Prescription Drugs, Alternative Designs, and the Restatement (Third): Preliminary Reflections †

Michael D. Green *

My focus in this paper is design defects for prescription drugs and the treatment of this subject matter in the Restatement (Third) of Torts: Products Liability (Restatement (Third)), which brings me to two important qualifications. The action with regard to design defects in the Restatement (Third) is in section 2(b),[1] not in the idiosyncratic design standard for drugs in section 6(c).[2] More importantly, for those interested in pharmaceutical liability, the focus in pharmaceutical products liability is not with section 6(c) and the

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* Professor of Law, University of Iowa College of Law. B.S., Tufts University, 1972; J.D., University of Pennsylvania School of Law, 1975. My thanks to Seton Hall University School of Law for inviting me to this symposium and to Professor William Powers for sharing his insights on differences between drugs and durables. This Article benefited substantially from conversations I had with Professors Gary Milavetz, Paul Perry, and Robert Wylie of the College of Pharmacy, University of Iowa, and Mary Teresi, Director, Pediatric Allergy / Pulmonary Clinical Trials, College of Medicine, University of Iowa. I am grateful for the superb research assistance provided by Stephanie Nyman and Richard Smith.

[1] Section 2 of the Restatement (Third) states:

> A product is defective when, at the time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings. A product: . . . (b) is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe . . . .

RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 (1997).

[2] Section 6(c) of the Restatement (Third) states:

> A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.

Id. § 6(c).

standard for design defects; rather, the focus should be with section 6(d),[3] which addresses the informational obligations of drug manufacturers.

Section 6(d) is critical to pharmaceutical products liability because prescription *drugs*, in contrast with medical devices,[4] are different in one respect from durable goods: the product itself, with some exceptions, cannot be designed more safely by modifying the structure of the product. With durable goods — an automobile, for example — manufacturers almost always can make the product safer by incurring further costs, either in expending money or diminishing functionality. For example, the manufacturer could add seat belts, add an interlock so that the car cannot be started unless everyone is buckled up, add front air bags, add side air bags, and add even more exotic safety devices, such as anti-collision sensing technology, currently in use in some commercial airplanes. In contrast, it is usually not possible for a manufacturer to redesign a drug.[5] With

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[3] Section 6(d) of the Restatement (Third) provides:

> A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:
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> (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
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> (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.

Id. § 6(d).

[4] The Restatement (Third) does not distinguish between drugs and medical devices in section 6 for purposes of design defects. There are significant differences between drugs and medical devices that I am inclined to think argue for different, rather than equal, treatment. Nevertheless, I leave medical devices and biologics (vaccines and genetically engineered health treatments) and their treatment for design defect purposes for another day.

[5] Some courts have relied on this difference between drugs and durables. *See, e.g.*, Castrignano v. E.R. Squibb & Sons, Inc., 546 A.2d 775, 781 (R.I. 1988); Grundberg v. Upjohn Co., 813 P.2d 89, 92 (Utah 1991); *see also* ERIC W. MARTIN, HAZARDS OF MEDICATION 24 (2d ed. 1978) ("The major objective of drug research and development is to create medications with high activity, low toxicity, and relatively few side effects. But separation of both toxic and side effects from therapeutic effects within a drug series is never easy and can never be completely accomplished."). Pratt and Parnon contend that

> [a]lthough machines often can be redesigned to eliminate defects without impairing their operation, redesign of a drug may be impossible. Side effects are frequently inseparable from the product itself and the current level of scientific knowledge about drug effects may not permit tailoring a drug to specific needs or conditions, much less to specific individuals. One who seeks a particular therapeutic

drugs, therefore, the liability game is with the warnings candle, not with design. Nevertheless, in the symposium for which this Article was prepared, I was asked to address design defect issues concerning pharmaceuticals, so that is the topic that I address.

My inquiry on the different design standard for drugs contained in the Restatement (Third) begins with identification of the proffered reasons that drugs require (or deserve) special treatment. After commenting briefly on those reasons, I canvass the different ways in which to conceptualize a design defect in a pharmaceutical. With that framework in place, I then reexamine the reasons for differential treatment in light of the Restatement (Third)'s design defect standard for pharmaceuticals. It is still too early to know how section 6 of the Restatement (Third) will affect pharmaceutical product liability litigation, and an assessment of the Restatement (Third) may change as the drug-designing technology of the industry continues to improve. The implications of this inquiry are that there is a limited class of situations for which design modifications of pharmaceuticals may exist, and which the Restatement (Third) ignores in its standard for design defects of drugs. Yet there are good reasons, some explained in the Restatement (Third) and some not, for providing a quite limited standard for liability for drug design. In the end, despite the design modification criticism and some qualifications and quibbles, the Restatement (Third) appears to have the matter of drug design liability largely correct.

In addition to our inability to manipulate the product to make it safer, why are drugs different from other goods? Comment k to section 402A,[6] section 6 of the Restatement (Third), and virtually every court to confront the question of design defects in pharmaceuticals all agree that drugs are different. These groups are less than unanimous, however, in explaining why drugs are different and the implications of those differences for the appropriate liability rule for drug design.

Courts and commentators have identified the following reasons drugs are different:

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effect often faces a difficult choice: either accept the drug's defects or forego its benefits.

George C. Pratt & Fred W. Parnon, *Diagnosis of a Legal Headache: Liability for Unforeseeable Defects in Drugs*, 53 ST. JOHN'S L. REV. 517, 520-21 (1979). *But see infra* note 46 and accompanying text.

[6] *See* RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

1) Drugs are highly regulated by the Federal Food, Drug, and Cosmetic Act.[7]

2) Drugs have high social utility. Or, to put the point in economic terms, drugs provide substantial consumer surplus; most of us would pay more for drugs than we are charged because drugs have a value to most consumers well in excess of their price.[8]

3) Learned intermediaries, physicians, assist their patients in determining which drugs will be appropriate for those individual patients.[9]

4) Drugs that are harmful for some patients may be beneficial for others.[10]

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[7] *See* 21 U.S.C. §§ 301-95 (1997); 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, 753 (1989-90); James A. Henderson, Jr., *Prescription Drug Design Liability Under the Proposed Restatement (Third) of Torts: A Reporter's Perspective*, 48 RUTGERS L. REV. 471, 473-74 (1996).

[8] *See Grundberg*, 813 P.2d at 97; 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, 83 (1994); 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, 659 (1997).

This claim often contains two components. First, exposing pharmaceuticals to design defect liability will create undesirable incentives for the development of new drugs that, the argument goes, are especially beneficial products. *See* Ausness, *supra* note 7, at 764. Second, permitting design defect liability will raise the price of drugs and thereby reduce their consumption. *See id.* The latter argument is in conflict with the position that drugs provide considerable consumer surplus. The conventional wisdom is that there is considerable price inelasticity for pharmaceuticals, especially because the consumption decision is made by physicians not bearing the cost of the product. *See* John A. Rizzo, *Advertising and Competition in the Ethical Pharmaceutical Industry: The Case of Antihypertensive Drugs*, 42 J. L. & ECON. 89, 91 (1999). The advent of managed care and cost-containment strategies for health care, including drug treatment, has likely had significant impact on the degree to which the conventional wisdom is true.

A variant on the social utility claim, applicable in the vaccine context, is that drugs have public good-like qualities: We all benefit from certain vaccines whether we are the vaccinee or not. Because this paper is limited to drugs, I put aside the public-good claim.

[9] *See* James A. Henderson, Jr. & Aaron D. Twerski, *A Proposed Revision of Section 402A of the Restatement (Second) of Torts*, 77 CORNELL L. REV. 1512, 1538-39 (1992); Henderson, Jr., *supra* note 7, at 473-74. Professor Henderson claims that substantial tort deference should be given "to a marketplace for prescription drugs that appears to function almost perfectly." *Id.* at 481. Considerable evidence contradicts his assessment of the functioning of the prescription drug market. *See, e.g.*, Rizzo, *supra* note 8, at 112-13 (concluding that advertising raises the cost of pharmaceuticals for consumers and also likely contributes to greater entry barriers to new firms); *infra* note 68.

[10] *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 cmt. b (1997).

Another reason drugs are different is that they frequently involve risks that cannot be identified through reasonable research and testing. Only after the extensive premarketing approval testing required by the Food and Drug Administration (FDA) and upon distribution to the general public do those risks emerge, often after many years of use by the public.[11] That difference, a significant one, raises an important issue that I want to identify and then put aside because the issue is not peculiar to drugs. Although far more prevalent with drugs than with durable goods, this characteristic applies to all chemical products that cause insidious disease. The question is whether risks must be foreseeable before a product manufacturer has an obligation to ameliorate them. In current New Jersey case law, this is the *Beshada*[12] issue.[13]

There is a great deal of truth to the idea that drugs cannot be designed differently in the way durable goods can. There are at least three exceptions to this truth:

Combination drugs. Because they contain multiple active ingredients, combination drugs can be designed differently by omitting one or more of the components.[14] For example, Bendectin was a combination drug designed for morning sickness that initially consisted of three different active ingredients: pyridoxine (vitamin B-6) hydrochloride, an antinauseant; doxylamine succinate, an antihistamine that also has antinauseant properties; and dicyclomine hydrochloride, an antispasmodic.[15] Twenty years after Bendectin was first marketed, in tests the manufacturer performed because of amendments to the Federal Food, Drug, and Cosmetic Act, the manufacturer and the FDA discovered that the three-ingredient drug was no more effective in fighting morning sickness than was a two-

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[11] The difficulty in identifying drugs that cause disease is that the mechanisms of action can rarely be observed and are often poorly understood, often the time from exposure to clinical symptoms is decades or more, and other causes of the disease exist, so that epidemiologic or toxicologic studies are required to determine whether causation exists. *See, e.g.*, TEXTBOOK OF ADVERSE DRUG REACTIONS 2 (D.M. Davies ed., 3d ed. 1985) (explaining that it was 39 years before aspirin was identified as a cause of gastric hemorrhage).

[12] Beshada v. Johns-Manville Prods. Corp., 90 N.J. 191, 447 A.2d 539 (1982).

[13] *See* Vassallo v. Baxter Healthcare Corp., 696 N.E.2d 909, 922-23 & n.17 (Mass. 1998) (overruling earlier case law that imputed knowledge of risks regardless of whether they could reasonably be known at time of manufacture and sale, and observing that very few jurisdictions continue to employ an imputing rule).

[14] *See* Cupp, Jr., *supra* note 8, at 94; Ausness, *supra* note 7, at 728.

[15] *See* Joseph Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 HASTINGS L.J. 301, 317 (1992).

ingredient drug that omitted dicyclomine hydrochloride.[16] The FDA required the manufacturer to remove dicyclomine hydrocholoride, and the manufacturer sold the drug thereafter with only two active ingredients.

A variation on the combination drug exception relates to the inert ingredients used to coat, bind, or deliver the active ingredients to the patient.[17] That inert ingredient can be changed and, at least on occasion, may pose real risks. The Federal Food, Drug, and Cosmetic Act was reconceived to protect against unsafe drugs in the wake of a 1938 tragedy that caused the deaths of over 100 children because a drug manufacturer employed diethylene glycol (antifreeze) as a solvent to prepare a liquid form of a popular antibiotic.[18]

Dosage. In a second exception to the idea that drugs cannot be designed differently, manufacturers might modify a drug by lowering its dose so that the same therapeutic benefits are provided, but the adverse effects are eliminated or ameliorated with the lower dose.[19] This merely reflects the toxicological dictum, now some four centuries old, that "the dose makes the poison."[20] In many cases, the physician must adapt the dose for a patient on an individual basis.

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[16] *See* JOSEPH SANDERS, BENDECTIN ON TRIAL: A STUDY OF MASS TORT LITIGATION 1, 4 & n.9 (1998). Another example is fiorinal, a prescription drug for headaches, which originally contained a barbiturate, aspirin, caffeine, and phenacetin, an analgesic. In 1981, phenacetin was removed from the market because of safety concerns, and fiorinal was redesigned without the phenacetin component. *See* FOOD & DRUG LETTER, May 22, 1981, at 3.

Combination drugs are generally disfavored by independent pharmacologists. *See* MARTIN, *supra* note 5, at 26 ("Fixed combinations of some drugs, one or more of which cause problems such as hypersensitization or rapid development of resistant organisms, have been prepared. Thus, not only is flexibility of dosage lost, but also the efficacy of a good drug that may be present.").

[17] *See* TEXTBOOK OF ADVERSE DRUG REACTIONS, *supra* note 11, at 25 (identifying, as potential sources of adverse effects, "the additives, solubilizers, stabilizers, colorizers, and excipients commonly incorporated in pharmaceutical preparations.").

[18] *See* CHARLES O. JACKSON, FOOD AND DRUG LEGISLATION IN THE NEW DEAL 152-61 (1970); MARTIN, *supra* note 5, at 26.

[19] *See, e.g., Improved Safety with Low-Estrogen Oral Contraceptives*, FDA MED. BULL. 11 (May 1994) (low-dose oral contraceptive users found at lower risk of thromboembolism than higher-dose oral contraceptive users); Brochu v. Ortho Pharm. Corp., 642 F.2d 652, 654 (1st Cir. 1981) (design defect claim against oral contraceptive manufacturer alleging excessive dosage of estrogen and concomitant higher risk of stroke); INSTITUTE OF MEDICINE, HALCION: AN INDEPENDENT ASSESSMENT OF SAFETY AND EFFICACY DATA (1997) (visited Nov. 8, 1999)<http://www.nap.edu/readingroom/books/halcion/>.

[20] Paracelsus provided this dictum in the sixteenth century. For a modern version of this tenet, see Ellen K. Silbergeld, *The Role of Toxicology in Causation: A Scientific Perspective*, 1 CTS. HEALTH SCI. & L. 374, 378 (1991).

But manufacturers provide recommended doses and, in some instances (oral contraceptives being a notable example), effectively determine the dose that each patient receives.

Drug Engineering. The final exception to the rule that manufacturers can redesign drugs is generally more theoretical than contemporaneously real, although sufficiently attainable that attention is justified. Already, rational drug design permits pharmaceutical researchers to identify a limited number of chemical compounds that are most likely to have the desired physiological effects, and thereby limit testing to those select compounds rather than conduct initial screening on tens of thousands of different compounds.[21] With the tools of microbiology and biotechnology, manufacturers may engineer drugs so as consciously to modify their molecular structure to weed out adverse effects while retaining therapeutic benefits. As technology continues its inexorable march, this exception will become more significant.

There is even more truth to the proposition that prescription drugs are heavily regulated. Indeed, a persuasive case can be made that drugs are the most heavily regulated industry in the United States.[22] That is not to say that the FDA never errs by approving a drug that should not be on the market.[23] Nor is it to say that the FDA does not delay approval of drugs for longer than is optimal — a matter of serious health concern, if not of tort law concern.[24] It is to say that the FDA probably does as good a job as any human institution can do, given its resources, in balancing protection of the populace with making new beneficial therapies available to the public in the new drug approval process.[25] If government oversight of drug

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[21] *See Combinational Chemistry Hits the Drug Market*, 272 SCI. 1266, 1266-68 (1996) (describing combinational chemistry methods that permit researchers to synthesize compounds with slightly altered molecular structures to target specific physiological actions); *see also infra* note 46 and accompanying text.

[22] The former director of the Food and Drug Administration's Bureau of Drugs observed that pharmaceuticals "are today the most heavily regulated consumer products in our society." J. Richard Crout, *The Drug Regulatory System: Reflections and Predictions*, 36 FOOD DRUG COSM. L.J. 106, 113 (1981); *see also* Grundberg v. Upjohn Co., 813 P.2d 89, 96 (Utah 1991) ("No other class of products is subject to such special restrictions or protections in our society.").

[23] *See infra* note 74.

[24] *See* Sam Kazman, *Deadly Overcaution: FDA's Drug Approval Process*, 1 J. REG. & SOC. COSTS 35, 35 (1990).

[25] *See* Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J.L. REFORM 461, 477 (1997) [hereinafter Green, *Statutory Compliance*]; *see also* Henderson, Jr., *supra* note 7, at 492 (stating that the Restatement (Third) "reflects the view that courts are institutionally unequipped to substitute their approval of a proposed new drug, on a case-by-case basis, for that of the FDA").

safety, ex ante, is as substantial as it is, why do we need tort law, ex post, to provide deterrence?[26]

The truth value of the third supposed difference has a significant drop-off from the first two differences. There are breakthrough drugs that promise enormous social benefit, and these are, no doubt, the drugs that are called to mind when this difference is cited. But, as many have cautioned, most drugs are not the social-utility equivalent of a cure for AIDS.[27] Indeed, the vast majority of new drugs provide little therapeutic advantage. Many new drugs are "me-too" drugs brought to market in the hope that their manufacturer will be able to obtain some market share for a disease or condition that is prevalent. Likewise, these drugs may provide modest or trivial therapeutic advantages.[28] Rogaine may be near and dear to the hearts of some, but it is not the social-welfare equivalent of antibiotics.

The learned intermediary, which might be idealized as the physician with perfect information about the available drug therapy (its characteristics, risks, and benefits) and her patient's condition, personal characteristics, and medical history, supports the theory that we do not have to worry about pharmaceutical market failure because of a lack of information or rational consumer behavior.[29]

The Food and Drug Administration's (FDA) competence in protecting safety in the new drug-approval process must be distinguished from its oversight of safety in the postmarketing phase. Resource and structural impediments impede the FDA in this sphere. *See* THOMAS J. MOORE, PRESCRIPTION FOR DISASTER: THE HIDDEN DANGERS IN YOUR MEDICINE CABINET 111-12, 115-17 (1998). And the postmarketing period is crucial in minimizing the risks of prescription drugs. *See* Green, *Statutory Compliance*, *supra*, at 496-500; Jeffrey N. Gibbs & Bruce F. Mackler, *Food and Drug Administration and Products Liability: Strong Sword, Weak Shield*, 22 TORT & INS. L.J. 194, 228 (1987).

[26] Of course, one might argue that tort law furthers goals other than deterrence and should be retained for one or more of those reasons. *See* Robert Rabin, *Reassessing Regulatory Compliance*, 88 GEO. L.J. (forthcoming 1999).

[27] *See* HENRY G. GRABOWSKI, DRUG REGULATION AND INNOVATION 20-22 (1976) (noting that most drugs are unimportant because they represent little or modest improvement over existing drugs); UNITED STATES GENERAL ACCOUNTING OFFICE, FDA REVIEW AND APPROVAL TIMES: STATEMENT OF MARY R. HAMILTON 4 (reporting that 83% of new drug applications (NDA) "were for drugs that FDA considered to offer little therapeutic benefit beyond that already available to patients").

[28] *See, e.g.*, UNITED STATES GENERAL ACCOUNTING OFFICE, FDA DRUG APPROVAL: REVIEW TIME HAS DECREASED IN RECENT YEARS 5 (1995) (less than 20% of new drug approvals are for priority drugs); MARTIN, *supra* note 5, at 27-28 ("Drugs essentially no more effective than those already available have been developed merely to compete in the market, perhaps a necessary goal in a highly competitive society."). *But see* GRABOWSKI, *supra* note 27, at 6-7 (claiming that the market disciplines manufacturers; drugs that do not offer an advantage over existing drugs are unprofitable).

[29] *See generally* Christine Jolls et al., *A Behavioral Approach to Law and Economics*, 50

The final difference claimed between drugs and durables is that some drugs that are unreasonably dangerous to some consumers may be beneficial to another class of consumers. But, at one level, this claim is unpersuasive. Professor Cupp has adverted to a hypothetical car in which the manufacturer decided to omit standard safety devices to better serve consumers desiring an economy vehicle: "In a nondrug context such as this automobile hypothetical, no court would preclude design liability solely because there exists a class of consumers who benefit from the dangerous design."[30] Even if the analogy is improved by considering trade-offs in functionality or effectiveness with safety (which is the case with drugs), rather than dollars and safety (which is the case with Professor Cupp's hypothetical), one can imagine a forklift with a roll-over protective device that simply could not be used on a ship with low ceilings, or a childproof cap for drugs that is also elderly-proof, or a redesigned Bic lighter for a childless couple with arthritis. Still, as Professor Cupp noted, no court would automatically rule out liability for a redesigned version of these products to meet the needs of these groups merely because a minority of consumers are made better off by the design.[31]

STAN. L. REV. 1471 (1998).

[30] Cupp, Jr., *supra* note 8, at 99.

[31] At least one case suggests that the statement in the text may be a bit cavalier. In *Dreisonstok v. Volkswagenwerk, A.G.*, the plaintiff claimed a design defect in a Volkswagen microbus after the vehicle crashed into a telephone pole. *See* 489 F.2d 1066, 1068 (4th Cir. 1974). The trial court ruled for the plaintiff based on the plaintiff's comparison of the crashworthiness of the microbus with a standard passenger automobile. *See id.* at 1069. The court of appeals reversed and stated:

> The defendant's vehicle, described as 'a van type multipurpose vehicle,' was of a special type and particular design. This design was uniquely developed in order to provide the owner with the maximum amount of either cargo or passenger space in a vehicle inexpensively priced and of such dimensions as to make possible easy maneuverability. To achieve this, it advanced the driver's seat forward, bringing such seat in close proximity to the front of the vehicle, thereby adding to the cargo or passenger space. This, of course, reduced considerably the space between the exact front of the vehicle and the driver's compartment. All of this was readily discernible to any one using the vehicle; in fact, it was, as we have said, the unique feature of the vehicle. The usefulness of the design is vouchsafed by the popularity of the type. It was of special utility as a van for the transportation of light cargo, as a family camper, as a station wagon and for use by passenger groups too large for the average passenger car. It was a design that had been adopted by other manufacturers, including American. It was a design duplicated in the construction of the large trucking tractors, where there was the same purpose of extending the cargo space without unduly lengthening the tractor-trailer coupling. There was no evidence in the record that there was any practical way of improving the 'crashability' of the vehicle that

Yet there may be more to this distinction than Professor Cupp and others recognize. Third-party effects are at least part of the reason for refusing to permit a car to be manufactured without standard safety features.[32] By this, I mean the risks that are posed to others — passengers, drivers of other automobiles, pedestrians — by the automobile purchaser's decision to buy a car without standard safety features. Similarly, the concern with an inadequately guarded industrial machine is not that the employer-purchaser will mangle her hand in the nip point, but that a worker who had no input in the decision to buy a more functional, but less safe, machine will be exposed to the risks it poses, or that a Bic lighter may be found by the visiting godchild of the childless couple, or that a grandchild may discover the vial of sedatives in her grandparents' medicine cabinet. To the extent that one is willing to leave decisions about safety to a marketplace with reasonably good information, as long as there are no third-party effects, drugs largely fit this profile, at least in theory. Only in the rarest situation is there any potential for third-party effects from drugs.

This recognition of the absence of third-party effects goes hand-in-hand with another difference between drugs and durables that supports the position of the Reporters of the Restatement (Third) and others who assert this "different benefit/risk ratio for different classes of consumers" argument. The Reporters conceive of a design defect claim as one in which the plaintiff claims that another drug constitutes a reasonable alternative design that has less risk than the original, thereby rendering the original drug defective under the design defect standard contained in section 2(b). Their view is that physicians, who have complete (or nearly so) information about the benefits and risks for different drugs, can assure that the appropriate drugs reach the appropriate patients, thereby averting any market failure due to inadequacy of information or even ill-conceived choices. The real distinction on which the supposed different-

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would have been consistent with the peculiar purposes of its design.

Id. at 1073-74 (footnotes omitted).

This case suggests that the question of whether a design for a limited market can be judged by comparison with alternative designs that would only meet the needs of a broader market cannot be answered categorically. Notably, the plaintiff was an injured passenger, not the purchaser of the vehicle. *See id.* at 1068.

[32] I should qualify this claim by recognizing that a strong strain of paternalism runs through products liability law. This view protects each of us from our cognitively imperfect, information-deprived selves. To the extent that this protective function is emphasized, drugs are no different from lawn darts for purposes of having tort law provide minimum levels of safety, regardless of consumer preference.

benefits difference rests is the existence of physicians exercising informed decisions about drug choice and the relative absence of third-party effects — not that drugs are different because they offer differential benefits and risks to different classes of patients.

As the foregoing discussion reveals, identifying the legal standard for defectively designed drugs is essential. This is a critical inquiry, the single most ignored issue in the area of pharmaceutical liability. There has been much ado about whether comment k abolishes negligent design defect liability as well as strict liability design claims.[33] But the real question is: What do we mean by a design defect of a drug, whether based on strict liability or negligence?

There are several possible answers. The first is the one that Prosser, no doubt, had in mind when drafting comment k.[34] Recall that the standard for defectiveness in section 402A was consumer expectations,[35] and for many years, the courts adopted that standard as the measure of defectiveness.[36] So, what about a drug that is defective because it is dangerous beyond consumer expectations?

The issue must first be modified because of our learned intermediary. The law decrees that drug manufacturers satisfy their information obligation by providing information to the physician, as agent for the consuming patient. Thus, we should edit our inquiry to: "What about a drug that is defective because it is dangerous beyond prescribing physician expectations?"[37] Note that the

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[33] *See, e.g.*, Cupp, Jr., *supra* note 8, at 88.

[34] Since first writing this, I have begun to doubt its correctness. What Prosser may have been concerned with in comment k was the possibility that strict liability would be imposed on drugs (or other unavoidably dangerous) products merely because of a decision maker's intuitive sense that the product's dangers are too great. This defect appears very much like categorical liability or product condemnation defects, which I address below. *See infra* notes 73-76 and accompanying text.

[35] *See* RESTATEMENT (SECOND) OF TORTS § 402A cmts. i & j (1965).

[36] *See, e.g.*, Caterpillar Tractor Co. v. Beck, 593 P.2d 871, 882 (Alaska 1979); Dunham v. Vaughan & Bushnell Mfg. Co., 247 N.E.2d 401, 403 (Ill. 1969); Lester v. Magic Chef, Inc., 641 P.2d 353, 361 (Kan. 1982).

[37] Informed consent law might require the physician to tell the patient of the risks involved in taking the drug, thereby ensuring that even consumer expectations will not be violated. *See* MacPherson v. Searle & Co., 775 F. Supp. 417, 423 (D.D.C. 1991) (citing Crain v. Allison, 443 A.2d 558 (D.C. App. 1982), in which the court stated that informed consent requires disclosure of the risks and benefits of a prescribed drug and denied summary judgment to doctor who prescribed drug to plaintiff). Whenever the drug therapy is significant in treating a serious medical condition, however, any breach of the informed consent obligation is unlikely to result in a viable cause of action because the consumer will be unable to demonstrate that she would have refused the drug and thereby avoided the adverse side effect.

consumer expectations standard does not require identification of an alternative design; only when we move to a risk-benefit test do we need to have an alternative design by which to compare risks and benefits.[38]

But a design defect claim under consumer expectations would not provide much beyond that which already is provided by the warnings obligation. If a pharmaceutical manufacturer provides adequate information about adverse effects, contraindications, and safe use of the drug, then expectations, informed by this information, will not be disappointed.[39] Thus, with an exception that need not detain us,[40] a consumer expectations-based design defect claim would

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[38] Of course, that explains the struggle in the Restatement (Third) to identify a design standard for drugs. The Restatement (Third) rejects the consumer expectations test as the basis for design defectiveness and replaces it with a risk-benefit test. The risk-benefit test, with its ancillary necessity for identification of an alternative design, explains the Restatement (Third)'s conceptualization of other drugs for the same health condition as being the alternative design that might be employed in order to conduct a risk-benefit analysis. True risk-benefit analysis requires identification of an alternative design. *See, e.g.*, Gary T. Schwartz, *Foreword: Understanding Products Liability*, 67 CAL. L. REV. 435, 468 (1979) ("The heart of the problem is this: one simply cannot talk meaningfully about a risk-benefit defect in a product design until and unless one has identified some design alternative (including any design omission) that can serve as the basis for a risk-benefit analysis."); Michael D. Green, *The Schizophrenia of Risk-Benefit Analysis in Design Defect Litigation*, 48 VAND. L. REV. 609, 623 (1995) [hereinafter Green, *Schizophrenia*].

[39] The consumer expectations test frequently insulated manufacturers from liability for dangers that were open and obvious. *See* Vincer v. Esther Williams All-Aluminum Swimming Pool Co., 230 N.W.2d 794, 799 (Wis. 1975) (holding that there could be no liability as a matter of law when the average consumer would be completely aware of the danger to children posed by an above-ground swimming pool and its retractable ladder that was left in the down position). The consumer expectations test also tended to protect manufacturers for risks that were adequately warned about, because once the dangers were in the open, consumer expectations would not be violated. The practical effect of such a rule, though many courts denied it, was to insulate design liability of a manufacturer as long as it provided an adequate warning. *See, e.g.*, Uloth v. City Tank Corp., 384 N.E.2d 1188, 1192 (Mass. 1978) (declining "to adopt any rule which permits a manufacturer or designer to discharge its total responsibility to workers by simply warning of the dangers of a product"); *see generally* Howard Latin, *"Good" Warnings, Bad Products, and Cognitive Limitations*, 41 U.C.L.A. L. REV. 1193 (1994).

[40] The exception relates to the need for a plaintiff to prove that the failure to provide adequate warnings caused the plaintiff's injury. Logically, this requires proof that the physician who made the decision to prescribe would have responded differently if adequate warnings had been provided. I suspect that some physicians, because of antilegal and antilitigation views, would be reluctant to acknowledge that they would have prescribed differently, even if they had been provided full information about the risks and benefits of a drug. *See* Chambers v. G.D. Searle & Co., 441 F. Supp. 377, 384 (D. Md. 1977), *aff'd*, 567 F.2d 269 (4th Cir. 1977) ("The evidence here shows that as a result of what [the doctor] knew and the conclusions he drew from what he knew, it would have made no difference if the warnings were

not seem to provide anything to consumers that the adequate warning obligation already provides.[41]

What about a risk-benefit test applied to drugs? Risk-benefit, in contrast with consumer expectations, imposes design obligations even when a risk is fully disclosed, but only when an alternative safer design is available.[42] Here, we should acknowledge an important aspect of the Restatement (Third)'s treatment of pharmaceuticals: It makes no provision for proof of a design defect based on the demonstration of an alternative design of the drug that would be safer, and, on balance, would provide a preferable drug. Indeed, section 6 appears not to have conceptualized this as a possibility for a design defect claim. One good reason for this omission is that, as was mentioned earlier, most single-agent drugs cannot be designed differently. But there are a number of exceptions, and each of the exceptions previously mentioned provides a plausible basis for a design defect analysis of a drug based on section 2(b) of the Restatement (Third), the general design defect section. Thus, in the case of the Massengill Company's "Elixir Sulfanilamide," the drug was defective because of the diethylene glycol solvent that its manufacturer employed to deliver sulfanilamide, the first of the sulfa drugs.[43] There was nothing wrong with the sulfanilamide. The risk was solely a result of the choice of solvent, a characteristic of sulfanilamide that was in no way immutable.[44] Surely, there is no reason a drug that, while still beneficial for some class of patients, but could be rendered safer for all patients without reducing its therapeutic benefit, should not be subjected to a risk-benefit analysis of the form set forth in section 2(b) of the Restatement (Third).

Similarly, there is no reason marginal improvements cannot be conceived of for combination drugs. The examples already mentioned, Bendectin and fiorinal,[45] illustrate the way in which some combination drugs may be designed alternatively to reduce their risk

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in the form which plaintiff contends would be adequate."). *But see* DeLuryea v. Winthrop Labs., 697 F.2d 222, 225-26 (8th Cir. 1983) (plaintiff not required to have physician testify about the impact of warnings on prescription decision); Wooderson v. Ortho Pharm. Corp., 681 P.2d 1038, 1057 (Kan. 1984).

[41] *But see* Ausness, *supra* note 7, at 736 (concluding that manufacturers would fare worse under a consumer expectations standard than they do with comment k). In reaching his conclusion, Professor Ausness fails to consider the role of warnings in affecting expectations.

[42] *See* Schwartz, *supra* note 38, at 468; Green, *Schizophrenia*, *supra* note 38, at 617.

[43] *See* PETER TEMIN, TAKING YOUR MEDICINE: DRUG REGULATION IN THE UNITED STATES 42 (1980).

[44] *See id.* at 42, 48; *see also* JACKSON, *supra* note 18, at 153-61.

[45] *See supra* notes 15-16 and accompanying text.

without diminishing their efficacy. Finally, medicinal chemistry, a branch of pharmacology that relies on rational drug design, has progressed to the point that some drugs can be engineered by modifying the molecular structure of a known substance in order to make it more efficacious or to remove adverse side effects. Tagamet (cimetidine), a billion-dollar anti-ulcer drug, is an example of a drug that was developed through manipulation of the molecular structure of other, similar chemicals.[46] While the number of such successful efforts in designing new drugs based on what is known about molecular structure and its effect on biological mechanisms of action is quite small, it seems safe to predict that these efforts will become more widespread and successful as technology improves.

Before drug engineering through medicinal chemistry can have a practical impact on drug design law, the technology will have to progress so that researchers can, with some confidence, know that specific modifications of a chemical's molecular structure will have predictable effects. Until that is the case, even rational drug design, while reducing the number of new substances required to be tested from thousands to a few, still requires that those few go through the full panoply of new drug testing to confirm that the drug has the predicted therapeutic benefits and adverse effects. As Professor Aaron Twerski pointed out to me, we surely do not want to require courts in drug design cases to determine what would happen in clinical trials and in the FDA new drug approval process of a potentially promising new compound identified through medicinal chemistry techniques.

Nevertheless, what emerges from this analysis is that a critical criterion for insulating drugs, or any other products for that matter, from the standard design defect analysis is that the drug itself is not capable of being changed in any fashion that would make it safer. When a drug can be made safer, the justifications for different design treatment no longer exist. But because drugs can, at least in some circumstances, be designed for increased safety, the Restatement (Third) seems correct in adopting the position that design defect liability for pharmaceuticals may sometimes be appropriate, if not in appropriately defining the scope of liability.

One possible response to this critique is to trot out another difference between pharmaceuticals and other durable goods — FDA regulation — and to assert that, with such careful regulatory

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[46] *See* WILLIAM O. FOYE et al., PRINCIPLES OF MEDICINAL CHEMISTRY 435-38 (4th ed. 1995).

oversight, we need not have tort law (and inexpert juries) second-guessing FDA expert determinations.[47] While there is considerable force to this claim that the FDA is better able to determine whether a drug's benefits outweigh its risks and what those risks are than is the civil justice system, there are a number of difficulties with this argument. First, the FDA's regulatory authority for drugs is reactive, not proactive. The FDA responds to a New Drug Application submitted by a pharmaceutical manufacturer that has identified and tested a new drug to determine whether the drug is effective and safe.[48] The FDA does not regulate the design of a drug and whether it might be formulated differently to improve the therapeutic benefit-to-risk ratio, although a combination drug would not be approved today unless the manufacturer had conducted studies that demonstrated that each active component made a positive contribution to the efficacy-to-risk ratio of the combination drug. Even if the FDA oversaw the design of drugs, and a great deal that the FDA does is done informally in negotiations with industry manufacturers,[49] an important qualification on reliance on the FDA with regard to drug design must be recognized.

The explanation for that qualification begins with the understanding that the FDA is entirely dependent on testing that is performed and reported by the sponsoring manufacturer when the FDA approves a new drug.[50] It should be noted, however, that the FDA regulates the testing process, including the study design, the method by which the design is carried out, and data integrity.[51] Thus,

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[47] *See* Henderson, Jr., *supra* note 7, at 491; Aaron D. Twerski, *Inside the Restatement*, 24 PEPP. L. REV. 839, 854 (1997).

[48] *See* 21 U.S.C. § 355(b) (Supp. III 1994) (describing the required contents of an NDA); *Id.* § 355(d) (describing criteria for FDA approval or rejection of NDA); Richard A. Merrill, *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1, 8-10 (1973) ("Although no provision of the Federal Food, Drug, and Cosmetic Act provides that the FDA may approve a drug only if the benefits outweigh the risks, this inevitably is the crux of any decision to permit a new drug to be marketed or to allow an old one to remain on the market."); Dixie Farley, *Benefit Vs. Risk: How FDA Approves New Drugs*, 21 FDA CONSUMER 7, 7 (Dec. 1987-Jan. 1988) (noting that both safety and efficacy must exist for the FDA to approve a drug, but some risk always is associated with a drug: "[i]t's when the benefits outweigh the risks that FDA considers a drug safe enough to approve").

[49] *See* PETER B. HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW: CASES AND MATERIALS 1178-1206 (2d ed. 1991).

[50] *See* 21 U.S.C. § 355(b) (Supp. III 1994); *see also* Merrill, *supra* note 48, at 17 n.59; *cf.* Paul Dueffert, *The Role of Regulatory Compliance in Tort Actions*, 26 HARV. J. ON LEGIS. 175, 206 (1989) (stating that "a drug . . . must undergo extensive testing by the [FDA]").

[51] See Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1778-83 (1996).

accepting, arguendo, that we can rely on the FDA to ensure optimal design before approving a drug, we must require that a manufacturer complied with FDA testing and reporting requirements before deferring to its judgment on design questions.[52] Yet one looks in vain

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[52] The Author has previously argued that:

> we should recognize that any defense based on FDA regulation would have to be structured as a compliance with FDA regulatory standards rather than as a defense based on FDA approval of the drug in question. The reason is quite simple but based on a fact that is not well known: the FDA's approval of a drug, which includes a determination of the appropriate labeling (i.e., warnings) is wholly dependent on testing performed and reported by the sponsoring manufacturer. The FDA conducts none of the testing [required to] demonstrate that a proposed new drug is safe and effective [as] required by the 1962 Kefauver-Harris Amendments to the Food, Drug, and Cosmetic Act for approval of new drugs by the FDA. The FDA does review the results of the tests performed by the manufacturer and submitted as part of its NDA; sometimes the FDA will request additional information or tests. In the end, it is the FDA that makes the judgment whether a drug is safe and efficacious. Any conclusion that the FDA's approval represents a considered assessment that an approved drug's therapeutic benefits outweigh its risks, however, is unwarranted without manufacturer investigation that complies with FDA requirements for adequate and well-controlled studies of the new drug, accurate reporting of the results of those tests, and truthful responses to inquiries by the FDA.

Green, *Statutory Compliance*, *supra* note 25, at 481 (footnotes omitted); *see also* Williams v. Ciba-Geigy Corp., 686 F. Supp. 573, 577 (W.D. La. 1988) (permitting plaintiff to make a design defect claim upon a showing that "FDA approval was based on erroneous data.").

While I do not know the incidence of manufacturers failing to provide complete and accurate information to the FDA during the premarketing testing phase, there are a number of notable examples in which manufacturers have not conscientiously fulfilled their obligations. *See* Benedi v. McNeil-P.P.C., Inc., 66 F.3d 1378, 1389 (4th Cir. 1995) (involving a manufacturer that failed to provide drug experience reports on a timely basis); Hearings on Preclinical and Clinical Testing by the Pharmaceutical Industry Before the Subcomm. on Health of the Senate Comm. on Labor and Pub. Welfare and the Subcomm. on Admin. Practice and Procedure of the Senate Comm. on the Judiciary, 94th Cong. 725 (1975) (statement of a former FDA Commissioner characterizing the problem of false and misleading reporting to the FDA as "serious and grave"); JOHN ABRAHAM, SCIENCE, POLITICS AND THE PHARMACEUTICAL INDUSTRY 92-96 (1995) (summarizing the inaccurate and incomplete data submitted to the FDA in support of the NDA for Naproxen); STEVEN GARBER, PRODUCT LIABILITY AND THE ECONOMICS OF PHARMACEUTICALS AND MEDICAL DEVICES 188 (1993) (noting that "there is substantial evidence of incomplete compliance with FDA regulations"); MICHAEL D. GREEN, BENDECTIN AND BIRTH DEFECTS: THE CHALLENGES OF MASS TOXIC SUBSTANCES LITIGATION 83-86, 128-29 (1996) [hereinafter GREEN, BENDECTIN AND BIRTH DEFECTS] (describing the events surrounding the cover-ups of the adverse effects and event reports of MER / 29 and Bendectin); Merrill, *supra* note 48, at 5-6 (recounting McNeil Laboratories' concealment of the adverse effects of Flexin); Teresa Moran Schwartz, *Punitive Damages and Regulated Products*, 42 AM. U. L. REV. 1335, 1348-52 (1993) (describing

at section 6 of the Restatement (Third) for any requirement that products meet regulatory *compliance*,[53] as opposed to merely regulatory approval, before design claims invoking alternative designs of the same product are barred.[54]

Might another difference between drugs and other goods support a design standard that imposes no obligation on the manufacturer to attempt to improve the drug itself? The only plausible possibility is the existence of a learned intermediary, the physician. In theory, the physician makes a careful judgment about

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several instances in which drug manufacturers concealed from the FDA the adverse effects of new drugs); *Excerpts from Dr. Goddard's Address*, N.Y. TIMES, Apr. 7, 1966, at 24 (expressing dismay on the part of the then-FDA Commissioner regarding poor quality and dishonesty in the submission of investigational drug studies).

[53] One might respond that, if a manufacturer fails to comply with FDA regulatory requirements, then it would be liable *per se* or the product would be deemed defective. The situation is considerably more complicated than that because of the need to connect the manufacturer's failure to comply with the plaintiff's harm. *See* Green, *Statutory Compliance*, *supra* note 25, at 490-96. Section 4(a), which provides that a product is defective if it fails to comply with an "applicable product safety statute or administrative regulation," arguably might apply in the situation in which a drug was approved based on studies that did not comply with FDA requirements or based on other misconduct by the manufacturer in the premarketing testing that produced a biased NDA. *See* RESTATMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4(a) (1997). The difficulty is that section 4(a) appears to be limited to product standard statutes and regulations, not ones that govern the process of testing.

[54] Several states have adopted statutes specifically addressing FDA drug approval, although most of the statutes require compliance with FDA regulations as a prerequisite to a tort defense, not merely FDA approval of the drug. *See, e.g.*, ARIZ. REV. STAT. ANN. § 2-701 (West 1992) (insulating drug manufacturer from liability for punitive damages if the drug was approved by and labeled in accordance with FDA requirements; no protection from liability, however, if plaintiff proves that manufacturer knowingly violated FDA regulations in failing to provide information or misrepresenting that which it provides); MICH. COMP. LAWS ANN. § 600.2946(5) (West Supp. 1999) (pharmaceutical manufacturer is not liable for drug approved by FDA subject to exception for fraud on or bribery of FDA); N.J. STAT. ANN. § 2A:58C-4 (West 1987) (rebuttable presumption that a warning provided in FDA-approved labeling is adequate); N.C. GEN. STAT. § 99B-6 (1996) (singling out drugs and providing that if they are approved by the FDA with labeling that conforms to government standards, that fact is relevant to whether the manufacturer is liable); OHIO REV. CODE ANN. § 2307.801(C) (Banks-Baldwin 1997) (barring punitive damages against manufacturer of drug manufactured and labeled in compliance FDA requirements, provided that manufacturer did not withhold or misrepresent material information to FDA); OR. REV. STAT. § 30.927 (1995) (barring punitive damages in pharmaceutical case in which drug and labeling was approved by FDA, provided that material information was not withheld or misrepresented to prescribing physicians or FDA); UTAH CODE ANN. § 78-18-2 (1996) (prohibiting the award of punitive damages if the drug causing the claimant's harm received premarketing approval or licensure by the FDA, unless it is shown, by clear and convincing evidence, that the drug manufacturer knowingly withheld or misrepresented material and relevant information from FDA).

the propriety of a given drug for the patient based on the drug's characteristics and the individual circumstances of the patient. Professor Henderson avowedly believes so: "Unless one is ready to admit to the possibility of frequent, massive failures in the 'FDA-learned intermediary' market system, the rule . . . adopted by the [American Law Institute] represents the appropriate judicial response to prescription drug design liability."[55]

Professor Henderson's argument is persuasive in one context. The presence of the physician may justify declining to permit a design challenge based on other drugs that are available to treat the patient's condition (as explained below).[56] But surely the physician has no role in overseeing the pharmaceutical manufacturer, and any choices that the manufacturer makes about how to coat, combinate, or formulate its drugs.[57] In those respects, the learned intermediary is of no more assistance in protecting the patient's interests than is a metal detector in providing security against a B-52 bombing.

The final difference to consider is the high social value of drugs: the importance of making them readily available and of encouraging research into new drugs by the pharmaceutical industry. The essential concern is overdeterrence, that tort liability may deter research that would yield socially beneficial drugs or that building the costs of adverse effects into the price of drugs would put them out of reach for some consumers.

With regard to overdeterrence, existing evidence is equivocal and does not get to the heart of the question. There is no method for systematically identifying or measuring the foregone research and development efforts of pharmaceutical companies, its consequences for new drug development, or the drugs that were driven off the market because of liability concerns.[58] Nor is there any means for

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[55] Henderson, Jr., *supra* note 7, at 486.

[56] *See infra* notes 67-69 and accompanying text.

[57] In short, the most that the learned intermediary function of the doctor can justify in terms of designing a liability regime is that, as long as adequate information is provided by drug manufacturers to physicians, we can rely on that information to protect against consumer behavior that is suboptimal in selecting drugs. *See* Henderson, Jr., *supra* note 7, at 481 & n.55 (claiming that the market for prescription drugs works "remarkably well"). The recent development of direct-to-consumer advertising of prescription drugs and its aggressive adoption by the pharmaceutical industry raises serious questions about whether physicians even serve this rational gatekeeping function. Of course, to the extent that pharmaceutical advertising concerns elective and cosmetic matters (such as advertising of Rogaine), we are dealing with products that are central to consumer choice and desire and do not implicate therapeutic decision making.

[58] This discussion is drawn from GREEN, BENDECTIN AND BIRTH DEFECTS, *supra*

comparing these costs of overdeterrence with the benefits derived from drugs that properly never made it to market because of their danger. There are some highly publicized reports of individual useful drugs that were removed from the market because of liability concerns, including Bendectin, several vaccines, and, to extend the list to medical devices, the Copper-7 IUD, and, as the evidence increasingly suggests, silicone gel breast implants. Counterbalancing this anecdotal list are a number of instances in which the tort system was the engine for the removal of dangerous drugs and medical devices, including diethylstilbestrol (DES) and the Dalkon Shield IUD. Steven Garber, the author of a careful Rand Institute study, concludes that liability is unlikely to deter efforts to develop drugs that offer a major breakthrough over existing therapies. Other factors, such as company's market niche, strategic goals, and regulation, probably play a more powerful role in determining the research and development activities of firms in the industry. The research activity that liability concerns do affect in high-risk areas such as birth control and pregnancy is likely shifted to other therapeutic areas, rather than completely lost. The vast majority of drugs do not have liability concerns, and even some that do, such as Accutane and thalidomide (both known teratogens), are currently being marketed. Especially with regard to design liability based on redesigning the drug itself, one would expect this quite limited theory to have modest adverse impact on drug firms' research and development behavior.

In the alternative design milieu, a risk-benefit analysis should impose liability only when the overall benefits of the drug can be improved. To refuse to examine alternative design possibilities is akin to saying, after a dialysis patient is electrocuted by a dialysis machine due to a defect in the grounding of the machine: "Because dialysis machines are so important to the health of those with damaged kidneys, we will not permit examination of the electrical design of this machine to determine if it might have been made in a way to eliminate the risk of electrocution." At the margin, we should always be willing to examine whether we can improve the overall benefit-to-risk ratio of a product.[59]

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note 52, at 339-41; *see also* GARBER, *supra* note 52, at 95-97, 103-04; JUDITH P. SWAZEY, *Prescription Drug Safety and Product Liability*, *in* THE LIABILITY MAZE: THE IMPACT OF LIABILITY ON SAFETY AND INNOVATION 291 (Peter W. Huber & Robert E. Litan eds., 1991).

[59] This is a mistake that many make. *See generally* Green, *Schizophrenia*, *supra* note 38; Mark F. Grady, *Why Are People Negligent? Technology, Nondurable Precautions, and the Medical Malpractice Explosion*, 82 NW. U. L. REV. 293 (1988) (explaining that advances

Another way to determine if a drug is defectively designed is to compare it with another drug available for the same disease or medical condition. For many diseases, illnesses, or other health conditions, multiple drugs are on the market and, to determine defectiveness, we might compare the benefit-to-risk ratio of one drug with an alternative drug. Yet, as mentioned earlier, the Restatement (Third) has no provision allowing for a drug's design to be challenged by comparison to an alternative drug. If another drug has a better benefit-to-risk ratio, why not permit a jury to compare it with the first, to determine whether the first is defectively designed?

One poor reason why we should not permit these comparisons is the FDA's regulatory oversight of pharmaceuticals. When the 1962 amendments to the Food, Drug, and Cosmetic Act were being debated, the pharmaceutical industry successfully removed a provision that would have permitted the FDA to make interdrug comparisons when passing on a New Drug Application.[60] If the FDA cannot decline to approve a drug because better drugs are already available on the market, it makes some sense for the courts to have a role in determining whether a new drug is truly designed more safely than others that are already available, or vice-versa.

Section 6 of the Restatement (Third)'s standard for design defect requires elaboration as a predicate to explaining why

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in technology provide the opportunity for more tort liability because errors in connection with technology can result in harm that otherwise would have been attributed to nature). The late Aaron Wildavsky made this mistake in his critique of tort law, asserting that advances in technology have been responsible for the enormous improvements in public health and life expectancy, and, therefore, tort law should be constrained so as not to impede new technology. *See* AARON WILDAVSKY, SEARCHING FOR SAFETY 212 (1988); Aaron Wildavsky, *Richer is Safer*, 60 PUB. INTEREST 23, 28-29 (Summer 1980).

[60] *See* John Ballin, *Who Makes Therapeutic Decisions?*, 242 JAMA 2875, 2875 (1979). As a practical matter, the FDA often employs informal mechanisms in its regulatory oversight of the pharmaceutical industry. With a number of substantial weapons and considerable discretion, the FDA frequently negotiates with a company to attain a result that the FDA might not have the legal authority to obtain or which, because of procedural requirements, would take much time and litigation to accomplish. The "voluntary" withdrawal of the popular allergy medicine, Seldane, by Hoechst Marion Roussel appears to have been accomplished through this informal negotiation method. The FDA wanted Seldane removed from the market because of serious adverse side effects and the availability of another drug that was equally effective but avoided the adverse effects. Hoechst resisted these efforts, and the FDA responded by making a public announcement in September 1997, warning of a "potentially fatal heart condition" caused by Seldane. *See Seldane: FDA Issues a New Heart Warning over Allergy Remedy*, CHI. TRIB., Sept. 26, 1997, at 7. In December 1997, Hoechst announced that it was withdrawing Seldane from the market after the FDA approved an alternative, decongestant version. *See Popular Seldane Being Withdrawn Because of Risks*, THE COMM. APPEAL, Dec. 30, 1997, at A4.

interdrug comparisons for design defect purposes are undesirable. Ironically, the design defect standard for pharmaceuticals provided in the Restatement (Third) is one that does not require proof of a feasible alternative design, but permits a finding of defect based on categorical liability. "Categorical liability" means that a determination of defectiveness is permitted based on the inherent risks that a product poses without proof of any alternative design. Such liability might be based on a judgment that a product's risks outweigh its benefits, and, therefore, the manufacturer should not be marketing the product because it is too dangerous, or, at a minimum, all harms caused by the product should be imposed on the manufacturer.[61]

There is a certain irony to the Restatement (Third)'s leniency on feasible alternative designs for challenged drugs because, during the drafting of the Restatement (Third), there was a pitched battle over categorical liability, with the Reporters insisting that it should not be recognized and with certain other forces (of darkness, or of light, depending on your perspective) insisting that it should.[62] Ultimately, a compromise was forged, although one far closer to the Reporters' views than to that of their antagonists.[63] So, while the design defect standard in section 6 permits categorical liability (condemnation of a drug as not worthy of being on the market), such liability is very limited. Only when no reasonable health-care provider would

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[61] That is not quite how the language of section 6 puts it. Rather, section 6 provides for liability for a design defect in a drug if its risks are such that "reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug . . . for any class of patients." RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(c) (1997).

[62] *See, e.g.*, Harvey M. Grossman, *Categorical Liability: Why the Gates Should Be Kept Closed*, 36 S. TEX. L. REV. 385, 386 (1995) (labeling categorical liability "a form of judicial outlawry, through the tort system, of entire categories of products now in use"); James A. Henderson, Jr. & Aaron D. Twerski, *Achieving Consensus on Defective Product Design*, 83 CORNELL L. REV. 867, 919-20 (1998) (defending the position adopted by the Restatement); Joseph W. Little, *The Place of Consumer Expectations in Product Strict Liability Actions for Defectively Designed Products*, 61 TENN. L. REV. 1189, 1193-94 (1994) (arguing that requiring plaintiff to show a reasonable alternative design "simply and neatly eliminates the concept of strict liability from product design law").

[63] *See* James A. Henderson, Jr. & Aaron D. Twerski, *Arriving at Reasonable Alternative Design: The Reporters' Travelogue*, 30 U. MICH. J.L. REFORM 563, 583-88 (1997) (describing the origin and adoption of the "Habush amendment," which allows a court to impose liability on the manufacturer of a product without proof of a reasonable alternative design if the product is so dangerous that it never should have been produced).

prescribe the drug for any class of patients is the drug defective in design.[64]

Whenever I have taught prescription drug liability and comment k, I ask my students about thalidomide. In recent years, the only response I get is a quizzical look. Among my nontraditional students, however, there is understanding. Thalidomide is the horror drug of all time, which produced terribly deformed children with flipper limbs or no limbs, described by the *Saturday Review* as "cocoons of flesh." Anyone who saw pictures of these children in the news magazines of the early 1960s appreciates that graphic description. Yet thalidomide would not be defective under section 6, and I would venture the prediction that eight out of ten judges would rule that way as a matter of law (or exclude an expert who opined otherwise in applying section 6), because thalidomide is effective in treating a complication of leprosy and received FDA approval for that use in July 1998.[65]

I do not mean to be critical of the Restatement (Third) with this observation. The Reporters were correct, in my opinion, in not permitting interdrug benefit-to-risk ratios as a basis for design defect litigation, for reasons they explain and for an additional reason that they do not. As the Restatement (Third) observes, different subsets of patients will have their own individual risk-to-benefit ratio for the same drug. A drug that may be the drug of choice for children may not be the drug of choice for those past child-bearing age. The drug of choice for an otherwise healthy patient with asthma may not be the drug of choice for someone with liver disease or liver sensitivity.[66] Within the range of diseases and illnesses for which drugs are prescribed, there are a large number of parameters with regard to

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[64] *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 (1997).

[65] *See* Sheryl G. Stolberg, *Thalidomide Approved to Treat Leprosy, with Other Uses Seen*, N.Y. TIMES, July 17, 1998, at A1 (reporting that, in addition to its use in treating leprosy, thalidomide is being investigated for its efficacy in treating other disorders, including AIDS and cancer). The approved use of thalidomide is for the prevention and suppression of erythema nodosum leprosum, the severe skin lesions characteristic of Hansen's disease (leprosy). *See* W. Martin Davis & I. Wade Waters, *New Drug Approvals of 1998 – Part 2*, DRUG TOPICS, Mar. 1, 1999, at 68.

[66] *See* NATIONAL ASTHMA EDUCATION AND PREVENTION PROGRAM, EXPERT PANEL REPORT II: GUIDELINES FOR THE DIAGNOSIS AND MANAGEMENT OF ASTHMA 3a-4 (1997) [hereinafter NATIONAL ASTHMA]; *see also* Sheryl G. Stolberg, *Stricter Rules Are Urged On Use of a Diabetes Drug*, N.Y. TIMES, Mar. 27, 1999, at A9 (reporting that an FDA panel recommended that Rezulin, a diabetes drug associated with fatalities and serious liver damage, remain on the market, but also recommended that Rezulin be employed only as a last resort when other therapeutic efforts have been unsuccessful).

the disease, illness, and patient that might bear on the most desirable drug (among those generally available for the disease or illness for that patient). This is where the physician, as learned intermediary, is critical. The knowledgeable physician should take into account the known, relevant characteristics of the patient and, from among the available drug therapies, choose the best one for that patient.[67] Thus, having multiple drugs available affords the advantage of some customizing in the choice of pharmaceutical.[68]

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[67] This idealized role of the physician is not borne out in practice. *See* MARTIN, *supra* note 5, at 2 ("Irrational prescribing has injured many patients and too often has been lethal. A major pitfall in prescribing is disregard of rational medication of the patient."); *see also* SELIG GREENMAN, THE QUALITY OF MERCY 296-97 (1971) (reporting on the results of a government task force that concluded that most physicians failed to meet the standard of "rational prescribing" because they lack training in pharmacology, do not have enough objective guidance in selecting proper drugs, and are often too busy to take advantage of such guidance even when it exists); MILTON SILVERMAN & PHILIP R. LEE, PILLS, PROFITS, AND POLITICS 282-304, 289 (1974) (examining evidence of widespread misprescribing of drugs and stating, specifically, that because most antibacterial drugs are prescribed without any evidence of bacterial infection, such drugs "were used as a pharmaceutical version of propitiating the gods"); F. M. Scherer, *Pricing, Profits, and Technological Progress in the Pharmaceutical Industry*, 7 J. ECON. PERSP. 97, 101 (1993) ("[P]hysicians tend to be risk averse, insensitive to cost, and creatures of habit, prescribing drugs by brand name even when much less expensive generic substitutes exist."); TEMIN, *supra* note 43, at 106-19 (asserting that physicians are frequently ignorant of the comparative risks and benefits of alternative treatments); *see generally* U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, OFFICE OF THE SECRETARY, TASK FORCE ON PRESCRIPTION DRUGS, THE DRUG PRESCRIBERS (1968).

[68] A cautionary note about this broad "marketplace of drugs" concept is appropriate. Most hospitals, managed-care organizations, and other health-care institutions have established pharmaceutical formularies, in which certain drugs are selected for availability based on the efficacy, safety, cost, the patient population, and other relevant considerations. In fact,

> [d]rug formularies, particularly in view of the growing importance of hospital-based medical practice, have considerable potential for the promotion of rational prescribing. "The formulary system is a method used by the medical staff of a hospital, working through a Pharmacy and Therapeutics Committee, to evaluate and to select, from among numerous medicinal agents available, those that are considered most useful therapeutically and to list dosage forms in which they may be administered most effectively."

William McFate Smith, *in* CLINICAL PHARMACOLOGY: BASIC PRINCIPLES IN THERAPEUTICS 17 (Kenneth L. Melmon & Howard F. Morrelli eds., 2d ed. 1978) (citation omitted); *see also* American Society of Hospital Pharmacists, *ASHP Statement on the Formulary System*, 40 AM. J. HOSP. PHARM. 1384, 1384-85 (1983); Steven B. Cano & Norman K. Fujita, *Formulary Evaluation of Third-Generation Cephalosporins Using Decision Analysis*, 45 AM. J. HOSP. PHARM. 566, 566-69 (1988). The prevalence of these formularies suggests that having every possible drug available may not be optimal. With the extent and influence of drug industry marketing, that is probably true as well in the world-at-large. The question is whether we could devise a system to establish a national formulary that would weed out the least beneficial and most

Another reason why the comparison of existing drugs for design defect purposes is undesirable is that benefit-to-risk ratios are determined in clinical trials in which researchers examine the effect of a drug on a group of patients. Inevitably, individual variations are not explainable based on identifiable variables, like age or liver health in the examples above. But when a patient has a chronic problem,[69] physicians can explore those unknown individual variations by initially employing the drug of general choice. The physician can assess how the patient responds, both in terms of therapeutic effect and in tolerating side effects. If the drug is, for some reason, unsuccessful or unacceptable, the physician can then try another drug to see whether that alternative works better for that individual patient.[70] Thus, having multiple drugs for the same condition, even with different overall benefit-to-risk ratios, still is beneficial because of our lack of knowledge about the mechanisms by which these chemicals operate.[71] Thus, the Restatement (Third)'s refusal to permit interdrug comparisons to serve as the basis for finding a defective drug design is well-grounded in two of the differences between drugs and durable goods. First, permitting individualized determination of the best version of a drug for an individual does not pose risks to third-parties, as durables often do. Second, because of our lack of understanding of the physiological mechanism of pharmacologic agents, only trial and error can

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dangerous drugs.

[69] Acute illnesses treated with a single drug administration and vaccines do not allow for experimentation with iterative therapies. This prevents health-care practitioners from employing and gauging the effectiveness of alternate therapies to determine which one best suits an individual patient.

[70] *See* MARTIN, *supra* note 5, at 108-09 ("Alternative medications (succedanea) that may be substituted for another with equivalent properties are essential in the practice of medicine because no two patients may react in exactly the same manner to a given drug product.").

[71] Thus, there are over 50 different drugs from six different drug categories available for treating hypertension. Different patient characteristics have a bearing on which drugs are most desirable, including, for example, longer-acting drugs that require only a single daily dose for patients who would have difficulty complying with a more frequent regimen. Other drugs are contraindicated for patients with heart problems. Yet other drugs produce depression in some patients, but there is no way to predict which patients will suffer this adverse effect; only trial and error can identify which adverse side effects, along with their severity, will occur. *See* Joint National Commission on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure and the National High Blood Pressure Education Program Coordinating Committee, *Special Report*, 157 ARCH. INTER. MED. 2413, 2424-27 (1997); *see also* NATIONAL ASTHMA, *supra* note 66, at 3a-1 to 18 (similarly listing numerous drugs in several biochemical categories for treatment of asthma with various advantages and disadvantages).

determine the characteristics that bear on the optimal drug for an individual.

The final possibility for determining design defect might be to compare a drug's overall benefits and risks and to declare a drug defective when its risks outweigh its overall therapeutic benefits. A variant on this might be a looser notion that when a drug causes serious injury, a gestalt judgment of defectiveness might be appropriate. A number of courts that have confronted the question of determining pharmaceutical design defect seem to have adopted one or the other of these conceptions.[72]

Consistent with its treatment of categorical liability for other products, the Restatement (Third) does not permit a risk-benefit assessment of a drug for design defect purposes, as long as the drug is useful for at least one patient population. Whatever one thinks of the Restatement (Third)'s general rule on categorical liability, one good reason for treating drugs in this fashion is the regulation provided by the FDA. 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.[73] Moreover, unlike the other conceptions of a design defect previously considered, overdeterrence is a more serious concern here because potentially any drug could be the subject of this open-ended design defect claim. With the vagaries of comparing statistical therapeutic benefits with the adverse effects suffered by the

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[72] *See* Cupp, Jr., *supra* note 8, at 89.

[73] I do not mean to claim that the FDA's NDA decisions are perfect. Quite often, newly marketed drugs reveal previously unappreciated adverse side effects that require either changes in labeling or removal of the drug from the market. *See* GENERAL ACCOUNTING OFFICE, FDA DRUG REVIEW: POSTAPPROVAL RISKS 1976-85 (1990) (finding that of 198 prescription drugs approved by the FDA during the decade from 1976 through 1985, slightly over one-half had serious postapproval risks that went undetected in the investigational new drug phase). Most of these problems are inherent in limitations on the clinical testing process and are not due to FDA error. *See supra* note 11 and accompanying text; *see also* Green, *Statutory Compliance*, *supra* note 25, at 496-98 & nn.123-31. Critics, however, cite a considerable number of approvals for which one might fault the FDA's judgment. *See supra* note 52. Nevertheless, the critical question is whether a jury is going to make fewer errors than is the FDA. More precisely, the inquiry is whether we are better off permitting juries to find contrary to the FDA's judgment on the overall balances of risks and benefits of a drug when a plaintiff who was injured by the drug seeks such review. In analyzing this issue, one should appreciate the political and social influences that cause the FDA to prefer errors of omission (incorrectly refusing (or postponing) approval of a drug) to errors of commission (incorrectly approving a drug). *See* Green, *Statutory Compliance*, *supra* note 25, at 478-80.

flesh-and-blood plaintiff before the jury,[74] one might legitimately be concerned about the judgments and consequences that would result.[75]

I conclude with where I began. Drugs are different because they cannot be manipulated physically to provide marginally greater safety. That was the central insight of the Restatement (Second)'s treatment of "unavoidably unsafe" products. The Restatement (Third)'s failure to appreciate that not all drugs under all circumstances are "unavoidably unsafe" causes concern.[76] To the extent that drugs can be manipulated to make them safer, the case for an exemption from tort liability is hard to justify, even with FDA regulatory oversight. The Restatement (Third)'s treatment of drug design ignores combination drugs, dosage, and the future of employing bioengineering to design drugs to improve their benefit-to-risk ratio.[77] The Restatement (Third)'s deference to the FDA should be conditioned on the manufacturers compliance with all FDA requirements. Whether these modest criticisms of the Restatement (Third)'s treatment of drug design are correct or not, these criticisms reflect a small niche of pharmaceutical products liability that is not the critical core of how the law allocates losses due to adverse drug effects. Far more critical is the informational dimension, a matter carefully regulated by the FDA and backstopped by the warnings obligation in tort law.

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[74] *See* Gary Schwartz, *The Myth of the Ford Pinto Case*, 43 RUTGERS L. REV. 1013, 1020-32 (1991). *See generally* Jeffrey J. Rachlinski, *A Positive Psychological Theory of Judging in Hindsight*, 65 U. CHI. L. REV. 571 (1998).

[75] *See* Ausness, *supra* note 7, at 753-54.

[76] Professor Ausness similarly focuses on "an unavoidable product risk" as justifying special treatment for pharmaceuticals. *See id.* at 761-64.

[77] *See id.* at 765 ("As mentioned earlier, comment k supposedly is limited to unavoidable danger, but as a practical matter, the courts have extended its provisions to product risks that are not truly unavoidable.").