

Drug Design Liability: Farewell to Comment k

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I. INTRODUCTION

For half a century, Comment k to § 402A of the Restatement, Second, of Torts¹ has caused confusion in prescription drug litigation, seemingly without end. Bidding farewell to Comment k is both justifiable and overdue. Although William Prosser drafted the Comment in a strategic move to protect his epic strict products liability Restatement provision from existential attack, the Comment constitutes an ill-conceived jumble of ideas that many American courts in the 1980s and 90s believed justified insulating pharmaceutical companies from design-based liability.² In recent decades, courts have been interpreting Comment k in different and more confusing ways. Over the latter part of the same time period, courts have begun to consider whether to adopt the prescription-drug provisions of the Restatement, Third, of Torts: Products Liability³ on which the authors served as Co-Reporters. This Article aims to sort things out and to suggest a sensible path for the future. Although the analysis concludes that courts should stop trying to make sense of Comment k, the authors have a few kind words to say about it as a first, but ultimately failed, attempt to address a complicated subject. Not surprisingly, the approach recommended in this Article is identical to the drug-design provision in the Restatement, Third. In any event, in what is likely to be the authors' final treatment of this topic,⁴ the Article reviews what might be termed “the Comment k era;”

¹ See RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (AM. LAW INST. 1965). Westlaw lists 449 cases and 494 law review articles that cite to Comment k. (January 29, 2015).

² See *Brown v. Superior Court*, 751 P.2d 470, 476 (Cal. 1988) (stating that Comment k, interpreted to mean no design-based liability for prescription drugs, has been adopted in the overwhelming majority of jurisdictions that have considered the matter).

³ See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 (AM. LAW INST. 1998).

⁴ The authors have addressed this subject in the past. See generally James A. Henderson, Jr. & Aaron D. Twerski, *Drug Designs Are Different*, 111 YALE L.J. 151 (2001); James A. Henderson,

assesses the current “darkness before dawn” period; and describes the “settled and sensible” era that hopefully lies just ahead.

Part I of the Article rehearses the origins of Comment k and how it came to support manufacturers’ nonliability for drug design. The discussion in Part I offers a modern-day parsing of the comment that, admittedly with the help of hindsight, reveals it to make somewhat more sense than judges ended up giving it. Part II considers § 6(c) of the Products Liability Restatement and offers new insights that occurred to the authors only while writing this Article. Part III describes where things stand now in the case law, grouping the decisions into functional categories. And the Conclusion charts the path that prescription drug design liability should, and the authors believe will, follow in the future. In this last connection, letting Comment k die in desuetude will be part of forging a sensible liability regime. Throughout, the Article’s perspective is descriptively analytical, concerned with craft and practicability rather than with normative philosophy. It observes that the American products liability system appears to aim instrumentally to create incentives for the relevant actors to invest in reasonable care, while being fair to all.⁵ The Article seeks to articulate an approach that fits comfortably into the general fabric of products liability law and that can be managed by courts, litigants, markets, and nonjudicial regulators.

II. COMMENT K: WHERE IT CAME FROM, WHAT IT MEANS

A. *How Comment k Became Part of § 402A*

The story behind Comment k is embedded within the broader story of the Restatement, Second, of Torts, § 402A.⁶ Up until the middle of the last century, American courts had struggled to replace negligence with strict tort

Jr., *Prescription Drug Design Liability Under the Proposed Restatement (Third) of Torts: A Reporter’s Perspective*, 48 RUTGERS L. REV. 471 (1996).

⁵The authors adhere to Professor Weinrib’s view that in many contexts it does not make a practical difference what tort law’s ultimate objectives are. See Ernest J. Weinrib, *Deterrence and Corrective Justice*, 50 U.C.L.A. L. REV. 621, 629–30 (2002) (instrumental means are compatible with noninstrumental ends as long as they are conceptually sequenced so that the former give way when the two come into conflict). Because no such conflicts arise in the mainly descriptive analysis that follows, the conclusions are relevant no matter what the ultimate objectives are.

⁶See JAMES A. HENDERSON, JR. ET AL., *THE TORTS PROCESS* 10–11 (8th ed. 2012). See generally Joseph A. Page, *Generic Product Risks: The Case Against Comment k and for Strict Liability*, 58 N.Y.U. L. REV. 853 (1983).

as the common-law basis for commercial sellers' liability for harm caused by mechanically defective products.⁷ Dean William Prosser, Reporter for the Restatement, Second, of Torts from 1954 to 1965, decided toward the end of that ambitious project to include a special provision—§ 402A—recognizing strict liability as the operative rule for sellers of defective products.⁸ Most of the attention in the years preceding the adoption of § 402A centered on manufacturing defects—dangerous physical departures from intended product designs.⁹ Far less attention focused on the generic risks presented by the product designs, themselves.¹⁰ In large part this reflected the traditional conflation of mechanical flaws with legal defects. By contrast, imposing liability for generic risks—holding a knife manufacturer liable whenever a user suffers a knife cut—seemed intuitively inappropriate.¹¹ And prescription drugs and medical devices, the focus of this Article, seemed to many observers to epitomize the type of inherently and unavoidably dangerous products that should not bring strict liability—or any liability, for that matter—when manufactured properly and marketed with disclosure of all known, nonobvious risks.¹² Although virtually everyone agreed that strict liability is appropriate for manufacturing defects,¹³ concerns over whether § 402A might eliminate traditional shelters from liability for generic product hazards posed a threat to the political attractiveness of the proposed strict products liability rule.

⁷ See JAMES A. HENDERSON, JR. & AARON D. TWERSKI, PRODUCTS LIABILITY: PROBLEMS AND PROCESS 4–19 (7th ed. 2011); William L. Prosser, *The Assault Upon the Citadel (Strict Liability to the Consumer)*, 69 YALE L.J. 1099, 1099–1103 (1960).

⁸ See RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (AM. LAW INST. 1965).

⁹ See *id.* at cmt. b. See generally HENDERSON & TWERSKI, *supra* note 7, at 1–22. But see Michael D. Green, *The Unappreciated Congruity of the Second and Third Torts Restatements on Design Defects*, 74 BROOK. L. REV. 807, 808 (2009) (arguing that § 402A covered not only manufacturing defects but also product designs that do not meet minimum standards of safety).

¹⁰ See James A. Henderson, Jr., *Judicial Review of Manufacturers' Conscious Design Choices: The Limits of Adjudication*, 73 COLUM. L. REV. 1531, 1552–73 (1973); George L. Priest, *Strict Products Liability: The Original Intent*, 10 CARDOZO L. REV. 2301, 2319–24 (1989).

¹¹ Intuitively, one understands that the intended use of a knife is to cut pliable material, including raw flesh, human or otherwise. If it were argued that cutting oneself is not an “intended use,” one might reply that slicing potatoes is the relevant activity, and it is clearly intended by the manufacturer. In any event, working out solutions to the problem of liability for design-related harms is complex and took much longer than did similar problems in connection with manufacturing defects. See generally Henderson, *supra* note 10, at 1552–73.

¹² See *infra* note 13 and accompanying text.

¹³ Indeed, that was the central thrust of the inclusion of § 402A in the Restatement, Second. See Prosser, *supra* note 7, at 1099–1103.

The question of whether prescription drugs' generic hazards, or any generic product hazards, should be covered by the rule of strict liability arose early in the American Law Institute deliberations concerning § 402A. Thus, the published Proceedings of the 38th Annual Meeting of the ALI in 1961 reveal a heated discussion among several ALI members and Dean Prosser in which some outspoken members sought a blanket exemption of prescription drugs from the purview of § 402A.¹⁴ Prosser expressed sympathy with the notion that presumably beneficial drugs might require more lenient treatment than products generally, but he resisted expressing such sympathies in the blackletter.¹⁵ A motion to exempt prescription drugs from § 402A was put to a vote, and the motion lost.¹⁶ Prosser then suggested that he would deal with the drug issue in a comment.¹⁷ A motion to include a comment specifically excluding drugs from § 402A coverage was also put to a vote, and it, too, lost.¹⁸ Thus, when Prosser sat down to draft what became Comment k, he must have felt free to include prescription drugs in § 402A, but also must have felt obligated to acknowledge the ways in which liability for prescription drugs deserved less onerous treatment than did products, generally.

B. What Comment k Says and What It Means

To appreciate how and why Comment k came to play a central role, it will be necessary to perform a bit of legal archeology. As it eventually became part of the § 402A Restatement package, Comment k divides naturally into two separate portions of roughly equal length, without formal subheadings. The first portion, which is of primary relevance to virtually all claims based on prescription drug designs, reads as follows:

Comment:

k. Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of

¹⁴ See William L. Prosser, *Continuation of Discussion of the Restatement of the Law, Second, Torts*, 38 A.L.I. Proc. 76, 90–92 (1961).

¹⁵ *Id.* at 92–97.

¹⁶ *Id.* at 97.

¹⁷ *Id.*

¹⁸ *Id.* at 98.

drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician.¹⁹

The “unavoidably unsafe” heading of Comment k would have led one to believe that the comment was addressing the broader question of how strict liability would apply to the generic, designed-in risks that every product categorically presents.²⁰ This position would have been clear beyond question if the Comment had begun:

All products carry with them categorical risks of injury that cannot be eliminated by re-design without destroying the product’s utility. Thus, automobiles designed without engines would be much safer but would be of little, if any, utility save perhaps as expensive lawn sculptures. Therefore, automobiles are not legally defective merely because they are inherently dangerous to use. As long as the risks are obvious or adequately warned against and the designs and marketing of the products are reasonable, sellers of automobiles are not strictly liable for harms caused by the categorical hazards these products present. The same rules apply to prescription drugs and devices

In any event, instead of beginning Comment k so that its content matched its heading, Prosser began by limiting his general rule to instances in which limits on “the present state of human knowledge” cause some products to be unavoidably unsafe.²¹ In modern terms this language appears

¹⁹ See RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (AM. LAW INST. 1965).

²⁰ See HENDERSON & TWERSKI, *supra* note 7, at 239–65.

²¹ See RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (AM. LAW INST. 1965).

to present the issue of whether, in judging the reasonableness of a product manufacturer's design and marketing, a defendant may argue against liability on the ground that the relevant risks were scientifically unknowable at time of sale.²² That is certainly an interesting question,²³ but it presents an altogether different problem from one of how courts should respond to generic product risks. Not just *some* products, but *all* products, are categorically dangerous.²⁴ For example, the residual, unavoidable risks of driving an automobile are, by definition, primarily a function of the deliberate choice of automobile users to travel at inherently dangerous speeds rather than a function of limits on human knowledge.²⁵ In any event, having established that generic product risks are unavoidable, the general rule of nonliability that follows in Comment k makes sense, even to modern sensibilities. At the same time, some measure of seller's responsibility for generic product risks may be warranted.²⁶ But when Comment k observes that as a general rule inherent categorical risks do not make products defective in design, it appears to be on sound footing after having gotten off to a stumbling start.

As noted earlier, Prosser follows the first portion of his Comment k with a second portion, whose peculiarity resides in its being included at all:

[The rule generally applicable to prescription drugs] is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that

²² See HENDERSON & TWERSKI, *supra* note 7, at 211–13; see also *infra* note 100 and accompanying text.

²³ See, e.g., Alan Schwartz, *Products Liability, Corporate Structure and Bankruptcy: Toxic Substances and the Remote Risk Relationship*, 14 J. LEGAL STUD. 689, 689 (1985).

²⁴ This does not mean that they are necessarily defectively dangerous. Fluffy cotton balls are far less dangerous than high-caliber firearms, and yet neither may be defective in any way. In any event, it is indisputably true that cotton balls present the generic risk of choking someone who attempts to swallow them in quantity.

²⁵ Another way to express this idea is to observe that the generic risks presented by automobiles are more a result of deliberate human choice than of unavoidable human error or shortcomings in human knowledge.

²⁶ See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(b) cmt. e (AM. LAW INST. 1998).

they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held strictly liable for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.²⁷

By seeming to eliminate the seller's responsibility for "purity of ingredients," thereby implying that the seller may not be strictly liable even for manufacturing defects, Prosser suggests that the seller's nonliability rests on the capacity of the purchaser of even mechanically-defective products contractually to agree to assume the relevant risks.²⁸ Thus, Prosser would have been well-advised to omit this second portion of Comment k. It adds nothing substantively to the first portion's development of the concept of "defect," and by implication addresses subjects—contractual assumption of the risk and liability for experimental, not-yet-FDA-approved drugs—that did not then play, and never have played, mainstream roles in products liability jurisprudence.²⁹ By including this second portion, Prosser accomplished nothing more than to sharpen the Comment's exclusive (and thus misleading) focus on prescription drugs and make the Comment more

²⁷ See RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (AM. LAW INST. 1965).

²⁸ Applied to nonprescription products in cases involving personal injury, such a capacity would be highly questionable. See RESTATEMENT (THIRD) OF TORTS: PHYSICAL & EMOTIONAL HARM § 18 cmt. a (AM. LAW INST. 2010). If Prosser intended to limit the "purity of ingredients" exception to experimental drugs, then contractual assumption of the risk (informed consent) would be less problematic. If patients were told that an experimental drug may contain a yet undiscoverable contaminant, they might agree to take part in a clinical test that for many would constitute their best and last chance. See RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (AM. LAW INST. 1965).

²⁹ The Federal Food, Drug, and Cosmetic Act of 1968 § 355(i)(4) requires that testing for investigational drugs is conditioned on obtaining informed consent from those to whom such drugs are administered. Given the formalities that attend obtaining informed consent, tort claims against suppliers of investigational drugs are uncommon. See Lars Noah, *This Is Your Products Liability Restatement on Drugs*, 74 BROOK. L. REV. 839, 906 (2009). Noah's article provides insightful analysis of many aspects of drug litigation and will be referred to throughout this article. See also *How Are Participants Protected?*, U.S. NATIONAL INSTITUTES OF HEALTH (Dec. 2014), <https://clinicaltrials.gov/ct2/about-studies/learn#HowAreParticipants>. Recently, the FDA announced that it would simplify the process of allowing investigational drugs for treating patients with terminal diseases. See Opinion, *The Right-to-Try Revolt*, WALL ST. J., Feb. 9, 2015, at A10. One would expect that the process of attaining informed consent from the patients who desire to be treated by unapproved drugs will be rigorous.

exotically mysterious. One can only conclude that this portion of Comment k served mostly political, rather than conceptual, ends.³⁰

C. How, for a Time, Comment k Helped Close and Dead-Bolt the Door on Design-Based Liability for Prescription Drugs

A brief review of design-based liability for nonprescription products will help clarify what American courts did in connection with prescription drugs following adoption of § 402A. While the general rule against liability for inherent, categorical risks applies to all products, not merely to prescription drugs,³¹ the law recognizes a narrow exception for egregiously dangerous, low-utility nonprescription products.³² Thus, the seller of an exploding-cigar novelty item capable of injuring the victim of a mean-spirited joke will be liable even though the risk is categorical to the product.³³ And when the plaintiff proves that the manufacturer of nonprescription products failed to adopt a safer reasonable alternative design (RAD) that would have reduced or avoided plaintiff's harm without destroying the relevant category, liability attaches for harm proximately caused by such failure.³⁴ Thus, for nonprescription products, design-based liability was (and remains) a very real option available to injured plaintiffs.³⁵ By contrast, relying on Comment k, American courts have traditionally limited drug manufacturers' liability for generic, designed-in hazards to their failures to provide adequate warnings to prescribing health

³⁰Restatement Reporters have, on occasion, agreed to address an issue in a Comment in order to bolster political support among the ALI membership for more salient positions in the black letter. See generally James A. Henderson, Jr. & Aaron D. Twerski, *The Politics of the Products Liability Restatement*, 26 HOFSTRA L. REV. 667, 686–94 (1998).

³¹See, e.g., *Parish v. ICON Health & Fitness, Inc.*, 719 N.W.2d 540, 544–45 (Iowa 2006). See generally 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, 1276–92 (1991).

³²See N.J. STAT. ANN. § 2A:58C-3b (West 2015); RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(b) cmt. e (AM. LAW INST. 1998).

³³See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 illus. 5 (AM. LAW INST. 1998). See generally James A. Henderson, Jr., *The “Habush Amendment”: Section 2(b), Comment e*, 8 KAN. J.L. & PUB. POL'Y 86 (1998-99). The category in the exploding cigar hypothetical is exploding cigar; removing that feature destroys the category.

³⁴See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(b) cmt. e (AM. LAW INST. 1998); Aaron D. Twerski & James A. Henderson, Jr., *Manufacturers' Liability for Defective Product Designs: The Triumph of Risk-Utility*, 74 BROOK. L. REV. 1061, 1094–97 (2009).

³⁵See HENDERSON & TWERSKI, *supra* note 7, at ch. 4.

care providers.³⁶ With regard to this special no-design-liability rule for drugs, two observations are in order. First, Comment k's language, even though confusing, supports that approach;³⁷ and second, powerful considerations of management, centering on the role of competent health care providers as learned intermediaries and the impossibility of litigating whether an alternative drug design would have received FDA approval, support the rule against RAD-based drug design liability.³⁸ Although one cannot attribute this no-liability rule entirely to Comment k, the Comment certainly played a significant role in the rule's legitimization.³⁹ Moreover, as will be made clear, as courts continue to struggle with the drug-design issue, Comment k continues to impose conceptual constraints that are making that task more confusingly difficult.⁴⁰

D. How the No-Design-Liability Rule of Comment k Began to Buckle Under Pressure from the Plaintiff's Bar

Obviously, the plaintiff's bar and pro-liability academics never have been very happy with the no-liability rule that seemed to flow from Comment k's confusing wording.⁴¹ Why, they have asked, should a highly profitable industry enjoy a subsidy in the form of a shelter from the design-based tort liability that all other product industries are required to face?⁴² As such questioning mounted, the issue became whether Comment k could be reinterpreted to allow for judicial review of prescription drug designs without seeming to reject an important part of William Prosser's legacy. Beginning in the 1980s, a growing number of courts responded to the challenge by requiring drug manufacturers to prove that the drug in question was unavoidably unsafe as a necessary condition to enjoying the

³⁶ See, e.g., *Brown v. Superior Court*, 751 P.2d 470, 477 (Cal. 1988).

³⁷ See RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (AM. LAW INST. 1965). Read literally, Comment k says that prescription drugs, being unavoidably dangerous, are not defective for that reason. *Id.*

³⁸ See Henderson & Twerski, *supra* note 4, at 170–72.

³⁹ See *Brown*, 751 P.2d at 477, in which the California high court surveys the alternatives and concludes that “the appropriate test for determining responsibility is the test stated in Comment k.”

⁴⁰ See *infra* Part II.D.

⁴¹ See Page, *supra* note 6, at 871–72.

⁴² *Id.* at 867.

Comment k-based no-liability rule.⁴³ According to these re-interpretations, a drug that is unavoidably unsafe should not bring design-based liability; but unavoidability should be proven, not presumed.⁴⁴ And because unavoidability is invariably a function of the unavailability of a reasonable alternative drug design, this new approach in effect rests on the same RAD-based test applicable to nonprescription product designs, but with the burden of proof shifted to the defendant manufacturer.⁴⁵ This new approach, its proponents argue, shows respect, rather than contempt, for Comment k.⁴⁶ Of course, this interpretation of Comment k leaves drug manufacturers with the unenviable task of proving a negative—that no RAD was available at the time of distribution. And it also presents the question conceptually of how a safer alternative drug, which constitutes a different molecule from the one plaintiff alleges to be defective in design, could be said to be a marginal, rather than categorical, variation of the drug under attack.⁴⁷ These, and other, puzzlements appear unavoidably to surround adoption of this new interpretation of Comment k.⁴⁸

Beyond these conceptual difficulties, adoption of a RAD-based test for drug-design defects presents interesting questions of process. What justifies, in the context of a claim of defective design, a rebuttable presumption that the risks presented by a drug are avoidable by means of safer alternatives when well-trained, expert medical providers are prescribing the drugs in question after being adequately appraised of the relevant risks and benefits? Of course, the relevant safer alternative drugs may not yet have reached the market and thus may not have been available to medical intermediaries; but in that event how could such safer drugs have

⁴³ See, e.g., *Kearl v. Lederle Labs.*, 218 Cal. Rptr. 453, 468 (Cal. Ct. App. 1985) (leading decision).

⁴⁴ *Id.* at 463.

⁴⁵ Under the RAD-based approach, the plaintiff must prove that a safer alternative design was available at time of sale. See *Henderson*, *supra* note 33, at 86; see also *supra* text accompanying note 33. Under the more recent reinterpretation of Comment k, in order to show that the risk was unavoidable, the defendant must prove that no safer alternative was available.

⁴⁶ See *Kearl*, 218 Cal. Rptr. at 461–62.

⁴⁷ See *infra* note 114.

⁴⁸ One puzzlement is how to handle the “unavoidability” issue procedurally. See *Brown v. Superior Court*, 751 P.2d 470, 475 (Cal. 1988); see also *Kearl*, 218 Cal. Rptr. at 463. Moreover, once the defendant proves unavoidability—i.e., that no RAD exists—should not that be the end of the controversy over defective design?

been of any benefit to the plaintiffs?⁴⁹ Could not a less-aggressive test for drug design defect be devised that would identify drugs that should not be marketed and yet avoid the financially crushing implications of allowing almost all drug design claims to reach the jury?⁵⁰ And even if the outcomes in drug-design litigation would not be dire for the industry, how could courts manage to litigate the question of whether a superior alternative drug would have been developed and approved by the FDA in time to benefit the plaintiff?⁵¹

II. THE ARRIVAL OF § 6(C) OF THE RESTATEMENT, THIRD, OF TORTS: PRODUCTS LIABILITY

A. *Where § 6(c) Came From, What It Is, and How It Works*

In the early 1990s, as the just-described confusions over Comment k-based burden-shifting approaches to drug-design liability were mounting steadily, the American Law Institute decided to undertake a Restatement, Third, of Torts that would, over time, replace Prosser's Restatement, Second.⁵² The authors of this Article served as Reporters on the first part of the larger project, a Restatement of Products Liability.⁵³ As finally approved and published in 1998, the products liability project contains a separate provision, § 6, covering prescription drugs, with a subsection (c) covering drug design liability.⁵⁴ Section 6(c) provides:

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

⁴⁹The answer here might be that the plaintiff would be required to prove that the RAD could have been developed in time to prevent the plaintiff's harm. But that would be a very difficult issue to litigate, given that it would involve the plaintiff proving that the RAD would have received FDA approval. *See infra* notes 95–126 and accompanying text.

⁵⁰This is the issue addressed by § 6(c). *See infra* Part III.

⁵¹*See infra* text accompanying notes 112–17.

⁵²*See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. FOREWORD (AM. LAW INST. 1998).

⁵³RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. REPORTERS (AM. LAW INST. 1998).

⁵⁴*See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 (AM. LAW INST. 1998).

prescribe the drug or medical device for any class of patients.⁵⁵

The rule expressed in § 6(c) rests on the premise that, as long as a prescription drug⁵⁶ provides a positive benefit-to-risk ratio such that a reasonable provider would prescribe it for at least one class of patients, it is not defective in design even if it would be unacceptably risky to prescribe it for a clear majority of patients in need of the type of therapeutic benefit the drug provides.⁵⁷ Observe that nonprescription products are quite different in this regard. For example, an automobile may be found defective in design if it is unacceptably dangerous for many users—ordinary humans prone to errors in judgment—even if for a special class of users—expert, experienced drivers—the vehicle is adequately safe without the suggested safety feature.⁵⁸ And the opposite is true. If most users can operate a vehicle with reasonable safety, it need not be made safer in design because a small minority of users require an additional, costly safeguard.⁵⁹ In those cases the plaintiff succeeds only by establishing the availability at time of distribution of a safer reasonable alternative design, a RAD, that would have avoided harm to the plaintiff at acceptable cost overall.⁶⁰

Stated somewhat differently, for all products other than prescription drugs and devices, courts approach the relevant benefit/risk balancing in aggregative fashion.⁶¹ The fact that a harm-causing product exposes a majority of inexperienced users to unreasonable risks that adoption of a RAD would have avoided may outweigh the fact that a minority of more expert users derive a significant benefit from using the product as actually designed.⁶² And the same is true when a minority of users who require more design safety are denied relief because a majority of users do not need

⁵⁵ *Id.*

⁵⁶ Section 6(c) includes “medical devices.” This Article speaks only of “drugs” out of editorial convenience.

⁵⁷ The reasoning supporting this position is that the “one class of patients” should be allowed to enjoy the benefits of a drug, and all the other classes of patients, for whom the drug is inappropriate, will be protected by their medical providers who will not prescribe it for them. In effect, the medical providers make it possible to allow the “one class of patients” to enjoy the benefits without harming other would-be consumers of the drug.

⁵⁸ See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. f (AM. LAW INST. 1998).

⁵⁹ *See id.*

⁶⁰ *See id.*

⁶¹ *See id.*

⁶² *See id.*

greater protection.⁶³ In effect, the design liability rule for nonprescription products routinely rejects arguments on behalf of a small minority of users in order to advance the interests of the large majority. Given that for most products courts adopt an aggregative-welfare perspective, why does § 6(c) adopt the opposite, nonaggregative perspective? Why does it preserve the minority's opportunity to derive benefits from a drug even if a much larger majority would face unreasonable risks if they were to consume the drug in question? The answer is that health care providers who prescribe prescription drugs are in a position to make reasonably sure, at least in theory, that the right drugs reach the right patients—that especially dangerous drugs are consumed mostly by patients for whom the benefits of consumption justify exposure to the heightened risks.⁶⁴ By contrast, with no similarly-expert extrajudicial screening apparatus in place to assure that especially dangerous automobile designs will reach only skillful, careful owner/drivers who can manage the risks, courts must take over that function and can do so only on the basis of overall, aggregative probabilities.⁶⁵

It follows that the prescription drugs that § 6(c) deems defective in design are drugs that, on any view of individual rights or social welfare, should not have been marketed for use by anyone at time of distribution to the plaintiff because they are unacceptably risky for all foreseeable classes of patients.⁶⁶ Why wouldn't market competition combined with FDA regulatory review combine to prevent, without the need for judicial intervention, such gratuitously dangerous prescription drugs from being

⁶³ See *id.*

⁶⁴ See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. f (AM. LAW INST. 1998).

⁶⁵ See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(b) cmt. e (AM. LAW INST. 1998). Product distributors sometimes attempt to segregate would-be users by warning that their products are for use “by experts only,” or are “not for children.” Courts have grappled with whether to give effect to such marketing when nonexpert users, or children, suffer injury. See M. Stuart Madden, *Products Liability, Products for Use by Adults, and Injured Children: Back to the Future*, 61 TENN. L. REV. 1205, 1220 (1994). Regarding drugs, prescribing physicians are privy to detailed information regarding the patient and the relevant patient-class. Regarding automobiles, with no learned intermediaries to sort things out, courts can deal only in aggregate generalities.

⁶⁶ From the perspective of an individual patient's rights to fair treatment, a drug manufacturer that distributes a worthless drug because it knows that some physicians will err and prescribe it is tantamount to an intentional wrongdoer. Cf. *infra* note 86 and accompanying text. From an efficiency perspective, keeping worthless drugs off the market promotes the social welfare, by reducing reasonably avoidable injuries. Which normative overview ultimately prevails is of no material significance to this analysis. See Weinrib, *supra* note 5, at 629–30.

distributed? Why, in other words, is design-based tort liability, even within the relatively narrow parameters of § 6(c), necessary at all? An adequate response to this question must show how alternative nonjudicial regulative processes are inadequate to perform the screening task that § 6(c) delegates to courts. The argument in the preceding paragraph justifies § 6(c)'s individualized, nonaggregative approach to benefit-risk analysis, which allows a minority class of patients access to a drug that would be unsuited for all other patients, on the assumption that courts may delegate to learned medical intermediaries responsibility for assuring that the right drugs reach the right patients.⁶⁷ Unless market competition coupled with FDA regulatory review can be shown to be systemically inadequate, the same logic would support replacing § 6(c) with judicial delegation to nonjudicial screening processes.

The reasons why courts cannot defer entirely to the prescription drug market to prevent inappropriate drugs from being distributed in the first instance or after superior drugs have become available—the reason why the market quite often fails in this regard—consists of a combination of excessive patent protection and informational overload.⁶⁸ Patent law becomes complicit in encouraging market failure when it extends the period of patent protection to drugs as those drugs approach the end of their original protective time periods, and does so in ways that effectively expand the breadth of patent protection.⁶⁹ The major anti-competitive effect of these patent extensions is to discourage the marketing of the sorts of new drugs that would tend to run the older, higher-risk, less-efficacious drugs off the market.⁷⁰ This consideration would seem to support a tort rule for prescription drugs similar to the rule generally applicable to nonprescription products—one under which the plaintiff would advance the superior, but not yet-approved or marketed, drug as a reasonable alternative design (RAD) that renders the defendant's drug defective in design regardless of whether anyone has marketed such a drug.⁷¹ However, for reasons identified in a Comment to § 6(c) and elaborated in a subsequent

⁶⁷ See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 (AM. LAW INST. 1998).

⁶⁸ 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, 761–63 (2002).

⁶⁹ See *id.* But see Noah, *supra* note 29, at 859–60 (arguing that the creator of a genuinely safer drug will not be barred by patent law from marketing the safer drug).

⁷⁰ See Conk, *supra* note 68, at 763.

⁷¹ See George W. Conk, *Is There a Design Defect in the Restatement (Third) of Torts: Products Liability?*, 109 YALE L.J. 1087, 1133 (2000).

discussion,⁷² only drugs *already on the market* may be considered in applying that section's "[unsuited] for any class of patients" standard.⁷³ Under that approach, when patent law discourages the marketing of newer, better drugs, patients are left without any recourse, either from the market or from tort. It follows that, while patent law may be contributing to market failures by increasing the number of gratuitously-dangerous, worthless prescription drugs that enter or remain on the market, § 6(c) does not purport to correct for such patent-related market failures because it does not allow liability to be based on the possibility that an unmarketed alternative drug could have been marketed.⁷⁴

But even if § 6(c) does not try to correct for market failures caused by over-protective patent law applications, it does respond to potential market failures—errors by drug prescribers—caused by the inability of such health care providers to cope adequately with overwhelming quantities of data regarding the comparative risks and efficacies of large numbers of more or less substitutable prescription drugs.⁷⁵ Assuming that companies provide full and fair warnings to prescribing medical providers, courts may be correct in relying on learned intermediaries to make routine judgment-calls regarding which drugs, among the significant majority that are suitable for consumption by large numbers of patients, should be prescribed for which patients. But regarding the less frequently-presented question of whether a drug is so inefficacious and risky compared with available alternatives that it should not be prescribed for any class for patients, a strong argument can be made that courts are justified in substituting their independent judgments for those of prescribing physicians. For one thing, it is reasonable to assume that doctors generally tend to continue to conform to patterns of drug prescriptions—even obsolete patterns—to which they have become accustomed.⁷⁶ Drugs that were efficacious when first marketed often are

⁷² See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. f (AM. LAW INST. 1998); see also *infra* text accompanying notes 117–44.

⁷³ See *infra* notes 117–44.

⁷⁴ See *infra* notes 117–44.

⁷⁵ In a study, appearing in the May 23, 2011 issue of the *Archives of Internal Medicine*, the researchers found that the average [drug] label contains seventy different side effects with more commonly prescribed drugs averaging around 100 side effects. See Jon Duke et al., *A Quantitative Analysis of Adverse Events and "Overwhelming" in Drug Labeling*, 171 *ARCHIVES OF INTERNAL MEDICINE*, no. 10, May 23, 2011, at 945–46, available at <http://archinte.jamanetwork.com/article.aspx?articleid=487051>.

⁷⁶ This tendency is commonly referred to as the "plan continuation bias," an unconscious cognitive bias to stick with one's original plan in spite of knowledge of changing conditions. It is

upstaged by new drugs marketed later, and physicians may be unreasonably slow in making adjustments.⁷⁷ And one may also reasonably assume that manufacturers are likely to allocate greater resources to promoting prescription of drugs whose continued medical viability is open to question, thereby increasing the probability of prescriber errors in judgment.⁷⁸

Assuming that total deferral to the market as a screening mechanism would be misplaced for the reasons just articulated, it remains to consider whether courts might delegate screening responsibility regarding questionably efficacious prescription drugs to the federal Food and Drug Administration (FDA)—that is, retreat to the traditional “no drug design liability” rule, thereby leaving it to the FDA to monitor doctor’s patterns of drug prescriptions. Several reasons militate against such total delegation. The first reason lies in the reality that, while the FDA screens for efficacy and risk in new drug applications⁷⁹ and drug manufacturers must continue to monitor the consumption of their products for potentially dangerous side effects and promptly report the relevant data to the FDA so that warnings to physicians may be revised and updated,⁸⁰ no regulatorily-imposed regime of review is in place seeking to determine whether more recent arrivals have rendered an established drug obsolete.⁸¹ Upon reflection, it is clear that no

frequently applied in the context of pilots of aircraft as they approach their destinations. Brent Owens, *Protect Yourself From “Get-There-Itis”*, GENERAL AVIATION NEWS, May 20, 2013, <http://generalaviationnews.com/2013/05/20/protect-yourself-from-get-there-itis/>.

⁷⁷ See *id.*

⁷⁸ See Henderson & Twerski, *supra* note 4, at 171.

⁷⁹ See *id.* at 164–66.

⁸⁰ 2 JAMES T. O’REILLY & KATHARINE A. VAN TASSEL, FOOD AND DRUG ADMINISTRATION § 15:4 (4th ed. 2015).

⁸¹ Professor Noah notes that the FDA has the authority to withdraw a drug from the market because a safer substitute is available. See Noah, *supra* note 29, at 853. He also cites instances where the FDA has requested that a drug be “voluntarily” withdrawn from the market. However, the inability of the FDA to move with dispatch in deciding that a drug should be removed from the market because another drug or modality of treatment is superior is exemplified by the continued approved use of Parlodel despite evidence that the drug was no longer proper for treating one of the ills for which it was marketed. The FDA approved Parlodel in 1980 to prevent post-partum lactation in women who could not or elected not to breast-feed their offspring. After approval, the FDA received adverse reaction complaints that implicated the drug as a possible cause of strokes. As these reports came in, the FDA sought to get Sandoz (the manufacturer) to issue warnings about the relationship of the drug and strokes. Sandoz resisted because the drug was very popular and the company was fearful that a sharply-worded warning would decrease its profits. In 1989, the FDA requested that Sandoz withdraw Parlodel from the market for post-partum lactation. Its reason for doing so was that it was not shown to be more effective than a combination of aspirin

such FDA-managed, largely post-distribution system of monitoring and review could hope to succeed—that the only regulatory regime that is practically feasible in this regard is a tort regime in which firms apply the legal standards to themselves in the first instance and tort liability follows subsequently upon a showing at trial that the FDA-approved drug that harmed the plaintiff has outlived its usefulness for all classes of patients.⁸² The second reason why delegation to the FDA will not work is that, in making decisions with regard to safety and efficacy, the FDA relies almost exclusively on data developed by private drug manufacturers.⁸³ FDA decisions are thus vulnerable, to an extent that judicial decisions are not, to being influenced by understatements and misstatements of the relevant risks.⁸⁴

Returning to a point raised earlier regarding an exception to the general rule against category liability—that courts will impose liability on generic product categories that are egregiously dangerous in that their substantial risks greatly outweigh their meager benefits⁸⁵—the liability rule in § 6(c) functionally resembles that exception to the no-category-liability rule. Prescription drugs that are so lop-sidedly dangerous that no reasonable health care provider would prescribe them for any class of patients may be said to be egregiously and gratuitously dangerous in a manner analogous to

and breast support to alleviate the discomfort of the cessation of lactation. Sandoz refused to acquiesce to the FDA request and Parlodel remained on the market as an anti-lactation drug until 1994. For a full history of the FDA's failure to act with regard to Parlodel *see* *Eve v. Sandoz Pharm. Corp.*, No. IP-98-1429-C-Y/S, 2001 U.S. Dist. LEXIS 4531, at *26–29 (S.D. Ind. Mar. 7, 2001). Parlodel was the subject of numerous lawsuits brought by women who suffered strokes after taking the drug. *See* Margaret A. Berger & Aaron D. Twerski, *Uncertainty and Informed Choice: Unmasking Daubert*, 104 MICH. L. REV. 257, 269–70 (2005); Aaron D. Twerski & Lior Sapir, *Sufficiency of the Evidence Does Not Meet Daubert Standards: A Critique of the Green-Sanders Proposal*, 23 WIDENER L.J. 641, 652–59 (2014).

⁸²Hart and Sacks refer to such a scheme as one of “self-applying regulation.” *See* HENRY M. HART, JR. & ALBERT M. SACKS, *THE LEGAL PROCESS: BASIC PROBLEMS IN THE MAKING AND APPLICATION OF LAW* 120–22 (William K. Eskridge, Jr. & Phillip P. Frickey eds., 1994).

⁸³1 JAMES T. O'REILLY & KATHARINE A. VAN TASSEL, *FOOD AND DRUG ADMINISTRATION* § 13:2 (4th ed. 2015).

⁸⁴Admittedly, drug design litigation relies on experts to determine whether a drug is defectively designed, but that testimony takes place in the context of an adversarial proceeding. Experts for both plaintiff and defendant present their opinions and they are subject to searching cross-examination. Under traditional approaches, no one asks the experts to predict what the FDA might do in the future. Rather, experts opine about the safety or efficiency of drugs already on the market.

⁸⁵*See supra* notes 32–33 and accompanying text; *see also* Noah, *supra* note 29, at 848–49.

the exploding cigar example mentioned in the earlier discussion of the exception to the category liability rule.⁸⁶ Thus, in the context of prescription drug designs, in most instances courts leave the relevant risk-benefit analyses to informed, health-care providers. But when a particular drug should not even be on the market in a fashion similar to harm-causing exploding cigars, courts make an exception and condemn such an egregiously dangerous drug design as defective.

B. Why Would Plaintiffs Choose to Pursue Drug Design Claims Under § 6(c) When Failure-to-Warn Claims, Which are Less Costly to Prosecute, Remain Available?

The increase in social welfare and the vindication of individual rights that flow from helping to eliminate gratuitously risky drugs from the market are obvious.⁸⁷ But drug design claims under § 6(c) are costly to present effectively, given the need for technical data and expert testimony to establish both defect and causation.⁸⁸ Why would individual plaintiffs choose to pursue design claims when failure-to-warn claims are generally available, and are presumably less costly to prosecute?⁸⁹ Part of the answer

⁸⁶ See *supra* note 33 and accompanying text. Another helpful analogy is to the “rational basis” standard of judicial review of governmental regulatory classifications, under which such classifications are presumed to be constitutional unless they are shown to have no rational basis whatsoever—that they could not possibly serve any legitimate governmental purpose. See, e.g., *McGowan v. Maryland*, 366 U.S. 420, 425–26 (1961).

⁸⁷ See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § (6) cmt. f (AM. LAW INST. 1998).

⁸⁸ Aaron D. Twerski & James A. Hendrson, Jr., *Fixing Failure to Warn*, 90 IND. L.J. 237, 242 (2015).

⁸⁹ A fairly recent study of the defense costs generated by tort claims against business corporations in the U.S. from 1988-2004 indicates that the two greatest influences on raising such costs are high stakes and complexity. Toni Hersch & W. Kip Viscusi, *Tort Liability Litigation Costs for Commercial Claims*, 9 AM. L. & ECON. REV. 330, 330 (2007). Both drug design claims and failure to warn claims are likely to be high stakes, although drug companies might be expected to view design claims as existential (designs can’t be changed) and warnings claims less so (marketing can be changed more easily); and the stakes are higher for design claims. See *infra* text accompanying notes 94–97. As for complexity, the study identifies four factors that increase that variable: (1) the claims are nonroutine; (2) the issues are novel; (3) the claim requires specialized expert witnesses; and (4) the case requires highly skilled trial lawyers. See Hersch & Viscusi, *supra*, at 334. Taking these factors in turn, drug design claims are less routine than warnings claims, given the requirement in § 6(c) that the drug be one that is unfit for all classes of patients. And that unusual issue is much more novel than is the issue of whether adequate warnings were given. Moreover, although the issue of causation will require experts in both design and warnings contexts, design claims require scientific expertise to a much greater extent

lies in the negative impact on failure-to-warn claims of testimony by the prescribing provider in a subset of cases that he knew of the relevant risks from outside sources, or would have prescribed the drug in question even if he had known of the risks.⁹⁰ Such testimony severely undermines the plaintiff's ability to establish a causal link between defendant's failure to warn and plaintiff's harm, likely to result in a ruling for the defendant as a matter of law.⁹¹ But the same testimony cannot undercut the plaintiff's design claim in connection with the issue of proximate causation because, if defendant's defective drug had not been marketed at all, the medical provider could not have prescribed it in any event.⁹² And even when a plaintiff pursues a failure-to-warn claim that is likely to survive the manufacturer's motion for judgment as a matter of law on proximate cause, adding a design claim when the facts warrant is advisable because the jury may be likely to allocate more significant percentages of fault to the health care provider (rather than to the drug company) based on "I knew about the

on the defect issue than do warnings claims, which are largely rhetorical in nature. See James A. Henderson, Jr. & Aaron D. Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn*, 65 N.Y.U. L. REV. 265, 292, 298-99, 316 (1990) (plaintiffs reach juries relatively easily with failure-to-warn claims). And finally, drug design cases, for the reasons just given, require top-notch trial lawyers on both sides. Thus, the suggestion in the text that design claims are more costly to prosecute than warnings claims seems borne out by the study. Hersch & Viscusi, *supra*, at 330, 334. To be sure, the study focused on defense costs; but the analysis above applies equally to plaintiffs' costs.

⁹⁰*E.g.*, *In re Fosamax Prods. Liab. Litig.*, 742 F. Supp. 2d 460, 466-67 (S.D.N.Y. 2010); *Miller v. Alza Corp.*, 759 F. Supp. 2d 929, 936 (S.D. Ohio 2010) ("Where treating physician unequivocally testifies that she would have prescribed the subject drug despite adequate warnings, judgment as a matter of law is appropriate."); *Wright v. Am. Home Prods. Corp.*, No. 06-CV-4183-NKL, 2008 U.S. Dist. LEXIS 32121, at *10 (W.D. Mo. Apr 18, 2008) (failure of drug manufacturer to provide adequate warning of risks associated with a prescription product is not a proximate cause of a patient's injury if prescribing physician had independent knowledge of the risk that the adequate warning should have communicated); *Rimbert v. Eli Lilly & Co.*, 577 F. Supp. 2d 1174, 1196-97 (D.N.M. 2008) (citing to extensive authority that if the physician knew of the risk or would have prescribed the drug in any event, the drug manufacturer's failure to warn of the risk is not the proximate cause of the patient's injury).

⁹¹*E.g.*, *In re Fosamax*, 742 F. Supp. 2d at 466-67; *Miller*, 759 F. Supp. 2d at 936; *Wright*, 2008 U.S. Dist. LEXIS 32121, at *10; *Rimbert*, 577 F. Supp. 2d at 1196-97.

⁹²See Aaron D. Twerski, *The Many Faces of Misuse: An Inquiry into the Emerging Doctrine of Comparative Causation*, 29 MERCER L. REV. 403, 421 (1978) (Proximate cause does not operate as a defense when the proposed design alternative was to prevent the very harm suffered by the plaintiff). On rare occasions, however, the conduct of a third party or plaintiff may be so outrageous that defendant may successfully raise a proximate cause defense. See *Morguson v. 3M Co.*, 857 So. 2d 796, 801 (Ala. 2003).

risks” testimony in connection with a failure-to-warn claim than in connection with a drug design claim.⁹³ To be sure, until recently such fault allocations mattered little to plaintiffs because of traditional rules governing joint and several liability—the manufacturer picked up the tab for the provider’s negligence at any event.⁹⁴ However, in the current age of tort reform, in which defendants are liable only for their individual percentages of fault, jury allocations of responsibility matter a great deal more.⁹⁵

Another telling advantage to a plaintiff of bringing a drug design, compared with only a warnings, claim concerns not so much the likelihood of recovery as the potential size of the award. The authors lack data with which to support their position empirically.⁹⁶ But common sense suggests that a design claim based on assertions that a manufacturer has deliberately continued to market a drug that it must know is so inherently inferior compared with available alternatives that no well-informed, reasonable health care provider would prescribe it to anyone is likely, if successful, to stir the passions of triers of fact and justify a relatively generous award. Indeed, there are bound to be instances in which mass tort claims seeking not only compensatory but also punitive damages for defective design are quite plausible.⁹⁷

⁹³Lack of proximate causation terminates the drug company’s liability, whereas under comparative fault the defendant’s liability is reduced but not eliminated. The logic here is that where the provider’s conduct is not quite bad enough to terminate a company’s liability in a failure-to-warn claim, the same considerations will lead the jury to find the provider comparatively more at fault than the company. By contrast, the provider’s conduct seems less consequential in relation to a claim of defective design.

⁹⁴See HENDERSON, JR. & TWERSKI, *supra* note 7, at 73–74; see also RESTATEMENT (THIRD) OF TORTS: APPORTIONMENT OF LIABILITY § 10 (AM. LAW INST. 2000).

⁹⁵See HENDERSON, JR. & TWERSKI, *supra* note 7, at 74–76.

⁹⁶See *id.* at 74–75.

⁹⁷It would depend, of course, on the legal standard for awarding punitive damages. See *id.* at 667 (“All of these tests [for punitive damages] require something more than mere negligence Either the conduct must be intentional, or it must exhibit awareness of, and indifference toward, significant attendant risks . . .”).

III. THE HALF-CENTURY JUDICIAL STRUGGLE TO DEVELOP AN APPROPRIATE STANDARD FOR DEFECTIVE DRUG DESIGN

A. *The Conceptual Chaos Reflected in the Comment k Decisions*

There can be no doubt that the confused language of Comment k has spawned chaos in the decisional law of drug design liability. Courts have embraced at least eight different standards for drug design liability.⁹⁸ Relying on Comment k, they have variously held that manufacturers of prescription drugs are entitled to escape liability for drug designs completely;⁹⁹ that they are entitled to escape from strict liability claims but not from claims of negligence;¹⁰⁰ that before a court allows a manufacturer to escape liability for an unavoidably unsafe drug it must make a threshold decision as to whether the drug in question confers an exceptionally important benefit that makes its availability highly desirable;¹⁰¹ that it is the plaintiff's burden to prove that the risks of a particular drug outweigh its benefits;¹⁰² that it is a defendant's burden to prove that a drug's benefits outweigh its risks;¹⁰³ that a drug may be deemed defectively designed if its

⁹⁸ See David S. Torborg, Comment, *Design Defect Liability and Prescription Drugs: Who's in Charge?*, 59 OHIO ST. L.J. 633, 655 (1998).

⁹⁹ See *infra* note 100.

¹⁰⁰ The often repeated statement that Comment k immunized drug manufacturers from strict liability and not from negligence is predicated on the belief that the two theories yield different results. See, e.g., *Lake-Allen v. Johnson & Johnson, L.P.*, No. 2:08CV00930DAK, 2009 WL 2252198, at *3 (D. Utah July 27, 2009); *Cavender v. Am. Home Prods. Corp.*, No. 4:02CV01830 ERW, 2007 WL 1378431, at *6 (E.D. Mo. May 7, 2007); *Toner v. Lederle Labs.*, 732 P.2d 297, 309 (Idaho 1987); *Feldman v. Lederle Labs.*, 479 A.2d 374, 385 (N.J. 1984) (strict liability focuses on defendant's product negligence center on defendant's conduct); *Lance v. Wyeth*, 85 A.3d 434, 451–52 (Pa. 2014). However, if a drug manufacturer is not liable for unforeseeable risks, see *supra* note 91, there is little if any difference between negligence and strict liability. E.g., *Olson v. Prosoco Inc.*, 522 N.W.2d 284, 289 (Iowa 1994); *Prentis v. Yale Mfg. Co.*, 365 N.W.2d 176, 184 (Mich. 1984); see also, DAVID G. OWEN, *PRODUCTS LIABILITY LAW* 556 (2005) (“Under a risk-utility test, whether it be called ‘negligence,’ ‘strict liability,’ or simply ‘design defectiveness,’ a manufacturer is subject to liability for failing to adopt a particular design feature that would have prevented the plaintiff's harm, if the safety benefits of the design feature were greater than its costs.”).

¹⁰¹ See, e.g., *Cavender*, 2007 WL 1378431, at *5; *Weiss v. Fujisawa Pharm. Co.*, No. 5:05-527-JMH, 2006 WL 3533072, at *3 (E.D. Ky. Dec. 7, 2006); *Feldman*, 479 A.2d at 382–83.

¹⁰² *Miller v. Alza Corp.*, 759 F. Supp. 2d 929, 939 (S.D. Ohio 2010).

¹⁰³ *Belle Bonfils Mem'l Blood Bank v. Hansen*, 665 P.2d 118, 122–23 (Colo. 1983); *Bryant v. Hoffman-La Roche, Inc.*, 585 S.E.2d 723, 728 (Ga. Ct. App. 2003); *Freeman v. Hoffman-La*

risks outweigh its benefits with regard only to a particular plaintiff or class of patients;¹⁰⁴ that plaintiffs may establish a drug design defect by introducing a reasonable alternative design that has not yet been approved by the Food and Drug Administration;¹⁰⁵ and that plaintiffs can establish liability if an alternative FDA-approved drug is as effective as, and safer than, the drug in question.¹⁰⁶

The early cases relying on Comment k focused on manufacturers' failures to warn about side effects that were not foreseeable at the time the drugs in question were placed on the market.¹⁰⁷ In denying liability for unforeseeable risks, the courts cited to Comment k's admonition that strict liability should not be applied to drugs.¹⁰⁸ With regard to drug design cases, a number of courts held that all drug companies were immune from design defect liability under Comment k, and for a time this was the received wisdom.¹⁰⁹ However, in the last several decades, the notion that courts have no role to play in reviewing drug designs has fallen into disrepute.¹¹⁰

Roche, Inc., 618 N.W.2d 827, 840 (Neb. 2000); *Tansy v. Dacomed Corp.*, 890 P.2d 881, 886 (Okla. 1994); *Castrignano v. E.R. Squibb & Sons, Inc.*, 546 A.2d 775, 782 (R.I. 1988).

¹⁰⁴ See *In re Fosamax Prods. Litig.*, 742 F. Supp. 2d 460, 472 (S.D.N.Y. 2010); *infra* text accompanying notes 155–78.

¹⁰⁵ *Toner v. Lederle Labs.*, 732 P.2d 297, 301, 306 (Idaho 1987).

¹⁰⁶ See *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 654–55 (1st Cir. 1981) (applying New Hampshire law).

¹⁰⁷ *Chambers v. G.D. Searle*, 441 F. Supp. 377, 380–81 (D. Md. 1975) (no difference between negligence and strict liability in a failure to warn case); *Christofferson v. Kaiser Found. Hosps.*, 92 Cal. Rptr. 825, 827 (Cal. Ct. App. 1971) (drug manufacturers liable only for failure to warn about foreseeable side effects); *Toole v. Richardson-Merrell Inc.*, 60 Cal. Rptr. 399, 412–13 (Cal. Ct. App. 1967) (no strict liability for unforeseen results if drug was properly manufactured and warnings are adequate).

¹⁰⁸ See *Chambers*, 441 F. Supp. at 381; *Christofferson*, 92 Cal. Rptr. at 827; *Toole*, 60 Cal. Rptr. at 412.

¹⁰⁹ *Transue v. Aesthetech Corp.*, 341 F.3d 911, 916 (9th Cir. 2003); *Tatum v. Schering Corp.*, 795 F.2d 925, 926 (11th Cir. 1986); *Hackett v. G.D. Searle & Co.*, 246 F. Supp. 2d 591, 595 (W.D. Tex. 2002); *Fellows v. USV Pharm. Corp.*, 502 F. Supp. 297, 300 (D. Md. 1980); *Stone v. Smith, Kline & French Labs.*, 447 So. 2d 1301, 1303 (Ala. 1984); *Brown v. Superior Court (Abbott Labs.)*, 751 P.2d 470, 482–83 (Cal. 1990); *Edwards v. Basel Pharms., Div. of Ciba-Geigy Corp.*, 933 P.2d 298, 300 (Okla. 1997); *McKee v. Moore*, 648 P.2d 21, 23–24 (Okla. 1982) (no claim for defective design if warnings are adequate to physician); *Grundberg v. Upjohn Co.*, 813 P.2d 89, 98 (Utah 1991) (“we do not believe that a trial court . . . is the proper forum to determine whether . . . a particular prescription drug’s benefits outweighed its risks”).

¹¹⁰ See, e.g., *Hill v. Searle Labs., Div. of Searle Pharms., Inc.*, 884 F.2d 1064, 1069 (8th Cir. 1989); *Singer v. Sterling Drug, Inc.*, 461 F.2d 288, 290–91 (7th Cir. 1972); *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293, 1301 (D. Minn. 1988); *Graham v. Wyeth Labs., Div. of Am.*

Today, although courts generally agree that they can review drug designs to determine defect, they disagree as to the standard by which to establish liability.¹¹¹

1. Basing Liability on Failure to Adopt a Safer Alternative Drug

Midway in the search for an appropriate drug design liability standard, several cases suggested that drug manufacturers, like other product manufacturers, could be held liable for failing to adopt a reasonable alternative design that would have avoided harm to the patient.¹¹² For good reason the overwhelming majority of scholars agree that courts are incapable of administering such a test, dependent as the test is on a judicial determination that the FDA would have approved the proposed alternative drug.¹¹³ Anyone proposing a change in the molecular structure of an

Home Prods. Corp., 666 F. Supp. 1483, 1496–97 (D. Kan. 1987); *West v. Searle & Co.*, 806 S.W.2d 608, 612 (Ark. 1991); *Adams v. G.D. Searle & Co.*, 576 So. 2d 728, 732 (Fla. Dist. Ct. App. 1991); *Bryant v. Hoffmann-La Roche, Inc.*, 585 S.E.2d 723, 728 (Ga. Ct. App. 2003); *Toner*, 732 P.2d at 308; *Glassman v. Wyeth Labs., Inc.*, 606 N.E.2d 338, 342 (Ill. App. Ct. 1992); *Savina v. Sterling Drug, Inc.*, 795 P.2d 915, 923–29 (Kan. 1990); *Bennett v. Madakasira*, 821 So. 2d 794, 809 (Miss. 2002), *abrogated by* *Hutzel v. City of Jackson*, 33 So. 3d 1116 (Miss. 2010); *Pollard v. Ashby*, 793 S.W.2d 394, 400 (Mo. Ct. App. 1990); *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 837 (Neb. 2000); *Ferrigno v. Eli Lilly & Co.*, 420 A.2d 1305, 1318 (N.J. Super. Ct. Law Div. 1980); *White v. Wyeth Labs., Inc.*, 533 N.E.2d 748, 752–53 (Ohio 1988), *superseded by statute*, Ohio Rev. Code Ann. § 2307.75(D) (LexisNexis 2010 & Supp. 2015), *as recognized in* *Miller v. Alza Corp.*, 759 F. Supp. 2d 929 (S.D. Ohio 2010); *Senn v. Merrell-Dow Pharms., Inc.*, 751 P.2d 215, 218 n.4 (Or. 1988); *Castrignano v. E.R. Squibb & Sons, Inc.*, 546 A.2d 775, 781 (R.I. 1988).

¹¹¹*See, e.g., Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 654–55 (1st Cir. 1981) (applying New Hampshire law); *In re Fosamax Prods. Litig.*, 742 F. Supp. 2d 460, 472 (S.D.N.Y. 2010); *Miller v. Alza Corp.*, 759 F. Supp. 2d 929, 939 (S.D. Ohio 2010); *Toner*, 793 P.2d at 301, 306; *Freeman*, 618 N.W.2d at 840; *Feldman v. Lederle Labs.*, 479 A.2d 374, 382–83 (N.J. 1984).

¹¹²*See Brown v. Superior Court*, 751 P.2d 470, 478 (Cal. 1988) (“plaintiff might be able to demonstrate at trial that a particular component of DES rendered it unsafe as a miscarriage preventative and that removal of that component would not have affected the efficiency of the drug”); *see also Feldman*, 479 A.2d at 383.

¹¹³*See* DAVID G. OWEN, PRODUCTS LIABILITY LAW § 8.10 (2005); William A. Dreier, *Manufacturers’ Liability for Drugs and Medical Devices Under the Restatement (Third) of Torts: Products Liability*, 30 SETON HALL L. REV. 258, 262 (1999) (“It certainly does not aid the tort system to turn each tort trial into a mini-FDA application procedure. A jury determination based upon trial proofs should not be substituted for the FDA’s extensive drug-approval process (or the equivalent) for new and untried drugs.”); Michael D. Green, *Prescription Drugs, Alternative Designs, and the Restatement (Third): Preliminary Reflections*, 30 SETON HALL L. REV. 207, 219–23 (1999); David S. Torborg, Comment, *Design Defect Liability and Prescription Drugs:*

already-approved drug must present the proposed altered molecule to the FDA for approval, thus initiating the selfsame review that is required for a new drug.¹¹⁴ The new-drug approval process generally takes ten to fifteen years, during which time the FDA reviews countless tests that check the drug for safety and efficacy, utilizing thousands of patients.¹¹⁵ The current cost of bringing a new drug to market runs between 1.2–1.8 billion dollars.¹¹⁶

Because of the rigor of the process, only a small percentage of drugs initially proposed to the FDA eventually receive final approval.¹¹⁷ No court

Who's in Charge?, 59 OHIO ST. L.J., 633, 649 (1998) (“[C]ourts have often noted that the chemical complexity involved in prescription drug design defect cases makes it difficult, if not impossible, for a jury to competently make a determination as to the true benefits and risks posed by the drug.”); see also Henderson, Jr. & Twerski, *supra* note 4, at 151. *But see* Conk, *supra* note 71, at 1106–07; 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, 99–103 (1994).

¹¹⁴See, e.g., *Mut. Pharm. Co. v. Bartlett*, 133 S.Ct. 2466, 2475 (2013) (If a drug manufacturer were to change the composition of a drug, the altered chemical would be a new drug that would require its own NDA to be marketed); see also Noah, *supra* note 29, at 863 (“even minor changes in formulation . . . would . . . require the submission of a new drug approval (NDA)”).

¹¹⁵For an extensive description of the FDA approval process see Henderson, Jr. & Twerski, *supra* note 4, at 163–66. The approval process requires a drug manufacturer to submit an investigational drug application (IND). On average, it takes eighteen months to get approval of an IND application. See 1 O'REILLY & VAN TASSEL, *supra* note 83, § 13:2, at 840–41. Once approval of an IND is received, a drug undergoes three phases of human clinical trials to test for both the safety and efficiency of the drug to attain a New Drug Application (NDA) approval. During these various phases the drug is tested on thousands of patients. See Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J.L. REFORM 461, 481, 487 (1997). For the most recent estimates as to the amount of time to develop a drug and attain approval for marketing see JOSEPH A. DIMASI & HENRY G. GRABOWSKI, R&D COSTS AND RETURNS TO NEW DRUG DEVELOPMENT: A REVIEW OF THE EVIDENCE, OXFORD HANDBOOK ECON. BIOPHARMACEUTICAL INDUSTRY, at 21, 25 (Patricia M. Danzon & Sean Nicholson eds., 2012) (11.8 years); PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, 2013 BIOPHARMACEUTICAL RESEARCH INDUSTRY PROFILE at 32 (2013) (10–15 years). An NDA typically consist of one hundred thousand pages or more. See Green, *supra*, at 487.

¹¹⁶See DIMASI & GRABOWSKI, *supra* note 115, at 23; PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, *supra* note 115, at 32.

¹¹⁷The FDA has found that “a new compound entering Phase I testing, often representing the culmination of upwards of a decade of preclinical screening and evaluation, is estimated to have only an 8 percent chance of reaching market.” See 1 O'REILLY & VAN TASSEL, *supra* note 83, § 13:1, at 838–39 (citing *Challenge and Opportunity on the Critical Path to New Medical Products*, CHALLENGES AND OPPORTUNITIES REPORT (March 2004),

could, even in a trial of much greater duration than normal, determine that a supposedly safer alternative drug would have been approved by the FDA. Of course, if another drug company has already marketed an FDA-approved drug that has greater benefits and fewer risks than the drug in question, liability may be imposed on the seller of the drug that harmed the plaintiff.¹¹⁸ In that instance, a court would be comparing two FDA-approved drugs rather than seeking to establish that a drug that has not undergone the FDA-approval process should be considered as an alternative. In that circumstance, the court would not be required to replicate the administrative approval process and the case would presumably be adjudicable.¹¹⁹ Why replicating the FDA process is highly problematic will be explained in what follows.

Several published decisions utilize the safer-alternative-design test for drugs. In *Brochu v. Ortho Pharmaceutical Corporation*,¹²⁰ plaintiff, a 27 year old woman who suffered a stroke after taking Ortho-Novum-2mg a birth control pill¹²¹ brought suit base on diversity of citizenship in federal district court in New Hampshire.¹²² The pill had a high estrogen content.¹²³ At the time that plaintiff ingested the pill, Ortho Pharmaceutical had on the market birth control pills that had a much lower estrogen content and that were equally effective as the Ortho-Novum 2mg.¹²⁴ Plaintiff alleged the high estrogen content was the cause of her stroke and that the Ortho-Novum 2mg pill was defectively designed.¹²⁵ Plaintiff's experts testified that there was no advantage to the pills with the higher estrogen content.¹²⁶ Defendant argued that, regardless of the test for defect, New Hampshire law barred drug design claims as a matter of law.¹²⁷ On appeal from a verdict and judgment for plaintiff, the Court of Appeals for the First Circuit affirmed,

<http://www.fda.gov/ScienceResearch/SpecialTopics/CriticalPathInitiative/CriticalPathOpportunitiesReports/ucm077262.htm>.

¹¹⁸ See *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 655 (1st Cir. 1981) (applying New Hampshire law); *Frazier v. Mylan Inc.*, 911 F. Supp. 2d 1285, 1298 (N.D. Ga. 2012).

¹¹⁹ 642 F.2d at 655 (applying New Hampshire law).

¹²⁰ See generally *Brochu*, 642 F.2d 652 (applying New Hampshire law).

¹²¹ *Id.* at 654.

¹²² *Id.* at 653.

¹²³ *Id.* at 654.

¹²⁴ *Id.* at 654 n.1.

¹²⁵ *Id.* at 654.

¹²⁶ *Id.* at 655 n.4.

¹²⁷ *Id.* at 655.

holding that New Hampshire would recognize a cause of action for defective drug design if plaintiff were able to establish the availability of an alternative drug, already on the market, that was equally effective and posed less risk.¹²⁸ In this limited context, where an FDA-approved drug was available that was equally efficacious and presented less risk, the case for defective drug design does not create the justiciability problems set forth in earlier discussions.

Similarly, in *Frazier v. Mylan Inc.*,¹²⁹ plaintiff brought a diversity action in federal district court in Georgia against the manufacturer of phenytoin, an anticonvulsant, claiming that the drug was defectively designed because it caused a malady that eventually led to the patient's death.¹³⁰ Plaintiff alleged that several other well-known safer alternative drugs were available to plaintiff's decedent that were equally effective, with a better safety profile and with a lower risk of harm.¹³¹ In denying defendant's motion for summary judgment, the district court held that "allegations of substitute products for phenytoin may be sufficient under a risk-utility analysis."¹³²

The only published decision holding that a drug manufacturer owes a duty to develop and make available a safer drug is *Toner v. Lederle Laboratories*.¹³³ In that case plaintiff, a three-month-old child, received Tri-Immunol vaccine manufactured by Lederle Laboratories.¹³⁴ The vaccine was designed to immunize children against diphtheria, pertussis, and tetanus.¹³⁵ Subsequent to the vaccination, the plaintiff developed a rare condition of the spine, causing him to become permanently paralyzed.¹³⁶ The heart of the design claim was that Lederle knew of the neuro toxicity of Tri-Immunol, a whole-cell vaccine, but failed to develop a safer alternative fractionated-cell vaccine and seek FDA certification of the safer alternative.¹³⁷ The case was tried in federal court under diversity jurisdiction and the jury rendered a verdict for the plaintiff based on a

¹²⁸ *Id.*

¹²⁹ 911 F. Supp. 2d 1285 (N.D. Ga. 2012) (applying Georgia law).

¹³⁰ *Id.* at 1287, 1297.

¹³¹ *Id.* at 1297.

¹³² *Id.* at 1298.

¹³³ *Toner v. Lederle Labs., a Div. of Am. Cyanamid Co.*, 732 P.2d 297, 311 (Idaho 1987).

¹³⁴ *Id.* at 299.

¹³⁵ *Id.*

¹³⁶ *Id.*

¹³⁷ *Id.* at 300.

finding that Lederle was negligent.¹³⁸ On appeal, the Court of Appeals for the Ninth Circuit certified questions regarding the applicability of Comment k to strict liability and negligence claims to the Idaho Supreme Court.¹³⁹ In a lengthy opinion, the Idaho high court held that Comment k did not bar a negligence claim for design defect against a drug manufacturer.¹⁴⁰ The court acknowledged that as of the date of the trial the FDA had refused to license any other fractionated-cell product and the sale of such a product would, therefore, constitute a criminal offense under the Food, Drug and Cosmetic Act.¹⁴¹

The Idaho court's opinion is downright baffling. Even if the defendant drug company owed a duty to develop a better vaccine, how could a jury determine that the FDA would have approved such a vaccine had it been developed? As noted earlier, obtaining FDA approval involves a complex, multi-year process requiring testing of thousands of patients.¹⁴² During this process, the FDA typically engages in an ongoing, back-and-forth dialogue with the applicant, leading to new paths of factual inquiry and the development of additional evidentiary data. And sometimes the FDA refuses to permit the applicant to continue, thereby terminating the application process altogether.¹⁴³ Imposing tort liability on a drug company for its failure to develop a better vaccine assumes that the alternative vaccine would have passed the rigorous FDA new drug approval process. A trial court on remand in a case like *Toner* could only guess as to what might have been the result had a fractionated-cell vaccine been put through the New Drug Application regimen. Expert testimony at trial cannot suffice to bridge this gap. The FDA frequently disagrees with, and refuses to approve drugs advocated by, drug industry experts.¹⁴⁴ A trial court could only speculate as to whether a given expert opinion would have been given credence by the FDA.¹⁴⁵ Furthermore, experts at trial would not have the data that the FDA would have required and might have helped to develop to continue the new drug application process. For all of these reasons, *Toner* must be reckoned a mistake. It is no wonder that there is so little support for

¹³⁸ *Id.* at 299.

¹³⁹ *Toner v. Lederle Labs., Div. of Am. Cyanamid Co.*, 779 F.2d 1429, 1433 (9th Cir. 1986).

¹⁴⁰ *See Toner*, 732 P.2d at 310–11.

¹⁴¹ *Id.* at 301.

¹⁴² *See supra* text accompanying notes 115–119.

¹⁴³ *See* 1 O'REILLY & VAN TASSEL, *supra* note 83, § 13:2, at 841.

¹⁴⁴ *See id.* § 13:6, at 845–46, § 13:8, at 848–49.

¹⁴⁵ *See id.*

the proposition that a drug manufacturer can be held liable for failing to develop a reasonable alternative drug.

2. Condemning Drug Designs Based on Macro Risk-Utility Balancing

A significant number of courts take the position that a drug can be declared to be defectively designed if, from an overall perspective, its risks outweigh its benefits.¹⁴⁶ Several considerations reveal why this sort of macro risk-utility balancing is inadvisable. First, to undertake an analysis of the overall social value of a drug for all uses would require highly complex evidentiary inquiry. A court would have to look at all potential uses of the drug for ailments that bear no relation to the case at bar. Potentially, many illnesses would have to be considered, together with all the possible benefits and detriments of the drug for each such illness. The trial would closely resemble a roving inquiry into all the issues that a regulator might have considered in deciding whether to allow the drug on the market. Second, and perhaps more important, for a court to decide that a particular drug's overall risks outweigh its overall benefits would mean that even if the drug was highly valuable for one or more distinct classes of users, the court might strike down the design as defective and thus by implication not worthy of being prescribed even for those who would benefit from its consumption. Of course, courts make such trade-offs all the time in connection with nonprescription products by adopting an "aggregative welfare" approach.¹⁴⁷ But as explained earlier, the availability of

¹⁴⁶ See *Miller v. Alza Corp.*, 759 F. Supp. 2d 929, 939 (S.D. Ohio 2010) (denying motion for summary judgment on drug design defect claim because plaintiff alleged that the risks of the drug outweighed its benefits); *In re Aredia & Zometa Prods. Liab. Litig.*, No. 3:06-MD-1760, 2009 U.S. Dist. LEXIS 72084, at *7, *9 (M.D. Tenn. Aug. 13, 2009) (denying defendant's motion for summary judgment because drug design defect cases require fact-based risk-utility analysis); *Wright v. Am. Home Prods. Corp.*, No. 06-CV-4183-NKL, 2008 U.S. Dist. LEXIS 32121, at *8 (W.D. Mo. 2008) (issue of fact whether diet drug "which has occasional or fractious benefit should enjoy insulation from strict liability in tort when the product's predominant effects are detrimental to individual and public safety"); *Weiss v. Fujisawa Pharm. Co.*, No. 5:05-527-JMH, 2006 WL 3533072, at *4 (E.D. Ky. Dec. 7, 2006) (defendant's motion for summary judgment denied because plaintiff alleged that the cancer risk posed by the drug [Elidel] outweighed the benefit of treating eczema); *Bryant v. Hoffman-La Roche, Inc.*, 585 S.E.2d 723, 728, 730 (Ga. Ct. App. 2003) (claims for drug design defect are to be determined by "balancing the risks inherent in a product design against the utility of the product so designed").

¹⁴⁷ See *supra* text accompanying note 65.

prescribing physicians as learned intermediaries support a nonaggregative, “cake and eat it, too” solution.¹⁴⁸

One might respond to the just-described difficulties by sheltering drug manufacturers from macro risk-utility liability if the drug is found to provide exceptional benefits.¹⁴⁹ But such a threshold requirement would deny the benefits of lifestyle drugs to those who value them.¹⁵⁰ To impose design liability on such drugs because they can cause serious side effects would effectively bar them from the market. Thus, a young man in his early twenties who finds himself balding,¹⁵¹ or an eighteen-year-old who is unable to date because his or her face is pockmarked with acne,¹⁵² would be denied a drug essential to their well-being as they define it because a court decides that the drug does not present exceptional, life-or-death medical benefits. Such denials strike the authors as overly paternalistic. Drugs rarely have third-party effects, so the choice should be the patient’s to make.¹⁵³ If the drug manufacturer adequately warns physicians about the risks associated with lifestyle drugs, then the risk created by misprescription of such drugs or devices should be dealt with by a malpractice action against

¹⁴⁸ That is, the court can determine that the drug is nondefective in design (thus allowing those who need the drug to have it—the “cake”), and at the same time allow the prescribing physicians to protect from injury those who should not take the drug to avoid injury (thus allowing the system to eat the cake free of a high rate injury). See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(c) (AM. LAW INST. 1998).

¹⁴⁹ See cases cited *supra* note 101.

¹⁵⁰ See Noah, *supra* note 29, at 861–68. The author has difficulty distinguishing which drugs are therapeutic and which are lifestyle. Nonetheless, it seems safe to conclude anti-balding and acne-reducing drugs are at one end of the spectrum and life-saving antibiotics are at the other end.

¹⁵¹ Rogaine is a drug that is used to help regrow hair on the scalp. Side effects include chest pain, swelling of hands or feet, dizziness, confusion, and serious allergic reaction. *Rogaine*, DRUGS.COM, <http://www.drugs.com/rogaine.html> (last visited September 7, 2015).

¹⁵² Accutane, a drug that is effective in controlling serious acne, is linked to a series of side effects including Crohn’s disease, liver damage, miscarriage, and birth defects if taken during pregnancy. Although Hoffman-LaRoche stopped marketing Accutane, the generic brands of Accutane are still available. *Accutane*, DRUGWATCH.COM, <http://www.drugwatch.com/accutane> (last visited January 23, 2015).

¹⁵³ A small subset of drugs do have third-party effects. For example, a drug that causes dizziness or seizures could cause injury to third parties if the drug affected the driver of a car and caused a two-car accident.

the physician who ignores those warnings rather than by a design case against the manufacturer.¹⁵⁴

3. Condemning Drug Designs Based on Micro Risk-Utility Balancing

One way to avoid the just-described difficulties presented by macro risk-utility balancing would be to determine only whether a drug is reasonably safe for the particular class of patients of which plaintiff is a member. Under this approach, instead of engaging in overall, macro risk-utility balancing, the court would engage in what may be characterized as micro risk-utility balancing. Although this approach might be appealing at first glance, it would present serious conceptual difficulties. A finding of product design defect, like a finding of negligence, sends a signal that the designer/actor should have acted differently and more safely.¹⁵⁵ Moreover, given the likelihood that a manufacturer's stubborn refusal to respond to that signal will support punitive damages in subsequent litigation,¹⁵⁶ one may reasonably assume that a manufacturer will change its design.¹⁵⁷

By contrast, if a court were to engage in micro risk-utility balancing and find a drug design defective for only a smaller subset of patients, the court would be signaling that the design should be changed for them. At the same time, by also finding the drug design nondefective for all other patients—those who derive net benefits—the court would be signaling that the design should remain the same for that group.¹⁵⁸ Obviously, the same drug design cannot simultaneously be changed and remain the same. For the court to signal otherwise, seemingly by fiat, would be self-contradictory and

¹⁵⁴ A physician might be negligent in prescribing the drug to those for whom the drug is not appropriate or for failing to inform the patient about side effects. The former would result in a medical malpractice case. The latter would support an action for informed consent.

¹⁵⁵ See generally Mark F. Grady, *Untaken Precautions*, 18 J. LEGAL STUD. 139 (1989).

¹⁵⁶ See *supra* text accompanying note 97.

¹⁵⁷ The company's course of conduct will, presumably, be dictated by the company's assessment of which course benefits the company more. If only a handful of lower courts have found a design defect, the drug generates significant profit, and punitives are unlikely to be imposed, the company could be expected to continue to market the drug in question.

¹⁵⁸ Technically, the signal would be that the drug *may* remain the same. But given the relevant market incentives, and the fact that the court has tacitly concluded that the drug's benefits outweigh its risks for a majority of patients, the court's signal will be more positive than more indifferent.

irrational.¹⁵⁹ If a court were nevertheless to employ such an approach, the defendant drug company would either continue to market the drug, presumably with strengthened warnings,¹⁶⁰ treating its exposure to liability to patients in the subset as a no-fault “activity tax” of sorts,¹⁶¹ or the company would withdraw the drug from the market.¹⁶² In the latter instance, those patients for whom the drug is beneficial—perhaps a large majority of users—would be deprived of its use.¹⁶³

In light of these conceptual embarrassments, it is hardly surprising that the authors have found only one published decision adopting a micro risk-benefit balancing approach.¹⁶⁴ In *In re Fosamax Products Liability Litigation*,¹⁶⁵ a seventy-two-year old woman developed a rare, debilitating condition called osteonecrosis of the jaw (ONJ) after taking Fosamax, a drug designed to treat and prevent osteoporosis.¹⁶⁶ The plaintiff was thought to have osteoporosis since her bone density was more than 2.0 standard deviations below the mean for patients of her age.¹⁶⁷ When the plaintiff’s

¹⁵⁹In *Dawson v. Chrysler Corp.*, 630 F.2d 950, 962 (3d Cir. 1980), the court confronted the very real possibility that different juries in separate cases might reach contradictory verdicts on the same automobile design:

The result . . . is that while the jury found Chrysler liable for not producing a rigid enough vehicular frame, a fact finder in another case [dealing with the same design] might well hold the manufacturer liable for producing a frame that is too rigid In effect, this permits individual juries . . . to impose on automobile manufacturers conflicting requirements. It would be difficult for members of the industry to alter their design and production behavior in response to jury verdicts in such cases Under these circumstances, the law imposes on the industry the responsibility of [an insurer].

¹⁶⁰Strengthened warnings would reduce the numbers of patients who take the drug when they should not, and would increase the company’s opportunity to raise proximate-cause and comparative-fault arguments at trial. See *In re Fosamax Prods. Liab. Litig.*, 742 F. Supp. 2d 460, 466 (S.D.N.Y. 2010); *infra* text accompanying note 178. And such warnings would show that the company tried to avoid harm to plaintiffs, reducing exposure to punitive damages.

¹⁶¹See *Toner v. Lederle Labs.*, 732 P.2d 297, 312–13 (Idaho 1987), in which the second-to-last sentence of the quoted opinion suggests that the court is imposing liability without fault.

¹⁶²Once again, it would be a function of the profits forgone vs. the liability costs avoided. See *id.* at 312.

¹⁶³Presumably if the company has good information and acts in its own self-interest, this will not occur when the aggregate benefits to such patients exceed the injury-related costs to the other patients as reflected in the company’s liability exposure to that subset of users.

¹⁶⁴See *In re Fosamax*, 742 F. Supp. 2d at 471.

¹⁶⁵*Id.*

¹⁶⁶*Id.* at 465–66. This disease involves bone loss and increased risk of bone fracture.

¹⁶⁷*Id.* at 467.

physician prescribed Fosamax in 1997, her T-score was 2.1.¹⁶⁸ Plaintiff's expert testified that statistical studies evaluating the efficacy of Fosamax showed that for the group of patients in the study with a T-score higher than 2.5 Fosamax had a thirty-six percent fracture reduction benefit versus the placebo.¹⁶⁹ However, for the group of patients with a T-score less than 2.5, the data did not show a statistically significant benefit for Fosamax use compared to the placebo.¹⁷⁰

Plaintiff brought suit alleging both failure to warn and design defect.¹⁷¹ The trial court held that plaintiff could not establish proximate cause with regard to the failure to warn claim, in that she did not introduce evidence from which a reasonable jury could conclude that the plaintiff's treating physician would not have prescribed Fosamax if he had been warned of the risk of ONJ.¹⁷² The trial thus commenced solely on the issue of design defect.¹⁷³ A jury returned a verdict of eight million dollars for the plaintiff.¹⁷⁴ In sustaining the jury verdict based on risk–utility balancing, the district court held that a jury could find that there was no “concrete scientific evidence that Fosamax prevents fractures in patients with a T-score better than—2.5.”¹⁷⁵ What is mystifying is how this finding constitutes defective design. As noted earlier, the statistical studies supported a finding that Fosamax was effective for patients with a T-score 2.5 and above.¹⁷⁶ It is not the design that was defective but rather the failure to warn physicians that patients with a T-score of less than 2.5 should not be given the drug because it presents significant risk and no benefit.¹⁷⁷ The

¹⁶⁸ *Id.*

¹⁶⁹ *Id.* at 468.

¹⁷⁰ In fact, there were more fractures in the group receiving Fosamax than in the placebo group. *Id.*

¹⁷¹ *Id.* at 466.

¹⁷² *Id.*

¹⁷³ *Id.* at 467.

¹⁷⁴ *Id.* at 469.

¹⁷⁵ *Id.* at 471 (applying Florida law, the court held that a “reasonable jury could conclude ‘that the risks of Fosamax outweigh its benefits when used for the prevention of osteoporosis by those with a T-score better than – 2.5’”).

¹⁷⁶ *Id.* at 468.

¹⁷⁷ The defendant argued for the application of Restatement, Third, of Torts: Prods. Liab. § 6(c). The court held that Florida had not adopted § 6(c) and thus would not adopt that test for this litigation. It then said that even if it were to apply § 6(c) to Fosamax, the defendant would not be entitled to judgment as a matter of law since plaintiff's expert testified that Fosamax had not been shown to provide more than eighteen months of fracture reduction benefit across all patient

drug was not defectively designed because it was an effective drug to treat patients with a T-score of 2.5 and above.¹⁷⁸

B. Condemning Drug Designs Based on the Restatement Test for Design Defect: Free From the Shadow of Comment k

Several federal courts sitting in diversity have predicted that their respective states would adopt § 6(c).¹⁷⁹ An Arizona federal district court dismissed a claim that Plavix, a blood thinner, was defective in design because it presents a heightened bleeding risk for patients who are poor metabolizers of the drug.¹⁸⁰ Predicting that Arizona would adopt § 6(c), the district court dismissed the design claim noting that the plaintiff did not allege that no reasonable physician would prescribe Plavix for any class of patients.¹⁸¹

One federal court deciding a drug design case based on the New Jersey Product Liability Act adopted a rule almost identical to § 6(c) of the Restatement.¹⁸² In *Appleby v. Glaxo Wellcome, Inc.*,¹⁸³ a plaintiff who suffered severe side effects after taking Lotronex to treat irritable bowel syndrome¹⁸⁴ sued the manufacturer for failure to warn and defective

groups. *Id.* at 472. Even if defendant was not entitled to judgment as a matter of law, it was entitled to reversal based on an instruction that allowed recovery based on micro risk-utility balancing. Furthermore, if § 6(c) were to be applied, the court could not conclude as matter of law that Fosamax should not be prescribed for any class of patients. It would at worst be an issue for the jury. *Id.*

¹⁷⁸By illegitimately characterizing the case as one of design rather than failure to warn, the court allowed the plaintiff to escape the finding of no proximate cause as to a warning claim. *Id.* at 473–74.

¹⁷⁹*Mills v. Bristol-Myers Squibb Co.*, No. CV 11-986-PHX-FJM, 2011 U.S. Dist. LEXIS 116701, at *7 (D. Ariz. Oct. 7, 2011); *see also* *Gerbhardt v. Mentor Corp.*, 191 F.R.D. 180, 185 (D. Ariz. 1999) (predicting that Arizona would adopt § 6(c)); *Madsen v. Am. Home Prods. Corp.*, 477 F. Supp. 2d 1025, 1037 (E.D. Mo. 2007) (predicting that Iowa would adopt § 6(c)). Several courts have rejected § 6(c). *See* *Fraser v. Wyeth, Inc.*, 992 F. Supp. 2d 68, 83–84 (D. Conn. 2014); *In re Fosamax Prods. Liab. Litig.*, 742 F. Supp. 2d 460, 471–72 (S.D.N.Y. 2010) (applying Florida law); *Bryant v. Hoffman-La Roche, Inc.*, 585 S.E.2d 723, 728 (Ga. Ct. App. 2003); *Mele v. Howmedia, Inc.*, 808 N.E.2d 1026, 1038–39 (Ill. App. Ct. 2004); *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 840 (Neb. 2000).

¹⁸⁰*Mills*, 2011 U.S. Dist. LEXIS 116701, at *12–13.

¹⁸¹*Id.* at *7–8.

¹⁸²*Appleby v. Glaxo Wellcome, Inc.*, No. Civ. 04-0062 RBK, 2005 WL 3440440, at *5 (D.N.J. Dec. 13, 2005).

¹⁸³*Id.*

¹⁸⁴*Id.* at *1.

design.¹⁸⁵ The court granted the defendant summary judgment on the warning claim because there was no proof that her physician would have refrained from prescribing the drug had a more extensive warning been given.¹⁸⁶ Turning to the design claim, the court said that under the New Jersey statute, plaintiff must present evidence of a reasonable alternative design to establish a prima facie case.¹⁸⁷ Given that plaintiff had failed to do so, the only other statutory ground for recovery based on defective design requires that plaintiff prove that the “product is ‘so dangerous and of such little use that under the risk-utility analysis [the] manufacturer [should] bear the cost of liability to others.’”¹⁸⁸ Plaintiff failed to provide evidence that would support that the drug was essentially worthless.¹⁸⁹ Thus, in the absence of a reasonable alternative design, the court applied a test that is the functional equivalent of § 6(c).¹⁹⁰

More recently, the Pennsylvania Supreme Court, in *Lance v. Wyeth*,¹⁹¹ after engaging in a wide ranging discussion of drug design liability, explicitly, albeit somewhat tentatively, adopted § 6(c) as the governing rule of the case.¹⁹² Plaintiff’s decedent, a thirty-five-year-old woman, had taken Redux, a weight-reducing pill, from January through April of 1997.¹⁹³ The plaintiff alleged that Wyeth knew or should have known that Redux caused pulmonary hypertension (PPH) and that as a result of ingesting the pill she died of PPH in 2004.¹⁹⁴ Plaintiff did not predicate her claim on failure to warn, presumably because as early as 1996 the product packaging contained a warning of an increased risk of PPH.¹⁹⁵ Her claim was that

¹⁸⁵ *Id.* at *4–6.

¹⁸⁶ *Id.* at *6.

¹⁸⁷ *Id.*

¹⁸⁸ *Id.* This test is set forth in N.J. STAT. ANN. § 2A:58C-3(b) (West 2014). Although the court refers to the New Jersey Product Liability Act, it does not cite to the specific section of the statute that is directly on point. *Appleby*, 2005 WL 3440440, at *6.

¹⁸⁹ *Appleby*, 2005 WL 3440440, at *7.

¹⁹⁰ *See generally id.*

¹⁹¹ *Lance v. Wyeth*, 85 A.3d 434 (Pa. 2014).

¹⁹² *Id.* at 459–60.

¹⁹³ *Id.* at 437.

¹⁹⁴ *Id.* at 460 n.40.

¹⁹⁵ *See id.* at 437. The court notes that the reason that the appellee (plaintiff) did not present a warning claim was that no warning concerning Redux would be sufficient. *Id.* at 459. Given the fact that as early as 1996 Redux had a warning about the side-effect of PPH, the real reason that plaintiff did not allege failure to warn was that Redux had a warning of PPH prior to the time that plaintiff ingested the drug. *See id.*

notwithstanding the warning, Redux was so dangerous that no physician knowing the risk and benefits of the drug would have prescribed the drug for any class of patients.¹⁹⁶

Defendant Wyeth argued that the only claims that can be made against a drug manufacturer are that a drug was adulterated (manufacturing defect) or that it failed to warn of the dangers associated with taking the drug.¹⁹⁷ Drug design claims cannot be made based on the theory that a reasonable alternative design was available since any alternative design would result in a “completely different compound with different properties and its own unique benefits and risks”¹⁹⁸ Wyeth further argued that Comment k sheltered drug manufacturers not only from claims based on strict liability but also from claims based on negligently marketing a drug that was so unsafe that it should not have been prescribed for any class of patients.¹⁹⁹ The decision as to whether a drug has met the basic threshold of safety to enter the market, Wyeth argued, should be delegated to the FDA.²⁰⁰ In rejecting these arguments and adopting § 6(c), the court grounded the plaintiff’s design claim in negligence, but continued to shelter claims based on strict liability from design liability.²⁰¹ The court acknowledged that drug design liability cannot be based on a claim that a pharmaceutical manufacturer should have developed a reasonable alternative design, noting that it is beyond judicial competence to replicate the FDA process for approval of new drugs.²⁰² However, the court saw no reason to shield drug manufacturers from design liability when a pharmaceutical manufacturer was negligent in marketing a drug that did not benefit any class of patients.²⁰³

IV. CONCLUSION

Litigation against drug manufacturers has traditionally been based on the failure to adequately warn about risks associated with taking the drug.

¹⁹⁶ *Id.* at 447.

¹⁹⁷ *Id.* at 441–42.

¹⁹⁸ *Id.* at 443.

¹⁹⁹ *Id.* at 458.

²⁰⁰ *Id.* at 444.

²⁰¹ *Id.* at 459–60.

²⁰² *Id.* at 458–59 (citing to Henderson & Twerski, *supra* note 4, at 175).

²⁰³ *Id.* at 461. Although the Court adopted § 6(c) as the governing rule in this case, it noted that whether a less restrictive test might be adopted in another setting was to be left to another day.

By contrast, since the advent of § 402A, imposing strict liability for the sale of defective products, courts have struggled with the question of whether there ought to be a cause of action for defective drug design. Dean Prosser, the reporter for the Restatement (Second) of Torts and the acknowledged father of § 402A, addressed liability for defective drugs in Comment k to § 402A.²⁰⁴ From the very start, the meaning of Comment k has eluded both courts and scholars. Over the decades, courts have moved from a position that Comment k absolutely bars actions for defective drug design to a broad range of different tests that allow limited judicial review.²⁰⁵ We have examined the various tests adopted by the courts and have found them to be seriously flawed.

A claim that seeks to find a given drug design defective because the manufacturer should have developed a safer alternative drug is inappropriate because courts are incapable of sensibly deciding whether the alternative proposed by the plaintiff would have met with FDA approval. Since any drug marketed in the United States must be approved by the FDA, a court must be able to determine that the FDA would have approved the drug. Given the many-year duration of the FDA approval process, which involves testing of thousands of patients, no court could rationally determine that an alternative drug would have been approved. A claim that a drug's risks outweigh its benefits, when considering all potential patients or a given class of patients, fails because it does not regard as sufficiently important the benefit of the drug to some patients. Imposing design-based liability for sale or distribution of a drug may lead to its removal from the market, thus denying that class of patients access to the drug. The traditional rule relying exclusively on supplying warnings to learned intermediaries who can direct a drug to the appropriate patients allows for sensible discrimination among different classes of patients. A finding of defective design does not allow for such discrimination. However, when a court determines that a drug provides so little benefit and such great risk that the drug should not be prescribed for any class of patients, then liability should not follow. That is the test for defective drug design set forth in § 6(c) of the Products Liability Restatement. As explained in this Article, the Restatement, Third, of Torts finds serious fault with the existing tests for drug design defect that rely on Comment k for support. Comment k

²⁰⁴ RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (AM. LAW INST. 1964).

²⁰⁵ See *supra* this article.

provides no guidance to courts and litigants in this modern era of American products liability. It is time to bid it an overdue farewell.