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## The Restatement (Third) of Torts: Products Liability-The Alps Cure for Prescription Drug Design Liability

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# THE RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY – THE ALI’S CURE FOR PRESCRIPTION DRUG DESIGN LIABILITY

Mark D. Shifton\*

“It has not been a well-kept secret. Anyone familiar with the law of products liability knows that [the *Restatement (Second)*] is out of date and requires revision.”<sup>1</sup>

“We conclude that [the *Restatement (Third)*] has no basis in the case law . . . Accordingly, we do not adopt . . . the *Third Restatement*.”<sup>2</sup>

## INTRODUCTION

In 1997, the American Law Institute (“ALI”) adopted the *Restatement (Third) of Torts: Products Liability* (“*Restatement (Third)*”).<sup>3</sup> After over thirty years as the definitive, yet somewhat confusing road map along the products liability highway, the *Restatement (Second) of Torts* (“*Restatement (Second)*”) was turned on its head. Before new case law involving the *Restatement (Third)* has been given a chance to develop, commentators have risen either to praise the *Restatement (Third)* as a clear guide to the chaotic products liability maze,<sup>4</sup> or to reject it as a pro-defense, industry-favoring curtailment of manufacturer liability.<sup>5</sup>

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\* J.D. candidate, Fordham University School of Law, 2003; B.A., Geography, State University of New York at Buffalo, 1999. I would like to thank Anna, my family, and friends for their love, support, and encouragement. I would especially thank Associate Dean Gail Hollister for guiding me through all stages of this project’s development.

1. James A. Henderson & Aaron D. Twerski, *A Proposed Revision of Section 402A of the Restatement (Second) of Torts*, 77 CORNELL L. REV. 1512, 1546 (1992) (arguing that varying interpretations and inconsistent application of section 402(a) of the *Restatement (Second)* have led to judicial disarray, necessitating the adoption of the *Restatement (Third)*, section 6(c)).

2. *Freeman v. Hoffman-LaRoche, Inc.*, 618 N.W.2d 827, 840 (Neb. 2000) (declining to adopt section 6(c) of the *Restatement (Third)*, in favor of section 402(a) of the *Restatement (Second)*).

3. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. (1997). This Note will focus mainly on section 6(c) of the *Restatement (Third)*.

4. See generally Henderson & Twerski, *supra* note 1.

5. See generally George W. Conk, *Is There a Design Defect in the Restatement (Third) of Torts: Products Liability?*, 109 YALE L.J. 1087, 1103-07 (2000) (criticizing the circumstances surrounding the adoption of the *Restatement (Third)*); Richard L.

Few disagree that the *Restatement (Third)* radically changes the nature of prescription drug design litigation.<sup>6</sup> Critics of the *Restatement (Third)* assert that the new standard sets a nearly impossibly high threshold for plaintiffs seeking to hold prescription drug manufacturers liable for defective design.<sup>7</sup> One court has agreed, describing the *Restatement (Third)* as setting a “[s]tandard that will never allow liability [for the defective design of prescription drugs].”<sup>8</sup> Some critics argue that the *Restatement (Third)* effects sweeping changes to prescription drug design litigation, and “comes very close to eliminating design defect claims altogether.”<sup>9</sup> Other commentators argue that the *Restatement (Third)* is not a true “restatement” of the law at all, but rather a complete revision.<sup>10</sup>

The *Restatement (Third)*’s reporters respond that these changes are not only justified, but necessary.<sup>11</sup> The failure of the *Restatement (Second)* in bringing about judicial uniformity has led courts to carve out their own respective “niches” in the law.<sup>12</sup> Due to evolving notions of strict liability and its application to prescription drug manufacturers, the analytical framework provided by the *Re-*

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Cupp, Jr., *Rethinking Conscious Design Liability for Prescription Drugs: The Restatement (Third) Standard Versus a Negligence Approach*, 63 GEO. WASH. L. REV. 76 (1994); Theresa Moran Schwartz, *Prescription Products and the Proposed Restatement (Third)*, 61 TENN. L. REV. 1357, 1364-68 (1994); Frank J. Vandall, *Constructing a Roof Before the Foundation is Prepared: The Restatement (Third) of Torts: Products Liability Section 2(b) Design Defect*, 30 U. MICH. J.L. REFORM 261 (1997).

6. *Hoffman-LaRoche*, 618 N.W.2d at 837; see also Ellen Wertheimer, *The Third Restatement of Torts: An Unreasonably Dangerous Doctrine*, 28 SUFFOLK U. L. REV. 1235, 1254-55 (1994); Schwartz, *supra* note 5, at 1380. While this Note will often refer to “prescription drugs,” many courts have applied this doctrine to prescription medical devices as well. *E.g.*, *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1232 (4th Cir. 1984) (“[T]he decision to prescribe a cardiac pacemaker involves precisely the sort of individualized medical balancing contemplated [by comment k of the *Restatement (Second)*].”); *Taylor v. Danek Medical, Inc.*, 1998 U.S. Dist. LEXIS 20265, at \*22-\*23 (E.D. Pa. Dec. 29, 1998).

7. See Schwartz, *supra* note 5, at 1380.

8. *Hoffman-LaRoche*, 618 N.W.2d at 839. This assertion may be too broad, as under the *Restatement (Third)*, a prescription drug manufacturer may still be held strictly liable for the defective design of a prescription drug if no reasonable health care provider would prescribe the drug to any class of patients. See *infra* notes 97-98 and accompanying text.

9. Schwartz, *supra* note 5, at 1380. “The [*Restatement (Third)*]’s reporters] said that they did not want to eliminate design claims, but it seems that they have, in effect, done so.” *Id.* at 1385.

10. See Cupp, *supra* note 5, at 98; see also Vandall, *supra* note 5, at 272 (arguing that the *Restatement (Third)*’s reporters ignored precedent when drafting it); Wertheimer, *supra* note 6, at 1254-57.

11. Henderson & Twerski, *supra* note 1, at 1513.

12. *Id.* at 1528-29.

statement (*Second*) is hopelessly out of date.<sup>13</sup> According to the reporters, "Anyone familiar with the law of products liability knows that [the *Restatement (Second)*] requires revision."<sup>14</sup>

Historically, safer alternative drug designs have often been unavailable. As a result, most prescription drug litigation has involved failure to warn and manufacturing defect claims, as opposed to claims that drugs have been defectively designed.<sup>15</sup> In the past two decades, however, courts have begun to take cognizance of design defect claims involving prescription drugs.<sup>16</sup> As courts are increasingly confronted with claims of defectively designed prescription drugs, they may look to the ALI for guidance on how to proceed.<sup>17</sup>

Courts and commentators have long debated the proper judicial treatment of defective design claims involving prescription drugs. Some commentators have argued that prescription drugs, as a product category, are fundamentally different from other consumer products.<sup>18</sup> A number of courts have agreed, citing a public policy supporting the research and development of new prescription drugs, and have sought to limit prescription drug manufacturer liability for defective design.<sup>19</sup> Other courts have refused to create a bright-line distinction between all prescription drugs and other consumer products.<sup>20</sup> According to its reporters, the *Restatement (Third)* clarifies murky judicial doctrine and reconciles these com-

13. *Id.* at 1513.

14. *Id.* at 1546.

15. *Id.* at 1537-38.

16. *Id.* at 1537 n.40 (citing *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652 (1st Cir. 1981), as the first prescription drug case raising a defective design claim).

17. *Id.* at 1512 (noting that courts have shown the *Restatement (Second)* "enormous deference"). In the reporters' opinion, courts would afford the *Restatement (Third)* same level of deference. *Id.*; see also Schwartz, *supra* note 5, at 1367 ("Courts would undoubtedly give the new *Restatement* great weight, and in time [the *Restatement (Third)*] would likely become the consensus, if not the universal, judicial standard for pharmaceutical liability."). *But see* Conk, *supra* note 5, at 98 ("[I]t seems unlikely that courts will uniformly adopt the [*Restatement (Third)*] . . .").

18. *E.g.*, *Brown v. Superior Court (Abbott Labs.)*, 751 P.2d 470, 478 (Cal. 1988) ("[T]here is an important distinction between prescription drugs and other products . . ."); see also James A. Henderson & Aaron D. Twerski, *Drug Designs Are Different*, 111 *YALE L.J.* 151, 170 (2001).

19. *E.g.*, *Brown*, 751 P.2d at 482 (holding manufacturers of prescription drugs immune from strict liability claims on the basis of defective design). *Contra* *Feldman v. Lederle Labs.*, 479 A.2d 374, 380 (N.J. 1984) (holding manufacturers of defectively designed prescription drugs strictly liable on the basis of defective design).

20. *E.g.*, *Feldman*, 479 A.2d at 383 (rejecting bright-line distinction between prescription drugs and other consumer products).

peting viewpoints.<sup>21</sup> Whether the ALI properly balances the societal utility of developing new prescription drugs against the need for liability for defective drug designs has been hotly debated.

Part I of this Note will trace the history and evolution of strict liability for defectively designed prescription drugs. This Part will explore exactly what makes a prescription drug "defective," and the standards adopted by the ALI in both the *Restatement (Second)* and (*Third*) will be explained. In addition, Part I will highlight the two competing methods by which different jurisdictions apply the *Restatement (Second)* standard. While most jurisdictions apply the *Restatement (Second)* to allow the imposition of strict liability on the basis of defective design against a prescription drug manufacturer,<sup>22</sup> a sizeable minority of jurisdictions apply the *Restatement (Second)* to except prescription drug manufacturers from strict liability on the basis of defective design.<sup>23</sup>

Part II will discuss the current controversy regarding the *Restatement (Third)*, section 6(c), and the competing philosophies regarding society's view of prescription drugs. Whether there should be a bright-line distinction between prescription drugs and other consumer goods will be explored, as well as the proper role of courts in reviewing prescription drug designs. The role of the FDA regulatory process in reviewing prescription drug designs, and how that role fits within the *Restatements (Second)* and (*Third*) will also be explored. Having established the fundamental disagreements between the two *Restatements*, Part II will discuss the arguments in favor and against the competing applications of both. Part II will also describe several recent federal cases discussing the *Restatement (Third)* in the context of defectively designed prescription drug claims.

Part III will argue that the *Restatement (Second)*, applied as it is by the majority of jurisdictions, is preferable to the *Restatement (Third)*. Under the *Restatement (Second)*, manufacturers of prescription drugs that serve an important societal interest will be excepted from strict liability on the basis of defective design, while

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21. See Henderson & Twerski, *supra* note 1, at 1513 ("[D]octrinal developments in products liability have placed such a heavy gloss on the original text and comments to [the *Restatement (Second)*] as to render them anachronistic . . . we hope to clarify much of the confusion that has arisen over the years."). *But see* Wertheimer, *supra* note 6, at 1255 ("[I]t is difficult to discern one consistent law of strict products liability across the United States; indeed, it is arguably impossible. Thus, the task of restating it . . . fails before it begins.").

22. See *infra* notes 58-75 and accompanying text.

23. See *infra* notes 78-92 and accompanying text.

manufacturers of less important drugs will remain strictly liable for the defective design of their products. In contrast, the *Restatement (Third)*, by rejecting the judicial risk-utility review of prescription drug designs, and deferring to the FDA regulatory process, reinforces an artificial distinction between prescription drugs and other consumer products. Part III explains that as the paradigm embraced by the *Restatement (Third)* has not been followed by most jurisdictions, the *Restatement (Third)* is an attempt by the ALI not to clarify the current state of law, but to endorse the approach employed by a minority of courts.

## I. THE EVOLVING PARADIGM OF STRICT LIABILITY FOR DEFECTIVELY DESIGNED PRESCRIPTION DRUGS

### A. The Foundations of Strict Liability

The modern doctrine of strict products liability found its birth in Justice Traynor's concurrence in *Escola v. Coca-Cola Bottling Co.*, after an exploding glass bottle of Coca-Cola injured a California waitress's hand.<sup>24</sup> While the California Supreme Court allowed the plaintiff's negligence claim to reach the jury under the doctrine of *res ipsa loquitur*, Justice Traynor argued that the bottle's manufacturer should be held absolutely liable "[w]hen an article it has placed on the market, knowing that it is to be used without inspection, proves to have a defect that causes injury to human beings."<sup>25</sup> Justice Traynor continued:

[P]ublic policy demands that responsibility be fixed wherever it will most effectively reduce the hazards to life and health inherent in defective products that reach the market . . . . It is to the public interest to discourage the marketing of products having defects that are a menace to the public. If such products nevertheless find their way into the market it is to the public interest to place the responsibility for whatever injury they may cause upon the manufacturer, who, even if he is not negligent in the manufacture of the product, is responsible for its reaching the market. However intermittently such injuries may occur and however haphazardly they may strike, the risk of their occurrence is a constant risk and a general one. Against such a risk there should be general and constant protection and the manufacturer is best situated to afford such protection.<sup>26</sup>

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24. *Escola v. Coca-Cola Bottling Co.*, 150 P.2d 436 (Cal. 1944).

25. *Id.* at 440 (Traynor, J., concurring).

26. *Id.* at 440-41 (Traynor, J., concurring). Justice Traynor's view was finally accepted in California when, almost twenty years after his concurring opinion in *Escola*,

The broad strokes of public policy painted by Justice Traynor forged the path for the modern doctrine of strict products liability.<sup>27</sup> These groundbreaking arguments created a fundamental shift in tort law, as under strict liability theory, a plaintiff need not prove negligence on the part of a defendant in order to recover for his injuries.<sup>28</sup> The focus of the strict products liability inquiry is not on the manufacturer's behavior, but on the product itself.<sup>29</sup> To recover under a strict products liability claim, the plaintiff need only show that: (1) the product was defective; and (2) the defect was a proximate cause of the plaintiff's injuries.<sup>30</sup> If the product is considered defective, the plaintiff may recover for his injuries, regardless of the care employed by the manufacturer of the product.<sup>31</sup>

Under strict products liability theory, a manufacturer may be held strictly liable for three types of product defects – defective manufacture, failure to warn, or defective design.<sup>32</sup> A manufacturing defect occurs when a product is not produced as the manufacturer intended.<sup>33</sup> In such a case, while the overall design of the product may be sound, one specific manufactured unit is flawed, causing injury to the user.<sup>34</sup> A product may also be considered defective when the manufacturer fails to provide adequate warnings regarding the risks associated with using the product.<sup>35</sup> In a failure to warn case, a plaintiff need not prove that the product was defective in the traditional sense; a plaintiff need only show that the manufacturer knew or should have known that use of the product carries risks which the manufacturer failed to warn the plaintiff

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he wrote the majority opinion in *Greenman v. Yuba Power Prod., Inc.*, 377 P.2d 897 (Cal. 1963), which expressly recognized a cause of action in strict liability.

27. *Greenman*, 377 P.2d at 901 (“The purpose of [strict liability] is to insure that the costs of injuries resulting from defective products are borne by the manufacturers that put such products on the market rather than by the injured persons who are powerless to protect themselves.”).

28. *Id.*

29. *Id.*

30. *Id.*

31. *See id.*

32. *See generally* W. PAGE KEETON, PROSSER AND KEETON ON THE LAW OF TORTS, 695-98 (5th ed. 1984) [hereinafter PROSSER & KEETON]. This Note will focus only on design defects.

33. *Id.* at 695 (defining manufacturing defect as “an abnormality or a condition that was unintended, and makes the product more dangerous than it would have been as intended.”).

34. *Id.*

35. *Id.* at 697 (stating “a product can be defective in the kind of way that makes it unreasonably dangerous by . . . failing to adequately warn about a risk or hazard related to the way a product is designed.”).

against.<sup>36</sup> In addition, even if produced exactly as the manufacturer intended and accompanied by adequate warnings, a product may still be defective by design.<sup>37</sup> Most early products liability cases involving prescription drugs alleged failure to warn claims.<sup>38</sup> However, courts have recently begun applying design defect theories to prescription drug manufacturers.<sup>39</sup>

Since before the adoption of the *Restatement (Second)*, courts have struggled with the issue of determining the existence of a design defect. To determine whether a product is defectively designed, some courts analyze the product's performance according to how safely the reasonable consumer would expect the product to perform.<sup>40</sup> If the product does not perform as safely as expected, the product is defectively designed.<sup>41</sup> Under this "consumer-expectation" test, a product is defective if it is "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchased it with the ordinary knowledge common to the community as to the product's characteristics."<sup>42</sup>

Some courts have rejected the consumer-expectation test as a means for determining a design defect.<sup>43</sup> These courts determine whether a product is defectively designed by measuring the product's relative risks and benefits.<sup>44</sup> Under this "risk-utility" analysis,

36. *E.g.*, *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1275-76 (5th Cir. 1974); PROSSER & KEETON, *supra* note 32, at 697.

37. *See* PROSSER & KEETON, *supra* note 32, at 698.

38. *See* Henderson & Twerski, *supra* note 1, at 1537.

39. *E.g.*, *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652 (1st Cir. 1981) (allowing recovery under design defect claim against prescription drug manufacturer). Many commentators cite *Brochu* as the first case allowing recovery under such a claim. *See* Henderson & Twerski, *supra* note 1, at 1537 n.40.

40. *See, e.g.*, *Castrignano v. E.R. Squibb & Sons*, 546 A.2d 775, 779 (R.I. 1988) (applying consumer-expectations test). Many courts, however, do not apply the consumer-expectation test in cases involving prescription drugs. *E.g.*, *Shanks v. Upjohn Co.*, 835 P.2d 1189, 1194-95 (Alaska 1992) (noting that in drug design cases, it is extremely difficult to determine the expectations of the "ordinary" consumer); *Heath v. Ortho Pharm. Corp.*, 722 P.2d 410, 414 (Colo. 1986) (finding that consumer-expectation test fails to adequately address issues involving technical or scientific information), *rev'd on other grounds*, *Armentrout v. FMC Corp.*, 842 P.2d 175, 183 (Colo. 1992). *See also* PROSSER & KEETON, *supra* note 32, at 698-99. *But see* *Heath*, 722 P.2d at 419 (Lohr, J., dissenting) (arguing that consumer-expectation test essentially parallels a risk-utility analysis).

41. *Castrignano*, 546 A.2d at 779; PROSSER & KEETON, *supra* note 32, at 698.

42. RESTATEMENT (SECOND) OF TORTS § 402(a) cmt. i (1965).

43. *E.g.*, *Brown v. Superior Court (Abbott Labs.)*, 751 P.2d 470, 477-78 (Cal. 1988) (rejecting consumer expectation test in cases involving prescription drugs).

44. *E.g.*, *Heath*, 722 P.2d at 414, *rev'd on other grounds*, *Armentrout*, 842 P.2d at 183 (applying risk-utility analysis); *Toner v. Lederle Labs.*, 732 P.2d 297, 306 (Idaho 1987); *Feldman v. Lederle Labs.*, 479 A.2d 374, 382 (N.J. 1984).



a product is defective if the magnitude of the dangers involved in using the product outweigh its utility.<sup>45</sup> Various courts have articulated other factors to be considered in a risk-utility analysis.<sup>46</sup>

### B. Design Defects Under the *Restatement (Second) of Torts*, Section 402(a)

In 1965, the ALI adopted the *Restatement (Second) of Torts*.<sup>47</sup> Section 402(a) of the *Restatement (Second)* established a standard under which a product's manufacturer was to be held strictly liable if its product was sold in a "defective condition unreasonably dangerous to the user."<sup>48</sup> Courts immediately seized upon section 402(a) as a convenient method of resolving design defect claims.<sup>49</sup>

45. See PROSSER & KEETON, *supra* note 32, at 699-700.

46. E.g., *Heath*, 722 P.2d at 414 (citing John W. Wade, *On the Nature of Strict Tort Liability for Products*, 44 MISS. L.J. 825, 837-38 (1973)). Professor Wade highlights several factors in a risk-utility analysis, including: (1) usefulness and desirability of the product; (2) safety aspects of the product; (3) availability of a safer alternative product; (4) the manufacturer's ability to increase the product's safety without impairing the product's usefulness, or making it too expensive; (5) the consumer's ability to avoid danger by exercising a degree of care when using the product; (6) the user's anticipated awareness of the inherent dangers in using the product; and (7) the feasibility on the part of the manufacturer to spread potential losses. See also, Aaron D. Twerski, *Seizing the Middle Ground Between Rules and Standards in Design Defect Litigation: Advancing Directed Verdict Practice in the Law of Torts*, 57 N.Y.U. L. REV. 521, 526 (1982).

47. See generally William L. Prosser, *The Fall of the Citadel, (Strict Liability to the Consumer)*, 50 MINN. L. REV. 791 (1966).

48. *Restatement (Second) of Torts*, section 402(a), titled "Special Liability of Seller of Product For Physical Harm to User or Consumer," provides in part:

- (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
  - (a) the seller is engaged in the business of selling such a product, and
  - (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
- (2) The rule stated in Subsection (1) applies although the seller has exercised all possible care in the preparation and sale of his product . . . .

RESTATEMENT (SECOND) OF TORTS § 402(a) (1965).

49. See Henderson & Twerski, *supra* note 1, at 1526-28. Many commentators argue that the drafters of the *Restatement (Second)* had not intended section 402(a) to cover design defects. According to the *Restatement (Third)*'s reporters, this misapplication of the *Restatement (Second)* led to the current judicial disarray of this area of products liability law. "No one . . . could have foreseen that language written primarily to govern manufacturing defect cases might be used by courts in design and warning defect cases." *Id.*

1. *Comment k*

Although the text of the *Restatement (Second)* seems to apply a strict liability standard to the entire universe of manufactured products, comment k to section 402(a) delineates an exception to this rule, by excepting certain products deemed “unavoidably unsafe” from strict liability on the basis of defective design.<sup>50</sup> If a product is deemed unavoidably unsafe, and thus falls within the scope of comment k, the product’s manufacturer will not be held strictly liable on the basis of defective design.<sup>51</sup> In a claim alleging the defective design of a prescription drug, comment k allows the manufacturer to escape strict liability if the risks of the prescription drug were unavoidable.<sup>52</sup> Once falling under comment k’s protections, the prescription drug manufacturer is not held strictly liable on the basis of defective design.<sup>53</sup> Courts that have been con-

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50. *Restatement (Second)*, section 402(a), comment k, titled “Unavoidably Unsafe Products,” provides:

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

RESTATEMENT (SECOND) OF TORTS § 402(a), cmt. k.

51. *E.g.*, *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 657 (1st Cir. 1981) (explaining the protections from strict liability afforded by comment k); *Kearl v. Lederle Labs.*, 218 Cal. Rptr. 453, 463 (Ct. App. 1985), *overruled by* *Brown v. Superior Court (Abbott Labs.)*, 751 P.2d 470 (Cal. 1988).

52. *E.g.*, *Brochu*, 642 F.2d at 657; *Kearl*, 218 Cal. Rptr. at 829; *Belle Bonfils Mem’l Blood Bank v. Hansen*, 665 P.2d 118, 125 (Colo. 1983) (noting that comment k properly applies to shield the manufacturer of an important, yet dangerous product, from strict liability, as the importance of the product bears upon the reasonableness of the risks involved).

53. RESTATEMENT (SECOND) OF TORTS § 402(a), cmt. b.

fronted with claims of defectively designed prescription drugs have generally adopted comment k.<sup>54</sup>

However, many courts disagree on the scope of prescription drug products that comment k should protect. Most courts apply comment k's protection from strict liability in a selective fashion, excepting from strict liability only manufacturers of prescription drugs deemed worthy of protection.<sup>55</sup> Under this view, comment k is treated as an affirmative defense, and the prescription drug's manufacturer bears the burden of showing it should be applied to the particular drug at issue.<sup>56</sup> However, a sizeable minority of courts apply comment k's protections to manufacturers of all prescription drugs, excepting manufacturers of all prescription drugs from strict liability on the basis of defective design.<sup>57</sup>

*a. Case-by-Case Application of Comment k.*

The New Jersey Supreme Court issued the initial landmark decision limiting comment k's application to a case-by-case analysis in *Feldman v. Lederle Laboratories*.<sup>58</sup> After ingesting an antibiotic as an infant, the plaintiff suffered severe tooth discoloration.<sup>59</sup> Rejecting the manufacturer's argument that all prescription drugs

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54. Comment k has been adopted by almost all jurisdictions that have applied Section 402(a). See *Brown*, 751 P.2d at 476 (collecting cases). *Contra* *Shanks v. Upjohn Co.*, 835 P.2d 1189, 1197-98 (Alaska 1992) (declining to adopt comment k); *Collins v. Eli Lilly*, 342 N.W.2d 37, 52 (Wis. 1984).

55. See, e.g., *Tobin v. Astra Pharm. Prods., Inc.*, 993 F.2d 528, 540 (6th Cir. 1993); *Hill v. Searle Labs.*, 884 F.2d 1064, 1069 (8th Cir. 1989); *Coursen v. A.H. Robins Co.*, 764 F.2d 1329, 1337 (9th Cir. 1985); *West v. Searle & Co.*, 806 S.W.2d 608, 613 (Ark. 1991); *Kearl*, 218 Cal. Rptr. at 463 *overruled by Brown*, 751 P.2d at 470; *Heath v. Ortho Pharm. Corp.*, 722 P.2d 410, 415 (Colo. 1986), *rev'd on other grounds*, *Armentrout v. FMC Corp.*, 842 P.2d 175, 183 (Colo. 1992); *Toner v. Lederle Labs.*, 732 P.2d 297 (Idaho 1987); *Savina v. Sterling Drug, Inc.*, 795 P.2d 915, 926 (Kan. 1990); *Freeman v. Hoffman-LaRoche*, 618 N.W.2d 827, 837 (Neb. 2000); *Feldman v. Lederle Labs.*, 479 A.2d 374 (N.J. 1984); *Castrignano v. E.R. Squibb & Sons, Inc.*, 546 A.2d 775, 781 (R.I. 1988). For a detailed discussion of cases holding that comment k should be applied in a selective fashion, see *infra* notes 58-75 and accompanying text.

56. E.g., *Hansen*, 665 P.2d at 122-23; *Toner*, 732 P.2d at 307; *Castrignano*, 546 A.2d at 782 (holding that defendant manufacturer bears burden of pleading comment k as an affirmative defense).

57. E.g., *Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87, 90 (2d Cir. 1980) (holding all prescription drugs unavoidably unsafe); *Brown*, 751 P.2d at 470 (holding comment k's protections from strict liability claims applicable to all prescription drugs); *McKee v. Moore*, 648 P.2d 21, 23 (Okla. 1982); *Grundberg v. Upjohn Co.*, 813 P.2d 89 (Utah 1991); *Young v. Key Pharms., Inc.*, 922 P.2d 59 (Wash. 1996). For a detailed discussion of cases that hold comment k applicable to manufacturers of all prescription drugs, see *infra* notes 78-92 and accompanying text.

58. 479 A.2d 374 (N.J. 1984).

59. *Id.* at 377-79.

were unavoidably unsafe, the court declined to hold comment k's protections applicable to all prescription drug manufacturers.<sup>60</sup> Rather, the court held that whether comment k would apply to the prescription drug at issue would be determined on a case-by-case basis.<sup>61</sup> Only those prescription drugs that were "more vital to the public health and human survival than others" would enjoy comment k protection.<sup>62</sup> Manufacturers of prescription drugs that served society with less utility would be held strictly liable for the defective design of their products.<sup>63</sup>

A California court of appeal followed New Jersey's analysis one year later in *Kearl v. Lederle Laboratories*, when a plaintiff who became paralyzed after receiving a polio vaccine sued the vaccine's manufacturer for strict liability on the basis of defective design.<sup>64</sup> Agreeing with the New Jersey Court's analysis in *Feldman*, the court rejected the argument that prescription drug manufacturers should be categorically excepted from strict liability on the basis of defective design.<sup>65</sup> Rather than apply comment k in blanket fashion, excepting all prescription drug manufacturers from strict liability on the basis of defective design, the court defined a "mini-trial" procedure that would determine if comment k should apply.<sup>66</sup> During this hearing, the trial court would determine whether comment k should except the prescription drug's manufacturer from strict liability.<sup>67</sup> Under the *Kearl* analysis, whether the manufacturer of the prescription drug at issue would enjoy comment k's protections would depend on several factors.<sup>68</sup> The trial judge

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60. *Id.* at 380, 383.

61. *Id.* at 383 (noting that "[Prescription] [d]rugs, like any other products, may contain defects that could have been avoided by better manufacturing or design.").

62. *Id.* at 382.

63. *Id.*

64. *Kearl v. Lederle Labs.*, 218 Cal. Rptr. 453 (Ct. App. 1985), *overruled by* Brown v. Superior Court (Abbott Labs.), 751 P.2d 470 (Cal. 1988).

65. *Id.* at 463 ("[W]e are uncomfortable with the rather routine and mechanical fashion by which many appellate courts have concluded that certain products, particularly [prescription] drugs, are entitled to such special treatment.").

66. *Id.* at 463-64. For criticisms of the *Kearl* mini-trial approach, see *Brown*, 751 P.2d at 481-82.

67. *Kearl*, 218 Cal. Rptr. at 464.

68. *Id.* The court identified a number of factors to be considered in a comment k analysis:

A trial court should take evidence as to: (1) whether, when distributed, the product was intended to confer an exceptionally important benefit that made its availability highly desirable; (2) whether the then-existing risk posed by the product was both 'substantial' and 'unavoidable'; and (3) whether the interest in availability . . . outweighs the interest in promoting enhanced accountability through strict liability design defect review.

would weigh these factors and determine if comment k should apply.<sup>69</sup> While the court ultimately decided in the manufacturer's favor, finding the vaccine to be unavoidably unsafe, the decision signaled a marked affirmation of the principles laid out in *Feldman*.<sup>70</sup>

*Feldman* and *Kearl* were soon followed by the Idaho Supreme Court in *Toner v. Lederle Laboratories*.<sup>71</sup> Answering certified questions from the Ninth Circuit, the Idaho Supreme Court held that whether comment k should except prescription drug manufacturers from strict liability on the basis of defective design should be decided on a case-by-case basis.<sup>72</sup> The court identified several factors to be taken into account during a comment k analysis, similar to the procedure outlined in *Kearl*.<sup>73</sup> Expanding on the *Kearl* inquiry, the court gave great weight to determining whether there existed a reasonable alternative design to the prescription drug at issue.<sup>74</sup> If a reasonable alternative design was available, the prescription drug would not be considered unavoidably unsafe, comment k would not apply, and the prescription drug's manufacturer would be held strictly liable for defective design.<sup>75</sup>

Most jurisdictions have followed the *Feldman* line of cases, holding that comment k should except prescription drug manufacturers from strict liability on the basis of defective design only when the prescription drug serves an important social utility.<sup>76</sup> While various courts employ different procedures for implementing the comment k analysis, most courts agree on the general proposition that

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*Id.* Under the *Kearl* analysis, whether the risk was unavoidable hinged on whether the product was designed to minimize its inherent risks to the extent possible when distributed, and the availability of an alternative product. *Id.*

69. *Id.*

70. *Id.* at 463-64. *Kearl* was later overruled by the California Supreme Court in *Brown*, 751 P.2d at 470.

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

72. *Id.* at 308-09.

73. *Id.* at 305-06.

74. *Id.* The court defined several new factors to be recognized within a comment k analysis, expanding upon the alternative design inquiry made in *Kearl*. Specifically, the *Toner* court instructed lower courts to consider: (1) whether, at the time of the prescription drug's distribution, no feasible alternative design existed that could replicate the drug's purpose with a lesser risk; (2) the magnitude of the risks to be avoided by adopting an alternative design; (3) the financial costs of the alternative design; (4) the benefits of the alternative design; and (5) the relative safety of the prescription drug in issue, compared to a potential alternative design. *Id.*

75. *Id.* at 306.

76. See *supra* note 55; see also Conk, *supra* note 5, at 1094-95 (noting the predominance of the *Feldman* line of cases).

comment k should be applied selectively.<sup>77</sup> Rather than advocating a blanket application of comment k to manufacturers of all prescription drugs, the majority of courts call for a case-by-case determination of whether the prescription drug at issue is worthy of comment k protection.

*b. Blanket Application of Comment k.*

Shortly after the development of the *Feldman* line of cases, the California Supreme Court overruled *Kearl v. Lederle Laboratories*, applying comment k's protections to manufacturers of all prescription drugs.<sup>78</sup> In *Brown v. Superior Court (Abbott Laboratories)*, plaintiffs who had been exposed to the prescription drug DES sued a number of drug manufacturers for strict liability on the basis of defective design.<sup>79</sup> The California Supreme Court declined to hold the prescription drug manufacturer strictly liable, holding that regardless of the prescription drug at issue, all prescription drug manufacturers were to be excepted from strict liability on the basis of defective design.<sup>80</sup> Noting a distinction between prescription drugs and other consumer products, the court asserted that the public policy interests in the development of new prescription drugs militated against imposing strict liability.<sup>81</sup> Besides overruling *Kearl*, the *Brown* decision signaled a fundamental shift away from the *Feldman* line of cases, toward a judicial policy of giving greater deference to prescription drug manufacturers. Over time, this new view has become a sizeable minority.<sup>82</sup>

Three years later, Utah joined the minority, siding with *Brown*.<sup>83</sup> The plaintiff alleged that she suffered severe psychological side effects after taking Halcion, a prescription drug used to treat insom-

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77. Some courts have held the applicability of comment k to be a question of law for the trial judge to decide. *E.g.*, *Johnson v. Am. Cyanamid Co.*, 718 P.2d 1318, 1323-24 (Kan. 1986). Other courts hold the issue to be strictly a question of fact for the jury. *E.g.*, *Ortho Pharm. Corp. v. Heath*, 722 P.2d 410, 414 (Colo. 1986), *rev'd on other grounds*, *Armentrout v. FMC Corp.*, 842 P.2d 175, 183 (Colo. 1992). Still other courts submit the issue to the jury only if reasonable minds could differ. *E.g.*, *Castrignano v. E.R. Squibb & Sons*, 546 A.2d 775, 782 (R.I. 1988).

78. *Brown v. Superior Court (Abbott Labs.)*, 751 P.2d 470 (Cal. 1988).

79. *Id.* at 473.

80. *Id.* at 482.

81. *Id.* at 478-79.

82. After the California Supreme Court's decision in *Brown*, several other jurisdictions followed suit. *E.g.*, *Grundberg v. Upjohn Co.*, 813 P.2d 89, 95 (Utah 1991); *Young v. Key Pharms., Inc.*, 922 P.2d 59, 64 (Wash. 1996). *See supra* note 57.

83. *Grundberg*, 813 P.2d at 95.

nia, ultimately causing her to kill her mother.<sup>84</sup> The plaintiff then sued the prescription drug's manufacturer for strict liability on the basis of defective design.<sup>85</sup> The Supreme Court of Utah, answering certified questions from a United States district court, held that manufacturers of all FDA-approved prescription drugs fall within the scope of comment k's protections.<sup>86</sup> Reaffirming the public policy interests asserted in *Brown*, and recognizing that it was expanding the "literal and restrictive interpretation of comment k," the court held that manufacturers of all FDA-approved prescription drugs were to be excepted from strict liability on the basis of defective design.<sup>87</sup> As Halcion was an FDA-approved prescription drug, comment k automatically applied, and the prescription drug's manufacturer was not held strictly liable.<sup>88</sup>

The Supreme Court of Washington, relying on the policy considerations in *Brown* and the reasoning in *Grundberg*, embraced the minority view.<sup>89</sup> Holding comment k applicable to manufacturers of all prescription drugs, the court rejected the case-by-case analysis of *Feldman* and its progeny.<sup>90</sup> The court argued that by virtue of the "character of the medical profession," and the fact that obtaining prescription drugs necessarily includes the involvement of a physician, such a case-by-case analysis was unnecessary.<sup>91</sup> In the court's opinion, the mere fact that prescription drugs require a prescription illustrate the unavoidable risks inherent in their use.<sup>92</sup>

Next to the *Feldman* line of cases, the *Brown* view is a minority.<sup>93</sup> However, this view is an influential one. Shortly after the development of the minority view, the ALI adopted Section 6(c) of the *Restatement (Third)*. While the *Restatement (Third)* seems to

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84. *Id.* at 90. The potential side effects of Halcion include depression, psychosis, depersonalization, aggressive assaultive behavior, and homicidal compulsion. *Id.*

85. *Id.*

86. *Id.* at 95.

87. *Id.* at 90, 95. For a discussion on FDA-approval as a complete exception from strict liability on the basis of defective design, see *infra* Part II.B.

88. *Id.* at 95.

89. *Young v. Key Pharms., Inc.*, 922 P.2d 59, 64 (Wash. 1996).

90. *Id.*

91. *Id.*

92. *Id.* ("As comment k notes, it is for this very reason that such drugs cannot be legally sold except to physicians or under prescription by a physician; i.e., it is precisely because they are unavoidably unsafe to some degree that they are prescription drugs.").

93. See *supra* note 57.

establish a standard never seen before, its approach is remarkably similar to the *Brown* view.<sup>94</sup>

### C. *Restatement (Third) of Torts: Products Liability*, Section 6(c)

In 1996, the ALI enacted the *Restatement (Third) of Torts: Products Liability*.<sup>95</sup> According to the *Restatement's* reporters, the *Restatement (Third)* purports to completely change the face of prescription drug design litigation.<sup>96</sup> As with the *Restatement (Second)*, the *Restatement (Third)* provides for the imposition of strict liability against a prescription drug manufacturer.<sup>97</sup> However, the standard by which a prescription drug may be considered defectively designed is radically different than under the majority view's application of the *Restatement (Second)*.<sup>98</sup>

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94. For a discussion on the parallel reasoning employed by the *Restatement (Third)* and the *Brown* line of cases, see *infra* Part II.

95. Many commentators criticize the circumstances surrounding the ALI's adoption of the *Restatement (Third)*. See generally Conk, *supra* note 5, at 1103-06 (noting that the ALI adopted much of the *Restatement (Third)* with little debate or discussion); Vandall, *supra* note 5.

96. See Henderson & Twerski, *supra* note 1, at 1545 (“[Comment k] is not an area in which we can satisfy ourselves with a restatement of the case law. Case law that is unintelligible cannot be intelligibly restated.”).

97. *Restatement (Third)*, section 6, titled “Liability of Commercial Seller or Distributor for Harm Caused by Defective Prescription Drugs and Medical Devices” provides in part:

- (a) A manufacturer of a prescription drug or medical device who sells or otherwise distributes a defective drug or medical device is subject to liability for harm to persons caused by the defect. A prescription drug or medical device is one that may be legally sold or otherwise distributed only pursuant to a health-care provider's prescription.
- (b) For purposes of liability under Subsection (a), a prescription drug or medical device is defective if at the time of sale or other distribution the drug or medical device:
  - (1) contains a manufacturing defect as defined in § 2(a); or
  - (2) is not reasonably safe due to defective design as defined in Subsection (c); or
  - (3) is not reasonably safe due to inadequate instructions or warnings as defined in Subsection (d).

RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 (1997).

98. *Restatement (Third)*, 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 prescribe the drug or medical device for any class of patients.

RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(c).



Under the *Restatement (Third)*, a prescription drug manufacturer will be excepted from strict liability on the basis of defective design if any reasonable health care provider would prescribe the drug to any class of patients.<sup>99</sup> Essentially, if a prescription drug confers a benefit upon a small class of patients, while harming other classes, it cannot be considered defectively designed.<sup>100</sup> Some have argued that the *Restatement (Third)* effectively creates a “reasonable physician” standard.<sup>101</sup>

In contrast to the *Restatement (Second)*, the *Restatement (Third)* creates an entirely new product category specifically for prescription drugs and medical devices.<sup>102</sup> This represents a complete categorical distinction between prescription drugs and other consumer products.<sup>103</sup> Under the *Restatement (Third)*, claims of design defects not involving prescription drugs are analyzed under a completely separate standard.<sup>104</sup> Whereas under the *Restatement (Second)*, prescription drugs and other consumer products were subject to the same standard, with comment k’s exception for certain prescription drugs, the *Restatement (Third)* categorically dis-

99. *Id.*; see also *id.* § 6 cmt. f (“A prescription drug or device manufacturer defeats a plaintiff’s design claim by establishing one or more contexts in which its product would be prescribed by reasonable, informed health-care providers . . . Given this very demanding objective standard, liability is likely to be imposed only under unusual circumstances.”).

100. *Id.* § 6 cmt. f (“Subsection (c) reflects the judgment that, as long as a given [prescription] drug or [medical] device provides net benefits for a class of patients, it should be available to them . . .”); see also Conk, *supra* note 5, at 1101-03 (noting that the *Restatement (Third)* essentially establishes a “net benefit” test, whereby if a prescription drug provides a net benefit, it is not considered defectively designed).

101. See Schwartz, *supra* note 5, at 1381-83; see also *Shanks v. Upjohn Co.*, 835 P.2d 1189, 1195 (Alaska 1992) (rejecting comment k in favor of reasonable physician standard).

102. Under the *Restatement (Third)*, while claims of defectively designed prescription drugs and medical devices are analyzed under section 6(c), claims of design defects not involving prescription drugs are analyzed under section 2(b), a completely different standard. *Restatement (Third)*, section 2, titled “Categories of Product Defect,” provides in part:

A product is defective when, at the time of sale or distribution, . . . [the product] is defective in design . . . A product:

- (b) is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design . . . and the omission of the alternative design renders the product not reasonably safe . . . .

RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2.

103. *Id.* § 6 cmt. b (“Because of the special nature of prescription drugs and medical devices, the determination of whether such products are not reasonably safe is to be made under [section 6(c)] rather than under [section 2(b)].”); see also Conk, *supra* note 5, at 1102.

104. RESTATEMENT (THIRD) OF TORTS: PRODS LIAB. § 6 cmt. b.

tinguishes between prescription drugs and other consumer products.<sup>105</sup>

In addition, the *Restatement (Third)* rejects the judicial risk-utility analysis inherent in the application of the *Restatement (Second)* embraced by the *Feldman* line of cases, in favor of the prescribing physician's expertise.<sup>106</sup> If a reasonable physician determines a prescription drug to have sufficient utility to warrant its prescription, the prescription drug is not considered defectively designed.<sup>107</sup>

## II. *Restatement (Second) Versus Restatement (Third): Paradigms In Conflict*

Most states have not yet had the opportunity to consider the *Restatement (Third)* standard, and no state has yet formally adopted it.<sup>108</sup> Some courts have shown a reluctance to directly confront the issue.<sup>109</sup> Recently, the Supreme Court of Nebraska explicitly rejected the *Restatement (Third)* standard, in the case of *Freeman v. Hoffman-LaRoche, Inc.*<sup>110</sup>

After the prescription drug Accutane caused her severe injuries, the plaintiff sued the drug's manufacturer for strict liability on the basis of defective design.<sup>111</sup> The manufacturer argued that as the prescription drug had received FDA approval, it was automatically excepted from strict liability on the basis of defective design.<sup>112</sup> The trial court sustained the manufacturer's motion to dismiss, and the plaintiff was given leave to amend.<sup>113</sup> After the plaintiff stood on her original complaint, the action was dismissed with prejudice.<sup>114</sup>

105. *Id.*; see also Schwartz, *supra* note 5, at 1379-81.

106. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. b ("[P]rescribing health-care providers . . . are able to assure that the right [prescription] drugs and medical devices reach the right patients.").

107. *Id.* § 6 cmt. f ("A prescription drug or device manufacturer defeats a plaintiff's design claim by establishing one or more contexts in which its product would be prescribed by reasonable, informed health-care providers.").

108. See Paul A. Scudato, *Outside Counsel: Reassessing Liability for Defective Design of Drugs*, N.Y.L.J., Aug. 16, 2001, at A1.

109. See, e.g., *Wheat v. Sofamor*, 46 F. Supp. 2d 1351, 1361 n.11 (N.D. Ga. 1999) (declining to apply *Restatement (Third)*, citing a complete absence of state precedent).

110. 618 N.W.2d 827 (Neb. 2000).

111. *Id.* at 832.

112. *Id.* at 833. Under then-existing state law, this argument was correct. *McDaniel v. McNeil Labs., Inc.*, 241 N.W.2d 822, 829 (Neb. 1976), *overruled by Hoffman-LaRoche*, 618 N.W.2d at 837.

113. *Hoffman-LaRoche*, 618 N.W.2d at 832.

114. *Id.*

The Supreme Court of Nebraska analyzed the plaintiff's defective design claim under the *Restatement (Second)* standard, and held that the plaintiff's claim could proceed.<sup>115</sup> The court overruled prior case law, and held that comment k should not except manufacturers of all prescription drugs from strict liability on the basis of defective design.<sup>116</sup> The court rejected the argument that providing blanket immunity to prescription drug manufacturers was necessary.<sup>117</sup> The court also discussed the possibility of adopting the *Restatement (Third)* standard.<sup>118</sup> Noting serious concerns with the *Restatement (Third)* standard, the court declined to adopt it.<sup>119</sup>

The opposing standards of the *Restatement (Second)* and (*Third*) reflect serious disagreement regarding the proper state of prescription drug manufacturer liability for defective drug design. This debate, well-illustrated by the competing views regarding the application of comment k, stems from fundamental disagreements with the proposition that prescription drugs, as a product category, are different from other consumer products.<sup>120</sup>

Critics of prescription drug manufacturer design liability have posed the argument that "prescription drugs are different" to justify the exclusion of design defect claims through both the *Restatement (Second)* and *Restatement (Third)*.<sup>121</sup> Courts that adhere to the view that all prescription drugs should be treated as a favored product category have given effect to this view with a blanket application of comment k.<sup>122</sup> Under this minority view, manufacturers of all prescription drugs are excepted from strict liability on the basis of defective design, regardless of the social utility of the prescription drug at issue.<sup>123</sup>

On the other side of the debate, proponents of prescription drug manufacturer design liability have sought to limit judicial distinc-

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115. *Id.* at 840-41.

116. *Id.* at 837.

117. *Id.* at 836 ("[S]ocietal interests in ensuring the marketing and development of prescription drugs will be adequately served without the need to resort to a rule of blanket immunity.").

118. *Id.* at 837-41.

119. *Id.*

120. See generally Henderson & Twerski, *supra* note 18, at 170 (arguing that prescription drugs, as a product category, are fundamentally different from other consumer products).

121. See generally Henderson & Twerski, *supra* note 1; see also, e.g., Brown v. Superior Court (Abbott Labs.), 751 P.2d 470, 478 (Cal. 1988).

122. See Brown, 751 P.2d at 478; Grundberg v. Upjohn Co., 813 P.2d 89, 94 (Utah 1991); Young v. Key Pharms., Inc., 922 P.2d 59, 64 (Wash. 1996).

123. Brown, 751 P.2d at 478; Grundberg, 813 P.2d at 94; Young, 922 P.2d at 64.

tion between prescription drugs and other consumer products.<sup>124</sup> Courts that do not recognize prescription drugs as a favored product category apply comment k's protections only to manufacturers of prescription drugs that confer an important social utility.<sup>125</sup> This debate about the application of comment k is reflected in the controversy over the ALI's adoption of the *Restatement (Third)*. In rejecting the *Restatement (Third)* and rethinking its blanket application of comment k, the Nebraska Supreme Court discussed several criticisms of both the *Restatement (Second)* and *(Third)* standards, as well as the competing views of comment k.<sup>126</sup> While this area of law may now be settled in Nebraska, the issue is far from clear in many other jurisdictions.

### **A. A Distinction With a Difference – Are Prescription Drugs Fundamentally Different from Other Consumer Products?**

Some courts and commentators argue that prescription drugs, as a product category, are more important to society than other consumer products.<sup>127</sup> While most consumer products may provide convenience or pleasure to their users, prescription drugs often serve a more important societal need, such as the preservation of life.<sup>128</sup> Accordingly, prescription drugs merit special attention, and prescription drug manufacturers should not be held strictly liable on the basis of defective design.<sup>129</sup> These courts apply comment k

124. *E.g.*, *Feldman v. Lederle Labs., Inc.*, 479 A.2d 374, 383 (N.J. 1984) (rejecting categorical distinction between prescription drugs and other consumer products). *See generally* Cupp, *supra* note 5, at 99 (“Prescription products are far from unique in potentially benefiting one class of consumers while harming others.”).

125. *E.g.*, *Feldman*, 479 A.2d at 383 (restricting comment k's protections to prescription drugs possessing an important societal utility).

126. *Freeman v. Hoffman-LaRoche*, 618 N.W.2d 827, 835-41 (Neb. 2000).

127. *E.g.*, *Brown*, 751 P.2d at 478 (addressing the distinction between prescription drugs and other consumer products); *see also* Conk, *supra* note 5, at 1093 (noting that the initial infrequency of defective design claims involving prescription drugs served to reinforce the idea that prescription drugs were a favored class of product, and should not be subject to strict liability); M. Stuart Madden, *The Enduring Paradox of Products Liability Law Relating to Prescription Pharmaceuticals*, 21 *PACE L. REV.* 313, 318 (2001) (arguing that societal recognition of the importance of prescription drugs militates against imposing strict liability).

128. *E.g.*, *Brown*, 751 P.2d at 478 (“[Consumer products are] used to make work easier or to provide pleasure, while [prescription drugs] . . . alleviate pain and suffering . . .”); *Grundberg*, 813 P.2d at 95-96 (noting unique characteristics of prescription drugs).

129. *See, e.g.*, *Brown*, 751 P.2d at 480; *Grundberg*, 813 P.2d at 94; *Young v. Key Pharms. Inc.*, 922 P.2d 59, 64 (Wash. 1996).

in blanket fashion, following the *Brown* line of cases.<sup>130</sup> The *Restatement (Third)* continues this approach, treating prescription drugs as a favored product category, and excepting prescription drug manufacturers from strict liability on the basis of defective design.<sup>131</sup>

Despite the development of the *Brown* line of cases, and the subsequent adoption of the *Restatement (Third)*, most courts reject this view. Courts following the *Feldman* line of cases decline to recognize a bright-line distinction between all prescription drugs and other consumer products. These courts argue that since not all prescription drugs confer an important benefit to society, prescription drugs should not be treated as a favored class of product.<sup>132</sup> Accordingly, not all manufacturers of prescription drugs should be exempted from strict liability on the basis of defective design.<sup>133</sup>

### 1. *The Restatement (Third)'s Distinction*

The *Restatement (Third)*'s view that prescription drugs are fundamentally "different" from other consumer products is evident from the text and comments of section 6. Additionally, the distinction is demonstrated by the fact that the *Restatement (Third)* analyzes design defect claims not involving prescription drugs under section 2(b), while defect claims involving prescription drugs are analyzed under section 6(c).<sup>134</sup> Such a categorical distinction indicates the *Restatement (Third)*'s view that prescription drugs constitute a favored class of product, and deserve protection from strict liability.

According to the *Restatement (Third)*, each type of prescription drug poses a "unique set of risks and benefits."<sup>135</sup> As such, it is improper to judicially determine that a particular prescription

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130. *E.g.*, *Brown*, 751 P.2d at 480; *Grundberg*, 813 P.2d at 94; *Young*, 922 P.2d at 64. See *supra* note 57.

131. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(c) cmt. b (1997); see also Henderson & Twerski, *supra* note 1, at 1545.

132. *E.g.*, *Hill v. Searle Labs.*, 884 F.2d 1064, 1069 (8th Cir. 1989) (rejecting complete distinction between prescription drugs and other consumer products); *Toner v. Lederle Labs.*, 732 P.2d 297, 308 (Idaho. 1987); *Feldman v. Lederle Labs.*, 479 A.2d 374, 383 (N.J. 1984).

133. *Toner*, 732 P.2d at 308 ("[Comment k should not] provide all ethical drugs with blanket immunity from strict liability design defect claims.").

134. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(b); *Id.* § 6(c) cmt. b.

135. *Id.* § 6(c); accord *Brown*, 751 P.2d at 482 ("[T]he advantages of a [prescription] drug cannot be isolated from the condition of a particular patient."); *Grundberg*, 813 P.2d at 95-96 (Utah 1991) ("Because prescription drugs are chemical compounds designed to interact with the chemical and physiological processes of the human body, they will almost always pose some risk of side effects in certain individuals.").

drug's design is "defective," as the drug may interact differently with each patient.<sup>136</sup> Unless the prescription drug at issue would provide no net benefit to any class of patients, it cannot be considered defectively designed.<sup>137</sup> Under the *Restatement (Third)*, a prescription drug that will cure one class of patients, but seriously injure another class, is not defective, since the drug has conferred a sufficient benefit.<sup>138</sup>

The *Restatement (Third)* also draws heavily on the learned intermediary concept in its distinction between prescription drugs and other consumer products.<sup>139</sup> In contrast to other consumer goods, prescription drugs are obtained through the help of a learned intermediary, who can make knowledgeable decisions as to a particular prescription drug's risks and efficacy for a specific patient.<sup>140</sup> Proponents of the *Restatement (Third)* argue that the involvement of a learned intermediary makes imposing strict liability on prescription drug manufacturers unnecessary.<sup>141</sup>

## 2. The Minority Regime's Distinction

Adhering to the view that prescription drugs, as a product category, are different than other consumer goods, courts following the *Brown* line of cases apply comment k's protections to manufacturers of all prescription drugs.<sup>142</sup> The *Brown* court recognized this

136. See Henderson & Twerski, *supra* note 1, at 1536; see also *Grundberg*, 813 P.2d at 95; *Young v. Key Pharms., Inc.*, 922 P.2d 59, 64 (Wash. 1996). As the *Restatement (Third)* soundly rejects judicial review of prescription drug designs, it necessarily defers to the regulatory framework of the FDA. See *infra* Part II.B. for a discussion of the FDA's role in reviewing prescription drug designs.

137. See Henderson & Twerski, *supra* note 1, at 1538 ("It appears elementary that so long as a group exists for whom the drug in question is the drug of choice, then the issue of design has no place in the applicable liability law.")

138. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. f.

139. *Id.* § 6 cmt. b ("The rationale supporting this 'learned intermediary' rule is that only health-care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy."). In support of a bright-line distinction between prescription drugs and other consumer products, the *Restatement (Third)* also takes note of the extensive regulatory system provided by the FDA to governing the distribution of prescription drugs. *Id.* For a discussion of the *Restatement (Third)*'s deference to the FDA, see *infra* Part II.B.

140. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. b; see also Henderson & Twerski, *supra* note 1, at 1538.

141. See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. f; see also Henderson & Twerski, *supra* note 1, at 1538-39.

142. *E.g.*, *Brown v. Superior Court (Abbott Labs.)*, 751 P.2d 470 (Cal. 1988) (holding comment k applicable to all manufacturers of prescription drugs); *Grundberg v. Upjohn Co.*, 813 P.2d 89, 95 (Utah 1991); *Young v. Key Pharms. Inc.*, 922 P.2d 59, 64 (Wash. 1996).

distinction by noting that while most consumer products are used merely for pleasure or convenience, prescription drugs often “save lives and reduce pain and suffering.”<sup>143</sup> Unlike other consumer products, harm resulting from using prescription drugs might be unavoidable.<sup>144</sup>

Supporting the *Brown* line of cases, many commentators agree with the view that prescription drugs are different from other consumer products.<sup>145</sup> For example, while many consumer goods may be redesigned to increase their safety, prescription drugs are often limited to a singular chemical structure, rendering them incapable of redesign.<sup>146</sup> Accordingly, this limitation bolsters the argument that prescription drugs are unavoidably unsafe.

Further, proponents of a distinction between prescription drugs and other consumer products argue that holding prescription drug manufacturers strictly liable for defective design does not serve the interests of public policy.<sup>147</sup> Many have noted that public policy demands the timely development and marketing of beneficial pre-

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143. *Brown*, 751 P.2d at 478.

144. *Id.*; *Grundberg*, 831 P.2d at 95 (“[Prescription drugs] will almost always pose some risk of side effects in certain individuals”); *Young*, 922 P.2d at 64 (“Some products are necessary regardless of the risks involved to the user.”).

145. See generally Michael D. Green, *Prescription Drugs, Alternative Designs, and the Restatement (Third): Preliminary Reflections*, 30 SETON HALL L. REV. 207, 209-15 (1999). Professor Green highlights four reasons why prescription drugs are distinguished from other consumer products: (1) Prescription drugs are highly regulated by the FDA; (2) prescription drugs have a high social utility; (3) prescription drugs are chosen with the assistance of a physician; and (4) prescription drugs that are harmful to some consumers produce benefits to others.

146. See generally Green, *supra* note 145, at 232 (“Drugs are different because they cannot be manipulated physically to provide marginally greater safety.”); Henderson & Twerski, *supra* note 1, at 1545-56. But see *Brown*, 751 P.2d at 478 (“[W]e seriously doubt [defendant’s] claim that a drug like DES cannot be ‘redesigned’ to make it safer.”); *Castrignano v. E.R. Squibb & Sons*, 546 A.2d 775, 781 (R.I. 1988) (arguing that the chemical redesign argument is too narrow, as there may be alternative prescription drugs available that could replace the prescription drug at issue with less side effects); see also Green, *supra* note 145, at 208. However, Professor Green notes that prescription drug manufacturers are increasingly able to engineer drugs, “so as consciously to modify their molecular structure to weed out adverse effects while retaining therapeutic benefits.” *Id.* at 213. This process will become increasingly possible through further technological advances. *Id.*

147. E.g., *Brown*, 751 P.2d at 478-79 (outlining reasons why holding prescription drug manufacturers strictly liable for design defects contravenes public policy); *Grundberg*, 813 P.2d at 94. While the Utah Supreme Court held that prescription drug manufacturers should be exempted from strict liability on the basis of design solely by virtue of the FDA regulatory framework, the court nevertheless agreed with the policy considerations outlined in *Brown*. *Id.* at 95.

scription drugs, and many argue that the public welfare is best served by making prescription drugs as affordable as possible.<sup>148</sup>

The California Supreme Court asserted that holding prescription drug manufacturers strictly liable for design defects could cause manufacturers to delay the release of important prescription drugs.<sup>149</sup> If prescription drug manufacturers could be held strictly liable on the basis of defective design, they would be more likely to delay the ultimate release of prescription drugs to the market in order to extend clinical testing.<sup>150</sup> Such a potential delay would be against public policy interests, as the interests of society "favor[ ] the development and marketing of beneficial new drugs."<sup>151</sup>

The *Brown* court also argued that holding prescription drug manufacturers strictly liable for design defects would dissuade them from researching beneficial new prescription drugs.<sup>152</sup> In the court's view, if a prescription drug manufacturer faced strict liability for potential design choices made when developing a new prescription drug, the manufacturer, fearing adverse judgments, would not likely undertake development of the drug.<sup>153</sup>

The court also asserted that imposing strict liability would increase the financial pressures on prescription drug manufacturers.<sup>154</sup> These financial pressures would likely come in the form of increased expenses from defending against lawsuits, as well as the additional costs of insurance.<sup>155</sup> Imposing these increased expenses upon prescription drug manufacturers would run counter to the public policy interests in the wide availability of prescription drugs, as the increased costs borne by prescription drug manufacturers

148. *Brown*, 751 P.2d at 479.

149. *Id.*

150. *Id.* ("Perhaps a drug might be made safer if it was withheld from the market until scientific skill and knowledge advanced to the point at which additional dangerous side effects would be revealed. But in most cases such a delay . . . would not serve the public welfare.")

151. *Id.*

152. *Id.*

153. *Id.* In outlining the reasons for excepting prescription drug manufacturers from strict liability on the basis of defective design, the *Brown* court cited Dean Prosser:

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

*Id.* (citing PROSSER & KEETON, *supra* note 32, at 661).

154. *Id.*

155. *Id.*



could discourage them from developing valuable new prescription drugs.<sup>156</sup> Due to these additional expenses, imposing strict liability on prescription drug manufacturers "could place the cost of medication beyond the reach of those who need it most."<sup>157</sup>

### 3. *The Majority View Rejects the Distinction*

Most courts have rejected such an abrupt conceptual schism between prescription drugs and other consumer products.<sup>158</sup> Courts following the *Feldman* line of cases recognize that some prescription drugs do confer an especially important societal benefit, and the manufacturers of those prescription drugs should be excepted from strict liability on the basis of defective design.<sup>159</sup> Under this view, however, not all prescription drugs have the same societal value.<sup>160</sup> As such, courts should not treat prescription drugs as a favored product category, excepting all prescription drug manufacturers from strict liability on the basis of defective design.<sup>161</sup>

The Eighth Circuit has held that the public policy arguments concerning strict liability for defective design are equally applicable to other products possessing "life-bettering" characteristics.<sup>162</sup> Many other consumer products, not excepted from strict liability, provide risks and benefits similar to prescription drugs.<sup>163</sup> Similarly, prescription drugs are not the only products that may provide some net benefit to a class of users, without the same benefit to other users.<sup>164</sup> Accordingly, there is little reason to completely dis-

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156. *Id.* at 479-80.

157. *Id.* at 479 (noting that the prescription drug Benedictin, the only anti-nauseant drug available for pregnant women, was withdrawn from the market due to increased insurance costs).

158. *E.g.*, *Hill v. Searle Labs.*, 884 F.2d 1064, 1069 (8th Cir. 1989) (rejecting complete distinction between prescription drugs and other consumer products); *Toner v. Lederle Labs.*, 732 P.2d 297, 308 (Idaho 1987); *Feldman v. Lederle Labs.*, 479 A.2d 374, 383 (N.J. 1984); *see also* *Cupp, supra* note 5, at 99-103.

159. *E.g.*, *Feldman*, 479 A.2d at 382.

160. *Id.*

161. *Id.*

162. *Hill*, 884 F.2d at 1069; *accord* *Shanks v. Upjohn*, 835 P.2d 1189, 1196 (Alaska 1992).

163. *See* *Cupp, supra* note 5, at 99.

164. *See id.* at 101. Professor Cupp employs an analogy where an automobile manufacturer designs an automobile with minimal safety features to minimize price. While there may exist a class of users to whom this product is ideal, strict liability on the basis of defective design would not be precluded merely because some class of users benefits from the dangerous design. *See also* *Green, supra* note 145, at 215 ("[N]o court would automatically rule out liability for a redesigned version of these products to meet the needs of these groups merely because a minority of consumers are made better off by the design.").

tinguish all prescription drugs from other consumer products.<sup>165</sup> Such a forced distinction between prescription drugs and other consumer products creates an artificial schism in favor of prescription drug manufacturers.<sup>166</sup>

In *Feldman v. Lederle Laboratories*, the New Jersey Supreme Court held that although prescription drugs are valuable to the public, there was no justification for excepting all prescription drug manufacturers from strict liability for defective design.<sup>167</sup> The court noted that “[prescription] [d]rugs, like any other products, may contain defects that could have been avoided by better manufacturing or design” and concluded that comment k should not except manufacturers of all prescription drugs from strict liability.<sup>168</sup> Rather than treat all prescription drugs as members of a favored class, the court noted the similarities between prescription drugs and other consumer products.<sup>169</sup>

Disagreeing with the *Brown* court, many courts have held that imposing strict liability for the defective design of some prescription drugs is appropriate.<sup>170</sup> The New Jersey Supreme Court has held that imposing strict liability for design defects may be appropriate when a transaction is product-oriented, such as the distribution of prescription drugs, as opposed to a service-oriented transaction, such as the direct service provided by a doctor.<sup>171</sup> The court noted that prescription drug manufacturers place their goods into the stream of commerce, like manufacturers of other consumer goods.<sup>172</sup> While certain prescription drugs may be valuable to society, prescription drug manufacturers are essentially profit-

165. See *Feldman*, 479 A.2d at 382 (“The evidence does not demonstrate why the drug-manufacturing industry should be placed in a different category from other manufacturers and suppliers of mass-produced products in which the enterprise bear the liability for a product that is not fit, suitable, or safe for its intended use.”).

166. See *Cupp*, *supra* note 5, at 99 (“A weakness in [the categorical distinction between prescription drugs and other consumer products] is that it could be applied to countless other products that the new *Restatement* does not immunize from liability.”); *Vandall*, *supra* note 5, at 271.

167. *Feldman*, 479 A.2d at 382.

168. *Id.*

169. *Id.*

170. *E.g.*, *Kearl v. Lederle Labs.*, 218 Cal. Rptr. 453, 459-63 (Ct. App. 1985), *overruled by* *Brown v. Superior Court (Abbott Labs.)*, 751 P.2d 470 (Cal. 1988); *Feldman*, 479 A.2d at 380 (holding strict liability principles applicable to prescription drug manufacturers).

171. *Feldman*, 479 A.2d at 381-82 (“[Prescription] [d]rug manufacturers, unlike doctors and dentists, do not render to consumers professional services involving skills in judgment and diagnosis.”).

172. *Id.* at 382.

making enterprises, and should be held strictly liable for the defective design of their products.<sup>173</sup>

Some courts have taken issue with the *Brown* court's assertions that imposing strict liability on the manufacturers of prescription drugs would contravene public policy.<sup>174</sup> Rather, courts following the *Feldman* line of cases have asserted that holding prescription drug manufacturers strictly liable on the basis of defective design will further the policy interests of the timely development of new drugs.<sup>175</sup> Some commentators have asserted that imposing strict liability upon prescription drug manufacturers for design defects will result in the development of safer prescription drugs.<sup>176</sup> If a prescription drug manufacturer faces strict liability on the basis of defective design, it will have an incentive to improve its products.<sup>177</sup> In contrast, if the manufacturer will not be strictly liable for defective design, it will have little incentive to improve the design of its products, other than competitive market pressures.<sup>178</sup> Accordingly, a selective application of comment k will encourage, rather than discourage, the research and development of new prescription drugs.

Several courts following the *Feldman* line of cases have emphasized the point that a selective application of comment k strikes an effective balance between a manufacturer's responsibility and the encouragement of research and development of new prescription

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173. *Id.*; see also, e.g., *Finn v. G.D. Searle & Co.*, 677 P.2d 1147, 1164-68 (Cal. 1984) (Bird, C.J., dissenting) (outlining reasons strict liability principles are generally applicable to prescription drug manufacturers).

174. See *Shanks v. Upjohn*, 835 P.2d 1189, 1196 n.8 (Alaska 1992) (disagreeing with the California Supreme Court's findings that imposing strict liability on the manufacturers of prescription drugs would adversely affect the availability and price of prescription drugs). The Alaska Supreme Court also noted that while the court in *Brown* claimed such adverse effects would result from imposing strict liability, the California Supreme Court stated, "[w]e are aware of only one decision that has applied the doctrine of strict liability to prescription drugs." *Brown*, 751 P.2d at 476 (citing *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 654-57 (1st Cir. 1981)). As claims against prescription drug manufacturers have been grounded in claims other than strict liability in the past, it is unclear exactly how the *Brown* court was able to establish a nexus between increased costs and the imposition of strict liability. See *Shanks*, 825 P.2d at 1195 n.8.

175. *Finn*, 677 P.2d at 1165 (Bird, C.J., dissenting) (arguing that imposing strict liability against prescription drug manufacturers would not delay the development and marketing of new prescription drugs).

176. *Id.* (Bird, C.J., dissenting)

177. *Id.* (Bird, C.J., dissenting); see also *Adams v. G.D. Searle & Co.*, 576 So. 2d 728, 732 (Fla. Dist. Ct. App. 1991), review denied, 589 So. 2d 290 (Fla. 1991).

178. *Finn*, 677 P.2d at 1165 (Bird, C.J., dissenting).

drugs.<sup>179</sup> Most courts have agreed, holding that the interests of developing new prescription drugs will be served without the need to provide blanket immunity from strict liability claims to prescription drug manufacturers.<sup>180</sup> Under this view, manufacturers of prescription drugs that serve society with an important utility deserve to be excepted from strict liability claims on the basis of defective design, while manufacturers of less important prescription drugs will be held strictly liable.

Many proponents of the *Feldman* line of cases have also rejected the argument that prescription drug manufacturers are incapable of redesigning drugs to increase their safety.<sup>181</sup> Prescription drugs may often be available in different recommended dosages or combinations, to increase safety without sacrificing efficacy.<sup>182</sup> In many instances, an alternative prescription drug is available, that will afford the same benefits as the drug in issue, with less risk of harm.<sup>183</sup> Under the *Feldman* view, this fact creates less of a reason to view all prescription drugs as a favored product category.

### B. Risk-Utility Design Review and the Role of the FDA

The competing views of the *Restatement (Second)* and (*Third*), as well as the opposing applications of comment k, illustrate the diverging view of the two regimes regarding judicial risk-utility review of prescription drug designs. The *Restatement (Third)* takes the position that courts should not engage in the judicial review of prescription drug designs.<sup>184</sup> Courts following the *Brown* line of cases agree with the *Restatement (Third)*, and apply comment k in

179. *E.g.*, *Hill v. Searle Labs.*, 884 F.2d 1064 (8th Cir. 1989); *Freeman v. Hoffman-LaRoche*, 618 N.W.2d 827, 835 (Neb. 2000).

180. *E.g.*, *Hill*, 884 F.2d at 1069 (“[O]nly exceptional products . . . should be excluded from the strict liability provisions [by comment k.]”); *Toner v. Lederle Labs.*, 732 P.2d 297, 308 (Idaho 1987).

181. *See generally* *Cupp*, *supra* note 5, at 94; *Green*, *supra* note 145, at 211-16. Many commentators also note that most prescription medical devices may be, and often are, redesigned to increase their safety. *Id.* at 213; *see also* *Castrignano v. E.R. Squibb & Sons*, 546 A.2d 775, 781 (R.I. 1988).

182. *E.g.*, *Brown v. Superior Court (Abbott Labs.)*, 751 P.2d 470, 478 (Cal. 1988) (“[The court] seriously doubt[s] [defendant’s] claim that a [prescription drug] cannot be ‘redesigned’ to make it safer.”); *Toner*, 732 P.2d at 308; *Castrignano*, 546 A.2d at 781 (discussing the availability of alternative prescription drugs that cause no side effects, which could replace a defective drug); *see also* *Green*, *supra* note 145, at 213 (noting that technological advancements have enabled the engineering of drugs, on the molecular level, to eliminate adverse effects).

183. *Castrignano*, 546 A.2d at 781.

184. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. b (1997); *see also* *Henderson & Twerski*, *supra* note 1, at 1536 (“[I]n our view, courts should not review the adequacy of prescription drug designs.”).

blanket fashion, excepting all prescription drug manufacturers from strict liability on the basis of defective design.<sup>185</sup> However, most courts, following the *Feldman* line of cases, argue that courts are competent to review prescription drug designs.<sup>186</sup> These courts apply comment k selectively, excepting from strict liability only manufacturers of those prescription drugs that supply an important social need.<sup>187</sup>

In addition, the two regimes hold competing views regarding the proper role of the FDA in reviewing prescription drug designs. The *Restatement (Third)* places a great deal of faith in the role of FDA regulation.<sup>188</sup> Some courts have explicitly deferred to the FDA-approval process, and have declined to hold manufacturers of FDA-approved prescription drugs strictly liable on the basis of defective design.<sup>189</sup> Other courts, while not explicitly deferring to the regulatory process, have implicitly agreed with this result.<sup>190</sup> However, most courts have held that FDA approval should not prevent judicial risk-utility review of prescription drug designs, or prevent a finding that a prescription drug has been defectively designed.<sup>191</sup>

### 1. *The Restatement (Third)'s Rejection of Review*

The *Restatement (Third)* soundly rejects judicial risk-utility review of prescription drug designs.<sup>192</sup> The *Restatement (Third)*'s reporters argue that courts are improper arenas to evaluate prescription drug designs.<sup>193</sup> Because courts should not engage in the design review of prescription drugs, prescription drugs of varying social utilities are treated as a favored product category.

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185. *E.g.*, *Brown*, 751 P.2d at 470 (rejecting risk-utility review of prescription drug designs); *Grundberg v. Upjohn*, 813 P.2d 89, 95 (Utah 1991); *Young v. Key Pharms., Inc.*, 922 P.2d 59, 64 (Wash. 1996).

186. *E.g.*, *Kearl v. Lederle Labs.*, 218 Cal. Rptr. 453, 463-64 (Ct. App. 1985) (accepting risk-utility review of prescription drug designs), *overruled by Brown*, 751 P.2d 470; *Toner*, 732 P.2d at 308-09; *Feldman v. Lederle Labs.*, 479 A.2d 374, 383 (N.J. 1984).

187. *E.g.*, *Kearl*, 218 Cal. Rptr. at 464 (“[S]ome special highly beneficial and yet inherently risky products may be deemed unavoidably dangerous and hence exempt from strict products liability design defect analysis.”).

188. See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. b.

189. *Grundberg*, 813 P.2d at 95.

190. *Brown*, 751 P.2d at 483 n.12; *Young*, 922 P.2d at 64.

191. *Tobin v. Astra Pharm. Prod., Inc.*, 993 F.2d 528, 537-38 (6th Cir. 1993); *Hill v. Searle Labs.*, 884 F.2d 1064, 1068 (8th Cir. 1989); *Shanks v. Upjohn Co.*, 835 P.2d 1189, 1197 n.10 (Alaska 1992); *Toner*, 732 P.2d at 311 n.12; *Savina v. Sterling Drug, Inc.*, 795 P.2d 915, 931 (Kan. 1990); *Feldman*, 479 A.2d at 390-92.

192. See *Henderson & Twerski*, *supra* note 1, at 1536.

193. See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. b; see also *Henderson & Twerski*, *supra* note 1, at 1536.

However, the *Restatement (Third)* does allow for risk-utility review, albeit in a different arena. Rather than allow a trial court to determine if a prescription drug was defectively designed, the *Restatement (Third)* limits that determination to the prescribing physician.<sup>194</sup> Under the *Restatement (Third)* standard, if a reasonable prescribing physician would prescribe the drug at issue, it is not considered defectively designed.<sup>195</sup>

Similarly, the *Restatement (Third)* relies heavily on the FDA's regulation of prescription drugs, without explicitly deferring to the FDA approval process.<sup>196</sup> Under the *Restatement (Third)*, an FDA-approved prescription drug is not automatically excepted from strict liability.<sup>197</sup> As a practical matter, however, the *Restatement (Third)* standard demands this result.<sup>198</sup> The *Restatement (Third)* holds that a prescription drug is not considered defective if any reasonable health care provider would provide the prescription drug to any class of patients.<sup>199</sup> Some commentators argue that as prescription drugs require FDA-approval, and a particular prescription drug will not receive FDA-approval if it provides no net benefit, it is unlikely that an FDA-approved prescription drug could provide so little utility that no reasonable health care provider would prescribe it.<sup>200</sup>

Under the *Restatement (Third)* view, the regulatory framework provided by the FDA to govern the distribution of prescription drugs adequately reviews prescription drugs for defective designs.<sup>201</sup> The *Restatement (Third)*'s reporters note that the FDA approval process is lengthy and comprehensive; no trial court could effectively replicate such a procedure.<sup>202</sup> As a consequence, once a

194. See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. f.

195. *Id.*

196. The text of section 6 does not refer to the FDA-approval process. In fact, the reporters note that, "[U]nqualified deference to these regulatory mechanisms is considered by a growing number of courts to be unjustified." *Id.* § 6 cmt. b.

197. *Id.* § 6 cmt. f.

198. See *id.* § 6 cmt. b. See generally Schwartz, *supra* note 5, at 1397.

199. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(c).

200. *E.g.*, Schwartz, *supra* note 5, at 1383-84.

201. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. b ("[T]he regulatory system governing prescription drugs is a legitimate mechanism for setting the standards for drug design . . . governmental regulatory agencies adequately review new prescription drugs and devices, keeping unreasonably dangerous designs off the market."); see also Grundberg v. Upjohn Co., 813 P.2d 89, 96 (Utah 1991).

202. See Henderson & Twerski, *supra* note 1, at 1538. The California Supreme Court noted a similar concern in Brown v. Superior Court (Abbott Labs.), 751 P.2d 470 (Cal. 1988). While the *Brown* court did not base its holding completely on the fact that prescription drugs are regulated by the FDA, the court noted the inadequacy of

prescription drug has received FDA-approval, a subsequent judicial proceeding to search for a defect within a prescription drug is unnecessary.<sup>203</sup>

## 2. *The Minority's Rejection of Risk-Utility Review*

Many courts following the minority view refuse to recognize the capacity of trial courts to engage in the risk-utility review of prescription drug designs.<sup>204</sup> The arguments for applying comment k in blanket fashion, excepting manufacturers of all prescription drugs from strict liability on the basis of defective design were first set out in *Brown*.<sup>205</sup> The California Supreme Court, holding that prescription drugs differ fundamentally from other consumer products, declined to recognize a difference in social utility between different prescription drugs.<sup>206</sup> The court initially noted that such a distinction would be ideal.<sup>207</sup> However, categorizing prescription drugs according to social utility would interfere with the policy reasons for excepting prescription drug manufacturers from strict liability claims.<sup>208</sup> Simply attempting to distinguish different prescription drugs according to their social utility would impair the public's interest in the development and marketing of new drugs.<sup>209</sup>

In rejecting the mini-trial hearing defined in *Kearl*, the California Supreme Court also expressed a concern that performing a separate comment k analysis to every prescription drug could lead to disparate results, as different trial judges would likely come to different conclusions.<sup>210</sup> As a result, prescription drug manufacturers would have no way to gauge the prospective level of liability that

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the judicial arena for reviewing prescription drug designs, because of the possibility of inconsistent decisions by different trial judges. *Id.* at 482.

203. See Hon. William A. Dreier, *Manufacturer 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.").

204. E.g., *Brown*, 751 P.2d at 481 (holding that the *Kearl* analysis, which took into account the social utility of prescription drugs, would "substantially impair[ ] the public interest in the development and marketing of new drugs, because the harm to this interest arises in the very process of attempting to make the distinction."); accord *Grundberg*, 813 P.2d at 95; *Young v. Key Pharms., Inc.*, 922 P.2d 59, 64 (Wash. 1996).

205. *Brown*, 751 P.2d at 479-80.

206. *Id.* at 481-82.

207. *Id.* at 481 ("It seems unjust to grant the same protection from liability to those who gave us thalidomide as to the producers of penicillin.").

208. *Id.*

209. *Id.*

210. *Id.* at 482.

would attach with its product.<sup>211</sup> In the court's view, this level of uncertainty would be unacceptable and would go against the policy reasons for protecting prescription drug manufacturers from liability.<sup>212</sup> Some commentators have gone so far as to argue that the text itself of comment k should be read to encompass all prescription drugs, excepting all manufacturers from strict liability on the basis of defective design.<sup>213</sup>

Few courts under the minority view have explicitly held that an FDA-approved prescription drug cannot be considered defectively designed. However, courts following the *Brown* line of cases, applying comment k to all prescription drug manufacturers, implicitly agree with the *Restatement (Third)*'s view.<sup>214</sup> While these courts do not explicitly defer to the FDA, they support the *Restatement (Third)*'s argument that courts should defer to the regulatory process when hearing claims involving prescription drug designs.<sup>215</sup>

In *Grundberg v. Upjohn Co.*, the Utah Supreme Court explicitly excepted all manufacturers of FDA-approved prescription drugs from strict liability on the basis of defective design.<sup>216</sup> The court noted the extensive regulatory system provided by the FDA.<sup>217</sup> In the court's opinion, a trial court is not the proper forum to deter-

211. *Id.*

212. *Id.*

213. Compare *id.* at 482 n.11 (holding that comment k "was intended to and should apply to all prescription drugs."), with *Grundberg v. Upjohn Co.*, 813 P.2d 89, 96 (Utah 1991) (disapproving of the *Brown* court's interpretation of the language of comment k, but approving of the policy implications behind the result). But see Cupp, *supra* note 5, at 99-103 (arguing that since comment k has proven difficult to interpret, it should not be read so broadly).

214. Compare RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. b (1997) ("Courts have also recognized that the regulatory system governing prescription drugs is a legitimate mechanism for setting the standards for drug design."), with *Brown*, 751 P.2d at 482 n.12; *Grundberg*, 813 P.2d at 97; *Young v. Key Pharms., Inc.*, 922 P.2d 59, 64-65 (Wash. 1996).

215. See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. b; see also *Brown*, 751 P.2d at 482 n.12; *Grundberg*, 813 P.2d at 97; *Young*, 922 P.2d at 64-65.

216. *Grundberg*, 813 P.2d at 99 (extending "broad grant of immunity from strict liability claims based on design defects" to manufacturers of FDA-approved prescription drugs).

217. *Id.* at 96. In excepting all manufacturers of FDA-approved prescription drugs from strict liability on the basis of defective design, the Utah Supreme Court noted:

Before licensing a new medication, the FDA employs an extensive screening mechanism to ensure that the potential benefits of the product outweigh any associated risks . . . The new drug approval process can require years of testing and review . . . [t]he FDA also conducts extensive post-market surveillance . . . We find this extensive regulatory scheme capable of and appropriate for making the preliminary determination regarding whether a prescription drug's benefits outweigh its risks.

*Id.*



mine whether a particular prescription drug is defective.<sup>218</sup> While most courts have not gone as far as *Grundberg*, courts following the *Brown* line of cases agree with the Utah Supreme Court's reasoning.<sup>219</sup> Applying comment k's protections to all prescription drug manufacturers, courts following the minority view reject trial courts as arenas inadequate to evaluate prescription drug designs.<sup>220</sup>

While the California Supreme Court did not base its holding in *Brown* on the FDA's regulation of prescription drugs, the court nevertheless rejected the trial court as a forum for determining adequate prescription drug designs.<sup>221</sup> The Washington Supreme Court implicitly agreed, holding that, "[I]t is precisely because [prescription drugs] are unavoidably unsafe to some degree that they are prescription drugs."<sup>222</sup>

### 3. *The Majority's Endorsement of Risk-Utility Review*

Many commentators, and courts following the *Feldman* line of cases, argue that a prescription drug's social utility should be a factor in determining whether the manufacturer of the prescription drug will be excepted from strict liability on the basis of defective design.<sup>223</sup> While some prescription drugs, such as lifesaving vaccines, serve a large social utility, many other prescription drugs, such as so-called cosmetic drugs, confer only a small benefit upon society.<sup>224</sup> Accordingly, as prescription drugs vary according to social utility, not all manufacturers of prescription drugs deserve to be excepted from strict liability on the basis of defective design.<sup>225</sup> As such, courts adhering to this view apply comment k in a selective fashion, excepting from strict liability on the basis of defective design only those manufacturers of prescription drugs deemed important to society.<sup>226</sup>

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218. *Id.* at 98.

219. *E.g.*, *Brown*, 751 P.2d at 482 (holding comment k applicable to all prescription drug manufacturers, and rejecting the trial court as the proper forum for the evaluation of prescription drug designs); *Young*, 922 P.2d at 64.

220. *Brown*, 751 P.2d at 482; *Grundberg*, 813 P.2d at 98.

221. *Brown*, 751 P.2d at 483 n.12 ("It should also be noted that the consumer of prescription drugs are afforded greater protection against [design] defects than consumers of other products, since 'the drug industry is closely regulated by the [FDA] . . . .'") (citing *Sindell v. Abbott Labs.*, 607 P.2d 924, 935 (Cal. 1980)).

222. *Young*, 922 P.2d at 64.

223. *E.g.*, *Freeman v. Hoffman-LaRoche*, 618 N.W.2d 827, 839 (Neb. 2000).

224. *Id.*

225. *Id.*

226. *See supra* note 55.

In *Freeman v. Hoffman-LaRoche*, the Nebraska Supreme Court found the *Restatement (Third)* standard inflexible, noting that it treats all prescription drugs equally, with no regard to societal utility.<sup>227</sup> The court noted that under the *Restatement (Third)*, a cosmetic drug that has very little utility will be protected from strict liability design review to the same degree as a life saving vaccine.<sup>228</sup> The Supreme Court of Alaska agreed, holding that while the social utility of prescription drugs as a product category may outweigh other consumer products, individual prescription drugs differ in social value.<sup>229</sup> The court expressed concern with “granting ‘the same protection from liability to those who gave us thalidomide as to the producers of penicillin.’”<sup>230</sup>

A California appellate court took the same view in *Kearl v. Lederle Laboratories*, holding that comment k should serve to except from strict liability on the basis of defective design only those prescription drugs that possess an important social utility.<sup>231</sup> The majority noted that several important factors called for a distinction between prescription drugs worthy of comment k’s protection and those subject to strict liability, such as whether a safer alternative was available.<sup>232</sup>

Many courts have rejected a blanket application of comment k as not in keeping with the purpose behind the comment.<sup>233</sup> In rejecting the argument that comment k should except all prescription drugs from strict liability on the basis of defective design, the Eighth Circuit defined the purpose of comment k as “protect[ing] defendants who supply critically needed but potentially harmful products . . . .”<sup>234</sup> Courts have argued that the language of comment k itself suggests that only exceptional products, which meet an important social need will fall under the comment’s protections.<sup>235</sup>

227. *Hoffman-LaRoche*, 618 N.W.2d at 839.

228. *Id.*

229. *Shanks v. Upjohn*, 835 P.2d 1189, 1195 (Alaska 1992).

230. *Id.* (quoting *Brown v. Superior Court (Abbott Labs.)*, 751 P.2d 470, 481 (Cal. 1988)).

231. *Kearl v. Lederle Labs.*, 218 Cal. Rptr. 453, 463 (Ct. App. 1985), *overruled by Brown*, 751 P.2d at 470.

232. *Id.*

233. *Hill v. Searle Labs.*, 884 F.2d 1064, 1069 (8th Cir. 1989) (“The drafters of comment k did not intend to grant all manufacturers of prescription drugs a blanket exception to strict liability.”); *Toner v. Lederle Labs.*, 732 P.2d 297, 308 (Idaho 1987).

234. *Hill*, 884 F.2d at 1069.

235. *Id.*; *see also Toner*, 732 P.2d at 308.

Many commentators agree with this majority view, arguing that prescription drugs of varying social utility should not be treated equally.<sup>236</sup> In addition, commentators argue that a blanket application of comment k limits the discretionary powers of the courts.<sup>237</sup> Applying such blanket immunity for one class of product leads to patently unjust results.<sup>238</sup>

In contrast to the *Restatement (Third)*'s position and the *Brown* line of cases, courts following the *Feldman* line of cases have declined to defer to the FDA as the ultimate arbiter of prescription drug designs.<sup>239</sup> Many courts have noted that the FDA does not review prescription drugs for optimal design.<sup>240</sup> Rather, the FDA's oversight consists merely of minimal standards of conduct.<sup>241</sup>

Many courts and commentators adhering to the *Feldman* line of cases have noted the inadequacies of the FDA regulatory scheme.<sup>242</sup> In the past, the FDA has failed to prevent defective and harmful prescription drugs and medical devices from reaching the market.<sup>243</sup> Worse yet, some commentators argue, the FDA has been plagued with instances of prescription drug manufacturer fraud.<sup>244</sup> Many commentators argue that the FDA's underfunding, understaffing, and exposure to changing political climates are strong factors weighing against the agency's role as the sole arbiter of prescription drug designs.<sup>245</sup>

Many commentators have argued that the *Restatement (Third)* standard represents a complete abdication of defective design review to the FDA.<sup>246</sup> Under the *Restatement (Third)*, a prescription drug is not considered defectively designed if any reasonable health care provider would prescribe the drug to any class of pa-

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236. See Cupp, *supra* note 5, at 103.

237. *Id.*

238. *Id.*

239. *E.g.*, *Tobin v. Astra Pharm. Prods., Inc.*, 993 F.2d 528, 537-38 (6th Cir. 1993); *Feldman v. Lederle Labs.*, 479 A.2d 374, 383 (N.J. 1984) ("[T]he FDA's determination, even if it consisted of a risk-utility balancing analysis, would not supplant the risk-utility balancing required in the judicial process.").

240. See Schwartz, *supra* note 5, at 1391-95.

241. *Id.*

242. See Cupp, *supra* note 5, at 104-05; Schwartz, *supra* note 5, at 1385-97 (noting inadequacies in past enforcement efforts by the FDA).

243. Schwartz, *supra* note 5, at 1396 (noting FDA criticism for lax oversight in reviewing new prescription drug applications).

244. *Id.* (noting cases where prescription drug manufacturers fabricated data supplied to the FDA, and failed to report adverse prescription drug effects during testing).

245. *Id.*

246. *Id.*

tients.<sup>247</sup> These critics assert that this standard places too much faith in the FDA's regulatory role.<sup>248</sup> By foreclosing liability from all but the most egregious situations, the *Restatement (Third)* effectively employs FDA approval as a bright line rule.<sup>249</sup> A drug will not receive FDA approval if there is no potential net benefit to any class of patients. Thus, if a prescription drug has received FDA approval, it must confer some benefit to some class of patients, and cannot be considered defective as a matter of law under the *Restatement (Third)*. This regime of unquestioning reliance on the FDA approval process has not been followed by many jurisdictions.<sup>250</sup>

Most commentators do not completely discount the FDA's role in regulating and protecting consumers from defectively designed prescription drugs.<sup>251</sup> However, some argue that the tort system should serve as an adjunct to the FDA regulatory system.<sup>252</sup> To the extent the FDA cannot ensure regulatory compliance, the tort system must act as a deterrent.<sup>253</sup>

### C. View From the Sidelines: Federal Predictions on the Future of the Debate

Although no state court has formally adopted the *Restatement (Third)* standard, several federal courts have discussed the application of section 6(c) in claims of strict liability on the basis of defective design. Although federal opinions are not dispositive on state law, federal courts may often provide a useful guide to the current state and likely evolution of state law.<sup>254</sup> In the absence of well-

247. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(c) (1997).

248. *Id.* § 6 cmt. b ("Courts have also recognized that the regulatory system governing prescription drugs is a legitimate mechanism for setting the standards for drug design."). This proposition is dubious. See Cupp, *supra* note 5, at 104.

249. Schwartz, *supra* note 5, at 1380.

250. See Cupp, *supra* note 5, at 97. *But see* Grundberg v. Upjohn, 813 P.2d 89, 96-97 (Utah 1991) (holding that FDA approval of a prescription drug precludes imposition of strict liability).

251. See Schwartz, *supra* note 5, at 1385-87.

252. See *id.* at 1386. Professor Schwartz notes that the FDA regulatory and tort systems often interact. For instance, as the FDA lacks the subpoena power possessed by many other agencies, it must often rely on the tort system to bring information to the forefront. The FDA frequently uses information obtained in this manner to initiate regulatory action. In addition, there are areas where the FDA does not have authority to regulate, or where the FDA has failed to regulate. In these situations, the tort system must act as a deterrent. *Id.*

253. *Id.*

254. See generally Geri J. Yonover, *A Kindler, Gentler Erie: Reining in the Use of Certification*, 47 ARK. L. REV. 305, 307-10 (1994).

settled state case law, a federal court's analysis may serve as a guide to future state decisions.

The federal courts that have confronted the *Restatement (Third)* handle the issue in several ways. One federal court has declined to apply the *Restatement (Third)* standard, noting a complete absence of state precedent.<sup>255</sup> Upon hearing motions for summary judgment in *Wheat v. Sofamor*, the United States District Court for the Northern District of Georgia was faced with the issue of applying the *Restatement (Third)* standard.<sup>256</sup> The plaintiffs had sued for strict liability on the basis of defective design, after suffering injuries subsequent to the implantation of "pedicle screws," medical devices used as a catalyst for the fusion of spinal vertebrae.<sup>257</sup>

Noting that Georgia had not yet directly confronted the *Restatement (Third)* the district court hesitated to apply it.<sup>258</sup> As the plaintiff's expert testified that implantation of the defendant's pedicle screws could be warranted in some instances, the court noted that the plaintiff's strict liability claim would fail under the *Restatement (Third)* standard.<sup>259</sup> While the court, without a detailed analysis, pronounced the *Restatement (Third)* standard "sound," the plaintiff's defective design claim was ultimately decided on other grounds.<sup>260</sup>

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255. See *Wheat v. Sofamor*, 46 F. Supp. 2d 1351 (N.D. Ga. 1999).

256. *Id.*

257. For a detailed discussion of bone-screw litigation, see James M. Beck & John A. Valentine, *Challenging the Validity of FDCA-Based Causes of Action in the Tort Context: The Orthopedic Bone Screw Experience*, 55 FOOD DRUG L.J. 389 (2000).

258. *Wheat*, 46 F. Supp. 2d at 1361 n.11. The court noted, however, a Georgia Supreme Court decision that had relied on a preliminary draft of the *Restatement (Third)*. *Banks v. ICI Americas, Inc.*, 450 S.E.2d 671, 675 (Ga. 1994) (citing preliminary draft of *Restatement (Third)* to support use of risk-utility analysis in design defect case). The district court also noted, however, that the Georgia Supreme Court's analysis of the *Restatement (Third)* was limited to adopting a risk-utility analysis and did not discuss section 6(c). *Wheat*, 46 F. Supp. 2d at 1361 n.11.

259. *Wheat*, 46 F. Supp. 2d at 1361 n.11.

260. *Id.* at 1361-62 (dismissing the plaintiff's design defect claim under risk-utility grounds). Although the court described the *Restatement (Third)* standard as "sound," the opinion should not be read as an endorsement of the *Restatement (Third)*. In support of the proposition that the Georgia Supreme Court had been willing to look to the *Restatement (Third)*, the court noted that in *Banks v. ICI Americas, Inc.*, the Georgia Supreme Court had cited the *Restatement (Third)*. However, the district court failed to reconcile its lukewarm endorsement of the *Restatement (Third)*, with the meaning behind the opinion in *Banks*, whereby the Georgia Supreme Court stressed the importance of a risk-utility analysis and reasonable alternative design analysis. While *Banks* did not involve a defectively designed prescription drug claim, the Northern District of Georgia failed to explain why the *Restatement (Third)* standard, without a reasonable alternative design provision or risk-utility analysis, was the preferable standard.

The United States District Court for the District of Arizona also applied the *Restatement (Third)* standard in a defective design claim, while noting that Arizona had not formally adopted the *Restatement (Third)* standard.<sup>261</sup> After suffering injuries subsequent to the implantation of defendant's esophageal device, the plaintiff sued for strict liability on the basis of defective design.<sup>262</sup> Although the plaintiff argued that the design claim should be analyzed under the *Restatement (Second)* standard, both parties agreed that Arizona had demonstrated a "willingness to look to the *Restatement (Third)* as the current statement of the law."<sup>263</sup> The court granted the defendant's motion for summary judgment, after the plaintiff's expert testified that he himself might have used the defendant's medical device under certain medical conditions.<sup>264</sup>

Other federal courts have also been faced with the issue of applying the *Restatement (Third)* standard, and have done so, with little analysis. In *Sita v. Danek Medical, Inc.*, plaintiffs sued a pedicle screw manufacturer in the Eastern District of New York, alleging strict liability on the basis of defective design.<sup>265</sup> The defendant moved for summary judgment, refuting the plaintiff's evidence of a design defect.<sup>266</sup> Answering the defendant's motion, the plaintiff urged the court to apply the *Restatement (Third)* standard.<sup>267</sup> The court held that the plaintiff's design defect claim would fail under

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261. See *Gebhardt v. Mentor Corp.*, 191 F.R.D. 180, 185 (D. Az. 1999).

262. *Id.* at 182.

263. See *id.* (citing *Jimenez v. Sears, Roebuck & Co.*, 904 P.2d 861, 867 (Ariz. 1994) (citing RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. §§ 10, 12 (Tentative Draft No. 2, 1995), in support of applying comparative fault principles to strict liability claim)). The District Court also noted that no Arizona case had actually adopted the *Restatement (Third)* standard. *Id.* at 185.

264. *Id.* The district court also noted that summary judgment in favor of defendant would be proper under section 2(b) of the *Restatement (Third)*, as the plaintiff's experts testified that it would not be possible to redesign the defendant's medical device to improve safety. *Id.* at 185 n.2. The court did not explain its reason for applying the *Restatement (Third)*, only that the parties had agreed that Arizona had indicated a willingness to look to the *Restatement (Third)* as the present state of the law. However, the authority cited by the court demonstrates that in no way had Arizona been planning a wholesale adoption of the *Restatement (Third)*, as the *Jimenez* court cited the *Restatement (Third)* solely for support that Georgia had accepted the entire *Restatement (Third)*, not that it had accepted the discrete principles contained therein. *Jimenez*, 904 P.2d at 867.

265. See *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 248-49 (E.D.N.Y. 1999).

266. *Id.* at 249.

267. *Id.* at 256 n.9.

the *Restatement (Third)*, as overwhelming evidence indicated that the defendant's product represented the proper standard of care.<sup>268</sup>

One federal court has applied the *Restatement (Third)* standard, and has used its analysis to predict the adoption of the higher standard by a state court.<sup>269</sup> In yet another pedicle-screw case, plaintiffs sued for strict liability on the basis of defective design.<sup>270</sup> Applying section 402(a) of the *Restatement (Second)*, the court granted the defendant's motion for summary judgment.<sup>271</sup> In dicta, the court predicted that as a consequence of Pennsylvania's blanket exclusion of prescription drugs from strict liability, Pennsylvania would eventually adopt section 6(c) of the *Restatement (Third)*.<sup>272</sup> In contrast to the other federal opinions discussing the *Restatement (Third)*, the Eastern District of Pennsylvania effectively furthers the debate on the future of the *Restatement (Third)* in Pennsylvania. The district court noted Pennsylvania law interprets comment k broadly, excepting all prescription drug manufacturers from strict liability on the basis of defective design.<sup>273</sup> In regards to state precedent, the court correctly made the connection between Pennsylvania's blanket application of comment k, and its eventual likely adoption of the *Restatement (Third)* standard.<sup>274</sup>

Overall, federal courts confronted with the *Restatement (Third)* in the context of defectively designed prescription drug claims do

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268. *Id.* at 258-59. The court also noted that under New York law, a party seeking damages in a strict products liability claim is required to present evidence of a reasonable alternative design. *See id.* at 258 (citing *Voss v. Black & Decker Mfg. Co.*, 450 N.E.2d 204, 208 (N.Y. 1983)). The court noted that summary judgment would have also been appropriate for the plaintiff's failure to present evidence of a reasonable alternative design. While the court briefly discussed applying the *Restatement (Third)*, it is unclear from the opinion whether the court actually applied the new standard, as the plaintiff had been unable to show any evidence of design defect. Furthermore, the court did not discuss the soundness of the *Restatement (Third)* standard in terms of policy, nor did the court discuss whether, and to what degree, the *Restatement (Third)* fit within established New York case law.

269. *See Taylor v. Danek Medical, Inc.*, 1998 U.S. Dist. LEXIS 20265, at \*1 (E.D. Pa. Dec. 29, 1998).

270. *Id.* at \*20.

271. *Id.* at \*21-\*23. The court noted that under Pennsylvania law, the strict liability provisions of the *Restatement (Second)*, section 402(a) are inapplicable to prescription drugs. *Id.* at \*21 (citing *Hahn v. Richter*, 673 A.2d 888, 891 (Pa. 1996)). The district court predicted that the Pennsylvania Supreme Court would extend this principle to prescription medical devices. *Id.* at \*22.

272. *Id.* at \*22-\*23.

273. *Id.*

274. *Id.* For an analysis of the connection between applying comment k to except all prescription drug manufacturers from strict liability on the basis of defective design, and the parallel effect of the *Restatement (Third)*, see *infra* Part III.A.

little to advance the debate.<sup>275</sup> Federal interpretations of the issues presented by the *Restatement (Third)* are spotty, and a true analysis of the future of design defect liability is wanting.<sup>276</sup> The federal opinions that have dealt with design defect claims under the *Restatement (Third)* have not discussed the higher standard's suitability in terms of policy.<sup>277</sup> Few decisions have truly analyzed the issues, and most have not debated the implications of adopting the *Restatement (Third)*.<sup>278</sup> In addition, when applying the *Restatement (Third)*, federal courts have not sought to determine whether the new standard squares with state precedent.<sup>279</sup> If states are to receive guidance on how to proceed, they will not find it looking to their sister federal courts.

### III. A UNIFIED ANALYTICAL FRAMEWORK

As the prescription drug manufacturer liability debate continues with the adoption of the *Restatement (Third)*, it appears that states have been given little guidance as to how they should proceed. Faced with the conflicting interpretations of law by the ALI and their own case law, states face the dilemma of either continuing with precedent set over the past two decades which may or may not conflict with the *Restatement (Third)*, or abandoning state precedent in favor of the standard put forth by the *Restatement (Third)*.

#### A. Prescription Drugs Should Not Be Treated as a Favored Product Category

By eliminating the review of prescription drug designs, and upholding a bright-line distinction between prescription drugs and other consumer products, the *Restatement (Third)* essentially mirrors the minority view, following the *Brown* line of cases. Under this paradigm, courts are to treat prescription drugs as a favored product category, and prescription drug manufacturers are to be completely excepted from strict liability claims on the basis of defective design. In a sense, the *Restatement (Third)* is a restatement

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275. See *supra* notes 255-268 and accompanying text.

276. See *supra* notes 255-268 and accompanying text.

277. See *supra* notes 255-268 and accompanying text.

278. See *supra* notes 255-268 and accompanying text.

279. See *supra* notes 255-268 and accompanying text. *But see Taylor*, 1998 U.S. Dist. LEXIS 20265, at \*22-\*23; *supra* notes 269-274 (noting that the District court's prediction that the Pennsylvania Supreme Court would eventually adopt section 6(c) of the *Restatement (Third)* squares with state precedent).



of the law; not of the law of the majority, but of the law as the reporters believe it should be.

The *Restatement (Third)*, by providing a completely separate standard for the analysis of design defect claims involving prescription drugs, creates a categorical distinction between prescription drugs and other consumer products. Courts following the *Brown* view agree with this distinction. This view argues that prescription drugs, as a product category, are more important to society. This analysis is too broad to be effective. It is true that some prescription drugs are extremely important to society. However, this proposition ignores the fact that different prescription drugs serve society with unequal utility. Excepting manufacturers of all prescription drugs ignores the important variations between different prescription drugs, and treats prescription drugs as a favored product category.

Although prescription drugs are important to society, many other consumer products are important as well. Manufacturers of countless other consumer products are held strictly liable for their products' design defects. Simply because some prescription drugs will confer a valuable benefit upon society is no reason to treat all prescription drugs as possessing this benefit. However, the *Restatement (Third)* does just that; treating all marketable prescription drugs as possessing the same utility. This view constitutes an unwarranted protection of prescription drugs, creating a favored product category.

The *Restatement (Third)* furthers the view that prescription drugs cannot be redesigned to increase safety. Adherents to this view argue that since prescription drugs are often limited to a fixed chemical composition, they are incapable of redesign. Such a proposition, if true, would further the minority view's argument for a distinction between prescription drugs and other consumer products. For example, assume the existence of a prescription drug, completely incapable of redesign, which provides an important societal utility. Such a prescription drug would deserve protection from strict liability on the basis of defective design, as the benefit provided by the drug would not be available by other, safer means.

However, the *Restatement (Third)*, as well as the minority view, fails to account for the fact that some prescription drugs can be redesigned. Future advances in pharmaceutical technologies will only make this more likely. Treating all prescription drugs as unavoidably unsafe ignores this reality. If the hypothetical prescription drug discussed above were capable of being redesigned, the

prescription drug may not be considered unavoidably unsafe, as the drug's benefits would be available in a different form, with less accompanying risks. The *Restatement (Third)* ignores this reality, treating a prescription drug as unavoidably unsafe even if there exists a safer and effective alternative.

Furthermore, if a prescription drug is indeed incapable of being redesigned, the same benefits may often be achieved by employing different combinations of prescription drugs, lower dosages, or alternative drugs altogether. Simply because a particular prescription drug is limited to a fixed chemical composition should not mean that the prescription drug's form is completely immutable. Yet the *Restatement (Third)* ignores this fact as well.

In contrast to the *Restatement (Third)*, and courts following the *Brown* line of cases, the majority view appropriately recognizes that prescription drugs should not be treated as a favored product category. Under the majority's application of comment k, if our hypothetical prescription drug were truly incapable of being redesigned, and should no reasonable alternative be available, the unavoidably unsafe determination would likely apply, and the prescription drug's manufacturer would be excepted from strict liability on the basis of defective design. However, if the prescription drug would be capable of being redesigned, or an alternative design was available, the manufacturer of our drug would properly be held strictly liable for its drug's design defects.

The *Restatement (Third)* also leans heavily on the learned intermediary concept, in support of a categorical distinction between prescription drugs and other consumer products. According to the reporters, prescription drugs are unique among products in that their use requires involvement by a prescribing physician. However, many prescribing physicians lack the superior knowledge of the prescription drug manufacturer. Most physicians prescribe drugs they know, not necessarily the best prescription drugs available. Deferring to the prescribing physician in blanket fashion ignores this reality.

In contrast to the *Restatement (Third)*, the *Restatement (Second)*, with a selective application of comment k, best recognizes that not all prescription drugs are fundamentally different from other consumer products. The majority view achieves the best balance in its treatment of prescription drugs, as a product category. While important prescription drugs, conferring a large societal utility are excepted from strict liability on the basis of defective design, manufacturers of less important drugs will continue to be held

strictly liable. A comparison of the two regimes illustrates the overbreadth of the *Restatement (Third)*, and of the jurisdictions following the *Brown* line of cases. Consider again our hypothetical prescription drug, a life-saving vaccine, incapable of being redesigned, the use of which is accompanied by serious risks. Under the *Restatement (Second)*, the vaccine's manufacturer would not be held strictly liable for injuries attendant with the drug's use. In such a situation, the vaccine would clearly be considered unavoidably unsafe. Although the risks of using the vaccine are high, public policy would clearly militate against imposing strict liability. Under the *Restatement (Third)*, the manufacturer of the life-saving vaccine would also be excepted from strict liability, if the vaccine's manufacturer could show that reasonable health-care providers, aware of the risks involved, would still prescribe the vaccine. Similarly, in jurisdictions following the *Brown* line of cases, the vaccine's manufacturer would also be excepted from strict liability, as under the minority view all prescription drugs are deemed unavoidably unsafe.

However, instead of a life-saving vaccine, consider at issue a cosmetic drug, one not used to save lives, but for convenience. In such a situation, assume that the prescription drug confers less of a societal benefit and is capable of redesign, or an alternate prescription drug is available. Under the *Restatement (Second)*, the manufacturer of such a drug will not be excepted from strict liability on the basis of design, and will be held liable for injuries resulting from the use of its drug. However, under the *Restatement (Third)*, the manufacturer will be completely excepted from strict liability. Even though the cosmetic drug provides little societal benefit, it is given the same protection as the life-saving vaccine. Jurisdictions following the *Brown* line of cases would reach the same result.

## **B. Courts Should Not Reject Prescription Drug Design Review**

Both the *Restatement (Third)*, and courts following the *Brown* line of cases, decline to allow judicial review of prescription drug designs. Courts following the *Feldman* line of cases disagree, arguing that courts should review the adequacy of prescription drug designs. As prescription drugs differ in the benefit they provide to society, the *Feldman* line of cases is correct.

Foreclosing review on the adequacy of prescription drug designs serves to enforce the categorical distinction between prescription drugs and other consumer products. By eliminating the possibility of judicial design review, the *Restatement (Third)*, and courts fol-

lowing the *Brown* line of cases effectively treat all prescription drugs as having an equal societal utility, higher than that of all other consumer products. This is an artificial, unwarranted distinction between prescription drugs and other consumer products.

Under the *Restatement (Third)*, no risk-utility review of prescription drug design is allowed. A cosmetic prescription drug that provides little utility, but poses high risks is treated the same as a lifesaving vaccine that involves few risks. Consequently, all prescription drugs are considered to confer a social utility higher than that conferred by other consumer products. While some prescription drugs such as lifesaving vaccines may perform miracles, there is little reason to place cosmetic drugs such as acne medications or sleep aides as having equal social value. The majority of courts are correct to observe the distinctions in efficacy possessed by different prescription drug.

By excepting virtually all prescription drug manufacturers from strict liability on the basis of defective design, the *Restatement (Third)* effectively conscripts the FDA as an arbiter of pharmaceutical quality. If a drug is FDA-approved, then it logically follows that some reasonable health care providers would prescribe the drug to some class of patients. Even if such a prescription drug killed more patients than it helped, the manufacturer of the drug would be excepted from strict liability.

Most courts have wisely rejected the notion that the regulatory system is the ideal, and sole arbiter of prescription drug designs. While the regulatory system provides an important function in ensuring the overall safety and efficacy of prescription drugs, the FDA should not serve as the sole arbiter of prescription drug designs. The FDA does not possess the resources or facilities to review all prescription drugs on the basis of design. The FDA does not attempt to determine the ideal design for a prescription drug; as such, courts must take on this role. In order to keep the quality of prescription drugs at an optimal level, the tort system is necessary to serve as an adjunct to the FDA.

### CONCLUSION

While the law of strict products liability involving prescription drugs has continued to evolve since the adoption of the *Restatement (Second)*, the paradigm represented by the *Restatement (Third)* represents an unwelcome mutation; the *Restatement (Third)*, as well as the *Brown* line of cases are not preferable to the existing standard, which fairly balances the public policy interests

in developing new prescription drugs against the need to maintain manufacturer liability for the defective design of their products.

The principles put forth by the *Brown* line of cases, holding on to a bare minority of jurisdictions, have been embraced by the *Restatement (Third)*, and touted as the law of the land. However, this assertion has not been borne out by the case law. Most courts have rightly chosen not to immunize all prescription drug manufacturers, recognizing that the societal utilities provided by “me-too” cosmetic drugs pale in comparison with more important, lifesaving drugs. Accordingly, the *Restatement (Third)* rejects this balanced approach, seeking to protect all prescription drug manufacturers, regardless of the value their products provide to society.