The Continuing Search for Proper Perspective: Whose Reasonableness Should Be at Issue in a Prescription Product Design Defect Analysis?[†]

Richard L. Cupp Jr.[*]

Whether a decision seems reasonable often depends on who is analyzing it. Decisions often appear sensible to some but foolish to others. Frequently, one's judgment depends on how expansively one considers the factors leading to the decision in question. Decisions that seem reasonable under a narrow analysis, for example, often reveal flaws when considered with a broader view. Perspective is central.

This Article focuses on identifying a proper perspective for judging the reasonableness of design decisions related to prescription products. The Restatement (Third) of Torts: Products Liability (Restatement (Third)), adopted by the American Law Institute (ALI) in 1997, judges prescription-product designs from the perspective of prescribing health-care providers.[1] Section 6 of the Restatement (Third) provides that a prescription-product manufacturer should be liable for design defects only if reasonable health-care providers, knowing of a drug's foreseeable risks and therapeutic benefits, would not prescribe the product to any class of patients.[2]

This Article compares the Restatement (Third)'s "reasonable physician" standard[3] to a standard judging the reasonableness of

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[*] Professor of Law, Pepperdine University School of Law. B.A., Pepperdine University, 1983; J.D., University of California at Davis, 1987. I thank Professor Michael Green for critiquing an earlier draft of this Article, and Morgan Stewart for providing outstanding research assistance. I also thank the Pepperdine University School of Law for supporting work on this Article with a research grant.

[1] *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(c) (1997).

[2] *See id.*

[3] *See id.* Although generally physicians will be in the position of making prescription decisions, the Restatement (Third) utilizes the broader description of "health-care providers." *See id.* This Article will use the phrase "reasonable physician test" with the understanding that the Restatement (Third) may allow for cases

prescription-product designs from the perspective of a reasonable manufacturer of such products. Part I explores a potential design defect problem involving a prescription drug to illustrate the differences between a reasonable physician standard and a reasonable manufacturer standard.

After introducing the issues with this illustration, the Article focuses on two questions. Part II addresses whether the Restatement (Third)'s reasonable physician standard restates existing law. The Restatement (Third) is an admirable scholarly work, and most of it will be well-received in the courts. Part II, however, contends that, unlike other aspects of the Restatement (Third), its reasonable physician standard for prescription product design defect claims is inconsistent with existing case law. Although courts vary in their approach to prescription-product design defects, most jurisdictions utilize a reasonable manufacturer standard. The Restatement (Third)'s reasonable physician standard is a new creation, not reflective of the law of any jurisdiction.

Part III addresses whether the new reasonable physician standard is preferable to the reasonable manufacturer standard. In most cases, following either of the two approaches will lead to the same conclusion. Because of the unique policy concerns surrounding prescription products, neither standard will often allow findings of liability. In relatively rare instances, however, these policy concerns are weaker or inapplicable, and imposing design liability is desirable. The Restatement (Third)'s reasonable physician standard provides manufacturers almost complete immunity from design liability and inappropriately blocks recovery in deserving cases. The broader reasonable manufacturer standard provides greater flexibility and allows for liability when appropriate. Liability is particularly appropriate in cases involving prescription products with cosmetic applications and in cases involving prescription medical devices. Since cosmetic medical products and prescription medical devices have multiplied rapidly in recent years and seem likely to continue their expansion, the importance of allowing design liability in deserving cases will increase over time.

I. PROSCAR VERSUS PROPECIA — A TEST CASE

Providing a somewhat involved illustration will assist in highlighting some of the issues courts face in choosing between the Restatement (Third)'s reasonable physician test and the broader

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involving nonphysician prescribers.

reasonable manufacturer test. Propecia is a prescription drug that Merck Company began marketing in early 1998.[4] Most Americans have heard of Propecia because Merck spent 13.9 million dollars advertising it in the first ten months of 1998 alone.[5] Propecia is prescribed solely to treat baldness.[6]

Since 1992, however, Merck has used finasteride, the active ingredient in Propecia, in another drug label. This earlier label, called "Proscar," is used to treat prostate enlargement.[7] Proscar is essentially the same as Propecia, except that one milligram of finasteride is used in a Propecia pill, whereas five milligrams of finasteride are used in a Proscar pill.[8] Proscar, like Propecia, prevents baldness, but Proscar has more finasteride than is needed for that purpose.[9]

A study published in the *New England Journal of Medicine* in 1996 reported that 214 men taking Proscar for prostate enlargement developed gynecomastia, an enlargement of the breasts.[10] Men who develop gynecomastia are susceptible to breast cancer.[11] Proscar has numerous other side effects, including insomnia, urinary tract infections, and urogenital birth defects.[12] Another 1996 study found that Proscar is no more effective at treating prostate enlargement than are placebos.[13] The study also found that Hytrin, a competing drug, was truly effective in the treatment of prostate enlargement.[14]

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[4] *See Battle Grows over Drugs for Hair Loss; Pharmacia & Upjohn, Merck Squaring Off in Marketing Race; Sales Said to Be Rising; Firms Seek to Enlarge Market: $1.5 billion, 7 million U.S. Men; Pharmaceuticals*, BALT. SUN, Mar. 1, 1998, at 1D [hereinafter *Battle Grows*].

[5] *See Spending on Rx Drug Ads Reaches 1.1 Billion in First 10 Months of 1998; Surpasses 1997 Total*, BUS. WIRE, Jan. 27, 1999, at 1.

[6] *See* Jacquelyn Mitchard, *We'll Shave Our Legs If You Grow Some Hair*, MILWAUKEE J. SENTINEL, Jan. 25, 1998, at 1.

[7] *See id.*; *Merck Proscar Phase IV Commitments Led to Claims for Reduced Risk of Prostate Surgery and Reduced Risk of Acute Urinary Retention*, PHARMACEUTICALS APPROVALS MONTHLY, June 1, 1989, *available in* 1998 WL 9724724.

[8] *See Battle Grows*, *supra* note 4, at 1D.

[9] *See id.*

[10] *See Proscar Can Cause Ill Effects*, HEALTHFACTS, Nov. 1, 1996, *available in* 1996 WL 9129123.

[11] *See id.*

[12] *See Patient Access to Unapproved Therapies and Treatments Before the House Gov't Reform and Oversight Comm.*, 105th Cong. (1998) (statement of Peter A. Defazio, representative of Oregon) [hereinafter *Patient Access*].

[13] *See* Laura Beil, *Drug Shows Promise for Prostate Patients*, DALLAS MORNING NEWS, Feb. 26, 1998, at 4A.

[14] *See Benign Prostate Cancer – Shedding Light on the Prostate Dilemma*, HARV. HEALTH LETTER, Jan. 1, 1997.

Yet another study reported that Saw Palmetto extract is more effective, far safer, and cheaper than Proscar.[15]

Despite these findings, doctors continue to prescribe Proscar for prostate enlargement on a huge scale. According to congressional testimony, sales of Proscar in 1998 exceeded one billion dollars.[16] This phenomenon is not unusual in the medical industry. Doctors often continue to prescribe drugs with which they are familiar, long after studies have shown that safer and perhaps better drugs are available.[17]

Fortunately for those taking it, Propecia seems effective in preventing baldness and appears to be not nearly as dangerous as Proscar, even though the drugs contain the same active ingredient. Apparently, the much lower dose of finasteride in Propecia makes it much safer.[18] Even though it has one-fifth of the active ingredient, however, Propecia costs much more than Proscar. Propecia costs approximately fifty dollars per month, whereas Proscar costs only about fourteen dollars per month.[19] Merck justifies the price difference as resulting from independent research performed to develop Propecia and from the hefty price of advertising Propecia.[20]

Given the significant price difference, many doctors prescribe Proscar to men seeking to prevent baldness.[21] Many doctors are instructing patients to use pill-cutters to divide the Proscar pills into five parts, so that each will provide as much finasteride as does a dose of Propecia.[22] This off-label prescribing is reportedly legal, and, from a financial perspective, it makes sense.[23] When taking one-fifth of a cheaper Proscar pill per day, men are receiving an effective dose of

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[15] *See Patient Access, supra* note 12.

[16] *See id.*

[17] *See* Teresa Moran Schwartz, *Prescription-products and the Proposed Restatement (Third)*, 61 TENN. L. REV. 1357, 1382 (1994). The inferior drug may continue to be prescribed because statutorily a drug may only be removed from the market when there is an "imminent hazard to the public health." *Id.*

[18] *See Battle Grows, supra* note 4, at 1D.

[19] *See* Nancy Ann Jeffrey, *Drugs: Drug Shuffle for Balding Men, A Cheaper Pill for Prostates Recovers Pates*, WALL ST. J., Apr. 13, 1991, at B1.

[20] *See id.*

[21] *See* Jim Thornton, *New Drug May Put Dent in Male Balding*, DENVER POST, Dec. 16, 1997, at 2D.

[22] *See id.* Because doctors write the off-label prescriptions, one possible response to concerns about using Proscar for hair loss is that these doctors, rather than manufacturers, are to blame. Off-label prescribing, however, is legal, quite foreseeable to manufacturers, and, in many cases, helpful rather than harmful. Of course, many cases involving poor design decisions do not involve off-label prescribing.

[23] *See id.*

baldness-preventing finasteride for much less than the fifty dollars per month needed to get the same result with Propecia.[24] Even if the consumer takes the entire Proscar pill, or cuts it in half or into thirds (which might be easier than cutting the pill into fifths), the consumer still saves substantially compared to the cost of Propecia.[25]

Assume, for purposes of discussion, that Proscar is not at all effective in treating prostate enlargement, that it causes enlarged breasts in men and causes breast cancer, and that cheap, safe, and effective alternatives for treating prostate enlargement exist.[26] Is it desirable to adopt a rule that holds that, even assuming these awful facts, Proscar is not defective because it can also be used fairly safely to remedy a cosmetic problem — baldness — even though a reasonable alternative design containing the same active ingredient exists to treat baldness in the lower-dose Propecia?

The Restatement (Third)'s reasonable physician standard might lead to such a finding.[27] The reasonable physician standard of the Restatement (Third) is that a prescription product is defective only if reasonable health-care providers, knowing of its foreseeable risks and benefits, would not prescribe the product to any class of patients.[28] It could be argued that physicians are acting reasonably in prescribing the cheaper Proscar to the subclass planning to cut the pills to use safely for baldness, even though Proscar's primary use, treating prostate enlargement, would be unhelpful and unreasonably dangerous. Thus, the Restatement (Third)'s approach might bar

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[24] The monthly cost of the $14 per month for Proscar, when divided into fifths, is approximately $2.80.

[25] Under this course of conduct, the consumer would pay $14 per month (full pill), $7 per month (half pill), or $4.77 per month (1/3 pill), as opposed to $50 per month for Propecia. *See supra* note 19 and accompanying text.

[26] Although all of these propositions have been alleged by critics of Proscar, this Article does not assert that these propositions have been proved. Considering these propositions as hypothetical is sufficient to illustrate differences between the reasonable physician test and the reasonable manufacturer test.

[27] When presented with this hypothetical, Professor Aaron Twerski, one of the Restatement (Third)'s Reporters, expressed the opinion that Proscar is defective in design even under the Restatement (Third)'s approach. Because the drug could be prescribed safely, effectively, and legally for purposes of treating baldness (with the added bonus of significant financial savings), this conclusion is not certain. In any event, even if one of the Reporters would read section 6 in this manner, it is not apparent that courts reading section 6 would share his conclusion. Indeed, if courts were to interpret section 6 in this manner, it might be to avoid the undesirable result that a less laborious reading of the section might render. Straightforward application of the dominant reasonable manufacturer standard might prove preferable to strained interpretation of the newly created reasonable physician test.

[28] *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(c) (1997).

from recovery all of the men harmed by using Proscar for its primary, health-related purpose. Finding just one reasonable use, even if that use is ancillary and for purely cosmetic purposes, in effect immunizes the manufacturer regardless of how much harm a drug inflicts overall.

In terms of the numbers of cases it will affect, my disagreement with the Reporters is relatively small. The Reporters are correct that most prescription products should receive greater design protection than do other products, and that findings of liability should be relatively rare. For example, Professor Michael Green noted that even an infamously harmful drug, such as thalidomide, might also provide medical benefits.[29] Although the drug causes horrid birth defects when taken by pregnant women, thalidomide may aid persons suffering from leprosy and other ailments.[30] Because strong warnings are available and the risk to pregnant women is well-known, and assuming that the drug has strong utility in treating leprosy, a court may well find that thalidomide is not defective under both the reasonable physician test and the reasonable manufacturer test. If, however, thalidomide's only utility were in treating baldness, the Restatement (Third)'s reasonable physician test would still exempt the drug manufacturer from liability, whereas the reasonable manufacturer test would allow at least the possibility of finding the design defective. Although I believe that liability is appropriate in only a relatively few cases, the Restatement (Third)'s approach allows for liability in almost no cases.

II. SEARCHING FOR PRECEDENT SUPPORTING THE REASONABLE PHYSICIAN TEST

A. *Cases Cited by the Restatement (Third)*

Whether the Restatement (Third) restates or conflicts with existing law is, of course, an important question.[31] Professor James A.

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[29] *See* Michael D. Green, *Prescription Drugs, Alternative Designs, and the Restatement (Third): Preliminary Reflections*, 30 SETON HALL L. REV. 193, 212 (1999).

[30] *See id.*

[31] The Restatement (Third) could be misinterpreted, in section 6, comment a, to contend that its reasonable physician standard for design liability is "generally recognized." Arguably, the Reporters are asserting only that allowing some form of design liability generally is recognized. A casual reader, however, might assume that the "generally recognized" exception to the no-liability rule "consistent with recent trends in the case law" refers to the Restatement (Third)'s standard. The Reporters' notes clarify that "some" jurisdictions have adopted "essentially" the same approach. This Article contends that no jurisdictions have adopted the same approach or the

Henderson, one of the Reporters for the Restatement (Third), has written that an "emerging body of law" supports the approach.[32] In the draft that originally proposed the reasonable physician standard, however, the Reporters cited only one case.[33] Following criticism that the standard conflicts with rather than restates existing law, the Reporters added two additional cases that they contend support their approach.[34] This Part briefly analyzes each of these three cases to demonstrate that the reasonable physician standard does not reflect the law of any of these jurisdictions.

Tobin v. Astra Pharmaceutical Products, Inc.[35] was, originally, the only case the Reporters cited to support the reasonable physician approach. The court in *Tobin* ruled that a prescription drug is defective when a product manufacturer, aware of the drug's risks, would not have marketed the drug.[36] The *Tobin* court held that "[t]he question is whether the product creates 'such a risk' of an accident of the general nature of the one in question that 'an ordinarily prudent company engaged in the manufacture' of the product 'would not have put it on the market.'"[37]

The Restatement (Third) argues that its reasonable physician standard is "essentially" the same as the standard in *Tobin* and other cases.[38] Although *Tobin*'s approach usually will reach the same result as the reasonable physician standard, it is not the same thing, essentially or otherwise. First, *Tobin* does not discuss what a

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essence of the approach. *See* RESTATEMENT (THIRD) OF TORTS § 6 cmt. a (1997).

[32] *See* James A. Henderson, Jr., *Prescription Drug Design Liability Under the Proposed Restatement (Third) of Torts: A Reporter's Perspective*, 48 RUTGERS L. REV. 471, 494 (1996).

[33] *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 reporters' notes (Tentative Draft No. 1, 1994).

[34] *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 reporters' notes (1997).

[35] 993 F.2d 528 (6th Cir. 1992) (applying Kentucky law).

[36] *See id.* at 536-37.

[37] *Id.* at 537 (quoting Montgomery Elevator Co. v. McCullough, 676 S.W.2d 776, 780 (Ky. 1984)). In this quotation, *Tobin* sets forth the general standard under Kentucky law for strict liability. *See id.* at 536. The trial court gave a jury instruction based on this standard, and *Tobin* approved it. *See id.* at 540. The trial court also gave the jury an instruction based on comment k, which *Tobin* approved. *See id.* The court noted that "Kentucky has ruled that comment k shields manufacturers from liability for 'highly useful and desirable products attended with a known but reasonable risk.'" *Id.* (quoting McMichael v. American Red Cross, 532 S.W.2d 7, 9 (Ky. 1975)). This does not detract from the reasonable manufacturer test because it requires a broad analysis of whether the product is "highly useful" and "desirable" and balances this against a "reasonable" risk.

[38] *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 reporters' notes (1997).

reasonable physician would do. Instead, the case analyzes whether a reasonable manufacturer would have marketed the drug as designed.[39] Further, *Tobin* does not ask whether a reasonable manufacturer would market its drug to any class of patients. Rather, *Tobin* asks, in a relatively straightforward manner, the broader question of whether a reasonable manufacturer would have marketed the drug as manufactured.[40]

In an article in the *Rutgers Law Review*, Professor Henderson asserts that "it is clear from the opinion that the court was unready to sacrifice – by labeling a drug defective – any class of patients for whom it might be the drug of choice."[41] *Tobin*, however, does not refer to classes of patients. Perhaps the closest *Tobin* comes to such a reference is in its quotation of a jury instruction indicating that a drug is not defective "if it cannot be made completely safe for all users, but is nevertheless a useful and desirable product which is accompanied by proper directions and warnings."[42] This jury instruction is based on language from comment k to section 402A of the Restatement (Second) that limits protection to "an apparently useful and desirable product."[43] The court noted that a Kentucky court supported comment k's shielding of manufacturers from liability for "highly useful and desirable products attended with a known but reasonable risk."[44] The *Tobin* court went on to state that if ritodrine prolongs pregnancy to reduce infant mortality (which it does not), this would be a "*highly* useful and desirable product."[45]

Thus, rather than holding that a drug is protected if its risks outweigh its benefits for any use, *Tobin* acknowledged that Kentucky simply follows comment k, giving protection when a product is highly useful and desirable. Although the lower court's jury instruction quoted in the opinion did not include the word "highly," the Sixth Circuit identified the designation as part of the appropriate standard under Kentucky law. A use that merely saves consumers some money to treat a cosmetic problem like baldness is unlikely to fall into the "highly" useful and desirable category contemplated by Kentucky law.

The difference between *Tobin*'s reasonable manufacturer test and the Restatement (Third)'s reasonable physician test is one of

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[39] *See Tobin*, 993 F.2d at 536-37.

[40] *See id.*

[41] Henderson, *supra* note 32, at 488.

[42] *Tobin*, 993 F.2d at 540.

[43] *Id.*

[44] *Id.*

[45] *Id.* (emphasis added).

perspective. The reasonable physician test uses blinders to maintain a narrow perspective; a prescription-product manufacturer is immune from liability no matter how much harm its design causes, as long as there is at least one class of persons for whom the design's benefits even marginally outweigh its risks. The reasonable manufacturer test utilizes a broader perspective and is flexible enough to recognize that, even if there is a class of persons for whom the drug is acceptable when taken as designed, the manufacturer still might be unreasonable in marketing the drug if its social costs outweigh its benefits. Professor Henderson acknowledged this difference between *Tobin* and the Restatement (Third) standard, implying that *Tobin* allows "netting out all risks and benefits globally," whereas the Restatement (Third) focuses on reasonableness for any one class of patients.[46]

The illustration involving Propecia and Proscar helps demonstrate how this difference in perspective between *Tobin*'s reasonable manufacturer test and the Restatement (Third)'s reasonable physician test plays out. Under the reasonable physician test, Proscar is immunized from liability because it can be used safely to treat the cosmetic problem of baldness and is cheaper than the lower dosage design. Using the reasonable manufacturer test, however, the court might hold that the manufacturer should not have marketed the higher-dose Proscar at all. In reaching this holding, the court would assume that Proscar is not effective in treating prostate enlargement, is dangerous when used in high-dose form, and, for the relatively unimportant use of treating baldness, is replaceable with the safer design of a lower dosage. "Net[ting] out all the risks and benefits globally"[47] might lead to a rejection of Proscar, whereas the Restatement (Third)'s search for benefits for any class of patients might spare Proscar.

The second case cited by the Restatement (Third) is *Williams v. Ciba-Geigy Corp.*[48] As with *Tobin*, *Williams* makes no mention of the reasonable physician standard or of classes of patients. Despite this, the Restatement (Third) points out that the court showed respect for the Food and Drug Administration's (FDA) approval process, and

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[46] Henderson, *supra* note 32, at 487.

[47] *Id.*

[48] 686 F. Supp. 573 (W.D. La.), *aff'd*, 864 F.2d 789 (5th Cir. 1988). The drug at issue was Tegretol, which is designed for the control of epileptic symptoms, including psychomotor and grand mal seizures and for relief of trigenminal neuralgia (suddenly recurring or intensifying severe pain focused roughly in the center of the head, below the brain). *See Williams*, 686 F. Supp. at 578. As a result, the plaintiff developed a serious skin condition. *See id.* at 580.

that the court required the plaintiff to provide evidence of "an articulable basis for disregarding the FDA's determination that the drug should be available."[49] The Restatement (Third) then quotes the court's finding that Tegretol, the drug at issue, has high utility and was the only drug available to treat the plaintiff's disorder.[50]

In fact, *Williams* supports the reasonable manufacturer test rather than the reasonable physician test. Courts frequently consider the FDA approval process as some evidence of reasonableness that the plaintiff must overcome.[51] Further, it is highly relevant under the reasonable manufacturer test that Tegretol has significant social utility and that it is the only drug available to treat a serious problem. This does not mean, however, that *Williams* immunizes drug manufacturers from liability if there was just some use, no matter how trivial, for which a design's utility outweighs its risks. Rather, *Williams* engages in the kind of global balancing of risks and utilities that the Restatement (Third) is seeking to avoid.

Williams' broad perspective on analyzing a manufacturer's reasonableness is apparent in the decision:

> Proper "risk" evidence for purposes of the risk-utility test is not a mere roster of isolated incidents. Rather, "risk" in a vaccine or pharmaceutical case, as with other cases, concerns not only the qualitative harmful effect, but also the quantitative harm or "incidence" of serious adverse effects, that is, the ratio of instances of harm compared to the total use or consumption of the product. Although the danger may be devastating to those individuals who experience the worst effects, the incidence may be statistically small and the composite risk may not outweigh the value of a high utility drug.[52]

Under the approach in *Williams*, a drug that is the only medication available for a serious condition would not be defective unless it caused even more serious harm. This is appropriate. Using its global perspective, however, *Williams* would likely condemn a drug design that presents serious risks of harm to most users, but provides a reasonable alternative to treating a medically insignificant problem, such as baldness, for one class of users. On the whole, marketing such a drug is not reasonable.

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[49] *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 cmt. f (1997) (citing *Williams*, 686 F. Supp. at 577.

[50] *See id.* (citing *Williams*, 686 F. Supp. at 578).

[51] *See* Schwartz, *supra* note 17, at 1377.

[52] *Williams*, 686 F. Supp. at 578-79 (citations omitted).

The Restatement (Third) cites only one more case, for a total of three, in an effort to support its reasonable physician approach. However, this case, *Ortho Pharmaceutical Corp. v. Heath*,[53] is not any more helpful than are *Tobin* and *Williams*. As with *Tobin* and *Williams*, *Ortho* does not mention reasonable physicians or classes of patients. *Ortho* is somewhat similar to the Proscar/Propecia illustration provided above in that the case involves higher versus lower dosages of an active ingredient as design alternatives. The plaintiff's doctor prescribed a relatively low-dose estrogen birth control pill, but the plaintiff experienced excessive bleeding associated with menstrual flow while taking the pill.[54] The plaintiff's doctor switched the prescription to a higher-dose estrogen pill to alleviate this problem.[55] However, the plaintiff allegedly developed kidney failure and other problems as a result of taking the higher-dose pill, and she claimed that making the higher-dose pill constituted a design defect.[56]

As with *Williams*, the Restatement (Third) relies on *Ortho*'s notation that the challenged design was the only one available to treat the plaintiff's serious medical problem — the lower-dosage alternative would not stop her bleeding.[57] However, this is quite different from finding the drug immune from design liability when its utility even marginally outweighs its risks for one class of users, regardless of the importance of the use. The Restatement (Third)'s reasonable physician test immunizes manufacturers not only in situations in which the drug at issue is the only one available, but also in situations in which the drug is one of several reasonable options for a small class of patients, but potentially deadly and unhelpful to most users. As shown in the passage below, *Ortho* follows a global, broad-perspective approach to determine whether the utilities in a drug's design outweigh its risks:

> [There are] four factors to be considered in determining whether a manufacturer is entitled to a defense based on comment k: the product's utility must greatly outweigh the risk created by its use; the risk must be a known one; the product's benefits must not be achievable in another manner; and the risk must be unavoidable under the present state of knowledge.[58]

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[53] 722 P.2d 410 (Colo. 1986).

[54] *See id.* at 411.

[55] *See id.*

[56] *See id.* at 411-12.

[57] *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 cmt. f (1997).

[58] *Ortho Pharm. Corp.*, 722 P.2d at 415.

B. *Cases Decided Since the ALI's Adoption of the Reasonable Physician Test*

At least two cases have addressed the reasonable physician standard since the ALI adopted the Restatement (Third). *Sita v. Danek Medical, Inc.*[59] presented a fact pattern in which, given the court's findings, design liability is inappropriate under either the reasonable manufacturer standard or the reasonable physician standard. In *Sita*, the plaintiffs asserted, among other things, that a manufacturer defectively designed a surgical screw system.[60] The defendants, however, presented "an impressive compendium" of 270 surgeons' testimony that use of the medical device as designed was helpful and appropriate.[61]

In ruling on the strict liability design defect claim, the court did not rely on a special standard for prescription products. Rather, the court applied a simple risk-utility balancing test generally applicable to strict liability design defect claims.[62] The court pointed out that the plaintiffs failed to present evidence that the screw systems were unsafe, and also that the plaintiffs failed to present evidence of a reasonable alternative design.[63] Thus, the court dismissed the claim. It noted in dicta that the plaintiffs' claims also would fail under the Restatement (Third)'s proposed reasonable physician test. In a footnote, the court indicated that reasonable health-care providers would prescribe the screw systems because use of the systems is the industry standard of care. Thus, the screw systems would not be defective even if the Restatement (Third)'s test were applied.[64] The court also pointed out that use of the surgical screws was the only viable option for patients who previously had undergone spinal surgery.[65] The court noted that this would be another ground for denying liability under the Restatement (Third) view.[66]

Although *Sita* did not criticize the reasonable physician test, the court was not presented a situation in which it needed to choose

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[59] 43 F. Supp.2d 245 (E.D.N.Y. 1999).

[60] *See id.* at 255.

[61] *See id.* at 255-56.

[62] *See id.* at 255. The court clearly articulated the applicable standard when it stated, "More precisely, the standard is whether, 'if the design defect were known at the time of manufacture, a reasonable person would conclude that the utility of the product did not outweigh the risk inherent in marketing a product designed in that manner.'" *Id.* (internal citations omitted).

[63] *See id.* at 257.

[64] *See id.* at 256 n.9.

[65] *See Sita*, 43 F. Supp.2d at 258.

[66] *See id.*

between the reasonable physician test and the reasonable manufacturer test. The plaintiffs failed to present any solid evidence that the product was problematic. Thus, the court understandably saw no need to analyze the strengths and weaknesses of the newly proposed reasonable physician test. Given its view of the evidence (or lack of plaintiff's evidence) the court would have easily rejected liability under either approach.

The second case, *Taylor v. Danek Medical, Inc.*,[67] involved a surgical screw system that was the same as or similar to the system at issue in *Sita*.[68] In its analysis, the *Taylor* court differentiated between strict liability and negligence in design defect claims. The court first predicted that Pennsylvania courts would not apply strict products liability to prescription medical devices, and it rejected the plaintiffs' strict liability claim on that basis.[69] The court also predicted that Pennsylvania courts would approve of the reasonable physician test for strict liability claims.[70] Thus, the court cited the plaintiffs' failure to establish that reasonable health-care providers would not prescribe the screw system to any class of patients as an additional basis for granting summary judgment on the strict liability design defect cause of action.

Although reading only *Taylor*'s strict liability analysis would give a sense of support for the reasonable physician test, ultimately the court undermined the Reporters' intended use of the test. Instead, the court firmly supported the reasonable manufacturer approach. In analyzing the plaintiffs' claim of negligent design defect (which was pleaded in addition to strict liability design defect), the court declined to apply, or even to discuss, the Restatement (Third) and its reasonable physician test. Rather, the court set forth the negligence standard for design defects as a straightforward reasonable prudent person approach.[71] Contrasting sharply with its strict liability analysis,

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[67] 1998 U.S. Dist. LEXIS 20265 (E.D.Pa., Dec. 29, 1998).

[68] *See id.* at *4. *Taylor* described the product, which the court called a Cotrel Dubosset device, as consisting of "screws, hooks, rods, transverse traction devices, connectors, and other components that allow surgeons to customize constructs." *Id.* *Sita* used the same language to describe the product before the court, but called it "the Texas Scottish Rite Hospital Spinal System." *Sita*, 43 F. Supp.2d at 249.

[69] *See Taylor*, 1998 U.S. Dist. LEXIS at *21-*22. The court noted that Pennsylvania courts disallow strict liability for prescription drugs, and the court predicted that the Pennsylvania courts would extend this rule to prescription medical devices. *See id.*

[70] *See id.* at *22-*23.

[71] *See id.* at *31-*32 ("Negligence is the doing of some act which a reasonably prudent person would not do, or the failure to do something which a reasonable prudent person would do. It is the failure to use the ordinary care a reasonably prudent person would use under the same or similar circumstances.").

the court found that the plaintiffs presented sufficient evidence of unreasonableness in the manufacturer's design to survive a summary judgment motion.[72]

Taylor's approach is plainly not what the Reporters had in mind when they created the reasonable physician test. Indeed, the Reporters' notes to comment f of section 6 expressly reject reserving the reasonable physician test for strict liability only and allowing a different standard under negligence.[73] Rather, the Restatement (Third) insists that its test be used in both negligence and strict liability claims.[74] By paying lip service, with little analysis, to the reasonable physician test in its strict liability discussion, but applying the reasonable manufacturer test under negligence, *Taylor* in effect rejects the Restatement (Third)'s attempt to severely limit prescription product design liability. *Taylor*'s approach allows plaintiffs to avoid whatever difficulties the reasonable physician test might present and to instead utilize the reasonable manufacturer test by merely pleading a negligence cause of action.

C. *Scholars' Analysis of the Case Law*

Since the Reporters first proposed their reasonable physician test, numerous law review articles have analyzed how the approach compares to existing case law. As acknowledged in the Reporters' notes to the Restatement (Third), at least two jurisdictions recently have gone to the opposite extreme of the near immunity provided by Restatement (Third)'s approach. These jurisdictions apply strict liability in prescription drug design cases with no protection for manufacturers at all.[75] Most jurisdictions addressing the issue,

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[72] *See id.* at *35.

[73] *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 cmt. f reporters' notes (1997). The Restatement (Third) suggests:

> It should be noted that some cases exempt drugs and medical devices from design review based on a strict liability theory only. They appear to allow plaintiffs to pursue a cause of action for negligence. The rule set forth in section 6(c) would provide the exclusive basis for a cause of action based on objective drug design. As with section 2, the test in section 6 is stated in functional terms. Thus, whether the case is brought under negligence or strict liability a plaintiff would be successful only if it could make out the elements set forth in section 6(c).

Id.

[74] *See id.*

[75] *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 cmt. f (1997); *see also* Shanks v. Upjohn Co., 835 P.2d 1189, 1193-94 (Alaska 1992); Allison v. Merck & Co., 878 P.2d 948, 954 (Nev. 1994).

however, have taken a middle-ground approach. Recognizing the need to give some protection to drug manufacturers, but also the need for some accountability, these jurisdictions have adopted some form of a broad perspective reasonable manufacturer test.

The legal literature overwhelmingly recognizes that the Restatement (Third)'s approach does not restate the dominant approach courts take in cases involving prescription-product designs. Not all, but most of the commentators are critical of the Restatement (Third)'s departure from the case law. A brief review of some of the commentary provided by these articles is helpful in providing a sense of how the reasonable physician test is being received in the first few years since its birth.[76]

One of the first articles addressing the reasonable physician test was published in 1994 and authored by Professor Teresa Moran Schwartz.[77] Professor Schwartz has extensive experience with food and drug regulation issues both in academia and in government service, and her article published in the *Tennessee Law Review* was critical of the Restatement (Third)'s approach to prescription product design defects:

> With respect to design standards, this Article finds that [the Restatement (Third)'s prescription product design defect test] departs significantly from common-law rulings by establishing a "super" negligence standard of liability. It raises concerns that the proposed standard will be difficult to apply as drafted, and will create such a narrow band of liability that it would effectively eliminate a cause of action for defective design.[78]

In the same year, I published an article in the *George Washington Law Review* that also disapproved of the reasonable physician approach and expressed doubt about its foundation in case law.[79] At that time, the Restatement (Third) draft cited only one case, *Tobin v. Astra Pharmaceutical Products, Inc.*,[80] to support the reasonable physician standard. My article notes:

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[76] I have omitted excerpts from law review articles written by the Reporters addressing the issue because their views on the case law are provided in the Restatement (Third). For the most detailed of the Reporters' law review articles setting forth their views, see generally Henderson, Jr., *supra* note 32. The article's analysis of relevant cases is, for the most part, repeated in the Restatement (Third)'s reporters' notes.

[77] *See generally* Schwartz, *supra* note 17.

[78] *Id.* at 1364.

[79] *See generally* 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).

[80] 993 F.2d 528 (6th Cir. 1993).

> If nothing else, wide judicial acceptance of the new Restatement's approach would clarify the unavoidably unsafe products doctrine. However, it seems unlikely that courts will uniformly adopt the new Restatement's version of the doctrine. Unlike many of the ALI's revisions to section 402A, its language addressing prescription products is far from a restatement of present law. Indeed . . . the new Restatement claims only one jurisdiction as presently utilizing its approach to conscious design defect actions, and even that claim is questionable.[81]

A 1995 student Note that appeared in the *Syracuse Law Review* provides what may be the most supportive analysis of the reasonable physician test.[82] The author contends that the Restatement (Third) captures the spirit of *Tobin* and provides some much-needed clarification:

> [T]he tentative draft of the Restatement of the Law (Third) Torts basically codifies what the court was emphasizing in *Tobin*. If a plaintiff can show that the reasonably foreseeable risks posed by a drug are so great that a reasonable health-care provider, who is informed of the risks, would not prescribe the drug to any patient then the design is defective and the plaintiff is entitled to recovery from the manufacturer. Similarly, the court in *Tobin* articulates that if an ordinarily prudent manufacturer of a product (such as a prescription drug) is aware of the risks and would not market the product, then the product is defectively designed and the plaintiff is entitled to recovery. The advantage of [the Restatement (Third)'s approach] is it is more clear than the ruling in *Tobin*.[83]

The next year, Professor Jerry Phillips added to the articles critical of the Restatement (Third)'s standard and its foundation in the case law.[84] In his article in the *Chicago-Kent Law Review*, Professor Phillips expresses special concern about over-reliance on the existence of learned intermediaries and the FDA approval process to justify using a restrictive approach:

> The Reporters' Notes . . . recognize that "in recent years many courts have imposed limited judicial review [of the reasonableness of design] on this special category of products," but they choose to disregard this developing trend. The rationale given is that [the Restatement's approach] "shows appropriate deference to

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[81] Cupp, *supra* note 79, at 98 (citations omitted).

[82] *See* Andrew Barrett, Note, *The Past and Future of Comment k: Section (4)(B)(4) of the Tentative Draft Restatement (Third) of Torts – Is It the Beginning of a New Era for Prescription Drugs?*, 45 SYRACUSE L. REV. 1291, 1324 (1995).

[83] *Id.*

[84] *See* Jerry J. Phillips, *The Unreasonably Unsafe Product and Strict Liability*, 72 CHI.-KENT L. REV. 129, 130 (1996).

> the regulated market, where the FDA and learned intermediaries select which drugs should be available." This rationale gives much greater credence to safety regulatory effect provided by the FDA and learned intermediaries than many persons would be willing to give, and shows much more reliance on those entities than is justified by existing and developing law.[85]

A student Comment also published in 1996 in the *Emory Law Journal* provides what may be the harshest assessment of the Restatement (Third)'s approach, serving up a laundry list of criticisms:

> Such an overbearing standard is wholly unsupported by case law and is problematic as a substantive rule of law. The broad standard imposed by this section completely immunizes pharmaceutical manufacturers from claims brought under a design defect theory. As such, this standard is likely to prove unworkable. [C]onsumers injured by prescription drugs or medical devices should be able, at the very least, to sue a manufacturer in negligence. The [Restatement (Third)'s standard] prohibits a negligence action unless the plaintiff can show that no reasonable doctor would prescribe the drug. This effectively poses an insurmountable burden on consumers and is wholly unsupported by case law. For a new prescription drug standard to be workable, it must provide a measure of protection to both manufacturers and consumers. Some believe a negligence standard would serve this purpose. This Comment strongly encourages the ALI to afford consumers more protection.[86]

In a 1997 article published in the *University of Michigan Journal of Legal Reform*, Professor Frank Vandall also opines that the reasonable physician approach is lacking in precedent and will be rejected by the courts:

> Instead [of looking at precedent the Reporters] take a clean sheet of paper and virtually grant immunity to all drug and medical device manufacturers for defective design cases. Because of these omissions [the Restatement (Third) standard] is void of precedent. Most likely, courts will not accept [the Restatement (Third)'s prescription product design section] until the Reporters evaluate the cases and the policies and draft a proposal that reflects the law.[87]

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[85] *Id.* at 155 (citations omitted).

[86] Angela C. Rushton, Comment, *Design Defects Under the Restatement (Third) of Torts: A Reassessment of Strict Liability and the Goals of a Functional Approach*, 45 EMORY L.J. 389, 419, 435-36 (1996) (citations omitted).

[87] Frank J. Vandall, *Constructing a Roof Before the Foundation Is Prepared: The*

1997 also produced an article by Kelley E. Cash in the *Review of Litigation* analyzing how the Restatement (Third) will affect possible litigation related to AIDS vaccines.[88] Cash supports limiting liability to encourage development of an effective AIDS vaccine but worries that the reasonable physician standard so "radically" differs from existing law that courts will reject it:

> [The Restatement (Third)'s section addressing liability for prescription products], unlike its predecessor, comment k, is not ambiguous in its goal to provide prescription drug manufacturers protection from design defect claims. Unfortunately, it so radically departs from the approach of many courts and some state statutes that it is unlikely to gain uniform adoption.[89]

One of the most detailed and thoughtful analyses of the Restatement (Third)'s standard is provided in a 1997 student Note published in the *Cornell Law Review*.[90] The author generally applauded the Reporters' goal of clarifying and limiting prescription product design liability, but he criticized use of the reasonable physician approach:

> One of the main functions of a Restatement is to survey the law – that is, to sift through the case law and statutes in order to assemble a body of work that at once explains the law and guides future lawmaking activities. A search of the case law indicates that no prescription drug or device design defect case refers to the "reasonable physician" or to the "reasonable health-care provider." In *Tobin v. Astra Pharmaceutical Products Inc.*, the only case relied upon by the co-reporters of the Restatement (Third) in support of [their approach], the court focused on the "prudent manufacturer." By asking the courts to accept this new test, the co-reporters invite criticism and potential rejection. Judges in jurisdictions whose case law has developed along the . . . risk-benefit approach to pharmaceuticals could well dismiss [the Restatement (Third)'s standard] out of hand as being unsubstantiated, because no court has ever employed a "reasonable health-care provider" approach for drug design liability claims.[91]

Restatement (Third) of Torts: Products Liability Section 2(b) Design Defect, 30 U. MICH. J.L. REFORM 261, 270 (1997) (citations omitted).

[88] *See* Kelley E. Cash, Note, *The New Restatement (Third) of Torts: Is It the Cure for the AIDS Vaccine Ailment?*, 16 REV. LITIG. 413, 428-37 (1997).

[89] *Id.* at 437-38.

[90] *See generally* Jeffrey D. Winchester, Note, *Section 8(c) of the Proposed Restatement (Third) of Torts: Is It Really What the Doctor Ordered?*, 82 CORNELL L. REV. 644 (1997).

[91] *Id.* at 671-72.

One of the more recent articles addressing the reasonable physician test was published in 1998 in the *Food & Drug Law Journal* and authored by Michael J. Wagner and Laura L. Peterson.[92] Wagner and Peterson point out that the lack of precedent supporting the reasonable physician test may lead to its rejection, and they argue that a reasonable manufacturer approach is preferable:

> The key element of the test articulated by this provision is the "reasonable health-care provider" standard. This proposed standard was created by the reporters without apparent precedent in case law. The Sixth Circuit's opinion in *Tobin v. Astra Pharmaceutical Products, Inc.*, cited in the reporters' note[s] . . . , comes closest to articulating a test similar to that found in [the Restatement (Third)]. In this case, the court applied Kentucky law and held that a defective design claim could succeed if the jury found that a product manufacturer who was aware of the risks associated with a drug would not have marketed it. This "reasonable manufacturer" standard, however, is a better test than the one provided in the new Restatement, because the actions and judgment of doctors should not be determinative of the reasonableness of a given drug or medical device. Moreover, because physicians largely rely on the manufacturers' representations about the products they market, having the physician set the standard of whether a product should be on the market would be nonsensical. Such problems increase the potential for rejection of the Restatement (Third) by the judiciary.[93]

Finally, a 1998 student Comment that appeared in the *Ohio State Law Review* summarily dismisses any notion that the reasonable physician test restates existing law:

> The ALI has taken a "clean slate" approach to the problem of pharmaceutical design defect liability. The design defect liability section of the proposed Restatement, however, is not a "restatement" of the current law practiced in most jurisdictions.[94]

This review of legal literature addressing the Restatement (Third)'s reasonable physician test reveals the paucity of support for the standard and the near-unanimous conclusion that it does not restate existing case law. Although failing to follow the courts is not

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[92] *See generally* 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 (1998).

[93] *Id.* at 233 (citations omitted).

[94] David S. Torborg, Comment, *Design Defect Liability and Prescription Drugs: Who's in Charge?*, 59 OHIO ST. L.J. 633, 644 (1998).

necessarily fatal to a Restatement's prospects for influencing future cases, the initial academic reviews of the reasonable physician test do not bode well for its widespread adoption.

III. EVALUATING THE REASONABLE PHYSICIAN TEST

Establishing that the Restatement (Third) approach fails to restate existing law does not settle the issue of whether it is better or worse than the dominant reasonable manufacturer standard. Sometimes the ALI's Restatements lead, rather than follow, the courts. For example, the strict liability standard adopted by section 402A of the Restatement (Second) of Torts certainly did not restate the dominant approach to products liability at the time. Within a few years, however, most courts followed the ALI's standard.

Unfortunately, the Restatement (Third)'s departure from the case law is not an improvement. From several perspectives, the existing reasonable manufacturer test seems preferable to the reasonable physician test. Part III of this Article expands upon concerns with the reasonable physician test illustrated in Part I's comparison of Proscar and Propecia.

A. *Artificiality and Complexity*

First, the Restatement (Third)'s reasonable physician standard is artificial and is difficult to apply. It asks fact finders to presume that physicians know all that the manufacturer knows about a drug and then determine what physicians' reasonableness analysis would be, given this knowledge, for any class of patients.[95] In reality, of course, physicians do not know nearly as much as manufacturers know about drug safety and efficacy.[96] The artificiality and complexity of the Restatement (Third)'s standard is bound to create confusion for jurors and may lead to erratic results.[97]

B. *Protecting Prescription Products of Unequal Utility Equally*

A greater concern with the reasonable physician test, however, is its narrowness and lack of flexibility. Not all prescription product designs are created equal, and not all uses of prescription product designs are created equal. The Restatement (Third), however, treats

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[95] *See* Schwartz, *supra* note 17, at 1381-82; Winchester, *supra* note 90, at 674-77.

[96] *See* Winchester, *supra* note 90, at 674-77.

[97] *See id.* at 678.

these designs equally, providing design immunity for any use of a drug that is even marginally reasonable for any class of patients.[98]

Because most drugs uniquely provide important health benefits to some classes of patients without unduly harming others, findings of defectiveness should be rare under both the reasonable physician test and the reasonable manufacturer test. However, there are some drugs that are only slightly helpful to a small class of users, or even slightly helpful to a large class of users, but create a great deal of harm overall. There are also drugs that are helpful only for a relatively unimportant use, but create significant harm overall. Courts need to have enough flexibility to treat these types of drugs differently.

Allowing design liability is especially likely to be appropriate in cases involving prescription products with cosmetic uses. A drug designed to treat wrinkles should not have the same level of protection given to heart medication. Often, drugs used for cosmetic purposes also have health-related uses, such as the finasteride found in Proscar and Propecia.[99] If the cosmetic use is acceptable, but the health-related use is disastrous, immunizing the manufacturer may be inappropriate. Given that the number of prescription products with cosmetic applications has multiplied rapidly in recent years and seems likely to continue to grow, this concern will likely become even more significant over time.[100]

It may be argued that, provided adequate warnings are given, consumer autonomy should be afforded special respect regarding products with cosmetic utility. Under this argument, consumers should have the freedom to purchase cosmetic products with potentially defective designs without the added cost or potential unavailability that would result from allowing design defect lawsuits.[101]

In considering this argument, it first should be noted that, presently, courts do not typically excuse design defects simply because adequate warnings are given.[102] The Restatement (Third)'s

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[98] *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(c) (1997).

[99] *See supra* notes 4-11 and accompanying text.

[100] *See generally* Richard L. Cupp Jr., *Sharing Accountability for Breast Implants: Strict Products Liability and Medical Professionals Engaged in Hybrid Sales/Service Cosmetic Products Transactions*, 21 FLA. ST. U. L. REV. 873 (1994).

[101] Professor Aaron Twerski suggested this as a potential argument during the February 12, 1999 symposium at the Seton Hall University School of Law, entitled *Proving Product Defect After the Third Restatement of Torts: Products Liability.*

[102] *See, e.g.*, Sturm, Ruger & Co. v. Day, 594 P.2d 38, 44 (Alaska 1979) (concluding that warnings of hidden dangers do not preclude design defect claims); Uloth v. City Tank Corp., 384 N.E.2d 1188, 1192 (Mass. 1978) (declining to "adopt any rule which

Reporters acknowledge in a law review article: "If a sensible design alternative can significantly reduce risk, the law will demand that the manufacturer design out the risk rather than merely warn against it."[103]

One could argue that products with cosmetic uses should be excepted from this general rule because, generally, cosmetic products are used only by the purchaser and do not have the potential to harm third persons. In contrast, a defectively designed automobile places at risk third persons beyond the purchaser warned of the danger. Passengers in the purchaser's vehicle, other motorists, and pedestrians also may be at risk. A defectively designed baldness medication, however, is likely to injure only the purchaser. It could be asserted that if the purchaser of such a medication is warned of its dangers, he should be permitted to decide whether to encounter it without the extra cost — or potential removal from the market — that could result from a finding of design liability in lawsuits brought by injured purchasers.

Courts have not made this kind of differentiation for design defects in products with cosmetic utility, and courts should not. Although promoting autonomy and individual responsibility is laudable, focusing only on consumers' choices and not at all on manufacturers' design choices in cases involving nonessential products, such as cosmetics, is unbalanced and inappropriate.

Baldness medication, for example, does not have an especially important utility that warrants exempting it from the general rules of design liability applied to nonprescription products. Certainly a person losing his hair may consider baldness medication extremely important. Courts should consider consumers' willingness to accept the risks as an important factor in deciding whether the baldness medication is defectively designed. However, owning a fast all-terrain vehicle (ATV) may be equally important to someone else. Although courts consider consumers' desire to buy fast ATVs as an important factor in deciding whether they are defectively designed, courts do not rule out the possibility of design liability on that basis. Neither the baldness medication nor the fast ATVs provide uses falling within

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permits a manufacturer or designer to discharge its total responsibility to workers by simply warning of the dangers of a product"); *see also* Jerry J. Phillips, *The Standard for Determining Defectiveness in Products Liability*, 46 U. CIN. L. REV. 101, 106 (1977) (noting that "[t]here may be instances where the product is so dangerous that the courts will find that the seller's obligation cannot be fulfilled merely by warning").

[103] James A. Henderson, Jr. & Aaron D. Twerski, *A Proposed Revision of Section 402A of the Restatement (Second) of Torts*, 77 CORNELL L. REV. 1512, 1538 (1992).

the broadly accepted rationale that prescription health products need special protection because they have special utility. No persuasive reason is apparent for singling out cosmetic medical products as more deserving of protection than are other products that individual consumers may value highly.

As mentioned above, an argument may be made that prescription products, even those with cosmetic utility, should be treated differently because they are unique in generally harming only the purchaser. This position, however, does not withstand close analysis. First, examples of prescription products that harm third persons, while not the norm, are not difficult to find. A prominent example is the drug Diethylstilbestrol (DES), which has been the subject of much products liability litigation. DES was prescribed to pregnant women as an antimiscarriage drug.[104] DES harmed the children of purchasing consumers, not the purchasers.[105] As a general rule, parents likely choose prescription products, including those with cosmetic utility, for their children, rather than allowing their children to choose the product for themselves. Although the parent/child relationship is much different than a consumer/bystander relationship (or, more accurately, lack of relationship), the parent/child relationship is still a step removed from an autonomous choice by the child injured by a defect.

Lawsuits asserting that Prozac and other prescription antidepressants cause some users to become violent and harm third persons also readily come to mind.[106] For example, in April 1999, when Eric Harris participated in killing thirteen of his classmates at Columbine High School in Littleton, Colorado, concerns were raised that the antidepressant Harris was taking may have contributed to his violence.[107] Although the substantive merit of such claims is questionable, such claims provide another prominent illustration of the potential for prescription products to cause harm to bystanders who did not choose to encounter the drugs.

Further, prescription products with cosmetic utility are not the only products that usually harm the purchaser alone. For example, dangerous nonprescription products for intimate bodily use, such as

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[104] *See* Sindell v. Abbott Lab., 607 P.2d 924, 925 (Cal. 1980).

[105] *See id.* at 925.

[106] *See, e.g.*, Carla Crowder, *Rage Fuelled by Antidepressants?: Psychologists Dispute Beliefs Medication Was Connected to Murderous Events*, DENVER ROCKY MOUNTAIN NEWS, May 30, 1999, at 60A.

[107] *See, e.g.*, Rick Montgomery, *Concerns Arise over Teen's Medicine*, KANSAS CITY STAR, Apr. 30, 1999, at A15.

hair products or pain medications sold over the counter, are also typically likely to harm only the purchaser or a family member. Such products, however, do not receive special protection from design liability if an adequate warning is given.

Finally, imagine that the purchaser of a three-wheeled ATV is injured when the vehicle rolls over. No bystanders are injured. Suppose that the ATV is designed in a manner in which rolling over is far too easy, and remedying the design problem is inexpensive and does not remove too much utility. Assume, however, that an adequate warning is provided. Courts looking at analogous facts would not hold that a design defect claim is necessarily precluded because only the purchaser is harmed (rather than a passenger or bystander), and the purchaser is adequately warned. Thus, the idea of using this reasoning in cases involving prescription products with cosmetic utility would introduce a basis for denying recovery that courts could, but choose not to, utilize presently under appropriate facts with almost all products. Courts' failure to adopt such reasoning in cases in which only the purchaser is injured by a defective design makes it doubtful that courts would be attracted to using it in cases involving prescription products with cosmetic utility.

C. *Including Blanket Protection for Prescription Medical Devices*

Providing prescription medical devices the same near-immunity given to drugs under the reasonable physician standard is an especially troubling aspect of the Restatement (Third)'s approach. Unlike some drugs, manufacturers are capable of making medical devices with a broad universe of design alternatives. Thus, defective designs may be more common in devices than in drugs. Further, medical devices are not subject to the same level of FDA scrutiny as are drugs.[108] Even with regard to drugs, the FDA's resources are stretched too thin to provide assurance that only safe drugs are approved and remain on the market.[109] For medical devices, with even less FDA scrutiny, design problems are likely be much more common. As with cosmetic drugs, we are likely to see many more prescription devices on the market as time progresses.

D. *Relying on Warnings Liability Alone to Protect Consumers*

Part of the Reporters' argument for their reasonable physician test seems to be that severely limiting design liability is not so bad

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[108] *See* Schwartz, *supra* note 17, at 1391-95.

[109] *See id.* at 1387-91.

because warnings claims are still available. However, courts have not treated the existence of a warning claim, or even the existence of an adequate warning, as a reason to bar design claims.[110] Further, some fact patterns simply fit a design claim better than a warning claim, even if a warning claim is theoretically available. Think again of the Proscar/Propecia illustration. How should the manufacturer's warning for Proscar read? Something like "Do not use except for treating baldness, and be sure you take only one-fifth of a pill?" Given that the obvious alternative design of a lower-dose pill exists, design defect is a much better fit. Further, as Professor Twerski notes in a 1997 article in the *Pepperdine Law Review*, tort reform has seriously compromised the doctrine of joint and several liability. The added option of a design defect cause of action may help plaintiffs recover a larger percentage of their damages from manufacturers than would merely the option of a warning claim.[111]

IV. CONCLUSION

The broad perspective of the reasonable manufacturer test is needed to provide at least some tort accountability for defective prescription-product designs. Again, when seeking to structure some well-deserved protection for extremely useful drugs, courts should note that prescription products are not all created equal, and that uses of prescription products are not all created equal.

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[110] *See supra* notes 86-87 and accompanying text.

[111] *See* Aaron D. Twerski, *Inside the Restatement*, 24 PEPP. L. REV. 839, 855 (1997). Professor Twerski stated:

> Furthermore, in a world in which the common-law doctrine of joint and several liability has been seriously compromised by both legislative and judicial reform, fault allocation and ultimate recovery may vary greatly depending on whether the cause of action against the drug manufacturer is based on failure to warn, defective design, or both. As between a physician who has committed malpractice in prescribing a drug and a drug manufacturer who has been found liable for manufacturing a defective drug, the fault allocation may be weighted more heavily against a drug manufacturer if, in addition to inadequate warning, a drug is found to be defectively designed.

Id.