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# Essay

## Drug Designs Are Different

James A. Henderson, Jr.<sup>†</sup> and Aaron D. Twerski<sup>††</sup>

In an essay published in this Journal entitled *Is There a Design Defect in the Restatement (Third) of Torts: Products Liability?*, George Conk criticizes the American Law Institute and the Reporters of the new *Restatement* for immunizing prescription drug manufacturers from liability for defective design.<sup>1</sup> In doing so, he joins other commentators who have been critical of this aspect of the new *Restatement*,<sup>2</sup> upon which we served

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

2. E.g., Richard L. Cupp, Jr., *The Continuing Search for Proper Perspective: Whose Reasonableness Should Be at Issue in a Prescription Product Design Defect Analysis?*, 30 SETON HALL L. REV. 233 (1999) [hereinafter Cupp, *The Continuing Search*]; 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 (1994) [hereinafter Cupp, *Rethinking Conscious Design Liability*]; Jerry J. Phillips, *The Unreasonably Unsafe Product and Strict Liability*, 72 CHI.-KENT L. REV. 129, 130 (1996); Teresa Moran Schwartz, *Prescription Products and the Proposed Restatement (Third)*, 61 TENN. L. REV. 1357, 1378-85 (1994) [hereinafter Schwartz, *Prescription Products*]; Teresa Moran Schwartz, *Regulatory Standards and Products Liability: Striking the Right Balance Between the Two*, 30 U. MICH. J.L. REFORM 431, 459 (1997); Frank J. Vandall, *Constructing a Roof Before the Foundation Is Prepared: The Restatement (Third) of Torts: Products Liability Section 2(b) Design Defect*, 30 U. MICH. J.L. REFORM, 261, 270 (1997); Michael J. Wagner & Laura L. Peterson, *The New Restatement (Third) of Torts—Shelter from the Product Liability Storm for Pharmaceutical Companies and Medical Device Manufacturers?*, 53 FOOD & DRUG L.J. 225, 232-34 (1998). Other articles support the *Restatement (Third)* position. See William A. Dreier, *Manufacturers' Liability for Drugs and Medical Devices Under the Restatement (Third) of Torts: Products Liability*, 30 SETON HALL L. REV. 258 (1999) (agreeing with the general thrust of section 6(c) of the RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY (1998) [hereinafter RESTATEMENT (THIRD)] but suggesting

as Reporters. Because Conk claims to have history on his side, and because this most recent criticism may prove to be disproportionately influential, we offer a response both to him and to other critics.

Conk praises the general product-design standard adopted by the *Restatement*, which predicates liability for almost all nonprescription products upon proof that a reasonable alternative design could have been adopted that would have avoided or reduced harm to the plaintiff.<sup>3</sup> However, he criticizes the *Restatement's* provisions relating to defective drug design for not applying the same "reasonable alternative" standard. (The *Restatement* deems a drug defective in design only if it would not be prescribed for any class of patients.) In his view, the *Restatement* test for defective drug design would protect prescription drug manufacturers from liability even if a plaintiff could show that an alternatively designed drug would have avoided unnecessary risk.<sup>4</sup> Conk argues that during the late 1970s and early 1980s, the absence of a reasonable alternative design standard for prescription drugs allowed distributors of blood to escape liability for supplying blood products contaminated with the hepatitis C virus and that the *Restatement* test would condone such noxious results in the future.<sup>5</sup> Claiming this regrettable history as support for his position, Conk urges that the defectiveness of prescription drug designs should be determined by the same standard as is generally applicable to nonprescription products.<sup>6</sup>

Our critics have misread the prescription drug design provision of the new *Restatement*.<sup>7</sup> It does not immunize prescription drug manufacturers for defective design. Plaintiffs may establish defectiveness by showing that safer alternative drugs were available on the market that reasonable health care providers would have prescribed in place of a defendant's drug for all classes of patients. Moreover, Conk's premise that the blood cases in the 1980s would have been decided differently if blood products had been subject to the reasonable alternative design rule of the new *Restatement* is false. Finally, the purportedly pro-plaintiff approach he advocates, which would require courts to deny classes of patients access to a particular drug that provides them unique benefits in order to protect other patients from the risks of misprescription by negligent physicians, is both unfair and

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several instances when a case might be made for alternative drug design); Michael D. Green, *Prescription Drugs, Alternative Designs, and the Restatement (Third): Preliminary Reflections*, 30 SETON HALL L. REV. 207 (1999) (same).

3. Conk, *supra* note 1, at 1087-88 (stating that section 2(b) of the RESTATEMENT (THIRD), *supra* note 2, which provides that a product is defective in design "when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design," successfully draws on risk-utility analysis).

4. *Id.* at 1089.

5. *Id.* at 1112.

6. *Id.* at 1118-32.

7. *See id.* at 1102; Schwartz, *Prescription Products*, *supra* note 2, at 1384.

inefficient. In short, the *Restatement* is quite correct in treating prescription drug designs differently from other product designs, although it does not treat them as differently as Conk supposes. Drug designs *are* different from other product designs, and they deserve different treatment under the new *Restatement*.

Part I of this Essay summarizes Conk's thesis, including his interpretation of the new *Restatement*. Part II identifies significant errors in Conk's critique: He has read the *Restatement* incorrectly, and his reliance on the blood cases is misplaced. Part III explains and justifies the substantive differences between the new *Restatement's* treatment of prescription drug design and its treatment of defective product design generally. These differences include the *Restatement's* refusal to allow courts to consider alternative, safer prescription products that have not yet received FDA approval (under the general design provisions, courts routinely consider not-yet-marketed alternative designs) and its refusal to sacrifice the welfare of one class of patients to enhance the welfare of another class of patients (under the general design provisions, such cross-consumer sacrifices of welfare are routinely condoned). Part III also explains why drug design litigation cannot legitimately be made more plaintiff-friendly by reducing its complexity and why the rule in the new *Restatement* should not significantly reduce manufacturers' incentives to discover new and safer prescription products.

#### I. CONK'S CRITIQUE OF THE NEW *RESTATEMENT* AND HIS SUGGESTED APPROACH TO JUDGING PRESCRIPTION DRUG DESIGN

Conk focuses his critique of the *Restatement* on section 6(c), which sets out the standard to be applied for defective drug design. Section 6(c) provides:

A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.<sup>8</sup>

Conk asserts that, under section 6(c), "if the medical product does more harm than good for at least one class of users, it will not be considered defective. This is true even if the product *unnecessarily* causes harm, in the sense that there is a feasible safer alternative design."<sup>9</sup> By his account,

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8. *RESTATEMENT (THIRD)*, *supra* note 2, § 6(c).

9. Conk, *supra* note 1, at 1102.

section 6(c) prevents a plaintiff from proving not only that a drug manufacturer was negligent in failing to develop an alternative safer drug and achieve timely FDA approval for its marketing, but also that an FDA-approved drug already on the market is a reasonable, safer alternative to the FDA-approved drug that harmed the plaintiff. Thus, Conk reads the *Restatement* language in section 6(c) to mean that, as long as a prescription drug standing alone provides a net benefit to a class of users, the drug cannot be found to be defectively designed.

The new *Restatement* deals with nonprescription product designs in section 2(b), which provides that a product is defective in design "when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design . . . and the omission of the alternative design renders the product not reasonably safe."<sup>10</sup> In establishing that the defendant's product design was not reasonably safe when distributed, the plaintiff proves that a reasonable alternative design (RAD) could have been conceived, developed, and marketed that would, at acceptable cost, have helped the plaintiff.<sup>11</sup> Conk argues that this RAD-based standard, generally applicable to nonprescription products, should also apply to prescription drugs and medical devices.<sup>12</sup> Were that general design standard applied to prescription products, a plaintiff would be free to prove that a drug manufacturer was negligent for failing to develop and market a drug that would have provided the same or greater benefits with less risk of harm.<sup>13</sup> In the event that no RAD can be established, Conk urges application of a "manifestly unreasonable design" standard. When the sum of the product's known risks at the time of sale outweighs its aggregate utility such that no reasonable manufacturer would have marketed the drug, he insists that liability for defective drug design should attach.<sup>14</sup>

Conk supports his argument that prescription drug designs are the same as other product designs, and thus should be measured by the general RAD-based standard, with what he views to be the unfortunate results of the litigation arising from use of hepatitis-infected blood during the late 1970s and early 1980s.<sup>15</sup> In that time frame, hemophiliacs who required blood plasma ran the risk of being transfused with blood contaminated with the hepatitis C virus. Later, when it became clear that AIDS is a blood-borne disease and public pressure mounted, manufacturers developed a heat-treatment process that eradicated HIV and hepatitis viruses from blood. If

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10. RESTATEMENT (THIRD), *supra* note 2, § 2(b).

11. *Id.* § 2(b) cmt. d.

12. Conk, *supra* note 1, at 1118.

13. *Id.*

14. *Id.* at 1118-19.

15. *Id.* at 1107-11.

the same methods had been implemented earlier, Conk insists, the hepatitis epidemic among hemophiliacs could have been avoided. In his view, hemophiliacs were barred from recovering for their injuries because the courts failed to adopt a RAD-based design standard such as that contained in section 2(b).<sup>16</sup> Conk concludes that the test for design defect embodied in section 6(c) will replicate such unfortunate results in the future, and courts should, for that reason, reject it.<sup>17</sup>

## II. CONK'S CRITIQUE CONTAINS SIGNIFICANT ERRORS

Before proceeding to show the errors of Conk's ways, we must clear the air. As what follows makes clear, some of the relevant language in both the blackletter of, and comments for, section 6(c) is ambiguous, and the authors, as retired Reporters, have no more standing than anyone else—including George Conk—to opine regarding the *Restatement's* meaning. Conk's reading of section 6(c) is rational and deserves a considered response. We submit that, when one objectively considers the relevant data relating to the new *Restatement's* meaning, Conk has read it wrong. We are as much to blame as he for the confusion; we should have been clearer in the relevant phraseology. In any event, even if we succeed in showing that our interpretation is correct, significant substantive differences between the true meaning of section 6(c) and Conk's preferred approach to drug design liability will remain to be considered in subsequent discussions.

### A. *Contrary to Conk's Reading, the New Restatement Does Allow Courts To Consider Already-Marketed Alternatives in Assessing a Drug Design's Defectiveness*

Conk reads the prescription drug design provision in section 6(c) to prevent plaintiffs from establishing defect by showing that a safer alternative to a defendant's drug was available. We emphatically disagree with Conk's insistence that section 6(c) does not allow any alleged RAD to be considered by the court in determining whether a prescription product's design is defective. The key to understanding the meaning of section 6(c) on this point lies in its explicit reliance on the construct of whether "reasonable health-care providers" would knowingly "prescribe the drug or medical device for any class of patients."<sup>18</sup> Obviously, such a reasonable

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16. *Id.* at 1112.

17. *Id.* at 1132-33.

18. RESTATEMENT (THIRD), *supra* note 2, § 6(c). The choice of "reasonable health-care provider," rather than "reasonable manufacturer," as the perspective from which to determine whether a drug serves to benefit any class of patients was made to objectify the test and to cleanse it from any sense of partisanship. Reasonable health-care providers have no stake whatsoever in

provider should consider available alternative drugs in deciding which drug, if any, to prescribe. Indeed, that may be said to be the essence of the healer's craft—assessing and comparing all available courses of medical treatment. Conk's suggestion that the new *Restatement* requires the hypothetical prescribing physician to focus exclusively on the risks and benefits of a given drug in isolation, wearing blinders that prevent consideration of other readily available drugs, attributes a meaning to section 6(c) that would require that physician to violate her Hippocratic oath.

Admittedly, section 6(c)'s description of the risks of harm that would support a finding of defectiveness as "great in relation to [the drug's] therapeutic benefits" might lead, at first blush, to Conk's conclusion. That is, this language might suggest that the drug is to be judged on its own bottom, in isolation from all other possible alternatives. And comment *f* appears to reinforce this reading with its first sentence: "Subsection (c) reflects the judgment that, as long as a given drug or device provides net benefits for a class of patients, it should be available to them . . ."<sup>19</sup> But the admittedly ambiguous phrase "provides net benefits" must, in fairness, be read to refer to "net benefits in light of available alternatives." This reading is made clear by the second sentence in comment *f*: "Learned intermediaries must generally be relied upon to see that the right drugs and devices reach the right patients."<sup>20</sup> This second sentence conjures the appropriate image of responsible prescribing physicians deciding what is best for their patients among available alternatives—not the distorted image that Conk reads into section 6(c) of a health-care provider acting with blinders firmly in place.

Our reading of section 6(c) is bolstered by the reality that, if Conk's contrary reading were correct—if the design standard under section 6(c) were whether, judged in isolation, a given drug benefited any class of patients—then there would be no reason to couch the standard in terms of what a reasonable physician would do for her patients. Section 6(c) could just as easily have said "a prescription drug or medical device is defective if, on balance, it benefits no class of patients." In fact, section 6(c) must have been intended to allow reasonable alternatives to be considered by the hypothetical prescribing physicians, because the blinders Conk reads into

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whether a drug should remain on the market. Drug manufacturers have a far greater stake in whether a drug truly benefits any class of patients. Professor Richard L. Cupp, Jr., in a recent article, argues that physicians often continue to prescribe drugs with which they are familiar even when safer drugs are available. Cupp, *The Continuing Search*, *supra* note 2, at 234-38. Cupp fails to appreciate that the "reasonable health-care provider" test, in most circumstances, provides far greater protection for plaintiffs by eliminating any possible pro-manufacturer bias from the test for liability.

19. RESTATEMENT (THIRD), *supra* note 2, § 6 cmt. f.

20. *Id.*

section 6(c), by forcing those physicians needlessly to harm many of their hypothetical patients, would otherwise constitute a gratuitous insult to the medical profession.

That the drafters of section 6(c) should not be read to have intended what Conk reads into that section is clear when its language and comments are placed in the context of contemporary analyses of drug design liability written and published by the drafters. Thus, the Reporters' note to section 6, published along with the final version of the *Restatement*, discusses several reported judicial decisions that the Reporters insist provide support for the position in section 6(c).<sup>21</sup> In at least two of those decisions, the courts compared defendants' drugs with alternative drugs approved by the FDA and available to the prescribing physician.<sup>22</sup> These considerations regarding alternative designs are manifest in the Reporters' discussion of these cases. No one reading these published notes could mistake the meaning that the Reporters intended section 6(c) to convey—that available alternative drugs are to be considered in determining whether an allegedly defective drug design provided net benefits to any class of patients.

Another contemporaneously published analysis of section 6(c), external to the *Restatement* but referred to repeatedly by Conk in interpreting the meaning of that provision, is Professor Henderson's article in the *Rutgers Law Review*, published while the *Restatement* project was in progress.<sup>23</sup> To explain and defend an earlier version of what finally appeared as section 6(c), Henderson employs an example in which an injured plaintiff relies on the availability of a safer alternative to prove that one type of breast implant design is defective.<sup>24</sup> Although Henderson defends the accused implant as nondefective as a matter of law on the ground that it provides a class of patients—those who especially value the aesthetics provided by a softer, more natural prosthesis—with an important benefit compared with the alternative, two points are unmistakably clear. First, Henderson explicitly assumes throughout his analysis that alternative prescription product designs that have received FDA approval are properly considered under section 6(c);<sup>25</sup> and second, he implicitly assumes that if the alternative implant design were better for all classes of patients, including those who

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21. *Id.* § 6 cmt. f Reporters' note.

22. See *Williams v. Ciba-Geigy Corp.*, 686 F. Supp. 573, 578 (W.D. La.), *aff'd*, 864 F.2d 789 (5th Cir. 1988); *Ortho Pharm. Corp. v. Heath*, 722 P.2d 410, 416 (Colo. 1986).

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

24. *Id.* at 484.

25. *Id.* at 482-83. The author considers the possibility that plaintiffs can always get medical experts to testify falsely that a new alternative drug on the market renders the defendant's drug obsolete for all classes of patients. The author concludes that testimony about safer, already-marketed alternatives is appropriate under section 6(c), but that the cynicism about easy availability of false testimony is uncalled for. *Id.*



value aesthetics, the accused design would be defective.<sup>26</sup> Conk refers to Henderson's article repeatedly, and yet he misses its clear import for the issue at hand.

It follows from the foregoing exposition of the meaning of section 6(c) that it does allow plaintiffs to condemn as defective prescription product designs based on proof of a RAD. Conk's criticism of section 6(c) for ruling out any such proof is, therefore, in error. But inasmuch as section 6(c) does not impose the same RAD-based standard as does the general design defect provision in section 2(b), his criticism retains vitality and deserves further consideration. Section 6(c)'s version of RAD departs from section 2(b) in two important respects. The first relates to the sources upon which plaintiffs may rely. Under section 6(c), plaintiffs relying on a RAD are limited to alternative drugs or medical devices actually approved by the FDA, marketed by manufacturers, and available to be prescribed by health-care providers at the time the plaintiff's physician prescribed the defendant's drug. In contrast, if section 2(b) applied to prescription products, plaintiffs would be able, in appropriate cases, to prove that the defendant could have and should have developed and marketed a safer alternative, even if none had actually been developed. We address this difference in Part III.

The second important difference between the *Restatement's* treatments of defective product design generally and defective prescription drug design in particular relates not to the sources of the potential RADs from which plaintiffs may draw, but to the analytical power wielded by the RAD once its availability has been established. Under the general design standard in section 2(b), a RAD that provides an overall increase in safety may condemn a defendant's design as defective even if the defendant's design would clearly and rationally be preferred by one or more classes of users or consumers. Under the rule in section 2(b), if the omission of the RAD renders a defendant's product not reasonably safe, the welfare of those classes of consumers who benefit from the defendant's design are sacrificed to the greater welfare of the greater number of consumers who are exposed to unreasonable risk by the same design.<sup>27</sup> In contrast, a RAD under section 6(c) condemns a given drug as defectively designed only if the RAD provides a net benefit to all classes of users. Under the prescription drug design provision, disadvantaging one or more classes of patients by denying them a particular drug or medical device is never warranted simply because

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26. See *id.* at 485-86. The author assumes that if the defendant's implant were comparatively inferior for all patients, it would be defective. His conclusion of nondefectiveness is clearly premised on the defendant's implant being preferable for many women when compared with the less aesthetically pleasing alternative, as well as the suggestion that the defendant's implant would be healthier for some. See *id.*

27. See *infra* notes 74-75.

such denial might benefit an even larger number of patients for whom the drug or service might be misprescribed. This difference, like the earlier-described difference relating to the proper sources of RAD upon which plaintiffs may rely, matters a great deal to critics such as George Conk who insist that the RAD-based standard in section 2(b) should apply to all products, including prescription drugs and medical devices.<sup>28</sup> We take up this issue as well in Part III. In the Section that follows, we demonstrate that the litigation involving blood products in the 1980s does not support Conk's thesis.

*B. Conk's Argument from Precedent Is Wrong: The Blood Hepatitis Cases Do Not Support His Conclusions*

A centerpiece of Conk's argument that the *Restatement* should adopt a RAD-based standard for prescription drugs and medical devices is that the refusal of courts to adopt such a standard was responsible for the failure of hemophiliacs to recover for injuries suffered as a result of blood transfusions during the late 1970s and early 1980s with hepatitis-infected blood.<sup>29</sup> He argues that commercial providers who saw the possibility of using heat pasteurization to kill viruses in blood products were researching blood-decontamination methods.<sup>30</sup> Until decontaminated blood became available, however, physicians ordered transfusions for hemophiliacs with blood that they knew might be contaminated with hepatitis because they had no safer, decontaminated alternatives available. Under section 6(c), Conk argues, the blood providers would not be held liable for the resulting hepatitis, because, given that decontaminated blood was unavailable, reasonable medical providers were correct in prescribing untreated, possibly contaminated blood for hemophiliacs.<sup>31</sup> Since only untreated blood was available, such blood was better for patients than no blood at all. Even so, Conk argues, plaintiffs should have been allowed to show that safe blood could have been made available by the exercise of reasonable care on the part of blood providers. According to Conk, "[i]f the alternative design test of section 2 had been applicable to the blood manufacturers during this period, courts might reasonably have concluded that the entire industry was negligent in its failure to develop and adopt alternative safer designs in a timely manner."<sup>32</sup>

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28. *E.g.*, Conk, *supra* note 1, at 1118; Cupp, *Rethinking Conscious Design Liability*, *supra* note 2, at 103, 105-10; Schwartz, *Prescription Products*, *supra* note 2, at 1384; Vandall, *supra* note 2, at 271.

29. Conk, *supra* note 1, at 1110-18.

30. *Id.* at 1109.

31. *Id.* at 1112.

32. *Id.*

Before reaching the merits of Conk's argument, some conceptual confusion must be eliminated. The plaintiffs in the blood cases did not claim that the blood products that harmed them were defectively designed, and therefore section 2(b) would not have been relevant. Instead, the contaminants that caused their harm constituted manufacturing defects for which manufacturers are generally held strictly liable under section 2(a) of the new *Restatement*.<sup>33</sup> Under section 2(a), a plaintiff need not even establish a RAD—proof that a manufacturing defect caused a plaintiff's harm triggers strict liability.<sup>34</sup> Thus, when Conk argues that application of the RAD-based design standard in section 2(b) would have produced different outcomes in the blood cases, from a technical standpoint, he is mixing apples with oranges. Technically, section 2(b) and its RAD-based standard do not purport to apply to cases involving manufacturing defects.

Nevertheless, the RAD standard embodied in section 2(b) is not so inapposite in the context of contaminated blood as might at first appear. Special blood-shield statutes immunize blood providers from strict liability,<sup>35</sup> forcing plaintiffs into the unusual position of being required to prove that the providers were negligent in allowing the harmful contaminants to pass through their screening and production processes.<sup>36</sup> To prove such negligence, plaintiffs in the blood cases were required to prove that defendants could have developed an alternative method of decontaminating the blood so as to prevent plaintiffs' harm.<sup>37</sup> This "alternative decontamination method" approach is the functional equivalent of the RAD-based approach in section 2(b), although in the

33. RESTATEMENT (THIRD), *supra* note 2, § 2(a). Strict liability for manufacturing defects is the almost unanimous rule throughout the United States. *See, e.g.,* Caterpillar Tractor Co. v. Beck, 593 P.2d 871, 881 (Alaska 1979); Back v. Wickes Corp., 378 N.E.2d 964, 970 (Mass. 1978); Thibault v. Sears, Roebuck & Co., 395 A.2d 843, 846 (N.H. 1978).

34. *See* RESTATEMENT (THIRD), *supra* note 2, § 2 cmt. a (contrasting manufacturing defects, for which liability attaches even if the manufacturer has acted reasonably, and design defects, for which liability attaches only when the product fails risk-utility balancing).

35. For a comprehensive listing of the states that have enacted blood-shield statutes, see 1 Prod. Liab. Rep. (CCH) ¶ 1630 (2001). Only four jurisdictions do not have blood-shield statutes: the District of Columbia, Minnesota, New Jersey, and Vermont. Two of these jurisdictions have held, as a matter of common law, that the supplier of blood is not subject to strict liability. *Kozup v. Georgetown Univ.*, 851 F.2d 437 (D.C. Cir. 1988); *Brody v. Overlook Hosp.*, 332 A.2d 596 (N.J. 1975).

36. This was the law prior to the adoption of strict liability. *See* RESTATEMENT (SECOND) OF TORTS § 395 (1965); *see also* *Nevels v. Ford Motor Co.*, 439 F.2d 251 (5th Cir. 1971) (holding that a claim that a steering wheel nut was not properly torqued was governed by negligence); *Ford Motor Co. v. Zahn*, 265 F.2d 729 (8th Cir. 1959) (holding that liability for injury caused by a defective ashtray depends on whether the manufacturer exercised reasonable care in inspection).

37. In all the cases brought by hemophiliacs against manufacturers of fractionalized blood products, the plaintiffs alleged that the manufacturers negligently failed to screen donors and failed to utilize heat pasteurization processes to eliminate the hepatitis or HIV virus in time to avoid harm to the plaintiffs. *See, e.g., In re Factor VIII or IX Concentrate Blood Prods. Litig.*, 169 F.R.D. 632, 633-34 (N.D. Ill. 1996); *Wadleigh v. Rhone-Poulenc Rorer, Inc.*, 157 F.R.D. 410, 414, 423 (N.D. Ill. 1994).

blood cases it applied to the design of defendants' methods of production rather than to defendants' products themselves. Under section 2(b), as under the negligence standard applied in the blood cases, manufacturers owe a duty to act reasonably in developing safer designs.<sup>38</sup>

It follows that, when judged on the merits, Conk's argument that the blood cases would have come out better for plaintiffs under the RAD-based standard in section 2(b) collapses of its own weight. Contrary to his assertions, the courts in those cases did not apply an "even possibly contaminated blood is better than no blood" test similar to the one that he claims section 6(c) embraces. Courts in the blood cases did, in fact, apply the functional equivalent of the RAD-based test in section 2(b) that he favors. Thus, by hypothesis, applying section 2(b) to the plaintiffs' claims would have made absolutely no difference whatsoever. Simply stated, the plaintiffs in the blood cases, on which Conk so heavily relies, lost because they were unable to establish through credible proof that an alternative method of decontaminating blood was reasonably available at the time of sale. And the defendants prevailed by establishing that they had implemented the heat-pasteurization process as soon as they were technologically able to do so.<sup>39</sup> Quite clearly, the same outcomes would have been reached, for the very same reasons, even if section 2(b) had somehow been applicable in the blood cases on which Conk's argument against section 6(c) rests.<sup>40</sup>

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38. Comment *d* to section 2 of the *Restatement (Third)* provides that in order to prevail under section 2(b), a plaintiff must establish that at the time of sale or distribution, a reasonable alternative design could have been practically adopted. This RAD standard for design defect is indistinguishable from a common law negligence action when brought against a manufacturer. See, e.g., DAN B. DOBBS, *THE LAW OF TORTS* § 359 (2000) ("The substantial effect [of the *Restatement*] is that manufacturers are strictly liable for manufacturing flaws . . . , but liable only for negligence in design defect cases."); Robert L. Rabin, *Restating the Law: The Dilemmas of Products Liability*, 30 U. MICH. J.L. REFORM 197, 213 (1997) ("Section 2 of the new *Restatement* . . . create[s] what amounts to strict liability for manufacturing defects and negligence liability for design and warning defects . . ."). Indeed, comment *n* to section 2 of the *Restatement (Third)* takes the position that a risk-utility case based on a strict liability theory and one based on negligence are virtually identical and that a jury should not be instructed on both theories.

39. See Conk, *supra* note 1, at 1113-14 (noting that defendants argued that they began the heat-pasteurization process as soon as they were technologically and legally able to do so). Defendants were victorious on this issue. See *Wadleigh*, 157 F.R.D. at 420 (discussing an earlier case in which a jury found for the defendants on the claim that they negligently failed to adopt methods to inactivate viruses); see also *In re Rhone-Poulenc Rorer, Inc.*, 51 F.3d 1293, 1296 (7th Cir. 1995) (denying, in a much-cited opinion by Judge Posner, class certification in a case brought by hemophiliacs against blood manufacturers and noting that of thirteen individual cases brought by plaintiffs, the defendants were victorious in twelve).

40. As noted in the text, Conk's argument that plaintiffs in the blood cases were prevented from proving alternative methods of quality control is inaccurate. Courts did allow plaintiffs to argue that technology could have been developed at an earlier stage that would have eliminated contaminants from blood. See *supra* notes 34 and 37. In Section III.A, we argue that it is beyond the competence of courts to litigate drug designs because to do so would require them to replicate the FDA approval process that stretches over many years and requires animal testing and controlled human clinical trials. Given that the new heat-treatment process required FDA approval, see Conk, *supra* note 1, at 1109, we believe that it is highly questionable whether courts

### III. RESPONDING MORE BROADLY TO CRITICS: THE NEW *RESTATEMENT* HAS CLEARLY GOT IT RIGHT

#### A. *The Restatement Is Correct in Not Allowing Plaintiffs To Argue That a Drug Manufacturer Should Have Developed a Safer Alternative Drug*

The new *Restatement's* refusal to consider not-yet-approved alternative drugs in assessing the defendant's drug design does not rest on judicial deference to the FDA's expertise.<sup>41</sup> As noted earlier, if two FDA-approved drugs are equally efficacious and one presents greater risk of harm, FDA approval does not insulate the manufacturer of the more dangerous drug from liability.<sup>42</sup> Nor does the fact that the warnings accompanying a drug meet FDA guidelines insulate the drug manufacturer from liability for failure to warn.<sup>43</sup> Finally, section 6(c) does not defer to the FDA when the approved drug would not be prescribed by reasonable medical providers to any class of patients.<sup>44</sup> In that circumstance, section 6(c) tacitly admits that

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should have permitted plaintiffs to argue that the technology for removing contaminants should have been developed earlier. However, even if Conk were correct that courts could fairly adjudicate a claim dealing with the availability of a process that would eliminate contaminants, it is a far cry to argue that courts should adjudicate drug design cases. Unlike drug design, which requires prolonged testing to deal with the interaction between drug toxicity and the human body and cannot be replicated in the courtroom, the development of a process for decontaminating blood requires no such testing and is, therefore, more easily subject to judicial review. Thus, it would be error to jump to the conclusion that merely because one might allow plaintiffs to argue for better quality control systems for blood products (even if the new process required FDA approval), plaintiffs should therefore be allowed to argue that an alternative new drug should have been designed and marketed. In any event, common-law claims of design defect involving medical devices remain beyond the capacity of the courts to adjudicate. The preapproval process is lengthy and complex and cannot be replicated by the courts. *See infra* Section III.A.

41. Some courts and commentators have argued that deference to FDA expertise is warranted. *E.g.*, *Grundberg v. Upjohn Co.*, 813 P.2d 89, 98 (Utah 1991) ("Although the FDA may have internal differences of opinion . . . the individuals making the ultimate judgment will have the benefit of years of experience in reviewing . . . products, scientific expertise in the area, and access to the volumes of data [that the FDA] can compel the manufacturers to produce. . . . Nor is the FDA subject to the inherent limitations of the trial process, such as the rules of evidence, restrictions on expert testimony, and scheduling demands."); *see also* David S. Torborg, Comment, *Design Defect Liability and Prescription Drugs: Who's in Charge?*, 59 OHIO ST. L.J. 633, 649 (1998) ("[C]ourts have often noted that the chemical complexity involved in prescription drug design defect cases makes it difficult, if not impossible, for a jury to competently make a determination as to the true benefits and risks posed by the drug.").

42. *See supra* Part II.

43. *RESTATEMENT (THIRD)*, *supra* note 2, §§ 4(b), 6 cmt. d. In the absence of federal preemption, compliance with FDA warnings is not dispositive of liability. Thus, "[f]ailure to instruct or warn is the major basis of liability for manufacturers of prescription drugs and medical devices." *Id.* § 6 cmt. d; *see also* Teresa Moran Schwartz, *The Impact of the New Products Liability Restatement on Prescription Products*, 50 FOOD & DRUG L.J. 399, 405-06 (1995) (noting that the *Restatement (Third)* "adopts the nearly universal common law approach that regulatory standards set minimal standards," such that while "[n]oncompliance renders a product defective," compliance is merely "evidence of non-defectiveness," which does not preclude a finding of defect).

44. *RESTATEMENT (THIRD)*, *supra* note 2, § 6 cmts. a, b; *see also id.* § 6 cmt. f Reporters' note (noting that in *Tobin v. Astra Pharmaceutical Products, Inc.*, 993 F.2d 528 (6th Cir. 1993),

the FDA occasionally makes mistakes by approving worthless drugs that no competent provider would prescribe for any class of patients.<sup>45</sup> Section 6(c)'s refusal to consider not-yet-approved drugs does not rest on unshakeable confidence in the FDA.

Why, then, does the rule in section 6(c) of the *Restatement* refuse to hold liable a manufacturer for not developing a safer alternative drug that would have prevented the plaintiff's injury? Such refusal rests not on deference to the FDA but on an understandable reluctance to allow courts to determine whether a proposed alternative drug would have received FDA approval. Development by a manufacturer of a safer alternative drug does not, by itself, help anyone. For physicians to prescribe such a safer drug, it must reach the market.<sup>46</sup> To reach the market, a prescription drug must be approved by the FDA.<sup>47</sup> Thus, the question of whether a new alternative

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the trial court essentially adopted the *Restatement (Third)* section 6(c) approach and thus "correctly instructed the jury that [a] defective design claim could succeed if [the jury] found that a product manufacturer, aware of the risks, would not have marketed the drug").

45. RESTATEMENT (THIRD), *supra* note 2, § 6 cmt. b (noting that "unqualified deference [to] . . . regulatory mechanisms is considered by a growing number of courts to be unjustified" and that "[a]n approved prescription drug or medical device can present significant risks without corresponding advantages"); see also Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J.L. REFORM 461, 478 (1997) (noting that while the FDA's decisionmaking using "imperfect information in a scientifically complex arena that requires balancing health benefits with the adverse effects . . . is not easy and will result, with some frequency, in incorrect or dubious outcomes[,] . . . the FDA beats anything else available").

46. An estimated three-fourths of all drugs for which drug manufacturers seek marketing approval fail to reach the market due largely to concerns regarding safety and efficacy, as well as undercapitalization of manufacturers. 1 JAMES T. O'REILLY, FOOD & DRUG ADMINISTRATION § 13.11, at 13-65 (1995) (citing FDA ALMANAC FISCAL YEAR 1992, at 32 (1992)).

47. 21 U.S.C. §§ 360c-360e (1994) (requiring approval of all "Class III" drugs and medical devices as defined in § 360c); see also 1 O'REILLY, *supra* note 46, § 13.11 (outlining the federal approval process for new drug applications); Green, *supra* note 45, at 476 (stating that "before a prescription drug may be marketed, regulatory approval is required"). The FDA also requires premarket approval for changes in existing Class III drugs that have received marketing approval when such changes affect "the safety or effectiveness" of the drug or device. 21 C.F.R. § 814.39(a) (2001).

Review of medical *devices*, meaning objects such as shunts, pacemakers, or breast implants, as opposed to *drugs*, may have been streamlined somewhat after several amendments made to the Food, Drug and Cosmetic Act that are embodied in three laws: the Medical Devices Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 575 (codified as amended in scattered sections of 15 U.S.C. and 21 U.S.C.), the Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511 (codified as amended in scattered sections of 15 U.S.C. and 21 U.S.C.), and, especially, the Food and Drug Administration Modernization Act of 1997 (FDAMA), Pub. L. No. 105-115, 111 Stat. 2296 (codified as amended at 21 U.S.C. §§ 301-394 (Supp. 1997)). However, it should be noted that neither the Food, Drug and Cosmetic Act, nor the FDA regulations on drug approval, actually make any distinctions between drugs and devices in their references to the premarket approval process required of any Class III device. *E.g.*, 21 U.S.C. §§ 360c-360e; 21 C.F.R. § 814.39. In fact, both prescription drugs and so-called devices, such as pacemakers, are embodied in the Act's and regulations' requirements for premarket approval of any Class III device; drugs are not referred to separately. *Id.* Moreover, in response largely to the silicone breast implant controversy of the 1990s, the FDA has issued statements that "the fundamental principles underlying the evaluation of any therapeutic intervention should be the same," so that notwithstanding any efforts at streamlining review, evaluation of devices must still uphold the same standards of safety and effectiveness. ROBERT TEMPLE ET AL., FINAL REPORT OF THE COMMITTEE FOR CLINICAL

drug should have been developed by the defendant must be recast as whether the proposed alternative drug would have won FDA approval in time to help the plaintiff. No court can answer that question without seeking, in some manner, to replicate the FDA approval process.<sup>48</sup> A brief description of the FDA approval process reveals why courts could never hope successfully to undertake such an inquiry.

To obtain FDA permission to market a prescription drug, a manufacturer must develop extensive information about the safety and efficacy of the proposed drug through human clinical trials.<sup>49</sup> The formal approval process begins with the manufacturer's submission of an investigational new drug application (IND) to conduct such clinical trials.<sup>50</sup> Before the FDA will consider an IND, biologically active agents of the proposed drug must have been subjected to comprehensive animal and human tissue testing.<sup>51</sup> Protocols for human testing must be detailed.<sup>52</sup> Only if the FDA does not object to the IND application, either by requesting more information or by seeking modifications to the protocols for clinical testing, may the manufacturer commence with human clinical trials.<sup>53</sup> On average, the investigation and testing necessary for the preparation and approval of an IND application take eighteen months.<sup>54</sup>

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REVIEW BASED ON A REVIEW OF SELECTED MEDICAL DEVICE APPLICATIONS (1993), *reprinted in* SUBCOMM. ON OVERSIGHT AND INVESTIGATIONS, HOUSE COMM. ON ENERGY AND COMMERCE, 103D CONG., LESS THAN THE SUM OF ITS PARTS: REFORMS NEEDED IN THE ORGANIZATION, MANAGEMENT, AND RESOURCES OF THE FOOD AND DRUG ADMINISTRATION'S CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (Comm. Print 1993). Consequently, it is likely that despite the amendments targeting streamlining of device review, any such devices subject to the Class III premarket approval requirement still undergo a lengthy and expensive review process similar to that for drugs.

48. *Cf.* Dreier, *supra* note 2, at 262 ("It certainly does not aid the tort system to turn each tort trial into a mini-FDA application procedure. A jury determination based upon trial proofs should not be substituted for the FDA's extensive drug-approval process (or the equivalent) for new and untried drugs.").

49. Drugs are also tested to set proper dosage. 21 C.F.R. § 314.3 (characterizing FDA approval under 21 U.S.C. § 360c as geared to "safety and effectiveness"); *see also* 1 O'REILLY, *supra* note 46, § 13.11 (describing the required phases of and reports on human clinical testing); Green, *supra* note 45, at 486-87 (same).

50. 21 C.F.R. § 312.20.

51. *Id.* § 312.23(a).

52. *Id.* § 312.21.

53. *Id.* §§ 312.21-23.

54. 1 O'REILLY, *supra* note 46, § 13.11, at 13-63 (citing FDA ALMANAC FISCAL YEAR 1992, *supra* note 46, at 33). However, the IND process is subject to "clinical hold[s]" once the application is filed whenever the FDA feels that the pretesting clinical data and proposed testing protocols are inadequate to proceed. *Id.* at 13-64. The clinical hold halts the conclusion of the thirty-day FDA review period between filing of the application and commencement of actual human testing. *Id.* At this stage, safety is the "paramount" concern of the FDA, and thus clinical holds are more likely to be imposed on proposed human experiments that are "larger or more risk-related." *Id.* *See generally* 21 C.F.R. § 312.21 (describing the three phases of clinical testing). Although the average pre-IND discovery and development phase has been cited as eighteen months, the actual time to develop a drug to readiness for human clinical trials could take any amount of time and could be suspended indefinitely due to variance in the time it takes to discover or develop a new compound, or by FDA clinical holds.

Human clinical trials take place in three phases and typically take five years or more to complete.<sup>55</sup> The clinical trials are staggered not only to maximize information, but also to protect the well-being of the participants.<sup>56</sup> Phase I clinical trials require that tests be performed on a limited group of healthy adults.<sup>57</sup> These tests are designed to provide information about “the metabolism and pharmacologic action of the drug in humans [and] the side effects associated with increasing doses.”<sup>58</sup> This initial stage is designed primarily to discover dangers related to ingestion of the drug and does not focus on the drug’s efficacy.<sup>59</sup> If Phase I is completed successfully, the manufacturer proceeds to Phase II in which the efficacy of the drug is evaluated in a controlled study.<sup>60</sup> Researchers dispense the drug to several hundred patients suffering from a condition to determine whether the drug ameliorates the condition.<sup>61</sup> If the second phase is successful, the drug is then provided to several thousand patients under the direction of many physicians who report to the drug manufacturer in Phase III.<sup>62</sup> The FDA may at any stage require additional testing or studies before allowing the manufacturer to proceed with further clinical trials.<sup>63</sup> As Professor Michael Green observes, “[t]he winnowing of potential new drugs during the IND process is in significant part responsible for the fact that it takes, on average, twelve years and costs more than \$200 million to develop and obtain approval for a new drug.”<sup>64</sup> Only upon completion of IND testing

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55. 21 C.F.R. § 312.21; 1 O'REILLY, *supra* note 46, § 13.11, at 13-63 (citing FDA ALMANAC FISCAL YEAR 1992, *supra* note 46, at 33).

56. Green, *supra* note 45, at 486.

57. The group is generally in the range of twenty to eighty adults. 21 C.F.R. § 312.21(a)(1).

58. *Id.*

59. *Id.* §§ 312.21(a), 312.22. Tests are run largely to gauge certain qualities of the drug, including absorption, elimination, metabolism, toleration, and toxicity, in order to determine the safety of administering the drug to larger human populations; subsequent testing phases focus more on efficacy.

60. Phase II studies employ larger, but still relatively limited, numbers of patients with the disease or condition targeted by the drug. *Id.* § 312.21(b).

61. *Id.*; 1 O'REILLY, *supra* note 46, § 13.11, at 13-64 to 13-65 (noting that Phase II testing “usually takes up to 2 years” and that “only one third of the drugs which begin the IND process will proceed beyond this stage, usually because of safety concerns”). In Phase III, the number of surviving drugs will be pared down further, since only approximately one-fourth of all drugs for which IND applications are filed survive this phase. *See infra* note 66 and accompanying text.

62. Phase III testing typically is done on several thousand patients and provides an improved ability to detect “infrequent effects that the drug may have on patients who take it.” Green, *supra* note 45, at 487; *see also* 21 C.F.R. § 312.21(c).

63. The IND testing process has been described as a years-long scientific debate between the FDA and the manufacturer. 1 O'REILLY, *supra* note 46, § 13.11, at 13-62 to 13-69. The IND process can be delayed repeatedly and indefinitely by requests from the FDA for additional testing or revision of testing protocols. *Id.*; *see also* Green, *supra* note 45, at 481, 487 (noting that Phase III testing as part of the IND process is especially vulnerable to requests for additional tests because by statute, such testing must be “adequate and well controlled,” and that “[b]ecause the perfect clinical study has yet to be performed, this general standard gives the FDA considerable discretion to require the sponsoring manufacturer to conduct additional studies”); *supra* notes 54, 61-62.



does the manufacturer submit a New Drug Application (NDA) to the FDA.<sup>65</sup> Three-fourths of all drugs that are subjected to human clinical trials never reach the NDA stage.<sup>66</sup> An NDA record frequently runs in the hundreds of thousands of pages,<sup>67</sup> cataloguing the entire history of the drug's development and reporting on all the premarketing studies.<sup>68</sup> Negotiations between the FDA and the manufacturer regarding whether a drug should be approved for marketing can continue indefinitely even after the filing of the NDA and throughout its review.<sup>69</sup>

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64. Green, *supra* note 45, at 486. A more recent, but less frequently cited, 1995 estimate suggests "an average development time of fifteen years and average costs in the range of 500 million dollars per new drug." Michael D. Greenberg, *AIDS, Experimental Drug Approval, and the FDA New Drug Screening Process*, 3 N.Y.U. J. LEGIS. & PUB. POL'Y 295, 300 n.24 (2000) (citing S. REP. NO. 105-43, at 6-7 (1997)); see also Edwin A.M. Gale & Anne Clark, *A Drug on the Market?*, LANCET, Jan. 1, 2000, 2000 WL 9004699, at \*1 (placing the cost of marketing approval at "up to \$350 million" or "more than \$500 million if failures are taken into account" and noting that "most of the money" goes toward meeting the regulatory requirements of "phase II and phase III clinical trials").

65. 1 O'REILLY, *supra* note 46, § 13.11, at 13-65 (citing 21 C.F.R. §§ 312.82, 314.102 (1983)). In practice, prior to the filing of the NDA, a drug manufacturer may seek a meeting with the FDA in order that the FDA may examine IND evidence to determine if further testing would be required in order to gain NDA approval. Formal denial of an NDA is described as a very "serious legal setback" to be avoided since it can imperil a company's financial situation, and since the only available subsequent remedies are internal FDA appeals and court lawsuits. *Id.* § 13.11, at 13-67. For example, after the FDA formally denied approval of an NDA filed by Aronex Pharmaceuticals, Inc., for its drug Atragen, the manufacturer's stock fell seventy-three percent, and the company expected to reduce its work force of eighty-five in order to preserve cash flow in pursuit of approval for other products. Kim Coghill, *FDA Denies Approval of Aronex's Atragen; Stock Falls 73 Percent*, BIOWORLD TODAY, Jan. 9, 2001, 2001 WL 7294624, at \*1. The regulatory "review clock" period allotted to the FDA for formal approval or denial of the NDA is just 180 days. 21 C.F.R. § 314.100 (2000). However, in practice, the FDA almost never satisfies this time limit, and the NDA process itself provides additional opportunities for substantial delays. See *infra* note 72 and accompanying text.

66. 1 O'REILLY, *supra* note 46, § 13.11, at 13-65.

67. "An NDA typically consists of a hundred thousand pages or more." Green, *supra* note 45, at 487 & n.96 (citing materials submitted by James T. Burns, Eli Lilly & Co., for the *Colloquy on Products Liability: Comprehensive Discussions on the Restatement (Third) of Torts: Products Liability* 12 (Mar. 22-23, 1996)); *Revitalizing New Product Development from Clinical Trials Through FDA Review: Hearing of the Senate Comm. on Labor and Human Resources*, 104th Cong. 5 (1996) (statement of Sen. Nancy Kassebaum describing a then-recent NDA of 200,000 pages in length). As an example, "the NDA for Prozac consisted of a million pages that included reports on twenty-five premarketing studies of the drug." Green, *supra* note 45, at 487. One FDA treatise notes that although FDA procedures have been somewhat streamlined recently, the average application, circa 1982, contained "100,000 pages, filling hundreds of volumes" and that "[a]pplications arrive[d] at the FDA, literally, in truck loads." 1 O'REILLY, *supra* note 46, § 13.11, at 13-62 to 13-63 n.353 (citing Richard S. Schweiker, Secretary of the Department of Health and Human Services, Address to the National Pharmaceutical Council (June 23, 1982)).

68. 21 U.S.C. § 355(a)-(d) (1994); 21 C.F.R. § 314.50.

69. The FDA review process does not end once the NDA is filed and can be delayed indefinitely. First, if the paperwork is determined to be incomplete, review will not even begin, and the NDA is sent back to the manufacturer. 1 O'REILLY, *supra* note 46, § 13.11, at 13-67 n.379 (citing Letter from Roger L. Williams, Director, FDA Office of Generic Drugs, to Applicants (January 15, 1993), in *Food Drug Cosm. L. Rep.* (CCH) ¶ 43,222 (1993)).

Requests for further testing can also delay or derail approval after filing of the NDA. For example, the General Accounting Office reported that even after filing an NDA, Schering-Plough's approval for an antihistamine was delayed by the FDA for "two-and-a-half years to

In light of these realities, the insistence by our critics that the *Restatement* should apply the same RAD-based standard to prescription products as it applies generally to all other products is manifestly improvident.<sup>70</sup> Given that a drug manufacturer cannot market a drug in the United States without FDA approval, for a court to find that an alternative drug should have been developed would require it to predict with confidence that the alternative drug would have actually been approved. No expert could honestly opine that approval would have been granted without engaging in rank speculation.<sup>71</sup> The approval process is accompanied by countless opportunities to decline or delay further progress. The data required to be developed for drug approval are beyond the capabilities of the litigants to replicate in a trial setting. Trials are compressed in time and scope; they do not allow for the expansive multi-year analysis and interaction between the manufacturer and the FDA that characterize the American drug regulatory process.<sup>72</sup> Even if comparing a defendant's drugs with drugs that might have been developed made sense substantively (it does not), from the standpoint of legal process it could never be accomplished fairly or sensibly.

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gather animal carcinogenicity data." *Claritin Patent Extension*, TAN SHEET, Aug. 14, 2000, 2000 WL 22792961, at \*1. The total FDA approval review of the drug took "77.4 months," or more than six years, a period that the FDA denied was too long. *Id.*

70. Conk, *supra* note 1, at 1118-19; Cupp, *Rethinking Conscious Design Liability*, *supra* note 2, at 99-103; Schwartz, *Prescription Products*, *supra* note 2, at 1384; Vandall, *supra* note 2, at 271-72.

71. Dreier, *supra* note 2, at 262 ("A jury determination based upon trial proofs should not be substituted for the FDA's extensive drug-approval process (or the equivalent)."); Green, *supra* note 45, at 490-91 (describing how the extensive preapproval testing and the written records documenting it, which often include a "variety of mistakes, deceptions," or other "errors," require extremely sophisticated and subjective interpretation and thus could present difficult inquiries beyond "the institutional competence of common law courts").

72. The approval process is "essentially a years-long scientific debate, the terms of which are developed through extensive paper submissions." 1 O'REILLY, *supra* note 46, § 13.11, at 13-62; see also Green, *supra* note 45, at 485-88 (describing the entire approval process and FDA/manufacturer interaction). It should be noted that the FDA has received considerable criticism, largely from pharmaceutical manufacturers and desperately ill patients, that its regulatory system, as implemented, unnecessarily creates an unwieldy "drug lag." Michael D. Green & William B. Schultz, *Tort Law Deference to FDA Regulation of Medical Devices*, 88 GEO. L.J. 2119, 2131 n.59 (2000) (noting that "[t]he criticism began in the early 1970s when Sam Peltzman published his pioneering work that identified the 'drug lag' delay" in FDA approval as "compared to other western countries"); Greenberg, *supra* note 64, at 300.

Although such critics of the FDA recognize that "[r]egulation is clearly necessary," they contend that "the bureaucracy that has evolved . . . generate[s] 'regulation by accretion' and 'has forced the drug development process into an excessively lengthy, expensive and wasteful mode.'" Gale & Clark, *supra* note 64, at \*4.

Even assuming such comparative drug lag arguments are valid, were the FDA to streamline its procedures significantly to be more in line with allegedly preferable standards in other countries, it nevertheless appears unlikely, because of concerns for safety and efficacy, that average approval times and costs could be cut by more than half. Therefore, even if the effort put into the average approval were reduced from twelve years to six, the sophisticated scientific judgment required to analyze even six years of such data collection would likely remain unwieldy for courts and juries.

B. *The Restatement Properly Rejects an Aggregative, All-Patients-Considered Approach to Defective Drug Design*

This Section compares the merits of the new *Restatement*'s narrower "benefits any class of patients" approach and the broader "reasonableness under all the circumstances" approach championed by our critics.<sup>73</sup> Once not-yet-approved alternative drugs are eliminated from judicial consideration, as the preceding Section makes clear they must be, the important difference between the approach in the new *Restatement* and the approach urged by our critics relates to the question of whose welfare should be taken into account in determining defectiveness. Section 6(c) of the *Restatement* considers only the welfare of patients who are helped by a defendant's prescription drug, refusing to deem a drug defective in design if it benefits any class of patients. In contrast, critics of the *Restatement* advocate an aggregative approach in which the defectiveness of a prescription drug's design is determined by considering the drug's potential impact on all patients for whom it might, properly or improperly, be prescribed. Under the latter approach, the court weighs the risks of injury to some patients caused by misprescription and detrimental consumption of the drug against the potential benefits to other patients from proper prescription and beneficial consumption. Even if a drug would benefit a significant number of people, the drug is defective in design if those for whom the drug is improperly prescribed by negligent physicians suffer, in the aggregate, greater harm. The welfare of all patients is taken into account under the proposed approach, not just the welfare of those helped by a drug's proper prescription and consumption.

The all-patients-considered approach based on aggregate consumer welfare is functionally equivalent to the approach taken in section 2(b) of the new *Restatement* in connection with most nonprescription products. In nonprescription contexts, aggregation of consumer interests—weighing potential risks to some consumers against potential benefits to others—represents a necessary compromise. If the products liability system could somehow refrain from deeming an inherently dangerous product defective in design when sold to and used by persons cautious enough to avoid accidents, while deeming the same product defective when sold to and used by accident-prone individuals, the liability system would presumably prefer to implement such a pattern of differential defectiveness and liability.<sup>74</sup> But

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73. See sources cited *supra* note 70.

74. A finding of defectiveness would presumably lead to a safer—albeit costlier—design for the accident-prone group, which would be cost-effective for them. The second, relatively cautious group would use the cheaper, less safe design and avoid paying for safety features they do not need. If the former group could somehow (at acceptable cost) be prevented from purchasing and using the cheaper products designed for the latter group, the result would be preferable.

such differentiation is not possible for nonprescription products, which are available to everyone on the open market.<sup>75</sup> It follows that aggregation of consumer interests is necessary; a product design is deemed defective or not defective taking into account all potential users and consumers. Under this aggregative approach, cautious users and consumers must pay for designed-in safety features that they do not need, a wasteful investment in care justified only because less cautious users and consumers who need the safety features benefit to a greater extent.

A concrete example will help to clarify this point. Suppose that a company distributes a hot-water vaporizer that is deemed defectively designed because when it tips over it allows scalding hot water to gush out of a wide top with a nondetached, liftable lid.<sup>76</sup> Suppose that the Twerski family has used the vaporizer for many generations without serious mishap.<sup>77</sup> The Twerskis always set it up carefully, where children cannot reach it, and enjoy the benefits of an easily refillable, liftable-lid vaporizer design. The Hendersons, in contrast, frequently and foolishly set up the same vaporizer where their children can reach it, resulting in accidental spills and burns. Notwithstanding warnings regarding the risks of tip-over and instructions regarding how to be more careful, the Hendersons persist in harming their children with the vaporizer.

Because the vaporizer is generally available for purchase by the public, and because the harm to the Hendersons is found to exceed the benefit to the Twerskis, the wide-top, liftable-lid vaporizer is deemed defectively designed and taken off the market, thereby depriving future generations of Twerskis the benefits they formerly derived from the same features that placed the Hendersons at risk.<sup>78</sup> (The hot water is desirable therapeutically

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75. Whenever a manufacturer attempts through marketing to limit relatively dangerous products for use "by experts only," courts deem nonexpert use foreseeable and judge the design in light of what ordinary persons may be expected to do with the product. *See, e.g., Barnes v. Litton Indus. Prods., Inc.*, 555 F.2d 1184 (4th Cir. 1977) (holding a manufacturer liable for failure to warn notwithstanding a label that said "For Professional Dental Use Only"). The one area where many courts have refused to judge products in light of modes of use and consumption by clearly unintended classes of users and consumers is when children harm themselves or others using or consuming products designed to be used only by adults. *See, e.g., Jennings v. BIC Corp.*, 181 F.3d 1250 (11th Cir. 1999) (holding that cigarette lighters are not intended to be used as children's playthings). Those who market such products to children may be liable for negligent entrustment. *See, e.g., Moning v. Alfano*, 254 N.W.2d 759 (Mich. 1977) (holding that a defendant may be found liable for marketing slingshots to an eleven-year-old who shot the plaintiff in the eye).

76. *See McCormack v. Hanksraft Co.*, 154 N.W.2d 488 (Minn. 1967) (holding a vaporizer manufacturer liable for injury to a child).

77. For an earlier variation of this hypothetical, see *Henderson, supra* note 23, at 479-81.

78. The court does not order the defendant to remove the product, of course. But if a marginal adjustment in the design will prevent future vaporizers from being deemed defective, the adjustment will presumably occur. For the impact of such adjustments on the likelihood that courts in future cases will deem the old design defective—the so-called subsequent remedial measure problem—see generally JAMES A. HENDERSON, JR. & AARON D. TWERSKI, *PRODUCTS LIABILITY* 602-06 (4th ed. 2000).

and the wide-top and liftable-lid features make refilling at night easier and safer.) Obviously, it would be preferable to allow the Twerskis to continue to purchase and use the wide-top vaporizer if doing so would not result in harming the Hendersons. One way to accomplish this would be to deem the vaporizer nondefective when sold to the Twerskis and defective when sold to the Hendersons. But it is not feasible to prevent the Hendersons from gaining access to the wide-top vaporizer except by denying access to all users, including the Twerskis. Moreover, even some of the Twerskis may suffer occasional lapses in care and have accidents, albeit much less frequently than the Hendersons.<sup>79</sup> Given these regrettable but understandable human shortcomings, the wide-top vaporizer is deemed defective in design for all users and effectively driven from the market by the tort system. An alternative, more safely designed vaporizer—more costly and less useful to the Twerskis—takes its place on the shelves, and life moves on. Given the practical impossibility of differentially distributing vaporizers, allowing some types to be used only by careful families or individuals within families and allowing other types to be used only by careless families or individuals, this is an appropriate, albeit sub-optimal, legal response to the social costs of hot-water vaporizers. In effect, the careless Hendersons impose the costs of their risky usage, through the collectivizing mechanism of tort, on the careful Twerskis. (And some of the Twerskis impose on others in their own families through comparatively less-frequent, though unavoidable, lapses in care.)

As section 6(c) of the new *Restatement* reflects, however, prescription products are different from products like vaporizers with respect to differential marketing. It is possible to allow the Twerskis access to prescription products that benefit them while denying the Hendersons access to the same products that, in their hands, would prove harmful. The mechanism that makes such differentiation possible is the power of physicians—often referred to as “learned intermediaries”<sup>80</sup>—to prescribe any given prescription drug or medical device to some patients and to refuse to prescribe it to others. Assuming that the possibility that the

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79. Everyone has a little Twerski and a little Henderson in him; safer product designs aim toward saving people from themselves as much as from others. What makes prescription products different is that the users/victims—medical patients—are far more passive than are the users/victims of other products. *But see infra* notes 91-92 and accompanying text (considering changes in the medical marketplace that are resulting in more proactive consumers of drugs).

80. It is generally accepted that the term “learned intermediary” was coined by the Court of Appeals for the Eighth Circuit in 1967. *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966) (noting that in the case of a “prescription drug rather than a normal consumer item[,] . . . the purchaser’s doctor is a learned intermediary between the purchaser and the manufacturer,” and thus the manufacturer has a duty to warn the consumer only through “reasonable efforts” to warn the doctor). However, the doctrine’s concept of relieving manufacturers of a duty to warn the consumer directly has been traced back as far as two decades earlier to two cases often cited for the doctrine’s origin: *Love v. Wolf*, 226 Cal. App. 2d 378 (Ct. App. 1964), and *Marcus v. Specific Pharmaceuticals, Inc.*, 77 N.Y.S.2d 508 (Sup. Ct. 1948).

products prescribed to the Twerskis will reach and harm the Hendersons is remote,<sup>81</sup> the Twerskis will enjoy access to the drug and the Hendersons will not. Of course, some physicians will predictably prescribe the wrong drug to the wrong patients notwithstanding adequate warnings from the manufacturer. When that occurs and patients suffer harm, the designs of the misprescribed drugs are not deemed defective, for to do so would deprive patients who benefit from those drugs access to them. Instead, the patients harmed by misprescription have tort remedies against negligent physicians who fail to heed presumably adequate warnings concerning the risks of prescribing the well-designed but risky drug.<sup>82</sup> When misprescription occurs because adequate warnings are not given to prescribing physicians, patients who suffer harm have actions against manufacturers for failure to warn;<sup>83</sup> and when misprescription occurs because manufacturers' marketing efforts overcome even adequate warnings, the patients have actions in some jurisdictions against the manufacturers for over-promotion.<sup>84</sup>

The new *Restatement* relies on this mechanism of differential product distribution—medical prescription on a selective basis by licensed physicians—to justify its rule in section 6(c) that a drug design is not defective (and thus deserves to be marketed with adequate warnings) as

81. In connection with nonprescription products, less cautious users and consumers will either buy the cheaper, more dangerous versions themselves, or borrow them from others. Regarding prescription products, patients who should not use or consume certain products will not receive prescriptions and therefore will not be able to buy them. Borrowing does occur and does present problems. Cautions against borrowing and lending prescription drugs are commonly issued in discussions of safe prescription drug use. *E.g.*, Preferred Health System, HealthNotes, at <http://www.phsystems.com/html/healthnotes/healthnotes.html> (last visited Apr. 23, 2001) (“[D]o not borrow or lend prescription drugs.”); N.Y. Weill Cornell Center, Columbia Presbyterian Center, Ask NOAH About: Mental Health: Factsheet: Clonidine (Catapres) & Guanfacine (Tenex), at <http://www.noah-health.org/english/illness/mentalhealth/cornell/medications/clonidine.html> (last visited Apr. 23, 2001) (“Don’t borrow or lend medicines.”).

82. *See, e.g.*, *Incollingo v. Ewing*, 282 A.2d 206, 212-18 (Pa. 1971) (upholding a jury verdict against two defendant doctors where the doctors negligently prescribed a drug despite warnings on the label that the drug should be used in limited fashion, for only serious cases, and that it posed dangers from repeated or prolonged use).

83. *See, e.g.*, *Moore v. Vanderloo*, 386 N.W.2d 108, 115-16 (Iowa 1986) (upholding a jury verdict against a manufacturer that failed to warn the chiropractor of risks to the patient receiving chiropractic manipulation while taking oral contraceptives); *Savina v. Sterling Drug, Inc.*, 795 P.2d 915, 928 (Kan. 1990) (denying summary judgment to a manufacturer on a claim of failure to warn the physician of the risk of patient paralysis resulting from use of the manufacturer’s dye in a hospital diagnostic procedure); *Martin v. Hacker*, 628 N.E.2d 1308, 1311 (N.Y. 1993) (holding that a manufacturer’s duty to warn is “fulfilled” by giving “adequate warning through [a] prescribing physician,” but that the “warning must provide sufficient information to that category of prescribing physicians who may be expected to have the least knowledge and experience with the drug”); *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 429 (Tenn. 1994) (recognizing that the learned intermediary doctrine “does not shield a drug manufacturer from liability for inadequate warnings to the physician”).

84. *See, e.g.*, *Incollingo*, 282 A.2d at 220 (upholding a jury verdict against a defendant drug manufacturer where there was evidence that “detail men” from the drug company effectively “nullified” warnings on the label as to the dangerous side effects of a drug which two doctors then negligently prescribed).

long as at least one class of patients derives benefit, in light of all other available drugs and drug-related therapies, from its use.<sup>85</sup> By rejecting this rule and treating prescription product designs the same as all other product designs, our critics reveal their lack of confidence in the capacity of learned intermediaries to see that the right drugs reach the right patients.<sup>86</sup> If the assumptions supporting judicial reliance on the mechanism of differential distribution via medical prescription were to erode too far—if most physicians arranged to be judgment-proof and joined in epidemics of misprescription—the critics' insistence that drug designs be treated the same as all other product designs might be persuasive. But we see no reason on the evidence before us to conclude that significant erosion has occurred. Indeed, we anticipate that the coming era of electronic information transmittal and retrieval will reinforce the continued efficacy of judicial reliance on learned intermediaries to maximize consumer welfare derived from having a wide array of prescription drugs available to health care providers and their patients.<sup>87</sup>

One further threat to continued reliance on the learned-intermediary model deserves mention in this context. In recent years, prescription drug manufacturers have increasingly advertised their products directly to consumers via the national media.<sup>88</sup> This phenomenon drew the

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85. RESTATEMENT (THIRD), *supra* note 2, § 6(c).

86. See Conk, *supra* note 1, at 1116, 1128; Cupp, *Rethinking Conscious Design Liability*, *supra* note 2, at 103-04; Schwartz, *Prescription Products*, *supra* note 2, at 1380; see also Margaret Gilhooly, *When Drugs Are Safe for Some but Not Others: The FDA Experience and Alternatives for Product Liability*, 36 HOUS. L. REV. 927, 947 (1999) (arguing that there should be a duty to warn patients directly when a manufacturer learns that drugs are being incorrectly prescribed by learned intermediaries).

87. Physicians are increasingly accessing online and electronic sources that provide twenty-four-hour, instant access to larger amounts of safety and efficacy information. *E.g.*, Mark Adams, *Forecast 2001: An E-Healthcare Odyssey*, PHARMACEUTICAL EXECUTIVE, Dec. 1, 2000, 2000 WL 12033861, at \*2 (noting that physicians are "using the Web in ever-increasing numbers," allowing drug companies to reach "prescribers they had previously ignored because it was not cost-effective to contact them individually"); Robin F. DeMattia, *High-Tech Hunger: Internet Advances Makes [sic] More Docs Curious About Computers*, MODERN PHYSICIAN, Sept. 1, 2000, 2000 WL 8130532, at \*3 (noting that the "Internet is invading every facet of the physician's professional life," including information retrieval) (internal quotation marks omitted); Michael Simonsen, *Physician's Office Market Grows with Changing Health Care Delivery*, BBI NEWSL., Nov. 1, 2000, 2000 WL 22121901, at \*4 (noting that some insurance companies are offering discounts to physicians who use online and electronic technology to facilitate error reduction in prescribing, such as checking for drug interactions); *Strong Growth Continues for Sales Force Service Companies*, MED. MARKETING & MEDIA, Nov. 1, 2000, 2000 WL 148503348, at \*2-3 (noting that "[t]he convenience to physicians of a 24/7/365 access" to electronic information regarding prescription drugs will make such retrieval "routine" for them) (internal quotation marks omitted); Ian Sutcliffe, *Capturing Physicians*, PHARMACEUTICAL EXECUTIVE, Dec. 1, 2000, 2000 WL 12033862, at \*1 (discussing pharmaceutical manufacturers' increasing targeting of physicians' use of the Internet as a means to provide information regarding drugs and to increase sales).

88. *E.g.*, Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory Liability Issues*, 32 GA. L. REV. 141, 141 (1997) (noting that 1997 represented a "watershed" year for direct drug company promotion to consumers, when "for the first time, this category of

*Restatement* Reporters' attention in connection with the possibility that section 6 would impose a duty on drug manufacturers to warn patients directly of the risks presented by directly-advertised drugs. Appropriate language for use in blackletter and comments was drafted and circulated.<sup>89</sup> In the end, the Institute decided to take no position on the direct-duty-to-warn issue, deferring to developing case law.<sup>90</sup> In the context of assessing section 6(c)'s standard for defective design, it is not inconceivable that these patterns of direct advertising (and warning) might grow in magnitude and importance to the point that reasonable persons would agree that prescription drug designs should be treated like other product designs—that aggregating consumer welfare in both contexts is appropriate.<sup>91</sup> The authors believe that such an unlikely juncture is, in any event, far in the future. If and when such time arrives, courts will presumably weigh heavily the social benefits derived from maximizing the choices available to patients in the marketplace for prescription products. If such a change in the legal standard should ever need to be implemented, it will, in contrast to the possible scenario involving massive misprescription by physicians, have been mostly the drug industry's own doing.<sup>92</sup>

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advertising expenditures . . . easily outpac[ed] promotional efforts directed to physicians"); Kelly N. Reeves, *Direct-to-Consumer Broadcast Advertising: Empowering the Consumer or Manipulating a Vulnerable Population?*, 53 FOOD & DRUG L.J. 661, 661-62 (1998) (noting that since the FDA released guidelines for consumer-directed broadcast ads in 1997, "[a]dvertising executives on Madison Avenue surely are salivating at the millions to be made in a prescription drug marketing bonanza under the relaxed conditions"); Bob Van Voris, *Drug Ads Could Spell Legal Trouble*, NAT'L L.J., July 21, 1997, at B1 (noting that a 1997 television ad promoting Pharmacia & Upjohn's Depo-Provera, which related the drug's "specific purpose," departed from the "vague 'ask your doctor' format of other televised prescription drug ads" providing "the latest indication that drug companies are more aggressively marketing their products directly to consumers"); Robert Pear, *Ads Spur Consumers To Buy Costlier Brand-Name Medicines*, MILWAUKEE J. & SENTINEL, Sept. 24, 2000, 2000 WL 26085853 (noting that "25 of the most heavily advertised drugs accounted for more than 40% of the increase in retail drug spending last year" and that "[c]onsumer advertising of drug products has exploded since the [FDA] relaxed the rules on such marketing").

89. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 103(a)(3) & cmt. e (Council Draft No. 1, 1993). In the final form of the *Restatement* (Third), the drug section was renumbered from section 103 to section 6 as it appears now.

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

91. If patients would routinely request doctors to prescribe drugs based on advertising and doctors would routinely acquiesce to patients' entreaties, then in effect, the likelihood that drugs appropriate for the Twerskis would reach the Hendersons is great. This breakdown of the learned intermediary as a screening device would make marketing of prescription drugs not substantially different from that of nonprescription products.

92. If misprescription of drugs resulted from widespread negligence of physicians whose standard of care deteriorated because they had decided to render themselves judgment-proof, the fault for such physician behavior would not lie at the doorstep of drug manufacturers. In contrast, if misprescription of drugs resulted from advertising designed to cause patients to apply pressure to physicians to prescribe the advertised drug, the fact that a physician may negligently do so is partially the responsibility of the drug manufacturer who sought to have the patient influence the physician to prescribe the drug.



It might be argued that, by generally relying on learned intermediaries to allocate the right prescription drugs to the right patients, the new *Restatement* is internally inconsistent in allowing for any possibility of design-based liability for prescription products. That is, once the aggregative, all-consumers-considered approach of section 2(b) is rejected in section 6(c) in favor of relying on prescribing physicians to make the critical allocative decisions, it can be argued that the only logical stopping place is to deny design liability altogether for prescription products and to rely exclusively on the adequacy of warnings to prescribing physicians. In effect, learned intermediaries would be presumed, for purposes of drug manufacturers' design liability, to be infallible; when misprescriptions by fully-informed physicians occurred, they would be the physicians' responsibility. That is the view traditionally implemented by a majority of courts in this country.<sup>93</sup> The new *Restatement* rejects this traditional view for several reasons. For one, the recent trend in judicial decisions, to which a *Restatement* must pay heed, clearly favors some form of independent judicial review of prescription product design.<sup>94</sup> For another, an irrebuttable presumption of physician infallibility seems factually unrealistic. Learned intermediaries may generally be relied on to get things straight, but they do make mistakes. When such mistakes take the form of misprescriptions of properly-marketed drugs and devices that legitimately provide benefits to some patients, legal responsibility for resulting harm should fall on the prescribing physicians alone. But when physicians misprescribe drugs and devices that should never have been marketed in the first place—that provide no net benefits to any class of patients—then the manufacturers of those products should share the responsibility.

If any aspect of the new *Restatement's* approach to defective prescription drugs is remarkable for its recognition of institutional fallibility, it is the tacit recognition that the FDA might administratively approve a worthless drug, not that physicians might misprescribe it. As was observed in an earlier discussion, section 6(c) does not so much defer to the expertise of the FDA as it recognizes that courts cannot replicate the FDA approval process in determining which not-yet-approved drugs should count as reasonable alternatives to drugs distributed by manufacturers.<sup>95</sup> By countenancing a finding that a defendant's drug is, essentially, worthless, section 6(c) tacitly assumes that the FDA will occasionally approve (or fail to order withdrawal of) a drug that should not be allowed on the market.<sup>96</sup>

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93. See *supra* note 83.

94. See James A. Henderson, Jr. & Aaron D. Twerski, *A Proposed Revision of Section 402A of the Restatement (Second) of Torts*, 77 CORNELL L. REV. 1512, 1543 n.65 (1992) (citing sources).

95. See *supra* Section III.A.

96. RESTATEMENT (THIRD), *supra* note 2, § 6 cmt. f, illus. 1.

However, as an earlier discussion reveals, section 6(c) properly refuses to allow courts to condemn the designs of approved drugs by comparing those drugs with alternatives that have not, at the time the plaintiff suffers injury, received FDA approval.<sup>97</sup>

*C. Suggestions by Critics for Reducing the Complexity of Drug Design Litigation Are Not Helpful*

As should by now be clear, section 6(c)'s "any class of patients" standard for drug design does not depend for its legitimacy on an assessment that reviewing drug design is too complex for courts to handle. Replicating the FDA process is the task beyond judicial competence, not reviewing the designs themselves. Nevertheless, critics of the new *Restatement* have tried to justify a more expansive, pro-plaintiff approach to drug design liability by suggesting ways in which the courts' design-review task might be rendered more manageable. Some commentators, for example, insist that we exaggerate the difficulties that courts would encounter in applying a robust, RAD-based review of prescription drug designs. In the emerging new world of genetic engineering, they argue, it is possible to rearrange molecular structures to create safer drugs that courts can compare relatively easily with existing drugs.<sup>98</sup> But as long as marketing of such safer drugs requires FDA approval, in-court replication of the formal approval process will continue to exceed the limits of adjudication. We offer the same response to suggestions that it will increasingly become possible for plaintiffs to point to safer drugs that have actually been approved in foreign jurisdictions, eliminating the need for courts to speculate over whether such drugs could have been developed and marketed in time to help the plaintiff.<sup>99</sup> Once again, these suggestions beg the question of whether such drugs would ever legitimately reach the American market. The history of the FDA is replete with drugs that have received regulatory approval and been marketed in foreign countries, only to be rejected here for lack of safety or efficacy.<sup>100</sup>

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97. See *supra* Section III.A.

98. But see Green, *supra* note 2, at 220 (noting that until researchers can know "with some confidence" that "specific modifications of a chemical's molecular structure will have predictable effects," rational drug design, "while reducing the number of new substances required to be tested from thousands to a few, still requires that those few go through the full panoply of new drug testing to confirm that the drug has the predicted therapeutic benefits and adverse effects").

99. See, e.g., Dreier, *supra* note 2, at 262 ("Notwithstanding the Thalidomide debacle in which European nations approved the drug, but the FDA did not, there may be drugs [approved elsewhere] with extensive trials and approvals that legitimately could pose as alternatives in the single-manufacturer or single-process case.").

100. The FDA has said that it "uses procedures that have caught unsafe drugs that were approved elsewhere" and that "[t]he FDA process has well served the public health and safety of the American people." Randall Mikkelsen, *FDA Red Tape Pushes Testing Overseas*, Drug

Critics have also assailed the willingness of the new *Restatement* to recognize aesthetic benefits as socially valuable in determining whether a reasonable physician would prescribe a drug or medical device for any class of patients.<sup>101</sup> By making aesthetics a legitimate part of the judicial calculus, critics argue, the *Restatement* increases the leeway given to drugs whose social benefits are otherwise questionable. This critique has been especially shrill with regard to drugs and devices that serve primarily aesthetic purposes. Thus, critics argue that drugs that treat baldness, acne, and other unattractive skin diseases—and types of breast implants that many patients prefer for aesthetic reasons—should be subject to a general risk-utility balancing in which aesthetics count for little. No matter that there exists a class of patients who benefit emotionally and psychologically from such a drug or medical device; no matter that the drug or device is accompanied by pronounced and explicit warnings; no matter that the physician plays an active role in assessing the patient's need for the product. Nonetheless, these critics argue, courts should sit as stern and final arbiters of whether,

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*Maker Says; Congressional Reforms To Speed Up Approvals Are Needed, Hoffman-La Roche Pres. Says*, ORANGE CITY REG., Aug. 18, 1995, 1995 WL 5866076, at \*2. (quoting FDA spokesman Jim O'Hara). For example, one commentator was able to identify at least twenty-six drugs for which clinical investigation in the United States was terminated during the 1960s and 1970s for safety reasons, either by the FDA or voluntarily by the manufacturer, but which drugs remained available on the market in other countries "despite these problems." WILLIAM M. WARDELL & LOUIS LASAGNA, REGULATION AND DRUG DEVELOPMENT 102-03 (1975).

The FDA also has significantly delayed approval of drugs that have received approvals outside the United States. *E.g.*, Veronica Henry, *Problems with Pharmaceutical Regulation in the United States*, 14 J. LEGAL MED. 617, 623 (1993) (describing drug "'buyer clubs,' which sell drugs that are still being tested" by obtaining them from other countries where such drugs have already received approval and then shipping the drugs to the United States); Gale & Clark, *supra* note 64, at \*6-7 (noting that the FDA "denied metformin to patients in the USA for more than a decade during which it was used widely, effectively, and with reasonable safety elsewhere in the world"). Some commentators and the FDA argue that such delays have benefited American consumers. *E.g.*, Morton Mintz, *The Cure That Could Kill You: FDA Reforms Are Bad Medicine*, WASH. POST, July 14, 1996, at C1 (describing how the FDA's delay in approving Thalidomide prevented thousands of the birth defects in this country that were suffered elsewhere). See generally WARDELL & LASAGNA, *supra*, at 101-03 (noting with respect to "toxic drugs [that] have been introduced into Britain but excluded from the United States during the current regulatory era," that "[i]gnoring any benefits conferred by these drugs," such drugs may be regarded "as cases in which the United States entirely escaped toxicity incurred in the process of drug development and marketing in Britain"). It should be noted that Conk criticizes section 6(c) on the ground that it would protect drug manufacturers from liability for not having introduced into the American market a safer polio vaccine that had been in use for many years in France, Finland, Sweden, and the Netherlands. Conk, *supra* note 1, at 1114-16. However, given the controversy over which vaccine was truly optimal, there was no assurance that the FDA would have approved the European vaccine for use in the United States. No court could predict whether and when the foreign-approved vaccine would have been approved by the FDA.

101. *E.g.*, Cupp, *The Continuing Search*, *supra* note 2, at 253 (denigrating the importance of cosmetic drugs); Cupp, *Rethinking Conscious Design Liability*, *supra* note 2, at 102 ("Courts following the new *Restatement's* approach thus would apply a much more defense-oriented liability standard to the breast implants than they would to manufacturers of automobiles, punch presses, and other nonprescription products with arguably much more social utility."); Green, *supra* note 2, at 214.

from the standpoint of physical, rather than emotional, health, the drug or device is good for society as a whole. We part company with such arrogant paternalism, especially when dealing with products that rarely have adverse third-party effects. If any place exists where we ought to give credence to consumer autonomy, it is with regard to prescription drugs and devices whose aesthetic properties can have profoundly beneficial effects on an individual's psychic well-being. If the manufacturer does not adequately warn against side effects or misrepresents findings to the FDA, then a patient will have classic failure-to-warn remedies to redress any resulting injury.<sup>102</sup> But for critics to relegate aesthetic benefits to second-class citizenship strikes us as demonstrably wrong-headed.

Finally, some critics suggest that the risk-utility balancing process, whether the broader version advocated by Conk and others or the *Restatement's* narrower version, should be avoided altogether. They suggest instead that a *prima facie* case for drug design liability can be established if the drug does not meet consumer expectations.<sup>103</sup> We most emphatically disagree. Whatever can be said in favor of the consumer expectations test with regard to nonprescription products such as hot-water vaporizers,<sup>104</sup> nothing whatever can be said for it as a test for prescription drug design. It proves too much—a patient *never* actually expects to suffer a devastating side-effect from taking a drug that is supposed to be beneficial. And it proves too little—assuming adequate warnings have been given, a reasonable, intelligent prescribing physician *always* expects that, over the run of patients, warned-against side-effects will occur. Unless the consumer

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102. If the manufacturer fails to warn a prescribing physician or consumers of an already-approved drug about newly discovered risks, the manufacturer may be liable to the injured patient under the traditional failure-to-warn doctrine. See *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121, 130-31 (9th Cir. 1968) (holding that "it is the responsibility of the manufacturer to see that warnings reach the consumer, either by giving warning itself or by obligating the purchaser to give warning"); *Feldman v. Lederle Labs.*, 479 A.2d 374, 388-89 (N.J. 1984) (recognizing a manufacturer's "unquestionabl[e]" duty to warn prescribing physicians of knowledge of risks obtained subsequent to approval and marketing, and its duty to "take reasonable steps" to warn "purchasers and consumers" of "newly-discovered" dangers resulting from both "actual and constructive" knowledge of such risks).

103. In *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827 (Neb. 2000), the court was faced with the question of whether Accutane, a drug intended to treat chronic acne, was defectively designed in light of a host of serious side effects. The court undertook a lengthy analysis of section 6(c) of the *Restatement* and found it to be unduly restrictive. It then said that to establish a *prima facie* case of drug design defect, the plaintiff was "only required to plead that the Accutane she took was unreasonably dangerous under a consumer expectations test" and that the defendant could avail itself of risk-utility balancing as an affirmative defense. *Id.* at 840.

104. E.g., Joseph W. Little, *The Place of Consumer Expectations in Product Strict Liability Actions for Defectively Designed Products*, 61 TENN. L. REV. 1189 (1994) (arguing that the consumer expectations test should be given more prominence in the *Restatement*); Marshall S. Shapo, *In Search of the Law of Products Liability: The ALI Restatement Project*, 48 VAND. L. REV. 631, 666-71 (1995) (criticizing the *Restatement* test for defect as too rigid and arguing that consumer expectations should have a greater role to play in determining liability for defective design).

expectations test is simply another way of expressing the cost-benefit test for defect,<sup>105</sup> it is a vacuous, ersatz test that allows triers of fact to decide drug design claims on nothing more than a fact-finder's whim.

*D. The Fact That Drug Design Claims Under Section 6(c) Are Relatively More Difficult To Establish Should Not Significantly Diminish Drug Manufacturers' Incentives To Make Their Products Safe*

No doubt about it. Section 6(c) makes prescription drug design claims more difficult for plaintiffs than does section 2(b) for nonprescription design claims. This comparatively greater difficulty is justified not only because courts are not required to replicate FDA drug approval processes, but also because classes of patients for whom a given drug is beneficial will be more likely to have the drug available to them. But are these benefits possibly outweighed by the negative effects of section 6(c) on drug manufacturers' incentives to improve drug safety through innovation? Conk's reliance on the blood cases as legal precedent is demonstrably in error, but might not his bottom-line conclusion—that reducing drug companies' exposure to design-based liability will significantly reduce their incentives to achieve greater drug safety—nevertheless have merit?

That any reduction in safety incentives under section 6(c) is likely to be insignificant is clear upon reflection. To begin with, it must be remembered that, no matter what standard for defective drug design is employed, design-based liability plays a relatively minor role with regard to prescription products. For reasons already developed in earlier discussions of prescribing physicians as learned intermediaries,<sup>106</sup> failure to warn is by far the more important basis of drug companies' exposures to liability. In contrast, under the relevant provisions of the new *Restatement* dealing with nonprescription products generally, the duty to design reasonably safe products logically precedes the duty to warn.<sup>107</sup> For such nonprescription products, the manufacturer's first obligation is reasonable design; warnings logically come after, in order to deal with any remaining pockets of hidden risk that cannot reasonably be designed out of the product. With respect to

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105. See, e.g., *Potter v. Chi. Pneumatic Tool Co.*, 694 A.2d 1319, 1334 (Conn. 1997) (adopting a "risk-utility balancing component" to the court's "consumer expectations test"); *Aller v. Rodgers Mach. Mfg. Co.*, 268 N.W.2d 830, 834-35 (Iowa 1970) (noting that "whether the doctrine of negligence or strict liability is being used," the same "weighing of the utility of the article against the risk of its use" occurs and thus applying this risk-utility balancing according to contemplation "by the ordinary consumer who purchases"); *Seattle-First Nat'l Bank v. Tabert*, 542 P.2d 774, 779 (Wash. 1975) (en banc) ("In determining the reasonable expectations of the ordinary consumer, a number of factors must be considered. The relative cost of the product, the gravity of the potential harm from the claimed defect and the cost and feasibility of eliminating or minimizing the risk . . .").

106. See *supra* notes 19-21, 87-100 and accompanying text.

107. *RESTATEMENT (THIRD)*, *supra* note 2, § 2 cmt. 1.

prescription products, this logical sequence is necessarily reversed. Exposure to design-based liability comes into play only as a measure of last resort, when the otherwise orderly and efficient market for prescription products has, inexplicably, failed. Given the very special roles played by the FDA and prescribing physicians, these assertions would be true with respect to prescription drugs even under a regime governed by the standard in section 2(b), though perhaps to a lesser degree.<sup>108</sup>

But that leaves the question of whether, in cases in which issues of defective drug design play out, section 6(c)'s standard will lead to manufacturers producing unreasonably dangerous prescription products. A brief review of the realities of the prescription drug market suggests that section 6(c) will have no such effect. In order to succeed, drug companies must invest substantially in research and testing to find new drugs that can be marketed as more efficacious and less risky than existing alternatives. It is difficult to overestimate the financial incentives that push these efforts. Thus, one may reasonably assume that, in such a competitive market, manufacturers face adequate incentives to innovate to make drugs better and safer independently of incentives supplied by tort law. To some extent, patent protections on proprietary drugs may inhibit competitive efforts to improve drug safety. But marginal adjustments in the formulations of existing drugs are by no means the only path to greater overall drug safety. Existing drugs that cause serious negative side-effects are especially vulnerable to new alternatives not protected by the patent system. Aware of this reality, drug companies will act rationally to reduce this vulnerability by making their patented drugs as safe as is reasonably possible.

Moreover, even if manufacturers as a general matter are inclined to place relatively greater research emphasis on improving efficacy than on eliminating negative side effects, both aspects of drug safety will receive adequate attention because both are required to be disclosed fully when the drug is marketed. In contrast to nonprescription products, where improvements in safety tend to represent a "hard sell," with prescription products the opposite is true. Prescription drugs are marketed specifically at reducing risk to patients, either by increasing efficacy (thereby reducing external risks) or diminishing side effects (thereby reducing internal risks). Presumably, prescribing physicians are concerned with both aspects of risk reduction. Thus, given the duty of full disclosure owed by manufacturers, the market supplies sufficient incentives to invest in making their products safe. Any notion that the "tough on plaintiffs" design standard adopted in section 6(c) might significantly reduce incentives for manufacturers to increase the safety of their products must be rejected as ill-conceived.

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108. See Conk, *supra* note 1, at 1102.

## IV. CONCLUSION

Our response to Conk and other critics should be clear enough. Drug designs *are* different, after all. The new *Restatement* allows courts to consider safer, FDA-approved drugs already on the market in determining the defectiveness of a prescription drug's design. But the new *Restatement* does not allow a plaintiff to assert that the defendant manufacturer could have developed and marketed a safer prescription drug in time to have avoided plaintiffs' injuries. To allow such claims would ask of courts more than they could responsibly deliver. Moreover, the new *Restatement* does not allow plaintiffs to demonstrate defectiveness by showing that a drug that provides benefits, when properly prescribed for one or more classes of patients, causes greater detriment when improperly prescribed for other classes of patients. Assuming that the manufacturer has given the necessary warnings and has not overpromoted the drug, misprescription should be solely the negligent physician's responsibility. To deny one group of patients a beneficial drug merely because adequately-warned physicians may misprescribe the same drug for another group of patients would be unfair and inefficient, and the new *Restatement* will have none of it.

As revealed in this Essay, the *Restatement's* treatment of defective prescription products has become a lightning rod for criticism. Most observers are in general agreement that the guidelines set forth a half-century ago in section 402A, comment *k* of the *Restatement (Second)* are unintelligible and that the cases seeking to interpret that section are confusing.<sup>109</sup> In connection with section 6(c) of the *Restatement (Third)*, we plead guilty to the charge that we did not restate existing case law. One could hardly be expected to restate gibberish. Instead, we opted for a fresh look at the question of design liability for prescription products and utilized the case law to illuminate the underlying issues in this difficult area. Some cases did get it right, and we drew on them for support. We do not, as our critics argue, defer blindly to FDA expertise. We do, however, question the institutional competence of courts to decide whether safer drugs could have received FDA approval and been brought to market in time to have helped any given patient. Finally, we reject outright the idea that drugs that well serve a class of patients should be declared defective either because physicians may negligently misprescribe the drugs or because patients who are fully warned of the relevant risks choose to accept those risks in order to

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109. Cupp, *Rethinking Conscious Design Liability*, *supra* note 2, at 81-82; Aaron D. Twerski, *From a Reporter: A Prospective Agenda*, 10 *TOURO L. REV.* 5, 15-16 (1993) (noting the author's propensity regularly to offer any of his students an "A" in his products liability course for a successful explanation of section 402A, but that, thus far, no students have succeeded); Kelley E. Cash, Note, *The New Restatement (Third) of Torts: Is It the Cure for the AIDS Vaccine Ailment?*, 16 *REV. LITIG.* 413, 424-26 (1997).

improve the aesthetic quality of their lives. Our critics wonder why the ALI approved the drug design section of the new *Restatement* without objection or serious debate.<sup>110</sup> We believe that it was so readily accepted because it made good common sense. It still does.

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110. Conk, *supra* note 1, at 1105.



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