drug products liability cases focus unduly on questions of safety and "do not consider effectiveness." Anita Bernstein, *Enhancing Drug Effectiveness and Efficacy Through Personal Injury Litigation*, 15 J.L. & POL'Y 1051, 1072 (2007); *see also id.* at 1058 (calling effectiveness "the neglected and undertheorized younger sibling of prescription drug safety"); *id.* at 1060 (pointing out that "the danger of harmful effects can be named in a warning much more clearly than the danger of futility"); *id.* at 1061 ("explor[ing] the contrary thesis that effectiveness is, and ought to be, central to personal injury litigation related to prescription drugs"); *id.* at 1100. Elsewhere, however, she correctly recognized that effectiveness inevitably gets taken into account when judging prescription drug defectiveness. *See id.* at 1084. (In contrast, Bernstein's repeated assertion that the federal regulatory "effectiveness" standard means nothing other than truth-in-labeling, *see id.* at 1066–68, 1082, 1098, and her passing suggestion that the FDA does not mandate labeling about comparative effectiveness, *see id.* at 1084–85, have no foundation, *see supra* notes 69 & 103.) If a therapeutic failure occurs because of subpotency in a particular dose, an injured patient clearly could allege a manufacturing defect, and, if it occurs because a properly manufactured product does not work at all (as found in *Tobin*), then the patient could allege a design defect (but, if the drug only happens to fail in a particular patient, then, at most, the patient might have an informational defect claim in the event

2. Thalidomide

Similarly, one cannot say that the infamous teratogen thalidomide suffers from a design defect. Currently approved by the FDA for the treatment of skin lesions associated with Hansen's disease (leprosy), though contraindicated for use in pregnancy (and accompanied by various other mechanisms designed to help ensure that physicians and patients take this limitation on use seriously),[139] this drug appropriately passes the section 6(c) test.[140] One wonders whether thalidomide would fare as well under a less structured risk-utility balancing approach in a case where a pregnant leprosy patient had used the drug: (1) from the perspective of her terribly deformed child, the risk clearly outweighs the utility; (2) from the perspective of the mother, the risk to her offspring also undoubtedly outweighs the drug's utility to her (after all, less effective and more dangerous, but non-teratogenic, options such as glucocorticoids might have worked for her);[141] and (3) from a societal

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that the manufacturer exaggerated effectiveness or failed to specify known limitations on use in certain patient subgroups). The tricky issues in therapeutic failure (as opposed to adverse side effect) cases relate to causation and damages, but, apart from a brief discussion of emotional distress, *see* Bernstein, *supra*, at 1080–82, she never mentions (much less grapples with) these complexities, *see, e.g.*, Willis v. Wu, 607 S.E.2d 63, 66 (S.C. 2004) ("A 'wrongful pregnancy' or 'wrongful contraception' action is brought by the parent of a healthy but unplanned child, seeking damages from [inter alia] a . . . pharmaceutical manufacturer who allegedly was negligent in . . . manufacturing a contraceptive prescription or device."); Noah, *supra* note 64, at 377–78 & n.32 (explaining that only in medical malpractice cases do courts recognize claims for the loss of a less-than-even chance for a better outcome); *see also* Rivera v. Wyeth–Ayerst Labs., 283 F.3d 315, 319–21 (5th Cir. 2002) (dismissing, for lack of standing, a nationwide class action lawsuit brought on behalf of healthy users and insurers seeking only to recover their economic losses after the withdrawal of Duract® prompted by safety concerns); New Jersey Citizen Action v. Schering–Plough Corp., 842 A.2d 174, 177–78 (N.J. Super. Ct. App. Div. 2003) (similar conclusion on claims based on direct-to-consumer advertising for Claritin®). *See generally* Moin A. Yahya, *Can I Sue Without Being Injured?: Why the Benefit of the Bargain Theory for Product Liability Is Bad Law and Bad Economics*, 3 GEO. J.L. & PUB. POL'Y 83 (2005).

[139] *See* Rochelle Sharpe, *FDA Approves the Use of Thalidomide to Treat Lesions Caused by Leprosy*, WALL ST. J., July 17, 1998, at B6; Sheryl Gay Stolberg, *Thalidomide Approved to Treat Leprosy, with Other Uses Seen*, N.Y. TIMES, July 17, 1998, at A1; *see also* Michael E. Franks et al., *Thalidomide*, 363 LANCET 1802, 1806–08 (2004) (identifying numerous other therapeutic uses under investigation).

[140] *See* Dreier, *supra* note 19, at 260–61; Green, *supra* note 19, at 228 (calling thalidomide "the horror drug of all time," but explaining that it would pass muster under section 6(c) now that the FDA has approved it for treating a serious skin condition associated with leprosy); *cf.* Brown v. Superior Court, 751 P.2d 470, 481 (Cal. 1988) ("It seems unjust to grant the same protection from liability to those who gave us thalidomide as to the producers of penicillin."). One can say much the same of diethylstilbestrol (DES), the drug at issue in *Brown*. Although the discovery of risks from in utero exposure rendered its continued use in the prevention of miscarriages unjustified (especially in light of doubts that it ever worked for that purpose), *see* Leef Smith, *The DES Legacy: Children of Women Given the Hormone DES Decades Ago Now Cope with Their Own—and Even Their Children's—Health Problems*, WASH. POST, Sept. 23, 2003, at F1, the drug had other legitimate uses, *see* FDA, Diethylstilbestrol as Postcoital Oral Contraceptive; Patient Labeling, 40 Fed. Reg. 5351, 5354–55 (Feb. 5, 1975) (codified at 21 C.F.R. § 310.501(b) (1988)), *revoked*, 54 Fed. Reg. 22,585, 22,586 (May 25, 1989); *cf.* Castrignano v. E.R. Squibb & Sons, Inc., 546 A.2d 775, 776 n.1, 781–82 (R.I. 1988) (recognizing other uses, but nonetheless allowing a jury to find a design defect).

[141] *Cf.* Harbeson v. Parke Davis, Inc., 746 F.2d 517, 523–25 (9th Cir. 1984) (affirming judgment for plaintiffs on an informed consent claim where physicians failed to advise an epilepsy

perspective,[142] the specter of a wave of birth defects arising from the very real possibility of the irresponsible use of this drug by physicians and patients might well outweigh the utility to the relatively small (and still stigmatized) community of leprosy sufferers.[143] Section 6(c) does a better job of managing such cases than either a particularized or aggregate form of risk-utility balancing.[144]

For another potent though far less notorious teratogen, consider methotrexate. It would make no sense to characterize this chemotherapy

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patient of the teratogenicity of Dilantin® after she specifically had inquired about such risks in order to decide whether to attempt to conceive); Gerber v. Hoffmann–La Roche Inc., 392 F. Supp. 2d 907, 920 (S.D. Tex. 2005) ("Mr. Gerber can only argue that Shirley Gerber would not have taken Accutane in the first place if Roche's warning had been adequate."); Hogle v. Hall, 916 P.2d 814, 816–17 (Nev. 1996) (affirming a plaintiff's judgment on an inadequate warning claim involving Accutane). If a physician had selected the drug to treat nausea during pregnancy rather than leprosy, then the patient and victim would have a clear malpractice claim but still not a design defect claim against the manufacturer.

[142] *See* Hill v. Searle Labs., 884 F.2d 1064, 1069 (8th Cir. 1989) (asking whether a prescription product serves an "exceptional social need"); *see also* W. Kip Viscusi, *Wading Through the Muddle of Risk–Utility Analysis*, 39 AM. U. L. REV. 573, 591–97 (1989) (noting that risk-utility analysis might proceed from the perspective of buyers, seller, or society); *cf.* David G. Owen, *Risk–Utility Balancing in Design Defect Cases*, 30 U. MICH. J.L. REFORM 239, 239 (1997) (calling the global approach "balancing bedlam"); David G. Owen, *Toward a Proper Test for Design Defectiveness: "Micro–Balancing" Costs and Benefits*, 75 TEX. L. REV. 1661, 1670–86 (1997) (explaining the flaws with a "macro-balancing" approach).

[143] *See* Calvin Sims, *Japan Apologizes to Lepers and Declines to Fight Isolation Ruling*, N.Y. TIMES, May 24, 2001, at A3; Sally Squires, *A Scary Diagnosis Hits Home: When a Tiny Rash Turns out to be Leprosy, a Teen and Her Community Learn the Modern Reality of Living with the Biblical Disease*, WASH. POST, May 27, 2008, at F1. Contrast this stigma with the continuing activism on behalf of thalidomide victims. *See* Sarah Boseley, *Thalidomide Victims Launch Battle for More Compensation*, GUARDIAN (LONDON), Apr. 4, 2008, at 15; Jamie Talan, *Thalidomide's Legacy*, WASH. POST, Jan. 4, 2000, at F10.

[144] Writing one year prior to its FDA approval for leprosy, one commentator used thalidomide to argue otherwise (on the assumption that agency had approved its use as an antinauseant during pregnancy and that the manufacturer marketed it as completely safe notwithstanding knowledge of reported birth defects in Europe). *See* Winchester, *supra* note 19, at 677–78. First, his hypothetical clearly would provide the basis for an informational defect claim. Second, it mistakenly assumes that the reasonable health care provider standard would ask what a physician presented with this inaccurate information would do. Third, even if the physician knew everything that the hypothetical manufacturer knew but failed to reveal, this commentator concluded that a design defect could not exist in the absence of a substitute. *See id.* at 678 ("If thalidomide were in fact the only 'available' tranquilizer for pregnant women, then section [6](c) automatically confers immunity."). I have no doubt that a fully-informed physician would advise the patient to tough it out (is that a substitute?) rather than assume a high risk of very serious birth defects in order to treat a non-life-threatening condition. *See* Henderson, *supra* note 19, at 492–93 ("It is theoretically possible under the proposed Restatement that a plaintiff might be able to show that, notwithstanding a drug's exclusivity for treating a particular medical condition, no reasonable, knowledgeable provider would prescribe the drug for any class of patients."). Writing one year after the FDA approved thalidomide for leprosy, another commentator conceded that it might not fail design defect scrutiny, so he imagined instead that it only had secured approval for treating baldness! *See* Cupp, *supra* note 44, at 238 (concluding, even given full risk labeling and the admitted availability of substitutes, that such a product would survive design defect scrutiny under section 6(c)). I find this suggestion equally absurd. Even if only indicated for the treatment of male pattern baldness (rather than by women or during pregnancy), such a drug would present serious teratogenic risks because semen can carry residues of thalidomide. *See* Rita Rubin, *Thalidomide Could Guide Use of Drugs That Risk Birth Defects*, USA TODAY, July 22, 1998, at 7D. Given the availability of effective but non-teratogenic treatments, no reasonable physician would prescribe it for any class of balding patients (even if the FDA approved it).

agent as defectively designed. As amply revealed in their labeling, cytotoxic agents have powerful and potentially lethal side effects. When used in cancer patients, often in various combinations and in conjunction with non-drug treatments such as surgery and radiation, the potential benefits may justify taking such risks. When a particular chemotherapy drug fails to slow cancer progression, it does not mean that the product suffers from any defect.[145] Now what if a physician uses a cytotoxic agent for something other than cancer? For instance, doctors have used methotrexate off-label as an abortifacient.[146] Could a patient who received this chemotherapy agent to terminate a pregnancy argue that the drug suffers from a design defect (especially now that the FDA has approved mifepristone for this purpose[147])? Perhaps a jury engaging in aggregate risk-benefit analysis would reach the correct conclusion (treating it instead as a case of either a failure to warn or medical malpractice[148]), but again section 6(c) better guards against the possibility of an absurd outcome.

3. Finasteride

Richard Cupp offered an entirely different illustration designed to criticize the operation of section 6(c). He explained that, four years after the FDA approved Proscar® (finasteride) for the treatment of benign prostatic hyperplasia (BPH), one study found an additional risk and another study failed to confirm its effectiveness.[149] A jury might well

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[145] Similarly, when such a drug does arrest the cancer but causes the patient's death, it also does not mean that the product suffers from a design flaw, and the availability of other (sometimes effective and less dangerous) interventions should not make any difference.

[146] *See* Richard U. Hausknecht, *Methotrexate and Misoprostol to Terminate Early Pregnancy*, 333 NEW ENG. J. MED. 537 (1995); *see also* John Leland, *Abortion Might Outgrow its Need for* Roe v. Wade, N.Y. TIMES, Oct. 2, 2005, § 4, at 14 (focusing on the off-label use of the ulcer drug misoprostol to induce a miscarriage). Methotrexate has other off-label uses. *See* Michael E. Weinblatt, Editorial, *Methotrexate for Chronic Diseases in Adults*, 332 NEW ENG. J. MED. 330, 331 (1995) (explaining that low doses may help to treat autoimmune diseases); *see also* Sidney A. Shapiro, *Limiting Physician Freedom to Prescribe a Drug for Any Purpose: The Need for FDA Regulation*, 73 NW. U. L. REV. 801, 819–20 (1978) (describing problems encountered with the off-label uses of methotrexate).

[147] *See supra* note 109.

[148] *See* Sheppard–Mobley v. King, 830 N.E.2d 301, 303 (N.Y. 2005) (summarizing tort claims brought on behalf of an infant whose mother declined to undergo a surgical abortion after a nonsurgical abortion using methotrexate failed and caused serious birth defects). Off-label prescribing does not invariably amount to a deviation from the standard of care. *See* David C. Radley et al., *Off-label Prescribing Among Office–Based Physicians*, 166 ARCHIVES INTERNAL MED. 1021 (2006); Bernadette Tansey, *Why Doctors Prescribe Off Label*, S.F. CHRON., May 1, 2005, at A12; *see also* Bell v. Maricopa Med. Ctr., 755 P.2d 1180, 1182 (Ariz. Ct. App. 1988) (alleging malpractice for the failure to use an approved drug for an off-label use); Bridges v. Shelby Women's Clinic, 323 S.E.2d 372, 374–76 (N.C. Ct. App. 1984) (same).

[149] *See* Cupp, *supra* note 44, at 235. In fact, the news article that he cited, though mentioning an earlier study that found no benefit over placebo, had focused on a newly published study that confirmed limited efficacy. *See* Laura Beil, *Drug Shows Promise for Prostate Patients*, DALLAS MORN. NEWS, Feb. 26, 1998, at 4A; *see also* Michelle I. Wilde & Karen L. Goa, *Finasteride: An Update of Its Use in the Management of Symptomatic Benign Prostatic Hyperplasia*, 57 DRUGS 557 (1999). For a discussion of the debate over the unflattering earlier study, see

second-guess the agency on the basis of such sparse evidence (as happened in *Tobin*), but, one decade later, the totality of published research continues to support the widespread use of this still-approved drug for treating BPH.[150]

Cupp added that the FDA had approved Hytrin® (terazosin), another drug for treating this condition,[151] and he even suggested that saw palmetto represented a safe and effective alternative for treating BPH.[152] Imagine jurors finding an FDA-approved prescription drug defectively designed because they agreed that a patient could have gone to his health food store and purchased a largely unregulated dietary supplement supported by some flimsy evidence of efficacy![153] Section 6(c), with its reasonable physician standard, helps guard against precisely such muddle-headedness.

There is, however, more to Cupp's story about Proscar: the FDA approved a low-dose version of finasteride (Propecia®) in 1998 for the treatment of baldness. Because, however, Proscar tablets offered five times the dose for less than one-third the price, physicians evidently prescribed it off-label (with instructions to split the pill) instead of prescribing Propecia.[154] Cupp argued that, given this pattern of off-label usage,[155] section 6(c) "might bar from recovery all of the men harmed by

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Lawrence K. Altman, *Common Drug for Prostrate Is Ineffective, Study Finds*, N.Y. TIMES, Aug. 22, 1996, at A18.

[150] *See* Gina Kolata, *New Take on a Prostate Drug, and a New Debate*, N.Y. TIMES, June 15, 2008, at A1 (reporting that finasteride also may have prophylactic value, and noting that Proscar now competes with half a dozen generic versions of the drug); *see also* Peter T. Scardino, Editorial, *The Prevention of Prostate Cancer—The Dilemma Continues*, 349 NEW ENG. J. MED. 297, 297–99 (2003); E. Darracott Vaughan, Jr., Editorial, *Medical Management of Benign Prostatic Hyperplasia—Are Two Drugs Better Than One?*, 349 NEW ENG. J. MED. 2449, 2449–53 (2003). As explained previously, *see supra* notes 54–58 and accompanying text, there is no absolutely basis for Cupp's suggestion that Proscar remains on the market only because the FDA lacks the authority to withdraw drugs except in extreme circumstances.

[151] *See* Cupp, *supra* note 44, at 235. The latest entrant in this growing class has a wonderful moniker: Rapaflo. *Watson Wins OK for Prostate Drug*, L.A. TIMES, Oct. 9, 2008, at C5.

[152] *See* Cupp, *supra* note 44, at 236 & n.15 (explaining that a "study reported that Saw Palmetto extract is more effective, far safer, and cheaper than Proscar," citing a statement made by a member of Congress). I hear that another member of that august scientific body, Senator Tom Harkin, used to swear by bee pollen.

[153] *See* Robert S. DiPaola & Ronald A. Morton, Editorial, *Proven and Unproven Therapy for Benign Prostatic Hyperplasia*, 354 NEW ENG. J. MED. 632, 632–33 (2006); Rob Stein, *Vitamin Didn't Lower Prostate Cancer Risk*, WASH. POST, Oct. 28, 2008, at A9 (describing the early termination of NIH study of vitamin E and selenium); Lindsey Tanner, *Many Go on Taking Discredited Remedies*, SEATTLE TIMES, Feb. 27, 2006, at A5 (reporting that recent studies have found no therapeutic value to glucosamine, chondroitin, saw palmetto, echinacea, St. John's wort, or shark cartilage); *see also* Whitaker v. Thompson, 353 F.3d 947, 948–49 (D.C. Cir. 2004) (upholding the FDA's decision to reject a petition requesting permission to label saw palmetto products with a claim that they could treat BPH); Lars Noah, *A Drug by Any Other Name . . . ?: Paradoxes in Dietary Supplement Risk Regulation*, 17 STAN. L. & POL'Y REV. 165, 190 (2006) (urging the FDA to make fuller use of its limited statutory authority to crack down on unsafe herbal products).

[154] *See* Cupp, *supra* note 44, at 236–37.

[155] *See id*. at 237 ("It could be argued that physicians are acting reasonably in prescribing the cheaper Proscar to the subclass planning to cut the pills to use safely for baldness, even though Proscar's primary use, treating prostate enlargement, would be unhelpful and unreasonably dangerous.").

using Proscar for its primary, health-related purpose."[156] Assuming just for the sake of argument (and very much contrary to reality) that finasteride would fail risk-utility analysis when used in the treatment of BPH, section 6(c) would do nothing to bar recovery for physician negligence (assuming that the manufacturer had fully warned) for using it in such patients. Moreover, I seriously doubt that any reasonable physicians would prescribe Proscar for their balding patients given the ready availability of Propecia,[157] especially when coupled with the hazards associated with pill splitting.[158]

4. Polio Vaccines

Another commentator offered a case study that superficially seemed to pose a more serious challenge to section 6(c). George Conk contrasted the Sabin oral polio vaccine (OPV), which uses an attenuated form of the viral agent, with the Salk injected (inactivated) polio vaccine (IPV), which uses killed virus: according to his description, both forms offer equal efficacy in all classes of recipients (at least after the development of an enhanced-potency version of IPV), but OPV carries a one-in-2.4 million risk of causing vaccine-associated paralytic polio (VAPP) in either recipients or close contacts.[159] Conk added that several

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[156] *Id.* at 237–38; *see also id.* at 238 ("Finding just one reasonable use, even if that use is ancillary and for purely cosmetic purposes, in effect immunizes the manufacturer regardless of how much harm a drug inflicts overall."); *id.* at 241 ("Under the reasonable physician test, Proscar is immunized from liability because it can be used safely to treat the cosmetic problem of baldness and is cheaper than the lower dosage design.").

[157] As explained above, reasonable physicians guided solely by "therapeutic" considerations under section 6(c) would not take cost into account. *See supra* notes 86–89 and accompanying text. Moreover, the availability of Propecia seriously weakens this hypothetical as a critique of section 6(c); it would have worked better to pretend that the FDA had never approved Propecia and focus instead on the recognized off-label use of Proscar (for baldness), which would create a class of patients in whom reasonable health care providers might prescribe a drug that, on Cupp's version of the record, has no legitimate use for its labeled (BPH) indication. If Propecia did not exist, then the tougher question becomes whether a reasonable physician would prescribe Proscar off-label for a class of "patients" with nothing other than a cosmetic condition. *See supra* notes 118–119 and accompanying text.

[158] *See* Nicolas G. Barzoukas, *Pill Splitting Raises Issues of Safety and Patent Coverage*, NAT'L L.J., May 22, 2000, at B9; *see also* Timmis v. Permanente, No. A102962, 2004 WL 2943993, at *1, *9 (Cal. Ct. App. 2004) (rejecting an unfair business practice claim against one HMO's pill-splitting program); Tara Parker–Pope, *Health Insurers Push Pill Splitting as a Way to Save Money on Drugs*, WALL ST. J., Nov. 22, 2005, at D1. If nothing else, some fool will think that taking the full five milligram tablet would mean thicker and quicker hair growth notwithstanding the serious side effects reported at that dosage. Moreover, if Proscar did not work for BPH (and physicians preferred using other drugs to treat this condition), a profit-maximizing manufacturer would have withdrawn the drug so that physicians could not cut into its Propecia revenues. *Cf.* Denise Gellene, *Avastin Use in Eyes Irks Genentech*, L.A. TIMES, Oct. 17, 2005, at C1 (reporting that ophthalmologists have used a colon cancer drug off-label on more than 1,000 patients with macular degeneration because it costs far less than the same ingredient marketed by the manufacturer for that use, adding that the manufacturer "is in discussions with the [FDA] to modify the Avastin label to state that the drug is not for ophthalmic use").

[159] *See* Conk, *supra* note 19, at 1114–15. Notably, the resulting litigation focused almost entirely on inadequate warnings of this risk. *See* Fay F. Spence, Note, *Alternatives to Manufacturer Liability for Injuries Caused by the Sabin–Type Oral Polio Vaccines*, 28 WM. & MARY L. REV. 711,

other industrialized countries rely exclusively on IPV (and that U.S. authorities recommended the same in 1999),[160] though he did note that professional and public health organizations had continued to favor OPV (except in infants with compromised immune systems or who may come in close contact with unvaccinated individuals) for a variety of reasons: expense (IPV costs almost twenty times as much per dose), ease of administration, an advantage in conferring intestinal immunity, and an opportunity for providing second-hand immunity by exposing unvaccinated individuals (in effect, the risk of VAPP may have a silver lining).[161]

In dismissing the intestinal immunity advantage as disputed, Conk failed to recognize that only OPV can prevent infection (IPV keeps an infected person from becoming sick but does not prevent them from becoming carriers and transmitting the illness to others) and that questions about (and research into) the enhanced-potency form of IPV continued well into the mid-1980s.[162] The delay in transitioning from OPV to IPV in this country had nothing to do with stalling by profit-driven manufacturers (after all, officials had licensed the enhanced-potency form of IPV in 1987); instead, it had everything to do with the continued circulation of the wild virus in the Western hemisphere (and

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716–35 (1987); *see also* Graham v. Am. Cyanamid Co., 350 F.3d 496, 514 (6th Cir. 2003) (rejecting a claim that OPV manufacturer had a duty to inform physicians that IPV represented the preferred choice); Johnson v. Am. Cyanamid Co., 718 P.2d 1318, 1326 (Kan. 1986) (same, though based on the fact that IPV was not commercially available at the relevant time). Conk's essay actually had focused on blood factor concentrates, but, as explained below, *see infra* note 332, that case study did not as directly raise questions about section 6(c). The Reporters penned a detailed response to Conk's arguments, but they largely ignored his polio vaccine illustration. *See* Henderson & Twerski, *supra* note 19, at 176 n.100 (noting simply that the FDA had not licensed the type of IPV used at the time in European countries); *see also* Conk, *supra* note 21, at 781–83 (conceding the same). They all failed to recognize that the FDA had licensed an enhanced-potency IPV product in 1987. *See* Recommendations of the Immunization Practices Advisory Comm., *Poliomyelitis Prevention: Enhanced–Potency Inactivated Poliomyelitis Vaccine—Supplementary Statement*, 36 MORBIDITY & MORALITY WKLY. REP. 795 (1987).

[160] *See* Conk, *supra* note 19, at 1115; *see also* Recommendations of the Advisory Comm. on Immunization Practices, *Poliomyelitis Prevention in the United States: Introduction of a Sequential Vaccination Schedule of Inactivated Poliovirus Vaccine Followed by Oral Poliovirus Vaccine*, 46 MORBIDITY & MORALITY WKLY. REP. No. RR-3, at 7–8 (1997) [hereinafter ACIP Recommendations] (discussing enhanced-potency IPV).

[161] *See* Conk, *supra* note 19, at 1116 n.132; *see also Graham*, 350 F.3d at 499, 514 (summarizing the advantages); *Johnson*, 718 P.2d at 1321–22 (same); ACIP Recommendations, *supra* note 160, at 12 tbl.3; Samuel L. Katz, *Conquering Polio: From Culture to Vaccine—Salk and Sabin*, 351 NEW ENG. J. MED. 1485, 1487 (2004); David Brown, *Global Polio Largely Fading: Stronger Vaccine Is Playing Key Role*, WASH. POST, Dec. 26, 2005, at A1 (describing a shift to monovalent OPV). Even researchers from the companies that produce enhanced-potency IPV had to concede that OPV enjoyed an advantage (though they thought only a marginal one) in spreading immunity. *See* Andrew D. Murdin et al., *Inactivated Poliovirus Vaccine: Past and Present Experience*, 14 VACCINE 735, 740–41 (1996).

[162] *See* ACIP Recommendations, *supra* note 160, at 7–8; *id.* at 13 (explaining that "continued use of OPV induces intestinal immunity among vaccine recipients, thereby enhancing community resistance to transmission of wild virus (should it be reintroduced)"); *see also* Kearl v. Lederle Labs., 218 Cal. Rptr. 453, 455 n.1 (Ct. App. 1985) (describing a series of efficacy failures with IPV reported in Finland), *abrogated by* Brown v. Superior Ct., 751 P.2d 470 (Cal. 1988).

the risk of importation into the United States) until the early 1990s.[163] Only after confirming its eradication did the Centers for Disease Control (CDC) decide that the slightly safer but in fact somewhat less effective IPV gradually should displace OPV.[164]

More so than other medical technologies, the use of childhood vaccines depends heavily on the recommendations of public health officials. Unlike the FDA (which lays things out in labeling and then leaves professionals to make sensible judgments), the CDC actively attempts to influence medical practice in the use of these products.[165] In effect, a vaccine licensed by the FDA but not yet blessed by the CDC might as well not exist. In hindsight, perhaps the CDC acted too slowly in deciding to transition from OPV to IPV in the late 1990s, but the information available at the time did not favor IPV as clearly as Conk has suggested. Would he really have wanted the manufacturer of OPV to withdraw its product from the market in the early 1980s (even before the FDA had licensed a competitor's enhanced-potency IPV in 1987, and long before the CDC dictated in 1999 that no reasonable health care professional should continue to use OPV except under unusual circumstances)? Alternatively, would he have expected health care professionals to switch from OPV to IPV in 1987 notwithstanding the CDC's contrary (even if now arguably questionable) recommendations? In fact, even in the wake of the CDC's revised recommendations, properly labeled OPV should not face design defect claims.

Just for the sake of argument, let us take Conk's story at face value (and entirely disregard the CDC's role) but also assume that, during the 1990s, the labeling for OPV accurately disclosed the incredibly small risk of VAPP and that, somewhat implausibly, the labeling for the FDA-approved enhanced-potency IPV revealed absolutely no peculiar risks at all (e.g., injection site reactions).[166] Conk

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[163] *See* CDC, *Certification of Poliomyelitis Eradication—The Americas, 1994*, 43 MORBIDITY & MORTALITY WKLY. REP. 720 (1994).

[164] *See* ACIP Recommendations, *supra* note 160, at 2, 5. Thus, starting in 1997, the CDC recommended a gradual (3–5 year) transition to IPV (with OPV used as a booster in the interim). *See id.* at 2, 9. It also explained, however, that parents should have the choice of using IPV alone. *See id.* at 12–14.

[165] *See* CDC, *Recommended Immunization Schedules for Persons Aged 0–18 Years—United States, 2007*, 297 JAMA 691, 691–94 (2007).

[166] *See* ACIP Recommendations, *supra* note 160, at 18–19 (noting sensitivity reactions to IPV). In addition, one would have to imagine away the National Childhood Vaccine Injury Act of 1986 (NCVIA), Pub. L. No. 99–660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa–1 to –34 (2006)), which aimed to discourage the filing of tort claims by, among other things, codifying the comment k defense for covered vaccines (and, with regard to inadequate warning claims, codifying the learned intermediary doctrine coupled with an FDA compliance defense), *see* 42 U.S.C. § 300aa–22(b)&(c); *cf.* Am. Home Prods. Corp. v. Ferrari, 668 S.E.2d 236, 238–42 (Ga. 2008) (interpreting this provision as incorporating a case-by-case rather than blanket version of comment k, and allowing plaintiffs to pursue design defect claims against manufacturers of childhood vaccines for using the preservative thimerosal). *See generally* Lainie Rutkow et al., *Balancing Consumer and Industry Interests in Public Health: The National Vaccine Injury Compensation Program and Its Influence During the Last Two Decades*, 111 PENN ST. L. REV. 681 (2007). If, instead, one focused on the early 1980s, before the NCVIA (and while other countries

argued that section 6(c) inappropriately would have protected OPV's manufacturer from design defect liability, while the risk-utility balancing of section 2(b) would lead to a conclusion that IPV represented a safer alternative design.[167] Unlike section 6(c), however, section 2(b) allows considerations of non-therapeutic utilities such as cost and convenience,[168] so it may not have treated IPV as a RAD for OPV.[169]

As it happens, courts applying comment k on a case-by-case basis (which meant engaging in a form of risk-utility balancing) uniformly rejected design defect claims against the manufacturer of OPV during all relevant time periods.[170] In fact, as Conk belatedly conceded, OPV continues to have a recognized but narrow use: "emergency mass administration to control polio outbreaks."[171] Thus, even with an FDA-licensed and CDC-endorsed safer alternative available, reasonable health care providers clearly would continue to select OPV for some classes of patients, and section 6(c) appropriately would foreclose a design defect claim brought by a patient injured by its use, whether or not such use had been appropriate in that particular case.

Undeterred, Conk finally revealed the premise underlying his opposition to the standard announced by the *Products Liability Restatement*:

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used enhanced-potency IPV but it had not yet reached the United States), it would suffice to point out that IPV remained only a hypothetical RAD (not yet licensed domestically and still subject to open questions about effectiveness). For a parallel trajectory involving the design of the whole-cell pertussis vaccine, with plaintiffs pointing to fractionated and acellular versions used overseas but not yet licensed in this country, see *supra* note 95.

[167] *See* Conk, *supra* note 19, at 1114 ("Section 6(c) would not permit, for example, a challenge to a live-virus vaccine that unnecessarily caused the disease it was designed to prevent, even if there had long been an equally effective killed-virus vaccine that does not cause infection."); *id.* at 1115–16.

[168] *See supra* notes 80–83 and accompanying text. Indeed, if these get delivered in mass immunization settings, the learned intermediary rule may not apply, which would require warnings directed to recipients. *See infra* note 216 and accompanying text. It also makes one wonder whether the intermediary-linked design defect standard then should fall away. *See infra* notes 246–250 and accompanying text.

[169] *Cf.* ACIP Recommendations, *supra* note 160, at 9, 12–15 (noting the absence of a licensed combination product that included IPV). Adding IPV to other routinely injected childhood vaccines eventually eliminated this disutility relative to OPV. *See* Rob Stein, *Vaccine Promises More Protection, Fewer Shots: FDA Approves Round of Three Inoculations That Protects Infants Against Five Diseases*, WASH. POST, Dec. 17, 2002, at A2.

[170] Courts rejected design defect claims (1) before 1968, when OPV competed against an early version of IPV (which required three separate injections followed by booster shots), (2) between 1968 and 1987, when it lacked any commercial competition (though limited quantities of IPV were imported, *see* Philip M. Boffey, *Polio: Salk Challenges Safety of Sabin's Live–Virus Vaccine*, 196 SCIENCE 35 (1977)), and (3) between 1987 and 2000, when it co-existed in the United States with the enhanced-potency IPV (but continued to have the CDC's endorsement), *see* Spence, *supra* note 159, at 723 & n.81; *see also id.* at 715 n.32 (quoting from the Orimune's package insert and consent forms used in the mid-1980s, which included references to the availability of IPV as an alternative).

[171] Conk, *supra* note 21, at 782; *see also* Updated Recommendations of the Advisory Comm. on Immunization Practices, *Poliomyelitis Prevention in the United States*, 49 MORBIDITY & MORALITY WKLY. REP. No. RR–5, at 15–16 (2000).

> The fact that emergency circumstances can be defined in which the more dangerous drug might be indicated, despite risks, does not save the sole manufacturer of polio vaccine from liability to the injured for failure to adopt the safer design in the ordinary course of mandatory inoculation. Imposition of liability for failure to offer the alternative safer design in such circumstances does not bar production of the challenged product—which may have residual uses. A finding that a design is defective—for the foreseeable conditions of product use—does not make the challenged design contraband. The factual finding that the product design is defective for the conditions for which it is marketed is simply a legal predicate for the judgment that there is a fair basis on which to impose the obligation to compensate the avoidably injured.[172]

Putting aside the mixing of entirely different time periods and counterfactual assumptions about inappropriate marketing (or the limited legitimate uses of OPV),[173] the fact that only a "sole manufacturer" served the U.S. market had at least something to do with other sellers' legitimate fears about the imposition of liability under just such circumstances.[174] If OPV's manufacturer faces design defect liability,

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[172] Conk, *supra* note 21, at 782–83. Like other commentators who find nothing distinctive about prescription products, *see supra* note 47, he appears ready to impose something approaching absolute liability. Section 6(c) does well to ensure that nothing of the sort will happen. His original essay concluded by summarizing and disputing the half dozen rationales typically offered in support of section 6(c). *See* Conk, *supra* note 19, at 1127–32. For instance, Conk argued that "[t]he designer should no more be freed from its duty to market safe products by the existence of an intermediary physician than a manufacturer of industrial equipment should be relieved of the duty to include safety devices merely because employers are obligated by law to provide a safe workplace." *Id.* at 1128. That parallel may, however, cut the other way. *See, e.g.*, Scarangella v. Thomas Built Buses, Inc., 717 N.E.2d 679, 683–84 (N.Y. 1999); *see also infra* note 317 (discussing the "sophisticated purchaser" defense).

[173] Conk made similar mistakes in suggesting elsewhere that the manufacturer of the sole vaccine against smallpox (Dryvax), which ceased production in the 1980s, might face design defect claims insofar as hypothetical RADs existed for this old—and, until remaining stockpiles were hurriedly pressed back into limited use in 2002, no longer used—vaccine, including a purportedly safer product used in Japan and licensed by VaxGen with plans to secure FDA approval. *See* George W. Conk, *Reactions and Overreactions: Smallpox Vaccination, Complications, and Compensation*, 14 FORDHAM ENVTL. L.J. 439, 459–61 & n.55 (2003). It took almost five years for a different company to secure FDA approval of a new vaccine, though one that differs little from Dryvax except for its method of production. *See* John Heilprin, *FDA Approves New, Easily Produced Smallpox Vaccine*, ORLANDO SENT., Sept. 2, 2007, at A9; *New Smallpox Vaccine to Be Reviewed by FDA*, STAR-LEDGER (NEWARK), May 20, 2007, at 23; *Original Smallpox Vaccine Shelved as Times Change: Dryvax Is Retired After Saving Many*, STAR-LEDGER (NEWARK), Mar. 1, 2008, at 6. A genuinely safer version remains on the drawing board. *See* Renae Merle, *Deal for Smallpox Vaccine Could Jump–Start BioShield*, WASH. POST, June 7, 2007, at D1; *see also* Justin Gillis, *Safer Smallpox Vaccines in Works: U.S. Preparing for Potential Bioterror Attack*, WASH. POST, Nov. 14, 2005, at A1 (reporting that, in contrast to VaxGen's less well studied but potentially more effective version, a modified version developed in Germany (licensed by Acambis and Bavarian Nordic) "essentially trades potency for safety"). Ultimately, VaxGen's smallpox project stalled, while its anthrax vaccine efforts collapsed entirely. *See* Renae Merle, *Anthrax Vaccine Contract Voided, Thwarting Administration*, WASH. POST, Dec. 20, 2006, at A1. The more interesting question with Dryvax arose from earlier plans to extend (dilute) the limited existing stockpiles. *See* Sharon E. Frey et al., *Clinical Responses to Undiluted and Diluted Smallpox Vaccine*, 346 NEW ENG. J. MED. 1265 (2002).

[174] *See* Noah, *supra* note 62, at 743 (discussing judicial recognition of price hikes and supply shortages that had coincided with dramatic increases in products liability litigation involving childhood vaccines); *id.* at 759–61, 763–64 (discussing the relationship between threatened tort liability and the removal of therapeutic products from the market); *see also id.* at 761–62, 764 (explaining that legislative reforms also have attempted to respond to such concerns); Noah, *supra*

then it can continue producing the product (so long as it pays for any injuries that result), but why would it choose to do so (and, when it leaves the market, what will happen if polio makes a comeback)?! In what sense does a manufacturer that continues to market OPV after 1999 (and properly labeled to indicate its use only in case of an emergency) act unreasonably—must it also offer IPV, or does it suffice that a pair of competitors had brought that allegedly superior product to the market more than a decade earlier?

5. Isotretinoin

In an article published two years later, Conk trotted out Accutane® (isotretinoin) as another example, though this one designed to illustrate the value of engaging in risk-utility balancing even in the absence of an FDA-approved RAD.[175] In retrospect, this illustration also backfired, nicely demonstrating the pitfalls of his approach to judging design defect claims. First, Conk argued that the manufacturer's method-of-use patent (perhaps one of the weakest types of patents[176]) gave it a monopoly that discouraged the introduction of safer alternatives.[177] Although it would keep others from selling isotretinoin

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note 48, at 2159 ("Critics of the regulatory compliance defense respond that a tort judgment does not dictate any alteration of primary conduct, but in the next breath they emphasize the need to retain the threat of liability to serve a deterrent function . . . . They can't have it both ways."). From 1977 to 2000, only Lederle marketed OPV (as Orimune®); after 2000, no company in the U.S. produced a trivalent OPV product for the domestic market.

[175] *See* Conk, *supra* note 21, at 761–71. As he explained in closing the discussion:

> The Accutane example demonstrates that the institutional competence problems with the section 2(b) alternative safer design test . . . are not so formidable as they might appear at first blush. . . . [S]mall changes yielded significant safety gains but were neglected until [the] approaching loss of a broad patent monopoly threatened the manufacturer-designer with loss of market control.

Id. at 771. Actually, upon closer examination, it demonstrates just the opposite.

[176] *See* William D. Noonan, *Patenting Medical Technology*, 11 J. LEGAL MED. 263, 283, 287–88 (1990); Richard A. Castellano, Note, *Patent Law for New Medical Uses of Known Compounds and Pfizer's Viagra Patent*, 46 IDEA: J.L. & TECH. 283, 294–301, 308–11 (2006); *see also* Peter Landers, *Nosed Out? With New Patent, Mayo Clinic Owns a Cure for Sniffles*, WALL ST. J., Apr. 30, 2003, at A1 (reporting that a researcher had secured method-of-use patents for antifungal agents to treat sinusitis and chronic asthma, and contrasting this situation with the failure of researchers to do so for the use of antibiotics in treating ulcers).

[177] *See* Conk, *supra* note 21, at 762–63 ("Such a patent-constrained market environment can create a type of market failure that impedes the availability of alternative, safer compositions or methods of manufacture, or alternative safer dosing methods."). The method-of-use patent for isotretinoin would not have limited "safer compositions or methods of manufacture" as he claimed because those represent different types of patents, and it would not even prevent a "safer dosing method" that fell outside of the bounds of the range of doses disclosed in the patent. *Cf.* Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241, 1249–54 (Fed. Cir. 2000) (holding that a generic drug manufacturer's micronized version would not infringe patents for nifedipine crystals of a defined specific surface area). Indeed, the decision in the Prozac case that he quotes at length, *see* Conk, *supra* note 21, at 758–59 n.87, invalidated a method-of-use patent, *see* Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 969–72 (Fed. Cir. 2001); *see also* Merck & Co. v. Teva Pharm. USA, Inc., 395 F.3d 1364, 1372–77 (Fed. Cir. 2005) (invalidating a method-of-use patent covering the once-weekly formulation of Fosamax® on grounds of obviousness); Warner–Lambert Co. v. Apotex

tablets of particular doses for the treatment of acne, it in no way prevented the development of other vitamin A derivatives for such uses (or of isotretinoin for entirely other uses).[178] He cited one patent covering short-course treatments for less serious forms of acne,[179] but this would not have involved any alteration in the dosage formulation (only revisions in the drug's labeling),[180] and nothing prevented researchers from publicizing such an off-label use.[181] Conk suggested that Roche should have had an obligation to look into this method and revise its instructions accordingly, but in the next breath he correctly recognized that this would have provided a basis for liability under section 6(d).[182]

Corp., 316 F.3d 1348, 1351–53, 1366 (Fed. Cir. 2003) (rejecting a claim by the manufacturer of Neurontin® (gabapentin), which was labeled only for treating epilepsy but widely used in patients with neurodegenerative diseases, that approval of a generic version would infringe (or induce infringement of) its method patent covering such off-label uses).

[178] *See* Ortho Pharm. Corp. v. Cosprophar, Inc., 828 F. Supp. 1114, 1117 (S.D.N.Y. 1993) (summarizing, in the course of resolving a Lanham Act case, the history behind tretinoin (Retin–A®), an FDA-approved retinoid-based topical acne drug sold by a subsidiary of Johnson & Johnson, which began developing a cream version (Renova®) for use against wrinkles after published research confirmed the efficacy of this off-label use), *aff'd*, 32 F.3d 690 (2d Cir. 1994); Lawrence K. Altman, *Medical Dilemma: Necessary Drugs with Intolerable Dangers*, N.Y. TIMES, May 3, 1988, at C3 (reporting that Accutane "was the first to be licensed in what is expected to be a series of drugs derived from Vitamin A, called retinoids"); Gina Kolata, *A Second Skin Drug Is Called Major Threat for Birth Defects*, N.Y. TIMES, May 1, 1988, § 1, at 1 ("Drug manufacturers have created 1,500 compounds that are closely related to Accutane, . . . and researchers are testing some to see if they can cure skin diseases, treat a variety of cancers or prevent cancer of the breast, lung or colon.").

[179] *See* Conk, *supra* note 21, at 763–64 & n.108. In arguing that Roche failed to investigate this potentially safer method of use, Conk misunderstood the difference between Accutane's indication (severe recalcitrant nodular acne) and the researcher's method-of-use patent (for "a patient having mild cystic acne or with scarring non-cystic acne"). Even after the expiration of Roche's method patent, the researcher could not market such a product without going through the FDA approval process for this new indication and dosing regimen.

[180] For more background on the drug's regulatory milestones, including a history of its many labeling revisions, see FDA, *Isotretinoin (Marketed as Accutane) Capsule Information*, http://www.fda.gov/cder/drug/infopage/accutane/default.htm (last visited June 19, 2008). In the last twenty-five years, the agency has imposed increasingly stringent controls on access to this drug. *See* Robert S. Stern, *When a Uniquely Effective Drug Is Teratogenic: The Case of Isotretinoin*, 320 NEW ENG. J. MED. 1007, 1008 (1989); Gardiner Harris, *F.D.A. Imposes Tougher Rules for Acne Drug*, N.Y. TIMES, Aug. 13, 2005, at A1 ("The new program is the latest and by far most drastic of more than 40 efforts by the agency in the last 22 years to reduce harm from Accutane . . . while allowing its continued use."); *see also* Ami E. Doshi, Comment, *The Cost of Clear Skin: Balancing the Social and Safety Costs of iPLEDGE with the Efficacy of Accutane (Isotretinoin)*, 37 SETON HALL L. REV. 625, 659–60 (2007) (concluding that the FDA should withdraw approval).

[181] *See, e.g.*, Boaz Amichai et al., *Low-dose Isotretinoin in the Treatment of Acne Vulgaris*, 54 J. AM. ACAD. DERMATOLOGY 644 (2006). Another commentator provided a better apparent illustration of Conk's point, suggesting that Amgen had shelved a patent on a protein binding factor that would have dramatically slowed the excretion (and therefore the dosages needed) of its blockbuster anemia drug Epogen® (recombinant erythropoietin). *See* Kurt M. Saunders, *Patent Nonuse and the Role of Public Interest as a Deterrent to Technology Suppression*, 15 HARV. J.L. & TECH. 389, 395–96 (2002). To support this allegation, he relied entirely on an e-mail message later posted on a blog. *See id.* at 395 n.31. The only published information about this episode that I could find suggested that government officials failed to take this conspiracy theory the least bit seriously. *See Consumer Advocates Say Company May Be Suppressing Research at University–Run Lab*, CHRON. HIGHER EDUC., May 1, 1998, at A49 (describing a letter from Ralph Nader and an associate requesting an investigation by the Federal Trade Commission).

[182] *See* Conk, *supra* note 21, at 764.

So why on earth does he keep complaining about the unduly narrow scope of design defect claims under section 6(c)?

Conk also emphasized that, shortly before expiration of its patent, Roche filed an application for FDA approval of a new and improved (micronized) formulation of isotretinoin, and he cited the favorable internal agency reviews prepared in advance of an advisory committee meeting held in 2000.[183] He expressed outrage that section 6(c) would allow the manufacturer to get away with "an egregious case of warehousing an alternative safer design for deployment when the patent term expires."[184] Sounding like the good plaintiff's lawyer that he is, Conk continued:

> A jury might reasonably conclude that the manufacturer's timetable for development of the new, low-dose, more controllable product was dictated too much by market considerations and too little by concern for the safety and health of those who consumed the product, those who were aborted, or those born with grave deformities that might have been avoided if the dosing pattern had been lowered and the new formulation had been deployed earlier.[185]

A clarion call for punitive damages if I ever heard one! Except for one minor problem: in spite of the endorsement of the internal reviewers, and notwithstanding the subsequent publication of the research that indicated limited advantages to the micronized version (though not at all with respect to the serious risk of birth defects),[186] the FDA never approved the new formulation.[187] Moreover, even if it had done so, this would not have prevented agency approval of generic versions of the original

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[183] *See id.* at 765–66, 767–69.

[184] *Id.* at 769; *see also id.* ("[T]he social cost of the tardy development of the new product provides the basis for a finding of liability in favor of the deformed children of mothers who took Accutane (the old formula) when Roche could have brought the new formulation to market earlier instead of waiting for the end of the old product's patent monopoly period.").

[185] *Id.* at 770; *see also id.* (adding that other plaintiffs probably will not have such damning evidence to use in bringing their design defect claims).

[186] *See* John S. Strauss et al., *A Randomized Trial of the Efficacy of a New Micronized Formulation Versus a Standard Formulation of Isotretinoin in Patients with Severe Recalcitrant Nodular Acne*, 45 J. AM. ACAD. DERMATOLOGY 187, 194–95 (2001); John S. Strauss et al., *Safety of a New Micronized Formulation of Isotretinoin in Patients with Severe Recalcitrant Nodular Acne: A Randomized Trial Comparing Micronized Isotretinoin with Standard Isotretinoin*, 45 J. AM. ACAD. DERMATOLOGY 196 (2001); *id.* at 199 & tbl.2 (indicating that the researchers removed one subject who had become pregnant while taking the micronized version and then aborted). Indeed, to the extent that patients might find the micronized version more tolerable (because less likely to cause bothersome side effects such as dry eyes), *see id.* at 207, and because nothing suggested a reduced teratogenic risk at the lower (but equally bioavailable) dosage, one might have seen an increase in the overall number of birth defects had the FDA approved the newer version.

[187] *See* Michelle Meadows, *The Power of Accutane: The Benefits and Risks of a Breakthrough Acne Drug*, FDA CONSUMER, Mar.–Apr. 2001, at 18 (discussing the limited product changes that came out of the September 2000 advisory committee meeting); *see also* John S. Strauss et al., *Guidelines of Care for Acne Vulgaris Management*, 56 J. AM. ACAD. DERMATOLOGY 651, 656 (2007) (discussing the latest views about the use of isotretinoin, but making no mention of a micronized version apart from citing his pair of co-authored articles from 2001). For the current version of Accutane's package insert, see http://www.rocheusa.com/products/accutane/pi.pdf (last visited Aug. 12, 2008).

formulation,[188] and sponsors willing to conduct new clinical trials could have secured approval of other variations of the original formulation of isotretinoin. Thus, Conk unwittingly again demonstrated the wisdom of the Reporters' refusal to allow plaintiffs to rely on hypothetical RADs for prescription products.

D. Designing Access Restrictions

Critics have objected that section 6(c) conflicts with the well-accepted proposition that product manufacturers should not get to warn their way out of a duty to adopt reasonable alternative designs.[189] Apart from the previously discussed difficulties with redesigning drugs, this complaint fails to appreciate the centrality of labeling in helping to define a pharmaceutical product's niche.[190] Moreover, these issues may go beyond labeling to include choices about how and to whom a seller markets a drug.[191]

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[188] In fact, generic versions of the drug became available in 2002. *See* Gideon Koren et al., *Generic Isotretinoin: A New Risk for Unborn Children*, 170 CAN. MED. ASS'N J. 1567 (2004); *see also* Margaret A. Honein et al., *Can We Ensure the Safe Use of Known Human Teratogens?: Introduction of Generic Isotretinoin in the US as an Example*, 27 DRUG SAFETY 1069, 1075 (2004) (explaining that each generic version must use a parallel risk-management program). Generic applicants would not, however, have gotten approval if the FDA had withdrawn the NDA for the pioneer's original formulation on safety grounds. *See* 21 C.F.R. § 216 (2008) (listing such withdrawals). I found only a single instance where, at the license holder's request, the agency had done so. *See* FDA, Notice, Hoffmann–La Roche, Inc.: Withdrawal of Approval of a New Drug Application, 68 Fed. Reg. 53,384, 53,385 (Sept. 10, 2003) (withdrawing Tegison® (etretinate) four years after its sponsor had begun marketing a safer version).

[189] *See, e.g.*, Cupp, *supra* note 44, at 253–54. As the Reporters subsequently explained:

> [T]he manufacturer's first obligation is reasonable design; warnings logically come after, in order to deal with any remaining pockets of hidden risk that cannot reasonably be designed out of the product. With respect to prescription products, this logical sequence is necessarily reversed. Exposure to design-based liability comes into play only as a measure of last resort . . . .

Henderson & Twerski, *supra* note 19, at 178–79.

[190] *See* Joe Collier & Ike Iheanacho, *The Pharmaceutical Industry as an Informant*, 360 LANCET 1405, 1405 (2002) ("Although the primary function of drug companies is to develop and market drugs, these companies spend more time and resources generating, gathering, and disseminating information."); Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL'Y L. & ETHICS 717, 717–18 (2005) ("Drugs are information-rich chemicals that in many respects are more akin to other information products (such as databases) than they are to other chemicals . . . . Creating new molecules has become relatively cheap, but determining which molecules are safe and effective for which therapeutic purposes has remained stubbornly expensive . . . ."); *see also* Lars Noah, *Authors, Publishers, and Products Liability: Remedies for Defective Information in Books*, 77 OR. L. REV. 1195, 1212 (1998) ("[D]rug companies are actually engaged in the business of producing and selling information for use by patients and their physicians . . . . [T]he product defectiveness inquiry depends entirely on the information accompanying the product, such as the indications and contraindications for use."); *id.* ("The conceptual separation between the product itself and information contained within the product, so evident in cases declining to hold authors and publishers strictly liable, is absent in the prescription drug liability context."); *cf.* Feldman v. Lederle Labs., 479 A.2d 374, 385 (N.J. 1984) (noting that "an inadequate warning could constitute a design defect").

[191] Comment k to section 402A had referred separately to proper marketing and proper warnings as prerequisites (along with proper preparation) for exempting sellers of unavoidably

For instance, with teratogens such as thalidomide and isotretinoin, plaintiffs might pursue negligent marketing claims on the theory that a prescription drug manufacturer should have further restricted distribution.[192] Such claims would represent a hybrid between more traditional defects in design and labeling,[193] challenging a manufacturer's choice about the appropriate channels for distributing potentially hazardous goods, such as items not appropriate for use by youngsters,[194] in a way that resembles novel (and largely unsuccessful) theories asserted against gun sellers.[195]

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unsafe products from strict liability claims. *See* Swayze v. McNeil Labs., Inc., 807 F.2d 464, 468 (5th Cir. 1987).

[192] *See* Lars Noah, *Too High a Price for Some Drugs?: The FDA Burdens Reproductive Choice*, 44 SAN DIEGO L. REV. 231, 236–37 & n.23, 256 & n.100 (2007) (noting that the manufacturer of Accutane has faced claims that it should have taken steps beyond the issuance of stern warnings to both doctors and patients to ensure that women would not become pregnant while using this teratogenic drug, and adding that these lawsuits have failed on other grounds); *cf. id.* at 239 (wondering whether the FDA could "demand that the manufacturer sell a bundled product (for example, a single pill that combined a teratogen with a hormonal contraceptive)"); Lars Noah, *Ambivalent Commitments to Federalism in Controlling the Practice of Medicine*, 53 U. KAN. L. REV. 149, 188–91 (2004) (discussing a variety of distribution restrictions on prescription drugs considered by regulatory officials). Congress recently granted the FDA express authority to restrict the distribution of prescription drugs to specially trained physicians. *See* Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110–85, § 901(b), 121 Stat. 823, 930 (to be codified at 21 U.S.C. § 355–1(f)(3)(A)).

[193] Some negligent marketing claims relate primarily to issues of product design, while others focus on the nature of the information communicated to users (i.e., advertising), but a third subset of negligent marketing claims—those that relate to distribution choices—do not fit as neatly into an existing liability box. *See* Richard C. Ausness, *Tort Liability for the Sale of Non–Defective Products: An Analysis and Critique of the Concept of Negligent Marketing*, 53 S.C. L. REV. 907, 909–10, 915–16, 944–46 (2002); *see also id.* at 939 ("Just a few years ago, it appeared that negligent marketing was about to become a powerful tool in products liability litigation, particularly where the products involved were not 'defective' in the traditional sense."); *id.* at 954 ("[A] manufacturer's failure to actively monitor retail sales or to supervise the conduct of distributors and retail sellers seems more like nonfeasance than misfeasance."); *id.* at 965 (concluding for a variety of reasons that courts should decline to recognize such claims). Although many of the broader critiques of this theory have force, the distinctive treatment of medical technologies for purposes of applying other liability rules may justify some willingness to entertain negligent marketing claims. Ausness also mentioned Rx drugs, though focusing primarily on OxyContin. *See id.* at 915–17, 945 & n.349; *see also id.* at 916 (making a passing reference to the diet drug combination fen-phen). OxyContin (like the handgun litigation) relates more to criminal misuse, *see infra* note 203, while fen-phen, which relates to problems of inappropriate off-label prescribing, better matches the type of negligent marketing claim that strikes me as worth considering.

[194] *See, e.g.*, Moning v. Alfono, 254 N.W.2d 759, 762 (Mich. 1977) (holding that a jury should resolve negligence claims against the manufacturer, wholesaler, and retailer of slingshots marketed directly to children); *id.* at 771 ("The issue in the instant case is not whether slingshots should be manufactured, but the narrower question of whether marketing slingshots directly to children creates an unreasonable risk of harm."); *cf.* First Nat'l Bank of Dwight v. Regent Sports Corp., 803 F.2d 1431, 1435 (7th Cir. 1986) (rejecting failure-to-warn and negligent marketing claims against the manufacturer of metal-tipped lawn darts sold as appropriate for adults only, but allowing claims for violations of federal regulations prohibiting sales of such products through toy stores and similar retail outlets).

[195] *See, e.g.*, Merrill v. Navegar, Inc., 28 P.3d 116, 119 (Cal. 2001); Chicago v. Beretta U.S.A. Corp., 821 N.E.2d 1099, 1148 (Ill. 2004); Hamilton v. Beretta U.S.A. Corp., 750 N.E.2d 1055, 1059 (N.Y. 2001); *see also* Jean Macchiaroli Eggen & John G. Culhane, *Gun Torts: Defining a Cause of Action for Victims in Suits Against Gun Manufacturers*, 81 N.C. L. REV. 115, 204–09 (2002). *But see* Ileto v. Glock Inc., 349 F.3d 1191, 1201–09 (9th Cir. 2003) (allowing a negligent marketing claim to proceed); City of Cincinnati v. Beretta U.S.A. Corp., 768 N.E.2d 1136, 1141

Although the *Products Liability Restatement* finds a bright line distinguishing prescription and nonprescription products, which it then uses to justify different rules for the former category (because of the power of differential marketing),[196] pharmaceuticals actually fall along a continuum. For instance, stricter prescription requirements apply to controlled substances and certain teratogens (and the most restrictive access restrictions apply to investigational drugs dispensed to subjects enrolled in clinical trials). Although most people use prescription drugs on an out-patient basis, physicians order the administration of some medications in hospitals and other controlled settings.[197] Conversely, the relatively recent phenomenon of advertising prescription drugs directly to consumers, as well as the advent of Internet prescribing and dispensing, may have made these products more similar to over-the-counter (OTC) drugs.[198] A few nonprescription drugs, in contrast, now require securing permission from a pharmacist,[199] and plaintiffs might argue that other OTC pharmaceuticals also should move "behind-the-counter" (or even to Rx status),[200] but the *Restatement* reserves the

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(Ohio 2002) (allowing a municipality to pursue such claims). Some of these lawsuits alleged that manufacturers of certain types of weapons or ammunition should not have sold these products to civilians, instead limiting their distribution to law-enforcement professionals and the military. *See, e.g.*, McCarthy v. Olin Corp., 119 F.3d 148, 152, 156–57 (2d Cir. 1997) (noting, in the course of rejecting such a claim, that the manufacturer of Black Talon® bullets subsequently limited sales to professionals); *id.* at 163 (Calabresi, J., dissenting) ("Selling tanks to the armed forces is fine; selling them to the general public is, I would think, clearly negligent.").

[196] *See* Henderson & Twerski, *supra* note 19, at 156, 170–73, 178–79; *id.* at 168–69 ("[S]uch differentiation [in design defect standards based on users] is not possible for nonprescription products, which are available to everyone on the open market.").

[197] *See, e.g.*, Press Release, *FDA Approves Entereg to Help Restore Bowel Function Following Surgery*, http://www.fda.gov/bbs/topics/NEWS/2008/NEW01838.html (May 20, 2008) (explaining that, in order to minimize risks relative to benefits, this drug will be restricted to inpatient use, only at specially certified hospitals, and patients may receive no more than fifteen doses).

[198] *See* 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, 1483 & n.131 (2000) (imagining the emergence of a new class of "quasi-prescription" drugs, and suggesting that Rx antihistamines might qualify); *id.* at 1453 ("In an online world where the physician is conspicuously absent, or at best virtual, the learned intermediary doctrine breaks down . . . ."); *see also* Henderson & Twerski, *supra* note 19, at 173 n.91 (conceding that, if physicians routinely acquiesced in patient demands for heavily advertised products, "[t]his breakdown of the learned intermediary as a screening device would make marketing of prescription drugs not substantially different from that of nonprescription products"); *infra* notes 246–250. For more about direct-to-consumer advertising, see *infra* Part III.B.

[199] *See* Daniel Healey, *Plan BTC: The Case for a Third Class of Drugs in the United States*, 63 FOOD & DRUG L.J. 375, 375–77, 385–86 (2008) (explaining that the FDA conditioned approval for switches from prescription status of emergency contraceptive and smoking cessation products on an age restriction enforced by pharmacists); *see also* FDA, Notice of Public Meeting, Behind the Counter Availability of Certain Drugs, 72 Fed. Reg. 56,769 (Oct. 4, 2007) (seeking input about the merits of this approach). Federal law now requires behind-the-counter status (though not limited to pharmacies) for products containing pseudoephedrine, though this statute sought to prevent criminal diversion rather than any direct risks to the consumer. *See* 21 U.S.C. § 830(e) (2006); Jean C. O'Connor et al., *Developing Lasting Legal Solutions to the Dual Problems of Methamphetamine Production and Use*, 82 N.D. L. REV. 1165, 1178–79 (2006).

[200] *See* Lars Noah, *Treat Yourself: Is Self–Medication the Prescription for What Ails American Health Care?*, 19 HARV. J.L. & TECH. 359, 382–83 (2006); *id.* at 381 ("If an OTC drug

narrow design defect test of section 6(c) for products already subject to prescription restrictions (though without drawing any distinctions among them).[201]

Some commentators have suggested that drug manufacturers have a duty to cut off supplies to Internet companies that engage in irresponsible online prescribing and dispensing.[202] More controversially, if general practitioners engaged in patterns of dangerous overprescribing,[203] then a plaintiff might claim that the drug manufacturer

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with otherwise unassailable labeling and design causes an injury, then the victim might argue that the product should have been made available only under professional medical supervision and never sold directly to consumers."); *see also* Howard Latin, *"Good" Warnings, Bad Products, and Cognitive Limitations*, 41 UCLA L. REV. 1193, 1271 (1994) ("Why should the presence of a 'good' warning, no matter how explicit, prevent courts from considering the value of alternative marketing strategies in light of the common tendency of people to overuse over-the-counter drugs that provide relief from chronic ailments?").

[201] *Cf. supra* note 15 (explaining that "medical foods" require a prescription). Separately, now that OTC drugs may offer some genuine clinical utility accompanied by non-trivial risks, why not treat these products as "unavoidably unsafe"? *See* Thomas M. Moore & Scott L. Hengesbach, *Comment k: A Prescription for the Over-the-Counter Drug Industry*, 22 PAC. L.J. 43, 55 n.57, 61–86 (1990) (arguing that sellers of OTC drugs should receive the same exemption from strict liability claims granted to sellers of prescription drugs); Daniel W. Whitney, *Product Liability Issues for the Expanding OTC Drug Category*, 48 FOOD & DRUG L.J. 321, 324 (1993) ("[I]t is difficult to fathom how a Rx drug would lose its social utility merely because it is being made available OTC."). After all, the movement of a product from prescription to nonprescription status does not alter its intrinsic character so much as the means of access and the method of marketing. *Cf.* Bober v. Glaxo Wellcome PLC, 246 F.3d 934, 939–40, 942 (7th Cir. 2001) (rejecting a consumer fraud claim against the manufacturer of Zantac® for suggesting that two doses of the 75 mg OTC version could not be substituted for the prescribed 150 mg version). The unpredictably of drug response would apply whether or not access requires a prescription, and OTC drugs encounter no less regulatory scrutiny than Rx drugs: indeed, for those that have gotten switched, they have undergone far closer FDA review. *See* Noah, *supra* note 200, at 365–66. In some instances, physicians may even "prescribe" OTC products. *See infra* note 249.

[202] *See* Richard C. Ausness, *Will More Aggressive Marketing Practices Lead to Greater Tort Liability for Prescription Drug Manufacturers?*, 37 WAKE FOREST L. REV. 97, 136 (2002) (forecasting that negligent marketing claims will be brought against manufacturers of prescription drugs when patients suffer injuries as a result of dispensing by unscrupulous Internet pharmacies); Chuang, *supra* note 198, at 1480–88; *cf.* Stephanie Feldman Aleong, *Green Medicine: Using Lessons from Tort Law and Environmental Law to Hold Pharmaceutical Manufacturers and Authorized Distributors Liable for Injuries Caused by Counterfeit Drugs*, 69 U. PITT. L. REV. 245, 265–72 (2007) (suggesting an entirely inapt nondelegable duty theory to hold manufacturers liable for hazardous counterfeiting). Serious practical difficulties would, however, complicate any such effort. *See* Chuang, *supra* note 198, at 1460–61 (noting that Pfizer had sought assistance from the Federal Trade Commission to combat online prescribing of Viagra); *cf.* Ceci Connolly, *Pfizer Cuts Supplies to Canadian Drugstores*, WASH. POST, Feb. 19, 2004, at A10. The FDA once conditioned drug approval on restricted distribution through a single pharmacy. *See* Aaron Zitner, *Date–Rape Drug OK'd to Treat Sleep Disorder*, L.A. TIMES, July 18, 2002, at A12 (GHB); *cf.* Anna Wilde Mathews & Leila Abboud, *FDA Approves Generic OxyContin*, WALL ST. J., Mar. 24, 2004, at A3 ("[T]he FDA has never limited any opioid to certain pharmacies, and agency officials say they don't have the authority to block certain physicians from prescribing a drug.").

[203] Courts generally have rejected negligent marketing claims involving the opioid analgesic OxyContin. *See, e.g.*, Labzda v. Purdue Pharma L.P., 292 F. Supp. 2d 1346, 1355 (S.D. Fla. 2003); *see also* Phillip J. Wininger, Note, *Pharmaceutical Overpromotion Liability: The Legal Battle over Rural Prescription Drug Abuse*, 93 KY. L.J. 269, 281–94 (2004–2005) (evaluating the prospects for such claims). Imagine, however, that the manufacturer had sold OxyContin without the required legend for Schedule II controlled substances (or, worse yet, without even the Rx legend, which would make it available on OTC shelves alongside analgesics such as acetaminophen and ibuprofen); I assume that—whether called a design defect, informational defect, or negligent

had a duty to limit access to only some subset of responsible physicians (perhaps only certain specialists or physicians who have registered with the manufacturer after attesting to their knowledge of the risks involved in the use of a product).[204] Such a theory might morph into a design defect claim (viewing the drug product as a package or bundle that includes choices about how patients may secure access to it),[205] which in turn would cast some doubt on the narrow conception of drug designs reflected in section 6(c).[206]

III. INFORMATIONAL DEFECTS

This Part considers alleged defects in the information that accompanies prescription products, especially those advertised directly to

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marketing claim—such a case would fall under the defectiveness per se rubric. *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 4 & cmt. d (1998).

[204] *See* Swayze v. McNeil Labs., Inc., 807 F.2d 464, 477 (5th Cir. 1987) (Goldberg, J., dissenting) ("McNeil could have prevented liability by removing, selectively, the [narcotic anesthesia] drug from hospitals that could not ensure that qualified doctors would prescribe [it, as opposed to certified nurse anesthetists who lacked prescribing privileges]."); *see also* Erik Eckholm & Olga Pierce, *Methadone Rises as a Painkiller with Big Risks*, N.Y. TIMES, Aug. 17, 2008, at A1 ("Methadone, once used mainly in addiction treatment centers to replace heroin, is today being given out by family doctors, osteopaths and nurse practitioners for throbbing backs . . . and a host of other severe pains. . . . [The FDA] is now considering requiring doctors to take special classes on prescribing narcotics."); *cf. In re* TMJ Implants Prods. Liab. Litig., 97 F.3d 1050, 1060 (8th Cir. 1996) (Heaney, J., dissenting) (suggesting that the manufacturer of Teflon should have ceased supplying this raw material to a medical device company because it knew of dangers associated with this application); Hunnings v. Texaco, Inc., 29 F.3d 1480, 1485–86 (11th Cir. 1994) (holding that a negligence claim could proceed against the supplier of mineral spirits where it knew that a retailer packaged the chemical in used milk jugs and sold the product without warnings); Mason v. Texaco Inc., 862 F.2d 242, 246 (10th Cir. 1988) (explaining that a "bulk seller [has] the obligation to sell only to knowledgeable and responsible distributors").

[205] *See, e.g.*, Carl Salzman, *Mandatory Monitoring for Side Effects: The "Bundling" of Clozapine*, 323 NEW ENG. J. MED. 827 (1990) (describing a controversial (and short-lived) system of restricted distribution adopted by the manufacturer of the new antipsychotic Clozaril® (partly in response to liability fears) that included weekly blood testing as a prerequisite for dispensing the drug to schizophrenic patients in order to guard against fatalities caused by agranulocytosis, a side effect reported during clinical trials in less than 2% of subjects); *see also* Noah, *supra* note 190, at 1214 (discussing other contexts that involve product bundling). When Celgene created its complex risk management program (S.T.E.P.S.) for Thalomid to guard against the risk of birth defects, it secured a patent on it (and, when Hoffmann–LaRoche had to create a similar program for Accutane, it purchased a license from Celgene). *See* Doshi, *supra* note 180, at 641 n.113.

[206] *See* Margaret Gilhooley, *When Drugs Are Safe for Some but Not Others: The FDA Experience and Alternatives for Products Liability*, 36 HOUS. L. REV. 927, 945–47 (1999); *id.* at 946 ("The best case for applying a distribution limit, if products liability law were to be extended to recognize a new type of defect, relates to misuse of a drug that poses grave risks not only to the immediate users, but also to the wider public."). With little explanation, however, this commentator dismissed the possibility:

> Limiting the distribution of drugs, however, is too novel to be an appropriate basis for a finding of products liability. It is not clear, for example, how such a responsibility fits into the structure of the Restatement. A limit on distribution goes beyond being a warning, but unlike the typical design defect, it does not relate to a change in the formulation or dose of the drug.

Id. at 945; *see also id.* at 946–49 (favoring, instead, patient-directed labeling to serve as a counterweight to inappropriate prescribing by physicians).

consumers. Under the "learned intermediary" rule, manufacturers satisfied their duty to warn of the hazards associated with Rx drugs by communicating risk information to physicians.[207] Accordingly, section 6(d) of the *Products Liability Restatement* provides as follows:

> A prescription drug . . . is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to: (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or (2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.[208]

When set alongside the blackletter formulation for design defects, which asked only whether a fully-informed health care professional would prescribe a product to any class of patients, the second clause of this provision imagines a different type of decisionmaking process when suggesting that manufacturers might have a duty to supply information to patients as well. Perhaps this language reflects an understanding of the physician's primary role as related to product selection and only secondarily concerned with communicating risk information.[209] The scope of section 6(d)(2)'s exception to the learned intermediary rule remains unclear.

The Reporters initially tried to recognize an exception in situations where manufacturers had engaged in direct-to-consumer

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[207] *See infra* Part III.A.

[208] RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(d) (1998) (omitting parallel reference to "medical device"). The reference to "other" (non-prescribing) health-care providers recognizes that the assessment and treatment of adverse events may occur outside of the prescribing relationship and that manufacturers distribute professional labeling widely (and not only in ways that immediately accompany the particular product). *See id.* cmt. d. *But cf.* Kaplan et al., *supra* note 27, at 66 ("Manufacturers should not be required to warn unascertainable 'others' who, because of independent decisions made by doctors, have been enlisted in the treatment of patients."). Non-physician prescribers may qualify as learned intermediaries. *See* Walker v. Merck & Co., 648 F. Supp. 931, 934–35 (M.D. Ga. 1986) (treating nurses as learned intermediaries when they administered a vaccine), *aff'd mem.*, 831 F.2d 1069 (11th Cir. 1987); Wyeth–Ayerst Labs. Co. v. Medrano, 28 S.W.3d 87, 92–93 (Tex. Civ. App. 2000) (same, in case of an implanted contraceptive); *see also infra* note 236 (noting the extension of prescribing privileges).

[209] *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. d (1998) ("When prescribing health-care providers are adequately informed of the relevant benefits and risks associated with various prescription drugs and medical devices, they can reach appropriate decisions regarding which drug or device is best for specific patients."); *see also* Thomas v. Hoffman–LaRoche, Inc., 731 F. Supp. 224, 229 (N.D. Miss. 1989) ("[T]he physician through education, experience, and specialized training is in the best position to make a benefit/risk analysis in making the determination to prescribe a particular drug for a specific patient."). One court suggested that the learned intermediary rule would not protect a manufacturer against a claim for failure to warn the general public of a drug recall. *See* Nichols v. McNeilab, Inc., 850 F. Supp. 562, 564–65 (E.D. Mich. 1993) (distinguishing the notification of a drug withdrawal prompted by safety concerns from the risk information conveyed to patients at the time that a drug is initially prescribed); *see also* Francesca Lunzer Kritz, *Recalls: Who Knew?*, WASH. POST, Oct. 22, 2002, at F1 (reporting that patients often do not receive notifications of drug recalls). *But cf.* Windham v. Wyeth Labs., Inc., 786 F. Supp. 607, 611 (S.D. Miss. 1992) (finding that manufacturer had no duty to warn a patient who had filled a prescription three years earlier of newly acquired risk information).

advertising (DTCA),[210] which would have greatly expanded the duty of pharmaceutical manufacturers to warn patients. The final draft did not include this exception, instead explaining that the ALI took no position on the issue and left it for developing case law.[211] As direct advertising of prescription drugs has continued to expand, plaintiffs predictably have urged courts to recognize such an exception to the learned intermediary rule,[212] but so far only a single jurisdiction has taken this step.[213]

A. Learned Intermediary Doctrine

In essentially all jurisdictions, manufacturers of prescription drugs satisfy their common law duty to warn by providing precautionary information to physicians and others who act in the capacity of learned intermediaries.[214] Thirty-five years ago the United States Court of Appeals for the Fifth Circuit offered the following oft-quoted justification for this rule:

> 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.[215]

The physician essentially acts as a proxy, selecting a therapeutic product on the patient's behalf.

Only in situations where such an individualized decision is unlikely to be made—for example, when individuals receive vaccines

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[210] *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 103(a)(3)(iii) (Council Draft No. 1, 1993); *see also* Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141, 161–68 (1997) (detailing the drafting history, and criticizing the claimed support for this exception). Parts III.A and III.B below borrow from (and update) my earlier article on this subject. *See id.* at 155–61, 169–79.

[211] *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. at 174 (1998); *see also* Charles J. Walsh et al., *The Learned Intermediary Doctrine: The Correct Prescription for Drug Labeling*, 48 RUTGERS L. REV. 821, 869 (1996) (calling section 6(d) a "tepid endorsement" of the learned intermediary doctrine).

[212] *See* Bob Van Voris, *Drug Ads Could Spell Legal Trouble: Consumer Campaigns May Result in Greater Liability*, NAT'L L.J., July 21, 1997, at B1 ("[L]awyers on both sides of the issue agree that plaintiffs will use the ads to assault the learned intermediary defense.").

[213] *See infra* Part III.B.1.

[214] *See* Ehlis v. Shire Richwood, Inc., 367 F.3d 1013, 1017 (8th Cir. 2004) (noting the nearly universal adoption of this doctrine); Guidry v. Aventis Pharm., Inc., 418 F. Supp. 2d 835, 840 (M.D. La. 2006); Vitanza v. Upjohn Co., 778 A.2d 829, 838 (Conn. 2001). *But see* State *ex rel*. Johnson & Johnson Corp. v. Karl, 647 S.E.2d 899, 901 (W. Va. 2007) (rejecting the rule); *id.* at 904 (finding that "the total number of jurisdictions recognizing the learned intermediary doctrine, either by decision of the highest court or by statute, is only twenty-two").

[215] Reyes v. Wyeth Labs., 498 F.2d 1264, 1276 (5th Cir. 1974) (declining, however, to apply the rule because, although the polio vaccine qualified as a prescription drug, it had not been prescribed to the recipient in a conventional sense and more closely resembled the unsupervised use of an OTC drug); *id.* at 1277 (concluding that "Wyeth knew or had reason to know that the vaccine would not be administered as a prescription drug").

through a mass immunization program—would a manufacturer have to provide a warning directly to the patient.[216] A few courts have extended the mass immunization exception to other drugs, such as contraceptives, for which a health care professional may not make an individualized judgment in prescribing a particular medication.[217] Even so, the overwhelming majority of courts do not recognize any exception for contraceptives.[218] In 1997, one state supreme court held that FDA-mandated patient package inserts (PPIs) eliminated the learned intermediary rule,[219] while several other courts have rejected any such exception.[220]

The learned intermediary doctrine reflects several related, subsidiary rationales. First, courts do not wish to intrude upon the doctor-patient relationship, and warnings that contradict information supplied by their physician might undermine the patient's trust in the physician's judgment.[221] Second, physicians may be in a superior position to convey meaningful information to their patients,[222] as they

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[216] *See, e.g.*, Mazur v. Merck & Co., 964 F.2d 1348, 1361–64 (3d Cir. 1992); Allison v. Merck & Co., 878 P.2d 948, 958 n.16 (Nev. 1994). With regard to childhood vaccines, however, federal legislation has overridden the mass immunization exception. *See* 42 U.S.C. § 300aa–22(c) (2006); *supra* note 166.

[217] *See, e.g.*, Odgers v. Ortho Pharm. Corp., 609 F. Supp. 867, 878–79 (E.D. Mich. 1985) (oral contraceptives); MacDonald v. Ortho Pharm. Corp., 475 N.E.2d 65, 69–70 (Mass. 1985) (same); *see also* Hill v. Searle Labs., 884 F.2d 1064, 1071 (8th Cir. 1989) (intrauterine devices).

[218] *See In re* Norplant Contraceptive Prods. Liab. Litig., 955 F. Supp. 700, 704–05 & n.18 (E.D. Tex. 1997) (collecting cases), *aff'd*, 165 F.3d 374 (5th Cir. 1999); *see also* Martin v. Ortho Pharm. Corp., 661 N.E.2d 352, 356 (Ill. 1996) (observing that a "majority of courts . . . have held that the FDA regulations concerning contraceptive pharmaceuticals should not serve as a basis to displace or create exceptions to the learned intermediary doctrine"); *cf.* Doe v. Solvay Pharm., Inc., 350 F. Supp. 2d 257, 272 (D. Me. 2004) (declining to extend the rationales underlying the contraceptive exception to an antidepressant prescribed for the treatment of obsessive-compulsive disorder).

[219] *See* Edwards v. Basel Pharm., 933 P.2d 298, 301 (Okla. 1997) ("When direct warnings to the user of a prescription drug have been mandated by a safety regulation promulgated for the protection of the user, an exception to the learned intermediary doctrine exists . . . ."). The court also held that compliance with the FDA's PPI requirement would not foreclose an inadequate warning claim. *See id.* at 301–03; *see also* Brochu v. Ortho Pharm. Corp., 642 F.2d 652, 658 (1st Cir. 1981) (holding that compliance with FDA labeling requirements would not preclude tort liability).

[220] *See, e.g.*, Presto v. Sandoz Pharm. Corp., 487 S.E.2d 70, 73–74 (Ga. Ct. App. 1997); *Martin*, 661 N.E.2d at 356; Mikell v. Hoffman–LaRoche, Inc., 649 So. 2d 75 (La. Ct. App. 1994); *see also In re* Norplant Contraceptive Prods. Liab. Litig., 165 F.3d 374, 379 (5th Cir. 1999) ("Why the learned intermediary doctrine should somehow be less applicable when the severity of the side effects encourages the FDA to promote additional labeling escapes us.").

[221] *See* Brooks v. Medtronic, Inc., 750 F.2d 1227, 1232 (4th Cir. 1984) ("One in a serious medical condition . . . faces unwanted, unsettling and potentially harmful risks if advice, almost inevitably involved and longwinded, from non-physicians, contrary to what the doctor of his choice has decided should be done, must be supplied to him during the already stressful period shortly before his trip to the operating room."); McKee v. Am. Home Prods. Corp., 782 P.2d 1045, 1055 (Wash. 1989) (suggesting that PPIs "may confuse and frighten the patient").

[222] *See Brooks*, 750 F.2d at 1232 (noting that "the question turns on who is in a better position to disclose risks"); *Martin*, 661 N.E.2d at 357 ("[P]rescribing physicians, and not pharmaceutical manufacturers, are in the best position to provide direct warnings to patients concerning the dangers associated with prescription drugs."); *MacDonald*, 475 N.E.2d at 74 (O'Connor, J., dissenting) ("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

must do to satisfy their duty to secure informed consent.[223] Third, drug manufacturers typically lack effective means to communicate directly with patients, making it necessary to rely on physicians to convey the relevant information—unlike OTC products, pharmacists usually dispense prescription drugs from bulk containers rather than as unit-of-use packages in which the manufacturer may have enclosed labeling.[224] Finally, because of the complexity of risk information about prescription drugs, comprehension problems would complicate any effort by manufacturers to translate physician labeling for lay patients.[225] For this reason, even critics of the rule do not suggest that pharmaceutical companies should provide warnings *only* to patients and have no tort duty to warn physicians.[226]

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whether to use a particular drug."). Professional labeling approved by the FDA may even urge physicians to communicate particular information to their patients. *See* Noah, *supra* note 42, at 321 & n.117. Manufacturers may supply PPIs to physicians who directly administer or implant a product. *See* Humes v. Clinton, 792 P.2d 1032, 1043 (Kan. 1990) (granting summary judgment to IUD manufacturer where physician had neglected to hand out its PPIs in favor of a homemade leaflet).

[223] *See, e.g.*, Hutchinson v. United States, 915 F.2d 560, 562–63 (9th Cir. 1990) (holding that doctor was liable for not warning patient of risks involved with the use of asthma medication); MacPherson v. Searle & Co., 775 F. Supp. 417, 423 (D.D.C. 1991); Korman v. Mallin, 858 P.2d 1145, 1149–51 (Alaska 1993) (describing the duty of physician to secure patient's informed consent to treatment); Niemiera v. Schneider, 555 A.2d 1112, 1119–21 (N.J. 1989) (absolving manufacturer but remanding claim that physician failed to warn patient); Martin v. Hacker, 628 N.E.2d 1308, 1311–13 (N.Y. 1993); *see also* Arato v. Avedon, 858 P.2d 598, 607 (Cal. 1993) (discussing the "uniquely human and necessarily situational ingredients that contribute to a specific doctor-patient exchange of information").

[224] *See* Davis v. Wyeth Labs., Inc., 399 F.2d 121, 130–31 (9th Cir. 1968) (observing that "it is difficult under such circumstances for the manufacturer, by label or direct communication, to reach the consumer with a warning," and contrasting OTC drugs, but noting that means of communication other than labeling are available in a mass immunization program); *see also* FDA, Prescription Drug Product Labeling; Medication Guide Requirements, 60 Fed. Reg. 44,182, 44,197 (Aug. 24, 1995) (defining "unit-of-use packaging" as "products [that] are pre-packaged in standardized amounts that can be dispensed directly to patients"); FDA, Revocation of Patient Package Insert Requirements, 47 Fed. Reg. 39,147, 39,150–51 (Sept. 7, 1982) (noting that oral contraceptives are unique in this sense, which assures that "each patient receives a patient brochure with the drug"). In recent years, pharmacists have experimented with computer-generated information sheets to accompany prescriptions, sometimes but not always with assistance from pharmaceutical manufacturers or medical associations. *See* Jonathan D. Rockoff, *Prescription Leaflets Lack Key Safety Data*, WALL ST. J., Dec. 17, 2008, at D3; Sheryl Gay Stolberg, *Faulty Warning Labels Add to Risk in Prescription Drugs*, N.Y. TIMES, June 4, 1999, at A27.

[225] *See, e.g.*, Hill v. Searle Labs., 884 F.2d 1064, 1070 (8th Cir. 1989) (noting that "the information regarding risks is often too technical for a patient to make a reasonable choice"); Reaves v. Ortho Pharm. Corp., 765 F. Supp. 1287, 1290 (E.D. Mich. 1991) ("As with other prescription drugs, patients are unlikely to understand technical medical information regarding the nature and propensities of oral contraceptives."); *see also* AMA Council on Sci. Aff., *Health Literacy*, 281 JAMA 552, 552 (1999); Lauran Neergaard, *Doctors' Orders, Drug Labels Often Misunderstood*, PHILA. INQUIRER, Apr. 9, 2004, at A3 (reporting an estimate from the Institute of Medicine that ninety million Americans have limited health literacy).

[226] Indeed, the first judicial opinion to use the "learned intermediary" terminology did so in a case where the prescription drug manufacturer had argued that it owed no duty to warn the physician. *See* Sterling Drug, Inc. v. Cornish, 370 F.2d 82, 85 (8th Cir. 1966). Similarly, evidently no one has suggested freeing physicians of their duty to secure informed consent from patients when prescribing drugs accompanied by PPIs.

The learned intermediary rule has important consequences for litigation. When reduced to the question of whether the warning conveyed to a physician or other health care practitioner was adequate, plaintiffs will encounter greater difficulties getting a case to a jury.[227] Although physicians may have an incentive to shift blame to the drug manufacturer,[228] normally they will testify that they understood the warnings provided by the company,[229] as contrasted with a plaintiff's testimony that the warning communicated to the physician seemed insufficient. Moreover, as contrasted with a consumer-directed warning to which jurors often can apply their own experience, plaintiffs may have to produce expert testimony to support an inadequacy claim.[230] In some cases, of course, plaintiffs succeed in convincing juries that a warning directed to their physicians was inadequate, either because it failed to mention known risks,[231] failed to draw sufficient attention to this information,[232] was diluted by overpromotion of the product,[233] or was not communicated through the most effective means available.[234]

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[227] *See, e.g.*, Ackermann v. Wyeth Pharms., 526 F.3d 203, 209–14 (5th Cir. 2008) (Effexor®); Ziliak v. AstraZeneca LP, 324 F.3d 518, 521 (7th Cir. 2003) (inhaled corticosteroid); Stahl v. Novartis Pharms. Corp., 283 F.3d 254, 264–68 (5th Cir. 2002) (Lamisil®); *id.* at 268 ("[W]hen a particular adverse effect is clearly and unambiguously mentioned in a warning label and the prescribing physician unequivocally states that he or she was adequately informed of that risk by the warning, the manufacturer has satisfied its duty to warn . . . ."); *id.* at 269–72 (finding no inadequacy in the instructions for monitoring liver function); Estate of LaMontagne v. Bristol–Myers Squibb, 111 P.3d 857, 862–65 & n.19 (Wash. Ct. App. 2005) (Glucophage®).

[228] *See* S.H. Willig, *Physicians, Pharmacists, Pharmaceutical Manufacturers: Partners in Patient Care, Partners in Litigation?*, 37 MERCER L. REV. 755, 769–77 (1986).

[229] *See, e.g.*, Hall v. Merck, Sharp & Dohme, 774 F. Supp. 604, 606–07 (D. Kan. 1991); Wooten v. Johnson & Johnson Prods. Inc., 635 F. Supp. 799, 802–04 (N.D. Ill. 1986). Alternatively, physicians may concede that they had learned of the information from other sources, which would mean that any failure to warn did not cause the patient's injury. *See* Motus v. Pfizer Inc., 358 F.3d 659, 660–61 (9th Cir. 2004); Ellis v. C.R. Bard, Inc., 311 F.3d 1272, 1283 n.8 (11th Cir. 2002); Eck v. Parke, Davis & Co., 256 F.3d 1013, 1021–24 (10th Cir. 2001) (physician's testimony that she already knew of the risk and would have selected the drug even with a fuller warning rebutted the heeding presumption); Miller v. Pfizer Inc., 196 F. Supp. 2d 1095, 1126–30 (D. Kan. 2002), *aff'd*, 356 F.3d 1326 (10th Cir. 2004); *id.* at 1129 n.108 (noting that the prescribing physician's consulting relationship with the defendant would not provide the jury with a sufficient basis for disbelieving his testimony); Harden v. Danek Med., Inc., 985 S.W.2d 449, 451 (Tenn. Ct. App. 1998); Noah, *supra* note 26, at 453; *see also id.* at 455 ("Courts have . . . declined to impose a duty on product sellers to educate health care providers about information that has appeared in the medical literature.").

[230] *See, e.g.*, Upjohn Co. v. MacMurdo, 562 So. 2d 680, 683 (Fla. 1990) ("[T]he adequacy or inadequacy of the warning to inform a physician must, except in the more obvious situations, be proved by expert testimony."); Wyeth Labs., Inc. v. Fortenberry, 530 So. 2d 688, 692 (Miss. 1988) ("The adequacy of a warning addressed to the medical community may fall into the category of issues requiring expert testimony.").

[231] *See, e.g.*, Wells v. Ortho Pharm. Corp., 788 F.2d 741, 745–46 (11th Cir. 1986); DeLuryea v. Winthrop Labs., 697 F.2d 222, 225 (8th Cir. 1983); Wooderson v. Ortho Pharm. Corp., 681 P.2d 1038, 1049–50, 1056–57 (Kan. 1984); Feldman v. Lederle Labs., 479 A.2d 374, 389 (N.J. 1984); *see also* Marks v. OHMEDA, Inc., 871 So. 2d 1148, 1156 (La. Ct. App. 2004) (sustaining the apportionment of full responsibility to the manufacturer of an anesthesia machine for carbon monoxide poisoning suffered by a patient where it had failed to warn hospital employees of this risk).

[232] *See, e.g.*, McNeil v. Wyeth, 462 F.3d 364, 368 (5th Cir. 2006); Thom v. Bristol–Myers Squibb Co., 353 F.3d 848, 853–54 (10th Cir. 2003) (holding that the adequacy of a warning presented a question for the jury where the package insert was "equivocal" in referring to reports of

The learned intermediary doctrine has attracted its share of critics who argue, among other things, that the defense reflects an anachronistic and excessively paternalistic model of the physician-patient relationship and fails to take into account changes in the delivery of health care services.[235] In particular, some critics argue that the emergence of managed care organizations has constrained physician autonomy so substantially that prescribing decisions may no longer reflect an informed medical judgment.[236] Even so, in 2004, one of the last remaining jurisdictions not to have ruled on this issue expressly adopted section 6(d),[237] while, in 2007, the West Virginia Supreme Court became the first jurisdiction to reject the learned intermediary rule altogether.[238]

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adverse effect as "rare" and only "temporally associated" but for which a "causal relationship . . . had not been established"); Bennett v. Madakasira, 821 So. 2d 794, 805–07 (Miss. 2002).

[233] *See, e.g.*, Caraker v. Sandoz Pharm. Corp., 172 F. Supp. 2d 1018, 1030 (S.D. Ill. 2001); *see also* Axen v. Am. Home Prods. Corp., 974 P.2d 224, 234 (Or. Ct. App. 1999) (relevant to punitive damages).

[234] *See, e.g.*, Hoffman v. Sterling Drug, Inc., 485 F.2d 132, 146–47 (3d Cir. 1975); Mahr v. G.D. Searle & Co., 390 N.E.2d 1214, 1232 (Ill. App. Ct. 1979); Richards v. Upjohn Co., 625 P.2d 1192, 1196–97 (N.M. Ct. App. 1980); *see also* Janssen Pharmaceutica, Inc. v. Bailey, 878 So. 2d 31, 55–59 (Miss. 2004) (noting that plaintiffs had argued "that Propulsid became a victim of label fatigue" by virtue of the five revisions to the package insert—sometimes accompanied by "Dear Doctor" letters—issued over the course of five years to convey increasingly alarming risk information, and concluding that this presented a question for the fact-finder).

[235] *See, e.g.*, Timothy S. Hall, *Reimagining the Learned Intermediary Rule for the New Pharmaceutical Marketplace*, 35 SETON HALL L. REV. 193, 195–99, 226–34, 261 (2004); Nancy K. Plant, *The Learned Intermediary Doctrine: Some New Medicine for an Old Ailment*, 81 IOWA L. REV. 1007, 1078 (1996) (concluding that "[r]adical changes in the health care system" justify elimination of the learned intermediary doctrine). *But see* Richard C. Ausness, *Learned Intermediaries and Sophisticated Users: Encouraging the Use of Intermediaries to Transmit Product Safety Information*, 46 SYRACUSE L. REV. 1185, 1229–35 (1996) (arguing that, although manufacturers are best situated to generate risk information, only physicians and other intermediaries should have the duty to communicate this information to end-users); Walsh et al., *supra* note 211, at 880 ("The learned intermediary doctrine has proven durable. Its continuing viability is supported by the common sense notion that, in the case of prescription drugs, information is best directed toward medical professionals.").

[236] *See* Hall, *supra* note 235, at 226–27; Plant, *supra* note 235, at 1023–32. In addition, prescribing privileges have spread to health care professionals who do not have a medical degree. *See* Mary Beck, *Improving America's Health Care: Authorizing Independent Prescriptive Privileges for Advanced Practice Nurses*, 29 U.S.F. L. REV. 951, 954 (1995) (explaining that eleven states give advanced practice nurses full prescribing authority, while thirty-seven states grant them limited prescribing authority subject to supervision by a physician); Phyllis Coleman & Ronald A. Shellow, *Extending Physicians' Standard of Care to Non–Physician Prescribers: The Rx for Protecting Patients*, 35 IDAHO L. REV. 37, 45–71 (1998) (criticizing the extension of limited prescribing authority to advanced practice nurses, physician assistants, pharmacists, optometrists, and psychologists); Brent Pollitt, *Fool's Gold: Psychologists Using Disingenuous Reasoning to Mislead Legislatures into Granting Psychologists Prescriptive Authority*, 29 AM. J.L. & MED. 489, 507–24 (2003).

[237] *See* Larkin v. Pfizer, Inc., 153 S.W.3d 758 (Ky. 2004) (declining, however, to take any position on possible exceptions).

[238] *See* State *ex rel*. Johnson & Johnson Corp. v. Karl, 647 S.E.2d 899 (W. Va. 2007); *see also* Jerica L. Peters, Note, State v. Karl*: An Unreasonable Rejection of the Learned Intermediary Doctrine*, 48 JURIMETRICS J. 285, 301–02, 305–08 (2008) (criticizing the decision).

B. Debate over an Advertising Exception

This Section canvasses the arguments made by proponents of an exception to the learned intermediary doctrine in DTCA cases,[239] as reflected in an important decision from the New Jersey Supreme Court, and suggests a number of responses. Until the central feature that defines the marketing of prescription drugs—namely, the requirement that a medical professional authorize the purchase by a particular patient—is modified,[240] the learned intermediary rule does not lose its force simply because a company chooses to promote its product directly to consumers.[241] Plaintiffs' lawyers do their share of tacky (and potentially hazardous) direct advertising to users of prescription products,[242] but surely they would not have to fear tort claims brought by

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[239] *See, e.g.*, Teresa Moran Schwartz, *Consumer–Directed Prescription Drug Advertising and the Learned Intermediary Rule*, 46 FOOD DRUG COSM. L.J. 829 (1991); Tim S. Hall, Note, *Bypassing the Learned Intermediary: Potential Liability for Failure to Warn in Direct-to-Consumer Prescription Drug Advertising*, 2 CORNELL J.L. & PUB. POL'Y 449 (1993). For my earlier and more detailed responses to their particular arguments, see Noah, *supra* note 210, at 169–79.

[240] Arguments about the reduced role of physicians in health care delivery, if taken to an extreme, may suggest that the existing prescription restrictions no longer make any sense. Perhaps someday patients will purchase any drugs that they would like, whether recommended by a physician, nurse, neighbor, or pharmaceutical company. In the meantime, however, a medical professional will continue to intervene in the decision to prescribe a drug and make the final judgment about its relative risks and benefits for a particular patient. It would constitute professional malpractice to do otherwise. *See supra* note 223; *see also* Plant, *supra* note 235, at 1055–62 (elaborating on the informed consent duties of prescribers).

[241] Wholly apart from the liability issues, DTCA continues to generate heated debate. *See* Julie M. Donohue et al., *A Decade of Direct-to-Consumer Advertising of Prescription Drugs*, 357 NEW ENG. J. MED. 673, 674 (2007); Matthew F. Hollon, Editorial, *Direct-to-Consumer Advertising: A Haphazard Approach to Health Promotion*, 293 JAMA 2030 (2005); Richard L. Kravitz, *Direct-to-Consumer Advertising of Prescription Drugs: Implications for the Patient–Physician Relationship*, 284 JAMA 2244 (2000); Nat Ives, *FDA Ponders Pros and Cons of the Ways Prescription Drugs Are Promoted to Consumers*, N.Y. TIMES, Sept. 29, 2003, at C11; Bruce Japsen, *AMA Urges a No–Ad Period for New Drugs*, CHI. TRIB., June 15, 2006, at 1.

[242] *See* Bernstein, *supra* note 118, at 1965, 1973, 1976–77, 1980 n.116, 1981; Schwartz & Goldberg, *supra* note 40, at 166 & n.204; Chen–Sen Wu, *Distributive Justice in Pharmaceutical Torts: Justice Where Justice Is Due?*, LAW & CONTEMP. PROBS., Fall 2006, at 207, 223–24; Mary Flood, *Drug Doubts Put Lawyers in Motion*, HOUS. CHRON., June 10, 2007, at Bus. 1 (reporting that plaintiffs' attorneys use newspaper and television ads and "case-soliciting Web sites that already look like a pharmacy's inventory, except that the drugs listed are alleged to cause harm," and adding that the manufacturer of the latest target (the diabetes drug Avandia®) expressed concern that "lawyer ads could frighten patients into discontinuing their medicine, which could endanger their health"); *id.* (noting that one Houston firm's phone number is "1-800-BAD-DRUG"); Joseph P. Fried, *Specialty Lawyers Gear up for Suits over Two Medications*, N.Y. TIMES, July 30, 2000, § 1, at 28; *see also* David Brown, *Scientist's Two Roles in Study May Conflict*, WASH. POST, Feb. 21, 2004, at A10 (reporting that the author of a controversial study linking autism to a type of vaccine had failed to disclose his closely related work for a plaintiff's lawyer done under a grant of nearly $90,000 from a legal aid society). One of my favorites aired during the summer of 2008, from a series of ads run by the firm Ferrer Poirot & Wansbrough on various cable channels, was styled as a "Medical Alert!" and did not focus on any particular drug but instead a class of serious side effects (Stevens Johnson syndrome or toxic epidermal necrolysis) allegedly associated with two dozen (mostly still marketed, and many OTC) pharmaceutical products. *See* http://www.pharmacy-video.com/medical-alert-tv-commercial-for-stevens-johnson-symdrome-and-toxic-epidermal-necrolysis/ (last visited Aug. 1, 2008). One of the firm's latest TV spots (focusing on the risk of diabetes associated with the atypical antipsychotic drug Seroquel®) helpfully tells prospective clients not to discontinue treatment without first checking with their doctors.

patients who discontinued a prescribed (and still net beneficial) course of treatment (or simply became anxious) in response to exaggerated risk information appearing in ads trolling for clients.[243]

Preliminarily, however, the possibility of recognizing an advertising (or other) exception raises questions about the interrelationship between the design and warning provisions of the *Products Liability Restatement*.[244] If an exception to the learned intermediary rule covers a particular case, such as mass immunizations, should that also render inapplicable section 6(c)'s physician-based design defect standard in favor of the more open-ended test of section 2(b)?[245] How about the far less common contraceptive exception—if section 6(d)(2) would allow a failure-to-warn claim because the learned intermediary has fallen out of the picture, would that also render inapplicable the protective design defect standard of section 6(c)?[246] The Reporters subsequently considered this difficulty, though only in connection with a possible advertising exception, but they thought that such an "unlikely juncture" lay "far in the future."[247]

Separately, if courts increasingly recognized exceptions to the learned intermediary rule that depended on the particulars of the relative degree of consumer and physician involvement in product selection,[248] then why not work it in the other direction—for instance, when health care professionals select OTC drugs for their patients?[249] Of course, a

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[243] *Cf.* Bailey v. Huggins Diagnostic & Rehab. Ctr., Inc., 952 P.2d 768, 770–73 (Colo. Ct. App. 1997) (rejecting tort claims against the author of a book that had exaggerated the risks associated with mercury in dental amalgam).

[244] Similarly, as a reasonable physician test has begun to displace the traditional custom-based standard of care, courts have had to rethink various subsidiary malpractice doctrines. *See* Philip G. Peters, Jr., *The Quiet Demise of Deference to Custom: Malpractice Law at the Millennium*, 57 WASH. & LEE L. REV. 163, 166–68 (2000).

[245] Courts following *Restatement (Second)* § 402A comment k did not do so categorically when finding that a drug had not satisfied one of the prerequisites for this immunity from strict liability design defect claims; instead, the failure, for instance, to supply a proper warning to patients might render comment k's protection against design defect claims inapplicable in the particular case. Under the *Products Liability Restatement*, at least insofar as prescription drug manufacturers had warned patients adequately in such cases, a design defect claim might offer plaintiffs their only recourse. The mass immunization exception may not, however, provide a good test of this difficulty because public health authorities have made a societal risk-benefit judgment. *See supra* note 165 and accompanying text.

[246] *Cf.* Shanks v. Upjohn Co., 835 P.2d 1189, 1195 n.7 (Alaska 1992) ("In strict liability design cases involving such [atypical prescription] products, it may be appropriate to apply the 'ordinary consumer expectation' test rather than the 'ordinary doctor expectation test.'").

[247] *See* Henderson & Twerski, *supra* note 19, at 173.

[248] As happened, for instance, in cases extending the mass immunization exception to other settings involving vaccine administration. *See* Hall, *supra* note 235, at 206 & n.55, 209–10; *see also id.* at 198 (advocating in all cases "a fact-based inquiry to determine whether the drug in question was in fact sold in the absence of an effective intermediary"); *id.* at 205, 239–54, 261 (same); *id.* at 220–21, 231, 244 (arguing that § 6(d) represented a move in this direction); *id.* at 216–19 (objecting to the blanket application of the rule subject only to narrow categorical exceptions). For a new twist on immunizations, see Stephen Smith, *Fly-by Flu Shot: No Need to Get out of the Car—Vaccination Is Available at Hospital's Drive-through*, BOSTON GLOBE, Oct. 29, 2008, at B1.

[249] *See, e.g.*, Ferrara v. Berlex Labs., Inc., 732 F. Supp. 552, 553–55 & n.1 (E.D. Pa. 1990) (applying the doctrine to reject claims for failing to warn of dangerous interaction against the

categorical rule—as the Reporters preferred for design defects and ultimately (though incompletely) accepted for warning claims—avoids the uncertainty that would attend a case-by-case inquiry into whether a particular physician-patient encounter passed some threshold for applying the learned intermediary doctrine.[250]

1. Norplant Litigation

In *Perez v. Wyeth Laboratories Inc.*,[251] the New Jersey Supreme Court adopted an exception to the learned intermediary rule whenever a prescription drug manufacturer has engaged in direct-to-consumer advertising. The case involved Norplant® (levonorgestrel), an implantable long-acting contraceptive product.[252] The consolidated lawsuits claimed that the manufacturer had failed to warn patients of a litany of alleged side effects of use and complications associated with removal of the product.[253] The trial judge dismissed the complaints,[254] but the state supreme court reversed. After taking apparent comfort in the fact that the *Products Liability Restatement* had left the question to developing case law,[255] the majority concluded that DTCA undermined most of the rationales thought to justify the learned intermediary rule.[256]

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manufacturers of a prescription antidepressant and an OTC decongestant prescribed by the plaintiff's physician); *see also* Kelley v. Wiggins, 724 S.W.2d 443, 449–50 (Ark. 1987) (affirming verdict against a clinic for negligently using Sudafed® in high-risk patient); Sharkey v. Sterling Drug, Inc., 600 So. 2d 701, 711 (La. Ct. App. 1992) (crediting a physician's testimony that he would not have recommended aspirin for a child with flu-like symptoms if the OTC label had included a fuller warning of the risk of Reye's syndrome); Noah, *supra* note 42, at 321 & n.117, 338 (noting that the FDA sometimes approves separate professional labeling for OTC drugs); Peter Temin, *Realized Benefits from Switching Drugs*, 35 J.L. & ECON. 351, 358–59 (1992); Whitney, *supra* note 201, at 329–30 (arguing that the learned intermediary rule should apply in such cases). *But see* Mitchell v. VLI Corp., 786 F. Supp. 966, 970 (M.D. Fla. 1992) (declining to apply the learned intermediary rule to an OTC contraceptive sponge that a physician had supplied to his patient).

[250] *See supra* notes 198–201 and accompanying text (explaining that the use of prescription status as a bright line rule for selecting among design defect standards suffers from both under- and overinclusiveness).

[251] 734 A.2d 1245 (N.J. 1999).

[252] *See id.* at 1247, 1251; *see also* Allan J. Coukell & Julia A. Balfour, *Levonorgestrel Subdermal Implants: A Review of Contraceptive Efficacy and Acceptability*, 55 DRUGS 861, 881–83 (1998); Gina Kolata, *Will the Lawyers Kill Off Norplant?*, N.Y. TIMES, May 28, 1995, § 3, at 1. Shortly after the court's decision, the defendant negotiated a global settlement. *See* Gardiner Harris & Robert Langreth, *After Setbacks, American Home Plans Remedies*, WALL ST. J., Aug. 31, 1999, at B1. The manufacturer no longer sells this product. *See* Erin Allday, *FDA Approves New Contraceptive Injected in Arm: Norplant-like Device Used in Europe Will Be Available in '07*, S.F. CHRON., July 19, 2006, at A2 (reporting that Norplant was withdrawn in 2002).

[253] *See Perez*, 734 A.2d at 1248.

[254] *See id.* at 1249.

[255] *See id.* at 1253; *cf. id.* at 1267 (Pollock, J., dissenting) ("Given the statutory basis for the learned intermediary doctrine in New Jersey, recourse to the *Restatement* . . . is gratuitous."). The majority rejected the argument emphasized by the dissenting opinion that the state legislature had codified the learned intermediary rule. *See id.* at 1253–54 (majority opinion).

[256] *See id.* at 1255–57, 1263. In the course of its opinion, the majority quoted several passages from my earlier article on the subject, *see id.* at 1251–52, 1255–56, 1258, but evidently failed to notice that I had concluded that the exception made no sense, citing instead a student note published in the *William Mitchell Law Review* as supporting its ultimate conclusion, *see id.* at 1256.

Although essentially no one doubts that direct advertising has altered the dynamic between patients and their physicians when considering the use of a drug promoted in this fashion,[257] the dissent emphasized that, at least with respect to Norplant (a hybrid drug-device product requiring surgical implantation),[258] doctors would continue playing a central role.[259] The majority also never explained how such advertising rendered inapplicable concerns that supplying comprehensive risk information directly to patients might cause them to discontinue

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Indeed, immediately after quoting my summary of the rationales underlying the learned intermediary rule, the majority offered a brief synopsis that blatantly mischaracterized some of these before explaining that at least three of the four became inapplicable when manufacturers engage in DTCA. *See id.* at 1255–56. As the dissent briefly explained, all four of the rationales remained pertinent. *See id.* at 1269 (Pollock, J., dissenting).

[257] *See* Matthew F. Hollon, *Direct-to-Consumer Marketing of Prescription Drugs: Creating Consumer Demand*, 281 JAMA 382, 383–84 (1999); Richard L. Kravitz et al., *Influence of Patients' Requests for Direct-to-Consumer Advertised Antidepressants: A Randomized Controlled Trial*, 293 JAMA 1995, 2000 (2005); Steven Pearlstein, *Drug Firms Take a Dose of Responsibility for Ads*, WASH. POST, Aug. 3, 2005, at D1 ("A study by the Kaiser Family Foundation found that each $1 invested in advertising yields an extra $4.20 in sales."); *FDA Survey Finds Drug Ads Influence Requests by Patients*, WALL ST. J., Jan. 14, 2003, at D5. *But see* John E. Calfee et al., *Direct-to-Consumer Advertising and the Demand for Cholesterol–Reducing Drugs*, 45 J.L. & ECON. 673, 683–86 (2002) (finding little evidence that DTCA increased short-term demand for statins, but noting beneficial effects such as improved patient compliance with already prescribed treatments). For instance, it appears that the aggressive marketing of COX-2 inhibitors led to the dangerous overprescribing of these drugs. *See* Marc Kaufman, *New Study Criticizes Painkiller Marketing: Arthritis Drug Ads a Factor in Overuse*, WASH. POST, Jan. 25, 2005, at A1; Barry Meier et al., *Medicine Fueled by Marketing Intensified Trouble for Pain Pills*, N.Y. TIMES, Dec. 19, 2004, § 1, at 1.

[258] *Cf.* William E. Boden & George A. Diamond, *DTCA for PTCA—Crossing the Line in Consumer Health Education?*, 358 NEW ENG. J. MED. 2197, 2200 (2008) ("[A drug-eluting] stent can be selected and implanted only by someone with a very sophisticated medical understanding . . . . It seems almost unimaginable . . . that a cardiologist would accede to a patient's request for a particular stent on the basis of the information gleaned from a television ad."). Implanted devices that have no drug component also have become the subject of such campaigns. *See* Ross Kerber, *Device Makers Target Consumers with Their Ads*, BOSTON GLOBE, Mar. 10, 2004, at C1; *see also* FDA, Draft Guidances for Industry on Improving Information About Medical Products and Health Conditions, 69 Fed. Reg. 6308, 6309 (Feb. 10, 2004) (issuing a guidance for consumer advertising of restricted devices).

[259] *See Perez*, 734 A.2d at 1267–68 (Pollock, J., dissenting); *see also* Jerry Menikoff, *Demanded Medical Care*, 30 ARIZ. ST. L.J. 1091, 1109 n.45, 1116 (1998) ("[I]t would be highly unusual for a physician to view her power to write a drug prescription as merely a requirement to make sure that the patient was adequately informed about the drug."); Steven H. Miles, *Informed Demand for "Non–Beneficial" Medical Treatment*, 325 NEW ENG. J. MED. 512, 513–14 (1991); Michelle D. Ehrlich, Note, *Doctors Can "Just Say No": The Constitutionality of Consumer–Directed Advertising of Prescription Drugs*, 12 HASTINGS COMM. & ENT. L.J. 535, 550, 553–55 (1990) ("[T]he physician—and not the patient/consumer—makes the ultimate decision of what drug a patient will purchase."); *cf.* Incollingo v. Ewing, 282 A.2d 206, 218 (Pa. 1971) ("We decline to accept the proposition that a qualified doctor can so easily turn himself into a dupe [by alleging that sales representatives had pressured him into prescribing the drug]."), *abrogated on other grounds by* Kaczkowski v. Bolubasz, 421 A.2d 1027 (Pa. 1980). The majority belatedly recognized as much. *See Perez*, 734 A.2d at 1263–64. Nonetheless, it decided as a matter of policy that physicians' foreseeable intervention (and their failure to convey or act upon risk information that they had received from the drug manufacturer) would not amount to a superseding cause. *See id.* at 1260–63 (adding, however, that a jury could allocate relative shares of responsibility to these joint tortfeasors). *But see* Krasnopolsky v. Warner–Lambert Co., 799 F. Supp. 1342, 1346 (E.D.N.Y. 1992) (superseding cause).

needed treatments,[260] much less that a manufacturer could do this in a way reasonably comprehensible to lay persons.[261]

Moreover, although no one doubts that physicians often fail to engage in meaningful (tailored) discussions with patients about drugs risks,[262] imposing such an obligation on manufacturers may further reduce the incentives of conscientious physicians even to try. Evidently the majority thought that Norplant, like some of the other examples it had cited, did not qualify as a therapeutically important product,[263] echoing suggestions made by some commentators that another exception to the learned intermediary doctrine should apply to "lifestyle" drugs and devices, whether or not directly advertised to consumers.[264]

The majority opinion repeatedly suggested that Wyeth should not enjoy protection from liability for failing to warn patients directly when it has aimed misleading advertisements at them,[265] but it conceded

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[260] Extensive warnings conveyed directly by pharmaceutical manufacturers might make patients lose trust in their physicians or discontinue necessary drug therapies because of undue anxiety about the reported side effects that the physician felt did not deserve mention or emphasis in a particular case—after all, advertisements emphasize benefits and come before the patient visits a physician, while PPIs emphasize risks and reach patients only upon drug dispensing.

[261] *Cf.* Raymond L. Woosley, *Drug Labeling Revisions—Guaranteed to Fail?*, 284 JAMA 3047, 3048 (2000) ("In the last 25 years, the package inserts for new drugs have increased in length more than 5–fold. For example, the 2–page package insert for cisapride, when printed in 12–point font on 8.5 x 11 paper, is more than 10 pages long and contains more than 470 facts about the drug."). For a critique of the *Perez* decision from the perspective of a practicing physician (enrolled in law school), see Timothy McIntire, Note, *Legal and Quality of Patient Care Issues Arising from Direct-to-Consumer Pharmaceutical Sales*, 33 U. MEM. L. REV. 105, 127–28, 130–33 (2002); *see also id.* at 108–09, 134 (emphasizing the difficulty in trying to translate complex risk information for patients); *supra* note 225.

[262] *See* Stolberg, *supra* note 224, at A27 ("In a 1997 survey of 1,000 patients, the F.D.A. found that only one-third had received information from their doctors about the dangerous side effects of drugs they were taking.").

[263] *See Perez*, 734 A.2d at 1257 ("Further, when one considers that many of these 'life-style' drugs or elective treatments cause significant side effects without any curative effect, increased consumer protection becomes imperative, because these drugs are, by definition, not medically necessary."); *infra* note 266 (discussing the majority's references to promotional campaigns for seemingly trivial drugs); *see also* Odgers v. Ortho Pharm. Corp., 609 F. Supp. 867, 878–79 (E.D. Mich. 1985) (oral contraceptives).

[264] *See, e.g.*, Kathy A. King–Cameron, Comment, *Carving Another Exception to the Learned Intermediary Doctrine: Application of the Learned Intermediary Doctrine in Silicone Breast Implant Litigation*, 68 TUL. L. REV. 937, 969–70 (1994); *see also* Hall, *supra* note 235, at 197 & n.10, 229–30, 237, 243, 250 (arguing that the "lifestyle" use of a drug should count as a factor against application of the learned intermediary rule); Susan A. Casey, Comment, *Laying an Old Doctrine to Rest: Challenging the Wisdom of the Learned Intermediary Doctrine*, 19 WM. MITCHELL L. REV. 931, 952–55 (1993) (arguing that an advertising exception should exist at least with regard to elective prescription drugs and medical devices promoted to consumers for cosmetic purposes, such as acne treatments and breast implants). For a critique of the suggestion that such a distinct category exists, see *supra* notes 105–119 and accompanying text.

[265] *See, e.g.*, *Perez*, 734 A.2d at 1257 ("It is one thing not to inform a patient about the potential side effects of a product; it is another thing to misinform the patient by deliberately withholding potential side effects while marketing the product as an efficacious solution to a serious health problem."); *id.* ("The question is whether the absence of an independent duty to warn patients gives the manufacturer the right to misrepresent to the public the product's safety."); *id.* at 1261 (declining to "insulate the manufacturer who has engaged in deceptive trade practices"); *id.* at 1264 ("[W]e must decide if a pharmaceutical manufacturer is free to engage in deceptive advertising to consumers. . . . [The learned intermediary rule] does not confer on pharmaceutical manufacturers a

that this characterization assumed that the plaintiffs would manage to prove their allegations at trial.[266] In fact, the plaintiffs may not have seen any of the allegedly misleading ads,[267] and it also seems implausible that the print ads in major magazines would have failed to comply with the FDA's relatively clear command that the full prescribing information appear on the next page.[268] What the plaintiffs wanted, however, was not clearer risk information in advertisements that they may not have seen (or remembered); instead, they sought printed warnings to accompany the drugs when later dispensed to them.

If other courts around the country followed New Jersey's lead in recognizing this exception to the learned intermediary rule, it would have the effect of requiring that manufacturers wishing to engage in DTCA produce and disseminate comprehensive PPIs. No other court has done so to this point, and several courts have rejected the proposed exception.[269] The West Virginia Supreme Court, however, relied heavily

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license to mislead or deceive consumers when those manufacturers elect to exercise their right to advertise their product directly to such consumers.").

[266] *See id.* at 1247–48; *id.* at 1263 ("acknowledg[ing] that the procedural posture of this case casts defendant's product in an unfair light"). Elsewhere in the opinion, the majority painted an unflattering picture of DTCA, citing advertisements involving entirely different pharmaceutical products, indicated for the treatment of allergies, baldness, erectile dysfunction, and excess weight. *See id.* at 1247, 1251–53, 1260, 1264. It also discussed changes in health care delivery that made it more difficult for physicians to spend time having meaningful discussions with their (increasingly pushy) patients. *See id.* at 1247, 1255, 1260; *see also id.* at 1262 n.6 (Internet prescribing). The dissent admonished the majority for going beyond the confines of the record developed in the Norplant cases before the court. *See id.* at 1268 (Pollock, J., dissenting) ("Through the incorporation of presumed facts, the majority has created a phantom record . . . .").

[267] *See id.* at 1260 (majority opinion); *id.* at 1268 (Pollock, J., dissenting); *cf. In re* Norplant Contraceptive Prods. Liab. Litig., 955 F. Supp. 700, 707–08 & n.45 (E.D. Tex. 1997) (declining to address arguments in favor of an exception because the plaintiffs had not seen any advertisements), *aff'd*, 165 F.3d 374 (5th Cir. 1999).

[268] *See Perez*, 734 A.2d at 1263 (referring to an agreed statement of facts that seemed to concede as much); *cf. id.* at 1258 (summarizing the agency's "brief statement" and other still evolving requirements). The majority referenced ads appearing in *Glamour*, *Mademoiselle*, and *Cosmopolitan* in 1991. *See id.* at 1248; *see also* William Green, *Consumer–Directed Advertising of Contraceptive Drugs: The FDA, Depo–Provera, and Product Liability*, 50 FOOD & DRUG L.J. 553, 555–58 (1995) (describing Upjohn's print ads for another long-acting contraceptive sold in the early 1990s); *id.* at 566 (concluding that "the Depo–Provera advertisement appears to comply with section 502(n)'s brief summary requirement"). No doubt the small print did not include disclosures of alleged risks that only later came to light, but, so long as these ads had included the latest prescribing information, they would not have run afoul of agency requirements (or, for that matter, represent inadequate warnings under state law if the risks were unknowable).

[269] *See In re* Norplant Contraceptive Prods. Liab. Litig., 165 F.3d 374, 379 (5th Cir. 1999); Porter v. Eli Lilly & Co., No. 1:06-CV-1297-JOF, 2008 WL 544739, at *7–9 (N.D. Ga. 2008); Beale v. Biomet, Inc., 492 F. Supp. 2d 1360, 1376 (S.D. Fla. 2007); Cowley v. Abbott Labs., Inc., 476 F. Supp. 2d 1053, 1060 n.4 (W.D. Wis. 2007); *In re* Meridia Prods. Liab. Litig., 328 F. Supp. 2d 791, 812 n.19 (N.D. Ohio 2004) ("Five years have passed since the New Jersey Supreme Court decided *Perez*. In the intervening period, no other state has followed New Jersey's lead."), *aff'd*, 447 F.3d 861 (6th Cir. 2006); Heindel v. Pfizer, Inc., 381 F. Supp. 2d 364, 378 (D.N.J. 2004) (applying Pennsylvania law); *see also* Banner v. Hoffmann–La Roche Inc., 891 A.2d 1229, 1236–37 (N.J. Super. Ct. App. Div. 2006) (declining to apply *Perez* where a drug manufacturer simply had provided brochures for doctors to give to their patients); Rowe v. Hoffmann–La Roche Inc., 892 A.2d 694, 700 (N.J. Super. Ct. App. Div. 2006). Nor have courts found the learned intermediary rule inapplicable when patients assert misrepresentation claims based on direct advertising. *See* Miller v. Pfizer Inc., 196 F. Supp. 2d 1095, 1119–22 (D. Kan. 2002) (Zoloft®); N.J. Citizen Action v.

on *Perez* when it recently decided to reject the learned intermediary rule altogether.[270]

2. Satisfying an Expanded Duty to Warn

The *Perez* majority hastened to add that, as provided by state statute, the defendant would enjoy a rebuttable (or stronger) presumption of adequacy so long as the warnings complied with FDA requirements.[271] This reflects a potentially serious misunderstanding of the intended purpose of the agency's advertising rules (and it also fails to appreciate the entirely flimsy nature of the FDA's recent non-rule pronouncements on the subject[272]): these do not attempt to fulfill a risk disclosure function so much as to ensure fair balance.[273] If the plaintiffs had not, in fact, seen any Norplant ads, then compliance with agency requirements designed to prevent misleading advertising could hardly have satisfied the new-found duty to warn patients directly.[274] If extended to broadcast ads, where the

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Schering–Plough Corp., 842 A.2d 174, 176–78 (N.J. Super. Ct. App. Div. 2003) (Claritin®). As suggested below, *see infra* note 274, that position strikes me as harder to defend.

[270] *See* State *ex rel*. Johnson & Johnson Corp. v. Karl, 647 S.E.2d 899, 908–10 (W. Va. 2007); *see also* Rimbert v. Eli Lilly & Co., 577 F. Supp. 2d 1174, 1214–24 (D.N.M. 2008) (predicting that the New Mexico Supreme Court would do the same). The *Karl* case involved Propulsid® (cisapride), and, although serious questions have arisen about promotional efforts for this drug aimed at physicians, it apparently was not heavily advertised directly to patients. *See* Gardiner Harris & Eric Koli, *Lucrative Drug, Danger Signals and FDA*, N.Y. TIMES, June 10, 2005, at A1.

[271] *See Perez*, 734 A.2d at 1259 ("For all practical purposes, absent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive of such claims."); *id.* at 1263 ("The FDA has established a comprehensive regulatory scheme for direct-to-consumer marketing of pharmaceutical products. Given the presumptive defense that is afforded to pharmaceutical manufacturers that comply with FDA requirements, we believe that it is fair to reinforce the regulatory scheme by allowing" these failure-to-warn claims.). In contrast, the dissent argued that this state statute had codified the learned intermediary doctrine without countenancing any exceptions along the lines crafted by the majority. *See id.* at 1264–67 (Pollock, J., dissenting); *see also id.* at 1269 (criticizing the majority's discussion of the compliance defense and proximate causation issues because the parties had not received any opportunity to address these issues).

[272] Some commentators also have made this mistake. *See, e.g.*, William A. Dreier, *Direct-to-Consumer Advertising Liability: An Empty Gift to Plaintiffs*, 30 SETON HALL L. REV. 806, 824–25 (2000); *id.* at 816–20 (asserting that "FDA standards are minute and definite," repeatedly citing the agency's guidance documents); Caroline L. Nadal, Note, *The Societal Value of Prescription Drug Advertisements in the New Millennium: Targeted Consumers Become the Learned*, 9 J.L. & POL'Y 451, 482–83, 487, 495 & n.229, 498–500, 504–05 (2001) (referring to the FDA's regulations and guidelines interchangeably); *cf.* Robert A. Bell et al., *Direct-to-Consumer Prescription Drug Advertising and the Public*, 14 J. GEN. INTERNAL MED. 651, 654–55, 656 (1999) (finding that many consumers harbor misconceptions about the stringency of the applicable regulatory controls). Although courts grant agencies substantial latitude in interpreting their own regulations, *see* Lars Noah, *Divining Regulatory Intent: The Place for a "Legislative History" of Agency Rules*, 51 HASTINGS L.J. 255, 284–90, 294–99 (2000), the FDA's guidance documents governing DTCA would not pass muster as mere interpretive rules if it ever made a formal attempt to enforce them directly.

[273] *See* Noah, *supra* note 210, at 175–76. So-called "reminder" and "help seeking" advertisements do not even have to satisfy the fair balance requirement. *See* Alicia Mundy, *Making a Name for Drugs Without Using Their Names: Some Ads Highlight Only Web Addresses So Side Effects Don't Have to Be Listed*, WALL ST. J., Aug. 29, 2008, at B1.

[274] *Cf.* Kaplan et al., *supra* note 27, at 69 ("Under the draft formulation [of the *Products Liability Restatement*], manufacturers seemingly would be liable if they advertised but failed to warn

FDA's "requirements" appear in technically non-binding (and hardly unambiguous) guidance documents,[275] then the compliance defense would offer essentially no protection unless courts understood the manner in which agency expectations operate as de facto requirements.[276]

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consumers directly—even if the advertisements were never seen or read by plaintiffs."). Conversely, if they had seen and relied on genuinely misleading ads, then perhaps the patients could assert a misrepresentation or breach of express warranty claim. *See, e.g.*, Desiano v. Warner–Lambert Co., 326 F.3d 339, 342 (2d Cir. 2003); *In re* Meridia Prods. Liab. Litig., 328 F. Supp. 2d 791, 811, 818 (N.D. Ohio 2004); Woods v. Gliatech Inc., 218 F. Supp. 2d 802, 810 (D. W. Va. 2002); RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 9 (1998) (recognizing misrepresentation claims); Dreier, *supra* note 19, at 264. This alternative would provide a more carefully tailored response to a compelling but entirely hypothetical set of facts imagined by the majority. *See Perez*, 734 A.2d at 1262 ("[W]e must consider as well a case in which a diabetic patient might have been influenced by advertising to request a drug from a physician without being warned by the manufacturer or the physician of the special dangers posed to a diabetic taking the drug. If an overburdened physician does not inquire whether the patient is a diabetic, the question remains whether the manufacturer should be relieved entirely of responsibility."). Of course, assuming that the manufacturer had supplied an adequate warning to the physician, a medical malpractice claim would do so as well. *Cf.* Ferrara v. Berlex Labs., Inc., 732 F. Supp. 552, 554–55 (E.D. Pa. 1990) (rejecting the plaintiff's argument that, given the dozens of dangerous interactions with MAO inhibitors, the manufacturer should have supplied patients with an information card); *id.* at 553 (noting that the plaintiff had secured a malpractice judgment against her physician for having missed this drug interaction warning).

[275] *See* FDA, Consumer–Directed Promotion of Regulated Medical Products; Public Hearing, 70 Fed. Reg. 54,054 (Sept. 13, 2005) (summarizing milestones in the agency's supervision of the practice); *see also* Lars Noah, *The FDA's New Policy on Guidelines: Having Your Cake and Eating It Too*, 47 CATH. U. L. REV. 113, 140–42 (1997) (criticizing the agency's practice of not taking definitive positions in guidance documents). At the time that the plaintiffs in *Perez* used Norplant, "[t]here [we]re no regulations that pertain specifically to consumer-directed promotional materials." FDA, Direct-to-Consumer Promotion; Public Hearing, 60 Fed. Reg. 42,581, 42,582 (Aug. 16, 1995). More than a decade has passed since the FDA announced plans to issue a notice of proposed rulemaking to address the issue. *See* Noah, *supra* note 210, at 153; *see also id.* at 146 & n.21 (explaining the procedural impediments to the issuance of advertising regulations). In 1999, the agency finalized its guideline governing broadcast advertising of prescription drugs. *See* FDA, Guidance for Industry on Consumer–Directed Broadcast Advertisements, 64 Fed. Reg. 43,197 (Aug. 9, 1999). Five years later, the FDA issued a draft guidance allowing advertisers to satisfy the brief summary requirement by using approved PPIs or highlights from package inserts in consumer-friendly language. *See* FDA, Draft Guidances for Industry on Improving Information About Medical Products and Health Conditions, 69 Fed. Reg. 6308 (Feb. 10, 2004); *see also id.* ("One of the principal objectives of the[se] three [draft] guidances is to encourage prescription drug firms to present risk information in their consumer-directed advertisements using language that is understandable by a lay user."); Francesca Lunzer Kritz, *FDA on Drug Ads: Less Is More*, WASH. POST, Feb. 10, 2004, at F1 (noting objections to the brief summary guidance). Congress recently granted the agency greater authority in this area, though only after the FDA issues binding rules. *See* Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110–85, § 901(d)(2), 121 Stat. 823, 939 (to be codified at 21 U.S.C. § 353b(a)) (authorizing advance review of broadcast DTCA); *see also id.* § 901(d)(6), 121 Stat. at 942 (to be codified at 21 U.S.C. § 352(n)) (eliminating formal rulemaking procedures applicable to drug advertising regulations).

[276] *See* Wash. Legal Found. v. Kessler, 880 F. Supp. 26, 34 (D.D.C. 1995) (anticipating that the FDA would "threaten[] (but never actually initiat[e]) enforcement procedures against companies which failed to comply with the agency's *de facto* policy" against the dissemination of information related to off-label uses, which it had announced in a "draft policy statement"); Noah, *supra* note 57, at 904–05; *see also* Thomas Ginsberg, *Drug Ads Pour in for Review: The FDA Said It Had Seen "A Huge Increase" in Advertising Submitted for Scrutiny Under a Voluntary Industry Program*, PHILA. INQUIRER, Feb. 23, 2006, at C1; Melody Petersen, *Who's Minding the Drugstore?*, N.Y. TIMES, June 29, 2003, § 3, at 1 (noting complaints that the agency has become less vigilant); Julie Schmit, *A Winded FDA Races to Keep up with Drug Ads That Go Too Far*, USA TODAY, May 31, 2005, at 1A (reporting that the agency has ordered more corrective advertising). *See generally*

Lastly, of course, only a handful of jurisdictions have recognized an FDA compliance defense.

If courts recognized an advertising exception to the learned intermediary rule (or abrogated it entirely), then pharmaceutical manufacturers would have to find a way of disseminating PPIs, ensure that these inserts contained references to all possible side effects in nontechnical language, and, in the unlikely event that they managed to design such an unassailable warning,[277] hope that a jury would not decide that continued advertising to consumers diluted the effectiveness of this warning. Even then, providing full risk information will offer only limited assistance to patients unless they receive equally clear information about all of the other products and procedures that might serve the same purpose: a manufacturer's duty to warn of risks associated with its product generally does not include such a broader duty to educate,[278] while physicians owe just such a duty when securing informed consent.[279] Precisely because of the difficult comparative judgments involved, patients must look to physicians for help in making treatment choices.

Extending a parallel suggested previously in connection with the design defect standard,[280] manufacturers of toys and other goods accessible to young children have a duty to warn their parents.[281] If

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Lars Noah, *Administrative Arm–Twisting in the Shadow of Congressional Delegations of Authority*, 1997 WIS. L. REV. 873.

[277] *See* Aaron D. Twerski, *Liability for Direct Advertising of Drugs to Consumers: An Idea Whose Time Has Not Come*, 33 HOFSTRA L. REV. 1149, 1153–54 (2005); *see also* Michael S. Jacobs, *Toward a Process–Based Approach to Failure-to-Warn Law*, 71 N.C. L. REV. 121, 149 (1992) ("By scrutinizing closely the seemingly trivial details of type size, warning location, and relative degree of expressed urgency, and by permitting outcomes to hinge on the presence or absence of one or two seemingly innocuous words, courts impose upon manufacturers a duty of virtual perfection, easily breached . . . .").

[278] *Cf.* Graham v. Am. Cyanamid Co., 350 F.3d 496, 514 (6th Cir. 2003) (rejecting claim that OPV manufacturer had a duty to inform physicians that IPV represented the preferred choice); Demmler v. SmithKline Beecham Corp., 671 A.2d 1151, 1154–55 (Pa. Super. Ct. 1996) (rejecting an inadequate warning claim for failure to specify the appropriate therapy in the event that a listed side effect occurred). For a recent proposal to impose such a broader duty, see *infra* note 302.

[279] *See* Lars Noah, *Informed Consent and the Elusive Dichotomy Between Standard and Experimental Therapy*, 28 AM. J.L. & MED. 361, 366–67 & n.25 (2002); *see also* Gerald F. Tietz, *Informed Consent in the Prescription Drug Context: The Special Case*, 61 WASH. L. REV. 367, 406–17 (1986) (urging stricter application of the informed consent duty with respect to prescribing).

[280] *See supra* notes 37–41, 194 and accompanying text; *see also* Marvin M. Lipman, *Bias in Direct-to-Consumer Advertising and Its Effect on Drug Safety*, 35 HOFSTRA L. REV. 761, 762 (2006) ("The only other commercials of this kind are the breakfast-cereal [ads that air during children's cartoon shows] . . . . In both instances, an intermediary is necessary—in one case a parent who has the money and, in the other case, a physician who has the prescription pad."); Michael Kirsch, *Even If They're Too Slick and Manipulative, Drug Ads Are Useful*, PLAIN DEALER, Sept. 8, 2000, at 11B ("This is analogous to marketing toys and breakfast cereals to children. Though our youngsters can't buy them, they have learned how to close the sale. In a similar manner, patients now ask their doctors to sign on to their wonder-drug requests."); *cf.* Francesca Lunzer Kritz, *What Teens Are Hearing About Drugs: Some Messages Help, Others Are Troubling*, WASH. POST, Sept. 9, 2008, at F1 (reporting that some DTCA campaigns target adolescents).

[281] *See, e.g.*, Metzgar v. Playskool Inc., 30 F.3d 459, 465–66 (3d Cir. 1994); *see also* Hahn v. Sterling Drug, Inc., 805 F.2d 1480 (11th Cir. 1986); Emery v. Federated Foods, Inc., 863 P.2d 426 (Mont. 1993); M. Stuart Madden, *Products Liability, Products for Use by Adults, and*

manufacturers choose to advertise directly to youngsters, and the kids then whine until their parents purchase inappropriate products, the manufacturers still would owe no duty to warn the kids directly (though, if overpromotion dilutes the force of information already supplied to adult purchasers, then it might well provide the basis for an inadequate warning claim). Although such promotional efforts may deserve criticism (and efforts at prohibition),[282] presumably no one would argue that recognizing a largely incoherent duty to warn children directly offered a second-best solution to the problem.

By definition, adequate consumer labeling cannot be designed for prescription drugs.[283] Although the FDA increasingly switches Rx drugs to OTC status,[284] products that continue to require prescription labeling reflect the agency's judgment that professional intervention remains necessary to ensure their safe use.[285] The FDA has in the past mandated PPIs for some drugs to supplement the labeling provided to physicians, and it continues to encourage their broad use, but no one suggests that PPIs should fully replace professional labeling. Direct advertising further encourages active participation by consumers in prescribing decisions, a favorable development that courts should not reward by expanding the tort duties of drug manufacturers and, because consumer-directed warnings inevitably would fall short, discouraging such advertising in the future.[286]

As the United States Supreme Court has observed repeatedly in deciding commercial speech cases, some information is better than

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Injured Children: Back to the Future, 61 TENN. L. REV. 1205, 1214 (1994) ("[A]n adult product with which children may have contact must contain warnings and instructions advising adults on the special risks to children that the product may create.").

[282] *See* Stephanie Clifford, *Tug of War in Food Marketing to Children*, N.Y. TIMES, July 30, 2008, at C5; David Crary, *Blitzed with Toy Ads, Cash-strapped Parents Push Back*, TRENTON TIMES (N.J.), Nov. 30, 2008, at B4 (describing the Campaign for a Commercial-Free Childhood); *see also* Comm. on Children's Television, Inc. v. Gen. Foods Corp., 673 P.2d 660, 676 (Cal. 1983) ("Defendants engaged in a nationwide, long-term advertising campaign designed to persuade children to influence their parents to buy sugared cereals."); Juliet B. Schor & Margaret Ford, *From Tastes Great to Cool: Children's Food Marketing and the Rise of the Symbolic*, 35 J.L. MED. & ETHICS 10 (2007); Symposium, *Food Marketing to Children and the Law*, 39 LOY. L.A. L. REV. 1 (2006).

[283] *See* Dunkin v. Syntex Labs., Inc., 443 F. Supp. 121, 123 (W.D. Tenn. 1977) ("[P]rescription drugs are sold on a prescription basis and not over-the-counter because the special expertise of a trained physician is necessary for their safe use. Thus, an effective warning could go only to the medical profession, and not to an untrained patient."); Peter Temin, *The Origin of Compulsory Drug Prescriptions*, 22 J.L. & ECON. 91, 103 (1979) ("[T]he FDA assumed that adequate directions for laymen could not be written for some drugs."); *see also supra* note 225.

[284] *See* Noah, *supra* note 200, at 360, 362–63, 371.

[285] A number of reasons may exist for prescription labeling, such as the difficulty with self-diagnosis, a product's margin of safety, and the extent to which dosages need to be carefully titrated for each patient. *See id.* at 366–68, 375.

[286] *See* Walsh et al., *supra* note 211, at 881 ("Ironically, preservation of this brightline [learned intermediary] rule would help create the conditions necessary for improved communications between pharmaceutical manufacturers and patients.").

none.[287] Drug advertising naturally emphasizes the benefits of a product, but even this may provide valuable information in the prescription drug context if consumers otherwise would leave bothersome conditions untreated. To the extent that advertising fails to highlight harmful attributes of prescription drugs, the FDA can modify its fair balance requirements. The ultimate safeguard, however, must be the physician. So long as prescription drugs continue to require the intervention of a medical professional, courts should focus on the duty of physicians to secure informed consent, while letting regulatory requirements work to supplement rather than supplant the drug information provided to patients.[288]

IV. MISCELLANEOUS ISSUES

This Part offers a glimpse at various other issues related to the design and informational defect standards that the *Products Liability Restatement* has announced for prescription drug manufacturers. First, experimental products do not receive distinctive treatment under section 6, and the new *Restatement* offered only ambiguous guidance about continuing duties to test after approval. Second, generic versions of prescription drugs raise curious questions as to which manufacturer should shoulder responsibility for injuries to patients. Third, prescription medical devices get identical treatment under section 6 notwithstanding fundamental differences from pharmaceuticals, while human tissue products get carved out entirely notwithstanding their similarities to implanted devices. Finally, questions arise about including other parties in the chain of distribution for purposes of imposing liability. Just as the purportedly bright line between prescription and nonprescription has become increasingly blurred,[289] the sharp distinction between manufacturers and health care providers imagined by the Reporters may break down over time.

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[287] *See, e.g.*, Thompson v. W. States Med. Ctr., 535 U.S. 357, 374 (2002) ("We have previously rejected the notion that the government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information."); *see also* Bolger v. Youngs Drug Prods. Corp., 463 U.S. 60, 69 (1983) (holding that a federal law prohibiting unsolicited mailings was unconstitutional when applied to a pharmaceutical company distributing informational pamphlets that encouraged the use of contraceptives); Lars Noah, *What's Wrong with "Constitutionalizing Food and Drug Law"?*, 75 TUL. L. REV. 137, 143–44 & n.40 (2000); David C. Vladeck, *The Difficult Case of Direct-to-Consumer Drug Advertising*, 41 LOY. L.A. L. REV. 259 (2007).

[288] *See* Walsh et al., *supra* note 211, at 880 ("[T]ruthful direct-to-consumer advertising will provide the consumer with useful information without eroding the paramount role of the prescribing physician. In any event, there is little evidence that direct-to-consumer advertising has harmed consumers or foisted medically inappropriate therapies upon them."); Catherine A. Paytash, Note, *The Learned Intermediary Doctrine and Patient Package Inserts: A Balanced Approach to Preventing Drug–Related Injury*, 51 STAN. L. REV. 1343, 1367–71 (1999) (urging an administrative solution, in particular FDA-mandated PPIs, rather than any judicial modifications of the learned intermediary rule).

[289] *See supra* notes 198–201 and accompanying text.

A. Experimental Drugs and the Duty to Keep Testing

The *Products Liability Restatement* does not separately address investigational products, even though these appeared to be a central concern in the *Second Restatement*'s comment k to section 402A.[290] Clinical trials of unapproved new drugs occasionally cause serious injury to subjects,[291] but only a few courts have resolved claims for injuries caused by drugs not yet approved by the FDA.[292] The last decade has witnessed growing tort litigation on behalf of subjects injured during clinical trials,[293] though claims against the suppliers of investigational products remain fairly uncommon.[294] Insofar as section 6 turns on differential access rather than deference to FDA approval decisions, it should encompass investigational products accessible only to subjects enrolled in trials and under the strict supervision of clinical investigators, even though the research aims to answer the very questions that lay at the

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[290] *See* RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965) ("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."); Adams v. G.D. Searle & Co., 576 So. 2d 728, 732 (Fla. Dist. Ct. App. 1991) ("Comment k was designed in part to protect new and experimental drugs."). During a floor debate, the Reporter apparently had focused exclusively on experimental drugs. *See* 41 A.L.I. PROC. 359–60 (1964) (remarks by Dean Prosser); *cf.* Joseph A. Page, *Generic Product Risks: The Case Against Comment k and for Strict Tort Liability*, 58 N.Y.U. L. REV. 853, 865–71 (1983) (identifying numerous ambiguities in these references to "experimental" drugs).

[291] *See, e.g.*, Elisabeth Rosenthal, *British Rethinking Test Rules After Drug Trial Nearly Kills Six*, N.Y. TIMES, Apr. 8, 2006, at A1 ("Although tests of [the monoclonal antibody] TGN1412 in monkeys showed no significant trouble, all six human subjects nearly died."); John Schwartz & David Brown, *A Deadly Medical Gamble: Test of Promising Drug Turns into "Calamity,"* WASH. POST, July 8, 1993, at A1; Dan Vergano, *Drug–Trial Deaths "Go Unreported,"* USA TODAY, Nov. 8, 2000, at 12D. Although manufacturers of investigational drugs might try to insulate themselves with liability waivers, the FDA prohibits their use. *See* 21 C.F.R. § 50.20 (2008). Separately, the *Products Liability Restatement* generally rejects such waivers. *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 18 (1998).

[292] *See, e.g.*, Kernke v. Menninger Clinic, Inc., 173 F. Supp. 2d 1117, 1121–22, 1124 (D. Kan. 2001) (applying the learned intermediary doctrine in granting summary judgment to the manufacturer of an investigational drug for schizophrenia); Mink v. Univ. of Chicago, 460 F. Supp. 713, 717–18 (N.D. Ill. 1978) (involving early clinical trials of DES, and including claims against the manufacturer); Gaston v. Hunter, 588 P.2d 326, 339–40 (Ariz. Ct. App. 1978) (extending comment k protection to an investigational drug, but requiring clear disclosure of its experimental status).

[293] *See* Sharona Hoffman & Jessica Wilen Berg, *The Suitability of IRB Liability*, 67 U. PITT. L. REV. 365 (2005); E. Haavi Morreim, *Litigation in Clinical Research: Malpractice Doctrines Versus Research Realities*, 32 J.L. MED. & ETHICS 474 (2004); Richard S. Saver, *Medical Research and Intangible Harm*, 74 U. CIN. L. REV. 941 (2006); Roger L. Jansson, Comment, *Researcher Liability for Negligence in Human Subject Research: Informed Consent and Researcher Malpractice Actions*, 78 WASH. L. REV. 229 (2003); Alice Dembner, *Lawsuits Target Medical Research*, BOSTON GLOBE, Aug. 12, 2002, at A1.

[294] Claims against sponsors of products subject to the FDA's investigational device exemption (IDE) have arisen with somewhat greater frequency. *See, e.g.*, Chambers v. Osteonics Corp., 109 F.3d 1243 (7th Cir. 1997) (finding such claims preempted); Martin v. Telectronics Pacing Sys., Inc., 105 F.3d 1090, 1098–101 (6th Cir. 1997) (same); Oja v. Howmedica, Inc., 111 F.3d 782 (10th Cir. 1997) (rejecting preemption defense); Guckin v. Nagle, 259 F. Supp. 2d 406 (E.D. Pa. 2003) (rejecting a manufacturer's effort to remove on the basis of federal question jurisdiction tort claims filed against multiple parties in state court by a subject injured during a clinical trial of an investigational device).

heart of design and informational defect claims (indeed, though subjects may hope to derive some therapeutic benefit from their participation, clinical trials aim primarily to generate scientific information rather than deliver medical treatment).[295]

FDA approval does not entirely remove the experimental aspect of new drugs,[296] and the agency demands that manufacturers conduct postmarket surveillance. The nature and extent of common law duties to engage in postapproval research have, however, received scant attention. Whether resolving a design or informational defect claim, courts may struggle to determine precisely when a seller should have known that its product presented a risk of injury.[297] Pharmaceutical manufacturers generally have no duty to guard against or warn of unknowable risks.[298]

According to the *Products Liability Restatement*, pharmaceutical "manufacturers have the responsibility to perform reasonable testing

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[295] *See* Noah, *supra* note 279, at 371 & n.50, 378–79, 384, 388; *id*. at 385 & nn.126–27 (discussing the "therapeutic misconception" in research). Patients not enrolled in clinical trials continue to press for access to investigational drugs. *See* Jerry Menikoff, *Beyond* Abigail Alliance*: The Reality Behind the Right to Get Experimental Drugs*, 56 U. KAN. L. REV. 1045 (2008); Judy Vale, Note, *Expanding Expanded Access: How the Food and Drug Administration Can Achieve Better Access to Experimental Drugs for Seriously Ill Patients*, 96 GEO. L.J. 2143 (2008); *see also* Gina Kolata & Kurt Eichenwald, *For the Uninsured, Drug Trials Are Health Care*, N.Y. TIMES, June 22, 1999, at A1; *supra* note 63 (discussing claims by subjects seeking continued access).

[296] *See* Noah, *supra* note 279, at 363 ("[P]roduct approval does not define the point at which an investigational intervention passes the threshold into standard therapy. Instead, the research phase continues after licensure, both in the sense that more safety data accumulates and insofar as physicians may improvise when using a product in ways not originally contemplated."); *id.* at 394 ("One common misconception is that FDA approval of a medical technology represents the point at which it crosses the line from experimental to standard therapy."); *id.* at 394–99 (elaborating); *see also id*. at 386–94 & nn.134&141 (discussing the indistinct line between treatment and research); *id*. at 400–08 (same). *See generally* Bernadette Tansey, *What FDA Approval Means: Agency Weighs Benefits, Risks Before Drugs Get to Market*, S.F. CHRON., Mar. 3, 2005, at C1.

[297] Imagine that a drug company receives a single report from a physician of an unexpected adverse drug event (ADE) in a patient. If the suspected ADE turns out to be spurious, subsequent patients will not suffer that injury or, if they do and attempt to file a lawsuit, patients will lose on causation at trial; if, however, the drug turns out to have caused the injury, plaintiffs often will have stronger evidence of causation by the time of trial even though the far less certain ADE might have served as the trigger for a duty to warn at the earlier time of sale. One would expect courts to require greater substantiation of risks before allowing a design defect (as opposed to a failure-to-warn) claim to proceed. Technologically sophisticated products subject to lengthy premarket review by administrative agencies pose tricky "state-of-the-art" questions. If risk information comes to light late in the agency's review, sellers generally still can make labeling modifications before sale, but designs become fixed earlier in the R&D process.

[298] *See* Toner v. Lederle Labs., 732 P.2d 297, 306–07 (Idaho 1987) ("Comment k does not require sellers to be clairvoyant."); Moore v. Vanderloo, 386 N.W.2d 108, 116 (Iowa 1986); Castrignano v. E.R. Squibb & Sons, Inc., 546 A.2d 775, 782 (R.I. 1988) (refusing to hold manufacturer of DES liable "for failure to warn of risks inherent in a drug [because] it neither knew nor could have known by the application of scientific knowledge available at the time of distribution that the drug could produce the undesirable effects suffered by plaintiff"); *see also* Kathleen H. Wilson, Note, *The Liability of Pharmaceutical Manufacturers for Unforeseen Adverse Drug Reactions*, 48 FORDHAM L. REV. 735, 745–50 (1980). A pair of jurisdictions impute knowledge to drug manufacturers, thereby shifting the burden of proof on this issue to the defendant. *See* Shanks v. Upjohn Co., 835 P.2d 1189, 1199–200 (Alaska 1992); Feldman v. Lederle Labs., 479 A.2d 374, 387–88 (N.J. 1984); *cf.* Carlin v. Superior Court, 920 P.2d 1347, 1349 (Cal. 1996) ("[W]e have expressly and repeatedly applied a strict liability standard to manufacturers of prescription drugs for failure to warn of known or reasonably scientifically knowable risks.").

prior to marketing a product and to discover risks and risk-avoidance measures that such testing would reveal."[299] Although a few courts resolving products liability claims against sellers of medical technologies have made a similar point,[300] the case law offers essentially no guidance about the contours of a duty to test.[301] One recent article urged the recognition of an expanded obligation to do so but suffered from similar ambiguities about the scope of such a duty.[302]

Drug-drug interactions provide an illustration of the potential difficulties in defining a broader duty to test. Obviously, if a manufacturer discovers a dangerous interaction during clinical trials or postmarket surveillance, then it would have a duty to communicate

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[299] RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. g (1998); *see also id.* § 2 cmt. m ("The harms that result from unforeseeable risks—for example, in the human body's reaction to a new drug, medical device, or chemical—are not a basis of liability. Of course, a seller . . . is charged with knowledge of what reasonable testing would reveal."); *id.* § 10 cmt. c ("With regard to . . . prescription drugs and devices, courts traditionally impose a continuing duty of reasonable care to test and monitor after sale to discover product-related risks.").

[300] *See, e.g.*, Kociemba v. G.D. Searle & Co., 707 F. Supp. 1517, 1528–29 (D. Minn. 1989) ("[T]he duty to test is a subpart of the duty to warn."); Bichler v. Eli Lilly & Co., 436 N.E.2d 182, 188–90 (N.Y. 1982) (allowing plaintiff's claim that a DES manufacturer could have discovered reproductive toxicity if it had undertaken rodent testing); Collins v. Eli Lilly Co., 342 N.W.2d 37, 52 (Wis. 1984) (same, focusing on postapproval period).

[301] *See* Daniel R. Cahoy, *Medical Product Information Incentives and the Transparency Paradox*, 82 IND. L.J. 623, 640–41 & nn.78–81 (2007) (discussing the limited recognition of a common law duty to test); Merrill, *supra* note 3, at 38 (discussing some of the earliest case law on this question); *see also* Valentine v. Baxter Healthcare Corp., 81 Cal. Rptr. 2d 252, 265 (Ct. App. 1999) (concluding that "imposition of liability for breach of an independent duty to conduct long-term testing, where the causal link to the known harm to plaintiff is the unknown outcome of testing that was not done, would be beyond the pale of any California tort doctrine we can identify" (emphasis omitted)).

[302] *See* George W. Conk, *Punctuated Equilibrium: Why § 402A Flourished and the* Third Restatement *Languished*, 26 REV. LITIG. 799, 856–62, 878–80 (2007); *id.* at 805–06 ("This patient-centered approach emphasizes the ongoing experimental quality of medical products, and a corresponding duty of product stewardship—a duty of ongoing study and product development, a duty of systematic manufacturer surveillance of the actual use of their products after obtaining regulatory approval to market the product."); *see also id.* at 879–80; *id.* at 856 & n.142 (suggesting incorrectly that section 6 relates only to FDA-approved uses); *id.* at 857 (suggesting incorrectly that the *Products Liability Restatement* deals with postapproval risks under the forgiving standard for post-sale warnings). Separately, Conk called on sellers to satisfy a broader duty to educate patients, *see id.* at 872–74, 877–78, which would mean laying out the pros and cons not just of their product but also competing products (and non-product substitutes). He noted that, contrary to recent pronouncements by the FDA, manufacturers may act unilaterally to revise approved labeling in order to communicate new risk information, *see id.* at 863–64 & n.171, but the agency certainly would never tolerate any of the other additional items that he would want to see included. Another proposal designed to encourage continued testing would recognize a broader duty to disclose (though only to physicians) uncertain risks, for instance when manufacturers have failed to investigate the teratogenic potential of drugs, coupled with awards of limited damages not dependent on proving that the drug actually caused a particular injury. *See* Berger & Twerski, *Informed Choice*, *supra* note 118, at 259, 287–88; *see also* Susanne L. Flanders, Note, *A Tough Pill to Swallow: The Insurmountable Burden in Toxic Tort Claims Against Manufacturers of Children's Medications*, 16 J.L. & POL'Y 305, 308, 315–18, 338–41, 348–55 (2007) (focusing on (primarily OTC) drugs marketed for use in children, but making broader claims that would include a duty to engage in pediatric testing of prescription drugs marketed solely for use by adults). For my detailed critique of these various proposals, see Lars Noah, *Platitudes About "Product Stewardship" in Torts: Continuing Drug Research and Education*, 15 MICH. TELECOM. & TECH. L. REV. (forthcoming 2009).

information about the risk.[303] What if, however, a patient experiences a previously unknown acute drug interaction and argues that the manufacturer should have tested for it?[304] A strict liability standard that focused on the knowability of this risk seemingly would ask only whether a manufacturer could have checked for the interaction, while a negligence standard would recognize the impracticality of advance testing for every conceivable drug-drug interaction.[305]

Package inserts serve, first and foremost, to define for health care professionals the range of uses and users that have undergone rigorous study and FDA review. Assuming that labeling accurately communicates what the seller knows (and does not know) about the safety and efficacy of the prescription product in different user populations, why impose liability when an unexpected injury occurs in a subpopulation not studied (and, therefore, not an indicated use)?[306] A duty to investigate all foreseeable uses to which health care professionals might put an approved drug would be entirely unmanageable, and it would threaten to deprive intended users of a valuable product.

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[303] *See, e.g.*, Garside v. Osco Drug, Inc., 976 F.2d 77, 81–82 (1st Cir. 1992) (allowing failure-to-warn claim against manufacturer of phenobarbital to proceed where drug allegedly interacted with amoxicillin and caused toxic epidermal necrolysis); Ferrara v. Berlex Labs., Inc., 732 F. Supp. 552, 553–55 (E.D. Pa. 1990) (rejecting failure-to-warn claim against manufacturer of MAO inhibitor because it had warned physicians of dangerous interactions with over forty substances, including a decongestant that the plaintiff's physician had prescribed).

[304] *See* Bryant v. Hoffman–La Roche, Inc., 585 S.E.2d 723, 728–30 (Ga. Ct. App. 2003) (allowing such a claim to proceed based on testimony from the plaintiffs' expert witnesses); *see also* Carl C. Peck et al., Editorial, *Understanding Consequences of Concurrent Therapies*, 269 JAMA 1550 (1993); D.I. Quinn & R.O. Day, *Drug Interactions of Clinical Importance*, 12 DRUG SAFETY 393 (1995) (cataloging known interactions); Langreth, *supra* note 34, at B16 (discussing the discovery of several additional serious interactions shortly after approval of Posicor that led to its withdrawal).

[305] *See* Richard McCormick, *Pharmaceutical Manufacturer's Duty to Warn of Adverse Drug Interactions*, 66 DEF. COUNS. J. 59, 67 (1999) (arguing that application of a strict liability standard in this context would threaten to impose limitless liability); *id.* at 68 ("If every concurrent use is foreseeable, then manufacturers would be obligated to test for these interactions, increasing the time beneficial drugs would take to go to market and pushing prices beyond the reach of most consumers."); *see also id.* at 65 ("[F]ew cases directly consider the manufacturer's failure to warn of an interaction that it should have discovered prior to marketing."); *cf.* Ceci Connolly, *Price Tag for a New Drug: $802 Million: Findings of Tufts University Study Are Disputed by Several Watchdog Groups*, WASH. POST, Dec. 1, 2001, at A10 (reporting that the figure had more than tripled in the space of a decade, largely because of demands for larger and more complex clinical trials).

[306] *See* Robak v. Abbott Labs., 797 F. Supp. 475, 476 (D. Md. 1992) ("Certainly, no manufacturer need explicitly spell out all of the conditions for which a drug is *not* indicated."). Obviously, if a seller knows of widespread off-label pediatric use, it cannot fail to disclose known risks in that foreseeable though unintended user population; similarly, if a seller knows of widespread off-label use for a different condition (or through a different method of administration), then it may have to disclose known risks. *See* Lars Noah, *Constraints on the Off–Label Uses of Prescription Drug Products*, 16 J. PROD. & TOXICS LIAB. 139, 159–62 (1994); Kaspar J. Stoffelmayr, Comment, *Products Liability and "Off–Label" Uses of Prescription Drugs*, 63 U. CHI. L. REV. 275, 299–305 (1996). But why suggest that the seller must comprehensively study safety and efficacy in every conceivable but unintended use or user? *Cf.* Medics Pharm. Corp. v. Newman, 378 S.E.2d 487, 488–89 (Ga. Ct. App. 1989) (recognizing a duty to test the safety of off-label uses).

B. Generic Drugs

Generic drug manufacturers might find themselves in a weaker litigating position than their brand-name brethren. For instance, in trying to mount a defense against design defect claims, they may face an evidentiary disadvantage because of their lack of access to the clinical trials underlying the NDA for the innovator product,[307] unless courts decided to apply a more forgiving standard of knowability to manufacturers of generic drugs.[308] In addition, if section 6(c) does not take cost into account,[309] then generic drug manufacturers routinely might face a design defect claim after the innovator introduces a new and slightly improved (and more expensive) version of the original.

Sellers of generic drugs may encounter peculiar problems when it comes to off-label uses: if an innovator company receives FDA approval for a new indication, then it may receive three years of additional market exclusivity for that use—this would not prevent the prescribing of the generic version for that new use,[310] but the labeling for the generic drug will not include any information (including, in all likelihood, risk information) associated with that new use. In the event

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[307] *See* Eisenberg, *supra* note 190, at 736–38 (discussing the applicable trade secrecy protections). If the alleged design defect related to the use of a different dosage form or an inactive ingredient not found in the brand-name product, then the supplier of the slightly altered generic version would have generated the necessary bioequivalence data. *See* Novartis Pharms. Corp. v. Leavitt, 435 F.3d 344 (D.C. Cir. 2006); Zeneca, Inc. v. Shalala, 213 F.3d 161 (4th Cir. 2000); *see also* Aaron S. Kesselheim et al., *Clinical Equivalence of Generic and Brand-Name Drugs Used in Cardiovascular Disease: A Systematic Review and Meta-analysis*, 300 JAMA 2514 (2008); Thomas M. Burton, *Doctors Raise Warnings About a Form of Clozapine*, WALL ST. J., Oct. 24, 2000, at B1 (describing clinical data suggesting that the generic drug's absorption rate and efficacy differed from that of the innovator); Melissa Healy, *FDA Standards Are Questioned*, L.A. TIMES, Mar. 17, 2008, at F7. In addition, generic drug manufacturers would have to abide by any risk labeling changes that the FDA mandates for the brand-name version, *see* Julie Schmit, *Updating Generic–Drug Labels Can Take Months*, USA TODAY, Apr. 21, 2005, at 3B, and any failure to do so would support a defectiveness per se claim.

[308] Courts have not done so. *See* Foster v. Am. Home Prods. Corp., 29 F.3d 165, 169–70 (4th Cir. 1994) (dictum); *id.* at 169 ("When a generic manufacturer adopts a name brand manufacturer's warnings and representations without independent investigation, it does so at the risk that such warnings and representations may be flawed."); Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 543–44 (E.D. Pa. 2006) (dictum), *aff'd*, 521 F.3d 253 (3d Cir. 2008); *id.* at 544 ("While it is true that the ANDA process requires generic manufacturers to use the same labeling as the previously approved innovator drug, we cannot agree that this absolves them of liability for the representations made on their own drugs."); Bell v. Lollar, 791 N.E.2d 849, 855 (Ind. Ct. App. 2003) ("We see no reason to provide greater protection against state law failure to warn claims to generic drugs than to pioneer drugs. . . . Purepac was free to strengthen its label [for a generic version of the Rx drug Tylenol 3] by adding an alcohol warning."). *See generally* FDA, Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950, 17,955, 17,961 (Apr. 28, 1992).

[309] *See supra* notes 86–89 and accompanying text.

[310] *See* Sigma–Tau Pharms., Inc. v. Schwetz, 288 F.3d 141, 145–48 (4th Cir. 2002) (holding that the approval of a second indication (protected by a separate exclusivity period) did not prevent the FDA from approving generic versions for only the original (and no longer protected) indication notwithstanding the likelihood of off-label prescribing of the generic drugs for the new indication); Eisenberg, *supra* note 190, at 724, 729–30; *see also* Bristol–Myers Squibb Co. v. Shalala, 91 F.3d 1493, 1500 (D.C. Cir. 1996) (sustaining the FDA's authority to approve a generic drug for only a subset of the innovator drug's labeled indications).

that a patient suffers an injury while using the generic version (which completely failed to mention risks associated with the new indication approved only for the brand-name version), would a court have any way of finessing this problem? If a physician prescribed the generic version for the new indication after consulting the labeling of the innovator drug, would that insulate the generic manufacturer from a failure-to-warn claim (and might it open the brand-name manufacturer to an inadequate warning claim in the event of any alleged shortcomings in the risk information)?

Even without such differences in labeling, patients who suffer injuries while taking a generic drug sometimes pursue claims against the manufacturer of the innovator product, but courts generally have rejected such efforts to find deeper pockets.[311] Even so, to the extent that physicians and patients may rely on representations made by brand-name manufacturers (after all, generic manufacturers generally do little to promote their versions of well-known prescription drugs), use of the generic version would not alter the fact that inadequate warnings accompanying the brand-name drug caused the injury. Indeed, the physician may have prescribed the brand-name product (based on information supplied by the manufacturer of that product), only to have the pharmacist dispense a generic version manufactured by an entirely different company.[312]

In rare cases, some courts have allowed victims to sue both brand-name and generic manufacturers when unable to identify the particular source of a drug. Under this "market share" theory, which courts have used almost exclusively in the DES litigation, the imposition of liability sometimes sought to approximate the aggregate risk created

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[311] *See, e.g.*, *Colacicco*, 432 F. Supp. 2d at 519–20 & n.2, 538–43 (dictum); Flynn v. Am. Home Prods. Corp., 627 N.W.2d 342, 350 (Minn. Ct. App. 2001); *see also* Doe 2 v. Ortho–Clinical Diagnostics, Inc., 335 F. Supp. 2d 614, 626–28 (M.D.N.C. 2004) (holding that the company that originally discovered and patented the mercury-based preservative thimerosal, which later was copied by other manufacturers and used in their vaccines and other drug products, owed no duty to warn users); *cf.* Piscitello v. Hobart Corp., 799 F. Supp. 224, 226 (D. Mass. 1992) ("It would be unfair to impose such an expansive view of tort liability on those whose original [meat grinder] design is mimicked without the designer's permission."). Occasionally, the innovator company supplies bulk quantities of drug product to a generic company for labeling, *see* Teva Pharm. Indus. Ltd. v. Crawford, 410 F.3d 51 (D.C. Cir. 2005), which would simplify the tort issues.

[312] *See* Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299, 309–17 (Ct. App. 2008) (allowing misrepresentation but not products liability claims against the brand-name manufacturer in such a case); *id.* at 320–21 ("We hold that Wyeth's common-law duty to use due care in formulating its product warnings extends to patients whose doctors foreseeably rely on its product information when prescribing metoclopramide, whether the prescription is written for and/or filled with Reglan or its generic equivalent."); *id.* at 318–19 (rejecting failure-to-warn claims against the manufacturers of the generic products that injured the plaintiff because her physician had not read or relied upon their labeling!); *cf.* Miles Labs., Inc. v. Superior Court, 184 Cal. Rptr. 98, 101–03 (Ct. App. 1982) (allowing a claim for failure to warn of risks of use during pregnancy against the manufacturer of a DES product labeled solely for use in male (prostate cancer) patients because it might have been dispensed in place of other DES products labeled for the prevention of miscarriages). *But see Foster*, 29 F.3d at 167–68, 170–72 (rejecting negligent misrepresentation claims against the manufacturer of the brand-name version of promethazine when a pharmacist had substituted a generic version); Goldych v. Eli Lilly & Co., 2006 WL 2038436, at *1, *6 (N.D.N.Y. July 19, 2006).

by the different suppliers,[313] with one jurisdiction going so far as to prevent exculpation by suppliers that clearly could not have caused a particular plaintiff's harm.[314] An extension of such risk-contribution notions even in cases where patients can identify the source of the drug as a generic manufacturer might justify imposing some tort liability on the manufacturer of the brand-name version (for causing the injury through a design defect or failure to warn, even if they did not supply the particular dosage unit that ultimately harmed the plaintiff).[315]

C. Medical Devices

Although comment k to section 402A of the *Second Restatement* mentioned only prescription drugs and vaccines, several courts have applied it to comparable medical devices.[316] Courts also have applied the learned intermediary rule to such devices,[317] and it makes even more

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[313] *See, e.g.*, Sindell v. Abbott Labs., 607 P.2d 924 (Cal. 1980); Conley v. Boyle Drug Co., 570 So. 2d 275 (Fla. 1990); Martin v. Abbott Labs., 689 P.2d 368 (Wash.1984); *see also* Allen Rostron, *Beyond Market Share Liability: A Theory of Proportional Share Liability for Nonfungible Products*, 52 UCLA L. REV. 151 (2004); Aaron D. Twerski, *Market Share—A Tale of Two Centuries*, 55 BROOK. L. REV. 869 (1989); Andrew B. Nace, Note, *Market Share Liability: A Current Assessment of a Decade–Old Doctrine*, 44 VAND. L. REV. 395 (1991); *cf.* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 15 cmt. c (1998) ("The Institute leaves to developing law the question of whether, given the appropriate factors, a rule of proportional liability should be adopted. However, if a court does adopt some form of proportional liability, the liability of each defendant is properly limited to the individual defendant's share of the market."); RESTATEMENT (THIRD) OF TORTS: APPORTIONMENT OF LIABILITY § 26 cmt. n (2000).

[314] *See* Hymowitz v. Eli Lilly & Co., 539 N.E.2d 1069 (N.Y. 1989); *In re* New York County DES Litig., 615 N.Y.S.2d 882, 885 (App. Div. 1994); *see also* Christopher J. McGuire, Note, *Market–Share Liability After* Hymowitz *and* Conley*: Exploring the Limits of Judicial Power*, 24 U. MICH. J.L. REFORM 759 (1991). Other jurisdictions allow exculpation. *See, e.g.*, Collins v. Eli Lilly Co., 342 N.W.2d 37, 52 (Wis. 1984). Nonetheless, they may allocate relatively greater shares of responsibility to those companies more actively involved in preclinical testing, securing original FDA approval, and marketing the product. *See id.* at 53–54; *see also id.* at 50 n.11 (rejecting the argument that market share liability would discourage the introduction of cheaper generic drugs).

[315] *Cf. supra* note 190 (explaining that drug manufacturers produce and distribute information as much as they sell products). Courts occasionally have indicated a willingness to entertain liability claims against entities that supply inaccurate information about therapeutic products even though they played no role in their production or distribution. *See* Coleman v. Danek Med., Inc., 43 F. Supp. 2d 629 (S.D. Miss. 1998) (allowing fraud claims against medical societies for sponsoring seminars at which allegedly unsafe uses of pedicle screws in spinal fusion were discussed); *In re* Factor VIII or IX Concentrate Blood Prods. Litig., 25 F. Supp. 2d 837 (N.D. Ill. 1998) (rejecting First Amendment defense raised by the National Hemophilia Foundation); *see also* Noah, *supra* note 26, at 464–65.

[316] *See* Transue v. Aesthetech Corp., 341 F.3d 911, 915–17 (9th Cir. 2003); Adams v. Synthes Spine Co., 298 F.3d 1114, 1117–19 (9th Cir. 2002); Parkinson v. Guidant Corp., 315 F. Supp. 2d 741, 747 (W.D. Pa. 2004); Harwell v. Am. Med. Sys., Inc., 803 F. Supp. 1287, 1300 (M.D. Tenn. 1992); Tansy v. Dacomed Corp., 890 P.2d 881, 885 (Okla. 1994) ("Most courts which have considered the question have found that Comment k applies to medical devices, especially those which are implanted in the human body.").

[317] *See, e.g.*, Toole v. Baxter Healthcare Corp., 235 F.3d 1307, 1313–14 (11th Cir. 2000); Talley v. Danek Med., Inc., 179 F.3d 154, 162–63 (4th Cir. 1999); Sita v. Danek Med., Inc., 43 F. Supp. 2d 245, 259 (E.D.N.Y. 1999); McCombs v. Synthes (U.S.A.), 587 S.E.2d 594, 595 (Ga. 2003); Bean v. Baxter Healthcare Corp., 965 S.W.2d 656, 663 (Tex. Ct. App. 1998); *see also* Lloyd C. Chatfield, II, Note, *Medical Implant Litigation and Failure to Warn: A New Extension for the Learned Intermediary Rule?*, 82 KY. L.J. 575 (1993–1994).

sense to do so in connection with the sale of sophisticated equipment used in the course of treating patients.[318] Consistent with this pattern, section 6 of the *Products Liability Restatement* drew no distinction between prescription drugs and medical devices.

1. Are Device Designs Different?

For a variety of reasons, design defect claims involving medical devices do not pose nearly the same difficulties that arise with prescription pharmaceuticals. Although the Reporters explained emphatically (and persuasively) that "drug designs *are* different," they have not offered a similarly detailed defense of their decision to apply the special design defect standard to medical devices.[319] Moreover, while other commentators have offered a range of both criticism and praise of section 6(c) with reference to the treatment of pharmaceutical products, it seems that not one of them has endorsed its extension to prescription devices.[320] Instead, the contours of express federal preemption as a defense to tort claims against medical device manufacturers, which has evolved fitfully and attracted its share of criticism,[321] may better define those contexts where courts should decline to engage in duplicative design defect review—namely, those devices that have undergone full

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[318] *See, e.g.*, Kirsch v. Picker Int'l, Inc., 753 F.2d 670, 671 (8th Cir. 1985) (X-ray machine); *cf.* Brown v. Drake-Willock Int'l, Ltd., 530 N.W.2d 510, 515–16 (Mich. Ct. App. 1995) (technician injured while cleaning dialysis machine). *But see* Piper v. Bear Med. Sys., Inc., 883 P.2d 407, 414–15 (Ariz. Ct. App. 1993) (ventilator valve). *See generally* Hall, *supra* note 235, at 221–26, 253–54 (comparing and contrasting the learned intermediary and sophisticated user doctrines); Carole A. Cheney, Comment, *Not Just for Doctors: Applying the Learned Intermediary Doctrine to the Relationship Between Chemical Manufacturers, Industrial Employers, and Employees*, 85 NW. U. L. REV. 562 (1991).

[319] In their essay "Drug Designs *Are* Different," the Reporters devoted only a single, lengthy (and error-filled) footnote to medical devices. *See* Henderson & Twerski, *supra* note 19, at 163 n.47. Contrary to what they said, the FDA has no such thing as "Class III drugs," Class III devices do not invariably require premarket approval (PMA), new drug approval comes under an entirely different provision of the statute (and, even if they have converged in practice, the statutory standards for safety and effectiveness differ for new drugs and Class III devices subject to PMA requirements), and Congress first subjected devices to any sort of premarket scrutiny in 1976 (it did not in that year, as they suggested, gradually start "streamlining" previously applicable requirements). *See* NOAH, *supra* note 3, at 49–50, 254–56, 269–70, 277–79.

[320] *See, e.g.*, Conk, *supra* note 21, at 783–86; *see also* Michael D. Green & William B. Schultz, *Tort Law Deference to FDA Regulation of Medical Devices*, 88 GEO. L.J. 2119, 2123–37 (2000) (comparing and contrasting the characteristics and regulation of drugs and devices); *id.* at 2138 ("[M]arginal design improvements are always possible for devices and almost never possible for drugs. . . . With the number of small manufacturers of medical devices . . . and the ability to manipulate the device to change its characteristics, we should expect design aspects to figure prominently in the safety of devices.").

[321] *See* Lars Noah, *Reconceptualizing Federal Preemption of Tort Claims as the Government Standards Defense*, 37 WM. & MARY L. REV. 903, 904–05, 926–28, 939–57, 967–78 (1996); Robert J. Katerberg, Note, *Patching the "Crazy Quilt" of* Cipollone*: A Divided Court Rethinks Federal Preemption of Products Liability in* Medtronic, Inc. v. Lohr, 75 N.C. L. REV. 1440 (1997).

premarket review and approval, at least where the FDA has made a particular judgment about a feature challenged by the plaintiff.[322]

In sharp contrast to prescription drugs, medical devices are built rather than discovered. Innovation in this field tends to be incremental,[323] and the FDA's premarket screening mechanism accommodates the introduction of new and slightly improved models of medical devices.[324] In addition, devices generally should not present the same unpredictable (and variable) responses encountered with metabolized drugs, though anatomical variation exists (as does variation in the skill of surgeons). In short, the risk-utility standard does not seem nearly as inapt in this context, and perhaps juries can more easily judge the trade-offs made in the course of designing devices.[325] Nonetheless, focusing on the presence of a learned intermediary (and the public policy rationales for limiting the liability of sellers that supply products of value to some patients), the *Products Liability Restatement* does not differentiate between prescription drugs and medical devices.

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[322] *See* Riegel v. Medtronic, Inc., 128 S. Ct. 999, 1007, 1011 (2008); Rachel Mervis, Note, *Furthering Consumer Safety of Medical Devices: The Necessity of a Device–Specific State Law as Required for Express Preemption Under the MDA*, 27 CARDOZO L. REV. 387 (2005); *cf.* Lars Noah, *Amplification of Federal Preemption in Medical Device Cases*, 49 FOOD & DRUG L.J. 183, 204–11 (1994) (arguing that the preemption defense extends to certain claims against devices that have not undergone full premarket approval).

[323] *See In re* Am. Med. Sys., Inc., 75 F.3d 1069, 1081 n.12 (6th Cir. 1996); James S. Benson, *Forces Reshaping the Performance and Contribution of the U.S. Medical Device Industry*, 51 FOOD & DRUG L.J. 331, 332 (1996) ("[M]edical device product development is inherently iterative, depending heavily on feedback from user experience in real-life clinical settings."); Aaron V. Kaplan et al., *Medical Device Development: From Prototype to Regulatory Approval*, 109 CIRCULATION 3068 (2004). Also, it takes little speculation to decide whether device redesigns would pass muster with the FDA, which, in most cases, would require only an abbreviated clearance process. *See, e.g.*, United States v. An Article of Device Consisting of 1,217 Cardboard Boxes, 607 F. Supp. 990, 996–97 (W.D. Mich. 1985).

[324] *See* Peter Barton Hutt et al., *The Standard of Evidence Required for Premarket Approval Under the Medical Device Amendments of 1976*, 47 FOOD & DRUG L.J. 605, 612–13 (1992); Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1808 (1996) ("[T]he [Medical Device] Amendments were promoted as a new type of regulatory statute, one that would assure careful review of the few high risk technologies but permit less intrusive, less costly regulation of most devices."); *see also* Michael VanBuren, Note, *Closing the Loopholes in the Regulation of Medical Devices: The Need for Congress to Reevaluate Medical Device Regulation*, 17 HEALTH MATRIX 441, 448–60 (2007) (identifying weaknesses in the FDA's pre- and post-market scrutiny of devices for safety and effectiveness).

[325] *See, e.g.*, Hopkins v. Dow Corning Corp., 33 F.3d 1116, 1119, 1126 (9th Cir. 1994) (affirming plaintiff's verdict based in part on an allegation that the manufacturer had failed to redesign breast implants to reduce the risk of leakage and rupture); Coursen v. A.H. Robins Co., 764 F.2d 1329, 1337–39 (9th Cir. 1985) (Dalkon Shield); Worsham v. A.H. Robins Co., 734 F.2d 676, 681–82 (11th Cir. 1984) (same); Webster v. Pacesetter, Inc., 259 F. Supp. 2d 27, 31–33 (D.D.C. 2003) (finding that plaintiff failed to identify a RAD for the pacemaker lead); Dyer v. Danek Med., Inc., 115 F. Supp. 2d 732, 738–39 (N.D. Tex. 2000) ("Plaintiffs have failed to clearly identify a safer design alternative [for a pedicle screw], which is a prerequisite for a finding of design defect."); Adams v. G.D. Searle & Co., 576 So. 2d 728, 731–34 (Fla. Dist. Ct. App. 1991) (reversing summary judgment for the manufacturer of an IUD on a design defect claim alleging that the use of a polypropylene withdrawal string was more likely than a polyethylene string to retract into the uterus where it might cause a perforation or pelvic inflammatory disease); Larsen v. Pacesetter Sys., Inc., 837 P.2d 1273, 1286 (Haw. 1992) (pacemaker); Tansy v. Dacomed Corp., 890 P.2d 881, 886 (Okla. 1994).

A few courts already have discussed the application of section 6(c) to implanted devices,[326] and the new design defect standard has not fared well among those that have squarely addressed the question. For instance, in a case involving an intravenous line that became detached from a catheter, the Illinois Supreme Court found that the plaintiff had satisfied either the consumer expectations or risk-utility test, and it declined to consider adopting section 6(c) because the defendant had not preserved that issue for appeal.[327] A few years later in a case involving a prosthetic hip, an intermediate appellate court in Illinois rejected the new standard, instead applying a modified consumer expectations test that allowed the defendant to introduce evidence of countervailing utilities of the challenged design.[328]

2. Tissue Engineering and Manufacturing Defects

Elsewhere, the *Products Liability Restatement* expressly excludes human tissue products from coverage,[329] which accurately

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[326] *See, e.g.*, Sita v. Danek Med., Inc., 43 F. Supp. 2d 245, 255–59 & n.9 (E.D.N.Y. 1999) (rejecting plaintiff's design defect claim against a manufacturer of pedicle screws used in spinal fixation for failing to establish a feasible safer design); *id.* at 256 n.9 & 258 (making only passing references to § 6(c)); Wheat v. Sofamor, S.N.C., 46 F. Supp. 2d 1351, 1361–62 & n.11 (N.D. Ga. 1999) (declining to predict whether Georgia courts would follow § 6(c), but concluding that, under a risk-utility test, pedicle screws had an appropriate role in securing long bones (as indicated in their labeling) even if not appropriate for plaintiff's spinal fixation surgery); Gebhardt v. Mentor Corp., 191 F.R.D. 180, 185–86 & n.2 (D. Ariz. 1999) (holding that the plaintiff's design defect claim against the manufacturer of an implanted device used to treat gastroesophageal reflux failed under either § 6(c) or § 2(b) of the *Products Liability Restatement*, and declining to resolve the applicability of § 402A comment k of the *Second Restatement*); *cf.* Anderson v. Siemens Corp., 335 F.3d 466, 470–71 (5th Cir. 2003) (declining to apply § 6 to an ICU ventilator with a malfunctioning alarm because it did not qualify as a "prescription" product).

[327] *See* Hansen v. Baxter Healthcare Corp., 764 N.E.2d 35, 43–46 (Ill. 2002); *see also* Peter Waldman, *Intravenous Bags, Tubes Redesigned for Safety*, WALL ST. J., Apr. 19, 2006, at D3.

[328] *See* Mele v. Howmedica, Inc., 808 N.E.2d 1026, 1038–42, 1045–46 (Ill. App. Ct. 2004); *id.* at 1037–38 ("Even if implantees have no expectation specific to this particular part of the artificial hip, they may have relevant expectations about the safety of the artificial hip as a whole. . . . The trial court correctly rejected the proposal to assess risks from the standpoint of the ordinary doctor."). *But cf.* Rosburg v. Minn. Mining & Mfg. Co., 226 Cal. Rptr. 299, 303–05 (Ct. App. 1986) (allowing expert testimony about the limited life expectancy of a breast implant to rebut the plaintiff's belief that the device should last a lifetime); Schindler v. Sofamor, Inc., 774 A.2d 765, 766, 775 (Pa. Super. Ct. 2001) (spinal fixation device could not be expected to last forever in case of nonfusion). *See generally* Kathleen Fackelmann, *Hip Implants Get the Active Back in Gear: New Ceramic Joints Can Benefit Aging but On-the-Go Boomers*, USA TODAY, June 24, 2003, at 8D (reporting that new ceramic versions should prove to be more durable than older metal and plastic hip implants); Stephen Smith, *As Americans Age, So Do Their Implants*, BOSTON GLOBE, July 18, 2005, at C1.

[329] *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 19(c) (1998) ("Human blood and human tissue, even when provided commercially, are not subject to the rules of this Restatement."). The status of non-human tissue products used in the treatment of patients remains unclear for liability purposes, though so-called xenotransplants have attracted regulatory attention. *See* Fritz H. Bach et al., *Ethical and Legal Issues in Technology: Xenotransplantation*, 27 AM. J.L. & MED. 283 (2001); Patrik S. Florencio & Erik D. Ramanathan, *Are Xenotransplantation Safeguards Legally Viable?*, 16 BERKELEY TECH. L.J. 937 (2001); Rhonda L. Rundle, *Edwards Lifesciences Says FDA Is to Clear Cow–Tissue Heart Valve*, WALL ST. J., Nov. 18, 2003, at D6; Rick Weiss, *Gene Alteration Boosts Pig–Human Transplant Feasibility*, WASH. POST, Jan. 4, 2002, at A11.

reflects judicial interpretations of the blood shield statutes found in most states,[330] but it fails to recognize the increasingly difficult categorization judgments that FDA officials encounter as the field of regenerative medicine develops.[331] If, instead, section 6 applied to drug-like blood derivatives and device-like human tissue products, then a separate doctrinal question would arise: are instances of contamination in source material treated as manufacturing defects or design defects?[332] I assume,

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Perhaps as raw materials (that surgeons integrate into patients), suppliers of non-human tissues would face liability only in the event of contamination and other sorts of manufacturing defects. *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 5 cmt. c (1998) (discussing the limited duties of raw material suppliers).

[330] *See, e.g.*, Condos v. Musculoskeletal Transplant Found., 208 F. Supp. 2d 1226, 1229 (D. Utah 2002) ("No court has ever applied strict liability to the distribution of human tissue."); *id.* at 1229–30 (citing § 19 as further authority, and concluding that the transplantation of processed bone tissue, which allegedly caused recipient to contract hepatitis C, did not constitute a "sale" subject to strict liability); Cryolife, Inc. v. Superior Court, 2 Cal. Rptr. 3d 396, 398, 402–05 (Ct. App. 2003) (same, in a case alleging bacterial contamination of a patellar tendon harvested from a cadaver and used during knee surgery); *see also* Jason L. Williams, Note, *Patient Safety or Profit: What Incentives Are Blood Shield Laws and FDA Regulations Creating for the Tissue Banking Industry?*, 2 IND. HEALTH L. REV. 295 (2005). Essentially all states exempt blood from strict products liability. *See* Zichichi v. Middlesex Mem. Hosp., 528 A.2d 805, 810 (Conn. 1987); Michael J. Miller, Note, *Strict Liability, Negligence and the Standard of Care for Transfusion–Transmitted Disease*, 36 ARIZ. L. REV. 473, 488–90 (1994); *see also* Hyland Therapeutics v. Superior Court, 175 Cal. App. 3d 509, 516 (Ct. App. 1985) (explaining the rationale in terms similar to comment k). These statutes generally also protect commercial suppliers of blood-derived products from strict liability claims. *See* McKee v. Cutter Labs., Inc., 866 F.2d 219, 221–22 (6th Cir. 1989); Weishorn v. Miles–Cutter, Inc., 721 A.2d 811, 814 (Pa. Super. Ct. 1998); Rogers v. Miles Labs., 802 P.2d 1346, 1350–52 (Wash. 1991); *cf.* Doe v. Alpha Therapeutic Corp., 3 S.W.3d 404, 419 (Mo. Ct. App. 1999) (applying the learned intermediary doctrine). *But see* JKB, Sr. v. Armour Pharm. Co., 660 N.E.2d 602, 605–06 (Ind. Ct. App. 1996) (rejecting such an extension).

[331] *See* 21 C.F.R. pt. 1271 (2008); Nw. Tissue Ctr. v. Shalala, 1 F.3d 522, 536 (7th Cir. 1993) (invalidating on procedural grounds the FDA's assertion of its device authority over heart valves recovered from cadavers); Lars Noah, *A Postmodernist Take on the Human Embryo Research Debate*, 36 CONN. L. REV. 1133, 1146–47 & n.66 (2004); Michael Leachman, Comment, *Regulation of the Human Tissue Industry: A Call for Fast–Track Regulations*, 65 LA. L. REV. 443 (2004); Rick Weiss, *First Bladders Grown in Lab Transplanted: Breakthrough Shows Promise for Creating Other Human Organs*, WASH. POST, Apr. 4, 2006, at A1; *see also* Noah, *supra* note 90, at 61 ("If biotechnology rendered untenable the traditional distinction between drugs and biologics, then nanomedicine may do the same to the line separating devices and biologics.").

[332] *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 19 cmt. c (1998) (assuming that, in the absence of blood shield statutes, such cases involve product contamination and would lead to the imposition of strict liability for manufacturing defects). In contrast, one commentator who focused on HIV contamination of blood factor concentrates used by hemophiliacs treated purported delays in adopting pasteurization and other viral inactivation processes as matters of defective design (and, on that assumption, criticized section 6(c)'s reasonable physician standard for not imposing liability under these circumstances). *See* Conk, *supra* note 19, at 1098–101, 1111–14, 1117. *But see* Henderson & Twerski, *supra* note 19, at 159–61; *id.* at 160 (arguing that "the contaminants that caused their harm constituted manufacturing defects"); *id.* at 161 (distinguishing between "the design of the defendants' methods of production" and the "products themselves"); *id.* at 161 ("[P]laintiffs in the blood cases . . . lost because they were unable to establish through credible proof that an alternative method of decontaminating blood was reasonably available at the time of sale."). In their response to Conk's essay, however, the Reporters never attempted to justify the exclusion of blood and tissue products, apart from recognizing the widespread adoption of blood shield statutes. His rejoinder curiously argued that the plaintiffs' failures in this negligence-based litigation demonstrated that courts have the capacity to engage in risk-utility balancing. *See* Conk, *supra* note 21, at 774, 779–81; *see also id.* at 774–79 (elaborating on the merits of the plaintiffs' claims, and explaining their litigation failures on other grounds); *id.* at 772–73 (reiterating his view that these cases involved design rather than manufacturing defects); *id.* at 780 (conceding that

for instance, that, after the recent discovery that foreign suppliers of the active ingredient used in heparin surreptitiously had substituted a dangerous material,[333] the finished good manufacturers would face manufacturing defect claims.[334]

D. Links in the Chain of Distribution

Although the title of section 6 refers to a "commercial seller or distributor" of prescription products, section 6(a) covers only a "manufacturer . . . who sells or otherwise distributes." Section 6(e) further provides as follows:

> A retail seller or other distributor of a prescription drug or medical device is subject to liability for harm caused by the drug or device if: (1) at the time of sale or other distribution the drug or medical device contains a manufacturing defect as defined in § 2(a); or (2) at or before the time of sale or other distribution of the drug or medical device the retail seller or other distributor fails to exercise reasonable care and such failure causes harm to persons.[335]

At the outset, this language leaves open some questions about the liability of entities other than manufacturers and retailers,[336] especially when contrasted with the blackletter language elsewhere in the *Restatement* that expressly addresses wholesalers as well as component part suppliers.

As for suppliers of inputs used by finished good manufacturers, generally these companies need fear liability only in case of a flaw in what they supplied or a failure to disclose information unknown to the immediate purchaser.[337] Nonetheless, when manufacturers of defective

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subsequently developed recombinant versions of blood factor concentrates would not have qualified as RADs).

[333] *See* Gardiner Harris, *F.D.A. Identifies Tainted Heparin in 11 Countries*, N.Y. TIMES, Apr. 22, 2008, at A1.

[334] *Cf.* Am. Tobacco Co. v. Grinnell, 951 S.W.2d 420, 434 (Tex. 1997) ("Although pesticide residue may be found in many if not all cigarettes, it is not an ingredient American intended to incorporate into its cigarettes. Analyzed in this light, the presence of pesticide residue could be a manufacturing defect, not a design defect."); Paul A. Offit, *The Cutter Incident, 50 Years Later*, 352 NEW ENG. J. MED. 1411 (2005) (describing early litigation over incompletely inactivated polio vaccine). Alternatively, because the finished drug deviated from the specifications of its license, the manufacturers might face a claim of defectiveness per se. *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 4(a) (1998).

[335] RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(e) (1998).

[336] For instance, does "other distributor" in section 6(e) refer only to the retail level of distribution? *See* Anderson v. Siemens Corp., 335 F.3d 466, 471 n.10 (5th Cir. 2003) (holding that the distributor of a ventilator used in a hospital ICU was not a "retailer" within the meaning of § 6(e)); *cf.* Fagan v. AmerisourceBergen Corp., 356 F. Supp. 2d 198, 204–07, 215 (E.D.N.Y. 2004) (dismissing claims against the manufacturer of Epogen® where counterfeiters had diverted, substantially diluted, and then sold the drug on the gray market); *id.* at 207–11 (allowing negligence claims against the distributor to proceed).

[337] *See, e.g.*, Fisher v. Prof'l Compounding Ctrs. of Am., 311 F. Supp. 2d 1008, 1019–21 (D. Nev. 2004) (holding that suppliers of bulk fenfluramine used to compound diet drugs had failed to ensure that pharmacists knew of the risks associated with this drug substance); White v. Weiner, 562 A.2d 378, 380 (Pa. Super. Ct. 1989) (upholding summary judgment for a company that had supplied bulk active ingredient to another company that manufactured a prescription drug that

medical devices go bankrupt, patients occasionally manage to prevail against raw material suppliers.[338] Even though such claims normally failed,[339] some suppliers of biomaterials expended substantial resources in defending against these sorts of lawsuits,[340] prompting them to stop supplying raw materials to medical device manufacturers.[341] At the other end of the chain of distribution for prescription drugs and devices, as discussed in the sections that follow, injured patients might try to name physicians, pharmacists, and hospitals.

1. Physicians, Pharmacists, and Compounding

Consistent with the available case law (and the broadly applicable sales-service distinction), the *Products Liability Restatement* clearly did not mean to treat physicians as retail sellers or other distributors,[342] even though some commentators have advocated

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caused a patient's death), *aff'd*, 583 A.2d 789 (Pa. 1991); George v. Parke–Davis, 733 P.2d 507, 515–16 (Wash. 1987) (rejecting a manufacturer's indemnification claim against a bulk supplier of DES). *See generally* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 5 (1998) (setting forth the bulk supplier doctrine). This standard roughly parallels section 6(c) insofar as it declines to impose liability for a design defect for injuries caused by a product supplied to a sophisticated purchaser so long as it has some reasonably safe uses.

[338] *See, e.g.*, Dow Chem. Co. v. Mahlum, 970 P.2d 98, 113–17 (Nev. 1998) (upholding a compensatory damage award of $4.2 million, but reversing a punitive damage award of $10 million, against the company that supplied silicone for use in breast implants). This also has happened when plaintiffs find it difficult to sue solvent finished good manufacturers, for instance because the injuries fall within the scope of the National Childhood Vaccine Injury Act. *See* Moss v. Merck & Co., 381 F.3d 501 (5th Cir. 2004) (holding that claims brought against the manufacturer of thimerosal used in vaccines were not covered); Blackmon v. Am. Home Prods. Corp., 267 F. Supp. 2d 667, 678 (S.D. Tex. 2003) (same).

[339] *See, e.g.*, *In re* TMJ Implants Prods. Liab. Litig., 97 F.3d 1050 (8th Cir. 1996); Anguiano v. E.I. Du Pont De Nemours & Co., 44 F.3d 806 (9th Cir. 1995); *In re* Silicone Gel Breast Implants Prods. Liab. Litig., 996 F. Supp. 1110 (N.D. Ala. 1997); Artiglio v. Gen. Elec. Co., 957 P.2d 1313 (Cal. 1998).

[340] For instance, DuPont ultimately prevailed in all of the temporomandibular joint (TMJ) implant lawsuits filed against it for supplying raw materials, but it expended significant resources for its string of victories during the decade that this litigation lasted, paying far more in legal fees than it ever earned on this minor application. *See* Gary Taylor, *A Discovery by DuPont: Hidden Costs of Winning*, NAT'L L.J., Mar. 27, 1995, at B1 (reporting one estimate that the company had spent more than $40 million defending itself).

[341] For instance, spooked by the breast implant lawsuits, Dow discontinued supplying silicone for other important medical device applications such as hydrocephalus shunts. *See* RAND Sci. & Tech. Policy Inst., *Biomaterials Availability: Potential Effects on Medical Innovation and Health Care*, Issue Paper No. 194, Jan. 2000, at 17, 32; *see also* Barnaby J. Feder, *Implant Industry Is Facing Cutback by Top Suppliers*, N.Y. TIMES, Apr. 25, 1994, at A1; *cf.* Cabrera v. Cordis Corp., 134 F.3d 1418, 1422–23 (9th Cir. 1998) (affirming the exclusion of plaintiff's expert testimony in her claims against the manufacturer of a hydrocephalus shunt composed of silicone). In response to fears of an emerging shortage of raw materials needed to make critical medical devices, Congress enacted the Biomaterials Access Assurance Act of 1998. *See* 21 U.S.C. §§ 1601–1606 (2006); *see also* FDA, Medical Devices Draft Guidance for the Implementation of the Biomaterials Access Assurance Act of 1998, 66 Fed. Reg. 17,562 (Apr. 2, 2001) (describing the procedure to petition for a declaration concerning a biomaterials supplier's compliance with establishment registration requirements). *See generally* Ann M. Murphy, Note, *The Biomaterials Access Assurance Act of 1998 and Corporate Supplier Liability: Who You Gonna Sue?*, 25 DEL. J. CORP. L. 715 (2000).

[342] *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(e) cmt. h (1998) (explaining that retailers "should be permitted to rely on the special expertise of . . . prescribing and treating

extending strict liability to surgeons who implant nonessential medical devices.[343] Instead, tort law uses the less exacting standards of medical malpractice to resolve personal injury claims arising from surgical and other medical procedures.[344] Courts have held physicians liable for negligent prescribing decisions,[345] including cases involving inadequate testing for the selection of the best available product for a particular patient,[346] failing to warn of risks,[347] and errors in drug administration.[348]

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health-care providers"). *See generally id.* § 19(b) ("Services, even when provided commercially, are not products.").

[343] *See* Richard L. Cupp, Jr., *Sharing Accountability for Breast Implants: Strict Products Liability and Medical Professionals Engaged in Hybrid Sales/Service Cosmetic Products Transactions*, 21 FLA. ST. U. L. REV. 873 (1994); Daniel F. Ryan, III & Timothy R. Lawn, *Strict Liability Claims Against Health Care Providers in Breast Implant Litigation*, 29 TORT & INS. L.J. 818 (1994); Laura Pleicones, Note, *Passing the Essence Test: Health Care Providers Escape Strict Liability for Medical Devices*, 50 S.C. L. REV. 463, 472–87 (1999); *see also* Natasha Singer, *The Little Botox Shop Around the Corner*, N.Y. TIMES, Apr. 19, 2007, at G3.

[344] *See, e.g.*, *In re* Breast Implant Prod. Liab. Litig., 503 S.E.2d 445, 449 (S.C. 1998) (holding that, though breast augmentation surgery entails the implantation of a device, the service aspect of the transaction predominates); Hoven v. Kelble, 256 N.W.2d 379, 391–93 (Wis. 1977) (declining to impose strict liability for medical services); Noah, *supra* note 32, at 646–47.

[345] *See* Linda A. Sharp, Annotation, *Malpractice: Physician's Liability for Injury or Death Resulting from Side Effects of Drugs Intentionally Administered to or Prescribed for Patients*, 47 A.L.R.5th 433 (1997 & Supp. 2008).

[346] *See, e.g.*, Lynch v. Bay Ridge Obstet. & Gyn. Assocs., 532 N.E.2d 1239, 1240 (N.Y. 1988) (allowing a claim against a physician for negligently failing to diagnose plaintiff's pregnancy and then prescribing a drug whose use was contraindicated in such patients); *see also* Edwards v. Tardif, 692 A.2d 1266, 1267–68 (Conn. 1997) (wrongful death action based on negligent prescribing without examination of patient); Hogle v. Hall, 916 P.2d 814, 816–17 (Nev. 1996) (sustaining a jury verdict for a child who suffered severe birth defects against a physician who negligently had prescribed Accutane during the mother's pregnancy); Eiss v. Lillis, 357 S.E.2d 539, 542–44 (Va. 1987) (negligent failure to monitor patient's drug therapy); *cf.* Forman v. Pillsbury, 753 F. Supp. 14, 18–20 (D.D.C. 1990) (rejecting claim where patient had disregarded physician's instructions for continued blood monitoring while on drug). Occasionally, a patient will allege that a physician committed malpractice for failing to switch the patient to a newly approved product that might have worked more effectively. *See* Reese v. Stroh, 907 P.2d 282, 283–84 (Wash. 1995). Courts also may entertain tort claims against physicians for undermedicating patients, for instance undertreating pain that would have responded to powerful analgesic products. *See* James R. Blaufuss, Note, *A Painful Catch–22: Why Tort Liability for Inadequate Pain Management Will Make for Bad Medicine*, 31 WM. MITCHELL L. REV. 1093 (2005); Rima J. Oken, Note, *Curing Healthcare Providers' Failure to Administer Opioids in the Treatment of Severe Pain*, 23 CARDOZO L. REV. 1917, 1968–81 (2002).

[347] *See, e.g.*, Hutchinson v. United States, 915 F.2d 560, 562–63 (9th Cir. 1990) (doctor held liable for not warning patient of risks involved with use of asthma medication); Bowman v. Songer, 820 P.2d 1110, 1113–15 (Colo. 1991) (dermatologist negligent for failing to warn patient of risk of sun exposure during use of topical prescription drug); Tenuto v. Lederle Labs., 687 N.E.2d 1300, 1301–02 (N.Y. 1997) (physician had a duty to warn plaintiff of risk of contracting polio from an infant who had received a polio vaccine); Shadrick v. Coker, 963 S.W.2d 726, 729–30, 734–35, 736–37 (Tenn. 1998) (informed consent doctrine requires physician to tell patient that medical device was not FDA approved); *see also* Noah, *supra* note 279, at 364–70. Physicians also may have duties to warn former patients when new risk information comes to light about a previously prescribed drug or implanted medical device. *See, e.g.*, Harris v. Raymond, 715 N.E.2d 388, 394–95 (Ind. 1999); Tanuz v. Carlberg, 921 P.2d 309, 312, 316 (N.M. Ct. App. 1996). In some jurisdictions, third parties involved in traffic accidents with a person driving under the influence of a sedating medication may have a claim against the patient's physician in case of a failure to warn of this side effect. *See, e.g.*, Burroughs v. Magee, 118 S.W.3d 323, 324–25 (Tenn. 2003) (holding, however, that the third party could not assert a claim for negligent prescribing). *But see* Lester *ex rel.* Mavrogenis v. Hall, 970 P.2d 590 (N.M. 1998).

[348] *See, e.g.*, Bazel v. Mabee, 576 N.W.2d 385, 387 (Iowa Ct. App. 1998) (holding that a jury could find a physician negligent for using Betadine despite knowledge of patient's allergy);

Even compounding or customization, which seem closer to the activities of a manufacturer, may escape strict liability.[349]

Pharmacists have a limited duty of care in connection with dispensing drugs and supplying information.[350] In addition, pharmacists may face tort liability for mistakes in compounding drugs,[351] and the *Products Liability Restatement* appears to treat them as within the chain of distribution for limited purposes,[352] but they generally escape strict liability because courts regard them as providers of a service rather than sellers of a product.[353] In fact, courts have rejected products liability

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Leiker *ex rel*. Leiker v. Gafford, 778 P.2d 823, 827–28, 857 (Kan. 1989) (negligence for administering excessive dose of a drug); Harrison v. Axelrod, 599 N.Y.S.2d 96 (App. Div. 1993) (nurse negligent for administering incorrect dose).

[349] *See* Dove *ex rel*. Dove v. Ruff, 558 N.E.2d 836, 837–40 (Ind. Ct. App. 1990) (drug compounding). *But see* Detwiler v. Bristol–Myers Squibb Co., 884 F. Supp. 117, 121–22 (S.D.N.Y. 1995) (physician modified silicone for cosmetic injection); *cf.* Putensen v. Clay Adams, Inc., 91 Cal. Rptr. 319, 323–24 (1970) (explaining that, in claims against supplier of bulk polyethylene, some surgeons had crafted cardiac catheters from this material). At some point, of course, entrepreneurial physicians decide to commercialize an idea, which would turn them into product sellers. *See* Bruce Ingersoll & Rose Gutfeld, *Medical Mess: Implants in Jaw Joint Fail, Leaving Patients in Pain and Disfigured*, WALL ST. J., Aug. 31, 1993, at A1 (describing the history behind Vitek, founded by Dr. Charles Homsy, and its Teflon-based interpositional implant for TMJ syndrome).

[350] *See, e.g.*, Fagan v. AmerisourceBergen Corp., 356 F. Supp. 2d 198, 213 (E.D.N.Y. 2004) ("[S]ince there is an allegation that the label on the Epogen was facially defective [and indicative of counterfeiting], the instant case does not involve a latent defect; but rather a patent defect, for which [the mail-order pharmacy] may be held liable for failing to discover upon reasonable inspection."); Harco Drugs, Inc. v. Holloway, 669 So. 2d 878 (Ala. 1995) (pharmacist should have double-checked prescription because it was illegible and an oncologist normally would not have prescribed a cardiology drug); Lou v. Smith, 685 S.W.2d 809 (Ark. 1985) (pharmacist who altered prescription to correct an assumed prescribing error held liable after a child suffered a severe reaction to the drug). When a pharmacist dispenses the wrong drug, the wrong dosage, or with the wrong label, he or she may be liable for negligence if the error harms the patient. In these circumstances, no matter how well-trained and careful a pharmacist may be, the processing error itself usually suffices to prove negligence. *See, e.g.*, Forbes v. Walgreen Co., 566 N.E.2d 90, 91 (Ind. Ct. App. 1991) (pharmacist liable for dispensing incorrect medication); Walter v. Wal–Mart Stores, Inc., 748 A.2d 961, 967–68 (Me. 2000) (same); *see also* Eric M. Grasha, Note, *Discovering Pharmacy Error: Must Reporting, Identifying, and Analyzing Pharmacy Dispensing Errors Create Liability for Pharmacists?*, 63 OHIO ST. L.J. 1419 (2002); Christopher Rowland, *CVS Faces Pharmacy Reviews: Settlement with State Comes After Scores of Prescription Errors*, BOSTON GLOBE, Feb. 10, 2006, at C1 (reporting that "pharmacies typically experience a 3 percent error rate"). A presumption of negligence in the case of processing errors differs, however, from strict liability for dispensing a product with a manufacturing defect that the pharmacist could not have detected.

[351] *See, e.g.*, Brown v. S. Baptist Hosp., 715 So. 2d 423, 426 n.2, 431 (La. Ct. App. 1998); Schroeder v. Lester E. Cox Med. Ctr., Inc., 833 S.W.2d 411, 416–19, 422 (Mo. Ct. App. 1992).

[352] *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(e) (1998) (manufacturing defects). Courts that reject strict liability claims against pharmacists seem, however, to do so without limitation, which would mean excluding responsibility for manufacturing defects as well. *See* Ashworth v. Albers Med., Inc., 395 F. Supp. 2d 395, 407–08 (S.D. W. Va. 2005) (rejecting claims against pharmacy that unknowingly dispensed counterfeit drug); Fontanez v. Parenteral Therapy Assoc., 974 So. 2d 1101, 1105 (Fla. Dist. Ct. App. 2007) ("[T]he imposition of strict liability on a pharmacist simply dispensing a prescription drug would improperly convert retail pharmacists into insurers of the safety of the manufactured drug."). Furthermore, the line between included manufacturing defects and excluded design defects may become particularly blurry in the context of pharmacy compounding operations.

[353] *See, e.g.*, Kohl v. Am. Home Prods. Corp., 78 F. Supp. 2d 885, 890 (W.D. Ark. 1999); Madison v. Am. Home Prods. Corp., 595 S.E.2d 493 (S.C. 2004); *see also In re* Rezulin Prod. Liab. Litig., 133 F. Supp. 2d 272, 292 (S.D.N.Y. 2001) ("[A]lmost every state that has considered the

claims against pharmacies even when they engage in large-scale compounding operations,[354] even though the FDA treats such activity as akin to commercial drug manufacturing.[355]

Again, as with other health care professionals, some have argued that pharmacists should face strict liability claims (after all, they do not differ markedly from retailers that simply sell products in sealed containers).[356] Pharmacies and other businesses that sell OTC drugs and devices face the same threat of products liability as any other retailer of consumer goods.[357] Indeed, pharmacies may have greater flexibility than manufacturers when it comes to regulating consumer access to nonprescription products,[358] which might make them more vulnerable to negligent marketing claims if they fail to adopt necessary safeguards.[359]

In the last decade, online prescribing and dispensing have become increasingly common. Aside from the difficulties that Internet

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issue has declined to find pharmacists liable for breach of either implied or express warranty with respect to properties of prescription drugs."); Walls v. Alpharma USPD, Inc., 887 So. 2d 881, 886 (Ala. 2004); Morgan v. Wal–Mart Stores, Inc., 30 S.W.3d 455, 461–66 (Tex. Ct. App. 2000) (declining to impose a duty to warn). *But see* Heredia v. Johnson, 827 F. Supp. 1522, 1524 (D. Nev. 1993) (rejecting pharmacy's motion for summary judgment on a strict liability claim for an alleged failure to transmit the manufacturer's warning to a consumer about a drug's risks).

[354] *See* Schaerrer v. Stewart's Plaza Pharmacy, Inc., 79 P.3d 922 (Utah 2003). *But cf. Fontanez*, 974 So. 2d at 1106 (allowing a breach of warranty claim); *id.* at 1105 ("[T]he risk of harm associated with the use of a drug which somehow became contaminated during the compounding process should be borne by the one best able to implement procedures to prevent the contamination, not by a consumer who is powerless to protect himself or herself.").

[355] *See* Thompson v. W. States Med. Ctr., 535 U.S. 357, 360–61 (2002); *In re* Establishment Inspection of Wedgewood Vill. Pharmacy, Inc., 270 F. Supp. 2d 525, 545–50 (D.N.J. 2003), *aff'd*, 421 F.3d 263, 272–73 (3d Cir. 2005); United States v. Sene X Eleemosynary Corp., 479 F. Supp. 970, 978–79 (S.D. Fla. 1979) (rejecting practice of pharmacy defense to misbranding charges associated with large-scale compounding). The resurgence in pharmacy compounding has raised concerns about product safety. *See* Erin Hallissy & Sabin Russell, *Who's Mixing Your Drugs*, S.F. CHRON., June 23, 2002, at A1 (documenting serious instances of contamination).

[356] *See, e.g.*, Furrow, *supra* note 47, at 404–13; *see also* Rhonda L. Rundle, *Getting Your Drugs from a Vending Machine*, WALL ST. J., June 21, 2005, at D1 (discussing efforts to use ATM-like kiosks to dispense prescription refills).

[357] *See, e.g.*, Morales v. Am. Home Prods. Corp., 214 F. Supp. 2d 723, 726 (S.D. Tex. 2002).

[358] Before Congress legislated in this area, concerns about methamphetamine prompted some retailers to place OTC cough-cold products containing the meth precursor pseudoephedrine behind the counter. *See* Margaret Webb Pressler, *Retailers Restrict Some Cold Medicines: Ingredient Can Be Used to Make Meth*, WASH. POST, May 14, 2005, at A1. Retailers also have begun to limit access to other OTC cough-cold products in response to problems with teenagers purchasing them to get high. *See* Rebecca Dana, *Household Medicine Abused by the Young: Trend Alarms Activists, Officials*, WASH. POST, Oct. 8, 2004, at A1; *cf.* Annys Shin, *Speeding up Safety*, WASH. POST, May 3, 2008, at D1 ("The rush to banish [bisphenol A] is an example of how businesses have learned to respond quickly when their customers become alarmed. Major retailers and manufacturers have been taking their own measures because of a regulatory system that has not kept up with changes in the marketplace . . . ."). Only once before has the manufacturer of an OTC drug created a "behind-the-counter" system of distribution. *See* Francesca Lunzer Kritz, *Over the Counter but Not Easy to Reach*, WASH. POST, Oct. 8, 2002, at F3 (Mucinex®).

[359] *See* Nora Lockwood Tooher, *Meth Suits Target Cold Medicine Makers and Sellers*, LAWYERS WKLY. USA, Feb. 27, 2006; *see also supra* note 199 and accompanying text (discussing "behind-the-counter" status).

sales of prescription drugs present for regulatory officials,[360] and the possibility that manufacturers might have a duty to limit such modes of distribution,[361] this phenomenon may justify rethinking the traditional view that physicians and pharmacists offer predominantly professional services and, therefore, lie outside of the chain of distribution.[362] Similarly, if an exception to the learned intermediary rule applies (e.g., mass immunization, contraceptives, DTCA),[363] then it seemingly would undermine the professional-status rationale underlying the exclusion of doctors and pharmacists from the chain of distribution for such drugs.

2. Will Pharmacogenomics Change Everything?

These issues may take on greater importance in the future as medical product development and use undergo fundamental changes. The improved understanding of the human genome promises advances in personalized medicine. "Pharmacogenomics" refers to the science of utilizing information about genetic variations to facilitate drug development and to create optimal patient treatments.[364] Moreover, because human beings exhibit a great deal of variation, better understanding of individual differences presents an opportunity for physicians to tailor drugs to suit their patients' individual genetic quirks and minimize the risk of side effects.[365] To the extent that

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[360] *See* Linda C. Fentiman, *Internet Pharmacies and the Need for a New Federalism: Protecting Consumers While Increasing Access to Prescription Drugs*, 56 RUTGERS L. REV. 119 (2003); Nicholas P. Terry, *Prescriptions Sans Frontières*, 4 YALE J. HEALTH POL'Y L. & ETHICS 183 (2004); Phil Ayres, Comment, *Prescribing a Cure for Online Pharmacies*, 72 TENN. L. REV. 949 (2005); John Richard Castronova, Comment, *Operation Cyber Chase and Other Agency Efforts to Control Internet Drug Trafficking: The "Virtual" Enforcement Initiative Is Virtually Useless*, 27 J. LEGAL MED. 207 (2006); Symposium, *Pharmaceuticals and the Internet*, 16 ALB. L.J. SCI. & TECH. 483 (2006); Erik Eckholm, *Abuses Are Found in Online Sales of Medication*, N.Y. TIMES, July 9, 2008, at A21; Sarah Rubenstein, *New Bill Targets Rogue Druggists on the Internet*, WALL ST. J., Oct. 9, 2008, at D1.

[361] *See supra* note 202 and accompanying text.

[362] *See* Joanna M. Carlini, Comment, *Liability on the Internet: Prescription Drugs and the Virtual Pharmacy*, 22 WHITTIER L. REV. 157 (2000); Kelly K. Gelein, Note, *Are Online Consultations a Prescription for Trouble? The Uncharted Waters of Cybermedicine*, 66 BROOK. L. REV. 209 (2000).

[363] *See supra* notes 244–247 and accompanying text (asking whether a different design defect standard would apply in such circumstances).

[364] *See* Jeffrey L. Moe, *Commercialization Considerations for Individualized Diagnostic and Drug Therapies Resulting from Pharmacogenomics*, 66 LA. L. REV. 103 (2005); Lars Noah, *The Coming Pharmacogenomics Revolution: Tailoring Drugs to Fit Patients' Genetic Profiles*, 43 JURIMETRICS J. 1 (2002); Symposium, *Pharmacogenomics*, 46 JURIMETRICS J. 237 (2006); Andrew Pollack, *A Special Drug Just for You, at the End of a Long Pipeline*, N.Y. TIMES, Nov. 8, 2005, at F1.

[365] *See* Barbara J. Evans, *What Will It Take to Reap the Clinical Benefits of Pharmacogenomics?*, 61 FOOD & DRUG L.J. 753 (2006); Yusuke Nakamura, Editorial, *Pharmacogenomics and Drug Toxicity*, 359 NEW ENG. J. MED. 856 (2008); Gina Kolata, *A Tale of Two Drugs Hints at Promise for Genetic Testing*, N.Y. TIMES, July 11, 2006, at F1; Ron Winslow & Anna Wilde Mathews, *New Genetic Tests Boost Impact of Drugs: Cancer Screens, Moves by FDA Help Launch Era of Personalized Medicine, but Strategy Is Still Young*, WALL ST. J., Dec. 21, 2005, at D1; *see also* Andrew Pollack, *F.D.A. Urges Genetic Test Before Giving AIDS Drug*, N.Y. TIMES,

pharmacogenomics blurs the line between manufacturing and compounding, courts may have to revisit the sales-service distinction as it applies to pharmaceutical products.

Even if pharmacogenomics never results in complete customization of drug therapy, it may affect the resolution of products liability litigation against pharmaceutical manufacturers. For instance, this research may help to identify subgroups of patients for whom reasonable physicians would prescribe a certain drug in the face of a plaintiff's allegations of defective design.[366] Conversely, it may expand the limited duty to warn of allergic reactions.[367] Historically, such claims rarely succeeded, either because the manufacturer could not have known of the risk of allergic reactions,[368] or because a warning would not have altered the consumer's decision to use a product if they did not know of their susceptibility.[369] Pharmacogenomics may eliminate both of these obstacles to recovery in drug products liability cases. For instance, in a class action lawsuit premised on a failure-to-warn theory, the plaintiffs alleged that the manufacturer of a vaccine against Lyme disease should have recommended that patients first get a genetic test for the HLA–DR4+ allele, which occurs in thirty percent of the population and produces an autoimmune reaction in response to an outer surface protein found on the vaccine.[370] As pharmacogenomic research reveals more such genetic variations, drug companies can expect to encounter an expansion in this sort of litigation.

July 24, 2008, at C3 (reporting the addition of a black box warning in the labeling for abacavir with instructions to screen for a particular gene variation found in approximately five percent of patients because they may suffer severe allergic reactions); *id.* ("The labels of several other drugs, like the blood thinner warfarin and the cancer drug irinotecan, also recommend [genetic] tests aimed at avoiding side effects or helping to adjust the dose.").

[366] *See* Ron Winslow & Marilyn Chase, *Genetic Research May Help Pick Patients' Best Cancer Drugs: Aid for Physicians May Narrow Market for Blockbusters*, WALL ST. J., June 2, 2008, at B4.

[367] Drug manufacturers have an obligation to warn when they should have known that an appreciable number of hypersensitive individuals may suffer serious injury. *See, e.g.*, Basko v. Sterling Drug, Inc., 416 F.2d 417, 430 (2d Cir. 1969); *see also* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(c) cmt. k (1998) ("[A] warning is required when the harm-causing ingredient is one to which a substantial number of persons are allergic."); Marcia Anne Mobilia, *Allergic Reactions to Prescription Drugs: A Proposal for Compensation*, 48 ALB. L. REV. 343, 346–49 (1984).

[368] *See* Burlison v. Warner–Lambert Co., 842 F.2d 991, 992–93 (8th Cir. 1988); Daley v. McNeil Consumer Prods. Co., 164 F. Supp. 2d 367, 373–74 (S.D.N.Y. 2001); Griggs v. Combe, Inc., 456 So. 2d 790, 792 (Ala. 1984).

[369] *See* James A. Henderson, Jr., *Process Norms in Products Litigation: Liability for Allergic Reactions*, 51 U. PITT. L. REV. 761, 778–79, 802–03 (1990); Noah, *supra* note 42, at 392 (supporting the use of ingredient disclosure statements to alert users with known allergies).

[370] *See* LORI B. ANDREWS ET AL., GENETICS: ETHICS, LAW AND POLICY 545–46 (2d ed. 2006) (describing the litigation in *Cassidy v. SmithKline Beecham Corp.*). The manufacturer subsequently discontinued marketing this vaccine, citing a significant decline in sales. *See Sole Lyme Vaccine Is Pulled off Market*, N.Y. TIMES, Feb. 28, 2002, at C5.

3. Hospitals and SUDs

Finally, hospitals that supply defective drugs or devices to patients generally need not fear strict liability claims,[371] and the *Products Liability Restatement* does not appear to treat them as retail sellers or other distributors who might face liability for manufacturing defects under section 6(e),[372] though some commentators have suggested that hospitals should qualify as links in the chain of distribution.[373] Hospitals may face negligence claims for supplying flawed devices,[374] for failing to supply state-of-the-art equipment,[375] and for failing to monitor drug therapy.[376] For the most part, however, courts refuse to treat hospitals as members of the chain of distribution on the notion that they provide a service (indeed, even more so than retail pharmacies, they look like sophisticated purchasers rather than mere retailers). Courts do not care that hospitals nowadays generate itemized bills that charge for everything used by a patient (often with a substantial mark-up),[377] may enter into exclusive (and lucrative) purchasing agreements with

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[371] *See, e.g.*, Hoff v. Zimmer, Inc., 746 F. Supp. 872, 873, 876 (W.D. Wis. 1990) (hip prosthesis); San Diego Hosp. Ass'n v. Superior Court, 30 Cal. App. 4th 8, 13 (1994); Budding v. SSM Healthcare Sys., 19 S.W.3d 678, 681–82 (Mo. 2000); Royer v. Catholic Med. Ctr., 741 A.2d 74, 75, 78 (N.H. 1999) (defective prosthetic knee implant); Parker v. St. Vincent Hosp., 919 P.2d 1104, 1106 (N.M. Ct. App. 1996) (TMJ implant); Cafazzo v. Cent. Med. Health Servs., Inc., 668 A.2d 521, 523 (Pa. 1995) (same). *But see* Karibjanian v. Thomas Jefferson Univ. Hosp., 717 F. Supp. 1081, 1085–86 (E.D. Pa. 1989); Skelton v. Druid City Hosp. Bd., 459 So. 2d 818, 823 (Ala. 1984); Garcia v. Edgewater Hosp., 613 N.E.2d 1243, 1245, 1247–49 (Ill. App. Ct. 1993) (defective heart valve); *cf.* David v. Our Lady of Lake Hosp., Inc., 857 So. 2d 529, 530–33 (La. Ct. App. 2003) (applying strict liability to hospital in a blood transfusion case). The use of *res ipsa loquitur* in this context may approach a rule of strict liability. *See, e.g.*, Chin v. St. Barnabas Med. Ctr., 734 A.2d 778, 783 (N.J. 1999); Anderson v. Somberg, 338 A.2d 1, 15–17 (N.J. 1975); Maciag v. Strato Med. Corp., 644 A.2d 647 (N.J. Super. Ct. App. Div. 1994); Jackson v. Oklahoma Mem'l Hosp., 909 P.2d 765, 770–73 (Okla. 1995).

[372] *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 20 cmt. d (1998) ("[I]n a strong majority of jurisdictions, hospitals are held not to be sellers of products they supply in connection with the provision of medical care, regardless of the circumstances.").

[373] *See, e.g.*, Rachel B. Adler, Comment, *Device Dilemma: Should Hospitals Be Strictly Liable for Retailing Defective Surgical Devices?*, 5 ALB. L.J. SCI. & TECH. 95, 103–10, 124–30 (1994). Commentators have made the same argument in connection with injuries caused by drugs administered within a hospital. *See* Furrow, *supra* note 47, at 393–404; *see also id.* at 424, 434 (suggesting that managed care organizations also should face products liability claims to the extent that they create restricted drug formularies).

[374] *See, e.g.*, Pearce v. Feinstein, 754 F. Supp. 308, 309 (W.D.N.Y. 1990).

[375] *See, e.g.*, Hernandez v. Smith, 552 F.2d 142, 144 (5th Cir. 1977); Washington v. Washington Hosp. Ctr., 579 A.2d 177, 180 (D.C. 1990) (CO_2 monitor); Suttle v. Lake Forest Hosp., 733 N.E.2d 726, 731 (Ill. App. Ct. 2000); *cf.* Emory Univ. v. Porter, 120 S.E.2d 668, 669 (Ga. Ct. App. 1961) (emphasizing the limited scope of this duty).

[376] *See, e.g.*, Newmann v. United States, 938 F.2d 1258, 1259–60 (11th Cir. 1991); Kelley v. Wiggins, 724 S.W.2d 443, 449 (Ark. 1987); Fleming v. Baptist Gen. Convention, 742 P.2d 1087, 1090 (Okla.1987) (allowing a negligence claim against a hospital and a physician for the improper administration of an injectable drug subcutaneously rather than intravenously); Thompson v. Nason Hosp., 591 A.2d 703, 707–09 (Pa. 1991) (anticoagulant therapy); Edinburg Hosp. Auth. v. Treviño, 941 S.W.2d 76, 78 (Tex. 1997).

[377] *See, e.g.*, Hector v. Cedars–Sinai Med. Ctr., 225 Cal. Rptr. 595, 600–01 (Ct. App. 1986) (noting that hospital had added a surcharge of 85%, but declining to impose strict liability for supplying a defective pacemaker).

particular wholesalers and manufacturers (almost the way an automobile dealership does),[378] and may have the clout to influence manufacturers' design choices. Moreover, hospitals have the expertise to select and inspect drugs and devices—and patients presumably depend on hospitals to exercise that expertise—to say nothing of their active role in storage and handling.

In the early 1980s, because of concerns about the difficulty of sterilizing increasingly sophisticated medical devices and surgical instruments after use (and no doubt also to promote repeat sales), manufacturers began to label these devices as "disposable" or "single-use devices" (SUDs). Many hospitals responded, however, by reusing certain SUDs in order to cut costs. This practice became widespread and can have frightening results. For example, some hospitals reused surgical instruments after operations on patients with Creutzfeldt–Jakob disease, but, because ordinary sterilization procedures do not destroy the prions that cause this fatal condition, subsequent patients may have been exposed.[379] The FDA now regulates hospitals engaged in reprocessing in the same manner as original equipment manufacturers.[380] Such reprocessing and reuse of SUDs might, of course, make hospitals vulnerable to negligence claims,[381] but why not apply rules of products

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[378] *See* United States *ex rel*. Schmidt v. Zimmer, Inc., 386 F.3d 235, 236–37 (3d Cir. 2004) (reversing summary judgment for defendant in False Claims Act lawsuit where surgeon alleged that the manufacturer of orthopedic implants had offered kickbacks to hospital chain for purchasing products that would get billed to Medicare); *In re* Cardiac Devices Qui Tam Litig., 221 F.R.D. 318, 323 (D. Conn. 2004) (allowing an action initiated by a manufacturer's sales representative against more than 100 hospitals that had received payments for services to patients enrolled in clinical trials of numerous different investigational devices not eligible for Medicare reimbursement); Reed Abelson, *Possible Conflicts for Doctors Are Seen on Medical Devices*, N.Y. TIMES, Sept. 22, 2005, at A1; Mary W. Walsh, *Senate Panel Weighs Tighter Rules for Hospital Suppliers*, N.Y. TIMES, Sept. 15, 2004, at C4.

[379] *See* Alec Klein, *Reused Devices, Surgery's Deadly Suspects: Patients May Be Exposed to Rare Brain Disease from Prior Operations*, WASH. POST, Dec. 30, 2005, at A3 ("Over the past five years, dozens of patients in at least four U.S. hospitals have been potentially exposed to the disease because their surgeons reused medical instruments first used on patients who had the rare brain disorder . . . .").

[380] Responding to concerns about inadequate sterilization and material degradation, the FDA announced plans to regulate hospitals as device manufacturers when they engage in such reprocessing. *See* John J. Smith & Jennifer A. Agraz, *Federal Regulation of Single–Use Medical Devices: A Revised FDA Policy*, 56 FOOD & DRUG L.J. 305 (2001); Diane Carey, Comment, *Reprocessing and Reusing Single–Use Only Medical Devices: Safe Medical Practice or Risky Business?*, 17 J. CONTEMP. HEALTH L. & POL'Y 657, 660 (2001); Alec Klein, *FDA Asked About Oversight of Reused Medical Devices*, WASH. POST, Dec. 17, 2005, at D1; *see also* Medical Device User Fee and Modernization Act of 2002, Pub. L. No. 107–250, §§ 301–303, 116 Stat. 1588, 1616–20. As a consequence of increasing regulation, hospitals now leave most of the work to companies that specialize in device reprocessing. *See* Alec Klein, *Good as New?: The Reuse of Medical Devices*, WASH. POST, Dec. 11–12, 2005, at A1.

[381] *See* Emil P. Wang, *Regulatory and Legal Implications of Reprocessing and Reuse of Single–Use Medical Devices*, 56 FOOD & DRUG L.J. 77, 93–95 (2001) (explaining that the duty of care "includes efforts to establish and maintain appropriate reprocessing protocols and to insure that reuse of the device is safe and presents no increased risk of harm or injury to the patient").

liability in such cases (even if that meant the more forgiving rules governing used products)?[382]

V. CONCLUSION

At least the medical technology industry got its own blackletter rules this time around. In contrast to some of the other special provisions in the *Products Liability Restatement* (e.g., food), section 6 has attracted substantial attention. Given the expansion in litigation concerning drugs and medical devices, it has the potential to have a substantial practical impact; it also raises intriguing doctrinal questions and provides some interesting contrasts with the core of products liability. Unfortunately (whether from a failure to appreciate some of the tricky regulatory or medical practice issues, a narrow focus on only one of the subsections, or a preoccupation with taking sides), much of the published literature has done a poor job of grappling with the genuinely difficult questions presented by section 6. This Article has tried to explore those issues and offer an overview of the interrelationships between different facets of this special provision.

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[382] *See* Janice M. Hogan & Thomas E. Colonna, *Products Liability Implications of Reprocessing and Reuse of Single–Use Medical Devices*, 53 FOOD & DRUG L.J. 385, 395 (1998) ("For health care entities with in-house reprocessing, however, the quasi-manufacturing role may increase the likelihood that claims for strict liability would be permitted."); *id.* at 393–94 (discussing earlier case law involving used consumer goods). *See generally* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 8 (1998).