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# The Products Liability Restatement in the Courts: An Initial Assessment

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# THE PRODUCTS LIABILITY RESTATEMENT IN THE COURTS: AN INITIAL ASSESSMENT

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In an age of instantaneous information retrieval, two years since promulgation would seem an ample period of time to begin to assess how courts have received the *Restatement (Third) of Torts*. In truth, of course, it will take a considerably longer period before one will be able to report with confidence as to how the *Restatement* has done. Unlike Section 402A of the *Second Restatement*, which consisted of only one section with limited commentary, the *Products Liability Restatement* contains twenty-one separate sections with extensive commentary on each section. Together with Reporters' Notes, it fills a book. Given its magnitude, the courts cannot be expected to respond to the new *Restatement* as a unitary whole. Instead they will consider it provision by provision, as the need arises. This process will, perforce, take time.

Notwithstanding these disclaimers, it is possible, even at this early date, to report that the *Products Liability Restatement* has been warmly received by the courts. It has been cited in more than 170 reported decisions. In some areas it is clear that the *Restatement* positions will carry the day and provide closure on issues that have up to now been somewhat problematic. In others, minority views will continue to be expressed. In yet others, the *Restatement's* position has been formally rejected. Taken as a whole, the case law to date clearly demonstrates that, unlike the dire prediction of the plaintiffs' bar that the *Restatement* would be utilized exclusively as a tool for defendants to stifle legitimate claims, in reality plaintiffs have aggressively relied upon a host of *Restatement* positions and have often prevailed where they would clearly have failed under the jurisprudence of Section 402A.

The ensuing discussion sets forth a review of the most important decisions decided under the new *Restatement*. We do not attempt to cover everything. Rather, we shall identify decisions both clearly accepting or rejecting the *Restatement*. We shall also take note of cases whose position on issues raised in the *Restatement* are so clear that they leave no doubt whatsoever as to how the jurisprudence of the state views the *Restatement*.

### I. SECTION 1: LIABILITY FOR SALE OF DEFECTIVE PRODUCTS

Section 1 sets forth the operative rule holding a commercial seller of a defective product liable for harm to persons or property caused by the defect. Every seller in the distributive chain is liable

if the product left the seller's hands in a defective condition.<sup>1</sup> Section 1, *Comment e* notes that a substantial number of jurisdictions have enacted statutes immunizing non-manufacturing sellers from strict liability so long as the manufacturer is subject to the jurisdiction of the court and is not insolvent. The comment observes that statutes immunizing nonmanufacturers can be unfair to plaintiffs. If a nonmanufacturing seller is dismissed from the action at the outset when it appears that the manufacturer will be able to pay a judgment, and the manufacturer subsequently becomes insolvent and is unable to pay the judgment, the plaintiff may be left unfairly to suffer the loss uncompensated. The *Restatement* advises courts to toll statutes of limitations against nonmanufacturers in the event of the ultimate insolvency of the manufacturer.

An Ohio court recently followed *Comment e's* advice. In *Crego v. Baldwin-Lima-Hamilton Corp.*,<sup>2</sup> an employee who suffered the amputation of several fingers on his right hand while operating a drum mixer sued both the manufacturer of the mixer, and the retailer who sold the mixer. Based on a statute that exempted a retailer from products liability if the manufacturer was subject to the jurisdiction of the state and was not insolvent, the retailer moved for summary judgment. Before the court could rule on the summary judgment motion, the plaintiff voluntarily dismissed the complaint against the retailer. The plaintiff later learned that the manufacturer was insolvent. Relying heavily on Section 1, *Comment e* of the *Restatement*, the court equitably tolled the statute of limitations so long as the plaintiff exercised due diligence to ascertain the solvency of the manufacturer. The court remanded for a factual finding as to whether the plaintiff exercised such due diligence and was thus entitled to have the statute of limitations tolled.<sup>3</sup>

## II. SECTION 2(b): LIABILITY FOR DEFECTIVE DESIGN

Clearly, the most controversial section in the *Restatement* is Section 2(b), which provides that a product is defective in design "when the foreseeable risks of harm posed by the product could

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<sup>1</sup>RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 1 cmt. e (1998) [hereinafter all references to *Restatement (Third) of Torts: Prod. Liab.* will be *Restatement*]. One court following *Restatement* Section 1 held a retailer liable for failure to warn even though the retailer had acted reasonably in selling the product. *Marcon v. K-Mart Corp.*, 573 N.W.2d 728 (Minn. Ct. App. 1998).

<sup>2</sup>No. 16515, 1998 WL 80240 (Ohio Ct. App. Feb. 27, 1998).

<sup>3</sup>*Id.* at 7.

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>4</sup> Before considering the case law dealing with Section 2(b), it is important to note that Section 2, *Comment b*, makes it clear that proof of a reasonable alternative design is not required in every case. Three exceptions are set forth:

Section 3 provides that when circumstantial evidence supports the conclusion that a defect was a contributing cause of the harm and that the defect existed at the time of sale, it is unnecessary to identify the specific nature of the defect and meet the requisites of § 2. *Section 3 frees the plaintiff from the strictures of § 2 in circumstances in which common experience teaches that an inference of defect may be warranted under the specific facts, including the failure of the product to perform its manifestly intended function.* When the defect established under § 3 may involve product design, some courts recognize consumer expectations as an adequate test for defect, in apparent conflict with the reasonable alternative design requirement in § 2(b). But when the claims involve a product's failure to perform its manifestly intended function and the other requisites of § 3 are met, the apparent conflict disappears.

Section 4, dealing with violations of statutory and regulatory norms, also provides an alternate method of establishing defect. A plaintiff is not required to establish the standard for design or warning under § 2, but merely to identify a government-imposed standard.

*Comment e* provides a further qualification of the rule in § 2(b). This Restatement recognizes the possibility that

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<sup>4</sup>Opponents of the Section 2(b) formulation argued that the *Restatement* should recognize the "consumer expectation test" as an alternative grounds for liability. For the arguments of the proponents, see James A. Henderson, Jr. & Aaron D. Twerski, *Achieving Consensus on Defective Product Design*, 83 CORNELL L. REV. 868, 882-893 (1998) [hereinafter *Achieving Consensus*]; James A. Henderson, Jr. & Aaron D. Twerski, *The Politics of the Products Liability Restatement*, 26 HOFSTRA L. REV. 667, 671-75 (1998); Theodore S. Jankowski, *Focusing on Quality and Risk: The Central Role of Reasonable Alternatives in Evaluating Design and Warning Decisions*, 36 TEX. L. REV. 283, 290-97 (1995); David G. Owen, *Toward a Proper Test for Design Defectiveness: "Micro-Balancing" Costs and Benefits*, 75 TEX. L. REV. 1661, 1662-66 (1997). The opponents' views are reflected in Phillip H. Corboy, *The Not-So-Quiet Revolution: Rebuilding Barriers to Jury Trial in the Proposed Restatement (Third) of Torts: Products Liability*, 61 TENN. L. REV. 1043, 1092-96 (1994); Marshall S. Shapo, *In Search of the Law of Products Liability: The ALI Restatement Project*, 48 VAND. L. REV. 631, 666-71 (1995); Frank V. Vandall, *The Restatement (Third) of Torts: Products Liability § 2(b): The Reasonable Alternative Design Requirement*, 61 TENN. L. REV. 1407, 1408 (1994).

product sellers may be subject to liability even absent a reasonable alternative design when the product design is manifestly unreasonable. When § 2(b) is read in conjunction with these other provisions that allow for other avenues for determining defective design, it reflects the substantial body of case law suggesting that reasonable alternative design is the predominant, yet not exclusive, method for establishing defective design. (emphasis added)

Section 2 (b)'s requirement that a plaintiff must establish a reasonable alternative design is grounded in the theory that liability for defective design is predicated on risk-utility balancing.<sup>5</sup> In the overwhelming majority of cases utilizing risk-utility balancing, the question is whether the product could have been made safer. Only in rare instances will a product be so manifestly unreasonable that a court may properly conclude that the entire product category should be declared unreasonably dangerous.<sup>6</sup> Thus, courts adopting risk-utility analysis are essentially in agreement with the *Restatement*.<sup>7</sup> The *Restatement* rejects the notion that a product can be declared defective in design solely because the product fails to meet consumer expectations.<sup>8</sup> This test is viewed to be so open-ended and without content as to provide no guidance whatsoever to

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<sup>5</sup>RESTATEMENT § 2 cmt. d; see also *Achieving Consensus*, 83 CORNELL L. REV. 868, 882-893 (1998).

<sup>6</sup>RESTATEMENT § 2 cmt. e.

<sup>7</sup>Courts that predicate liability for defective design on risk-utility balancing can only be making one of two judgments. They can either be saying that given the risk-utility trade offs, the product should have been made with a reasonably safer design or that it should not have been marketed at all. Liability under the former is captured in Section 2(b) of the *Restatement*. Liability based on the latter theory, that the product is so dangerous that it should not have been marketed at all, is a rare phenomenon limited to products whose danger level is extraordinarily high and social utility very low. Section 2, *comment e* of the *Restatement* recognizes that liability without proof of a reasonable alternative design may be warranted for products whose design is manifestly unreasonable. For an extensive discussion of this point see *Achieving Consensus*, *supra* note 4, at 882-887. Courts that apply risk-utility balancing often say that the availability of an alternative design is a factor to be weighed in the balance. *Campbell v. Struder, Inc.*, 970 P.2d 389, 392 n.1 (Wyo. 1998). Care must be taken to distinguish the issue of the availability of an alternative design and the question of whether the alternative design is reasonable. Clearly the technological availability of an alternative design is one factor to be weighed in a risk-utility balancing. However, the ultimate answer to the risk-utility question is whether the product as designed is acceptable or whether a reasonable alternative design should have been adopted. For a full discussion of this point see *Achieving Consensus supra* note 4, 83 CORNELL L. REV. at 888-889.

<sup>8</sup>RESTATEMENT § 2 cmt. g.

manufacturers and courts in deciding whether a product design is defective.

Since promulgation of the new *Restatement*, eight courts have reaffirmed their commitment to risk-utility balancing as the appropriate theory for design defect litigation.<sup>9</sup> Two others, Connecticut and Kansas, have rather decisively rejected Section 2(b) and have opted for a consumer expectations test.<sup>10</sup> One state has rejected

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<sup>9</sup>Krummel v. Bombardier Corp., No. 98-30961, 1998 WL 433803 at \*11 (E.D. La. July 28, 1998) (applying risk-utility analysis and reasonable alternative design tests relying on *RESTATEMENT* § 2(b)), *rev'd on other grounds*, 206 F.3d 548 (5<sup>th</sup> Cir. 2000); Hollister v. Dayton Hudson Corp., 5 F. Supp. 2d 530, 531 (E.D. Mich. 1998) (applying the risk-utility test and holding that Michigan law is consistent with *RESTATEMENT* § 2(b)), *aff'd*, 201 F.3d 731 (6<sup>th</sup> Cir. 1999); Banks v. ICI Americas, Inc., 450 S.E.2d 671, 673 (Ga. 1994) (holding that, consistent with *Restatement* Section 2(b), "the reasonableness of choosing from among various alternative product designs and adopting the safest one...is considered the "heart" of design defect cases"); *see also* Ogletree v. Navistar Int'l Transp. Corp., 500 S.E.2d 570, 571 (Ga. 1998) (adopting the risk-utility analysis for determining whether a product is defectively designed and relying on *Restatement* § 2, cmt. d)); Nissan Motor Co. v. Nave, 740 A.2d 102, 117 (Md. Ct. Spec. App. 1998) (requiring proof of reasonable alternative design in determining unreasonable danger and risk-utility, although neither party sought to invoke *Restatement*); *In re Hunter*, 729 So. 2d 1264, 1277 (Miss. 1999) (utilizing risk-utility analysis for determining defect); Cavanaugh v. Skil Corp., 751 A.2d 518 (N.J. 2000). The New Jersey Supreme Court held that plaintiff has the burden of proving a reasonable alternative design under *Restatement* Section 2(b). Defendant is then free to rebut the plaintiff's prima facie case or to raise the statutory state-of-the-art defense. Where the defendant shows that there exists no design alternative which was "practical and technically feasible," the jury need not weigh the plaintiff's proposed design against the defendant's. *Cavanaugh*, 751 A.2d at 521; *Lewis v. Am. Cyanamid Co.*, 715 A.2d 967, 983 (N.J. 1998) (requiring analysis of risk-utility and proof of reasonable alternative design under *Restatement* § 2(b)); *Green v. Gen. Motors Corp.*, 709 A.2d 205, 210 (N.J. Super. Ct. App. Div. 1998) ("[T]he issue upon which most claims will turn is the proof by plaintiff of a 'reasonable alternative design'" in accordance with *Restatement* § 2(b)); *Brooks v. Beech Aircraft Corp.*, 902 P.2d 54, 62 (N.M. 1995) (applying risk-utility "in light of the technology available at the time of design or distribution."); *Hernandez v. Tokai Corp.*, 2 S.W.3d 251, 257 (Tex. 1999) (adopting risk-utility analysis and requiring proof of reasonable alternative design under the *Restatement* 2(b) "as does the law in most jurisdictions"); *Ford Motor Co. v. Miles*, 967 S.W.2d 377, 388 (Tex. 1996) ("We have held that "if there are no safer alternatives, a product is not unreasonably dangerous as a matter of law" quoting Caterpillar, Inc. v. Shears, 911 S.W.2d 379, 384 (Tex. 1995)). In addition, two jurisdictions have applied risk-utility analysis without outright adopting Section 2(b). *Lovick v. Wil-Rich*, 588 N.W.2d 688, 699 (Iowa 1999); *Campbell v. Studer, Inc.*, 970 P.2d 389, 392 n.1 (Wyo. 1998).

<sup>10</sup>*Potter v. Chicago Pneumatic Tool Co.*, 694 A.2d 1319, 1330 (Conn. 1997) ("[C]onsumer expectation standard is now well established in Connecticut strict products liability decisions."); *Delaney v. Deere & Co.*, 999 P.2d 930, 946 (Kan. 2000) ("Kansas has adopted the consumer expectation test...as the standard for design defect."). For an extensive discussion of *Potter* arguing that the holding is

both risk-utility balancing and consumer expectations as the appropriate theory, choosing to rely on its statute that requires proof that a product be "unreasonably dangerous."<sup>11</sup>

Those who argued against the "reasonable alternative design" requirement in the debates preceding adoption of the new *Restatement* contended that they were fearful that courts adopting such a requirement would demand that plaintiff prove that she had actually developed a prototype alternative design in order to establish a prima facie case of defective design. Section 2, *Comment f*, of the *Restatement* specifically rejects such a requirement and states that qualified expert testimony suffices even though no prototype has been produced. Several courts have explicitly agreed with this proposition.<sup>12</sup>

### III. SECTION 2 (b) COMMENT *d*: THE DEMISE OF THE OPEN AND OBVIOUS DANGER RULE FOR DEFECTIVE DESIGN

The rule that a manufacturer has no duty to design against open and obvious dangers had fallen into disrepute over the last two decades prior to adoption of the new *Restatement*. However,

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consistent with the general structure of the *Restatement*, see *Achieving Consensus supra* note 4. In *Gen. Motors Corp. v. Farnsworth*, 965 P.2d 1209, 1220

(Alaska 1998) the court continued its allegiance to the two-pronged test for design defect allowing recovery on either the consumer expectations test or the risk-utility test. That case is, however, consistent with the authors' contention that where courts invoke the consumers expectations test, they are dealing with cases that would be identically resolved under the *Restatement* Section 3. *Achieving Consensus*, 83 CORNELL L. REV. at 889-90. Where an ordinary consumer cannot draw an inference of defect from common everyday experience then risk-utility balancing must be invoked to establish defect. For a recent case so holding in a state following the two-pronged test for defect see *Pruitt v. Gen. Motors Corp.*, 86 Cal. Rptr. 2d 4 (Cal. Ct. App. 1999).

<sup>11</sup>*Rodriguez v. Suzuki Motor Corp.*, 996 S.W.2d 47, 65 (Mo. 1999) (expressly rejecting consumer expectations and risk-utility analysis and holding that neither theory is Missouri's statutory standard, which require proof that the product be "unreasonably dangerous").

<sup>12</sup>*Martin v. Michelin N. Am.*, 92 F. Supp. 2d 745, 759-60 (E.D. Tenn. 2000) (holding that, under the *Restatement* Section 2(b) cmt. f, "plaintiff was not required to produce a prototype tire in order to make out a prima facie case. "[Q]ualified expert testimony on the subject suffices"); *Leaf v. Goodyear Tire & Rubber Co.*, 590 N.W.2d 525, 535 (Iowa 1999) (relying on the *Restatement* Section 2(b) cmt. f in "not requiring the plaintiff to produce a prototype in order to make out a prima facie case."); *Gen. Motors Corp. v. Sanchez*, 997 S.W.2d 584, 592 (Tex. 1999) (holding that "plaintiffs did not have to build and test an automobile transmission to prove a safer alternative design. A design need only be "capable of being developed" under the *Restatement* Section 2(b) cmt. f).



several states stubbornly clung to this position.<sup>13</sup> In *Ogletree v. Navistar Int'l Transp. Corp.*,<sup>14</sup> one of the holdouts, Georgia, relying on the *Restatement*, has now joined the majority. Adverting to the fact that Georgia had earlier adopted risk-utility balancing as its test for defect<sup>15</sup> (relying on an early draft of the *Products Liability Restatement*), the court held that the obviousness of a danger was only one factor to be taken into account in performing risk-utility balancing and should not stand as a no-duty rule barring recovery.

#### IV. SECTION 2(b) COMMENT *e*: POSSIBILITY OF MANIFESTLY UNREASONABLE DESIGN

The courts generally reject the idea that products that have no reasonable alternative design and are accompanied by adequate warnings are defective because their risks outweigh their general utility to society.<sup>16</sup> The *Restatement*, however, does suggest that some products might have such a low social utility and a high degree of danger that liability should attach even absent proof of a reasonable alternative design.<sup>17</sup> To date, no post-*Restatement* case recognizes such an exception. In *McCarthy v. Olin Corp.*,<sup>18</sup> a suit against the manufacturer of Black Talon bullets brought by victims of a slaughter that took place on the Long Island Railroad in December, 1993 at the hands of a crazed gunman, the court refused to recognize that Black Talon bullets were "unreasonably dangerous per se." (i.e. a reasonable person would conclude that the danger of the product outweighs its utility). Interestingly, Judge Calabresi, in dissent, suggests that Black Talon bullets might meet

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<sup>13</sup>*Weatherby v. Honda Motor Co.*, 393 S.E.2d 64, 66 (Ga. Ct. App. 1990) (holding that the "open and obvious rule imposes on a plaintiff the burden of proving that the peril causing injury is latent . . ."), *overruled by*, *Ogletree v. Navistar Int'l Transp. Corp.*, 500 S.E.2d 570, 571 (Ga. 1998); *McCollum v. Grove Mft. Co.*, 293 S.E.2d 632, 636 (N.C. Ct. App. 1982) ("Under our case law, a manufacturer has no duty to . . . protect against defects and dangers that are obvious."), *aff'd*, 300 S.E.2d 374 (N.C. 1983).

<sup>14</sup>500 S.E.2d at 575.

<sup>15</sup>*See generally* *Banks v. ICI Am.*, 266 Ga. 607, 469 S.E.2d 171 (1996).

<sup>16</sup>*Wasylow v. Glock, Inc.*, 975 F. Supp. 370, 381 (D. Mass. 1996) (refusing to apply category liability against a gun manufacturer relying on *Restatement* (Tentative Draft No. 2) (Section 2 cmt. d in final draft of the *Restatement*)). For a comprehensive list of authorities, *see* James A. Henderson, Jr. & Aaron D. Twerski, *Closing the American Products Liability Frontier: The Reflection of Liability Without Defect*, 66 N.Y.U. L. Rev. 1263, 1314-1322 (1991).

<sup>17</sup>RESTATEMENT § 2 cmt. e.

<sup>18</sup>119 F.3d 148, 156 (2d Cir. 1997).

the requisites for liability under *Comment e*.<sup>19</sup>

#### V. SECTION 2(c), COMMENT *i*: INFORMED CHOICE WARNINGS

In a new comment, The *Products Liability Restatement* sets forth a role for informed choice warnings. *Comment i* provides:

In addition to alerting users and consumers to the existence and nature of product risks so that they can, by appropriate conduct during use or consumption, reduce the risk of harm, warnings also may be needed to inform users and consumers of nonobvious and not generally known risks that unavoidably inhere in using or consuming the product. Such warnings allow the user or consumer to avoid the risk warned against by making an informed decision not to purchase or use the product at all and hence not to encounter the risk. In this context, warnings must be provided for inherent risks that reasonably foreseeable product users and consumers would reasonably deem material or significant in deciding whether to use or consume the product.

The new *Restatement* notes that the duty to provide informed choice warnings has been imposed almost exclusively with regard to toxic agents and pharmaceutical products because courts have recognized a distinctive need to provide risk information so that consumers can decide whether they wish to purchase or utilize the product.<sup>20</sup> Several recent cases have suggested that the duty to provide informed-choice warnings applies to other products as well. In *Watkins v. Ford Motor Co.*,<sup>21</sup> the driver and occupants of a Ford Bronco II sued for injuries suffered when the Bronco rolled over after the driver lost control of the vehicle. Plaintiff alleged defective design and failure to warn about the tendency of the vehicle to roll over. The case was complicated by the fact that Georgia (the state whose law governed the accident) has a ten-year statute of repose governing negligent design claims unless the conduct of the defendant was reckless or wanton. In reversing the trial court's grant of summary judgment in favor of Ford, the court held that a trier of fact could find that Ford's conduct in not choosing a more stable design with less propensity to roll over was wanton and reckless. Turning to the failure to warn claim, the court noted that the

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<sup>19</sup>*Id.* at 162 (Calabresi, J., dissenting).

<sup>20</sup>RESTATEMENT § 2 cmt. i.

<sup>21</sup>190 F.3d 1213 (11th Cir. 1999).

statute does not relieve a manufacturer from liability for failing to warn once the danger becomes known to it. The court cited post-sale evidence that came to Ford's attention as to the magnitude of the Ford Bronco's instability and noted that Ford had provided no post-sale warnings to consumers.

Ford contended that even had a more complete warning been given to consumers, it would not have prevented the accident. Ford's expert testified that once a user made a decision to drive the Bronco II, no warning could guard against the dangers of rollover. The court rejected the argument, concluding that though a warning might not serve to reduce the risk of harm, it could serve to allow him to make an informed decision as to "whether to take the risks warned of."<sup>22</sup> The court referred to the language of Section 2, *Comment i* that provides:

Whether or not many persons would when warned, nonetheless decide to use or consume the product, warnings are required to protect the interest of those reasonably foreseeable users or consumers who would, based on their own reasonable assessment of the risks and benefits, decline product use or consumption.

#### VI. SECTION 2(c), COMMENT *j*: NO DUTY TO WARN ABOUT OBVIOUS DANGERS

Unlike design defects where manufacturers owe a clearly established duty to design against open and obvious dangers when a reasonable alternative design is available that could have avoided or reduced the risk of harm, the *Restatement* takes the position that manufacturers owe no duty to warn about obvious dangers.<sup>23</sup> The obviousness of the danger is the surrogate for a warning and warnings about obvious and well known risks diminish the significance of warnings and tend to clutter warning labels with useless information. *Comment j* has been oft-cited by the courts.<sup>24</sup> Of course,

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<sup>22</sup>*Id.* at 1219. For a similar view see *Krummel v. Bombardier Corp.*, 1998 WL 433803 at \*11 (E.D. La. July 28, 1998), *rev'd, on other grounds*, 206 F.3d 548 (5<sup>th</sup> Cir. 2000).

<sup>23</sup>RESTATEMENT § 2 cmt. j.

<sup>24</sup>*E.g.*, *McMahon v. Bunn-o-Matic Corp.*, 150 F.3d 651, 655-56 (7<sup>th</sup> Cir. 1998) (relying on *Restatement* § 2 cmt. j in holding that the defendant not required to warn customer of obviously hot coffee); *Maneely v. Gen. Motors Corp.*, 108 F.3d 1176, 1179 (9<sup>th</sup> Cir. 1997) (citing to *Restatement* Section 2 cmt. j in holding that "a manufacturer need not provide a warning" when dangers are generally obvious); *Sauder Custom Fabrication, Inc.*, 967 S.W.2d 349, 351 (Tex. 1998) (holding, in accor-

whether a risk is obvious may be a question to be submitted to the trier of fact when reasonable minds can differ.<sup>25</sup>

# VII. SECTION 2(c), COMMENT L: WARNINGS CANNOT SERVE AS A SUBSTITUTE FOR INADEQUATE DESIGN

The *Third Restatement* takes a bold position directly contrary to that set forth in Section 402A. It has been utilized aggressively by plaintiffs in several high-profile cases. First, a brief look at history. *Restatement, (Second) of Torts*, Section 402A., *Comment j* states that:

Where warning is given, the seller may reasonably assume that it will be read and heeded; and a product bearing such a warning which is safe for use if it is followed, is not in defective condition, nor is it unreasonably dangerous.

This comment has come under heavy attack from academic critics.<sup>26</sup> They argue that a warning should not be a panacea exempting manufacturers from adopting reasonable designs. Consumers often fail to read or remember warnings. Many accidents result from user inadvertence and inattention. If a reasonable alternative design could have been adopted, the manufacturer should bear responsibility even if the danger was adequately warned against.

The *Products Liability Restatement* sets an entirely new and different tone. It provides:

Reasonable designs and instructions or warnings both play important roles in the production and distribution of reasonably safe products. In general, when a safer design can reasonably be designed out of a product, adoption of the safer design is required over a warning that leaves a significant residuum of such risks. For example, instructions and warnings may be ineffective because users of the product may not be adequately reached, may be likely to be inattentive, or may be insufficiently motivated to follow

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dance with Section 2 cmt. j, the manufacturer's duty to warn only extends to that which is not obvious to the "ordinary user"); *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 382 n.2 (Tex. 1995) (noting that, under Section 2 cmt. j, "the warnings of obvious risks tends to undermine the effectiveness of warnings of unobvious risks").

<sup>25</sup>*Manely*, 108 F.3d at 1179; *Liriano v. Hobart Corp.*, 700 N.E.2d 303, 308 (N.Y. 1998).

<sup>26</sup>Howard Latin, *Good Warnings, Bad Products, and Cognitive limitations*, 41 U.C.L.A. L. REV. 1193, 1206-07 (1994); see also Aaron D. Twerski, Alvin Weinstein, William Donaher, & Richard Piehler, *The Use and Abuse of Warnings in Products Liability: Design Defect Comes of Age*, 61 CORNELL L. REV. 495, 506 (1976).

the instructions or heed the warnings. However, when an alternative design to avoid risks cannot reasonably be implemented, adequate instructions and warnings will normally be sufficient to render the product reasonably safe....Warnings are not, however, a substitute for the provision of a reasonably safe design.<sup>27</sup>

In *Uniroyal Goodrich Tire Co. v. Martinez*,<sup>28</sup> a mechanic was injured when a 16-inch tire he was attempting to mount on a 16.5-inch wheel exploded. The tire bore a prominent warning label containing yellow and red highlights and a pictograph of a worker being thrown into the air by an exploding tire. The label conspicuously stated that it was highly dangerous to mount a 16-inch tire onto 16.5-inch rim and warned that serious injury or death could result if the user failed to comply with the warning. Plaintiff did not claim that the warning was inadequate but argued instead that the tire was defectively designed due to its use of an 0.037 gauge multistrand wetless bead rather than an 0.050 single stranded programmed bead. Use of the alternative design would have prevented the injury to the plaintiff. Defendant relied on Section 402A, *Comment j* and contended that a comprehensive warning should absolve it from liability. The Texas Supreme Court, citing the *Products Liability Restatement*, disagreed and upheld the jury verdict in favor of the plaintiff.<sup>29</sup> The court noted that the presence of a warning is a factor to be considered in deciding whether a manufacturer should have adopted a safer design but that it should not stand as a barrier to the imposition of liability.<sup>30</sup> The new *Restatement* position was heavily relied on in *Rogers v. Ingersoll-Rand Co.*,<sup>31</sup> where the court upheld the refusal of trial court to instruct the jury that an adequate warning would render the product not defective. The court held that despite an adequate warning, availability of a safer design could serve as a predicate for liability despite an adequate warning.

#### VIII. SECTION 2 (b) AND (c): COMMENT *m*: LIABILITY FOR FORESEEABLE RISKS

Sections 2(b) and (c) impose liability only when the foresee-

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<sup>27</sup>RESTATEMENT § 2, cmt. 1.

<sup>28</sup>977 S.W.2d 328 (Tex. 1998).

<sup>29</sup>*Id.* at 336.

<sup>30</sup>*Id.*

<sup>31</sup>144 F.3d 841 (D.C. Cir. 1998).

able risks of harm could have been avoided or reduced by the adoption of a safer design or a warning. The requirement that the risk of harm be foreseeable represents the overwhelming majority opinion in the country.<sup>32</sup> Two post-*Restatement* opinions have addressed the issue. In *Sternhagen v. Dow Co.*,<sup>33</sup> plaintiff alleged that he contracted cancer as a result of exposure to the spraying of a herbicide during the years 1948-1950. Defendants raised the defense that neither they, nor medical science, knew or had reason to know of any alleged cancer-causing properties of the herbicide during the years 1948-1950. Answering a certified question from a federal court, the Montana Supreme Court rejected a state-of-the-art defense.<sup>34</sup> The court took issue with comments to both Section 402A and the Products Liability *Restatement* and concluded that the "evidence that a manufacturer knew or through the exercise of reasonable foresight should have known of the dangers inherent in his product is irrelevant."<sup>35</sup>

In a case decided a year later, *Vassallo v. Baxter Healthcare Corp.*,<sup>36</sup> the Massachusetts Supreme Court reversed a long-standing position that foreseeability of risk is irrelevant to a strict liability claim. Citing the position set forth in Section 2, *Comment m* in the *Products Liability Restatement* and the authority set forth in the Reporters' Notes in support of that comment, the court noted that it was in a distinct minority of states that had heretofore applied a hindsight analysis to the duty to warn. Recognizing the strong judicial trend that imposed liability only when the risks were foresee-

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<sup>32</sup>See e.g., *LaMontagne v. Du Pont & Co., Inc.*, 41 F.3d 846, 859 (2d Cir. 1994) (applying Connecticut law and observing that duty to warn only extends to those risks that are known or reasonably known"); *Anderson v. Owens-Corning Fiberglas Corp.*, 810 P.2d 549, 556 (Cal. 1991) (limiting liability to "knowable" risks and noting that strict liability has incorporated some well-settled principles from negligence); *Fibreboard Corp. v. Fenton*, 845 P.2d 1168, 1172 (Colo. 1993) (holding state-of-the-art evidence admissible and recognizing that "a manufacturer cannot warn of dangers that were not known to it or knowable in light of the generally recognized and prevailing scientific and technical knowledge available at the time of the manufacture and distribution."); *Olson v. Prosoco, Inc.*, 522 N.W.2d 284, 289 (Iowa 1994) ("The burden on plaintiffs [is to prove] a defendant knew or should have known of potential risks associated with the use of its product, yet failed to provide adequate directions or warnings to users."); *Owens-Illinois, Inc. v. Zenobia*, 601 A.2d 633, 641 (Md. 1992) (holding under *Restatement (Second)* Section 402A cmt. j, that in order to be found liable, a seller must have knowledge or reason to know of potential dangers to users of its products).

<sup>33</sup>935 P.2d 1139 (Mont. 1997).

<sup>34</sup>*Id.* at 1147.

<sup>35</sup>*Id.* at 1144.

<sup>36</sup>696 N.E.2d 909 (Mass. 1998).

able or could have been discovered by reasonable testing prior to marketing the product, the court said that it would henceforth embrace the *Restatement* position.<sup>37</sup>

#### IX. SECTION 2: COMMENT N: REJECTING MULTIPLE DOCTRINAL THEORIES OF LIABILITY FOR THE SAME CAUSE OF ACTION

It has become commonplace for plaintiffs to allege multiple doctrinal theories of liability for the same cause of action. Thus, in actions for design defect and failure to warn, plaintiffs typically allege separate counts in negligence, strict liability and the implied warranty of merchantability. For those few courts that embrace the consumer expectations test based on the implied warranty of merchantability, it is justifiable to send a case to the jury both on a tort (risk-utility) test and an implied warranty (consumer expectations) test.<sup>38</sup> However, for the vast majority of courts that subscribe to risk-utility balancing for both design and failure to warn cases, sending a case to the jury on multiple theories invites inconsistent jury verdicts. For example, it is not uncommon for a jury to find a product to be not defective yet also conclude that the defendant was negligent in designing or failing to provide adequate warnings about the product. The *Restatement* in Section 2, *Comment n*, notes that design and warning cases are grounded in risk-utility balancing and, whether the theory of liability is negligence, strict liability or the implied warranty of merchantability, the essence of the claim remains the same. Thus, it urges that courts not submit the same risk-utility based case to juries on multiple theories of liability.

Courts that have confronted this issue have agreed with the *Restatement* position.<sup>39</sup> Some have been forced to reverse plaintiff ver-

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<sup>37</sup> *Id.* at 921-922.

<sup>38</sup> *E.g.*, *Denny v. Ford Motor Co.*, 662 N.E.2d 730, 735-36 (N.Y. 1995).

<sup>39</sup> *See e.g.*, *Jarvis v. Ford Motor Co.*, 69 F. Supp. 2d 582, 586-87 (S.D.N.Y. 1999); *Lawley v. Chevron Chem. Co.*, 720 So. 2d 922, 928 n.6 (Ala. 1998) ("[T]wo or more factually identical...failure to warn claims...should not be submitted to the trier of fact in the same case under different doctrinal labels" under *Restatement* § 2 cmt. n); *Hyundai Motor Co. v. Rodriguez*, 995 S.W.2d 661, 667 (Tex. 1999) (holding, under § 2 cmt. n, that plaintiff should "not be free to submit a case to a jury based on both the implied warranty of merchantability and strict liability theories since they are based on the factual base...."); *Lecy v. Bayliner Marine Corp.*, 973 P.2d 1110, 1114 (Wash. Ct. App. 1999) (citing Section 2 cmt. n for the proposition that, in a design defect case under admiralty law, a jury cannot consider separately strict liability and negligence claims). The exceptional jurisdiction refusing to follow *Restatement* § 2 cmt. n is Wisconsin where dual instructions are still allowed. *See Sharp v. Case Corp.*, 595 N.W.2d 380, 383 (Wis. 1999) (upholding as consistent a

dicts because the jury has rendered inconsistent verdicts. For example, in *Jarvis v. Ford Motor Co.*,<sup>40</sup> a design defect case, the judge submitted both negligence and strict liability courts to the jury. The jury found the automobile to be nondefective but found Ford Motor Co. negligent in designing the auto's cruise control system. In reversing judgment on the verdict the court cited the *Restatement* and said that "in New York, as in virtually all jurisdictions, in a products liability action premised on a design defect theory, a jury finding that a product is not defective precludes a parallel finding that the manufacturer is negligent in designing the product."<sup>41</sup> Indeed, the court expressed displeasure with counsel for both plaintiff and defendant for not alerting it to the identical nature of the claims and the possibility that instructing on multiple theories would lead to inconsistent verdicts.<sup>42</sup>

#### X. SECTION 3: DRAWING INFERENCE OF DEFECT WITHOUT THE NECESSITY OF PROVING SPECIFIC DEFECT

Ofttimes a product causes injury in such a manner that common sense tells us that the product must have been defective. Section 3 recognizes that when the incident that harmed the plaintiff was of a kind that ordinarily occurs as a result of product defect and when one can fairly exclude other causes as the sole cause of the injury it is not necessary to identify the specific defect that was responsible for injury-causing event.<sup>43</sup> When such a common sense inference of defect can be drawn, courts often observe that the product failed consumer expectations. Indeed, most of the cases cited by courts supporting a consumer expectations test are of this genre.<sup>44</sup>

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jury verdict allowing "recovery for the negligent design of a product even though the product [was] not unreasonably dangerous in a strict product liability sense.").

<sup>40</sup>69 F. Supp. 2d 582 (S.D.N.Y. 1999).

<sup>41</sup>*Id.* at 606; *see also Lawley*, 720 So. 2d at 928-29; *Rodriguez*, 995 S.W.2d at 667-68; *Lecy*, 973 P.2d at 1116.

<sup>42</sup>*Jarvis*, 69 F. Supp. 2d at 587 n.8.

<sup>43</sup>RESTATEMENT § 3.

<sup>44</sup>*See e.g.*, *Cassisi v. Maytag Co.*, 396 So. 2d 1140, 1146 (Fla. Dist. Ct. App. 1981) (stating "[E]vidence of the nature of an accident itself may, under certain circumstances, give rise to a reasonable inference that the product was defective because the circumstances of the product's failure may be such as to frustrate the ordinary consumer expectations of its continued performance"); *Tulgetske v. R.D. Werner Co., Inc.*, 408 N.E.2d 492, 496 (Ill. App. Ct. 1980) (holding that plaintiff can make out a strict liability claim by proving product failed to perform reasonably in light of its intended function); *Cincinnati Ins. Co. v. Volkswagen of Am., Inc.*, 502



Drawing a common sense inference of defect from the occurrence of an injury-causing event has a well known analog in the general law of torts. Under the doctrine of *res ipsa loquitur* courts have recognized that an inference of negligence may be drawn when the defendant's negligence is the best explanation for the cause of an accident, even if the plaintiff cannot explain the exact nature of the defendant's wrongful conduct.<sup>45</sup> Because the doctrine of *res ipsa loquitur* has been historically connected to negligence, many courts have said that it does not apply to products liability cases.<sup>46</sup> Courts seek out different articulations to support liability in cases where the inferential process should lead to a finding of liability without the necessity of establishing whether the product failed due to a manufacturing defect or a defective design. As noted, some courts invoke the consumer expectations test as the reason for imposing liability;<sup>47</sup> others rely on something called the "malfunction theory" of liability.<sup>48</sup> At bottom the elements of this cause of action are the same as those set forth in Section 3 of the *Products Liability Restatement*. Section 3 provides:

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

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

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N.E.2d 651, 654 (Ohio App. Ct. 1993) (holding that in a fire case, "the reasonable expectations of the buyer of a motor vehicle is that the main electrical cable harness of such vehicle will not start a fire").

<sup>45</sup>RESTATEMENT (SECOND) TORTS § 328D (1965).

<sup>46</sup>See generally *Welge v. Planters Lifesavers Co.*, 17 F.3d 209, 211 (7<sup>th</sup> Cir. 1994); *Brooks v. Colonial Chevrolet-Buick, Inc.*, 579 So. 2d 1328, 1333 (Ala. 1991); *Tresham v. Ford Motor Co.*, 275 Cal. App. 2d 403, 407 (1969); *Myrlak v. Port Auth. of N.Y. & N.J.*, 723 A.2d 45, 54 (N.J. 1999).

<sup>47</sup>*Supra* note 44.

<sup>48</sup>See e.g., *Troy v. Kampgrounds of Am., Inc.*, 581 A.2d 665, 668 (Pa. Super. Ct. 1990) ("The 'malfunction' theory of products liability encompasses nothing more than circumstantial evidence of product malfunction"); *Anderson v. Chrysler Corp.*, 403 S.E.2d 189, 194 (W. Va. 1991) ("[W]e hold that circumstantial evidence may be sufficient to make a prima facie case in the strict liability action, even though the precise nature of the defect cannot be identified, so long as the evidence shows that a malfunction in the product occurred that would not ordinarily happen in the absence of a defect.").

In *Myrlak v. Port Authority of New York and New Jersey*,<sup>49</sup> the New Jersey Supreme Court adopted Section 3, noting that it accomplishes for product defect cases that which *res ipsa* did for negligence cases. The court noted its agreement with those states that allow an inference of defect to be drawn when "common experience indicates that certain accidents do not occur absent some defect."<sup>50</sup>

#### XI. SECTION 5: LIABILITY FOR SELLERS OF COMPONENT PARTS

Section 5 has been enormously influential. It has been cited favorably in a host of cases and is likely to put to rest this vexatious issue. Very simply, Section 5 provides that the seller of a component part which is not itself defective is not liable for harm caused by a product into which the component was integrated unless the seller of the component substantially participates in the integration of the component into the design of the product.<sup>51</sup> Most often component part sellers are brought into litigation when the manufacturer of the product into which the component has been integrated is insolvent. For the most part, component part sellers are in no position to monitor how the components are utilized by end-manufacturers. If liability were to be imposed on component sellers, they would have to develop "sufficient sophistication to review the decisions of the business entities that are already charged with the responsibility for the integrated product."<sup>52</sup> Placing such a duty on component part manufacturers is not practically feasible and would result in enormous economic inefficiency.

The first case to apply Section 5 was *Zaza v. Marquess & Nell, Inc.*<sup>53</sup> In that case defendant, a sheet metal fabricator manufactured a quench tank to specifications. The specifications did not require that the fabricator prepare or install any safety devices. Instead, the specifications called for the fabricator to cut holes for the safety devices. When the quench tank was ultimately integrated into a working regeneration system, the safety devices were not in-

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<sup>49</sup>723 A.2d 45 (N.J. 1999).

<sup>50</sup>*Id.* at 56; *see also* *Urbach v. Indus. Chem.*, No. A-96-368, 1997 WL 576595 at \*7 (Neb. Ct. App. Sep. 9, 1997) (citing to *Restatement* Section 3 in permitting plaintiff to present circumstantial evidence "since it is unrealistic to expect a plaintiff to otherwise prove that a particular product was sold in a defective condition").

<sup>51</sup>RESTATEMENT § 5.

<sup>52</sup>*Id.* at cmt. a.

<sup>53</sup>675 A.2d 620 (N.J. 1996).

stalled. The plaintiff alleged that the fabricator had a non-delegable duty to see to it that the quench tank was properly integrated into the regeneration system utilizing the safety devices. He also alleged that the defendant had a duty to warn of the dangers of operating the quench tank without safety devices. The court found that the quench tank was not itself defective. It reasoned that it was not feasible for a sheet metal fabricator such as the component manufacturer to attach safety devices to a quench tank nor was it reasonable for the fabricator to provide warnings to the end-product manufacturer about the dangers attendant to using the product without such safety devices.<sup>54</sup> According to the court, that responsibility resided with the party charged with integrating the entire system and should not fall on the manufacturer of the component part. Recent decisions have absolved manufacturers of such components as teflon used in medical implants,<sup>55</sup> silicone used in breast implants,<sup>56</sup> raw asbestos used in insulation<sup>57</sup> and a wing pulley that was to be integrated into a conveyor belt system.<sup>58</sup>

Courts have been careful in applying the exception that imposes liability if there has been substantial participation by the

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<sup>54</sup>*Id.* at 634-35.

<sup>55</sup>*See generally* Kealoha v. Du Pont Co., 82 F.3d 894 (9th Cir. 1996) (not citing to *Restatement*); *In re* TMJ Implants Prod. Liab. Litig., 872 F. Supp. 1019 (D. Minn. 1995) (not citing to *Restatement*).

<sup>56</sup>*In re* Silicone Gel Breast Implants Prod. Liab. Litig., 996 F. Supp. 1110, 1114 (N.D. Ala. 1997) (relying on *Restatement* Section 5 in affirming grant of summary judgment to defendant and holding "raw material manufacturers . . . not subject to liability for harm caused by defective design of the end product"); *In re* Silicone Breast Implants Prod. Liab. Litig., 887 F. Supp. 1463, 1467 (N.D. Ala. 1995) (granting summary judgment to manufacturer of bulk foam used in breast implants citing to *Restatement*, Tentative Draft, No. 2); *Artiglio v. Gen. Elec. Co.*, 61 Cal. App. 4<sup>th</sup> 830, 839 (1998) (holding, in accordance with Section 5, "component and raw material suppliers are not liable to the ultimate consumers when . . . they sell goods to a sophisticated buyer").

<sup>57</sup>*Cimino v. Raymark Indus., Inc.*, 151 F.3d 297, 334 (5th Cir. 1998). The Fifth Circuit predicted that Texas would follow *Restatement* Section 5 and accordingly held that a seller of raw asbestos which was not defective in itself was not liable when the asbestos is integrated into an end-product. *Id.* But see *Arena v. Owens-Corning Fiberglas Corp.*, 74 Cal. Rptr. 2d 580, 588 (Cal. Ct. App. 1998) (citing to § 5 but holding that raw asbestos is a defective product in itself and is not an innocuous component material such as sand or gravel).

<sup>58</sup>*Buonanno v. Colmar Belting Co.*, 733 A.2d 712, 716 (R.I. 1999) (adopting *Restatement* § 5); *see also* Cipollone v. Yale Industrial Prod., Inc., 202 F.3d 376, 379 (1<sup>st</sup> Cir. 2000) (relying on *Restatement* Section 5 in holding that under Massachusetts law, a manufacturer of a customized dock-lift that was a component of a material-handling system was not liable since the component part was not defective itself).

component maker in the integration of the component into the design of the integrated product.<sup>59</sup> The mere provision of technical support and general processing advice does not sufficiently implicate the component part seller in the design process.<sup>60</sup> However, presented with evidence of more substantial involvement, courts have been willing to impose liability.<sup>61</sup> This is an area where the courts are keenly aware of the serious economic ramifications of imposing liability on a party who is most often not in a position to control the design of the end-product and have been cautious about imposing liability for either defective design or failure to warn.<sup>62</sup>

## XII. SECTION 6 : LIABILITY FOR DEFECTIVE PRESCRIPTION DRUGS AND MEDICAL DEVICES

Two aspects of the *Restatement's* treatment of liability for prescription drugs have been dealt with by the courts. The first deals with the issue of liability for defective drug design. Section 6(c) imposes liability for defective drug design only if the foreseeable risks of harm posed by the drug are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers knowing of such foreseeable risks and benefits would not prescribe the drug for any class of patients.<sup>63</sup> If a class of patients exists for whom the drug is the reasonable therapeutic choice, the drug is not defectively designed. It has a legitimate place on the market if sold with fully adequate warnings. However, if another FDA approved drug is available on the market that provides the benefits of the drug in question and has reduced risk of harm or side effects, presumably no reasonable health-care provider would

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<sup>59</sup> See e.g., *In re Silicone Gel Breast Implants*, 996 F. Supp. at 1116 (citing to § 5 cmt. e, illus. 6); *Artiglio*, 61 Cal. App. at 840.

<sup>60</sup> RESTATEMENT § 5 cmt. e.

<sup>61</sup> *Buonanno*, 733 A.2d at 716 (recognizing *Restatement* Section 5(b)(1) and remanding for trial to determine whether the manufacturer had "substantially participated in the integration of the component into the design of the final product").

<sup>62</sup> *Supra* note 54; see also *Port Auth. of N.Y. & N.J. v. Arcadian Corp.*, 189 F.3d 305, 313 (3d Cir. 1999) (refusing, under *Restatement* § 5, to hold liable a manufacturer of fertilizer used in producing bomb that terrorists set off in the World Trade Center); *Ogletree v. Navistar Int'l. Trans. Corp.*, 511 S.E.2d 204, 209 n.22 (Ga. 1999) (citing § 5 in recognizing that sellers of component parts are not ordinarily "liable for failing to incorporate a safety feature that is peculiar to the specific adaptation for which another utilizes the incomplete product").

<sup>63</sup> RESTATEMENT § 6 (c).

prescribe the riskier drug.<sup>64</sup> Recent events suggest that FDA approved drugs have remained on the market even when other FDA approved drugs with the same benefits and lesser risks were available.<sup>65</sup> Ultimately, the more dangerous drugs are either voluntarily withdrawn from the market by the manufacturer or ultimately banned by the FDA.<sup>66</sup> The *Restatement* rejects the notion, however, that courts should be able to declare drugs defective because the drug manufacturer failed to develop a reasonable alternative design for the drug. New drugs can only be approved in this country after a very extensive and rigorous approval process by the FDA. Such a review generally takes about twelve years to complete and costs more than \$200 million dollars to perform.<sup>67</sup> The courtroom cannot replicate this approval process. To allow a plaintiff to make out a design claim that is less rigorous than the FDA approval process is to indulge in rank speculation as to whether an alternative drug could legitimately reach the commercial drug market. Several courts have indicated general approval of Section 6(c).<sup>68</sup>

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<sup>64</sup>But see George W. Conk, *Is There a Design Defect in the Restatement (Third) of Torts: Products Liability?*, 109 YALE L. REV. 1087, 1102 (2000). Conk argues that Section 6(c) would insulate a manufacturer from liability if the product unnecessarily caused harm in that there is a feasible safer design available. The authors believe that Conk has misread Section 6(c) since, if there was available on the market an FDA approved drug that provides the benefits of the drug in question with lesser risks, no reasonable medical provider would prescribe the drug in question.

<sup>65</sup>Denise Grady, *Doctors Call for Caution on Two More Diabetes Drugs*, N.Y. TIMES, A10, May 20, 2000. Rezulin, a drug used by diabetes sufferers, remained on the market until recently despite availability of two apparently "safer" drugs, Avandia and Actos. *Id.*

<sup>66</sup>*Id.* Rezulin remained on the market until there were ninety attributed cases of liver failure resulting in sixty-three deaths before the FDA ordered Rezulin removed from the market. *Id.*

<sup>67</sup>For a description of the exhaustive nature of the FDA approval process, see Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. OF MICH. J. L. Ref. 461, 485-488 (1997).

<sup>68</sup>*Gebhardt v. Mentor Corp.*, 191 F.R.D. 180, 184-5 (D. Ariz. 1999) (predicting that Arizona would adopt Section 6(c) and granting summary judgment to drug manufacturer since plaintiff did not demonstrate that a reasonable health care provider would not prescribe the drug "Anglechich" for any class of patients); *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 255 (E.D.N.Y. 1999) (relying on *Restatement* Section 6(c) in granting summary judgment to defendant manufacturer of surgical screw systems used in spinal surgeries); *Jones v. Sofamor, S.N.C.*, No. 1:96-CV-3167, 1999 WL 1062103 (N.D. Ga. Apr. 29, 1999) (stating that, in a case involving design defect claim against manufacturer of surgical screws, *Restatement* Section 6(c) appears to be sound. However, in the absence of Georgia case law, the Court granted summary judgment for defendant because plaintiff did not present an adequate risk-utility case); *Taylor v. Danek Med., Inc.*, No. Civ. A. 95-7232 1998 WL 962062, at \*6 (E.D. Pa. Dec. 29, 1998) (predicting that Pennsylvania will adopt *Restatement*

The second aspect of Section 6 that has been influential is that dealing with the applicability of the "learned intermediary" rule when drug manufacturers advertise their drugs to the public. Traditionally, a drug manufacturer fulfils its obligation to warn when it directs warnings concerning risks associated with a drug to health-care providers who prescribe the drug.<sup>69</sup> The *Restatement* recognizes a duty to warn the patient directly when the manufacturer knows or has reason to know that the health-care provider will not be in a position to reduce the risk of harm in accordance with the warnings.<sup>70</sup> Thus, with regard to vaccines that are administered in clinics without the participation of physicians who can evaluate or communicate the risk of inoculation, courts have found a duty to warn patients directly if such warnings are feasible.<sup>71</sup> A more difficult question arises with regard to drugs that are marketed through direct advertising to patients but cannot be purchased by the patient without a physician's prescription. In Section 6, *Comment e*, the *Restatement* recognizes that a strong argument can be made that, given direct advertising to patients, the learned intermediary rule should not protect drug manufacturers from claims that their advertisements do not adequately inform patients of the risks attached to use of the drug. Nonetheless, the *Restatement* leaves to developing case law the question of whether an exception to the learned intermediary rule should be recognized for drugs that are advertised to the public.<sup>72</sup> In *Perez v. Wyeth Laboratories Inc.*,<sup>73</sup> the

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Section 6(c). For articles generally approving Section 6(c) but arguing that there may be instances where a reasonable alternative drug design may be established, see Michael D. Green, *Prescription Drugs, Alternative Designs, and the Restatement (Third): Preliminary Reflections*, 30 SETON HALL L. REV. 207 (1999); and William A. Drier, *Manufacturers' Liability For Drug and Medical Devices Under the Restatement (Third) of Torts: Products Liability*, 30 SETON HALL L. REV. 258 (1999).

<sup>69</sup>RESTATEMENT § 6(d)(1). For cases citing to this Section, see, e.g., *Vitanza v. Upjohn Co.*, No. 99-7539, 2000 WL 545245 (2d Cir. Dec. 15, 2000) (granting summary judgment for defendant on grounds that the learned intermediary doctrine barred claim); *Uribe v. Sofamos*, No. 8:95CV464, 1999 WL 1129703 (D. Neb. Aug. 16, 1999) (holding that where a user or learned intermediary is fully aware of inherent dangers of a product, there is no proximate causation).

<sup>70</sup>RESTATEMENT § 6(d)(2).

<sup>71</sup>E.g., *Reyes v. Wyeth Lab.*, 498 F.2d 1264, 1271 (5<sup>th</sup> Cir. 1974) (applying Texas law); *Davis v. Wyeth Lab.*, 399 F.2d 121, 131 (9<sup>th</sup> Cir. 1968); *Tenuto v. Lederle Lab.*, 695 N.Y.S.2d 259 (S. Ct. Richmond Co. 1999) (citing to Section 6(d)(1) and holding learned intermediary defense inapplicable when drug manufacturer failed to warn learned intermediary of ways to avoid risks involved in administering polio vaccine).

<sup>72</sup>RESTATEMENT § 6(d)(2) cmt. e.

<sup>73</sup>734 A.2d 1245 (N.J. 1999).

New Jersey Supreme Court, reviewed the relevant *Restatement* sections, and clearly held that the "learned intermediary" rule would not necessarily shield manufacturers from liability for drugs commercially advertised. Thus, even ample warnings to physicians will not protect a drug manufacturer from liability if its public advertisements do not adequately inform consumers of risks associated with use of the drug.

### XIII. SECTION 10: POST-SALE FAILURE TO WARN

The *Products Liability Restatement* recognizes a cause of action not even hinted at in Section 402A. Even when a product is not defective at the time of sale, a manufacturer may be subject to liability if it subsequently learns of dangers attendant to the use of the product or methods to avoid serious risks and fails reasonably to communicate that information to product users.<sup>74</sup> The *Restatement* recognizes that the imposition of a post-sale duty to warn is more onerous than imposing a duty to warn at the time of original sale.<sup>75</sup> Including a warning accompanying the sale of a product is relatively easy. Communicating with consumers many years after they have purchased the product typically entails considerable difficulty. Section 10 sets forth the special elements that must be considered before concluding that a seller has a post-sale duty to warn.<sup>76</sup>

Several cases have considered Section 10. In *Lovick v. Wil-Rich*,<sup>77</sup> the Iowa Supreme Court adopted section 10 as the governing rule for post-sale duty to warn in that state. Holding inadequate a lower court's instruction on post-sale warning because it did not alert the jury to the special considerations that the *Restatement* sets forth as requisites for finding a post-sale duty, the court remanded the case for retrial on that issue.<sup>78</sup> However, an intermediate appellate court in Pennsylvania in *DeSantis v. Frick Co.*,<sup>79</sup> rejected Section 10, concluding that, in the absence of original defect in the

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<sup>74</sup>RESTATEMENT § 10.

<sup>75</sup>*Id.* at § 10 cmt. a.

<sup>76</sup>*Id.* at § 10(b)(1)-(4).

<sup>77</sup>588 N.W.2d 688 (Iowa 1999). See also *Liriano v. Hobart Corp.*, 700 N.E.2d 303, 307 n.3 (N.Y. 1998) (citing § 10 with approval).

<sup>78</sup>*Lovick*, 588 N.W.2d at 695-96. See also *Lewis v. Ariens*, 729 N.E.2d 323,326 (Mass. 2000) (holding that *Restatement* Section 10(b)(2) liability for a post-sale failure to warn will not be imposed for injury suffered by second hand purchasers because the burden of communicating to them would be onerous).

<sup>79</sup>745 A.2d 624 (Pa. 1999). See also *Modelski v. Navistar Int'l Transp. Corp.*, 707 N.E.2d 239 (Ill. App. Ct. 1999) (refusing to recognize post-sale failure to warn).

product, no post-sale duty to warn would be recognized. Thus, according to the court, a post-sale duty to warn exists only if the product was defective at the time of sale.<sup>80</sup> One wonders why the post-sale warning is simply not surplusage if the product was defective at time of sale. The true function of a post-sale warning is to provide a remedy for a plaintiff who was not warned about a risk or risk-avoidance measure when that information was not available at time of original sale.

#### XIV. SECTION 16: CRASHWORTHINESS—LIABILITY OF SELLERS WHEN THE ADD-ON DAMAGES CANNOT BE QUANTIFIED

Section 16 addresses a problem that arises occasionally in “crashworthiness” cases.<sup>81</sup> A plaintiff who brings an action against an auto manufacturer for injuries suffered as a result of the fact that the auto did not provide for adequate safety in the event of a collision is entitled to recover only for those injuries that were increased as a result of the lack of crashworthiness.<sup>82</sup> Injuries that would have been suffered even had the car been reasonably crashworthy are not proximately caused by the auto manufacturer. They are the result of the happening of the accident. Most often plaintiffs are able to establish with considerable precision the nature of the add-on injuries that were caused by the absence of the safety feature that rendered the auto defective. On occasion, a plaintiff’s expert can only opine that the desired safety feature would have reduced the plaintiff’s injuries but cannot quantify the extent of the injury reduction. A majority of courts take the position that as long as the plaintiff establishes that the injuries that occurred exceed those that would have resulted from the accident in any event, plaintiff is entitled to recover the entirety of the damages suffered.<sup>83</sup> A minority of courts deny the plaintiff recovery in that circum-

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<sup>80</sup> *Id.* at 630.

<sup>81</sup> *Restatement* Section 16 addresses the issue of liability for increased harm due to product defect. Enhanced injury cases arise most frequently in claims based on an automobile classification. However, other products can bring about claims for increased harm. *E.g.*, *Tafoya v. Sears, Roebuck & Co.*, 884 F.2d 1330 (10<sup>th</sup> Cir. 1989) (riding lawnmower); *Roe v. Deere & Co.*, 855 F.2d 151 (3d Cir. 1988) (agricultural tractor); *McGee v. Cessna Aircraft Co.*, 188 Cal. Rptr. 542 (Cal. Ct. App. 1983) (airplane); *Farrell v. John Deere Co.*, 443 N.W.2d 50 (Wis. Ct. App. 1989) (corn picker).

<sup>82</sup> *RESTATEMENT*, § 16(b); *Larsen v. Gen. Motors Corp.* 391 F.2d 495, 503 (1968).

<sup>83</sup> For a list of states following the majority rule see *RESTATEMENT* §16 cmt. d Reporters’ Notes at 242-250.



stance, insisting that if plaintiff cannot quantify the add-on damages, plaintiff cannot recover.<sup>84</sup> The *Restatement* sides with the majority view allowing plaintiff's recovery.<sup>85</sup>

Since the advent of the *Restatement*, four courts have addressed the issue just described and each has adopted the *Restatement* position.<sup>86</sup> It is interesting to note that *Huddell v. Levin*<sup>87</sup> long regarded as the leading case espousing the minority position, is almost certainly no longer valid authority. *Huddell* was decided by the Third Circuit Court of Appeals in 1976. The court's Erie-guess was that New Jersey would require the plaintiff to quantify damages and if plaintiff failed to do so, recovery would be barred. Two New Jersey intermediate appellate courts have now concluded that New Jersey would not follow *Huddell* and instead would follow Section 16 of the new *Restatement*.<sup>88</sup> Once again, a strong pro-plaintiff position was espoused by the *Restatement* and appears now to be carrying the day.

## XV. CONCLUSION

Consistent with the decisions referred above, one may fairly conclude that the *Products Liability Restatement* has been well received by American courts. In addition to the sections set forth in the body of the article, considerable case law has followed sections of the *Restatement* dealing with such issues as the role of comparative responsibility,<sup>89</sup> the liability of successors for harm caused by defective products sold by a predecessor,<sup>90</sup> and the exclusion of

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<sup>84</sup>For a list of states adhering to the minority rule see RESTATEMENT § 16 cmt. d Reporters' Notes at 250-251.

<sup>85</sup>RESTATEMENT § 16(c).

<sup>86</sup>*Gen. Motors Corp. v. Farnsworth*, 965 P.2d 1209, 1219-20 (Alaska 1998); *Lally v. Volkswagen Aktiengesellschaft*, 698 N.E.2d 28, 36-37 (Mass. 1998); *Poliseno v. Gen. Motors Corp.*, 744 A.2d 679, 686 (N.J. Super. Ct. App. Div. 2000); *Green v. Gen. Motors Corp.*, 709 A.2d 205, 214-16 (N.J. Super. Ct. App. Div. 1998); *cert. denied*, 718 A.2d 1210 (N.J. 1998). See also *Trull v. Volkswagen of Am., Inc.*, 187 F.3d 88 (1<sup>st</sup> Cir. 1999) (certifying the question as to whether New Hampshire would adopt Section 16(c) to the New Hampshire Supreme Court).

<sup>87</sup>537 F.2d 726 (3d Cir. 1976).

<sup>88</sup>*Poliseno*, *supra* note 86; *Green*, *supra* note 86.

<sup>89</sup>*Jiminez v. Sears, Roebuck & Co.*, 904 P.2d 861, 866 (Ariz. 1995); *Webb v. Navistar Int'l Transp. Corp.*, 692 A.2d 343 (Vt. 1997).

<sup>90</sup>See e.g., *Corbin v. Farmex, Inc.*, 490 S.E.2d 395, 397 (Ga. Ct. App. 1997) (following Section 12); *City of New York v. Pfizer*, 688 N.Y.S.2d 23, 24 (N.Y. App. div. 1999) (following Section 12(b)); *Lockheed Martin v. Gordon*, 16 S.W.3d 127 (Tex. Ct. App. 2000) (applying Delaware law that follows RESTATEMENT Section 12). But see, *LeFever v. K.F. Hounanian Enter.*, 734 A.2d 290, 294 (N.J. 1999) (criticizing

economic loss arising from harm to the product itself from the law of products liability.<sup>91</sup> It is, of course, impossible to measure empirically the actual influence of the *Products Liability Restatement* on the courts. Discussions dealing with the *Restatement* are intertwined with discussion of the law in other jurisdictions and considerable talk of policy considerations that moved the courts in one direction or another. Nonetheless, in many cases discussion of the *Restatement* is extensive and thoughtful and gives evidence that the courts have considered the *Restatement's* positions seriously. Even where courts have disagreed, we believe that the *Products Liability Restatement* has helped sharpen the issues and shape the debate. The goal of a *Restatement* is not only to restate the law and choose between competing rules. It is to get behind the verbiage of the cases and to make sense out of the vast body of case law. Initial evidence indicates that the *Products Liability Restatement* has fulfilled that task.

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*Restatement* Section 12); *Saez v. S&S Corrugated Paper Mach. Co.*, 695 A.2d 740 (N.J. Super. Ct. App. Div. 1997) (noting that New Jersey is one of a small minority of states to have rejected the rule set forth in *Restatement* Section 12).

<sup>91</sup>See e.g., *Koss Constr. v. Caterpillar, Inc.*, 960 P.2d 255, 260 (Kan. Ct. App. 1998) (adopting Section 21(c)); *Steiner v. Ford Motor Co.*, No. 990155, 2000 WL 1996112 (N.D. Feb. 22, 2000) (citing Section 21, that damages to the product itself cannot be recoverable in tort); *Clarys v. Ford Motor Co.*, 592 N.W.2d 573, 577-78 (N.D. 1999) (finding that Section 21 comports with the Court's interpretation of its own statute); *State Farm Mut. Auto. Ins. Co. v. Ford Motor Co.*, 592 N.W. 201, 216 (Wis. 1999) (following Section 21).

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