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Sex, Drugs, & The Restatement (Third) of Torts, Section 6(c): Why Comment E Is the Answer to the Woman Question

Dolly M. Trompeter

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Sex, Drugs, & The Restatement (Third) of Torts, Section 6(c): Why Comment E Is the Answer to the Woman Question

Keywords

Torts, Torts Restatement, Ortho Pharmaceutical Corp. v. Heath, Williams v. Ciba-Geigy Corp, Feminist tort theory

SEX, DRUGS, AND THE *RESTATEMENT* (*THIRD*) OF TORTS, SECTION 6(C): WHY COMMENT E IS THE ANSWER TO THE WOMAN QUESTION

DOLLY M. TROMPETER*

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* Dolly M. Trompeter, J.D. Candidate, 2000, *American University, Washington College of Law*; B.A. 1996, *College of William & Mary*. I am indebted to the following for their contributions to this Comment in substance and spirit: My parents, Maxyne and Steven Trompeter, for unapologetically raising a feminist amidst the often unforgiving hills of Southwest Virginia. My mentor, Professor Andrew Popper, for sharing his thoughtful passion for the law and his sincere compassion for those most vulnerable to it, inspiring me to want to achieve his marvelous aesthetic for myself. Finally, my muse, Star Trompeter, for singing me her beautiful song which led me to believe in the power of my own voice.

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Tort law should begin with a premise of responsibility rather than rights, of interconnectedness rather than separation, and a priority of safety rather than profit or efficiency. The masculine voice of rights, autonomy, and abstraction has led to a standard that protects efficiency and profit; the feminine voice can design a tort system that encourages behavior that is caring about others' safety and responsive to others' needs or hurts, and that attends to human contexts and consequences.¹

INTRODUCTION: ASKING THE WOMAN QUESTION OF THE *RESTATEMENT (THIRD) OF TORTS*

Before the tort reform movement swept through the American political agenda, if a medical product harmed a consumer, recourse would likely come through a tort claim against the drug manufacturer under the *Restatement (Second) of Torts*. In most instances, this consumer could establish liability by proving either that the manufacturer lacked due care in designing the drug under a

1. Leslie Bender, *A Lawyer's Primer on Feminist Theory and Tort*, 38 J. LEGAL EDUC. 3, 31-32 (1988).

negligence theory,² or that the product was in a defective condition unreasonably dangerous under the theory of strict liability.³ Therefore, under the *Restatement (Second) of Torts*, section 402A,⁴ a consumer could find protection in a tort system more concerned with “caring about others’ safety” and being “responsive to others’ needs or hurts”⁵ than insulating corporations from liability.

A “questionable” breed of tort law has emerged, however, focusing more on addressing corporate “needs” and “hurts” than considering those of the consumer. In 1997, the American Law Institute approved the *Restatement (Third) of Torts: Products Liability*.⁶ One of

2. Negligence design theory relates to the reasonableness of the manufacturer’s decisions concerning product design. See DAVID G. OWEN ET AL., *PRODUCTS LIABILITY AND SAFETY* 62 (3d ed. 1996) (noting that injuries resulting from design defects “are sometimes traceable to the manufacturer’s failure to exercise reasonable care in designing the product”).

3. See BLACK’S LAW DICTIONARY 1422 (6th ed. 1990) (defining strict liability as “liability without fault”) (citing *Goodwin v. Reiley*, 176 Cal. App. 3d 86, 90 (1985)). *Black’s Law Dictionary* continues its definition as follows:

A concept applied by the courts in product liability cases in which seller is liable for any and all defective or hazardous products which unduly threaten a consumer’s personal safety. This doctrine imposes strict liability on one who sells a product in defective condition unreasonably dangerous to user or consumer for harm caused to ultimate user or consumer if seller is engaged in business of selling such product, and product is expected to and does reach user or consumer without substantial change in condition in which it is sold.

Id. (citing *Davis v. Gibson Prods. Co.*, 505 S.W.2d 682, 688 (Tex. Civ. App. 1973)). The first case to adopt strict liability was *Greenman v. Yuba Power Products, Inc.*, 377 P.2d 897 (Cal. 1963) (en banc), essentially removing the requirement of privity for establishing defect, thus transferring liability from contract law to tort law. See David Owen, *Products Liability Law Restated*, 49 S.C. L. REV. 273, 276-78 (1998) (noting that *Greenman* was decided at the time the American Law Institute was revising the *Restatement of Torts*, therefore resulting in the incorporation of strict liability into the *Restatement (Second) of Torts*).

4. RESTATEMENT (SECOND) OF TORTS: LIABILITY OF PERSONS SUPPLYING CHATTELS FOR THE USE OF OTHERS: STRICT LIABILITY § 402A (1965) [hereinafter RESTATEMENT (SECOND)]. In his famous article discussing strict liability and section 402A, Dean William L. Prosser, Reporter of the *Restatement (Second)*, explains that strict liability is grounded in notions of fairness and consumer protection. Dean Prosser quotes Justice Traynor’s opinion in *Escola v. Coca Cola Bottling Co.*, 150 P.2d 436, 441 (Cal. 1944):

Those who suffer injury from defective products are unprepared to meet its consequences. The cost of an injury and the loss of time or health may be an overwhelming misfortune to the person injured, and a needless one, for the risk of injury can be insured by the manufacturer and distributed among the public as a cost of doing business. 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.

William L. Prosser, *The Assault Upon the Citadel (Strict Liability to the Consumer)*, 69 YALE L.J. 1099, 1120 (1960) (quoting *Escola*, 150 P.2d at 441).

5. Bender, *supra* note 1, at 32.

6. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY (1998) [hereinafter

the most controversial aspects of this new *Restatement* is section 6(c). Section 6(c) governs design defect liability for medical products.⁷ To establish liability under section 6(c), a consumer must prove not only that a medical product caused her harm, but also that a reasonable health care provider would not have prescribed the product for any class of patients.⁸ In other words, if every user suffered harm, and no one derived benefit from a medical product, only then could a victim bring a successful claim for design defect.⁹ This new standard reduces company liability and responsibility and increases both corporate profits and public harm.

Section 6(c) will disproportionately affect women for two reasons:

RESTATEMENT (THIRD)].

7. There have been numerous articles written opposing the strict standard of the *Restatement (Third)*, section 6(c). See, e.g., Richard L. Cupp, Jr., *Rethinking Conscious Design Liability for Prescription Drugs: The Restatement (Third) Standard Versus a Negligence Approach*, 63 GEO. WASH. L. REV. 76, 110 (1994) (contending the new design liability standard for medical products is unconvincing and advocating the adoption of a negligence standard for medical product design defect claims); Teresa Moran Schwartz, *The Impact of the New Products Liability Restatement on Prescription Products*, 50 FOOD & DRUG L.J. 399, 408 (1995) ("Not only does . . . [section 6(c)] increase the . . . evidentiary burdens for plaintiffs who bring design claims involving prescription products, it may pose initial problems of interpretation for the courts."); Teresa Moran Schwartz, *Prescription Products and the Proposed Restatement (Third)*, 61 TENN. L. REV. 1357, 1381 (1994) [hereinafter Schwartz, *Prescription Products*] (arguing that the design liability standard for medical products in the *Restatement (Third)* is "especially troubling" because it creates a new approach to design defect claims for prescription products that "reject[s] the usual risk-utility test that measures the overall risks and benefits of a product's design and compares them to alternative designs. The proposed standard appears not to invite comparisons with alternative products, and its narrow risk-utility test for sub-classes of product users seems not only difficult to apply but effectively to eliminate design claims."). But see, e.g., James A. Henderson, Jr., *Prescription Drug Design Liability Under the Proposed Restatement (Third) of Torts: A Reporter's Perspective*, 48 RUTGERS L. REV. 471, 476 (1996) [hereinafter Henderson, *Reporter's Perspective*] (noting that the purpose of the law review article was to "explain and defend the position taken in section [6(c)] of the *Restatement (Third)*"; James A. Henderson, Jr., *Restatement Third, Torts: Products Liability: What Hath the ALI Wrought?*, 64 DEF. COUNS. J. 501, 516-18 (1997) [hereinafter Henderson, *ALI Wrought?*] (discussing the narrow standard of liability for design defect claims for medical products); Andrew Barrett, Note, *The Past and Future of Comment K: Section (4)(B)(4) of the Tentative Draft Restatement (Third) of Torts—Is It the Beginning of a New Era of Prescription Drugs?*, 45 SYRACUSE L. REV. 1291, 1322 (1995) (advocating that the *Restatement (Third)*'s medical product design defect liability standard "best advances public policy" because it allows prescription drugs to reach groups needing them most); Jeffrey D. Winchester, Note, *Section 8(c) of the Proposed Restatement (Third) of Torts: Is it Really What the Doctor Ordered?*, 82 CORNELL L. REV. 644, 692-93 (1997) (arguing that physicians are not the appropriate people to judge pharmaceutical product design and as such, advocating that the *Restatement (Third)* adopt a "reasonable manufacturer" rather than a "reasonable physician" approach).

8. Section 6(c) of the *Restatement (Third)* states:

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

RESTATEMENT (THIRD), *supra*, note 6, § 6(c).

9. See *id.* § 6(c) cmt. b (noting that under section 6(c) "a drug is defectively designed only when it provides no net benefit to any class of patients").

(1) women consume a greater share of medical products than men;¹⁰ and (2) the regulatory system has not adequately tested and monitored products for women.¹¹ Section 6(c), however, is not the *Restatement (Third)*'s only product design defect provision. Section 2 establishes a separate standard of liability for general product design defect apart from medical or prescription products.¹² As compared to Section 6, Section 2 provides an aggrieved consumer more opportunity to establish design defect liability. The *Restatement (Third)*'s authors (the "Reporters") acknowledge that the requirements to establish design liability for general product defect are less stringent than for medical products.¹³ Section 2 permits the plaintiff to present a reasonable alternative design to establish a design claim for general product defect, rather than requiring proof that the product was ineffective for all users.¹⁴

In addition, section 2 provides for an exception to the liability standard for general product design defect claims.¹⁵ Under the comment e exception, if the product's design renders its social utility low in relation to its potential to cause harm, liability attaches regardless of the existence of a reasonable alternative design.¹⁶ The

10. See LESLIE LAURENCE & BETH WEINHOUSE, OUTRAGEOUS PRACTICES: THE ALARMING TRUTH ABOUT HOW MEDICINE MISTREATS WOMEN 295 (1994) (noting that "[w]omen take more prescription drugs than men and buy more over-the-counter medications for themselves and their families"); L. Elizabeth Bowles, *The Disfranchisement of Fertile Women in Clinical Trials: The Legal Ramifications of and Solutions for Rectifying the Knowledge Gap*, 45 VAND. L. REV. 877, 878 (1992) (discussing the fact that women consume more prescription drugs than men and also disproportionately suffer a greater number of side effects from these drugs).

Women's greater use of medical products is further revealed through an analysis of the nature of products liability suits involving women. For example, one survey revealed that "of all women winning punitive awards in any kind of trial, nearly 70% were injured by defective drugs or medical devices." Linda Marsa, *The Breast Implant Backlash*, WORKING WOMAN, Apr. 1, 1996, at 46, 76.

11. See *infra* note 153 and accompanying text (discussing the failure of the regulatory system to test and monitor drugs for women).

12. See *RESTATEMENT (THIRD)*, *supra* note 6, § 6(c) 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 subsection [6](c) and (d) rather than under §§ 2(b) and 2(c).").

13. See *id.* ("Subsection c [of section 6] imposes a more rigorous test for defect than does 2(b) which does not apply to prescription drugs and medical devices.").

14. The *Restatement (Third)* provides for design defect liability for a general product defect standard under section 2(b):

A Product:

(b) is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe.

Id. § 2(b).

15. See *infra* Part I.B.2 (discussing the comment e exception).

16. See *RESTATEMENT (THIRD)*, *supra* note 6, § 2(b).

rationale behind comment e is that rigid liability standards should not apply to products with low social utility.¹⁷ Section 6(c), however, does not provide any such exception for medical product design defect claims.

The importance of comment e's general product defect exception is realized when one views the new theories of liability through the eyes of the aggrieved female consumer. Analyzing the *Restatement (Third)* from a gender perspective reveals its potential to minimize the obstacles women face when asserting medical product design defect claims. This Comment's approach to analyzing the *Restatement (Third)* is not unlike that taken by scholars who examine the law in gendered terms. For example, the "Woman Question" is one method of inquiry "designed to identify the gender implications of rules and practices which might otherwise appear to be neutral or objective."¹⁸ Many scholars have asked the Woman Question as it relates to tort law.¹⁹

In keeping with this body of thought, this Comment poses the Woman Question to the *Restatement (Third)*. The response is troubling as this inquiry reveals that section 6(c)'s liability standard for medical product defect claims will disproportionately harm women.

Unsettled by the *Restatement (Third)*'s response to the Woman Question, this Comment offers a more favorable answer: Comment e. That is, the tort system should recognize an exception for "manifestly unreasonably designed" *medical* products failing to meet the difficult standard of section 6(c).

By extending comment e to section 6(c), the tort system would embrace the idea that women's safety demands a more reasonable standard of liability for medical product defect claims. Absent such an exception, women will continue to suffer harm at the hands of the tort system as companies lack incentive to design safer products and to recall harmful products from the market.²⁰ Furthermore, products

17. *See id.*

18. Katharine T. Bartlett, *Feminist Legal Methods*, 103 HARV. L. REV. 829, 837 (1990) (defining the application of the Woman Question to the law as an examination of "how the law fails to take into account the experiences and values that seem more typical of women than of men . . . or how existing legal standards and concepts might disadvantage women"). In addition to analyzing the gender impact of various provisions of law, the Woman Question proposes possible solutions to remedy disparities. *See id.* ("The Woman Question asks about the gender implications of a social practice or rule: [H]ave women been left out of consideration? If so, in what way; how might that omission be corrected?").

19. *See infra* Part II.B.1 (discussing the works of feminist tort scholars and the application of their theories to an analysis of section 6(c)).

20. *See infra* notes 139-45 and accompanying text (discussing the effect that the threat of liability has on a manufacturer's motivations to redesign and recall harmful medical products).

genuinely helpful to a subset of users will remain on the market, as comment e's risk-benefit test will factor in the critical need for the product when determining whether to impose liability.

Part I of this Comment provides background on the relevant provisions of the *Restatement (Second)* and *Restatement (Third)*. With regard to the *Restatement (Second)*, Part I addresses the theories behind strict liability, unavoidably unsafe products, and the *res ipsa loquitur* standard. With regard to the *Restatement (Third)*, Part I discusses general product design defect, "circumstantial evidence supporting the inference of product defect" (*res ipsa loquitur*), the concept of manifestly unreasonable design, and the design defect standard for medical products.

Part II of this Comment analyzes the case law offered in support of the section 6(c) standard in the *Restatement (Third)*. This Part focuses on two primary issues. First, Part II argues that the one case cited by the Reporters of the *Restatement (Third)* for direct support of section 6(c) creates a "super" *res ipsa loquitur* standard like that in section 3 of the *Restatement (Third)*. Additionally, the two cases relied upon by the Reporters for supplemental support for section 6(c) fail to reflect the section 6(c) standard. Second, Part II analyzes the feminist application of tort law by asking the Woman Question and focusing on the relationship between women and medical products. Part II argues that the special classification of medical products apart from other products in the *Restatement (Third)* is a tenuous distinction, that the regulatory system has many general flaws which prevent it from adequately monitoring and testing medical products, and that women's exclusion from drug testing renders the Food and Drug Administration ("FDA") unable to regulate harmful products for women.

Part III advocates the adoption of the comment e exception for general product design defects in section 2 to the liability standard under section 6(c) for medical product design defects. Part III determines that although the Reporters did not intend comment e to apply to section 6(c), case law, the prior application of comment k of the *Restatement (Second)*, and the theory behind the comment e exception suggest that comment e should apply to section 6(c).

I. BACKGROUND: THE TRANSFORMATION OF TORT LAW: FROM THE
RESTATEMENT (SECOND) TO THE *RESTATEMENT (THIRD)* OF TORTS

A. *The Restatement (Second) of Torts*

The American Law Institute adopted the *Restatement (Second) of Torts* in 1963. Since that time, the theory of strict liability in section 402A of the *Restatement (Second)* has governed products liability doctrine in most states.²¹ The *Restatement (Second)* serves as a basis to compare the changes in products liability law encompassed in the *Restatement (Third)* which adversely affect female consumers of medical products. First, the Reporters of the *Restatement (Third)* eliminated strict liability from both medical and general product defect claims.²² Second, comment k of the *Restatement (Second)* establishes immunity from strict liability for drug manufacturers.²³ Most jurisdictions, however, have historically exempted manufacturers from strict liability only after conducting an individualized review to determine whether a medical product constituted an "unavoidably unsafe product."²⁴ The *Restatement (Third)*, however, precludes a case-by-case application of a design defect liability standard. Finally, section 328D of the *Restatement (Second)* (*res ipsa loquitur*) provides for liability based on circumstantial evidence of negligence as indicated by the defendant's relationship to events.²⁵ This section of the *Restatement (Second)*

21. After the American Law Institute approved the *Restatement (Second)* in 1963, most states quickly adopted section 402A or some form of strict liability:

[T]he general adoption of the doctrine [of strict liability] in this country from 1963 to the mid-1970s is one of the most rapid and dramatic doctrinal developments to occur in the law of torts. As of 1996, all states except Delaware, Massachusetts, Michigan, North Carolina and Virginia had adopted strict products liability in tort.

OWEN ET AL., *supra* note 2, at 165.

22. See *RESTATEMENT (THIRD)*, *supra* note 6, § 6 reporters' note, cmt. f ("As with § 2, the test in § 6 is stated in functional terms. Thus whether the case is brought under negligence or strict liability, a plaintiff would be successful only if it could make out the elements as set forth in § 6(c).").

23. See *RESTATEMENT (SECOND)*, *supra* note 4, § 402A cmt. k (recognizing that manufacturers/sellers of certain products, such as prescription drugs which have fully justified risks given their intended purpose, should not be subject to strict liability).

24. See Barrett, *supra* note 7 (noting that the individualized risk-benefit analysis is the predominant application of comment k); see also Jeffrey Nolan Diamant, Comment, *Texas Senate Bill 4: Product Liability Legislation Analyzed*, 31 Hous. L. Rev. 921, 949 (1994) (indicating that while some courts interpret comment k as giving total immunity to manufacturers from design defect suits relating to approved medical products, other jurisdictions use a case-by-case approach to assess whether medical products fall within the comment k exemption).

25. See *RESTATEMENT (SECOND)*, *supra* note 4, § 328D cmt. b.

strongly resembles section 3 of the *Restatement (Third)*.²⁶ Section 3 serves as a basis to reveal the overly stringent nature of the medical product design defect standard in the *Restatement (Third)*, section 6(c).

1. *Section 402A: strict liability*

Section 402A of the *Restatement (Second)* established strict liability in tort law and has served as the basis of thousands of products liability decisions.²⁷ As embodied in section 402A, strict liability imposes liability without requiring a showing of negligence on the part of the product seller or manufacturer.²⁸ Strict liability concerns the nature of the product (i.e., whether the product is defective), whereas negligence focuses on the manufacturer's actions (i.e., whether the manufacturer designed the product negligently).²⁹ In applying strict liability to design defect claims, courts will find a manufacturer liable for the defective design of a drug regardless of whether negligence exists. The rationale behind strict liability is that the manufacturer, in a better position than the consumer to assume loss associated with a defective product, should bear the responsibility for harm caused by the product.³⁰ The *Restatement (Third)*, however, eliminates strict

26. See *RESTATEMENT (THIRD)*, *supra* note 6, § 3 cmt. a (noting that section 3 traces its origins to section 328D of the *Restatement (Second)*).

27. See generally John F. Vargo, *The Emperor's New Clothes: The American Law Institute Adorns "New Cloth" for Section 402A Products Liability Design Defects—A Survey of the States Reveals a Different Weave*, 26 U. MEM. L. REV. 493 (1996) (providing a survey of the 50 states' application of section 402A to product liability cases).

Restatement (Third) Reporters, Professors James A. Henderson and Aaron D. Twerski characterize section 402A of the *Restatement (Second)* as a "holy writ" because of its pervasive influence on products liability cases. See James A. Henderson & Aaron D. Twerski, *A Proposed Revision of Section 402A of the Restatement (Second) of Torts*, 77 CORNELL L. REV. 1512, 1512 (1992).

28. Section 402A imposes liability in the absence of negligence:

- (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
 - (a) the seller has exercised all possible care in the preparation and sale of his product, and
 - (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

RESTATEMENT (SECOND), *supra* note 4, § 402A.

29. See Mark McLaughlin Hager, *Don't Say I Didn't Warn You (Even Though I Didn't): Why the Pro-Defendant Consensus on Warning Law is Wrong*, 61 TENN. L. REV. 1125, 1133 (1994) (analyzing the difference between a negligence and strict liability inquiry).

30. See Prosser, *supra* note 4, at 1120; see also Hager, *supra* note 29, at 1132-33 (noting that the purpose of strict liability includes "facilitating victim compensation, corrective justice, supplier wealth relative to victim's wealth, incentives for safe products, social loss-spreading

liability for design defect claims.³¹

2. *Comment k: unavoidably unsafe products*

The *Restatement (Second)* includes comment k as an exception to section 402A's strict liability provision.³² Comment k recognizes that some products are "quite incapable of being made safe for their intended and ordinary use."³³ Comment k states that if a manufacturer properly markets a drug and provides for adequate warnings, strict liability does not attach.³⁴ The rationale behind comment k is that a manufacturer should escape strict liability for developing drugs and other conceivably dangerous, yet socially beneficial, products.³⁵

Courts, however, have applied the comment k exception primarily on a case-by-case basis.³⁶ Most courts engage in a risk-benefit analysis to determine whether to exempt the manufacturer from strict liability under comment k.³⁷ The *Restatement (Third)* Reporters, however,

through insurance and price mechanisms, and efficiency in reducing costs of both accidents and accident prevention") (citations omitted).

31. See *infra* notes 49-53 and accompanying text.

32. See *RESTATEMENT (SECOND)*, *supra* note 4, § 402A cmt. k.

33. *Id.*

34. Comment k of section 402A reads, in part, as follows:

[Unavoidably unsafe products] 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 they involve. Such a product, properly prepared, and accompanied by proper directions and warning is not defective, nor is it *unreasonably* dangerous.

Id. (emphasis added).

35. See *id.*

36. The predominant application of comment k is an individualized analysis to determine if the product's risks outweigh its benefits. See Barrett, *supra* note 7, at 1314 ("[T]o date the 'risk-benefit' analysis is predominant in the application of comment k."); see also Diamant, *supra* note 24, at 949 (recognizing how jurisdictions apply a case-by-case approach to see whether products are unavoidably unsafe and therefore, shielded from liability under comment k).

37. There have been a number of reasons suggested to explain why most state courts have failed to extend comment k immunity to all medical products. The first is the confusing nature of comment k. See Winchester, *supra* note 7, at 657 (noting that Professor Aaron D. Twerski, the senior Reporter of the *Restatement (Third)*, offers an "A" in his course to any student who can explain comment k to him, and Professor Twerski has yet to award an "A" for a student's comment k explanation) (citing Aaron D. Twerski, *From a Reporter's Perspective: A Proposed Agenda*, 10 *TOURO L. REV.* 5, 15-16 (1993)). Second, application of comment k usurps a court's discretionary power. See *id.* at 658 ("Given the seriousness and scope of real and potential injury posed by mass-marketed pharmaceuticals, courts wishing to provide relief for injured individuals are likely to seek ways around comment k."). Finally, comment k immunity can ultimately provide "patently unjust results" by protecting "products that should, by all accounts, not be on the market." See *id.* (citing *Brown v. Superior Court*, 751 P.2d 470, 481 (Cal. 1988)).

There are, however, a minority of jurisdictions adhering to a pure application of comment k. That is, these jurisdictions have determined that the overall social benefit of drug development and availability outweighs the application of strict liability to drug manufacturers. The California case, *Brown v. Superior Court*, 751 P.2d 470 (Cal. 1988), exemplifies a pure comment k

failed to incorporate this precedent of risk-benefit analysis into section 6(c).³⁸

3. *Res ipsa loquitur: liability without proof of defect*

The *Restatement (Second)* includes section 328D, the *res ipsa loquitur*³⁹ standard of inferring negligence and causation.⁴⁰ Section 328D establishes liability absent evidence of negligence. This theory is based on the concept that harm would not have occurred but for the existence of negligence.⁴¹ *Res ipsa loquitur* originated with *Byrne v. Boadle*,⁴² a case in which a flour barrel rolled from the defendant's warehouse window onto a passing pedestrian.⁴³ Because the barrel would not have fallen without negligence on the part of the warehouse owner, the plaintiff was not required to establish the defendant's negligence.⁴⁴ Under section 328D, if an event ordinarily would not occur absent negligence, and the defendant owed the plaintiff a duty of care, the plaintiff need only demonstrate that he/she or other third parties were not responsible for the harm in order to establish liability.⁴⁵ This section of the *Restatement (Second)* is the basis of section 3, "Circumstantial Evidence Supporting Inference

application. In *Brown*, the California Supreme Court affirmed the lower court's decision to uphold a pretrial ruling dismissing the plaintiffs' design claim against the manufacturer of diethylstilbestrol (DES). See *id.* at 487. The plaintiffs claimed that the defective design of DES harmed them *in utero*. See *id.* at 473. The *Brown* court concluded, in part, as follows:

[A] drug manufacturer's liability for a defectively designed drug should not be measured by the standards of strict liability . . . and because of the public interest in the development, availability, and reasonable price of drugs, the appropriate test for determining responsibility is the test stated in comment k.

Id. at 477; see also Winchester, *supra* note 7, at 653-54 (commenting that prior to *Brown*, California did not follow a pure comment k application, but rather a case-by-case analysis using a risk-benefit test).

38. See *RESTATEMENT (THIRD)*, *supra* note 6, § 6 reporters' note, cmt. f (indicating that while certain courts have historically imposed judicial review for claims alleging defectively designed medical products, the rule set forth in section 6(c) provides "the exclusive basis for a cause of action based on objective drug design"). Therefore, because section 6(c) fails to incorporate a risk-benefit analysis into the liability standard for defectively designed medical products, section 6(c) essentially lacks the element of individual assessment of a drug's risks and benefits before granting blanket immunity from liability to a drug manufacturer.

39. The term *res ipsa loquitur* translates as "the thing speaks for itself." See *RESTATEMENT (SECOND)*, *supra* note 4, § 328D cmt. a.

40. See *id.*

41. See *id.* § 328D(1) (a) ("It may be inferred that harm suffered by the plaintiff is caused by negligence of the defendant when . . . the event is of a kind which ordinarily does not occur in the absence of negligence . . .").

42. 159 Eng. Rep. 299 (Ex. 1863).

43. See *RESTATEMENT (SECOND)*, *supra* note 4, § 328D cmt. a (recognizing that the concept of *res ipsa loquitur* is derived from the case of *Byrne v. Boadle*).

44. See *Byrne*, 159 Eng. Rep. at 301 (stating that when a barrel falls from the window of a warehouse while under the control of a defendant and then injures the plaintiff, there is *prima facie* evidence of negligence, and the plaintiff is not required to show that the barrel could not have fallen without negligence).

45. See *RESTATEMENT (SECOND)*, *supra* note 4, § 328D(1) (a)-(c).

of a Product Defect," in the *Restatement (Third)*.

B. The Restatement (Third) of Torts

Approved in 1997 by the American Law Institute, the *Restatement (Third)* created new liability standards for claims alleging both medical and general product design defect. These changes in the liability standards have generated controversy among members of the American Law Institute and other torts commentators.⁴⁶ The conflict stems from the fact that the new standards for both general and medical product defect are much stricter than in the *Restatement (Second)*.⁴⁷ The following section discusses section 2(b), comment e, and section 3 of the *Restatement (Third)*, essential elements in the analysis of section 6(c) and its effects on female consumers.

1. Section 2(b): general product design defect liability

Section 2(b) of the *Restatement (Third)* governs claims alleging general product design defect.⁴⁸ Section 2(b) eliminates strict liability under the *Restatement (Second)*, section 402A, and replaces it with a stringent negligence standard.⁴⁹ Under section 2(b), a plaintiff establishes design defect liability by demonstrating that a reasonable alternative product design exists.⁵⁰ This standard is a marked departure from section 402A's strict liability standard.⁵¹ For example, under the *Restatement (Second)*, a plaintiff harmed by an exploding car engine would establish design defect by proving either manufacturer

46. See *supra* note 7 (discussing articles in support of, and in opposition to, the section 6(c) standard for medical product design defect liability). In addition, section 2(b), requiring proof of a reasonable alternative design to establish general design defect liability, was controversial as well. See, e.g., James A. Henderson, Jr. & Aaron D. Twerski, *Achieving Consensus on Defective Product Design*, 83 CORNELL L. REV. 867, 882-87 (1998) (arguing that the reasonable alternative design provision in section 2(b) is the best standard for determining general product design defect); Henderson, *ALI Wrought?*, *supra* note 7, at 507 (noting that aspects of section 2(b) are likely "to take practitioners by surprise" because of a substantial departure in section 2(b) from the consumer protection standards of section 402A in the *Restatement (Second)*); Alan J. Lazarus et al., *Recent Developments in Products, General Liability and Consumer Law*, 33 TORT & INS. L.J. 605, 606 (1998) ("More controversial is the ALI's conclusion that, in most instances to prevail under section 2(b), the plaintiff must introduce evidence of a reasonable alternative design that would have prevented the injury in question and produced a net safety benefit as compared with the existing design.").

47. See *supra* note 46.

48. See RESTATEMENT (THIRD), *supra* note 6, § 2(b).

49. See *id.*; see also *supra* note 22 (noting that regardless of whether the plaintiff makes a claim for negligence or strict liability, the requirements of 2(b) must be met to establish liability).

50. See RESTATEMENT (THIRD), *supra* note 6, § 2(b).

51. See RESTATEMENT (SECOND), *supra* note 4, § 402A (providing for liability for harm caused by "any product in a defective condition unreasonably dangerous to the user or consumer").

negligence in the engine design process or, under section 402A, that the engine was in a defective condition unreasonably dangerous regardless of manufacturer negligence.⁵² Under section 2(b), however, the plaintiff must prove that a reasonable alternative engine design exists.⁵³

2. *Comment e: the exception to section 2(b)*

The *Restatement (Third)* provides comment e as an exception to section 2(b)'s demanding design defect liability standard.⁵⁴ Invoking comment e, a plaintiff claiming design defect is not required to establish the existence of a reasonable alternative design.⁵⁵ Rather, the products undergo a risk-benefit test to determine whether their potential harms outweigh their social utility.⁵⁶ The rationale for comment e is that liability should extend to include products whose intended purpose is such that no alternative design would be reasonable.⁵⁷ To illustrate the comment e exception, the *Restatement (Third)* presents the example of a toy gun that shoots rubber pellets.⁵⁸ If the purpose of the toy gun is to cause harm with the rubber pellets, a safer pellet design would defeat the purpose of the toy gun.⁵⁹ Therefore, no alternative gun design exists.⁶⁰ Comment e would apply, absent a reasonable alternative design, if the court determined that the gun was "manifestly unreasonably design[ed]" because its purpose contained little social utility.⁶¹

Under section 6(c), there is no such exception for manifestly unreasonably designed *medical* products. Consumers of medical

52. *See id.*

53. *See* RESTATEMENT (THIRD), *supra* note 6, § 2(b).

54. *See id.* § 2(b) cmt. e.

55. *See id.*

56. *See id.* (noting that a product is defective when its capacity for danger "substantially outweighs" its social utility).

57. *See id.* Comment e states that:

There might be cases in which the jury would be permitted to hold the defendant liable on account of a dangerous design feature even though no safer design was feasible. If, for example, the danger was relatively severe and the product had only limited utility, the court might properly conclude that the jury could find that a reasonable manufacturer would not have introduced such a product into the stream of commerce.

Id. (citing *Wilson v. Piper Aircraft Corp.*, 577 P.2d 1322, 1328 n.5 (Or. 1978)).

58. *See id.*

59. *See id.*

60. A court may deem a product "manifestly" unreasonably designed because no alternative design would render the product safe for society: "[T]he realism of the hard-pellet gun, and thus its capacity to cause injury, is sufficiently important to those who . . . use such products to justify the court's limiting consideration to toy guns that achieve realism by shooting hard pellets . . ." *Id.*

61. *See id.*

products are thus at a double disadvantage: Not only is the standard for medical product design defect claims more difficult under section 6(c), but this stringent liability standard is subject to no exception in the *Restatement (Third)*. Further compounding the general inequity of section 6(c) are the specific gender ramifications of such a stringent standard of liability. As greater consumers of medical products⁶² that generally lack adequate testing and monitoring,⁶³ women will be most affected by the absence of an exception for medical product design defect claims.

3. Section 3: the *res ipsa loquitur* of the *Restatement (Third)* of Torts

One of the few concepts surviving the transition from the *Restatement (Second)* to the *Restatement (Third)* is *res ipsa loquitur*. Section 3 is the *res ipsa loquitur* standard found in the *Restatement (Second)*, section 328D.⁶⁴ Section 3 provides for liability absent evidence of a manufacturing or design defect when "a product fails to perform its manifestly intended function, thus supporting the conclusion that a defect of some kind is the most probable explanation."⁶⁵ Examples of defect scenarios considered under section 3 include a blender shattering and causing eye damage to the user and a new car seat's collapse and the car's subsequent propulsion into oncoming traffic.⁶⁶ In both situations, these products

62. See *supra* note 10.

63. See *infra* Parts II.B.2.b-c.

64. Section 328D of the *Restatement (Second)* serves as the basis of section 3 of the *Restatement (Third)*. See *RESTATEMENT (THIRD)*, *supra* note 6, § 3 cmt. a (explaining that tort law permits the inference of negligence to establish liability where that negligence is the "best explanation" for the cause of the harm).

65. *Id.* § 3. Section 3 of the *Restatement (Third)*, "Circumstantial Evidence Supporting Inference of a Product Defect," states:

It may be inferred that the harm sustained by the plaintiff was caused by a product defect existing at the time of sale or distribution, without proof of a specific defect, when the incident that harmed the plaintiff:

(a) was of a kind that ordinarily occurs as a result of a product defect; and
(b) was not, in the particular case, solely the result of causes other than product defect existing at the time of sale or distribution.

Id.

Furthermore, the Reporters discuss the application of section 3 to both manufacturing and design defects: "Section 3 allows the trier of fact to draw the inference that the product was defective whether due to a manufacturing defect or a design defect." *Id.* § 3 cmt. b.

66. The Reporters present the first illustration as follows:

John purchased a new electric blender. John used the blender approximately 10 times exclusively for making milkshakes. While he was making a milkshake, the blender suddenly shattered. A piece of glass struck John's eye, causing harm. The incident resulting in harm is of a kind that ordinarily occurs as a result of product defect.

Id.

The Reporters present the second illustration as follows:

Mary purchased a new automobile. She drove the car 1,000 miles without incident. One day she stopped the car at a red light and leaned back to rest until the light

failed to perform their intended functions and were therefore defective, even absent proof of manufacturer negligence.⁶⁷

The purpose of incorporating a discussion of section 3 into an analysis of section 6(c) is to reveal the unreasonably stringent nature of section 6(c). As will be discussed, section 6(c) can be characterized as a “super” *res ipsa loquitur* standard.

4. *Section 6(c): medical product design defect liability*

a. *Background*

Section 6(c) is one of the most controversial sections in the *Restatement (Third)*.⁶⁸ The section 6(c) standard governs design defect liability for medical products.⁶⁹ Section 2(b)’s general design defect liability requiring proof of a reasonable alternative design to establish liability is not applicable to medical products.⁷⁰ Instead, the Reporters created a more rigid standard for medical product design defect claims, grounding liability in the plaintiff’s ability to establish the product’s lack of utility for any group of users.⁷¹ The Reporters acknowledge the stringency of section 6(c),⁷² but justify this standard based on two general rationales: (1) medical products are unique in relation to other products,⁷³ and (2) the regulatory system will

changed. Suddenly the seat collapsed backward, causing Mary to hit the accelerator and the car to shoot out into oncoming traffic and collide with another car. Mary suffered harm in the ensuing collision. As a result of the collision, Mary’s car was set afire, destroying the seat assembly. The incident resulting in the harm is of a kind that ordinarily occurs as a result of a product defect. Mary need not establish whether the seat assembly contained a manufacturing defect or a design defect.

Id.

67. *See id.*

68. *See supra* note 7 (noting numerous articles both in support of and in opposition to the stringent section 6(c) standard).

69. *See* *RESTATEMENT (THIRD)*, *supra* note 6, § 6(c) (“A . . . medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the . . . device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers . . . would not prescribe the . . . device for any class of patients.”).

70. *See id.* § 6(c) cmt. b (“[T]he determination of whether . . . [prescription drugs or medical devices] are not reasonably safe is to be made under Subsections [6](c) and (d) rather than under §§ 2(b) and 2(c).”).

71. *See id.* § 6(c) cmt. f (stating that “when a drug or device provides net benefits to no class of patients, when reasonable, informed healthcare providers would not prescribe it to any class of patients—then the design of the product is defective and the manufacturer should be subject to liability for the harm caused”).

72. *See* Henderson, *Reporter’s Perspective*, *supra* note 7, at 494 (“The test for drug design liability in section [6(c)] is deliberately narrow.”); *see also* *RESTATEMENT (THIRD)*, *supra* note 6, § 6(c) cmt. f (discussing the Reporters’ recognition that few claims will succeed under the standard of section 6(c): “Given this very demanding objective standard, liability is likely to be imposed only under unusual circumstances”).

73. The Reporters argue that “a prescription drug or medical device entails a unique set of risks and benefits.” *RESTATEMENT (THIRD)*, *supra* note 6, § 6 cmt. b. Furthermore, the Reporters contend that “[w]hat may be harmful to one patient may be beneficial to another.”

perform comprehensive product screening and monitoring.⁷⁴ As will be discussed, these rationales fail to constitute adequate justifications for the rigorous section 6(c) standard.

b. Tobin v. Astra Pharmaceuticals, Inc.

The Reporters based section 6(c) on one case,⁷⁵ *Tobin v. Astra Pharmaceuticals, Inc.*⁷⁶ The plaintiff, pregnant with twins, took ritodrine to control her pre-term labor.⁷⁷ As a result of taking the drug, she suffered an adverse reaction and ultimately was forced to undergo a heart transplant.⁷⁸ The plaintiff presented evidence that ritodrine was ineffective in controlling pre-term labor for any class of patients.⁷⁹ Furthermore, evidence indicated that the FDA may not have adequately tested ritodrine, or even approved the drug.⁸⁰ The jury returned a verdict upholding the plaintiff's defective design claims.⁸¹ The Sixth Circuit affirmed the verdict based on evidence indicating that the drug was generally ineffective.⁸²

Id.

The Reporters applied the section 6(c) standard to the issue of breast implant availability, discussing the existence of two different breast implant designs. *See* Henderson, *Reporter's Perspective*, *supra* note 7, at 484. The first design presented a greater risk of side effects while offering a more aesthetically pleasing shape and feel. *See id.* The other design had a lower risk of side effects but produced a less natural shape and feel. *See id.* The Reporters deem as paternalistic those who advocate for the removal of the first breast implant design from the market:

Finding the softer implant design defective prevents its use by those women for whom it is the healthiest choice. Moreover, a finding of defectiveness also deprives those knowingly willing to run the health risks of the softer alternative for aesthetic benefits. It is paternalistic in the extreme to conclude that a woman's informed choice to incur remote health risks for aesthetic reasons does not deserve to be respected.

Id. at 485.

74. The Reporters discuss the role of the regulatory system in relation to the section 6(c) standard:

Courts have . . . recognized that the regulatory system governing prescription drugs is a legitimate mechanism for setting the standards for drug design. . . . This deference also rests on . . . [the assumption] . . . that governmental regulatory agencies adequately review new prescription drugs and devices, keeping unreasonably dangerous designs off the market.

RESTATEMENT (THIRD), *supra* note 6, § 6 cmt. b; *see also* Henderson, *Reporter's Perspective*, *supra* note 7, at 491-92 (discussing the rigorous nature of the FDA approval process).

75. *See* Henderson, *Reporter's Perspective*, *supra* note 7, at 487 (acknowledging that the Reporters derive direct support for section 6(c) from only one case); *see also* RESTATEMENT (THIRD), *supra* note 6, § 6 reporters' notes, cmt. f (citing *Tobin* for the proposition that "some jurisdictions have essentially adopted the approach taken in section 6(c)").

76. 993 F.2d 528 (6th Cir. 1993).

77. *See id.* at 532.

78. *See id.*

79. *See id.* at 540.

80. The *Tobin* court discussed the nature of the FDA drug approval process, which includes the requirement that the drug undergo two controlled studies. *See id.* at 539. Evidence suggested that one of the FDA studies on Ritodrine was faulty. *See id.*

81. *See id.* at 540.

82. *See id.*

The Reporters argue that *Tobin* advances the section 6(c) position that a drug is not defectively designed unless it fails for all classes of patients.⁸³ The Reporters reason that a “netting out of costs and benefits” of a drug for “different classes of patients” would be inappropriate because “if a drug exists that is clearly the drug of choice for one or more classes of patients, it should not be denied to them simply because other patients who should not take the drug do . . . and suffer harm.”⁸⁴

II. ANALYSIS OF SECTION 6(C): SEARCHING FOR THE ANSWER BY
ASKING THE QUESTION

A. *Does the Case Law Support Section 6(c)?*

1. *Section 6(c): a “super” res ipsa loquitur standard*

Tobin is an anomalous case, failing to reflect the typical design defect scenario adequately. The holding in *Tobin*, therefore, is not an appropriate rationale on which to base section 6(c).

The rarity of *Tobin* is twofold. First, under most circumstances the FDA will not grant approval to a completely ineffectual drug.⁸⁵ Therefore, *Tobin* will not be applicable to the average medical product design defect claim. Second, the *Tobin* court discussed evidence indicating that the FDA may not have approved Ritodrine.⁸⁶ The fact that medical products require FDA approval before their release onto the market⁸⁷ further enhances *Tobin*’s atypicality as a medical product design defect case. Rarely will a drug enter the market lacking basic FDA approval, as may have happened in *Tobin*. *Tobin*, therefore, is not an appropriate case on which to base section 6(c).

One could argue that the *Tobin*/section 6(c) standard of product

83. See Henderson, *Reporter’s Perspective*, *supra* note 7, at 488 (“The [*Tobin*] opinion leaves no doubt that defendant’s proof of the drug’s efficacy for *any* class of patients was weak and inconclusive.”).

84. *Id.*

85. Professor Schwartz commented on the rare set of circumstances presented in *Tobin*: [*Tobin*] uphold[s] a jury verdict on a design claim where the evidence showed that the drug posed serious risks but, despite FDA approval, was not efficacious for any class of patients. Arguably, only cases like *Tobin* come within the scope of liability established by section [6]. Obviously such a case is rare. Seldom does an FDA-approved drug or device prove to be totally worthless.

Schwartz, *Prescription Products*, *supra* note 7, at 1383-84.

86. See *supra* note 80 and accompanying text (noting that evidence in *Tobin* suggested that one of the FDA studies on Rotodrine was faulty).

87. Drug companies seeking FDA approval for new drugs must produce a rigorously tested prototype. See Henderson, *Reporter’s Perspective*, *supra* note 7, at 492.

defect liability actually represents a demanding section 3, *res ipsa loquitur* analysis. Section 3 applies in situations where “a product fails to perform its manifestly intended function, thus supporting the conclusion that a defect of some kind is the most probable explanation.”⁸⁸ Stripped down, section 6(c) is exposed as a “super” *res ipsa loquitur* standard. Like a shattering blender or a collapsed car seat,⁸⁹ the issue facing the section 6(c) plaintiff is efficacy; the drug failed to work as intended and caused harm.⁹⁰ Couched in section 3 language, the *Tobin* drug “fail[ed] to perform its manifestly intended function.”⁹¹ In *Tobin*, the plaintiff did not demonstrate the existence of either a specific defect or an alternative design, but rather merely established the drug’s general failure.⁹²

The essential difference between section 6(c) and section 3, therefore, is the definition of failure. Under section 6(c), a drug “fail[s] to perform its manifestly intended function” if it fails for everyone who uses the drug.⁹³ In contrast, the definition of failure under section 3 is more expansive. The section 3 plaintiff is merely required to prove the product’s failure in a specific instance.⁹⁴ Thus, section 6(c) is a “super” *res ipsa loquitur* standard, forcing the plaintiff to shoulder the difficult burden of establishing *comprehensive* product failure not just for her, but for every class of users.⁹⁵

88. RESTATEMENT (THIRD), *supra* note 6, § 3, cmt. b.

89. See *supra* note 66 and accompanying text (presenting the illustrations in section 3 of *res ipsa loquitur*-type scenarios where liability is established absent proof of negligence).

90. In *Tobin*, the plaintiff won her design defect claim by establishing that the drug at issue failed to perform as intended. See *Tobin v. Astra Pharm., Inc.*, 993 F.2d 528, 540 (6th Cir. 1993).

91. See RESTATEMENT (THIRD), *supra* note 6, § 3 cmt. b.

92. The *Tobin* court concluded:

Plaintiff introduced evidence . . . that a reasonably prudent manufacturer would not market Ritodrine if the evidence of its efficacy was inconclusive. Plaintiff also introduced sufficient evidence regarding the various clinical studies concerning the efficacy of Ritodrine. The jury found that Ritodrine, as manufactured and marketed by Astra, was in a defective condition and unreasonably dangerous to plaintiff. We find that there was sufficient evidence before the jury to conclude that a prudent manufacturer knowing all the risks would not market Ritodrine.

Tobin, 993 F.2d at 540.

93. See RESTATEMENT (THIRD), *supra* note 6, § 6(c).

94. “Under section 3, [the] plaintiff need not establish a specific defect if the plaintiff meets the requisites of section 3(a) and (b).” RESTATEMENT (THIRD), *supra* note 6, § 3 reporters’ note, cmt. b(1).

95. In addition, comment f of section 6 reveals the nature of section 6(c) as a “super” *res ipsa loquitur* standard. See RESTATEMENT (THIRD) *supra* note 6, § 6 cmt. f. According to comment f of section 6, the *defendant* technically bears the burden of proving a drug’s efficacy: “A defendant 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.” *Id.* Therefore, to present a section 6(c) claim, the plaintiff initially need only establish the drug’s failure in a single circumstance. In this respect, section 6(c) adheres to a traditional *res ipsa loquitur* standard. Section 6(c) deviates from section 3, however, and transforms into a “super” *res ipsa loquitur* standard as the defendant can defeat

2. *The failure of supplemental case law to support section 6(c)*

Although *Tobin* served as the primary basis for section 6(c), the Reporters cited two cases, *Ortho Pharmaceutical Corp. v. Heath*⁹⁶ and *Williams v. Ciba-Geigy Corp.*,⁹⁷ as supplemental support.⁹⁸ The Reporters conclude that these courts assigned design defect liability for medical products based on a determination of whether the drug proved effective for any group of patients.⁹⁹ These cases, however, fail to advance section 6(c) and instead represent the use of a risk-benefit test to impose design defect liability for medical products.

a. *Ortho Pharmaceutical Corp. v. Heath*

Ortho Pharmaceutical Corp. v. Heath involved a suit against a drug manufacturer by a consumer of an oral contraceptive. The plaintiff presented evidence that the extra thirty milligrams of estrogen in the oral contraceptive caused her to develop kidney failure,¹⁰⁰ necessitating a kidney transplant.¹⁰¹ In addition, the immunotherapy medication administered in conjunction with the kidney transplant caused the plaintiff to develop cervical dysplasia, a condition

the section 6(c) claim by establishing the product's benefit to a subgroup of users. *See id.* ("Subsection c reflects the judgment that as long as a given drug or device provides net benefits for a class of patients, it should be available to them . . ."). Thus, the plaintiff bears the ultimate burden under section 6(c) to establish sweeping inefficacy:

The risk-benefit test of section [6(c)] is . . . unique in that it must be applied to particular subclasses of product users. This may create particularly difficult problems of proof for the plaintiff, since she may have to establish that a product's risk not only outweigh its benefits generally, but also with respect to particular sub-classes of users. However, the provision could be read to shift the burden of proof on the risk-utility issue to the defendant, at least with respect to any subclasses of users. Although this reading of the provision helps the plaintiff somewhat, ultimately she must counter the defendant's proof as to the effects on particular classes of patients. In the final analysis the plaintiff faces an enormously difficult task in claiming that a prescription product is defective in design. Only the narrowest set of circumstances would seem to warrant such a claim.

Schwartz, *Prescription Products*, *supra* note 7, at 1384-85.

96. 722 P.2d 410 (Colo. 1986), *overruled on other grounds*, *Armentrout v. FMC Corp.*, 842 P.2d 175 (Colo. 1992).

97. 686 F. Supp. 573 (W.D. La.), *aff'd*, 864 F.2d 789 (5th Cir. 1988).

98. *See* Henderson, *Reporter's Perspective*, *supra* note 7, at 488-90 (noting that "*Tobin* is not the only reported decision to support the position adopted in section [6](c)" and citing *Williams* and *Ortho Pharmaceutical* as supplemental support for Section 6(c) in the *Restatement (Third)*); *see also* *RESTATEMENT (THIRD)*, *supra* note 6, § 6 (citing *Williams* and *Ortho Pharmaceutical* as supplemental support for section 6(c)). The Reporters cite additional case law and scholarly articles in their discussion of section 6(c) in the comments and Reporters' notes; however, the Reporters rely on *Ortho Pharmaceutical* and *Williams* as the main source of supplemental support for section 6(c).

99. *See* *RESTATEMENT (THIRD)*, *supra* note 6, § 6(c), reporters' note; *see also infra* notes 105, 114 and accompanying text.

100. The plaintiff's doctor prescribed the oral contraceptive, Ortho-Novum 1/80, after the plaintiff experienced break-through bleeding while taking Ortho-Novum 1/50. *See Ortho Pharm.*, 722 P.2d at 412.

101. *See id.* at 411.

requiring the plaintiff to undergo a hysterectomy.¹⁰² The plaintiff sued the contraceptive manufacturer for defective design under negligence and strict liability theories.¹⁰³ The Supreme Court of Colorado held that a risk-benefit test was the proper standard to determine design defect liability.¹⁰⁴

The Reporters claim that the holding in *Ortho Pharmaceutical* reflects section 6(c)'s liability standard.¹⁰⁵ A close reading of *Ortho Pharmaceutical*, however, reveals that the court applied a risk-benefit test unlike the section 6(c) standard. First, the court held that a risk-benefit analysis was the proper test of design defect.¹⁰⁶ The court held that the benefits of an extra thirty milligrams of estrogen outweighed the attendant risks of the higher estrogen content.¹⁰⁷

Second, the court concluded that the jury must weigh the drug's risks and benefits before assessing liability. The court did not base its final judgment on the drug's effect on one class of patients.¹⁰⁸ Rather, the court applied four factors to determine defective design.¹⁰⁹ The court concluded that evidence was conflicting, and that the jury ought to weigh the evidence and make a determination

102. See *id.* at 411-12. Cervical dysplasia is a condition in which a woman has a high risk of cervical cancer. The plaintiff, therefore, elected to have a hysterectomy. See *id.* The plaintiff's doctors believed that the immunotherapy medication required to prevent kidney rejection following transplant was responsible for the cervical dysplasia. See *id.*

103. See *id.* at 412.

104. See *id.* at 415 ("The failure of the trial court to give an instruction on the risk-benefit test was reversible error.").

105. In the Reporters' notes to section 6(c), the Reporters determine: "[T]he Supreme Court of Colorado revealed unambiguously [in *Ortho Pharmaceutical*] that the drug should be found non-defective if the jury concluded that the drug was the drug of choice for at least one class of patients." RESTATEMENT (THIRD), *supra* note 6, § 6, reporters' note.

106. The court discussed two types of jury instructions used in design defect cases: a consumer expectation test and a risk-utility test. See *Ortho Pharm.*, 722 P.2d at 413. The court defined the risk-utility test: "[T]he plaintiff proves that the product's design proximately caused injury and the defendant fails to prove, in light of the relevant factors, that on balance the benefits of the challenged design outweigh the risk of danger inherent in such a design." *Id.* The Colorado Supreme Court determined that the lower court should have instructed the jury under a risk-benefit analysis and not a consumer expectations test. See *id.* at 415.

107. See *id.* at 414 (comparing the risk-benefit test to the consumer expectation test).

108. See *id.* at 415.

109. See *id.* The court enumerated the factors used to determine if a product merits a comment k instruction: "[T]he product's utility must greatly outweigh the risk created by its use; the risk must be a known one; the product's benefits must not be achievable in another manner; and the risk must be unavoidable under the present state of knowledge." *Id.* The drug's unique ability to remedy a certain condition was only one of four factors balanced by the court in its determination whether to issue a comment k instruction. See *id.* at 415-16 (applying the four aforementioned factors to the case, with the fact that there was no alternative drug available to treat break-through bleeding weighing equally among three other factors).

Furthermore, one of the Colorado Supreme Court's recent statements on design defect liability cited to *Ortho Pharmaceutical*, interpreting the decision as providing for a "straightforward risk-benefit analysis." See *Barton v. Adams Rental*, 938 P.2d 532, 537 (Colo. 1997).

of risk and benefit.¹¹⁰ The Reporters, however, overlooked the weighing of factors in the case, concluding that *Ortho Pharmaceutical* stood for the single proposition that a drug is not defective if it is “the drug of choice for one class of patients.”¹¹¹

b. Williams v. Ciba-Geigy Corp.

Williams v. Ciba-Geigy Corp. also involved a suit against a drug manufacturer by an aggrieved consumer. The issue concerned whether a prescription drug for psychomotor seizures was designed defectively after the plaintiff experienced an adverse drug reaction.¹¹² The *Williams* court weighed the plaintiff’s severe drug reaction against the medication’s overall benefits to determine that the drug was not designed defectively.¹¹³ The Reporters argue that *Williams* “emphas[izes] the drug’s efficacy for certain classes of patients, notwithstanding its sometimes severely negative side effects,” thus supporting section 6(c).¹¹⁴

The Reporters made a leap in linking section 6(c) to *Williams*. The *Williams* court utilized a risk-benefit test unlike any found in section 6(c).¹¹⁵ The court characterized defective design analysis as a quantitative determination: “[R]isk . . . concerns not only the qualitative harmful effect, but also the quantitative harm or ‘incidence’ of serious adverse effects, that is, the ratio of instances of harm compared to the total use or consumption of the product.”¹¹⁶

110. See *Ortho Pharm.*, 722 P.2d at 416.

111. In the Reporters’ note to section 6(c), Professors Henderson and Twerski write that in *Ortho Pharmaceutical*:

[T]he record contained testimony which indicated that the increased risk of adverse reactions occasioned by the extra thirty milligrams of estrogen outweighed any benefits the product might produce. The record also contained evidence that [defendant’s drug] was the only available product for patients who experienced breakthrough bleeding and therefore, produced benefits that outweighed any increased risk.

RESTATEMENT (THIRD), *supra* note 6, § 6, reporters’ note (quoting *Ortho Pharm.*, 722 P.2d at 414) (emphasis added). Upon citing this passage, the Reporters subsequently determine that “[t]he emphasized language clearly indicates that if one class of patients is found to exist for whom defendant’s drug is the one of choice, then it is not defective.” *Id.* The conclusion of the passage of the Reporters states that the jury should weigh risks and benefits: “Where there is conflicting evidence, the question is properly submitted to the trier of fact.” *Id.* (quoting *Ortho Pharm.*, 722 P.2d at 414).

112. The plaintiff was taking Tegretol and developed Stevens-Johnson Syndrome, a serious adverse reaction known to occur from Tegretol. See *Williams v. Ciba-Geigy Corp.*, 686 F. Supp. 573, 575 (W.D. La. 1988).

113. See *id.* at 578-79 (weighing the degree of quantitative risk evidence against the “value of the high utility drug” to determine that the drug was not defectively designed).

114. See RESTATEMENT (THIRD), *supra* note 6, § 6 reporters’ note, cmt. f; see also Henderson, *Reporter’s Perspective*, *supra* note 7, at 488-89 (discussing the Reporters’ determination that *Williams* supported the section 6(c) standard).

115. See *Williams*, 686 F. Supp. at 578-79 (discussing benefits and risks of Tegretol).

116. *Id.* The court further discussed the importance of engaging in an overall assessment of risk and benefit when determining whether a medical product is defectively designed:

Therefore, to escape liability under *Williams*, a product's overall quantitative harm must be low.

The section 6(c) standard, however, is not a quantitative assessment of harm. Rather, if any subgroup exists for whom the drug provides benefit, the product is not defectively designed despite its overall incidence of harm.¹¹⁷ Under *Williams*, if the overall ratio of harm to benefit is high, the drug is defectively designed. The *Williams* court emphasized that "the quantitative risk evidence . . . is very scant" when determining whether the drug at issue was not defectively designed.¹¹⁸ Therefore, the *Williams* decision fails to support section 6(c), as the court engaged in a quantitative assessment of risk and benefit.

The Reporters, despite being unable to boast substantial case law support, created a stringent liability standard for medical product design defect. As acknowledged by the Reporters, rarely will a plaintiff be able to establish a claim for medical product design defect.¹¹⁹ Thus, given that harm will befall the consuming public, which is impotent against drug manufacturers shrouded in the *Restatement (Third)*'s corporate-friendly liability standards, the inquiry becomes: Who will most be harmed? The answer is found by asking the Woman Question.

B. What is the Relationship Between Women and Medical Products?

1. Feminist tort theory

Asking the Woman Question in the context of the *Restatement (Third)* begins with an analysis of feminist tort theory. Early feminist legal theory focused on the struggle for "formal" constitutional equality which segued into advocacy for the right to privacy (abortion rights) and protection from domestic violence and sexual harassment.¹²⁰ Feminist legal theory encompasses varied aspects of

"Although the danger may be devastating to those individuals who experience the worst effects [of the drug], the incidence may be statistically small and the composite risk may not outweigh the value of a high utility drug." *Id.*

117. "[A] prescription drug or medical device that has usefulness to any class of patients is not defective in design even if it is harmful to other patients." RESTATEMENT (THIRD), *supra* note 6, § 6 reporters' note, cmt. f.

118. See *Williams*, 686 F. Supp. at 579.

119. See *supra* note 72 and accompanying text (noting the Reporters' declaration that they purposefully designed section 6(c) to be a difficult standard of liability).

120. See Carrie Menkel-Meadow, *Mainstreaming Feminist Legal Theory*, 23 PAC. L.J. 1493, 1504-07 (1992) (tracing the effects of feminist legal theory in the legal system); see also Bartlett, *supra* note 18, at 838-42 (discussing the historical application of the Woman Question in law beginning with the efforts of Elizabeth Cady Stanton in the quest for suffrage, continuing through the 1970s formal gender equality cases, and culminating in today's changed legal

women's experiences and needs which bleed¹²¹ into different areas of law and policy, including the realm of tort law.

"[T]ort suits define and signify basic social values about what human activities are worthy of protecting" ¹²² Runoff from women's social inequality has seeped into the tort system,¹²³ as legal scholars have established a body of thought regarding the tort system's disparate treatment of women.¹²⁴ One of the most prevalent examples derives from the discussion of tort reform and women.

As the cry for tort reform is currently sending Congress scrambling to pass legislation limiting punitive damages¹²⁵ and insulating companies from liability,¹²⁶ scholars are examining the reforms' effects on women. Men and women suffer different types of harms under tort reform.¹²⁷ According to one study, "mass torts affecting

conception of a woman's consent in rape cases).

121. See Menkel-Meadow, *supra* note 120, at 1510 (using the term "bleeding" in a feminist sense to discuss the interconnection of women's issues in the law).

122. Lucinda M. Finley, *Female Trouble: The Implications of Tort Reform for Women*, 64 TENN. L. REV. 847, 849-50 (1997) (arguing that the societal devaluation of women is reflected in the tort system).

123. See Thomas Koenig & Michael Rustad, *His and Her Tort Reform: Gender Injustice in Disguise*, 70 WASH. L. REV. 1, 8 (1995). The authors note:

Social scientists have documented the ways that gender discrimination and sex role socialization track women and men into separate, although overlapping, social and occupational spheres Many scholars argue that by not taking full account of the manifold differences between males and females, law and the courts are deeply biased against women.

Id.

124. Feminist tort scholarship has addressed such issues as punitive damage awards and compensation for emotional injuries. See, e.g., Leslie Bender, *An Overview of Feminist Torts Scholarship*, 78 CORNELL L. REV. 575, 577-79 (1993) (discussing the historical trend in tort law to discount "emotional" injuries claimed more often by women); Finley, *supra* note 122, at 858-61 (addressing the tort system's characterization of reproductive harm suffered by women as an emotional harm ultimately resulting in smaller pecuniary damage awards); Koenig & Rustad, *supra* note 123, at 3 (examining patterns of punitive damages and concluding that "awards are subdivided into 'his' and 'her' tort worlds"). Further issues identified by feminist legal scholars include the gender implications of the reasonable person standard, loss of consortium, wrongful life/wrongful birth cases, and duty to rescue. See generally Bender, *supra*, at 581-82 (proposing the application of feminist legal theory to influence corporate practices and to change laws controlling corporate forms, decision-making, and public access to corporate records); see also Koenig & Rustad, *supra* note 123, at 9 (arguing that given the social inequality of women, tort reforms that appear neutral can have "unanticipated negative impacts on women").

125. See Koenig & Rustad, *supra* note 123, at 27 (characterizing the purpose of tort reform as "to attack excessive jury awards, especially in the fields of products liability and medical malpractice"). The power of the tort reform movement is evidenced by the fact that 40 states have either eliminated or curbed punitive damages. See *id.* at 30-31.

126. For example, President William J. Clinton recently signed the Biomaterials Access Assurance Act into law, a measure granting suppliers of raw materials and component parts of medical implants immunity from liability for defectively designed products. See Pub. L. No. 105-230, 112 Stat. 1519 (1998) (to be codified at 21 U.S.C. §§ 1601-1606).

127. See Marsa, *supra* note 10, at 46. Groups such as the Women's Legal Defense Fund, the Boston Women's Health Collective, and trial lawyers argue that because women and men suffer different product harms, limits on products liability damages will unfairly affect women and

women feature injuries from defective products placed inside their bodies, whereas men are seldom injured in this fashion.”¹²⁸ These injuries often manifest as reproductive¹²⁹ and emotional harms,¹³⁰ not readily quantifiable in economic terms.¹³¹ These harms can, however, directly influence the very tangible economic choices involving a woman’s education and career.¹³² In addition, the lost value of a woman’s domestic labor fails to translate into the market-based tort reform formula.¹³³ Therefore, changes in tort law rendering it more

produces “gender injustice.” See *id.* This point is illustrated by comparing the products liability cases involving men and women:

Of the largest product-liability suits of the last 20 years, the one against the makers of the Vietnam War defoliant Agent Orange, filed primarily on behalf of men, with about 250,000 claimants, is only as large as one of the smallest suits involving women, against the manufacturers of the Dalkon Shield IUD (intra-uterine device) . . . [The statistics support the claim that women] ‘have born the brunt of America’s worst product and medical travesties.’

Id.

128. Koenig & Rustad, *supra* note 123, at 48.

129. Feminist torts scholar, Professor Lucinda Finley, presents an example of the undervaluation of women’s reproductive injuries in tort law. A woman suffered three ectopic pregnancies, the loss of both of her fallopian tubes, and years of expensive infertility treatment as a result of exposure to DES. The jury awarded her \$50,000. After appeal, she settled for \$45,000. See Lucinda Finley, *Feminist Jurisprudence—The 1990 Myra Bradwell Day Panel*, 1 COLUM. J. GENDER & L. 5, 22 (1991). Professor Finley personally interviewed the plaintiff, and discussed this woman’s comments on the nature of the relationship between women and the tort system:

[The Plaintiff] said that the message that she got from society was that the most important thing about being a woman was her reproductive capacity, and that what women are really valued for is their reproductive, nurturing role. And then . . . when she had the opportunity to make the legal system ‘put society’s money where its mouth was,’ they told her that all of that was really worth only \$50,000. Why? Because she did not have any lost income She did not lose marketplace time, even though her entire reproductive capacity had been taken from her.

Id. at 22-23.

130. Juries have historically awarded punitive damages to compensate women for psychological harms suffered as a result of defective IUDs and breast implants, sexual assaults by health care providers, unnecessary reproductive surgeries, and grossly deficient cosmetic surgery. See Finley, *supra* note 122, at 866. Professor Finley argues that the effects of tort reform could have severe effects on women suffering non-pecuniary injuries in the form of psychological and sexualized harms: “[A]n examination of the types of injuries for which punitive damages have been awarded to women in products liability and medical malpractice cases demonstrates that the [punitive damages] cap would primarily serve to devalue women’s reproductive and sexual well-being.” *Id.*; see also *infra* notes 143-47 (presenting an example of the effects of punitive damage awards on a manufacturer’s safety decision regarding the Copper-7 intrauterine device).

131. See Finley, *supra* note 122, at 855 (maintaining that women’s reproductive and emotional harm from medical products has little or no economic value in the marketplace). Courts often fail to consider the mental health therapy often needed by women who experience reproductive loss, infertility, sexual harassment, or assault when awarding damages for future medical expenses. See *id.* at 857-58. As these harms often derive from the emotional rather than the physical realm, courts often overlook them. See *id.*

132. The adverse effects that these types of injuries have on a woman’s earning potential can manifest in a slow accretion “from the way a woman shrinks back or fails to seek certain assignments or a slow accumulation of too many stress induced absences.” See *id.* at 858.

133. See Lucinda M. Finley, *A Break in the Silence: Including Women’s Issues in a Torts Course*, 1 YALE J.L. & FEMINISM 41, 52 (1989) (contending that most torts text books fail to address issues

difficult to establish liability will disparately impact women.

The discourse involving the adverse relationship between the goals of tort reform and the needs of women bleeds into a discussion of the *Restatement (Third)* and its impact on women. Specifically, as greater consumers of inadequately tested and monitored prescription products and medical devices, section 6(c)'s limitations on liability pose a threat to women.

2. *Women, medical products, and the regulatory system*

Section 6(c) is an extremely stringent standard for establishing medical product design defect liability. The Reporters justify this standard based on two general arguments: (1) medical products are unique in nature as compared to other types of products, therefore meriting greater protections by the tort system;¹³⁴ and (2) the regulatory system will perform adequate testing and monitoring and thus protect the consumer.¹³⁵ The subsequent section addresses the fallacies underlying these arguments.

a. *The "special" categorization of medical products*

The distinction between medical products and other products is tenuous. There are expansive categories of medical products on the market fulfilling cosmetic or "pleasure" purposes.¹³⁶ Furthermore, a number of products serve medical purposes despite the FDA's

concerning the loss of a woman's household management and child rearing services, as these types of remedies do not fit within the confines of a market economy).

134. See *supra* note 73.

135. See *supra* note 74.

136. In the seminal case of *Brown v. Superior Court*, the Supreme Court of California held that strict liability under the *Restatement (Second)* did not apply to prescription drugs. See 751 P.2d 470, 483 (Cal. 1988). The court justified its decision by reasoning that a distinction existed between prescription products and other products. See *id.* at 478. The court differentiated between products that provide pleasure or make work easier and those medical products that "may be necessary to alleviate pain and suffering or to sustain life." See *id.* The reasoning expressed by the California Supreme Court parallels the Reporters' rationale behind section 6(c) concerning the special nature of medical products. See *supra* note 73 and accompanying text (noting the Reporters' argument that medical products differ from other products and as such merit a more stringent standard of liability).

The line dividing medical products from other products, however, is not as distinct as the Reporters claim. There is an entire gray area of cosmetic prescription products designed and marketed with the purpose of "providing pleasure" rather than alleviating pain. See Terrie Bialostok Brodie, *Brown v. Superior Court: Drug Manufacturers Get Immunized From Strict Liability for Design Defects*, 19 GOLDEN GATE U. L. REV. 435, 443 (1989) (contending that *Brown*'s distinction between prescription drugs and other products is artificial because medical products exist that can be characterized as "providing pleasure" thus blurring the line between prescription products and other types of products); see also Richard L. Cupp, Jr., *Sharing Accountability for Breast Implants: Strict Products Liability and Medical Professionals Engaged in Hybrid Sales/Service Cosmetic Product Transactions*, 21 FLA. ST. U. L. REV. 873, 874-75 (1994) (addressing the increased use of implants for cosmetic purposes).

characterization to the contrary.¹³⁷

The special categorization of medical products may preclude the development of safer, more effectively designed medical products and the removal of harmful medical products from the market. Even if a medical product benefits one subclass, a redesigned product may prove more useful to a larger group.¹³⁸

Furthermore, the threat of liability creates the incentive for drug manufacturers to remove less effective and potentially unsafe products from the market.¹³⁹ For example, in *Kociemba v. G.D. Searle & Co.*,¹⁴⁰ the jury awarded \$7 million in punitive damages against the manufacturers of the Copper-7 intra-uterine device ("IUD") after the plaintiff established that the device caused her infertility.¹⁴¹ The

137. For example, the FDA classifies newly developed vaginal moisturizing products under the heading of "cosmetics" and not "drugs." See LAURENCE & WEINHOUSE, *supra* note 10, at 308. The FDA distinguishes between cosmetics and drugs. See Jacqueline A. Greff, *Regulation of Cosmetics That Are Also Drugs*, 51 FOOD & DRUG L.J. 243, 243 (1996). Unlike drugs, the FDA does not subject cosmetics to pre-market approval, safety or efficacy testing, or good manufacturing practices. See *id.* Of all the major FDA-regulated products, cosmetics are the only group without their own FDA center. See *id.* The FDA has classified some products, however, as "cosmetic drugs," defined as products "typically . . . formulated and marketed as cosmetics, with drug functions providing an additional benefit." See *id.* at 249-50. These products are subject to both cosmetic and drug regulations. See *id.* at 250. It is unclear under the *Restatement (Third)* whether "cosmetic drugs" would fall under Section 6(c), as the text and comment only provide for liability for "defective prescription drugs and medical devices." See *RESTATEMENT (THIRD)*, *supra* note 6, § 6. Standards of liability for defective medical products may produce incongruous results under the *Restatement (Third)* depending on how a product is classified. For example, the FDA classifies vaginal products with similar purposes differently:

Astringent products intended and labeled for the relief of minor vaginal irritation or reduction in local edema would be considered as drugs, while astringent products intended and labeled for a refreshing effect would be considered cosmetics. A product making both claims would be both a drug and a cosmetic.

Vaginal Products for Over-the-Counter-Human Use; Withdrawal of Advance Notice of Proposed Rule Making, 59 Fed. Reg. 5226, 5231 (1994) (to be codified at 21 C.F.R. pt. 351).

Therefore, under the *Restatement (Third)*, a manufacturer's liability for harm suffered upon use of a vaginal product would vary depending on the product's classification. If the product's classification was "cosmetic," it would face a more lenient standard of liability under section 2(b), whereas if the product was considered a "drug" (or possibly a "cosmetic drug"), a plaintiff would have a more difficult time establishing liability under Section 6(c)'s more demanding standard.

138. See Jerry J. Phillips, *The Unreasonably Unsafe Product and Strict Liability*, 72 CHI.-KENT L. REV. 129, 156 (1996) ("[B]y using a reasonable alternative design approach—which is curiously rejected here—a product that is useful to a subclass of patients may be of even greater use to that class if redesigned.").

139. If manufacturers believe they can avoid liability under section 6(c), the incentive to design the best product is eliminated:

[T]he tort system, with its threat of large demand awards, supplies incentives to comply with the federal safety requirements. Indeed, since tort damages can dwarf monetary penalties under regulatory statutes, the tort system can serve as a greater deterrent to unsafe practices than the regulatory system itself.

Schwartz, *Prescription Products*, *supra* note 7, at 1385.

140. 707 F. Supp. 1517 (D. Minn. 1989).

141. See *id.* at 1523-24. The plaintiff won on negligent failure to warn, failure to test, and product misrepresentation claims. See *id.* at 1524.

Kociemba verdict led to thousands of out-of-court settlements¹⁴² and the removal of the Copper-7 IUD from the market.¹⁴³ Cases involving the Dalkon Shield¹⁴⁴ and Parlodel¹⁴⁵ further exemplify how the mere *threat* of liability is often a strong enough weapon to protect women from defective products.

b. The "protective" regulatory system

The FDA has received criticism that its drug approval and monitoring process is overly thorough.¹⁴⁶ Research reveals, however, that this charge is relatively unfounded. Rather, various political and institutional factors within the FDA combine to raise questions concerning consumer safety.

As a governmental body, the FDA is vulnerable to influence from

142. See Koenig & Rustad, *supra* note 123, at 41 (noting that the defendant in *Kociemba* was subject to only one punitive damage verdict involving the IUD, but that the large amount of damages coupled with the threat of future awards prompted the company to settle and not to litigate any further claims).

143. See Finley, *supra* note 122, at 875 (discussing the congressional testimony of the Copper-7 IUD's attorney, and stating that the first punitive damages award, combined with the subsequent loss of insurance coverage, "led to the demise of this IUD"). The IUD manufacturers in the United States now encounter few lawsuits because of the safety lessons they learned from the past. See *id.* at 874. Often the threat of litigation is a more effective means of removing dangerous products from the market than complaints of death and injury: "The overall irony of the argument that litigation costs drove some IUDs off the market is that 'reports of injuries and deaths of women, which came years before the devices were withdrawn, never had that effect.'" *Id.* (citing NICOLE GRANT, *THE SELLING OF CONTRACEPTION: THE DALKON SHIELD CASE, SEXUALITY AND WOMEN'S AUTONOMY* 147 (1992)).

144. See Finley, *supra* note 122, at 874. Professor Finley notes that before punitive damages in excess of one million dollars were assessed against A.H. Robins, the company was not inclined to remove the Dalkon Shield from the market:

A.H. Robins continued to market the Dalkon Shield IUD despite mounting reports of pelvic inflammatory disease, perforated uteruses, infertility, septic abortions, and internal corporate reports acknowledging that the infection causing propensity could be greatly reduced for a cost of a few cents per device. Indeed until juries started awarding large punitive damages judgments in Dalkon Shield litigation, A.H. Robins continued to market, promote, and defend the device.

Id.

145. For five years, the FDA requested the manufacturer, Sandoz, to cease marketing Parlodel as a lactation suppressant drug as the drug was linked to strokes, seizures, and heart attacks in women. See Rick Weis, *Drug Will No Longer Be Sold to Stop Breast Milk*, WASH. POST, Aug. 23, 1994, at Z7. Despite FDA pressure, the threat of a lawsuit was the impetus behind the drug's removal from the market as a lactation suppressant drug. See *id.*; see also *infra*, notes 174-76 and accompanying text.

146. Many commentators have written on the issue of the FDA and its role in the tort system. See, e.g., Michael D. Green, *Safety as an Element of Pharmaceutical Quality: The Respective Roles of Regulation and Tort Law*, 42 ST. LOUIS U. L.J. 163, 164 (1998) (discussing current FDA reform proposals that focus less on consumer protection and more on accelerating drug approval rates); see also Charles J. Walsh & Alissa Pyrich, *Rationalizing the Regulation of Prescription Drugs and Medical Devices: Perspectives on Private Certification and Tort Reform*, 48 RUTGERS L. REV. 883, 886-87 (1996) (discussing the "conservative" nature of the FDA's regulatory approach and determining that "[t]he price of this thorough and detailed pre-market review is a long, and often extremely costly, gestation period between development and approval of new drugs and devices").

powerful political and industrial groups.¹⁴⁷ The FDA is also susceptible to regulatory lag, as slowly changing agency approval standards clash with fast-moving medical technology.¹⁴⁸ Furthermore, increased responsibility and decreased resources suggest that the FDA will be unable to ensure safety.¹⁴⁹ A 1991 comprehensive study of the FDA's resources revealed that the FDA was able to monitor a smaller share of prescription products than ten years prior.¹⁵⁰ Finally, the FDA has failed to adequately regulate due to manufacturer fraud¹⁵¹ and "regulatory laxness."¹⁵²

147. See Margaret Gilhooley, *Innovative Drugs, Products Liability, Regulatory Compliance and Patient Choice*, 24 SETON HALL L. REV. 1481, 1489 (1994) (arguing that agencies often rely on industries for information, resulting in the "capture" of agencies by industries which ultimately produces regulation based on industry influence); see also Teresa Moran Schwartz, *Regulatory Standards and Products Liability: Striking the Right Balance Between the Two*, 30 U. MICH. J.L. REFORM 431, 445 (1997) (addressing the regulatory agency's dependency on the drug industry for information about a product and the consequent influence the drug industry has on a product's approval). The Reagan Administration's relationship with the FDA exemplifies the FDA's vulnerability to political pressure:

The overall philosophical bent of [President Ronald Reagan's] administration was anti-regulatory. It was reflected almost immediately in FDA actions. Pending regulations were withdrawn or postponed. FDA's use of its enforcement authority to ban or to recall products fell sharply, and criminal prosecution of cases was anemic. In the first five years of the Reagan administration, the FDA staff was cut by more than 12%. Industry influence on the regulatory process grew enormously, with industry members enjoying special access to decision makers . . . who in turn influenced agency action. Numerous examples of FDA decisions not to regulate, to delay regulations, or not to bring enforcement actions were traced to pressure from industry members on political officials at the Department of Health and Human Resources or Office of Management and Budget.

Schwartz, *Prescription Products*, *supra* note 7, at 1389-90; see also Schwartz, *supra*, at 448 ("[T]he regulatory environment shifts with the political environment. Such shifts should raise serious concerns for the judiciary about relying on the regulatory system to set the safety standards for the tort system.").

148. See Schwartz, *supra* note 147, at 444-45 (arguing that government standards are not completely reliable as accurate measures of safety because agencies are often unable to keep pace with the speed of technology).

149. See Schwartz, *supra* note 7, at 1387-89 (discussing the impact of the simultaneous expansion of FDA jurisdiction to regulate over 8,000 drugs and 16,000 medical devices and the reduction of funding for retaining scientists and maintaining laboratories and equipment).

150. See Schwartz, *supra* note 147, at 446.

151. In 1993, a manufacturer of defective heart catheters, responsible for one death and 20 emergency surgeries, admitted lying to the FDA concerning the device's experimental use on humans and concealing the product's failures from the FDA. See Schwartz, *supra* note 7, at 1391 & n.217 (citing Philip J. Hilts, *Manufacturer Admits Selling Untested Devices for Heart*, N.Y. TIMES, Oct. 16, 1993, at A1).

152. The FDA received complaints about silicone breast implants for 20 years while attempts to classify breast implants as "high risk devices" began in 1982 and were not complete until 1992. See Schwartz, *supra* note 7, at 1394. The results of a Government Accounting Office study reveals that between 1976 and 1985, over 50% of FDA approved drugs produced "serious post-approval risks leading to hospitalization or worse," many instances of which the FDA had knowledge but failed to act. See Koenig & Rustad, *supra* note 123, at 50.

c. *Asking the question: drug testing and monitoring for women*

In addition to the general problems concerning drug testing and monitoring, the FDA has a particular problem with inadequate drug testing and monitoring of products for women. Justifying the stringent standard of liability, the Reporters assumed that “governmental regulatory agencies adequately review new prescription drugs and devices, keeping unreasonably dangerous designs off the market.”¹⁵³ The Reporters further contend that the FDA’s “long, drawn out meticulous [approval] process” is an appropriate substitute for “judicial decision-making.”¹⁵⁴ Research reveals, however, that this “long, drawn out meticulous [approval] process,” has traditionally not included women. Thus, the FDA is not “an appropriate substitute” for judicial decision making.

Clinical drug trials have systematically excluded women. Male subjects have been the prototypes for medical products designed for the general population, under the rationale that men and women will experience similar drug reactions.¹⁵⁵ Furthermore, drug trials have tested women’s products using only male subjects.¹⁵⁶ The medical community has criticized this practice,¹⁵⁷ arguing that the complexities of female biology,¹⁵⁸ the economic cost of providing for

153. *RESTATEMENT (THIRD)*, *supra* note 6, § 6 cmt. b.

154. Henderson, *Reporter’s Perspective*, *supra* note 7, at 491-92.

155. See Bowles, *supra* note 10, at 878 (noting that researchers reason that the effects of drugs on men are applicable to women). For example, researchers conducted a study on the prophylactic benefits of aspirin for the general public using only male models because the effects were thought to be the same for women. See Council on Ethical and Judicial Affairs, American Med. Ass’n, *Gender Disparities in Clinical Decision Making*, 266 JAMA 559, 559 (1991) [hereinafter *Gender Disparities*]. The FDA announced that it had doubts about the applicability of the study’s results to women. See Guideline for the Evaluation of Gender Differences in the Clinical Evaluation of Drugs, 58 Fed. Reg. 39,406 (1993) (“Certain major studies of the role of aspirin in cardiovascular and cerebrovascular disease, for example, did not include women, and this omission left the scientific community with doubts about whether aspirin was, in fact, effective in women for these indications.”).

156. For example, a report by the Task Force on Women’s Health Issues revealed that men were the only test subjects in a project examining the impact of obesity on breast and uterine cancer under the rationale that estrogen metabolism in men and women are similar. See Karen H. Rotenberg, *Gender Matters: Implications for Clinical Research and Women’s Health Care*, 32 HOUS. L. REV. 1201, 1208 & n.28 (1996).

157. See Bowles, *supra* note 10, at 880 (noting the criticisms of the claim that women and men experience similar drug reactions as justification for excluding women from clinical drug trials).

158. These “complexities” include factoring the female menstrual cycle, pregnancy, and menopause into drug trials. See *id.* at 881-82; see also R. Alta Charo, *Protecting Us To Death: Women, Pregnancy, & Clinical Research Trials*, 38 ST. LOUIS U. L.J. 135, 141 (1993). The author observed the inherent contradictions in the justifications put forth by the medical establishment for excluding women from medical drug trials:

There are two assumptions [that are contradictory] The first is the idea that men are typical of all humans According to this logic, if an aspirin a day can prevent heart attacks in men, it will surely do so in women The second assumption contradicts the first. It is the idea that women are so different from men that their

these biological variables,¹⁵⁹ and the liability risk of teratogenic effects¹⁶⁰ are the actual reasons for women's exclusion from drug trials.

In 1977 the FDA issued "General Considerations for the Clinical Evaluation of Drugs"¹⁶¹ (the "1977 Guidelines"). These policies advocated¹⁶² the exclusion of women of childbearing potential¹⁶³ from clinical drug trials.¹⁶⁴ The rationale behind the exclusion of women

inclusion would destroy both the homogeneity of the experimental population and the purity and simplicity of the experiment.

Id. (citing Joan W. Scott, *How Did the Male Become the Normative Standard for Clinical Drug Trials?*, 48 FOOD DRUG COSM. L.J. 187, 188 (1993)).

159. See Bowles, *supra* note 10, at 881-82 (noting that the "complex" and "expensive" nature of drug research is a rationale offered by researchers to justify the exclusion of women from drug studies). The economic considerations involved in excluding women from drug research extends into the realm of grant funding. The small number of female researchers in positions of power may be the cause of the low economic prioritization of women's health research. See *id.* at 883 (noting how the selection process for research funding by the National Institute of Health is "skewed to the detriment of women" because the few female medical researchers submitting proposals are "in the lower echelons of the research hierarchy and thus have less extensive track records than most of their male counterparts").

Despite the dearth of funding for projects concerning women's health, collective efforts by female researchers are necessary to ensure the safety and progress of medical products for women. For example, the drug Thalidomide was developed by a German company as a tranquilizer for pregnant women, among other uses. See ANALYZING GENDER: A HANDBOOK OF SOCIAL SCIENCE RESEARCH 444 (Beth B. Hess & Myra Marx Ferree, eds. 1987). One female researcher in charge of the approval process of Thalidomide, Dr. Frances Kelsey, was responsible for exposing the drugs' harmful effect on pregnant women. See *id.* at 445. Despite heavy pressure from drug companies and the worldwide acceptance of Thalidomide, Dr. Kelsey refused to permit companies to openly market the drug. See *id.* It is estimated that Thalidomide was responsible for producing at least 10,000 deformed babies. See *id.* Dr. Kelsey eventually received a presidential citation for her efforts concerning Thalidomide. See *id.*

160. See Bowles, *supra* note 10, at 880 ("[P]harmaceutical houses fear liability for injuries to a woman or her fetus that might occur in a clinical trial.").

161. FDA, DEP'T OF HEALTH, EDUC. & WELFARE, PUB. NO. 77-3040, GENERAL CONSIDERATIONS FOR THE CLINICAL EVALUATION OF DRUGS (1977) [hereinafter 1977 GUIDELINES].

162. The Guidelines are not necessarily requirements for drug approval. The Foreword to the Guidelines states:

These guidelines are not to be interpreted as mandatory requirements by the FDA to allow continuation of clinical trials with investigational drugs or obtain approval of a new drug for marketing. . . . [They] contain recommendations for clinical studies which are recognized as desirable approaches to be used in arriving at conclusions concerning safety and effectiveness of new drugs; . . . they consist of the views of outstanding experts in the field as to what constitutes appropriate methods of study of specific classes of drugs.

Id. at 5.

163. "A woman of childbearing potential is defined as a premenopausal female capable of becoming pregnant. This includes women on oral, injectable, or mechanical contraception; women who are single; women whose husbands have been vasectomized or whose husbands have received or are utilizing mechanical contraceptive devices." *Id.* at 15.

164. See *id.* The 1977 Guidelines recommend excluding women from the earliest dose ranging studies. See *id.* The Guidelines advocate that before studies include women of childbearing potential in large-scale clinical trials, adequate safety and efficacy studies, including animal reproduction studies, must be performed. See *id.* The 1977 Guidelines provide for women of childbearing potential to receive investigational drugs without the performance of adequate animal reproduction studies for drugs used as a life-saving or life-

of childbearing potential was to avoid possible teratogenic effects. The 1977 Guidelines, however, recognized the possibility of genetic harm to males from experimental drugs. Yet the Guidelines failed to impose such restrictive testing policies on male subjects.¹⁶⁵ These policies have resulted in a pervasive lack of drug testing on fertile women.¹⁶⁶

In 1993, the FDA revised the section of its Exclusionary Guidelines entitled, "Women of Childbearing Potential," to include fertile women in these trials.¹⁶⁷ The FDA admitted that its 1977 policy all but excluded women from phase 1, non-therapeutic studies, and the earliest controlled effectiveness studies.¹⁶⁸ The FDA further conceded

prolonging measure or drugs which teratogenic potential has been established in animals. *See id.* The Supreme Court's decision in *Roe v. Wade*, 410 U.S. 113 (1973), four years prior to the issuance of the Guidelines, may have influenced the FDA's concern for fetal protection. *See* Charo, *supra* note 158, at 139.

165. The 1977 Guidelines provide:

Male Reproductive System:

Where testicular abnormalities of spermatogenesis have occurred in experimental animals or where chromosomal abnormalities are anticipated . . . the criteria for inclusion of males in Phases I, II, and III depend upon the nature of the abnormalities, the dosage at which they occurred, the disease being treated, the importance of the drug, and the duration of the drug administration. In some cases, special written consent forms, even in Phase III, may be required.

1977 GUIDELINES, *supra* note 161, at 16.

166. *See* Charo, *supra* note 158, at 145 ("The result [of these testing policies] is to make all women who use these drugs into unwitting, unconsenting post-marketing research subjects, because the damage caused by untested drugs could be equally or more harmful to the general population of fertile women than to fertile participants in the trials.").

167. The FDA announced that it would require fertile women in these studies to undergo pregnancy screens and counseling on the importance of using birth control devices while participating in the trials. *See* Guideline for the Evaluation of Gender Differences in the Clinical Evaluation of Drugs, 58 Fed. Reg. 39,406, 39,408 (1993).

168. *See id.* Phase 1 drug studies generally lack therapeutic intent, the exception being early studies of life-threatening diseases. *See id.* at 39,407. Phase 1 studies include the testing of a new drug on normally healthy humans to examine the drug's tolerability, metabolism, and short-term pharmacokinetics. *See id.* Phase 2 drug studies begin from the premise that the drug lacks therapeutic value in humans. *See id.* These studies include the initial controlled effectiveness study of a particular drug. *See id.* The 1977 Guidelines permitted the inclusion of fertile women in later phase 2 and 3 studies if the phase 1 and 2 trials had amassed adequate drug safety and effectiveness information and had completed studies involving animal teratogenicity and female part of animal fertility. *See id.* at 39,407-08. Apparently, the 1977 Guidelines failed to address the means by which researchers could utilize the effectiveness information and animal studies to determine whether a phase 2 or 3 study merited the inclusion of fertile women. *See* Charo, *supra* note 158, at 139 n.23. The determination was therefore left to the patient and physician to perform a risk-benefit assessment subject to FDA review. *See id.*

The result of the exclusion policy regarding fertile women and early drug trials is that women subsequently are excluded from later trials, despite the FDA's revised policies. *See id.* at 143 ("Unfortunately, streamlining early drug studies by excluding women tends to make the exclusion of women attractive in later phases as well."). The FDA confessed that its studies have neglected women such that "there has been little study of the effects of such aspects of female physiology as the menstrual cycle and menopause, or of the effects of drugs widely used in women such as oral contraceptives and systemic progestins and estrogens, on drug action and pharmacokinetics." Guideline for the Evaluation of Gender Differences in the Clinical

that its policies fostered a male-oriented drug research scheme: "The early exclusion also may have perpetuated . . . a view of the male as the primary focus of medicine and drug development, with women considered secondarily."¹⁶⁹ This revised drug testing policy fails to absolve the FDA, however, because it does not require companies to include women in trials as a quid pro quo for drug approval.¹⁷⁰ Therefore, regardless of the new FDA policy, drug trials may still exclude women based on their absence from earlier trials and/or the lack of an official mandate to include them.

Compounding its pre-approval deficiencies, the FDA's post-approval track record for protecting women from harmful products is equally poor. Women who have suffered strokes and seizures from the drug Parlodel,¹⁷¹ or ruptured silicone breast implants,¹⁷² are not likely to be comforted by the fact that a product bears the FDA's stamp of approval. Although medical devices are subject to FDA monitoring, the FDA may require mounting complaints of injury and death before it removes these products from the market.¹⁷³ For example, the FDA withdrew the lactation-suppressant drug Parlodel from the market only after amassing reports that the drug caused thirty-one strokes (nine of which were fatal), sixty-three seizures, and seven heart attacks (one of which was fatal).¹⁷⁴ Furthermore, the impetus to remove Parlodel from the market did not originate within the FDA, but rather from a consumer group's suit against the FDA

Evaluation of Drugs, 58 Fed. Reg. at 39,406.

169. Guideline for the Evaluation of Gender Differences in the Clinical Evaluation of Drugs, 58 Fed. Reg. at 39,408. The FDA additionally admitted that this discrimination may have affected medical dosing recommendations for women: "[T]here is reason to believe that earlier participation of women in studies would increase the likelihood that gender-specific data might be used to make appropriate adjustments in larger clinical studies (e.g., different doses in women or weight adjusted (milligram per kilogram) dosing instead of fixed doses)." *Id.*; see also Rotenberg, *supra* note 156, at 1206 (discussing the scientific community's prevalent perception of the male as the physical norm and consequent characterization of the female's differences as "unknown variables").

170. See Guideline for the Evaluation of Gender Differences in the Clinical Evaluation of Drugs, 58 Fed. Reg. at 39,408-09. The FDA's 1993 Guidelines state:

We do not at this time perceive a regulatory basis for requiring routinely that women in general or women of childbearing potential be included in particular trials, such as phase 1 studies The agency is confident that the interplay of ethical, social, medical, legal and political forces will allow greater participation of women in the early stages of clinical trials.

Id.

171. See *infra* notes 174-75 and accompanying text.

172. See *supra* note 152 (discussing the FDA's slow response to women's complaints concerning defective breast implants).

173. See Finley, *supra* note 122, at 874.

174. See Edward R. Silverman, *Novartis Pays \$20 Million to Settle Suit*, STAR-LEDGER (Newark, N.J.), June 11, 1997, at 49 (discussing the decision by Novartis Ltd., manufacturer of Parlodel, to settle a lawsuit alleging that Parlodel rendered a 24-year old woman brain damaged).

aimed at forcing restriction of the drug's use.¹⁷⁵

Asking the Woman Question of section 6(c) engenders an unfavorable response. Medical products, like other products, have an alarming capacity for harm, yet face the most rigid standard of liability in the *Restatement (Third)*. Furthermore, the FDA cannot adequately ensure the safety of medical products for women. Therefore, concepts of fairness and safety demand an exception to this stringent liability standard for harmful medical products falling short of section 6(c)'s standard.

III. RECOMMENDATION: THE ANSWER TO THE WOMAN QUESTION:
COMMENT E SHOULD APPLY TO SECTION 6(C)

Comment e was designed as an exception to the design defect liability standard in section 2(b) requiring proof of a reasonable alternative design.¹⁷⁶ Comment e is the only provision in the *Restatement (Third)* that protects society from defectively designed products without requiring proof of either a reasonable alternative design, as in section 2(b),¹⁷⁷ or the product's complete inefficacy, as in section 6(c).¹⁷⁸

This Comment advocates that comment e should apply to section 6(c). The Reporters specifically note, however, that section 2(b) does not apply to prescription drugs and medical devices.¹⁷⁹ Therefore, the question becomes whether comment e of section 2(b) can and *should* apply to section 6(c).

A. *Was Comment e Designed to Apply to Section 6(c)?*

Comment e and section 6(c) are different variations of the same principle. Under comment e, a product is defectively designed precisely because it performed as intended.¹⁸⁰ Proof of a reasonable

175. See Weis, *supra* note 145, at Z7. Five years before the FDA withdrew its approval for Parlodel, the agency merely encouraged the manufacturer to withdraw the drug; however, after Public Citizen filed a lawsuit against the FDA, the agency filed a notice in the *Federal Register* formally withdrawing approval for Parlodel. One day later, the manufacturer of Parlodel determined it would remove lactation suppression from the drug's labeling. See *id.*

176. See *RESTATEMENT (THIRD)*, *supra* note 6, § 2(b) cmt. e.

177. See *id.* § 2(b).

178. See *id.* § 6(c).

179. See *id.* § 6 cmt. b ("2(b) . . . does not apply to prescription drugs and medical devices."); see also *id.* § 6 reporters' note, cmt. f ("The rule set forth in section 6(c) would provide the exclusive basis for a cause of action based on objective drug design.").

180. See *supra* notes 58-61 and accompanying text (discussing the example of the toy gun in relation to comment e). The Reporters created the comment e exception for certain products with a specific design purpose. The toy gun example illustrates how the Reporters have not included comment e to cover malfunctioning products. Rather, comment e includes only properly functioning products since an alternative design would create the same social harm as the original product. See *RESTATEMENT (THIRD)*, *supra* note 6, § 2 cmt. e.

alternative design is unnecessary because the product's intended purpose possesses such low social utility that no alternative design would be reasonable.¹⁸¹

Under section 6(c), however, inefficacy is the basis of liability.¹⁸² If the medical product is effective for any group, the drug is not defectively designed.¹⁸³ For example, in *Tobin*, evidence indicated that the drug failed to provide benefit to any class of persons.¹⁸⁴ In other words, the drug was defectively designed only because it completely failed.

The concepts behind comment e and section 6(c), therefore, differ in the *Restatement (Third)* in their respective characterizations. That is, under section 2(b), the comment e risk-benefit exception is invoked if the product's *purpose* lacks social utility.¹⁸⁵ In contrast, section 6(c) focuses on whether the product's *result* lacks utility.¹⁸⁶ In sum, comment e applies to products having a base purpose whereas section 6(c) applies to products producing a base result.

B. Should Comment e Apply to Section 6(c)?

Although the Reporters may not have designed comment e to apply to section 6(c), their intentions do not preclude the possibility that comment e *should* apply to section 6(c). *Restatements* are not formal pronouncements of law, and thus a court is not required to adhere strictly to their provisions.¹⁸⁷

The Reporters erected a roadblock, however, to keep section 6(c) claimants from accessing comment e. Under comment e, the trier of fact must first pass judgment on the social utility of the product's purpose.¹⁸⁸ Comment e, therefore, will never technically apply to a

181. See RESTATEMENT (THIRD), *supra* note 6, § 2, cmt. e.

182. See *id.* § 6(c).

183. See *id.*

184. See *Tobin v. Astra Pharm., Inc.*, 993 F.2d 528, 540 (6th Cir. 1993).

185. See RESTATEMENT (THIRD), *supra* note 6, § 2(b).

186. See *id.* § 6(c).

187. The Reporters acknowledge that the purpose of a Restatement is to provide clarity in the law and not to bind judges and legislatures to every provision in a Restatement. See James A. Henderson & Aaron D. Twerski, *Will a New Restatement Help Settle Troubled Waters: Reflections*, 42 AM. U. L. REV. 1257, 1262-63 (1993) (noting that "a restatement is . . . not primary authority," and that "[c]ourts are free to disagree with restatement positions and do so with considerable frequency").

188. The Reporters discuss the example of the toy gun in relation to comment e. See *supra* notes 58-61 and accompanying text. The Reporters note that the toy gun merits the comment e exception only if the court first determines that the gun's purpose is socially unacceptable:

[I]f the realism of the toy pellet gun, and thus its capacity to cause injury, is sufficiently important to those who purchase and use such products to justify the court's limiting consideration to toy guns that achieve realism by shooting hard pellets, then no reasonable alternative will, by hypothesis, be available.

RESTATEMENT (THIRD), *supra* note 6, § 2(b) cmt. e.

medical product claim. Common sense dictates that no manufacturer will produce a medical product with an “egregiously unacceptable” purpose, subsequently gaining FDA approval.¹⁸⁹

This roadblock to comment e should be lifted to allow consumers harmed by defective medical products access to its protections. Comment e’s purpose is to provide liability in the absence of a reasonable alternative design to ensure the elimination of products containing “a low social utility and a very high risk.”¹⁹⁰ Comment e, therefore, serves to protect society from truly dangerous products not covered by other sections of the *Restatement (Third)*.

By extension, one can argue that defectively designed medical products are so truly dangerous that claims neglected by section 6(c) should find protection in comment e. Notwithstanding a medical product’s benign purpose, its effect could nonetheless be “egregiously unacceptable” and have “low social utility and a very high risk.”¹⁹¹ Furthermore, there may be a subclass of people deriving small benefit from a drug, while the drug’s overall effect is damaging.¹⁹² Under section 6(c), a consumer has no recourse in defective design theory. In addition, a manufacturer would have no incentive to redesign the product to satisfy both the benefiting subgroup and also a larger class of users.

In addition, one may argue that the application of comment e to section 6(c) will be fatal to a subgroup of users for whom a certain product is the only treatment. This fear is unfounded. Comment e’s risk-benefit test will ensure that genuinely beneficial products remain on the market. The fact that a certain product is the exclusive treatment for a subgroup will weigh heavily in the risk-benefit analysis. A blanket standard of liability, lacking a risk-benefit provision, however, subjects the public to dangerous products with relatively little means of redress.

Finally, because women are greater consumers of inadequately tested and monitored medical products, they will be disproportionately harmed by products having “low social utility and

189. Although medical products may *cause* harm, they are never designed with the *purpose* of causing harm. For example, a drug is not designed and put on the market with the explicit purpose of causing birth defects or heart problems. The drug could, however, have such an effect despite its benign purpose. Medical products are, therefore, unlike the toy gun example, as the gun at issue was specifically designed to cause harm, “an egregiously unacceptable purpose” for a child’s toy.

190. See *RESTATEMENT (THIRD)*, *supra* note 6, § 2(b) cmt. e.

191. *Id.*

192. See *id.* § 6 cmt. b (noting that a drug will not be considered defective as long as it provides net benefits to some people under some circumstances). Such an analysis will be applied irrespective of whether the drug’s overall effect is damaging. See *id.*

very high risk." Thus, women need comment e to apply to section 6(c) in order to establish liability and drive harmful products from the market.

C. Case Law, Comment k, and a Cigar: Comment e and Section 6(c)

The *Ortho Pharmaceutical* and *Williams* decisions provide additional support for the application of comment e to section 6(c). These courts applied a risk-benefit analysis to determine defective design similar to that found in comment e.¹⁹³ The *Williams* and *Ortho Pharmaceutical* courts did not base their holdings solely on the existence of a subgroup deriving benefit from the drug. Rather, the courts ultimately decided the issue of design defect by assessing whether a drug's overall harm outweighed its benefit.¹⁹⁴

This rationale reflects the principle underlying comment e. Comment e provides an illustration depicting a person (Jack) injured by an exploding prank cigar.¹⁹⁵ Comment e suggests that "the utility of the exploding cigar is so low and risk of injury is so high as to warrant a conclusion that the cigar is defective and should not have been marketed at all."¹⁹⁶ The cigar may not be injurious to people who find that the benefits from the cigar's amusement outweigh the risks. The degree of harm suffered by those injured, however, may be higher than the benefit the cigar provides to that subclass of people. The *Ortho Pharmaceutical* and *Williams* courts recognized that the danger of a defectively designed medical product is comparable to that of an exploding cigar. That is, like the test employed in comment e, these courts determined that an overall risk-benefit analysis should be conducted to assess whether a drug is defectively

193. See *id.* § 2(b) cmt. e.

194. See *Ortho Pharm. v. Heath*, 722 P.2d 410, 413-14 (Colo. 1986) (ruling that a risk-benefit analysis should be employed in assessing whether Ortho-Novum was defectively designed and rejecting the use of the consumer expectation test); *Williams v. Ciba-Geigy Corp.*, 686 F. Supp. 573, 580-81 (W.D. La. 1988) (employing a risk-benefit analysis to determine whether Tegretol was defectively designed).

195. The illustration in comment e reads:

ABC Co. manufactures novelty items. One item, an exploding cigar, is made to explode with a loud bang and the emission of smoke. Robert purchased the exploding cigar and presented it to his boss, Jack. . . . Jack lit the cigar. When it exploded, the heat from the explosion lit Jack's beard on fire causing serious burns to his face. If a court were to recognize the rule identified in [comment e], the finder of fact might find ABC liable for the defective design of the exploding cigar even if no reasonable alternative design was available that would provide similar prank characteristics. The utility of the exploding cigar is so low and the risk of injury is so high as to warrant a conclusion that the cigar is defective and should not have been marketed at all.

RESTATEMENT (THIRD), *supra* note 6, § 2 cmt. e, illus. 5.

196. *Id.*

designed.¹⁹⁷

Furthermore, invoking the *Restatement (Second)*, courts historically have recognized the need for individual assessments of a medical product's risks and benefits to determine liability. A majority of courts have refused to grant blanket comment k immunity to medical products under the *Restatement (Second)*. Instead, these courts engage in a case-by-case determination before applying comment k.¹⁹⁸ Contrary to precedent, however, Section 6(c) of the *Restatement (Third)* is tantamount to the blanket immunity provision in comment k, as few claims will meet its difficult standard of liability.¹⁹⁹

By extension, courts need the freedom to render individual assessments before establishing liability under the *Restatement (Third)*. Comment e is the only place in the *Restatement (Third)* where a medical product can receive individual attention. Thus, comment e is necessary to protect consumers from products which may not meet the stringent standard of section 6(c), but nevertheless are responsible for causing harm, rendering the design "manifestly unreasonable."

CONCLUSION: THE WOMAN QUESTION REVISITED

This Comment asked the Woman Question of the *Restatement (Third) of Torts* and received an unsettling response. Women consume more medical products than men. This factor alone indicates that women will suffer disproportionate harm at the hands of section 6(c), all products being equal. All products are not equal, however, as medical products lack adequate testing and monitoring for women. The potential for harm to women is large, while the reality of successfully winning a design defect claim is small.

In light of this response to the aforeposed Question regarding medical product liability and women, this Comment proposes that the incorporation of comment e into section 6(c) is the best answer.

197. See *supra* notes 106-11, 115-18 (discussing the *Ortho Pharmaceutical* and *Williams* courts' determinations that a risk-benefit test is the appropriate form of analysis to be employed in assessing whether a drug is defectively designed).

198. See *supra* note 36 (discussing the fact that most courts subject each medical product to an individualized assessment before applying comment k). In an article defending the section 6(c) standard, Professor Henderson admits that the current judicial trend is against blanket comment k immunity. See Henderson, *Reporter's Perspective*, *supra* note 7, at 475 (observing that "the trend toward judicial design review of some kind is unmistakable").

199. See *supra* note 72 and accompanying text (discussing the Reporters' recognition that under the 6(c) standard, very few design claims against a prescription product's manufacturer will be successful). See also Schwartz, *supra* note 7, at 1385 ("[Section 6(c)'s] heightened negligence standard makes it virtually impossible to pursue a successful claim. The drafters said that they did not want to eliminate design claims, but it seems that they have, in effect, done so.").

Section 6(c) is a stringent standard imposing severe restrictions on a woman's ability to establish liability and ultimately to remove unsafe products from the market.

The Reporters consider the capacity for harm in a toy gun and a prank cigar as meriting exception in the *Restatement (Third)*, while subjecting a medical product with inadequate testing and monitoring for women to the most stringent standard of liability. This disparate level of protection is insulting and unfair to women and violates the spirit of comment e to keep manifestly unreasonably designed products from harming society. As comment e protects Jack when a prank cigar harms his face,²⁰⁰ so too should comment e protect Jane when a medical product harms her body.

When this Comment asked the Woman Question of the *Restatement (Third)*, it was ultimately asking whether the tort system "encourages behavior that is caring about others' safety and [is] responsive to others' needs or hurts, and that attends to human contexts and consequences."²⁰¹

Without the application of comment e to section 6(c) in the *Restatement (Third)*, the answer to the Woman Question is simply: No.

200. See *supra* notes 195-97 and accompanying text (presenting an illustration of the comment e standard).

201. Bender, *supra* note 1, at 31-32.