Section 8(c) of the Proposed Restatement (Third) of Torts: Is It Really What the Doctor Ordered

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SECTION 8(c) OF THE PROPOSED RESTATEMENT (THIRD) OF TORTS: IS IT REALLY WHAT THE DOCTOR ORDERED?

Introduction ................................................................................................................................................. 645

I. The Development of Comment k Blanket Immunity...
   A. "Unavoidably" Unsafe Products ........................................................................................................ 648
   B. Comment k Exempts Prescription Drugs From Design-Defect Claims ........................................ 650
   C. Does Comment k Apply Only to Prescription Drugs? ....................................................................... 651

II. The Current Judicial Application of Comment k: A Mixed Bag .......................................................... 653
   A. "Pure" Comment k Jurisdictions ........................................................................................................ 653
   B. Tears in the Immunity Blanket ........................................................................................................... 655
   C. Potentially Dangerous Imbalances in Other Jurisdictions ................................................................ 659
      1. The "Exceptional Social Need" Approach ......................................................................................... 659
      2. Absolute Liability ............................................................................................................................ 662
      3. Striving for Balance ......................................................................................................................... 663

III. The ALI's Proposed Solution: Section 8(c) of the Proposed Restatement (Third) of Torts: Products Liability ........................................................................................................................................ 664
   A. Proposed Section 8(c): The "Reasonable Health Care Provider" Standard .................................... 664
   B. The Approach of Section 8(c): A Drug is Defectively Designed Only If It Has No Business Being on the Market in the First Place ...................................................................................... 670

IV. Problems with the Proposed "Reasonable Health Care Provider" Wording of Section 8(c) .............. 671
   A. The "Reasonable Physician" or "Reasonable Health Care Provider" Does Not Appear in the Case Law ........................................................................................................................................ 671
   B. Physicians Are Inappropriate Standard-bearers for the Reasonableness of Pharmaceutical Product Design .............................................................................................................................................. 673
   C. The "Reasonable FDA" Is Not a Satisfactory Standard ...................................................................... 678
      1. The FDA Is Not Equipped to Determine the Public Need for the Product in Question ................ 678
      2. The Outcome of the FDA's Approval Process is Largely Determined by the Manufacturer .......... 681
INTRODUCTION

One notable exception to the general rule that courts may hold manufacturers strictly liable for injuries caused by their defectively designed products is the law governing prescription drugs and devices. Makers of prescription drugs and devices produce their wares knowing that a certain percentage of them will injure, or even kill, consumers. Of course, drug manufacturers strive to keep this number as low as possible, because reputation and public perception carry great economic consequences. Nevertheless, every year scores of unwitting men, women, and children are injured or killed by the very drugs or devices to which they turned for relief from discomfort and disease.

One problem facing the American Law Institute ("ALI") when it created the Restatement (Second) of Torts\(^4\) was how to establish a universal rule of strict products liability, while at the same time encouraging the manufacturers of such "unavoidably unsafe products"\(^5\) to continue to supply vital, yet sometimes injurious, pharmaceuticals. As a solution, the ALI promulgated comment k, which urged that courts grant the makers of pharmaceutical products a blanket exemption from this new regime of strict liability.\(^6\)

Until recently, most courts adhered to the edict of comment k and uniformly refused to hold drug makers liable for drug-related in-

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1 See Restatement (Third) of Torts: Products Liability § 8 reporters' note, cmt. f (Tentative Draft No. 2, 1995) [hereinafter Restatement (Third)] ("Unlike most products, which confer essentially the same benefits to all users, prescription drugs and medical devices have the capacity to do great harm or great good depending on the patient.").
2 See Steven Garber, Rand Inst. for Civil Justice, Product Liability and the Economics of Pharmaceuticals and Medical Devices 36 (1993) (asserting that safety concerns regarding a pharmaceutical product may cause doctors to stop prescribing it, patients to avoid seeking treatment, or patients to fail to fill prescriptions). See also Herbert Burkholz, The FDA Follies 43-45 (1994) (reporting that the public revulsion prompted by photographs of European thalidomide victims resulted in increased government regulation of the pharmaceutical industry's practices and prices.).
3 See Burkholz, supra note 2, at 17 (noting that even normal dosages of aspirin can prove to be deadly in some children).
4 Restatement (Second) of Torts (1965) [hereinafter Restatement (Second)].
5 Id. § 402A cmt. k.
6 Id.
juries.\(^7\) Courts held this stance even when plaintiffs could prove the drug directly caused injury.\(^8\) So long as the maker: (1) manufactured the drug in compliance with its FDA-approved design, and (2) the maker adequately warned of all known dangers, side-effects, and contra-indications, the court could not lay the cost of the injury at the drug maker’s door.\(^9\) The rationale for the judicial system’s reticence to apply design liability for drug-induced injury boils down to a common-sense trade-off—many, if not most, drugs cannot be made completely safe.\(^10\) If courts hold drug companies liable for every injury their products cause, they will be disinclined to market their product, and as a result society will suffer.\(^11\) According to Steven Garber of the

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\(^7\) Only design defect claims are granted immunity by comment k. The viability of claims that a prescription product was improperly manufactured or that the maker failed to warn of risks associated with it is well established. See Teresa Moran Schwartz, *Prescription Products and the Proposed Restatement (Third)*, 61 TENN. L. REV. 1357, 1369-70 (1994) (asserting that the prescription product manufacturing defect and failure to warn standards adopted by the *Restatement (Third)* are not controversial, but rather are “well-settled”).

\(^8\) See Grundberg v. Upjohn Co., 813 P.2d 89, 92 (Utah 1991) (“Until recently, most courts refrained from applying a design defect theory to products liability cases involving prescription drugs.”).

\(^9\) See, e.g., Johnson v. American Cynamid Co., 718 P.2d 1318 (Kan. 1986). In this case, the plaintiff contracted polio via his daughter’s inoculation with a Sabin-type live virus vaccine. The plaintiff claimed that because the non-infectious Salk-type killed virus vaccine existed, the maker of the live vaccine should be held strictly liable for defective design. Relying on comment k, the Kansas Supreme Court held that the live virus vaccine was a “useful and desirable product” and that “[p]ublic policy requires that the mere manufacture of the vaccine not be actionable on the ground of design defect.... As a matter of law there is no . . . design defect in the product at issue ....” Id. at 1323-24.

\(^10\) See *Restatement (Third)*, supra note 1, § 8 reporters’ note, cmt. f (“Unlike most products, which confer essentially the same benefits to all users, prescription drugs and medical devices have the capacity to do great harm or great good depending on the patient.”).

\(^11\) See id. § 8 cmt. b (asserting that protection of prescription drug designs from strict liability claims “reflects concerns over the possible negative effects of judicially imposed liability on the cost and availability of valuable medical technology”). Courts and commentators treat as axiomatic the notion that strict liability for drug design will have a negative effect on the price and availability of prescription products. See Grundberg, 813 P.2d at 94 (“Drug manufacturers might stop producing valuable drugs because of lost profits resulting from lawsuits . . .”); 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, 96 (1994) (noting that a driving force behind section 8(c) of the *Restatement (Third)* is the notion that “[a]pplying design liability to drugs, thereby raising the costs of drugs and discouraging their development, would . . . fail to serve society’s interests”); Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 289 (1985) (asserting that “the tort system’s vagaries will ultimately drive mass immunization programs out of the private sector altogether”); Harvey L. Kaplan et al., *Third Restatement: New Prescription for Makers of Drugs and Medical Devices*, 61 DEF. COUNS. J. 64, 74 (1994) (arguing that prohibiting of design defect claims will ensure that “drugs and medical devices would remain available and affordable because manufacturers would have some assurance that the designs of their FDA-approved products would not later be deemed defective by lay jurors”); Emily C. Aschinger, *Note, The Selling of the Perfect Breast: Silicone, Surgeons, and Strict Liability*, 61 UMKC L. REV. 999, 406 (1992) (“If manufacturers . . . were to be held strictly liable for [drug design] defects, the advances made in
Rand Institute for Civil Justice, "Reports from independent panels conclude that product liability has substantially discouraged innovation efforts in vaccines, contraceptives, and orphan drugs. There have also been claims that product liability concerns hinder development efforts in biotechnology, especially for vaccines in general and an AIDS vaccine in particular." However, despite warnings of the potentially dire consequences of applying product liability to drug design, judicial restraint is weakening. Most jurisdictions have begun to allow juries, in certain circumstances, to consider holding drug makers liable for injuries caused by their products, based on injured plaintiffs' allegations that the maker's defective design of the pharmaceutical product caused their injury. As a result, the vitality of comment k has come under serious question.

In its proposed Restatement (Third) of Torts: Products Liability, the ALI attempts to breathe new life into the all-but-moribund comment k. Section 8(c) of the proposed Restatement (Third) adopts a "reasonable health care provider" standard. This section directs courts to eschew entertaining drug design defect claims, so long as the defense can prove the existence of one group of patients for whom the drug (or prescription device) in question is the product of choice. How-

modern medicine would come to a halt."); 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 for Prescription Drugs?, 45 SYRACUSE L. REV. 1291, 1305 (1995) ("Strict liability would stifle society's desire to encourage manufacturers in the research, development and manufacture of ethical drugs."). However, some commentators have expressed skepticism of this position. See, e.g., Joseph A. Page, Generic Product Risks: The Case Against Comment k and for Strict Tort Liability, 58 N.Y.U. L. REV. 853 (1983) (arguing that strict liability for drug design defects would actually result in more efficient allocation of producers' funds in the form of preventive safety research).

12 Garber, supra note 2, at 144 (citations omitted).
13 See Brown v. Superior Court, 751 P.2d 470, 479-80 (Cal. 1988) (listing "examples of [therapeutic] products which have greatly increased in price or have been withdrawn or withheld from the market because of the fear that their producers would be held liable for large judgments"). See also Ava J. Abramowitz, Blueprint for Trouble, BRIEF, Fall 1986, at 16 (asserting that because of the costs associated with strict liability claims "[v]accines are not being sold").
14 See RESTATEMENT (THIRD), supra note 1, § 8 reporter's note, cmt. f.
15 RESTATEMENT (SECOND), supra note 4, § 402A cmt. k.
16 RESTATEMENT (THIRD), supra note 1, § 8(c) reads:

A prescription drug or medical device is not reasonably safe due to defective design when the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits so that no reasonable health care provider, knowing of such foreseeable risks and therapeutic benefits, would prescribe the drug or medical device for any class of patients.

(emphasis added). See also id. § 8 cmt. b ("[A] prescription drug or medical device that provides net benefits to any class of patients is not defective in design even if it is harmful to other patients."). It has come to the author's attention that § 8 of the proposed Restatement Third is scheduled to be renumbered as § 6. Since no significant changes are, to the
ever, given both the fervor with which some jurisdictions have rejected
comment k, \textsuperscript{17} and the contrasting stubbornness shown by at least one
jurisdiction in clinging to comment k blanket immunity for pharma-
ceutical products, \textsuperscript{18} it is unclear whether the courts will embrace the
standard proposed in section 8(c). Failure of the jurisdictions to fol-
low a single standard in adjudicating pharmaceutical design defect
cases could have serious repercussions on the development and sale of
medicines and medical devices in this country. \textsuperscript{19}

Part I of this Note analyzes the tensions and concerns that led to
the inclusion of comment k blanket immunity for pharmaceutical
products in section 402A of the \textit{Restatement (Second)}. Part II outlines
the various approaches to drug design defect claims taken by modern
courts. Part III examines the ALI's proposed solution to the confu-
sion that has developed in this area: section 8(c). Part IV argues that
although the underlying policy of proposed section 8(c) presents a
desirable compromise and has support from a limited number of
cases, its use of the words "reasonable health care provider" endan-
gers its adoption. Instead, this Note suggests that in section 8(c) the
ALI should adopt a "reasonable pharmaceutical products manufac-
turer" standard. This alternative finds support in the case law and
avoids the potentially fatal problems posed by the "reasonable health
care provider" standard.

I

THE DEVELOPMENT OF COMMENT K BLANKET IMMUNITY

A. "Unavoidably Unsafe" Products

In 1965, the ALI published its \textit{Restatement (Second) of Torts}. \textsuperscript{20} In
section 402A of the \textit{Restatement (Second)}, the ALI undertook to define
and standardize strict products liability. To assert that section 402A
has been influential is an understatement. Two commentators write
that section 402A has "rise[n] to the dignity of holy writ" in many
jurisdictions. \textsuperscript{21} According to section 402A, "special liability" arises on
the part of a "seller" of "any product in a defective condition unreas-
onably dangerous to the user or consumer" for "physical harm

\textsuperscript{17} See \textit{infra} Parts II.B-C.
\textsuperscript{18} See \textit{infra} Part II.A.
\textsuperscript{19} See \textit{supra} note 11 and accompanying text.
\textsuperscript{20} \textit{RESTATEMENT (SECOND)}, supra note 4.
\textsuperscript{21} James A. Henderson, Jr. & Aaron D. Twerski, \textit{A Proposed Revision of Section 402A of the Restatement (Second) of Torts}, 77 \textit{CORNELL L. REV.} 1512, 1512 (1992) (noting that
thousands of reported cases have cited to section 402A since its inception). A recent
search of Westlaw revealed that over 3,400 cases available on that service cite to sec-
tion 402A. Search of \textit{WESTLAW}, Allcases Database (Feb. 22, 1997).
thereby caused,” even when the “seller has exercised all possible care in the preparation and sale of his product.”22 Section 402A provided the courts with the ammunition they needed to enforce change. After the adoption of section 402A, in response to a manufacturer’s argument that it had taken all possible care in the quality control of its production, the courts could simply say, “You argue that your actions were reasonable. But the times have changed. Reasonableness is no longer a defense in this new world of strict products liability.”23 Courts reached this result despite the declaration of section 402A that they should hold only “unreasonably dangerous” products to strict liability standards.24 The tension between these two standards—“unreasonably dangerous” and “despite the exercise of all due care”—has resulted in a maelstrom of conflicting opinions, especially in the areas of strict products liability that arguably overlap with the negligence doctrine of tort law: failure-to-warn and negligent design.25 Because such claims were not common on the legal landscape at the time the ALI wrote the Restatement (Second)26 it does not provide guidance on how courts should approach them.27

Products liability proponents have offered a number of rationales to support the necessity of the doctrine.28 They generally assert that

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22 Restatement (Second), supra note 4, § 402A. The pertinent parts of section 402A read:

Special Liability of Seller of Product for Physical Harm to User or Consumer

(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.

24 Restatement (Second), supra note 4, § 402A(1).
26 Twerski, supra note 23, at 9-11.
27 Barrett, supra note 11, at 1302 (asserting that the “question of distinguishing between a manufacturing defect and a design defect” was not adequately addressed until 1978).
28 Comment c of the Restatement (Second), supra note 4, § 402A puts forth several rationales for the doctrine:

On whatever theory, the justification for the strict liability has been said to be that the seller, by marketing his product for use and consumption, has
(1) the threat of liability will motivate the production of better, safer products; (2) the manufacturer/seller is in a better position than the injured consumer to insure against the injury; and (3) the seller can spread the costs of insurance and reparations for injuries across the population in the form of increased prices. Although these policy considerations are widely accepted as the foundations of products liability, they are not without their critics. Furthermore, these basic policy considerations do not easily address the problem of unavoidably dangerous products—products that, when used as designed, will injure or kill a known percentage of consumers.

B. Comment k Exempts Prescription Drugs From Design-Defect Claims

Pharmaceutical drugs and devices comprise one category of products that challenges the underlying policies of strict products liability. ALI members working on the Restatement (Second) worried that holding the makers of pharmaceutical products liable for injuries undertaken and assumed a special responsibility toward any member of the consuming public who may be injured by it; that the public has the right to and does expect, in the case of products which it needs and for which it is forced to rely upon the seller, that reputable sellers will stand behind their goods; that public policy demands that the burden of accidental injuries caused by products intended for consumption be placed upon those who market them, and be treated as a cost of production against which liability insurance can be obtained; and that the consumer of such products is entitled to the maximum of protection at the hands of someone, and the proper persons to afford it are those who market the products.

One commentator characterizes comment c as "somewhat vague," but offers the following rationales:

(1) the product seller, by its position in the marketing chain, has a special responsibility for product safety;
(2) consumers expect safe products;
(3) helpless consumers are forced to rely on manufacturers for product safety;
(4) product sellers are in a better position to spread the risk of loss; and
(5) product sellers can better afford to bear the loss of product injuries.


See id. at 644.
See id. at 643 (insisting that courts have failed to justify why products cases are treated differently from negligence cases). See also Malcom Wheeler, The Need for Narrow Tort Reform: Abolishing Strict Product Liability, in CTR. FOR THE STUDY OF AM. BUS., FORMAL PUB. NO. 98, PRODUCT LIABILITY REFORM: DEBATING THE ISSUES 23, 24 (Kenneth Chilton ed., 1990) (arguing for a "nationwide abolition of strict product liability claims in design-defect and inadequate-warning litigation").

See Barrett, supra note 11, at 1308-05. Barrett argues that the reporters of the Restatement (Second) struggled with the need to "show with specificity what [section 402A] did not cover. The reporters believed that products exist which are unable to be made safe in their ordinary use . . . . Such products were especially common in the field of prescription drugs. Although unsafe, some drugs were still desirable. Enter comment k." Id. at 1304.
avoidably caused by these products would severely hamper the development and sale of essential drugs. They argued for exempting "unavoidably unsafe" products, such as prescription drugs, from strict liability. The resulting compromise was comment k, subtitled "Unavoidably Unsafe Products." The relevant portions of section 402A comment k read as follows:

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified . . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous . . . . The seller of such products . . . is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Using the Pasteur rabies vaccine, a prescription drug, as its comment k example, the ALI cautioned the courts to remember the needs of people who rely on prescription drugs to alleviate pain, for relieving the crippling effects of disease, or to stave off death, no matter how briefly. In short, comment k urges the courts to remember that not only is society prepared to risk injury or death in exchange for the clear benefits of pharmaceutical products, but that reasonable patients are also clearly willing to take such risks in exchange for possibly ameliorating their afflictions. The ALI, it seems, considered the consequences of holding pharmaceutical makers liable for injuries flowing naturally and foreseeably from their products, imagined a world where drugs and other critical yet potentially harmful products were unavailable to the public, found such an eventuality unacceptable, and granted "unavoidably unsafe" products immunity as a class.

C. Does Comment k Apply Only to Prescription Drugs?

The case law has not entirely settled the question of whether medical products other than drugs and vaccines should benefit from

35 Restatement (Second), supra note 4, § 402A cmt. k.
37 See Brown, 751 P.2d at 475.
38 See id.
39 Restatement (Second), supra note 4, § 402A cmt. k.
comment k's special treatment. However, the drug companies have strongly advocated that the courts bring their devices under comment k's protective blanket. Courts that have elected to extend comment k protection to devices such as pacemakers, breast implants, penile implants, and even to an "antibacterial surgical drape," have reasoned that (1) such products can be obtained only by prescription; and (2) like prescription drugs, prescription products' main functions are to improve the patient's condition, to alleviate his or her pain and suffering, or to postpone his or her death. Those courts that have struggled with whether to grant comment k protection to medically necessary devices while withholding it from arguably cosmetic implants have avoided segregating cosmetic devices from non-cosmetic ones, and instead have extended protection to all of these devices. According to Richard L. Cupp, these jurisdictions "generally agree that the reasoning behind immunizing prescription drugs applies equally well to most medical devices." Moreover, proposed section 8(c) of the Restatement (Third) specifically refers to "prescription drug[s] and medical device[s]" as forming a "special product market." Thus, this Note considers medical devices indistinguishable from prescription drugs, despite the "optional," or "cosmetic" quality of certain "non-therapeutic" medical devices. This inclusion of medical devices has been attacked by critics who at the least would prefer to see "cosmetic" prescription products exempt from comment k protection or at most would prefer to see all drugs treated the same way as any other product.

40 See Cupp, supra note 11, at 80-82
41 See id. at 83-84.
46 See Cupp, supra note 11, at 83-84.
48 See Cupp, supra note 11, at 84 n.48.
49 Id. at 84. For an overview of case law on the issue of treating prescription devices the same as other prescription products, see Jennifer S.R. Lynn, Implantable Medical Devices: A Survey of Products Liability Case Law, 38 MED. TRU. TECH. Q. 44 (1992).
50 RESTATEMENT (THIRD), supra note 1, § 8(c). See also id. reporters' note cmt. d. ("Most of the cases that have addressed the issue have held that medical devices which require a medical provider's prescription are subject to the same rules that apply to prescription drugs.").
52 See generally Aschinger, supra note 11 (arguing that the aggressive way manufacturers market breast implants should disqualify them from design defect immunity).
53 See Cupp, supra note 11, at 110.
II

THE CURRENT JUDICIAL APPLICATION OF COMMENT k: A MIXED BAG.

A. “Pure” Comment k Jurisdictions

Some jurisdictions interpret comment k to mean what it says: that there shall be no liability for the design of “unavoidably unsafe” products such as prescription drugs and devices.54 The leading “pure” comment k jurisdiction is California, and the leading case on point in that jurisdiction is Brown v. Superior Court.55 In Brown, the plaintiffs were all daughters of women who had taken DES, a drug prescribed for the prevention of miscarriages.56 The plaintiffs claimed that they had been injured in utero by DES, and that the drug’s design was responsible for their injuries.57 The court refused to allow the plaintiffs to pursue their design defect claim, reasoning that “a drug manufacturer’s liability for a defectively designed drug should not be measured by the standards of strict liability... because of the public interest in the development, availability, and reasonable price of drugs.”58 Thus, even if the plaintiffs could prove that the defendant’s product caused their harm, the special nature of prescription drugs in society absolutely precludes any claim that a pharmaceutical product was defectively designed. Because no drug can be made completely safe, the court reasoned that holding manufacturers liable for injuries that inevitably arise from the use of their products would have devastating effects on the production, distribution, and price of pharmaceuticals.60

California, however, did not always follow the pure form of comment k. Indeed, the California Supreme Court’s decision in Brown was a direct reaction to the California Court of Appeals’ ruling in Kearl v. Lederle Laboratories.61 In that case, the plaintiffs alleged the defendant’s vaccine caused their injuries. Kearl held that, despite the special treatment seemingly prescribed for drugs by comment k, defective drug design claims are mixed questions of law and fact that should be decided on a case-by-case basis on “evidence... taken by

54 See, e.g., Grundberg v. Upjohn Co., 813 P.2d 89, 95 (Utah 1991) (“We agree with the principles that comment k embodies, that manufacturers of unavoidably dangerous products should not be liable for a claim of design defect. We are persuaded that all prescription drugs should be classified as unavoidably dangerous in design...”).
55 751 P.2d 470 (Cal. 1988).
56 Id. at 472.
57 See id.
58 Id. at 477.
59 See id. at 478-79.
60 See id. at 479-80.
the trial judge out of the presence of the jury." The judge should then determine:

(1) whether, when distributed, the product was intended to confer an exceptionally important benefit that made its availability highly desirable; (2) whether the then-existing risk posed by the product was both "substantial" and "unavoidable"; and (3) whether the interest in availability . . . outweighs the interest in promoting enhanced accountability through strict liability design defect review." Therefore, to evaluate the evidence, the Kearl court followed the risk/benefit test applied in the non-pharmaceutical case of Barker v. Lull Engineering Co. According to the Kearl court, comment k should only apply if the benefit of the drug outweighed the risk associated with it. Comment k would thus exempt a beneficial drug from liability for the injury it caused. Otherwise, the maker should be held liable under a defective design test.

The Brown court, however, saw a great danger in this approach. It asserted that drugs are a special product, produced to alleviate pain, reduce suffering, and sustain life. By contrast, other products are meant to improve the quality of life, with consumer satisfaction and the enhancement of convenience as their major goals. A slow-down in the development of faster in-line skates or more powerful chain saws resulting from producers' concerns with liability is one thing; decreased research and production of pharmaceuticals due to products liability concerns is quite another. The Brown court perceived that judicial meddling in the drug design process would mean that while today's unavoidable victims of medicine were being compensated, vast groups of patients would ultimately be deprived of potentially lifesaving medications and devices that have yet to be developed. Unwilling to interfere with the decisionmaking process behind the production of new drugs and medical devices, the Brown court invoked comment k. In doing so, the California Supreme Court made clear its choice to stay out of the business of conducting "mini-trials" to adjudicate the reasonableness of pharmaceutical design. So long as the drug was properly manufactured and accompanied by an adequate warning of the risks known to the manufacturer at the time of

62 See Brown, 751 P.2d at 481 (citing Kearl v. Lederle Labs., 172 Cal. App. 3d. at 829-30 (Ct. App. 1985)).
63 Id.
64 573 P.2d 443 (Cal. 1978).
65 See Kearl, 172 Cal. App 3d. at 829-30.
66 Brown, 751 P.2d at 478.
67 See id.
68 See id.
69 Id. at 479-80.
70 Id. at 481.
sale, it was not, by definition, defectively designed. This is still the law in California, as well as in Utah.

B. Tears in the Immunity Blanket

Although California has traditionally led the development of strict products liability doctrine, "the vast majority of jurisdictions" that have considered the question of product liability for pharmaceutical products have explicitly refused to follow California's approach of blanket immunity from design defect claims for prescription drugs and devices. Even though Brown explicitly overruled Kearl in California, most other jurisdictions still apply Kearl as good law. One of the leading decisions advocating the Kearl case-by-case approach to prescription drug design-defect claims is Toner v. Lederle Laboratories. In that case, the plaintiff was allegedly paralyzed by the defendant's vaccine. The plaintiff argued that the defendant could have and should have developed a safer vaccine. He claimed negligence, strict liability, and breach of warranty. The jury found the maker liable for negligence, but not liable under strict products liability or breach of warranty. The U.S. Court of Appeals for the Ninth Circuit turned to the Idaho Supreme Court for guidance on the controversy via certified question. The Idaho Supreme Court responded that a defendant could, indeed, be held negligent in its designing of a pharmaceutical product. Furthermore, the Idaho Supreme Court held that comment k analysis was generally the same as a typical negligence analysis. In doing so, the Idaho Supreme Court linked strict drug-

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71 See id. at 480-81.
72 See Grundberg v. Upjohn Co., 813 P.2d 89 (Utah 1991). In this decision, the Utah Supreme Court explicitly followed the reasoning of Brown, stating: "We agree with Brown that the case-by-case method . . . articulated in Kearl is unworkable . . . . We find the Brown result more in line with the public policy considerations in the important area of pharmaceutical product design." Id. at 95.
73 See Brown, 751 P.2d at 473-74.
74 Barrett, supra note 11, at 1314.
75 Brown, 751 P.2d at 477.
76 See, e.g., Violette v. Smith & Nephew Dyonics, Inc., 62 F.3d 8, 13 (1st Cir. 1995). See also Tansy v. Dacomed Corp., 890 P.2d 881 (Okla. 1994). The Oklahoma Supreme Court listed a total of 13 states that followed the "risk-benefit" approach to comment k: Arizona, Colorado, Idaho, Illinois, Kansas, Michigan, Minnesota, Missouri, New Jersey, New Mexico, Oklahoma, Texas, and Utah. Id. at 886 & n.2.
77 828 F.2d 510 (9th Cir. 1987).
78 Id. at 511.
79 See id.
80 See id.
81 See id.
82 See id.
83 See id.
84 See id. at 512 ("[T]he determination under comment k that the design of a product is unavoidably unsafe and yet affords benefits outweighing its risks varies little from the
design claims to a negligence-based, case-by-case, risk-benefit standard. Consequently, in Idaho, the finder of fact in drug design cases will be asked to determine whether the benefits of the drug in question outweighed the risks associated with it.85 If not, then the court can deem the manufacturer negligent in its design of the drug, and the defendant will be unable to invoke the blanket protection of comment k.

The following year, the Rhode Island Supreme Court applied the risk-benefit test to a drug design-defect claim in Castrignano v. E.R. Squibb & Sons.86 As in Brown, the claim was brought by daughters of women who had ingested DES during pregnancy.87 Castrignano, unlike Brown, held that the apparent benefits of the drug must exceed its apparent risks if the maker is to invoke comment k protection from liability for the injury it caused.88 Under the Castrignano rule, if the risks of the drug outweigh the benefits it confers, then the claim of defective design may stand.89

The instability evident in court decisions and the confusion among jurisdictions is caused by a central tension.90 On the one hand, courts proffer a protective blanket to drug makers to induce them to bear the risks involved in developing and marketing new drugs. On the other hand, courts also wield the whip of liability for makers' failure to follow new developments and discoveries. That courts often give some deference to the FDA drug approval process91 only adds to this tension. Moreover, allowing juries to decide, on a case-by-case basis, whether or not a given drug's risks outweighed its benefits is likely to lead to inconsistent results92 and to plunge drug
NOTE—RESTATEMENT (THIRD) OF TORTS 657

and medical device manufacturers into a world of uncertainty.\textsuperscript{93} Drug manufacturers need to know the standard by which their acts will be judged. Manufacturers need to know if it is unreasonable to market any medication that results in any fatality or injury, even if that same drug is a lifesaver for certain patients.\textsuperscript{94} One could easily imagine that a jury, faced with the tragic facts of the case before it, could be convinced that the act of marketing an injury-causing drug was inherently unreasonable, simply because the drug did indeed cause the injury its maker knew would occur in a certain percentage of the people who took it. Allowing this standard to control the medical industry would jeopardize the marketing and the development of useful drugs and medical devices.\textsuperscript{95} The ALI recognized this problem in 1965 and attempted to protect the supply of vital medical goods by including comment k in section 402(A) of the \textit{Restatement (Second)}.\textsuperscript{96}

There are three reasons why the majority of state courts have moved away from the blanket protection provided by comment k.\textsuperscript{97} First, comment k is something less than a paradigm of clarity. Comment k has proved difficult to interpret and apply.\textsuperscript{98} Comment k has been called "a model of confusion"\textsuperscript{99} and is said to have "befuddled courts and scholars alike."\textsuperscript{100} Professor Aaron Twerski reports that he regularly offers an "A" to any student in his course who can explain comment k to him, but, so far, no one has received an "A" from Professor Twerski in this way.\textsuperscript{101}

\textsuperscript{93} See \textit{id.}; see also Kaplan, \textit{supra} note 11, at 71 (arguing that if juries are allowed to subject drugs and prescription devices to risk-benefit analysis drug manufacturers "would have no way of forecasting when or how often a jury would impose design defect liability," and that "[i]t[his] unpredictability would discourage the development of new and potentially efficacious drugs and medical devices").

\textsuperscript{94} See \textit{Restatement (Third), supra} note 1, § 8 cmt. b ("What may be harmful to one patient may provide net benefits to another.").

\textsuperscript{95} See \textit{supra} notes 11-13 and accompanying text.

\textsuperscript{96} \textit{Restatement (Second), supra} note 4.

\textsuperscript{97} See Teresa Moran Schwartz, \textit{The Impact of the New Products Liability Restatement on Prescription Products}, 50 \textit{Food \& Drug L.J.} 399, 407 (1995) ("A majority of courts . . . [have] ruled that the determination of whether strict liability should apply to a prescription product should be made on a case-by-case basis."). See also Barrett, \textit{supra} note 11, at 1306 (asserting that the case-by-case risk-benefit analysis of prescription product design is followed "by the majority of courts that have considered the issue").

\textsuperscript{98} See Grundberg v. Upjohn Co., 813 P.2d 89, 92 (Utah 1991) ("C[omment k is unclear on the scope of its protection.").

\textsuperscript{99} Cupp, \textit{supra} note 11, at 79.

\textsuperscript{100} James A. Henderson, Jr. & Aaron Twerski, \textit{Will a New Restatement Help Settle Troubled Waters: Reflections}, 42 Am. U. L. Rev. 1257, 1262 (1993). See also Schwartz, \textit{supra} note 7, at 1306 ("[N]early thirty years after the adoption of section 402A [comment k], significant points of dispute and uncertainty remain in this area of the law."). Moreover, Cupp reports that "Writers have labeled . . . comment [k] 'an enigma,' 'unclear in many respects,' 'poorly drafted and internally inconsistent,' 'a masterpiece of confusion and double-speak,' and 'a monumental failure.'" Cupp, \textit{supra} note 11, at 81-82 (footnotes omitted).

\textsuperscript{101} Twerski, \textit{supra} note 28, at 15-16.
A second reason why courts are likely to resist blanket immunity for drug design defect claims is that immunity limits their discretionary powers. Courts naturally perceive their systemic role to be adjudicators of conflicts between individuals, and blanket immunity greatly reduces that role. 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.

The third, and perhaps most important, reason for the erosion of comment k immunity for manufacturers of medical products is that this immunity can lead to patently unjust results. The Brown court acknowledged this very problem, pointing out that to be consistent, comment k would have to "grant the same protection from liability to those who gave us thalidomide as to the producers of penicillin." Blanket immunity for medical product design can protect products that should, by all accounts, not be on the market. This sense of potential injustice, combined with a reticence to abandon its social role as adjudicator of tort claims, has likely led courts away from Brown blanket immunity and toward the risk/utility approach of Kearl and Toner. When faced with a defective product design claim, many courts have directed the finder of fact to engage in a case-by-case analysis of the overall product utility. This analysis includes consideration of "any alternative product that would have as effectively accomplished the full intended purpose of the ... product" at hand. Courts have done this despite the California Supreme Court's strong warning in Brown that prescription products are different from other products, and thus should be treated differently.

102 Cf. Marbury v. Madison, 5 U.S. (1 Cranch) 137, 170 (1803) ("The province of the court is, solely, to decide on the rights of individuals.").
103 See Schwartz, supra note 7, at 1389-60 ("Courts are ... concerned that liability rules be sufficiently stringent to deter ... [prescription product related] tragedies."). See also Barrett, supra note 11, at 1925 (arguing that most jurisdictions have rejected blanket immunity for drug design defect claims because the "'blanket immunity' test is overreaching in its efforts to protect the manufacturer [and] contradicts the entire reasoning behind strict liability which was designed to protect the consumer.").
105 See id.
106 See Schwartz, supra note 7, at 1403 ("It is clear that the tort system forced the Dalkon Shield to be withdrawn from the market, and it is also clear to most observers that the tort system served the public interest in doing so.").
107 See infra notes 164-66 and accompanying text.
C. Potentially Dangerous Imbalances in Other Jurisdictions

1. The "Exceptional Social Need" Approach

The **Kearl** decision, which most courts still follow in defective drug design claim cases,\(^{110}\) revolves around an analysis of the concept of "benefit." **Kearl** is in accord with the influential decision rendered in **Barker v. Lull Engineering Co.**,\(^{111}\) a non-medical products case. However, given the basic differences between the nature and use of medical products and other products, it is unwise to follow the lead of non-medical product cases to establish liability rules.\(^{112}\) A drug's benefit cannot be expressed simply in numerical terms, in the number of lives saved, the number of white blood cells increased, or the number of weeks remission is prolonged. Nor is "benefit" a social or moral term, to be determined by applying local community standards.\(^{113}\)

Great uncertainty permeates how to define the "benefit" and "risk" of medical products, and thus the reasonableness of marketing the challenged medical product. Under this approach, judges are able to impose a moral litmus test upon the product itself. If the judge deems the product "essential" to society,\(^{114}\) it receives blanket immunity; otherwise, it is relegated to the pile of "ordinary" products, where its makers must fight a **Barker v. Lull** risk-utility battle. This "exceptional need" test is best illustrated by **Hill v. Searle Laboratories, Inc.**\(^{115}\) In that case, the plaintiff claimed that defendant's defectively-designed intrauterine device ("IUD") was the cause of her injury.\(^{116}\) The trial court granted the defendant comment k immunity from the design claim.\(^{117}\) On appeal, the Eighth Circuit Court of Appeals held that in order to qualify for comment k protection, the defendant must first demonstrate an "exceptional social need"\(^{118}\) for the product in question. Given the wide array of birth control methods

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\(^{110}\) See supra note 97 and accompanying text.

\(^{111}\) 573 P.2d 449 (Cal. 1978).

\(^{112}\) See Twerski, supra note 23, at 17 (arguing that "[i]t is clear that drug design cases are a different animal" from non-drug design cases).

\(^{113}\) Cf. Leslie A. Rubin, Note, Confronting a New Obstacle to Reproductive Choice: Encouraging the Development of RU-486 through Reform of Products Liability Law, 18 N.Y.U. Rev. L. & Soc. Change 151 (1990-91) (arguing that religious beliefs have been responsible for keeping abortion-inducing drugs such as RU-486 off the market in the United States and other countries, despite the fact that such drugs are safer than invasive abortion procedures).

\(^{114}\) See **Kearl v. Lederle Labs.**, 172 Cal. App. 3d 812, 830 (Ct. App. 1985) (holding that a judge considering whether to subject a pharmaceutical product to a design defect claim should be empowered to determine, outside the presence of the jury, "whether the interest in availability [of the product] ... outweighs the interest in promoting enhanced accountability through strict liability design defect review").

\(^{115}\) 573 P.2d 449 (Cal. 1978).

\(^{116}\) 884 F.2d 1064 (8th Cir. 1989).

\(^{117}\) See id. at 1065.

\(^{118}\) See id. at 1066.

\(^{119}\) Id. at 1069.
available in our society, including prescription birth control devices, non-prescription birth control devices, as well as "abstention, coitus interruptus, and the rhythm system," the court held that there was no obviously exceptional need for the product, therefore it did not merit comment k protection.

The danger of the Hill "exceptional social need" approach is that it forces drug manufacturers to guess whether there is a subjective "exceptional social need" for a given product before they embark upon the resource-consuming procedure of development, testing, and marketing a new drug. This approach represents an additional burden on drug manufacturers. Whereas once a drug manufacturer only had to identify an actual medical need for a given product, in jurisdictions following Hill, manufacturers must now determine whether a jury will deem the product socially necessary.

Improvements in drugs often proceed gradually. Manufacturers regularly obtain FDA approval for generic products nearly identical to those already available because of the low investment, relative to the possible returns, of doing so. However, under the "exceptional social need" test, Manufacturer A, which marketed its pain killer first, might receive comment k immunity while subsequent Manufacturer B must face a risk-utility test for a generic version simply because there was arguably no "exceptional social need" for it. Therefore, the first-in-time manufacturer would enjoy an unfair advantage over its rivals. Competitors would thus be challenged to either come up with a significantly cheaper product, or stay out of the market altogether.

Given that generic copies of once-patented drugs are widely accepted and encouraged by the FDA, and given that the availability of a wide range of therapeutic products is essential to successful treatment of most maladies, the Hill court likely did not intend to create a "first in time" standard. However, if the Hill court did not intend

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120 Id. at 1070 n.9.
121 Id. at 1070-71.
123 See Hill, 884 F.2d at 1069.
124 See Burkholz, supra note 2, at 12 (noting that since 1984 the FDA has allowed producers of generic versions of currently available drugs to gain approval "without requiring the sponsors to duplicate the costly human tests that were required for the originals").
125 The production of bioequivalent drugs is an important source of revenue for most manufacturers. See id. at 28 (reporting that the production of generic drugs can result in profits ranging in the millions of dollars).
126 See Jeffrey Yorke, FDA Ensures Equivalence of Generic Drugs, FDA CONSUMER, Jan. 1995, at 53-54 (discussing the priority placed by Congress, the FDA, and the medical insurance industry on making generic drugs available to the public as soon as possible after patented drugs have lost their market exclusivity).
this test, then it could have intended a more insidious one: a judicial examination of the use for the product, contrasted against the community’s, or the judge’s, moral or religious beliefs of its “value.” Thus, pain killers might qualify for comment k protection, because it is generally agreed that the alleviation of pain is a good, socially desirable thing. However, birth control drugs might not meet the “exceptional social need” test, because the alternative methods of abstention and coitus interruptus exist. Moreover, even pain killers might not be safe from judicial scrutiny, if the judge or jury believes that other, more socially desirable alternatives such as acupuncture or prayer exist. Likewise, surgical implants would likely receive protection, while breast implants might not. But what about breast implants after mastectomy? Should the judge or jury decide whether they are socially valuable or not? Despite current medical trends, this approach might encourage more surgical intervention and fewer less invasive treatments. Moreover, and perhaps most insidious, a product that is invaluable to a certain group of patients, yet is mis-prescribed by doctors and abused by certain segments of society,

[A] widened array of choice is important in the treatment of patients even if the new drugs are no more effective than those already available. Professor Wardell has pointed out that “Failure to show a difference in efficacy between a new drug and an older one should not be taken to mean that the new drug cannot be a worthwhile advance.... First, each drug’s efficacy may be exerted on a different segment of the population; if both drugs were available, the proportion of patients treatable might be much higher than if either drug were available alone. By the same argument, a drug that is ‘on average’ less effective and more toxic than existing therapy may still be highly desirable for some segments of the population.... Second, it is common to find that the spectrum of side effects differs for each drug, or that the pharmacokinetics are different enough to confer different dosage regimens upon each drug. Third, in the actual treatment of many types of conditions, a patient should receive several drugs in turn on a trial-and-error basis until the one that is best for his needs is determined empirically.... All these factors can be crucial for tailoring therapy to an individual patient to achieve maximal efficacy, safety, comfort, convenience, and compliance with the therapeutic regimen. To achieve these goals it is desirable to have a number of alternative therapies from which to choose.”

128 Hill, 884 F.2d at 1070 n.9.
129 See Guido Calabresi & Jeffrey O. Cooper, New Directions in Tort Law, 30 Va. U. L. Rev. 859, 865 (1996). According to Judge Calabresi and Professor Cooper, the risk-utility approach “asks... an agent of the state... to say what actions or products are worth it, and which are not. It bases liability on the answer given to that question. That strikes us as a mistake.” Id. (footnote omitted).
130 Cf. Daniel F. Ryan, III & Timothy R. Lawn, Strict Liability Claims Against Health Care Providers in Breast Implant Litigation, 29 Tort & Ins. L.J. 818 (1994) (arguing that cosmetic nature of breast implants ought to give rise to strict liability on the part of the doctor or hospital that sells them).
131 This is actually the essence of the holding of a recent case, Violette v. Smith & Nephew Dyonis, Inc., 62 F.3d 8 (1st Cir. 1995). In that case, the plaintiff was injured by the defendant’s endoscopic device, used in the treatment of his carpal tunnel syndrome. The court held that because a clearly safer surgical procedure existed, the device could be declared “in a defective condition unreasonably dangerous.” Id. at 12-13.
might lose comment k protection if injuries come to see the product in a negative light. In such a climate, drug companies might only produce drugs for mainstream illnesses, and avoid developing treatments for those conditions, patient groups, and needs that may offend certain moral sensibilities.

2. Absolute Liability

The worst-case scenario for a drug manufacturer is, of course, to be held absolutely liable for any and all injury that can be causally linked to its product. The Nevada Supreme Court has adopted this approach. For example, in Allison v. Merck & Co., the plaintiff, a small boy, was inoculated with the defendant's MMR (measles, mumps, and rubella) vaccine, as required by the local school board to enter public pre-school. He suffered a severe reaction to the vaccine and developed encephalitis, which left him blind and mentally retarded. His parents claimed that the vaccine was defectively designed. The Nevada Supreme Court rejected the defendant's argument that the boy's reaction was an "unavoidable danger" associated with all state-of-the-art MMR vaccines. The court instead held that proof the drug in fact caused the plaintiff's injury was sufficient to create liability on the part of the manufacturer.

The danger associated with this approach is that domestic manufacturers of drugs would likely reduce all marketing of drugs that have even remote possibilities of injury, unless the injury would be minor, and the profits from the drug large. Potentially injurious drugs, including the most common, would increase radically in cost. Essential but potentially fatal drugs (examples include the Pasteur treatment for rabies, many vaccines, flu shots, even aspirin) would pose a great monetary risk to manufacturers. Manufacturers would be forced to either raise their prices drastically, or pull potentially injuri-

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132 If this were the rule, the prescription drug quaalude, which during the 1970s and 80s was widely abused as a recreational drug, would be subject to design defect scrutiny despite the fact that it has therapeutic uses.

133 See Rubin, supra note 113, at 134 (attributing the unavailability of the abortion-inducing drug RU-486 in the United States to pressure brought upon the government by religious extremists).

134 878 P.2d 948 (Nev. 1994).

135 See id. at 954 n.9.

136 See id. at 951.

137 See id.

138 Id. at 954.

139 See id.

140 Even a drug as commonly used as aspirin can be deadly in some individuals. See Burkholtz, supra note 2, at 14-16.

141 See id.
3. Striving for Balance

One notable case that adroitly navigates the line between protecting public safety while providing incentives to manufacturers to develop and market new drugs, is that of *Tobin v. Astra Pharmaceutical Products, Inc.* In that case, the plaintiff claimed that the defendant's product, ritodrine, a drug prescribed to help prolong her pregnancy, worsened her pre-existing heart condition, ultimately forcing her to undergo a heart transplant. She claimed strict liability under failure-to-warn and defective design theories, and urged the court to find that the drug's risks—a potential worsening of patients' heart conditions, and perhaps even death—outweighed its benefits, namely, the increased likelihood of carrying a baby to full term. The court declined to adopt this proposed test, and instead applied a "prudent manufacturer" test. Under this approach, the court held that a drug was defectively designed only if "an ordinarily prudent manufacturer of such a drug, being fully aware of the risks associated with [it] would not have put the drug on the market." Given the scientifically questionable benefits of ritodrine, and given reports that "[r]itodrine is a very potent drug that has side effects that are extremely disturbing and may be lethal," the *Tobin* court ruled that "there was sufficient evidence before the jury to conclude that a prudent manufacturer knowing all the risks would not market ritodrine." By applying this test, the court ordered the manufacturer of this dangerous drug to compensate the injured plaintiff, without endangering the availability of the overwhelming majority of drugs that are potentially injurious, but arguably not dangerous.

It might be useful to consider how the other jurisdictions might have decided this case had it been brought before them. Jurisdictions following *Brown* would have granted the drug blanket immunity simply because it is an FDA-approved drug, without any inquiry into its safety. This assumes, of course, that it was correctly produced as designed and the manufacturer was not negligent in its warnings of

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142 See supra notes 33-39 and accompanying text.
143 993 F.2d 528 (6th Cir. 1993).
144 See id. at 532.
145 See id. at 536.
146 Id. at 536-37.
147 Id. at 537.
148 See id. at 539-40.
149 Id. at 540.
150 Id.
151 See supra notes 33-39 and accompanying text.
the potential dangers associated with the drug. Courts following the Nevada Supreme Court's decision in *Allison* would, upon determining that the drug had, indeed, worsened the plaintiff's heart condition, have simply found the maker liable for her injuries, without any inquiry into the drug's benefits (that is, the number of borderline pregnancies saved). It is not clear how a jurisdiction applying the *Hill* "exceptional social need" test would decide the issue. The outcome would likely depend on the value attached to extending pregnancies to term and preventing spontaneous abortions compared to the availability of socially-preferred alternative methods of prolonging pregnancy (acupuncture, extended bed-rest, herbal treatments, surgical procedures, etc.).

III

THE ALI'S PROPOSED STANDARD: SECTION 8(C) OF THE PROPOSED RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY

A. Proposed Section 8(c): The "Reasonable Health Care Provider" Standard

As outlined above, many jurisdictions seem uncertain of how to treat prescription drugs and devices. Despite California's attempts to shore up the crumbling banks of comment k blanket immunity, most jurisdictions have moved away from a pure application of comment k, finding it confusing and difficult to apply fairly. In response, the co-reporters of the Proposed Restatement (Third) have, in section 8(c), proposed a new rule for the treatment of drug design defect claims. By proposing the so-called "super negligence" standard of section 8(c), the co-reporters of the Restatement (Third) endeavored to strike a balance between protecting the public from "improperly" designed and/or marketed drugs, while simultaneously protecting the development and production of beneficial drugs. The Restatement (Third) indicates that manufacturers of prescription drugs and devices can be held liable for injuries caused by their products when the products contain manufacturing defects or when "the drug or medical device is not reasonably safe due to defective design or because of inadequate instructions or warnings." The Restatement (Third) further explains:

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153 See supra Part II.B. See also Cupp, supra note 11, at 87-88 ("The disagreement over which prescription products merit [comment k] protections . . . [marks a deep] rift.").
154 RESTATEMENT (THIRD), supra note 1, § 8(c).
155 Schwartz, supra note 97, at 407.
156 RESTATEMENT (THIRD), supra note 1, § 8 cmt. f.
157 Id. § 8(b)(2).
A prescription drug or medical device is not reasonably safe due to defective design when the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits so that no reasonable health care provider, knowing of such foreseeable risks and therapeutic benefits, would prescribe the drug or medical device for any class of patients.\(^{158}\)

Thus, in order for a plaintiff to claim that the drug or medical device that injured her was defectively designed, section 8(c) requires the plaintiff to convince the court that there is no class of patients for whom this drug is the drug of choice.\(^{159}\) The plaintiff can still argue that the drug or device that injured her was manufactured improperly, or that the drug or device was accompanied by inadequate warnings or directions.\(^{160}\) However, unless the plaintiff can show that no reasonable physician would have prescribed the product for any identifiable group of patients, she cannot claim that it was defectively designed.\(^{161}\) This is true even if the plaintiff did not belong to the class of patients for whom the drug in question was the drug of choice because the proposed Restatement only requires that such a group exist.\(^{162}\) When the defendant is able to show that a class of patients exists for whom there is no other preferred drug available, the plaintiff would be limited to arguing either that the drug was improperly manufactured or that the drug was improperly administered because of the manufacturer's insufficient warning to the plaintiff's doctor.\(^{163}\)

Some commentators have claimed that instead of restating the law, section 8(c) invents it.\(^{164}\) Specifically, they claim that the co-reporters have created a super-stringent standard that rejuvenates comment k on behalf of defendants,\(^{165}\) while paying mere lip service to the majority view\(^{166}\) that claims of defective drug design ought to be allowed on a case-by-case basis. There is, however, a fairly substantial body of case law supporting the section 8(c) approach to the special

\(^{158}\) *Id.* § 8(c).

\(^{159}\) See Schwartz, *supra* note 7, at 1378-79.

\(^{160}\) See *Restatement (Third)*, supra note 1, § 8(c) cmt. a.

\(^{161}\) See *id.* § 8 cmt. f.

\(^{162}\) See *id.*

\(^{163}\) See *id.* § 8(a)-(b).

\(^{164}\) See, e.g., Cupp, *supra* note 11, at 98 (“Unlike many of the ALI’s revisions to section 402A, its language addressing prescription products is far from a restatement of present law.”).

\(^{165}\) Schwartz, *supra* note 7, at 1381 (dubbing section 8(c) a “heightened, super negligence standard”).

\(^{166}\) Indeed, in their reporters’ notes the co-reporters list no less than twelve cases supporting the position that drugs should be subject to some sort of case-by-case risk-benefit assessment in defective design cases, while citing only *Tobin v. Astra Pharmaceutical Products* as a case that has clearly “adopted . . . the approach taken in § 8(c).” *Restatement (Third)*, supra note 1, § 8, cmt. f.
case of drugs and society's need to ensure their supply. The most obvious case that supports section 8(c) is the one that the co-reporters cite in their reporters' note to section 8, comment f: *Tobin v. Astra Pharmaceutical Products, Inc.* As mentioned above, the *Tobin* court held that a claim of defective drug design brought against a manufacturer could succeed only if the manufacturer, aware of the risks associated with the drug, would not have marketed it.

In this way, the *Tobin* court, like the co-reporters, attempted to craft a unique definition of "reasonableness," tailored to apply to the special area of pharmaceutical products. According to the co-reporters, it is reasonable to produce and market a drug or medical device if it is the pharmaceutical product of choice for at least one group of patients. Again, therapeutic medical products are different from other products. Depriving ill individuals necessary medical products can result in serious human suffering. For this reason, reasonableness in design of a medical product should not be analyzed under the *Barker v. Lull* approach, which assumes that everyone can live without products whose dangerous aspects outweigh their overall usefulness to society. This assumption is simply not true where medical products are concerned. The lack of a certain drug or medical device can result in severe suffering, even death. Public policy dictates that medical science provide therapeutic products to those in need as quickly as possible. Thus, for pharmaceutical products, one must adopt a view of "reasonableness" that does not apply to other products. Under this special view, it is "reasonable" to take steps to ensure that the supply of vital drugs is protected. It follows that a drug is "vital" if

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167 993 F.2d 528 (6th Cir. 1993).
168 *Id.* at 537, 540.
169 *Restatement (Third), supra* note 1, § 8 cmt. f.
170 *See* Twerski, *supra* note 23, at 17 ("If we were to take the position that a drug is defectively designed, when that drug can service a specific group of patients who need the drug . . . we would be making a terrible mistake.").
171 *See Brown v. Superior Court, 751 P.2d 470, 478-79 (Cal. 1988). But see Cupp, supra note 11, at 99-100. (arguing that manufacturers of products other than drugs or medical devices could validly claim that certain groups of consumers "need" products that are dangerous to the user and that such a claim is likely to fall on deaf judicial ears).
172 *See supra Part II.B.
173 *See Restatement (Third), supra* note 1, § 8 cmt f. Moreover, current popular sentiment holds that the regulatory system should not stand in the way of medical science's providing therapeutic products to those who need them. *See Burkholz, supra* note 2, at 111-13 ("Only after the AIDS community had roared, screamed, and bullied the subject onto the front pages and the six o'clock news did the FDA begin to stir itself into a search for a better way to approve certain drugs.").
174 *See, e.g., Brown, 751 P.2d at 478-79 ("[T]here is an important distinction between prescription drugs and other products . . . "). But see Cupp, *supra* note 11, at 99-101 (arguing that because no court would grant immunity from design defect claims to manufacturers of consumer products merely on the grounds of social need and consumer desire for cheaper yet more dangerous devices, pharmaceutical manufacturers should not be granted such immunity either).
there is no safer replacement for it for an identifiable class of patients. If the consumer is injured by a vital drug or medical device, then the public policy of protecting the supply of such products precludes the individual from challenging the design of that product.\textsuperscript{175} However, if the product that caused injury is found to be not "vital," that is, there is no group of patients for whom this and no other product will do, then the injured plaintiff may claim that the drug or device should not have been available in the first place. A rule such as the one proposed in section 8(c) serves a dual function: it not only protects the supply of vital drugs, but it also provides an incentive for manufacturers to market only those drugs that are truly vital.

Once one recognizes that the real issue here is how one defines "reasonableness" as it applies to the special activity of manufacturing drugs and prescription devices,\textsuperscript{176} it becomes clear that a number of decisions adhere to the policy of section 8(c).\textsuperscript{177} For example, in \textit{Ortho Pharmaceutical Corp. v. Heath},\textsuperscript{178} the plaintiff allegedly suffered kidney failure as a result of taking the defendant's birth-control pills. The pills contained a higher dose of estrogen than normal birth control pills and were specifically designed to prevent the "breakthrough" bleeding the plaintiff had suffered.\textsuperscript{179} Although the court ostensibly followed the \textit{Barker v. Lull} "risk-benefit test to measure the reasonableness of a danger,"\textsuperscript{180} it went on to hold that "a comment k instruction was warranted" as well.\textsuperscript{181} The \textit{Heath} court then enumerated a four-part test it had developed in a previous case, \textit{Belle Bonfils Mem. Blood Bank v. Hansen},\textsuperscript{182} to determine if comment k protection of a drug's design was justified.\textsuperscript{183} The test for analyzing the reasonableness of employing a therapeutic product is: "[1] The product's utility must greatly outweigh the risk created by its use; [2] the risk must be a known one; [3] the product's benefits must not be achievable in another manner; and [4] the risk must be unavoidable under the present state of knowledge."\textsuperscript{184} The court held that because the birth control drug did what it was prescribed to do, that is, prevent breakthrough bleeding, a jury could conclude that its "benefits outweighed

\begin{footnotes}
\item[175] See \textit{Brown}, 751 P.2d at 478-79 ("[T]he broader public interest in the availability of drugs ... must be considered in deciding the appropriate standard of liability for injuries resulting from their use.").
\item[176] See Twerski, supra note 23, at 16-17.
\item[177] For a discussion of the problems posed by the current wording of section 8(c), see \textit{infra} Part IV. See also \textit{Schwartz}, supra note 97, at 408-09.
\item[178] 722 P.2d 410 (Colo. 1986).
\item[179] See \textit{id.} at 414.
\item[180] \textit{Id.} at 413.
\item[181] \textit{Id.} at 415.
\item[182] 665 P.2d 118 (Colo. 1983).
\item[183] \textit{Heath}, 722 P.2d at 415.
\item[184] \textit{Id.}
\end{footnotes}
More importantly, because "Ortho presented testimony that no other alternative could prevent break-through bleeding and maintain the same high degree of effectiveness against pregnancy," a jury could find that the third prong—"the product’s benefits could not be achieved in any other manner"—had been satisfied, thus precluding liability for injury caused by the drug.

With the exception of prong number two, which refers to how much the manufacturer knew of the drug’s dangerous propensities, the Heath/Belle Bonfils approach to the application of comment k echoes that of section 8(c) of the proposed Restatement (Third). So long as the drug does what it is designed to do, and so long as there is no other treatment that is safer for this particular ailment, the drug should be protected from design defect claims. The same test could be stated as: "so long as there is an identifiable class of patients" to whom it would be "reasonable" to supply this drug, that is, for whom this drug works and no other substantially preferable alternative presently exists, then the court must afford it comment k protection from "strict liability for consequences attending [its use]."

Williams v. Ciba-Geigy Corp. also indirectly supports the rule proposed in section 8(c). In that case, the plaintiff suffered serious side effects after ingesting the defendant’s drug tegretol, a treatment for trigeminal neuralgia and epilepsy. Although the court claimed to apply a risk-benefit test to the drug, it was not the standard it applied to most products. Instead, the court wrote that "[i]n light of the wise principles embodied in comment k, it is presumptively inappropriate for a jury to apply the pure risk-utility test... to a known... risk of a prescription drug." Discussing the risk of a pharmaceutical product, the court commented that "risk’ in a vaccine or pharmaceutical case... concerns not only the qualitative harmful effect, but also the quantitative harm or ‘incidence’ of serious adverse effects, that is, the ratios of instances of harm compared to the total use or consumption of the product." Even more significant is the court’s statement that "[r]ather than simply permitting juries to apply, haphazardly and case-by-case, the risk-utility test whenever harm results, the court must require, as part of the plaintiff’s burden of [proof], an articulable ba-

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185 Id. at 415.
186 Id.
187 Id.
188 See id.
189 See id.
190 RESTATEMENT (SECOND), supra note 4, § 402A cmt. k.
192 See id. at 574, 578.
193 Id. at 577.
194 Id. at 579.
sis for disregarding the FDA’s determination that the drug should be available.\textsuperscript{195} Thus, unless the plaintiff can show that the FDA’s approval of the drug was somehow unreasonable or unwarranted, which means that a “reasonable” FDA, aware of all the risks and therapeutic benefits associated with the drug, would not have put it on the market, then the drug cannot get to the jury under a design defect claim. The court went on to say that:

[t]here is no showing that any drug other than [Tegretol] is effective in treating trigeminal neuralgia. Tegretol is indicated only for those sufferers of psychomotor and grand mal seizures who do not respond to, or are endangered by, more conventional anticonvulsants. . . . The consequences of the nonavailability of Tegretol for those patients who suffer serious seizures, which can be fatal if not controlled, but who cannot take other anticonvulsants, would be grave, indeed.\textsuperscript{196}

Thus, the Williams court echoed the serious concern that motivates both section 402(A), comment k, of the Restatement (Second) and section 8(c) of the Restatement (Third): the fear that strict liability for prescription drug and device design will ultimately deprive a vital drug from a group of patients in dire need of it.\textsuperscript{197}

A recent First Circuit case also supports the policy underlying proposed section 8(c) of the Restatement (Third). In Violette v. Smith & Nephew Dyonics, Inc.,\textsuperscript{198} the First Circuit Court of Appeals was faced with a claim that the defendant’s prescription device, designed to treat carpal tunnel syndrome, had injured the plaintiff, a patient suffering from that ailment.\textsuperscript{199} At trial, the Magistrate Judge had refused to invoke comment k and declare the device unavoidably unsafe as a matter of law.\textsuperscript{200} The jury found for the plaintiff.\textsuperscript{201} On appeal, the Court of Appeals analyzed the device in light of the benefits it offered patients over existing methods of treating carpal tunnel syndrome. According to the court, “[t]his process involves an examination of utility, risk, and the feasibility of safer alternatives.”\textsuperscript{202} The court stated that, based on expert testimony, “the risk involved [in using the defendant’s device] was enormous, and . . . the product’s use provided no benefit beyond those available with the safer, proven, alternative technique of open carpal tunnel surgery.”\textsuperscript{203} Because the device did not provide increased safety or increased efficacy over the alternative, and

\textsuperscript{195} Id. at 577.
\textsuperscript{196} Id. at 578 (emphasis added).
\textsuperscript{197} See Twerski, supra note 23, at 17.
\textsuperscript{198} 62 F.3d 8 (1st Cir. 1995) (applying Maine law).
\textsuperscript{199} See id. at 10.
\textsuperscript{200} See id.
\textsuperscript{201} See id.
\textsuperscript{202} Id. at 12-13.
\textsuperscript{203} Id. at 13 (emphasis added).
because the defendant failed to prove that this device and technique were the only choice for this (or any other) patient, the defendant lost. It did not lose simply because there was another technique available\textsuperscript{204} or because its device posed a danger and, in fact, caused the plaintiff's injury.\textsuperscript{205} Instead, the defendant lost because its device was not an improvement over the alternative—it was, if anything, more dangerous than the alternative.\textsuperscript{206} Thus, the court may have believed that no reasonable professional enterprise, fully informed of the dangers associated with the device, would make it available to any group of patients. This approach fully agrees with the spirit of section 8(c) of the Restatement (Third)\textsuperscript{207}.

B. The Approach of Section 8(c): A Drug is Defectively Designed Only If It Has No Business Being on the Market in the First Place

In Tobin\textsuperscript{208}, the Court of Appeals for the Sixth Circuit created what may be called a "reasonable manufacturer" test, while a "reasonable FDA" test seems to have been followed by the U.S. District Court for the Western District of Louisiana in Williams\textsuperscript{209}. Moreover, the decision in Violette\textsuperscript{210} suggests that the First Circuit Court of Appeals applied a "reasonable medical professional" standard in evaluating pharmaceutical product design defect claims. Clearly, courts are concerned with ensuring that the drugs and devices on the market are as safe as possible, while taking care not to render effective pharmaceutical drugs unavailable to patients who depend on them.\textsuperscript{211} Yet these courts, like many others,\textsuperscript{212} are uneasy about closing the strict product liability door completely on the injured plaintiff. The courts mentioned above have responded by allowing the plaintiff to proceed with her claim that it was unreasonable for the drug or device to even be on the market. This is what drives section 8(c) of the proposed Restatement (Third).

However, no published decision proffers the "reasonable physician" or "reasonable health care provider"\textsuperscript{213} as a legal test for deter-

\textsuperscript{204} Compare id., with Hill v. Searle Labs., 884 F.2d 1064 (8th Cir. 1989), discussed supra text accompanying notes 116-23.

\textsuperscript{205} Compare Violette, 62 F.3d 8, with Allison v. Merck & Co., 878 P.2d 948 (Nev. 1994), discussed supra Part II.C.2.

\textsuperscript{206} See Violette, 62 F.3d at 13.

\textsuperscript{207} Restatement (Third), supra note 1, § 8(c).

\textsuperscript{208} Tobin v. Astra Pharm. Prods., Inc., 993 F.2d 528 (6th Cir. 1992).


\textsuperscript{210} 62 F.3d 8 (1st Cir. 1995).

\textsuperscript{211} See Restatement (Third), supra note 1, § 8 cmt. b.

\textsuperscript{212} For a discussion of what some other courts have proffered, see supra notes 73-76 and accompanying text.

\textsuperscript{213} Restatement (Third), supra note 1, § 8(c).
mining whether or not the drug or prescription device in question is unavoidably unsafe.\textsuperscript{214} Professors Henderson and Twerski, the co-reporters of the \textit{Restatement (Third)}, assert that proposed section 8(c) embodies the courts' decisions, acceptably replaces comment k, and protects the availability of effective drugs. It also allows those injured by "junk" drugs or devices marketed despite \textit{clearly preferable} alternatives to seek recovery.\textsuperscript{215} This Note argues that, for the reasons set forth below, the best wording of proposed section 8(c) is not the "reasonable health care provider" but rather "the reasonable manufacturer."

\section*{IV

PROBLEMS WITH THE PROPOSED "REASONABLE HEALTH CARE PROVIDER" WORDING OF SECTION 8(c)

A. The "Reasonable Physician" or "Reasonable Health Care Provider" Does Not Appear in the Case Law

One of the main functions of a Restatement is to survey the law—that is, to sift through the case law and statutes in order to assemble a body of work that at once explains the law and guides future lawmaking activities.\textsuperscript{216} A search of the case law indicates that no prescription drug or device design defect case refers to the "reasonable physician" or to the "reasonable health care provider."\textsuperscript{217} In \textit{Tobin v. Astra Pharmaceutical Products Inc.},\textsuperscript{218} the only case relied upon by the co-reporters of the \textit{Restatement (Third)} in support of section 8(c), the court focused on the "prudent manufacturer."\textsuperscript{219} By asking the courts to accept this new test, the co-reporters invite criticism and potential rejection.\textsuperscript{220} Judges in jurisdictions whose case law has developed along

\begin{footnotesize}
\textsuperscript{214} See Schwartz, \textit{supra} note 7, at 1380. Schwartz argues that the reasonable physician test "has no precedent. Under traditional . . . tests, the focus is either on the product itself or on whether a reasonable manufacturer, with knowledge of the risks, would put the product on the market." \textit{Id.}

\textsuperscript{215} See \textit{Restatement (Third)}, \textit{supra} note 1, § 8 cmt. f.

\textsuperscript{216} See Calabresi & Cooper, \textit{supra} note 129, at 866-67 ("[T]he Restatement's influence depends on whether courts pay attention to it, which in turn depends on whether the Restatement actually reflects what is happening in the courts.").

\textsuperscript{217} See Cupp, \textit{supra} note 11, at 98 ("Unlike many of the ALI's revisions to section 402A, its language addressing prescription products [in section 8(c)] is far from a restatement of the present law."); Schwartz, \textit{supra} note 7, at 1381 ("[The reasonable physician test] has no precedent. Under traditional . . . tests, the focus is either on the product itself or on whether a reasonable manufacturer, with knowledge of the risks, would put the product on the market.") (footnotes omitted).

\textsuperscript{218} 993 F.2d 528 (6th Cir. 1993).

\textsuperscript{219} \textit{Id.} at 540 ("We find that there was sufficient evidence before the jury to conclude that a prudent manufacturer knowing all the risks would not market ritodrine.").

\textsuperscript{220} See, e.g., Marshall S. Shapo, \textit{Should Courts Buy the Proposed Restatement?}, TRIAL, Nov. 1996, at 25, 25-26 (arguing that proposed section 8 "illustrates the departure of the [proposed \textit{Restatement (Third)}] from the foundations of basic tort law").
\end{footnotesize}
the *Kearl/Toner* risk-benefit approach to pharmaceuticals could well dismiss section 8(c) out of hand as being unsubstantiated, because no court has ever employed a “reasonable health care provider” approach for drug design liability claims. The co-reporters are asking the courts to apply a test that has never been articulated this way.\(^{221}\) For this reason, section 8(c) may be shot down before it ever has a chance to fly, resulting in a continuation of the current “deep rift” among the jurisdictions.\(^{222}\)

Most of the commentators who have spoken to the “reasonable health care provider” language of proposed section 8(c) have indicated discomfort with it. Even one staunch supporter of section 8(c) acknowledges the inadequacy of its language, albeit parenthetically: “[A]n informed and reasonable health care provider would not prescribe the drug [in question] to anyone (or an informed and reasonable manufacturer would not market the drug) . . . .”\(^{223}\) Other commentators have not been so circumspect in their criticism of the wording of the test. Professor Richard Cupp comments that the co-reporters’ “reading” of *Tobin* as the basis for their “reasonable health care provider” standard is “inaccurate”\(^{224}\) and “unclear.”\(^{225}\) Moreover, Teresa Moran Schwartz argues that the “[reasonable health care provider standard] has no precedent. Under traditional risk-utility tests, the focus is either on the product itself or on whether a reasonable manufacturer, with knowledge of the risks, would put the product on the market.”\(^{226}\) Schwartz further asserts that section 8(c) is “an artificial test . . . that could create considerable confusion for the fact finder . . . . [It seems] more straightforward and less confusing to ask whether a reasonable manufacturer, presuming full knowledge of the risks and benefits of its product, would have put the product on the market.”\(^{227}\) Suffice it to say that case law and academic support for the proposed “reasonable health care provider” standard is sparse at best, and hostile at worst.

It is even more significant that in their reporters’ note to section 8(c), the co-reporters themselves suggest that the proposed “reasonable health care provider” standard is, for all intents and purposes, the same as the “reasonable manufacturer” standard:\(^{228}\) “[W]hen a

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\(^{221}\) See *Schwartz*, supra note 7, at 1381 (“[The language of section 8(c)] has no precedent.”).

\(^{222}\) *Cupp*, supra note 11, at 85-88.

\(^{223}\) *Barrett*, supra note 11, at 1296. See also *id.* at 1295 (“A drug is in [an unreasonably dangerous] condition if an ordinarily prudent manufacturer . . . being aware of the risks . . . would not market the drug.”).

\(^{224}\) *Cupp*, supra note 11, at 106.

\(^{225}\) *Id.* at 106 n.182.

\(^{226}\) *Schwartz*, supra note 7, at 1381 (footnotes omitted).

\(^{227}\) *Id.* at 1383.

\(^{228}\) *RESTATEMENT (THIRD)*, supra note 1, § 8 cml. f.
drug or device provides no net benefits to any ascertainable patient class—when no reasonable, informed medical provider would prescribe the drug and no reasonable, informed manufacturer would prescribe it—then the design of the product is defective and the manufacturer should be liable for the harm. . . .”229 This language suggests that the co-reporters suspect courts will be less than willing to embrace the proposed “reasonable health care provider” language of section 8(c). By adding the “reasonable manufacturer” language to their reporters’ note, the co-reporters may hope to increase the chances that courts accept section 8(c). However, there is no clear reason why this “equal” standard must be relegated to the reporters’ notes—why courts must be forced to dig for language that is likely to make section 8(c) more palatable. To do so is to risk rejection of section 8(c) altogether, because courts are likely to hold that reporters’ notes are something less than the law. The following section argues that the proposed “reasonable health care provider” standard language of section 8(c) is problematic and thus likely to lead to judicial rejection. Given that most commentators prefer the “reasonable manufacturer” standard over “the reasonable health care provider”230 standard, and given that the co-reporters themselves seem to equate the two,231 the ALI should replace the language of section 8(c) with the “reasonable manufacturer” standard.

B. Physicians Are Inappropriate Standard-Bearers for the Reasonableness of Pharmaceutical Product Design

In addition to the dearth of case law supporting the “reasonable health care provider” language of section 8(c), detractors have argued that it is improper to rely upon the actions and judgment of doctors to determine the reasonableness of a given drug or medical device. Traditionally, doctors have been exempt from liability for any injury caused by the products they prescribe.232 Therefore, sparse case law exists regarding the reasonableness of physicians’ actions vis-a-vis pharmaceutical prescriptions.233 Even if a doctor prescribes a drug that ultimately injures the patient, a court is likely to deem the doctor as having engaged in a service, not a sale, and thus simply find her not

229 Id.
230 See, e.g., Cupp, supra note 11, at 98; Schwartz, supra note 7, at 1380.
231 See Restatement (Third), supra note 1, § 8 cmt. f.
232 See Ryan & Lawn, supra note 130, at 821 (“[T]he large majority of reported decisions have recognized that a physician or a hospital is primarily providing a service and therefore is not engaged in the business of selling the product at issue. Under this rationale, most courts have refused to extend the doctrine of strict liability to health care providers.”).
233 Case law on medical malpractice has been developed to an extensive degree, but it is not clear that a medical malpractice standard is desirable for adjudicating products liability cases. See Schwartz, supra note 7, at 1381-82.
amenable to suit under a theory of products liability. For example, in *Magrine v. Krasnica*, the plaintiff was injured when the needle the defendant-dentist used to inject a local anaesthetic broke off in his jaw. The court held that because he was not a "seller" for the purposes of products liability, the dentist could not be subjected to a claim of strict products liability. In a subsequent case, the New Jersey Supreme Court was called upon to hold doctors and other medical professionals liable for injury caused by the products they prescribed, in the same way that a hairdresser is held liable for injuries caused by cosmetics that injure customers. The court refused to do so, holding that the dentist or doctor is "engaged . . . in a profession" in which he "exercises his best judgment in diagnosing the patient's ailment or disability, prescribing and sometimes furnishing medicines or other methods of treatment which he believes, and in some measure hopes, will relieve or cure the condition." The court further observed that "[n]either medicine nor dentistry is an exact science; there is no implied warranty of cure or relief . . . . There is no guarantee that the diagnosis is correct." Courts have generally deferred to the medical professional's best judgment, exempting doctors and other medical professionals from strict liability for any damage their prescriptions may cause.

Furthermore, given the drug manufacturer's tight control over information relating to its products' efficacy and safety, it seems that even if a doctor were to prescribe a dangerous drug that should not be on the market in the first place, such an action would not be prohibited by current medical malpractice doctrine. In order for a doctor to be liable for medical malpractice, she must "have deviated from the accepted standards of practice and . . . this deviation was a substantial factor in producing the injuries complained of." Medical malpractice concerns the lapse of the doctor's professional judgment, and the doctor's failure to do everything expected from an

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234 *See Restatement (Third), supra note 1, § 4(b) ("Services, even when provided commercially, are not products.").*  
236 *See id.* at 540.  
237 *See id.* at 543-45.  
239 *Id.* at 702-03.  
240 *Id.* at 703.  
241 *Cf. Aschinger, supra* note 11 (arguing that even though physicians are not held liable for injuries caused by the pharmaceutical products they sell, they should be held liable for harm caused by products that are purely cosmetic in nature and aggressively marketed by the prescribing physician).  
243 *Id.* at 3-4.
ordinary professional in the field. The drug manufacturer is in a much better position to design drugs and inform doctors of their uses, efficacy, and dangers than are physicians.

It is practically impossible for a doctor to keep abreast of the broad field of medical product innovation. Doctors are busy people, with very demanding caseloads, and it is often difficult for them to keep up with new developments, even in their own fields, much less in the field of pharmacology. Most doctors are not in a position to collect data on the drugs they prescribe, nor to keep track of side effects that patients experience, except on a local, anecdotal basis. Doctors generally do not subject new drugs to their own animal, computer, or human tests. According to one commentator:

Both drug manufacturers and prescribing physicians are potential ... cost avoiders when it comes to obtaining ... information about the risks of pharmaceutical products. As far as the generation of basic research on product safety is concerned, pharmaceutical manufacturers are clearly the cheapest cost avoiders. Not only do drug manufacturers have superior resources to devote to research, but they are already required to conduct a thorough investigation of product related risks ... [by the FDA]. In contrast, physicians have neither the resources nor the expertise to conduct basic research on the biochemical properties of the pharmaceutical products that they prescribe.

Moreover, doctors often continue to prescribe medical products with which they are familiar, even when the safety of the product comes under question or safer products of equal efficacy become available. The reasonable physician is one who reads the material supplied by the manufacturer, who listens to the information provided by the ubiquitous pharmaceutical salesperson, and acts ac-

244 See id.
245 See Castrignano v. E.R. Squibb & Sons, 546 A.2d 775 (R.I. 1988) (asserting that pharmaceutical manufacturers are the experts who retain the responsibility for protecting the public from danger).
246 See Schwartz, supra note 7, at 1382 ("[P]hysicians are flooded with promotion materials and often are unable to keep abreast of pharmaceutical developments.").
247 See id.
248 See id.
249 Richard C. Ausness, Learned Intermediaries and Sophisticated Users: Encouraging the Use of Intermediaries to Transmit Product Safety Information, 46 SYRACUSE L. REV. 1185, 1229 (1996).
250 See Schwartz, supra note 7, at 1382 n.160 ("[E]ven though Darvon has been shown to be no more effective for pain relief than aspirin and poses risks of addiction, doctors continue to prescribe it, so that sales of the drug continue in the range of $100 million a year.") (citing Michael S. Wilkes & Miriam Shuchman, Pitching Doctors, N.Y. TIMES, Nov. 5, 1989, § 6 (Magazine), at 88).
251 See id. at 1382 n.157. According to Schwartz, "The [pharmaceutical] industry has a sales force of 'detailers' who number about 45,000 and who visit doctors' offices on a regular basis. They constitute 'the primary source of information on new drugs.'" Id. (citing DONALD DRAKE & MARIAN UHLMAN, MAKING MEDICINE: MAKING MONEY 25 (1993)).
Doctors are literally inundated by pharmaceutical makers' advertising. Pharmaceutical manufacturers spend millions of dollars each year to convince doctors that their products are useful, reliable, and safe. Because of the difficulties involved in accessing independent, objective information about the efficacy of each drug on the market, it is not unreasonable for a physician to rely upon manufacturers' representations. Thus, the "reasonable health care provider" language of proposed section 8(c) renders it an unworkable standard when used to determine whether a given drug should have been marketed by the manufacturer.

Moreover, because the "reasonable health care provider" standard is likely to affect a jury's objectivity, courts may hesitate to employ section 8(c) as written. Juries tend to be deeply swayed by the testimony and opinions of doctors and are inclined to defer to their professional judgment. In almost all prescription drug and device cases, a doctor recommended the drug or device to the patient, and the doctor was instrumental in procuring the product, either via prescription or direct sale. Medicine is an inexact science. Reasonable doctors are too busy to keep up with every new development, and thus their reliance on information provided by drug manufacturers is generally deemed reasonable. Therefore, it is easy to see how an injurious product prescribed by a qualified doctor may be enough to persuade a jury that the prescription of the drug was reasonable, regardless of the drug's harmfulness.

Thus, as currently written, section 8(c) provides the manufacturer of an unreasonably dangerous product a shield against design defect claims—the act of the medical professional who prescribed the product. The co-reporters acknowledge this eventuality, warning "[t]hat some providers do, in fact, prescribe defendant's product does not necessarily suffice to defeat plaintiff's claim. Evidence regarding the actual conduct of health care providers, while relevant and admissible, is not necessarily controlling." However, critics like Schwartz

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252 See Garber, supra note 2, at 21 ("[Pharmaceutical product] marketing competition is often fierce and costly. . . . Sales promotion efforts are extensive even for drugs with no present competitors.").

253 See Schwartz, supra note 7, at 1382.

254 If recent studies on drug manufacturers' advertising practices are accurate, such a standard may be necessary. According to Schwartz, "Recent studies have found that drug advertising is often inaccurate and unreliable." Id.

255 See id. at 1381-82.

256 Cf. Restatement Third, supra note 1, § 8 cmt. f.

257 See Schwartz, supra note 7, at 1382.

258 See id.

259 See id. at 1382 n.157.

260 See id. at 1381-82.

261 Restatement (Third), supra note 1, § 8 cmt. f.
note that juries are likely to give "great weight" to the actions of the actual physician(s) involved.\textsuperscript{262} Judicial awareness of jurors' tendency to defer to physicians may lead courts to reject this new standard, in fairness to the plaintiff.\textsuperscript{263} Moreover, even if the jury is instructed not to consider the actions of the particular health-care givers who prescribed the product, it may still find the drug prescription reasonable, given the representations, advertising, and information provided to the medical community by the manufacturer. As a result, courts are likely to find the proposed "reasonable health care provider" test unacceptable, especially those jurisdictions that have developed case law that allows the factfinder to subject prescription drug design claims to a case-by-case risk-benefit analysis.\textsuperscript{264} This existing case law may, in turn, keep the courts from wholeheartedly embracing the rest of the Restatement (Third).\textsuperscript{265}

In short, the "reasonable health care provider" standard may potentially protect manufacturers who knowingly place products on the market that simply should not be there, given the extreme risk associated with the product. For example, imagine that thalidomide had actually been approved for sale in the United States.\textsuperscript{266} Assume, also, that despite learning that some women in Europe who had taken thalidomide had given birth to severely deformed babies,\textsuperscript{267} the maker disregarded the risk and continued to market the drug as the only "completely safe" tranquilizer "for pregnant women."\textsuperscript{268} Because it is reasonable for a doctor to prescribe a drug that she believes to be safe, and because the company claimed that this was a safe tranquil-

\textsuperscript{262} Schwartz, supra note 7, at 1381-82.
\textsuperscript{263} See generally id. (arguing that both comment k and section 8(c) unfairly protect defendant pharmaceutical makers to the detriment of injured plaintiffs).
\textsuperscript{264} See Cupp, supra note 11, at 98 ("Over the years, jurisdictions have developed substantially different approaches to the doctrine. It seems doubtful that they will quickly abandon their existing case law in favor of the ALI's proposed new approach.") (footnote omitted).
\textsuperscript{265} See Calabresi & Cooper, supra note 129, at 866-67. Indeed, Professor Henderson himself has noted that courts may not universally accept the Restatement (Third): "I believe the [new] Restatement will have normative force. The prestige of the [ALI] will give it weight. However, I doubt that every court will adopt it." James Henderson, Revising Section 402A: The Limits of Tort as Social Insurance, 10 Touro L. Rev. 107, 108 (1993). Adopting a problematic standard such as the unsupported "reasonable health care provider" will only increase the potentiality of rejection of the Restatement (Third).
\textsuperscript{266} This actually nearly happened but for the efforts of a few well-placed skeptics. See Burkholz, supra note 2, at 43 ("That thalidomide was never marketed in the United States was largely due to the stubborn skepticism of the FDA's Dr. Frances Kelsey .... She fought a dogged defensive battle, blocking and parrying every attempt by Richardson-Merrell to gain approval ....").
\textsuperscript{267} See id. at 42 ("Mothers who took [thalidomide] ... produced children with a wide but distinctive range of deformities. Some had no arms, just flippers extending from the shoulders ... others were born with just a head and a torso. It was the nightmare come true of every prospective parent.").
\textsuperscript{268} Id. at 43.
izer to prescribe for an identifiable patient group—pregnant women—under proposed section 8(c), the actions of the health care providers who prescribed the drug should be considered reasonable. If thalidomide were in fact the only "available" tranquilizer for pregnant women, then section 8(c) automatically confers immunity. However, if other drugs are available for the patient class, then section 8(c) requires that juries engage in the mental gymnastics of imputing the knowledge held by the manufacturer to the prescribing physician, then asking if, given that information, the doctor would still have prescribed it. Additionally, the jury must take into account the representations of safety the manufacturer actually made to the physician, and the inherent reasonableness of the physician's reliance on such information.

Thus, courts are likely to find that the language of section 8(c) forces the jury to take unnecessary steps to (1) gauge the mental state of the manufacturer; (2) ascribe the mental state of the manufacturer to the reasonable physician; and (3) then determine if the physician would have prescribed the drug to any patient, given all available information, including that provided by the manufacturer itself. Courts will likely resist a rule that would at best force the jury to make abstract mental leaps, and at worst automatically grant a manufacturer immunity in the face of a conscious choice to sell a drug that clearly should not be on the market. The co-reporters themselves equate the "reasonable health care provider" standard with the "reasonable manufacturer" test. If so, there is no clear reason why the rule of section 8(c) cannot be written to direct the finder of fact to determine whether a reasonable manufacturer of prescription drugs and devices would have marketed the product in the first place. This inquiry is not the same as asking if the FDA should have approved the product or not. This distinction is addressed in the next section.

C. The "Reasonable FDA" is not a Satisfactory Standard

1. The FDA Is Not Equipped to Determine the Public Need for the Product in Question

The average pharmaceutical company profits by identifying promising patient populations that need new treatments. Manufac-

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269 See supra note 223 and accompanying text.
270 See supra notes 242-54 and accompanying text.
271 See RESTATEMENT (THIRD), supra note 1, § 8 cmt. f.
272 See Jeffrey P. Cohn, The Beginnings: Laboratory and Animal Studies, FDA CONSUMER, Jan. 1995, at 3 ("In some cases, a pharmaceutical company decides to develop a new drug aimed at a specific disease. . . . [I]n . . . others, new findings from university, government or other laboratories may point the way for drug companies to follow in their own research.")
urers employ their own researchers;\textsuperscript{273} in addition, the average pharmaceutical manufacturer sponsors research conducted by scientists at academic research centers all over the world.\textsuperscript{274} Manufacturers, through their employees, monitor various medical fields, and amass information in the form of articles, case reports, as well as direct correspondence from researchers, doctors, and other professionals.\textsuperscript{275} To survive, the manufacturer must spot potentially profitable areas,\textsuperscript{276} and then either improve existing medications or produce novel treatments. Once it identifies a target area, and finds a possible treatment, the drug company performs extensive tests on the prospective product.\textsuperscript{277} Tests are done at the molecular level, in vitro, then in vivo, using animals.\textsuperscript{278} Based on these test results, the drug manufacturer decides whether a market exists for its product.\textsuperscript{279} The manufacturer then begins the procedure for approval with the FDA by submitting an Investigational New Drug Application ("IND").\textsuperscript{280} The IND contains information, compiled by the manufacturer, on the drug’s "chemistry, manufacturing, pharmacology, and toxicology."\textsuperscript{281} Once the FDA approves the IND, the manufacturer then collects further data on "clinical safety and efficacy needed for a New Drug Application ("NDA"), the formal license application."\textsuperscript{282} The NDA must include "very detailed reports [by the manufacturer] of all animal studies and clinical testing performed with the drug, reports of any adverse reactions, and any other pertinent information from worldwide scientific literature."\textsuperscript{283} Throughout this process, the FDA must rely upon the manufacturer for the data essential for approval.\textsuperscript{284}

\textsuperscript{273} See id.
\textsuperscript{275} See id. supra note 272, at 3.
\textsuperscript{276} See Douglas R. Dennis, What Impact Will Health Care Reform Have on Vaccine and Drug Makers?, 62 DEF. COUNS. J. 165, 169 (1995): See also John Henkel, Orphan Products: New Hope for People with Rare Disorders, FDA CONSUMER, Jan. 1995, at 47-49 (analyzing the government’s response, in the form of funding and guaranteed market exclusivity, to the problem of "orphan disorders," namely, diseases affecting otherwise unprofitable populations of less than 200,000 patients).
\textsuperscript{277} Cohn, supra note 272, at 3-4.
\textsuperscript{278} See id.
\textsuperscript{279} See Henkel, supra note 276, at 48 (indicating that the most important factor in a drug company’s decision to proceed with the development of a new drug is the drug’s "money making potential").
\textsuperscript{280} See Barrett, supra note 11, at 1312-13.
\textsuperscript{282} Id. See also Barrett, supra note 11, at 1312-13.
\textsuperscript{283} Grundberg, 813 P.2d at 96 (citing 21 U.S.C. § 355(b) (Supp. 1991); 21 C.F.R. § 314.50 (1990)).
\textsuperscript{284} See Cohn, supra note 272, at 5 ("FDA physicians, scientists and other staff review test results submitted by drug developers. The purpose: ... to decide whether the drug can be sold to the public . . . "). Recently a Japanese university researcher was allegedly bribed by an American drug company to skew research results to support the efficacy of the com-
Once the manufacturer convinces the FDA and its panel of experts\textsuperscript{285} that the drug is safe, the FDA grants its approval.\textsuperscript{286}

This system, however, is far from fool-proof. Even though the agency’s regulations and procedures governing the approval of prescription drugs are “extensive,”\textsuperscript{287} one commentator has reported that the FDA “has failed on a number of occasions to prevent violations of these regulations, and . . . allowed unsafe drugs to reach or stay on the market.”\textsuperscript{288} A variety of deregulatory pressures may compromise the FDA’s effectiveness.\textsuperscript{289} High-ranking members of Congress and the administration have been known to lobby the FDA on behalf of a company whose product is undergoing FDA review.\textsuperscript{290} Large, influential associations such as the American Medical Association have argued that FDA regulations may make valuable drugs unavailable to patients in the United States.\textsuperscript{291} Meanwhile, public opinion also plays a role in the regulatory process. According to Paul J. Quirk, “When FDA actions offend public opinion . . . Congress [is] ready to consider reversing them. Congress legislatively reversed the FDA’s vitamin and mineral regulations and delayed implementation of the saccharin ban.”\textsuperscript{292} The public demand for laetril, which at one time was thought to be a miracle cure for cancer, led Congress to introduce a bill “to legalize laetril by eliminating proof-of-efficacy as a requirement for drug-marketing approval.”\textsuperscript{293} According to Quirk, “cases of intense public opposition are significant not only because of the possibility of legislative or judicial reversal, but also because they threaten

\textsuperscript{285} See Grundberg, 813 P.2d at 96 (“The application is reviewed by physicians, pharmacologists, chemists, microbiologists, statisticians, and other professionals within the FDA’s National Center for Drugs and Biologics who are experienced in evaluating new drugs.”) (citing 47 Fed. Reg. 46626 (Oct. 19, 1982)).

\textsuperscript{286} After granting approval, the FDA requires the manufacturer to continue to monitor any adverse effects of the drug post-approval. “All reports of adverse drug reactions (‘ADRs’) must be reported to the FDA . . . . The manufacturer must also periodically submit reports as to what actions it took in response to ADRs and must submit data from any post-marketing studies, reports in the scientific literature, and foreign marketing experience.” Id. at 96-97 (citing 21 C.F.R. § 314.80(b)-(c)).

\textsuperscript{287} Grundberg, 813 P.2d at 97.

\textsuperscript{288} Schwartz, \textit{supra} note 7, at 1387.


\textsuperscript{290} See \textit{id.} at 211-12.

\textsuperscript{291} See \textit{id.} at 213 (“By the mid-1970s, disaffection of the medical profession with the FDA had become quite severe. State and national medical conventions passed resolutions calling for reduction of the agency’s authority.”).

\textsuperscript{292} Id. at 214.

\textsuperscript{293} Id.
the agency's political support and its access to needed resources."

Perhaps the entity that has the most intense effect on the FDA is the pharmaceutical industry. Quirk comments:

Undoubtedly the most significant pressure on the FDA to approve drugs results directly from industry lobbying of the agency. In the drug-evaluation process there are necessarily frequent contacts between agency officials and representatives of drug companies.... Such contacts on a regular basis over a period of years may strongly shape the attitudes of FDA officials. Moreover, there are no regular, direct contacts between reviewing officials and any parties inclined to oppose drug approvals. In addition to its psychological effects, this lobbying imbalance also creates an imbalance of information and analysis—arguments favorable to a drug approval will be discovered and articulately put by company representatives while criticisms must be discovered by the reviewer unassisted.

The FDA is overworked and underfunded. New developments in the pharmaceutical field are increasing, in both number and complexity, especially in the field of prescription medical devices. However, given the recent political emphasis on a "laissez faire" approach to agency regulation of the pharmaceutical industry, and the current fervor for budget slashing and deregulation, the FDA cannot sufficiently oversee the development and safety of each drug that passes before it.

2. The Outcome of the FDA's Approval Process is Largely Determined by the Manufacturer

The only way to determine the need for a proposed pharmaceutical product is to review the data available to the manufacturer at the

294 Id.
295 Id. at 211.
296 See Schwartz, supra note 7, at 1388 ("In addition to regulating drugs and medical devices, [the FDA] is responsible for food, radiological products, and cosmetics.... Over 8,000 different drugs fall under its jurisdiction. Some 16,000 device manufacturers are registered with the agency.").
297 See id. ("In the 1980's the overall size of the [FDA's] staff was reduced by 7.5% and the agency's budget grew by only 2% in constant 1980 dollars. By the end of the decade, the FDA estimated that it needed 2,000 more positions to carry out its responsibilities.").
298 See id. at 1389.
299 See generally Ken Flieger, FDA Finds New Ways to Speed Treatments to Patients, FDA CONSUMER, Jan. 1995, at 19-22 (outlining the "numerous steps" the FDA has taken to "shorten the time devoted to pre-approval testing").
300 See Schwartz, supra note 7, at 1388; Clinton Offers Middle-Class Tax Cuts in Budget Plan, SEATTLE TIMES, Feb. 6, 1997, available in 1997 WL 3218577 (reporting that the Republican Congress is likely to be hostile to any requested increases in the FDA's budget).
301 See Schwartz, supra note 7, at 1387-88; see also Barrett, supra note 11, at 13.
time it proposes the drug for marketing. Such relevant data includes the product's risks relative to its benefits. Determining reasonableness demands an overview of the relevant market and those products already available. Products that provide even marginal improvement over those already on the market, for even a single patient group, should be made available.

Yet the FDA alone is unable to make this reasonableness determination. Rather, the FDA relies heavily on the drug manufacturers to in effect regulate themselves. It gives only a "cursory" review of medical devices before approving them for the market. Its current level of regulation of prescription drugs has been described as "lax." In one case, an arthritis drug was given approval despite the fact that the same drug had caused a number of fatalities overseas. Within four months of the drug's appearance on the market, it had resulted in around fifty deaths and even more lawsuits. The maker took the drug off the market before the FDA took any action.

Given the FDA's increasingly scarce resources and its extensive and necessary reliance on industry, the "reasonable FDA" is clearly not a viable standard for drug design claims. In fact, it may be "reasonable" for the FDA to approve a dangerous product in reliance on the manufacturer's data. The FDA commonly allows producers who violate its regulations to continue their business, safe in the knowledge that the FDA is too bureaucratically bound-up to take effective action against it. The realization that the FDA sometimes cannot guarantee prescription product's safety has led some courts to hesitate before declaring FDA approval as preempting products liability claims involving drugs and prescription de-

303 See Grabowski, supra note 127, at 7 n.18 (describing the therapeutic importance of the availability of a variety of treatments for a given ailment).
304 Schwartz, supra note 7, at 1392-93.
305 Id. at 1395.
306 See id. at 1396-97 (describing the use of the drug Oraflex).
307 See id. at 1397.
308 See Quirk, supra note 289, at 212.
309 See Schwartz, supra note 7, at 1386 ("[T]he FDA lacks the general subpoena power that other agencies have, and therefore, in most instances cannot compel the disclosure of information about product risks. Sometimes through tort litigation, the information does come to light, and the FDA is able to use it to initiate regulatory action.") (footnotes omitted).
310 See Burkholz, supra note 2, at 20 ("[A]ll too often [the FDA] ceded [its] authority, or declined to exercise it. It was clearly in the interests of the agency to punish incompetence within its ranks, and to reward diligence, but all too often the opposite occurred.").
311 See id. at 26-27 (reporting on "the ineffectiveness of the [FDA enforcement] system, as well as the inefficient and industry-oriented attitudes of the FDA reviewing officers").
vices\textsuperscript{312} (although many state legislatures are increasingly willing to do so).\textsuperscript{313}

In addition to being a less-than-ideal source of protection for consumers of pharmaceutical products,\textsuperscript{314} the scope of the FDA’s authority is statutorily limited\textsuperscript{315} to the simple determination of whether or not a new drug’s “safety and effectiveness”\textsuperscript{316} are adequate for marketing approval.\textsuperscript{317} The FDA determines safety by performing a risk-benefit analysis on the product:

No drug is completely safe or without the potential for side effects. Before a drug may be approved for marketing, the law requires the submission of results of tests adequate to show the drug is safe under the conditions of use in the proposed labeling. Thus, “safety” is determined case by case and reflects the drug’s risk-vs.-benefit relationship.\textsuperscript{318}

The FDA is not required to ask whether or not the drug or medical device under consideration is a desirable addition to, or an improvement over, those products already available.\textsuperscript{319} The FDA deals with each product on a case-by-case basis, as if in a vacuum.\textsuperscript{320} Indeed, the producer itself may claim that the product is a significant improvement over existing products, in which case the FDA may grant the new product “priority” status that entitles it to expedited review.\textsuperscript{321} All other drugs and devices are designated “standard” and subjected to a slower (twelve-month) review process.\textsuperscript{322}

Thus, the FDA does not consider whether the product under scrutiny is significantly more dangerous than existing products. When it first requests FDA review, the manufacturer has the option of demonstrating that the product in question provides a significant improve-

\textsuperscript{312} See, e.g., Allison v. Merck & Co., 878 P.2d 948, 965 (Nev. 1994) (“[C]omment k should not provide blanket protection to all drug manufacturers of any FDA approved drugs . . . .”).
\textsuperscript{314} See Garber, supra note 2, at 38 (discussing low FDA standards and the detection of non-compliance with its current standards). “Clearly, the FDA does not have the resources” to effectively guarantee pharmaceutical product safety. Id.
\textsuperscript{316} Originally, the FDA’s statutory mandate was to ensure drug safety. In 1962 the Food, Drug and Cosmetic Act was amended to require the agency to determine the “effectiveness” of new drugs. See Grabowski, supra note 127, at 11-12.
\textsuperscript{319} See Goodman & Rheingold, supra note 302, § 5.2(C)(1) (noting that so long as the manufacturer meets its burden of convincing the agency that its proposed product is effective and safe, the FDA will approve it).
\textsuperscript{320} See id.
\textsuperscript{321} See Farley, supra note 318, at 25.
\textsuperscript{322} See id.
ment over available products, only if it desires expedited review. After that determination, the issue does not arise again.

The FDA's statute requires it only to determine the "safety and efficacy" of this drug, on its own terms, for its intended purpose, vis-a-vis the disease or disorder it is designed to combat. The FDA does not undertake a comparative analysis as part of the approval process. The FDA does not consider whether, aside from the product's general risks in comparison to its benefits, there are products out there designed for the same purpose that are clearly preferable for all groups of patients.

Undoubtedly, providing a wide range of therapeutic choices to health care providers benefits patients. Similar products can affect different patients differently; thus, doctors need an array of therapeutic products to best serve their individual patient. But preserving similar products to treat the same disease assumes that no alternative treatment available is significantly worse than its competing products. Stated otherwise, the therapeutic need to preserve a variety of treatments does not require the availability of a treatment that would never be a reasonable choice, given the alternatives, for any patient or group of patients.

In short, under the current FDA approval process, manufacturers have the responsibility to identify potentially profitable patient popu-

323 See id.
324 See id. at 29.
325 See Grabowski, supra note 127, at 17-37 (attributing market forces, rather than increased regulation, to a measurable decrease in the approval of "unimportant" drugs.). Essential to Grabowski's analysis is the fact that, for approval purposes, the FDA does not distinguish between "unimportant" new drugs (those that offer little or no improvements over existing drugs) and those representing "modest or major therapeutic advances." Id. at 21. See Farley, supra note 318, at 24 ("[C]ontrolled clinical trials are especially important because they provide the only basis, under law, for demonstrating effectiveness.") (emphasis added). FDA approval hinges upon only two issues: effectiveness and safety. See id. at 29. Relative therapeutic value is simply not an issue in the approval scheme.
326 However, the FDA has recently shown a willingness to consider asking a manufacturer of a drug to pull that product from the market if a clearly safer alternative is available. See Tom Jackman, Seldane Producer Sues Rival, KANSAS CITY STAR, Feb. 8, 1997, at B1 (reporting that the FDA considered pulling its approval of the antihistamine Seldane in response to the makers release of a safer form of the drug). However, this evaluation affects only older drugs on the market, and does not enter into the decision as to whether or not to approve a given new drug. Furthermore, given the close relations of drug companies to the FDA, it is likely that the FDA will merely ask a company to remove an outdated drug from the market. See id. Thus, due to considerations other than consumer safety the FDA allows arguably unreasonably unsafe drugs to remain on the pharmacist's shelf. See supra notes 287-88 and accompanying text.
327 See Grabowski, supra note 127, at 7 n.18.
328 See id. at 7.
lations, design new products, test them, garner FDA approval, and convince doctors to prescribe them. As the political climate continues to inhibit the government’s regulation of drugs and medical devices, the profit-motivated manufacturer alone will make the crucial decisions. Drug makers, not drug regulators, will decide whether or not the product will reach the patient population. For this reason, the jury must adjudicate the reasonableness of the manufacturer's decisionmaking, “reasonableness” meaning whether an identifiable group of patients, given all the information available to the manufacturer at the time of sale, required this drug. In short, the proper test is: given all the data available to the manufacturer at the time of marketing, and the state of the market at the time, was it reasonable for the manufacturer to make and sell this product?

D. Only the “Reasonable Manufacturer Standard” Can Respond When a Manufacturer Withholds Improved Pharmaceutical Products from the Market

Proposed section 8(c) has a further weakness, as it does not address the situation where a manufacturer has a clearly preferable product available, but chooses to withhold it and markets an inferior one instead. This weakness makes it more likely that courts will reject section 8(c) as unworkable. Under proposed section 8(c), when a product on the market is the drug of choice for at least one group of patients, that is, the best drug or device available to treat them, the product should not be subject to claims of defective design, no matter what the side effects are. Courts may well accept the policy arguments that drive this standard.

Moreover, courts are likely to agree with how this new rule works when two or more products on the market are designed to treat a patient class, but have clearly disparate benefits and levels of safety. If the safer drug is clearly preferable to the one in question under all

329 See Henkel, supra note 276, at 47-48 (noting that profitability considerations are essential to the pharmaceutical producer’s decision whether or not to undertake to develop and market a new drug).
331 See Schwartz, supra note 7, at 1385 (arguing that budget constraints have left the FDA inadequately staffed, and, as a result, the tort system functions “as a greater deterrent to unsafe practices than the regulatory system itself”).
332 See Calabresi & Cooper, supra note 129, at 865-66 (“[T]he [proposed] Restatement’s test would impose liability only for harms that were reasonably foreseeable.”).
333 See supra notes 217-31 and accompanying text.
334 This analysis assumes, of course, that the manufacturer sufficiently warned the prescribing physician of the product’s known dangers. See Barrett, supra note 11, at 1322-23.
335 See id. at 1297 (“[T]here is a strong possibility that [section 8(c)] will provide a resolution to the controversy over the underlying policy concerns of strict liability and comment k.”).
circumstances, without being prohibitively costly, then clearly no reasonable manufacturer would have placed it on the market. But what about the case in which there is only one drug available on the market for an identifiable group of patients, yet the plaintiff learns through discovery that the manufacturer had in fact determined how to make the product safer, but decided not to? Imagine that just before marketing the product in question, the manufacturer discovered a new, much safer one, but because it had invested so much in the first drug, it decided to keep the new one secret until it had recouped its costs. Under the proposed language of section 8(c), because the drug that caused the injury was the only one available, the reasonable physician had no choice but to prescribe it.

The manufacturer may have perfectly reasonable safety explanations for withholding substantially improved drugs and devices. However, a company might choose to delay producing a superior product for a variety of profit-motivated reasons. For example, a company might desire to “sit” on a new or improved product when the one it already is currently marketing has been heavily advertised, especially if the better product is more expensive to produce, or if the revelation of the improvement might somehow tarnish the image of the product currently on the market. It is conceivable that a researcher toiling away in an isolated facility might come up with a safer form of product X, only to find that the sponsor, the holder of the patent through a research sponsorship deal, squelches any word of the development until the “time is right.” Although one hopes that drug companies do not operate in this way, it is evident that, at least

336 That is, it does not fulfill medical science’s requirements for diverse yet similar treatments in order to account for individual differences. See Grabowski, supra note 127, at 7 n.18.
337 Restatement (Third), supra note 1, § 8(c).
338 It would be interesting to see whether courts would allow marketing or profit considerations to count as legally acceptable reasons to withhold substantially better medical products. In the case of non-medical products, the trend has been to disallow such a “reasonableness” defense.
339 For a comparable example, the drug manufacturer Hoechst Marion decided to continue to sell its antihistamine Seldane despite the fact that it came out with an arguably safer equivalent product, Allegra. This occurred despite the FDA’s proposal that the company pull the older product from the market for safety reasons. See Jackman, supra note 326.
340 For researchers, drug company funds can be a major source of income. See Andrea Rock, The Lethal Dangers of the Billion-Dollar Vaccine Business, MONEY, Dec. 1996, at 148, 158-55 (reporting that one influential pediatrician, who previously found that the DPT vaccine was dangerous to a large number of children, but who now regularly defends the actions of vaccine manufacturers against charges of irresponsibility, was the recipient, both directly and indirectly, of approximately $1.2 million dollars in fees and unrestricted research funds from one major DPT manufacturer).
on some occasions, some do.\textsuperscript{341} As it is currently written, section 8(c) does not require a manufacturer who is in litigation, and, thus, subject to discovery, to defend the reasonableness of its actions. No matter what damage it caused, no matter how many fatalities, so long as the product in question was the only one on the U.S. market that could help the class of patients identified, then the fact finder must concede that the reasonable physician would have had no choice but to prescribe it. Even if the manufacturer is responsible for an improved drug not being on the market, it does not have to answer to the jury. Courts are likely to see this outcome as unfair, and may reject section 8(c) on these grounds.

Admittedly, such cases should not be common. Drug companies are subject to a variety of forces that motivate them to produce safer products.\textsuperscript{342} However, given that the FDA’s review of new drugs is limited to their individual safety and efficacy,\textsuperscript{343} it is tempting for manufacturers to target large patient populations with new drugs and devices that pass the FDA’s minimal scrutiny.\textsuperscript{344} If the consumer population is large enough, the producer can profit greatly by convincing a sufficiently large number of physicians (or by directly convincing the patients themselves) to use the product, notwithstanding its comparatively lower safety level.\textsuperscript{345} Moreover, the FDA is often reluctant to pull its approval, even when the product in question is much more

\textsuperscript{341} See id. at 150. In recent years, American drug companies have actively kept a safer, more effective DPT vaccine off the market simply because the one they currently produce has a much higher profit margin. According to one researcher,

\begin{quote}
you can produce a much less toxic [DPT vaccine] in very low yields, and I think anyone who has worked on pertussis knows this... What we are really faced with is... going from a vaccine that costs literally cents to produce to one that... is going to cost dollars to produce.
\end{quote}

\textit{Id.} at 153.

\textsuperscript{342} See Garber, \textit{supra} note 2, at 103 (asserting that even without a products liability system, market and other forces would act to force dangerous drugs off the market, “albeit more slowly”).


\textsuperscript{344} See Garber, \textit{supra} note 2, at 165. Garber refers to medical products designed for large patient populations and having the potential of generating huge revenues as “blockbusters”:

\begin{quote}
A potential blockbuster has enormous profit potential. The top performers in the industry have achieved $1 billion a year in worldwide sales, and the annual profits associated with such a product may be on the order of one-half this figure. For a product believed to have this kind of profit potential, even a large proportionate reduction in the investment incentive [due to predicted losses associated with the product’s relative danger] is unlikely to deter a company from proceeding.
\end{quote}

\textit{Id.}

\textsuperscript{345} See Rock, \textit{supra} note 340, at 153 (reporting that drug manufacturers pay out huge amounts of money to keep doctors thinking that their products are safe, even when newer, safer ones become available).
Therefore, only manufacturers are able to effectively replace outmoded products with better ones. If injured plaintiffs are denied the opportunity to challenge the reasonableness of the manufacturer’s decision to market, or continue to market, an inferior product, the result is likely to be perceived as unjust. A similar sense of injustice inherent in the argument that the manufacturer’s desire for huge profits can justify its disregard for safety concerns may have led the majority of courts to move away from granting blanket immunity for drug design claims.347

E. Failure to Convince the Jurisdictions to Adopt a Uniform Approach to Drug Design Defect Claims Will Result in Inconsistencies, Inequities, and Confusion

Given that the majority of courts are moving away from blanket immunity for drug design defect claims,348 it seems to be in everyone’s interest to settle upon a newer and more equitable standard. Patient groups need new pharmaceutical products. Meanwhile, pharmaceutical producers need to assess liability risks before embarking upon the research and development of new products.349 Failure to do so is likely to give rise to inconsistent results and confusion across the jurisdictions, resulting in drug manufacturers engaging in strategic behavior on a state-by-state basis.350

The current state of comparative negligence jurisprudence illustrates some of the problems that could result if the approach to drug design defect claims varies from state to state. Historically known as contributory negligence, the common-law rule regarding plaintiff’s

346 See generally id. (reporting that drug companies continue to market the relatively dangerous polio vaccine despite the existence of a safer acellular version).
347 See, e.g., Barrett, supra note 11, at 1314 (“The vast majority of jurisdictions that have considered the issue have cast aside the ‘blanket immunity’ of comment k . . . .”).
348 See id.
349 See Garber, supra note 2, at 159. Garber asserts that:

The incentive to invest in clinical trials is even more sensitive to liability risks than the incentives to introduce a product that has already been developed. For example, unusual liability risks as discouraging as a 1 percent annual probability of product failure reduces the incentive to invest in clinical trials by about 15 percent. Unusual liability risks as discouraging as a 4 percent probability of product failure reduce this incentive by about one-half.

Garber’s analysis is based on the assumption that comment k serves to block most pharmaceutical product claims. Id. at 39 (“[P]rescription drugs and biologicals are not often subjected to liability for design defects.”). However, Garber warns that “if the liability environment were very different from the prevailing one, the market and regulatory environments might differ as a result.” Id. at 78. Given the general risk aversion of most pharmaceutical makers, an unsettled design liability environment is very likely to cause them to develop fewer new drugs and devices, and to focus instead on producing and promoting already-existing ones. Cf. id. at 159.
350 See id.
fault was simple: if the finder of fact assigned any amount of fault to the plaintiff, he was totally barred from recovery. The injustice of this rule became apparent to modern jurists, for it allowed even the most negligent of defendants to escape all liability simply by proving that the injured plaintiff had also been at fault, however slightly. Courts and legislatures began to agitate for a more equitable approach to dividing the fault between plaintiffs and defendants.

Although an absolute bar on recovery may seem unfair, it is difficult to establish an alternate rule that all will agree is a desirable replacement. In the case of contributory negligence, various jurisdictions came up with disparate replacements. The modern rules that have developed to replace contributory negligence fall under the general heading of "comparative negligence." Some states apply a so-called "pure" form of contributory negligence, in which the finder of fact determines the amount of damage caused by the defendant’s action or defective product, then reduces that amount by the percentage of fault it assigns to the plaintiff for the injury. Other jurisdictions follow a variety of "modified" forms of contributory negligence. In some of these jurisdictions, the plaintiff’s negligence must be less than the defendant’s in order for the plaintiff

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351 See VICTOR E. SCHWARTZ, COMPARATIVE NEGLIGENCE § 1.2, at 3-4 (2d ed. 1986) (noting that the comparative fault rule was firmly established in the case of Butterfield v. Forrester, 11 East 60, 103 Eng. Rep. 926 (1809)). According to Schwartz, In [Butterfield, the] plaintiff was injured by a fall from his horse when, riding at a fast pace, he ran into an obstruction left in the road by defendant. The court held that, under these circumstances, plaintiff could not recover. Butterfield became the principal authority for the contributory negligence rule—that when a plaintiff’s negligence contributes to the happening of an accident, he cannot recover damages from a defendant who negligently injures him. Id. Schwartz goes on to report that Butterfield “was given full and broad application in the nineteenth and occasionally in the twentieth century. In fact, in 1854 a Pennsylvania judge called the contributory negligence defense a ‘rule from time immemorial’ and ventured to guess that it was ‘not likely to be changed in all time to come.’” Id. § 1.2, at 4 (footnotes omitted).

352 See id.

353 See id. (“It is only recently that jurisdictions in this country have in substantial numbers joined the trend [away from contributory negligence and toward comparative negligence]. However, the contributory negligence rule has been on the decline in most states for much of the twentieth century . . . .”) (footnotes omitted).

354 See id. §§ 1.3-6, at 9-27 (tracing the history of transformation from contributory negligence to comparative negligence in the United States).

355 See id. § 2.1, at 29 (“The term ‘comparative negligence’ [may] be used to describe any system of law that by some method . . . apportions costs of an accident, at least in part, on the basis of the relative fault of the responsible parties.”). Six states and the District of Columbia still follow the contributory negligence rule. See Carol A. Mutter, Moving to Comparative Negligence in an Era of Tort Reform: Decisions for Tennesseans, 57 TENN. L. REV. 199, 200 (1990) (“The doctrine of comparative negligence . . . has supplanted contributory negligence in forty-four states.”) (footnote omitted).

to recover. This is known as the "forty-nine percent rule,"357 for if the plaintiff’s fault is equal to or greater than the defendant’s fault, the plaintiff recovers nothing.358 However, other jurisdictions apply a "fifty percent rule" under which plaintiffs whose fault is found to be equal to that of the defendant may still recover.359

Different comparative negligence rules can result in very different results in similar cases, depending on the state in which they are heard. In pure comparative fault states, even very negligent plaintiffs can hope for at least some amount of damages; if the amount of damages set by the jury is high, even the collection of a small percentage can mean that a very negligent plaintiff can still collect a large sum of money.360 In addition, the different approaches to comparative negligence taken by the various jurisdictions have caused uncertainty and various strategic behavior from state to state.361

The current movement away from the blanket immunity rule for drug design claims is similar in nature to the movement away from contributory negligence in that both were prompted by concerns of fairness to injured plaintiffs.362 However, if the rule regarding drug and medical device design-defect claims is allowed to develop in the same hodge-podge manner that has been the hallmark of contributory negligence,363 confusion and potentially detrimental variations in behavior are likely to result. The frequency of claims and judgment amounts are likely to vary from jurisdiction to jurisdiction. Given pharmaceutical makers’ high level of sensitivity to increases in poten-

357 See id. § 2.1 (2d ed. 1986 & Supp. 1993) (reporting that 12 states have adopted the 49% rule).
358 See id.
359 See id. § 2.1 (2d ed. 1986 & Supp. 1993) (noting that so far 20 states have adopted the 50% rule).
360 See Mutter, supra note 355, at 251-52 (reporting a number of cases in which plaintiffs responsible for significantly more than 50 percent of the accidents that led to their injury nonetheless were granted awards, ranging from $3,500 (for a plaintiff adjudicated to be 99% responsible for his injuries) to $1.1 million (for a plaintiff found to be 70% responsible for the accident that caused his injuries)).
361 See id. at 241-42 (citing a number of studies that have found the changeover from contributory negligence to comparative negligence to have been responsible for an increase in claims ranging from 6% to 20%, depending on the jurisdiction studied).
362 See SCHWARTZ, supra note 351, § 1.4, at 10 (asserting that the contributory negligence defense was favored by American courts interested in protecting burgeoning industries, but that “the very harsh treatment of injured [plaintiffs] by the [contributory] fault system . . . led to demands for abolition or modification of the system”). Cf. Barrett, supra note 11, at 1325 (arguing that most jurisdictions have rejected blanket immunity for drug design defect claims because the “‘blanket immunity’ test is overreaching in its efforts to protect the manufacturer,” and that “[Blanket immunity] contradicts the entire reasoning behind strict liability which was designed to protect the consumer”).
363 See supra notes 351-61 and accompanying text.
tial liability, manufacturers are likely to either (1) avoid investing in the long, expensive process of new drug development, focusing instead on improving products already available in profitable markets, and/or (2) market new products only in jurisdictions offering extended protection of designs, and refuse to sell the same products in "risky" jurisdictions with unsettled or more liberal rules. Moreover, manufacturers may lobby for increased protection from design claims from the legislatures of states with large patient populations, and may leave smaller states to their own devices. As a result, patients with certain afflictions may find it necessary to travel thousands of miles to receive more effective, albeit more risky, treatments. This is not a future that the ALI is likely to favor.

Thus, in promulgating section 8(c) of the Restatement (Third), the ALI seems to be taking steps to avoid the comparative-negligence like chaos that is likely to result from the adoption of varied approaches to drug design defects. However, the extent to which the jurisdictions are willing to accept this proposed standard is the extent to which American jurisprudence will avoid comparative-negligence like confusion and contradiction. As mentioned above, the "reasonable health care provider" language of section 8(c) may prove to be problematic for some judges, who may reject the proposed standard. Instead, the ALI should adopt a "reasonable prescription products manufacturer" standard, one that protects manufacturers from design liability for injury caused by prescription products, so long as they can show that marketing the product was reasonable by medical standards—in other words, it was the product of choice for at least one identifiable group of patients.

Conclusion

Products liability law evolves and changes. Even the most stalwart exemptions are subject to revision, for example, section 402A's com-

364 See Garber, supra note 2, at 159-62 (asserting that even slight increases in the risk of potential liability can cause pharmaceutical producers to drastically scale back production and marketing efforts).
365 See Cohn, supra note 272, at 2-3 ("FDA estimates that, on average, it takes eight and a half years to study and test a new drug . . . . Drug companies spend $359 million, on average, to develop a new drug . . . .")
366 See Garber, supra note 2, at 164 (asserting that even slight risks of increased liability "can deter R&D investments in products with limited profit prospects"). Moreover, "[e]ven very substantial liability risks may be insufficient to deter investments in developing products that are viewed as potential blockbusters." Id. at 165.
367 See id. at 159 (reporting that even moderate liability risks can "reduce [the incentive to invest in clinical trials] by about one-half").
368 See supra Part IVA-B.
369 See Brown v. Superior Court, 751 P.2d 470, 478 (Cal. 1988) ("[T]here is an important distinction between prescription drugs and other products such as construction machinery . . . .") (citations omitted).
ment k. No longer is blanket immunity the norm for prescription drugs and devices.\textsuperscript{370} The courts are now struggling to find a fair replacement for comment k, one that ensures a thriving pharmaceuticals market yet also allows the injured plaintiff to challenge the reasonableness of the product's presence in the market. Indeed, given FDA regulation and market forces, one might conclude that most medical products on the market are as safe as possible, that they cause more good than they do harm. Yet in light of the enormous amounts of money at stake in the global pharmaceutical industry,\textsuperscript{371} manufacturers are inevitably tempted to market products that are clearly less effective and more dangerous than others. Manufacturers must be held accountable for the decision to market products with no comparative therapeutic value.

Into the fray steps the ALI with section 8(c) of its proposed Restatement (Third). The approach of proposed section 8(c) is to allow juries evaluating an injurious prescription drug or device to put themselves in the shoes of the reasonable physician, with reasonableness defined as a willingness to make this drug available if there is at least one identifiable group of patients for whom it is the best product, even if that “group” is composed of one patient. The proposed rule has been called “the best approach to resolving [the debate] surrounding strict liability exceptions for prescription drugs.”\textsuperscript{372} Proposed section 8(c) is an equitable standard, because it allows individuals to bring drug and medical device design claims, while at the same time satisfying the public policy goal of ensuring that therapeutic products will remain available to those who need them. A plaintiff can win on a design defect claim only if she can show that \textit{no identifiable patient(s)} needed the product that caused her injury. The problem lies not with the proposed standard’s policy, but rather with its use of the “reasonable health care provider” language. The reasonable doctor is captive to the market, and can only prescribe what is currently available. The reasonable physician is not in a position to make products safer, to invest money to accelerate research of promising replacements, or to amass data on the product. Reasonable doctors do what the reference materials compiled by drug and medical device manufacturers tell them to do.\textsuperscript{373} The responsibility for gaug-

\textsuperscript{370} See supra Part II.B.
\textsuperscript{371} For example, in the world’s ten largest markets, sales in the first three quarters of 1996 alone amounted to over 100 billion dollars. See Daniel Green, Pharmaceutical Sales Rise in World’s Biggest Markets, FIN. TIMES (London), Nov. 25, 1996, at 5.
\textsuperscript{372} Barrett, supra note 11, at 1327.
ing the market and the relative need for its products rests squarely upon the manufacturer's shoulders.

For this reason, the ALI should adopt the "reasonable manufacturer" approach proposed in Tobin v. Astra Pharmaceutical Products, Inc.974 Failing this, the courts should read this language into section 8(c) and instruct the finder of fact in such cases to consider whether the manufacturer acted reasonably, given the special circumstances of the medical marketplace. This approach will function to protect vital pharmaceutical products, while simultaneously holding manufacturers accountable for marketing unreasonably unsafe products that offer neither essential variety nor any discernable improvement over safer, existing products. If the courts do not choose to follow this fair and equitable modification of proposed section 8(c), manufacturers and patients are likely to find themselves in the unsure, chaotic world of jurisdiction-by-jurisdiction rule. In such a world, the availability of prescription products will vary from state to state, depending on the approach taken by the courts of the locale. In such a regime, there are few winners.976 The list of losers will undoubtedly include both the manufacturers of pharmaceutical products as well as the sick and suffering individuals who may be denied the treatment they so critically need.977

Jeffrey D. Winchester

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974 993 F.2d 528, 536 (6th Cir. 1993).
975 See supra note 127.
976 Of course, the obvious winners in such a regime always include the lawyers on both sides.
977 See Brown v. Superior Court, 751 P.2d 470, 478-79 (Cal. 1988) ("[T]he broader public interest in the availability of drugs at an affordable price must be considered in deciding the appropriate standard of liability for injuries resulting from their use.").
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