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Comment: The Concept of Defect in American and English Products Liability Discourse: Despite Strict Liability Linguistics, Negligence is Back With a Vengeance!
n1

By Abed Awad

The enthusiastic adoption of 402A by the majority of jurisdictions unleashed a rich and diverse body of case law unrivaled anywhere. n2 The abstract, and to a great extent unclear, formulation of 402A is out-dated. A restatement of products liability law, therefore, is welcome. n3 The Restatement (Third) of Torts: Products Liability (Proposed Final Draft) (April 1, 1997) n4 recognizes that the present day strict products liability regime has caused much confusion. In particular, the Restatement (Third) views, as a misnomer, the notion that strict liability applied to design and warning defects. With this said, what is the appropriate standard in design and inadequate warning defects? The answer does not lie in an abstract re-formulation but rather lies in the judicial application of a standard that results in a fair and equitable balance between consumer interests and manufacturer interests. Did the Restatement (Third) achieve this golden mean? It does not appear to have done so, only with judicial application will we know for certain.

It is no secret that American products liability law is retreating back to negligence. In England, however, products liability law is embracing the so-called American brand of strict liability. The objective of this comparative study is twofold. First, given that the American products liability regime has more experience than its English counterpart, American products liability developments might define and forecast the trend of English products liability. Second, because England is the cradle of the common law, English products liability developments may be relevant to the American experience.

This paper consists of five parts. Part one surveys the evolution of products liability law in the United States from Winterbottom to 402A. Part two surveys the evolution of relevant English law from Winterbottom to 1987. Part three includes a case analysis between English law prior to 1987, and American law prior to the Restatement (Third); the analysis pertains to manufacturing, design, and inadequate warning defects, concluding that only minor differences existed between both systems. Part four analyzes the Restatement (Third) and surveys the scholarly response. Part five analyzes the U.K. Consumer Protection Act 1987 Part I, with the Restatement (Third) in the background. Finally, part five finds that the products liability regime in the United States and in England is negligence based, yet couched in strict liability terminology, or strict liability linguistics.

I. United States

(A) The Beginning: Winterbottom v. Wright

Although it is not a products liability case, *Winterbottom v. Wright* n5 is the best starting point to examine the evolution of products liability in both the United Kingdom and the United States. n6 In *Winterbottom*, the plaintiff, a coachman, was injured as the result of the defendant's failure to maintain the coach. n7 The defendant was a contractor in charge of maintaining coaches for a stagecoach company. n8 Lord Abinger concluded that liability would not attach to the contractor because "there [was] no privity of contract between these parties." n9

Both U.S. and U.K. courts extended the *Winterbottom* privity rule to products liability cases. n10 *Winterbottom* came to stand for the proposition that plaintiffs injured by a defective product could only maintain a cause of action in negligence or warranty if there was privity of contract. n11

(B) *Thomas v. Winchester*: the beginning of the end of *Winterbottom*

Numerous exceptions to the *Winterbottom* rule evolved. n12 In 1852, the earliest exception to the rigid *Winterbottom*-privity rule came in the New York Court of Appeals' decision in *Thomas v. Winchester*. n13 In *Thomas*, the plaintiff consulted a physician about an illness. The physician prescribed medicine for her. The plaintiff took a dose of the medicine and then became extremely ill suffering from "febleness of circulation, spasms of the muscles, giddiness of the head, dilation of the pupils of the eyes, and derangement of mind." n14 Fortunately, she recovered; however, the plaintiff eventually learned that the medicine was mislabeled and contained a deadly poison. n15

Acknowledging that injury was not likely to fall on the dealer who purchased the drug from a manufacturer, but "more likely to be visited on a remote purchaser," the court found that "the defendant's negligence put human life in imminent danger." n16 The court held that where life is put in imminent danger, "the party guilty of the negligence is liable to the party injured, whether there be a contract between them or not." n17 Subsequently, numerous other exceptions to the privity rule emerged, and as one commentator correctly observed, "eventually the exceptions swallowed the rule." n18

(C) *Macpherson v. Buick*: The End of *Winterbottom*:

In 1916, Judge Cardozo hammered in the final nail in the *Winterbottom* coffin. In *Macpherson v. Buick*, n19 the defendant, a car manufacturer, sold a car to a car dealer who then sold it to plaintiff. Plaintiff was injured when the car "suddenly collapsed." n20 Apparently one of the car's wheels was made of defective wood, and its "spokes crumbled into fragments." n21 Judge Cardozo summarized the issue in the dispute as follows: "The question to be determined is whether the defendant owed a duty of care and vigilance to any one but the immediate purchaser." n22 Sifting through case law and relying upon the celebrated *Winchester* exception, Cardozo held that,

Thomas v. Winchester is not limited to poisons, explosives, and things of like nature, to things which in their normal operation are implements of destruction. If the nature of a thing is such that it is reasonably certain to place life and limb in peril when negligently made, it is then a

thing of danger. Its nature gives warning of the consequences to be expected. If to the element of danger there is added knowledge that the thing will be used by persons other than the purchaser ... irrespective of contract, the manufacturer of this thing of danger is under a duty to make it carefully. n23

The Winterbottom "bastard offspring" n24 that "plagued the law for four generations" were once and for all laid to rest. n25 In short, as stated by Cardozo, a manufacturer owes a duty of care to foreseeable users irrespective of privity.

(D) The Strict Liability Seeds Planted: Escola v. Coca Cola Bottling Company

Although a plaintiff need not be in privity to maintain an action in products liability, they must prove the manufacturer breached their duty of due care, i.e., that the manufacturer was at fault. This requirement was not easily proven. Recognizing the difficulty this requirement was causing, the courts began to construe *res ipsa loquitur* liberally. This approach was illustrated in *Escola v. Coca Cola Bottling Co.* n26 In that case plaintiff, a waitress in a restaurant, was injured when a bottle of coca cola exploded in her hand. n27 Plaintiff recovered a jury verdict, and on appeal, the court affirmed, holding that *res ipsa loquitur* applied, relieving the plaintiff from the burden of proving that defendant was negligent. n28 The court found no direct evidence of negligence on the part of the retailer, nor that the defendant manufacturer was negligent in manufacturing the bottle or in preparing the beverage; yet, the court found sufficient circumstantial evidence to satisfy the requirements "necessary to entitle plaintiff to rely on the doctrine of *res ipsa loquitur* to supply an inference of negligence" n29

The *Escola* decision is not known for its *res ipsa loquitur* application, but rather for Justice Traynor's famous concurring opinion that planted the seeds for strict products liability. "I concur in the judgment[,] asserted Traynor, "but I believe the manufacturer's negligence should no longer be singled out as the basis of a plaintiff's right to recover in cases like the present one." n30 Judge Traynor desired a standard which would hold a manufacturer, absolutely liable "when an article that he has placed on the market, knowing that it is to be used without inspection, proves to have a defect that causes injury to human beings." n31

(E) Greenman v Yuba Power Products: the strict liability seed bears fruit

Nineteen years later, the Supreme Court of California adopted Traynor's concurrence. In *Greenman v. Yuba Power Product, Inc.*, n32 plaintiff's wife purchased a power tool for plaintiff. While using the machine, a piece of wood flew out, and struck plaintiff on the forehead injuring him. n33 Writing for the majority, Justice Traynor held that "[a] manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being." n34 With this elucidation, modern strict products liability law was born. Justice Traynor elaborated that though strict liability was initially restricted to food-stuffs, the rule has been extended to many other situations. n35 The seminal nature of *Greenman* lies in its announcement that liability in cases of product defect "is not one governed by the law of contract warranties but by the law of strict liability in tort." n36

(F) The Triumph of Strict Liability: 402A

While the judicial evolution in products liability was taking its natural common law course, the American Law Institute n37 was considering a Second Restatement of Torts. In 1954, the task of drafting the Second Restatement of Torts was assigned to William L. Prosser. n38 It was no secret that Prosser was a strong advocate of strict products liability. In a highly influential article, *The Assault Upon the Citadel (Strict Liability to the Consumer)*, Prosser, with great enthusiasm and a bit of precedent exaggeration, vehemently advocated a strict liability regime for products injures. n39 Suggesting that the time had come for the adoption of strict liability, Prosser explained, "there is nothing so shocking about it today that cannot be accepted and stand on its own feet in this new and additional field, provided always that public sentiment, public demand, and 'public policy' have reached the point where the change is called for." n40 With the *Greenman* decision at his side, Prosser was able to include a strict liability scheme into the Restatement (Second), which was subsequently adopted by ALI in 1964. n41 Section 402A provides that a seller is liable to the "ultimate user or consumer" for injury caused by his product that is "in a defective condition unreasonably dangerous." n42

Although decided prior to the Restatement (Second) of Torts, *Greenman* and 402A advocate the same black letter law. n43 Immediately after the publication of 402A, many jurisdictions throughout the country either adopted 402A, or a *Greenman* type strict liability rule. Never in the history of ALI Restatements has a section received such pervasive adoption among the jurisdictions. n44

II. United Kingdom.

(A) The Death of Winterbottom: *Donoghue v. Stevenson*

Like the United States, English products liability law was based on *Winterbottom v. Wright*. Prior to 1932, English law recognized a duty of care to users or consumers in two situations: (1) where an article was dangerous in-and-of-itself; and (2) where an article was in fact dangerous due "to a defect or any other reason, and this was known to the manufacturer." n45 Unlike the in United States, *Winterbottom* survived in England with minor exceptions for almost a century. n46

In 1932, the House of Lords overruled *Winterbottom's* privity rule in *Donoghue v. Stevenson*. n47 In that case, plaintiff was drinking a ginger beer ice cream float, purchased at a tavern by a friend, when the remains of a decomposed snail floated out of the bottle. n48 In a major departure from precedent, the court held the manufacturer liable notwithstanding the lack of privity. n49 Lord Atkin stated that:

[A] manufacturer of products which he sells in such a form as to show that he intends for it to reach the ultimate consumer in the form in which they left him, with no reasonable possibility of intermediate examination, and with the knowledge that the absence of reasonable care in the preparation or putting up of the products will result in injury to the consumer's life or property, owes a duty to the consumer to take that reasonable care. n50

Donoghue created a negligence cause of action for injuries caused by defective products. The court emphasized that a manufacturer of a defective product owed a duty of care to the "ultimate consumer" irrespective of privity. The range of persons to whom that duty is owed expanded to include anyone who may foreseeably come into contact with the product. n51

The legal development embodied in the Donoghue decision was achieved in the United States 15 years earlier in MacPherson. n52 While English law remained stagnant at the Donoghue stage until 1987, the United States' products liability law developed beyond MacPherson culminating in Greenman and 402A. n53

(B) U.K. prefers products liability legislation

Since *Donoghue v. Stevenson*, no major departure from the rule had occurred. Unlike in the United States, England relied upon a legislative evolution toward strict liability rather than a judicial evolution. n54 While the natural common law course was shaping American products liability law with seminal decisions like *Greenman*, the U.K. Parliament was passing statutes to protect consumers. The legislative intervention ranged from implying quality of goods as a matter of law, to statutory protection of consumers against particular goods, to specific legislation protecting children. n55 Even with all of these legislative developments, Lord Griffiths, Lord of Appeal in Ordinary, observed that "England has not developed into a generalized law of products liability." n56 Lord Griffiths explained that although the legislative trend increased protection of consumers, the legislation "concentrated on creating criminal sanction for certain types of trading activity, and on providing for administrative remedies rather than for remedies in contract or tort." n57

III. U.S.-U.K. Case Law Comparison.

(A) Introduction

The evolution of case law applying 402A classified the concept of defect into manufacturing, design, and inadequate warning or instruction defect. n58 Unlike the U.S., English products liability law remained negligence based until the enactment of the Consumer Protection Act (1987). English product-liability case-law, to a certain extent, made reference to the type of defect involved: manufacturing, design or inadequate warning. The purpose of this section is to place the Restatement (Third) of 1997 and the Consumer Protection Act of 1987 within their historical decisional context. To observe how American courts applied 402A, compared to how the English negligence based regime functioned, a case on each defect was chosen for comparative review.

(B) Manufacturing defects.

(1) United Kingdom.

In *Hill v. James Crowe Ltd.*, n59 the plaintiff was standing on a wooden case while loading his truck. The wooden case collapsed because it was poorly constructed and plaintiff fell injuring himself. n60 Rejecting the defendant's proof that his factory was run with reasonable care, the court held that:

The manufacturer's liability in negligence did not depend on proof that he had either a bad system of work or that his supervision was inadequate. He might also be vicariously liable for the negligence of his workmen in the course of their employment. If plaintiff's injuries were a reasonably foreseeable consequence of such negligence, the manufacturer's liability would be established under *Donoghue*. n61

Theoretically, as long as the manufacturer exercised reasonable care in his factory, he would not be liable for manufacturing defects. *James* illustrated that courts are willing to find negligence based solely upon circumstantial evidence. This may indicate the court's liberal application of *res ipsa loquitur*. Many commentators posit that "the law is tantamount to the automatic imposition of liability for injuries caused by defects due to the product's failing to conform to its specifications and design." n62

(2) United States

In *Orth v. Emerson Electric Co., White-Ridgers Division*, n63 plaintiffs were severely burned when their propane furnace in their mobile home exploded. n64 The furnace in question was a "sealed combustion" furnace appropriate for mobile homes. The furnace was equipped with a control valve manufactured by defendant. The expert testimony concluded that the "safety valve malfunctioned due to a manufacturing defect." n65 Consequently, propane seeped out of the furnace combustion causing the explosion and fire. n66 The expert testimony, the court pointed out, "though based on circumstantial evidence, was sufficiently reliable." n67 "This certainly," noted the court, "justifies an inference of probability' that the valve malfunctioned." n68 The Court of Appeals affirmed finding that there was sufficient evidence presented at trial to sustain the jury's verdict for the plaintiffs. n69

(3) Comparison

Both *James* and *Orth* involved a manufacturing defect. As in *James*, the court in *Orth* was willing to infer negligence solely on circumstantial evidence. Although in *James* the court adhered to a negligence based regime, its outcome and reasoning was almost indistinguishable from *Orth*, which was based on a strict liability regime (absent the words 'reasonable foreseeability'). Thus when it comes to manufacturing defects, a negligence scheme is tantamount to strict liability.

(C) Design defects

(1) United Kingdom

In *Lambert v. Lewis*, n70 the plaintiffs, a mother, father, and their two children were passengers in a car. n71 Suddenly, the tow jaw of a trailer detached from a nearby Land Rover and the trailer "careered across the road" colliding with plaintiffs' car. n72 The father and one child were killed and the mother and the other child were injured. All the parties to the action conceded that the coupling connection to the Land Rover failed resulting in the accident. n73 The court analyzed the liability of the manufacturer of the tow jaw as follows: (1) was the tow jaw's design defective, thus dangerous in use? And if so, (2) was the danger foreseeable? n74 The court answered both questions in the affirmative holding that the tow jaw manufacturer was "liable in tort

to the plaintiffs" because he "supplied and put into circulation for use without intermediate examination a coupling that was defective in design and dangerous in use." n75

Relying upon expert testimony and on numerous past incidents where the tow jaw failed, Judge Stocker held that the tow jaw manufacturer was liable on the ground that the tow jaw was defective in design, and that the dangerous use of the tow jaw was foreseeable by any skilled engineer. n76 Judge Stocker pointed out that the defect in the design "could have been overcome, for example by substituting a knob or plunger, or by redesigning the casting so as to afford a shroud for the handle." n77

(2) United States

In *Voss v. Black & Decker Manufacturing Co.*, n78 a power saw operated by the plaintiff severed his thumb. n79 The saw was equipped with a guard that "as soon as the pressure from the contact with the wood stops, [would] automatically close[] to its original position." n80 The plaintiff testified that while he was using the saw it "hit a knot, projecting the saw upward." When it came down the blade was exposed and severed the plaintiff's thumb. n81 The plaintiff presented expert testimony illustrating that by extending the movable guard, the saw would have been made safer. n82

To establish a prima facie case in strict liability for design defect, the court asserted that, "the plaintiff must show that the manufacturer breached its duty to market safe products when it marketed a product designed so that it was not reasonably safe that the defective design was a substantial factor in causing plaintiff's injury." n83 The court defined "not reasonably safe" as "whether it is a product which, 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." n84 The court also found that the plaintiff had the burden to show that the product was defectively designed and "was not reasonably safe because there was a substantial likelihood of harm and it was feasible to design the product in a safer manner." Based on the foregoing elucidation of the law, the court held that the plaintiff had presented sufficient evidence to submit the defective design to the jury for it to decide whether the unprotected portion of the blade met the minimum safety standards. n85

(3) Comparison

Unlike manufacturing defects, there are some differences between design defect cases under English negligence law and American strict liability law. The differences are actually in form not in substance. Both, albeit in different wording, require that the product be defective rendering it dangerous, and that the harm be foreseeable. Voss's "substantial likelihood of harm" standard is another way of stating Lambert's "reasonably foreseeable" standard. Like Lambert, Voss required that there be a safer alternative design. Voss, however, emphasized that the alternative design must pass a cost-benefit test. It was clear that the manufacturer in Lambert was only concerned with convenience and not financial cost, and as such, the cost-benefit analysis of alternative designs was not an issue. If the product was more complex or the cost was not so negligible and the benefit so great, as is the case in Lambert, the English court would have engaged in a cost-benefit analysis. n86 In sum, the differences between English negligence based design defect and American strict liability n87 design defect are minor.

(D) Inadequate warning defects

(1) United Kingdom

In *Vacwell Engineering v. B.D.H. Chemicals*,ⁿ⁸⁸ an explosion occurred while the plaintiff-physicists, were washing ampoules of a chemical called boron tribromide.ⁿ⁸⁹ One physicist was killed and another injured.ⁿ⁹⁰ The defendant, B.D.H. Chemicals, was a manufacturer and supplier of the boron tribromide.ⁿ⁹¹ The defendant was not aware that boron tribromide explodes when it comes in contact with water.ⁿ⁹² At the time of the accident, the defendant supplied plaintiff with tribromide contained in glass ampoules "upon which the label had been placed containing the warning 'Harmful Vapour.'"ⁿ⁹³

In addition to holding B.D.H. liable under an implied-purpose contractual cause of action, the court found B.D.H. liable under tort. Judge Rees stated:

BDH failed to comply with their duty in two respects: first, they failed to provide and maintain a system for carrying out an adequate research into scientific literature to ascertain known hazards, secondly, [defendants] failed to carry out an adequate research into the scientific literature available to them in order to discover the industrial hazards of a new, or little known, chemical. If that duty had been complied with, I have no doubt that the explosion hazard noted by Gautier [a scientist] and others would have come to light and a suitable warning given, which would have prevented Vacwell dealing with the ampoules of boron tribromide as they did." (emphasis added).ⁿ⁹⁴

The court found that the likelihood of the tribromide making contact with water was foreseeable, and not remote; thus, the plaintiff prevailed.ⁿ⁹⁵

(2) United States

In *Ross Laboratories v. Thes*,ⁿ⁹⁶ a mother purchased Polycose for her infant from a retailer. After reading the label on the bottle, the mother fed her daughter the Polycose. The daughter became very ill and dehydrated.ⁿ⁹⁷ Polycose is "a solution consisting of glucose and water which is dangerous to infants if it is not sufficiently diluted." The Polycose label contained no such warning.ⁿ⁹⁸

The court found that "the nipple ready bottle, taken together with the similarity in name, label, and contents with recognized baby products, required Ross to foresee that some consumers would mistakenly believe that Polycose was a product to be fed to infants."ⁿ⁹⁹ The court concluded that Ross should have "placed a warning on the product to protect consumers against mistakes by Pay 'N Save or other merchants."ⁿ¹⁰⁰ The safety of infants, the court emphasized, "should not rest on the stocking wisdom of the retailer."ⁿ¹⁰¹

(3) Comparison

In warning-defect cases, it appears that English negligence is identical to American strict liability. In both cases foreseeability and an assumption that a warning will be heeded, form the crux of the action. Although knowledge of the harm was not an issue in *Ross*, the court in *Vacwell* addressed the issue of knowledge and stated that the manufacturer must use reasonable care in

researching and testing a product before putting it into the market. Consulting four books was found to be inadequate research and thus not reasonable. This reasoning is illustrated in numerous American decisions, most notably in *Anderson v Owen-Corning Fiberglas Corp.*,¹⁰² where the court held "that knowledge or knowability is a component of strict liability for failure to warn." In sum, the differences between English negligence and American strict products liability are, overall, minor.

(IV) Restatement (Third) of Torts: Products Liability (1997)

(A) Introduction

In May 1992, the ALI¹⁰³ decided it was time to restate the law of Products Liability. They appointed Professors Aaron D. Twerski of Brooklyn Law School, and James A. Henderson Jr. of Cornell Law School as Co-Reporters for this massive project.¹⁰⁴ After five years of debate, amendments, and controversy, the ALI adopted the Restatement (Third) of Torts: Products Liability on May 20, 1997.¹⁰⁵

The concept of defect is the "heart and soul" of the Restatement (Third).¹⁰⁶ The Reporters defined the concept of defect functionally as opposed to doctrinally.¹⁰⁷ One of the consequences of the Reporters functional approach may result in the elimination of other theories of products liability, in favor of creating a new functional products liability system.¹⁰⁸ In fact, the revised draft article 2 of the UCC¹⁰⁹ indicates that the Restatement (Third)'s conceptualization of defect would become the standard under the UCC's implied warranty of merchantability, where personal injury is involved.¹¹⁰ In effect, this abolishes contract remedies in personal injury cases.¹¹¹ Even negligence doctrine, as it relates to injuries caused by products, has been radically altered. In addition to the traditional elements of negligence,¹¹² persons injured by a defective design must prove a feasible alternative design.¹¹³ The courts will determine whether these far reaching consequences take hold in American products liability.¹¹⁴

The Restatement (Third) indicates that design and warning defects are, to a great extent, subject to negligence principles. Commentators have long suggested "that strict tort liability is but a chimera that hides de facto negligence analysis."¹¹⁵ The Reporters admit that the new theory for design and warning defect is similar to the "reasonableness test traditionally used in determining whether an actor has been negligent."¹¹⁶ Thus there will be no strict liability, in the full sense of the word, in cases of defective design and inadequate warnings or instructions. Nonetheless, the Reporters observe that "many courts insist on speaking of liability based on the standards described in 2(b) and (c) as being 'strict.'"¹¹⁷

At this point in the discussion, Justice Cardoza's reflections on ALI's mission seem appropriate. Describing the arduous and agonizing task of a restatement, J. Cardoza stated,

At the beginning there has been need to gather from the pronouncements of the courts the principle or the rule implicit in their judgments, to find the soul of the decision beneath its integument of clay. This in itself is a wearisome and poignant task, especially when the soul reveals itself in the end as a soul already lost, an erring and blighted spirit, unworthy to be released, lest, meeting its fellow spirits, it poison and corrupt them.¹¹⁸

Courts have realized that the standard for design and warning defects, in essence have become negligence, but they do not want to confess that this negligent spirit exists; perhaps because they feel it is an "erring and blighted spirit, unworthy to be released." The soul of strict liability, the protection of the consumer, has been lost. What now, many would ask?

To say the least, commentators are split on this strict liability/negligence anomaly. Some commentators believe that the Restatement (Third) honestly restated the law of products liability as it stands in the majority of jurisdictions; n119 others charge that the Restatement (Third) has brought back the old "rule of caveat emptor." n120

Although this inquiry is by no means exhaustive, the literature and case law consulted for this Comment suggests that the Restatement (Third) restated products liability law as it stands in the majority of jurisdictions, but runs contrary to a strong minority of jurisdictions. The Reporters could have done a better job by incorporating the minority jurisdictions in the Restatement (Third). Particularly, the requirement of an alternative design should not be absolute. An alternative design could have been emphasized in the comments but not incorporated into the black letter law. The risk-utility test should have been either an alternative test to consumer expectations or should have given consumer expectations a more prominent role in the risk-utility balance.

Some would respond to these reflections as not representative of the majority jurisdictions, and that a restatement basically restates the law as it stands in the majority of jurisdictions. But, a restatement is not a rigid and simple exercise of counting the jurisdictions. It is an attempt to clarify and better the existing law within the parameters of the common law. While the intent of 402A was pro-consumer, the intent of the Restatement (Third) is pro-manufacturer. Neither 402A nor the Restatement (Third) achieved the objective of a liability system, mainly the protection of the consumer, and a balance between manufacturer interests and consumer interests.

(B) Liability under Restatement (Third)

The Restatement (Third) begins its restatement of products liability law with section 1 entitled "Liability of Commercial Seller or Distributor for Harm Caused by Defective Products." n121 Setting the stage for products liability, section 1(a) affirms that a seller or distributor of a defective product is liable "for harm to persons or property caused by the product defect." n122

The Restatement (Third)'s predecessor, the Restatement (Second), did not expressly divide the concept of defect into manufacturing, design, and inadequate warning defect. The evolution of case law applying 402A, however, classified the concept of defect into the above three categories. n123 Recognizing the overwhelming authority dividing the concept of defect into different types, n124 the concept of defect under the Restatement (Third), to borrow David Owen's description, "is now trifurcated." n125 This explicit classification, it is suggested, will abolish strict liability and re-establish negligence as the American products liability regime. n126 Some commentators maintain that the different types of defect routinely overlap or coincide. n127 Arguing that the differences may be subtle and difficult to distinguish, these commentators, in contrast to the Restatement (Third), seemingly advocate a unitary concept of defect. Finally, at least one commentator believes that misrepresentation should be classified as a type of defect. n128

(1) Manufacturing defects

In accord with commentators and decisional law, the Restatement (Third) preserves the strict liability basis for a manufacturing defect, embodied in 402A of the Restatement (Second) of Torts. Section 2(a) provides that a product contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product. n129

More distinctly than design defects and inadequate warning defects, the Reporters observe, manufacturing defects "disappoint consumer expectations." n130 The Reporters recognize that liability without fault in manufacturing defect cases "has a long history in the common law." n131 Retail and wholesale sellers are also strictly liable for manufacturing defects. The Reporters believe that "holding retailers and wholesalers strictly liable creates incentives for them to deal only with reputable, financially responsible manufacturers and distributors, thereby helping to protect the interests of users and consumers." n132

There is unanimous agreement favoring strict liability in the case of a manufacturing defect. n133 Some commentators, however, disagree with the Reporters' "element of deliberation" distinction between design and manufacturing defects. Marshall Shapo, for example, laments that the Reporters "refusal to recognize the close parallels between these two kinds of deliberation and choice renders their justification an ipse dixit." n134 Be that as it may, this section clearly subjects a manufacturing defect to strict liability, i.e. liability will attach "even though all possible care was exercised." n135

(2) Design defects

Determining the appropriate liability standard for design defect cases has vexed courts and scholars, alike. n136 True to its past, the Restatement (Third)'s design defect formulation has proved to be most controversial. n137 It has resulted in a slue of law review articles postulating that the Reporters have substantially departed from 402A jurisprudence without decisional support, n138 while others maintain that the Restatement (Third) correctly restates design defect jurisprudence as it stands in the majority of jurisdictions. n139

Unlike manufacturing defects, design defects conform to the manufacturer's unit specifications. The issue in a design defect case is "whether the specifications themselves create unreasonable risks." n140 The Reporters emphasize that design and inadequate warning defects "are predicated on a different concept of responsibility" - philosophical utility and economic efficiency. n141 In such context, section 2(b) provides that a design is defective "when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design ... and the omission of the alternative design renders the product not reasonably safe." n142

Finding that design defects should be viewed from the "philosophical notion of utility and in the economic concept of efficiency," n143 the Reporters assert that the ultimate benefit to society is to achieve "the right or optimal amount of product safety." n144 Unlike manufacturing defects, n145 the Reporters felt that warning and design defect cases "require determinations that the product could have reasonably been made safer by a better design or instruction or warning." n146 The Reporters continue that 2(b) and (c) of the Restatement (Third) "rely on a reasonableness test traditionally used in determining whether an actor has been negligent." n147 The appropriate rules in design defect cases, according to the Reporters' survey of decisional law, n148 should be "some sort of independent assessment of relevant advantages and disadvantages, to

which some attach the label 'risk-utility balancing.'" n149 The risk-utility test conducted within the context of reasonable foreseeability, eschew the Reporters, establishes a "fair and efficient" liability system. n150 Relying on Learned Hand's negligence risk-utility formula $B < PL$ and Professor John Wade's seven factors, n151 the Reporters accurately state that the "risk-utility balancing" approach "achieves the same general objectives as does liability predicted on negligence." n152 Although the Reporters claim that a risk-utility test "nicely describes the decisional calculus that lies at the heart of products liability law," they admit that a risk-utility analysis "may be problematic if relied upon excessively as a mechanical device for producing automatic 'right' answers." n153

The Reporters set up the risk utility test in the following construction: "whether a reasonable alternative design would, at reasonable cost, have reduced the foreseeable risks of harm posed by the product n154 and, if so, whether the omission of the alternative design ... rendered the product not reasonably safe." n155 Comment f lists several factors to guide courts in their risk-utility balancing inquiry. n156 The main factors are "magnitude and probability of the foreseeable risks of harm," "strength of consumer expectations," and the "relative advantages and disadvantages" of the alteration considering "production costs, product longevity, maintenance, repair, and esthetics." n157 The alternative design is assessed by the reasonableness standard, i.e., a standard that evaluates "the overall safety of the product." n158

The burden of proving a reasonable alternative design, "at the time of sale or distributions" rests on the injured person. n159 The Reporters further explain that the inquiry into the availability of an alternative design is "undertaken from the view point of a reasonable person." n160 In addition to the availability of a reasonable alternative design, the plaintiff needs to show that said alternative design "could have been practically adopted" in order to establish defect. n161 The Reporters point out that both the plaintiff and defendant may introduce evidence on the issue of alternative design and the "trier of fact may conclude that the product was defective notwithstanding that such a design was not adopted by any manufacturer, or even considered for commercial use, at the time of sale." n162 The plaintiff further needs to prove causation, i.e., that the alternative design "would have prevented or reduced the harm for which the plaintiff seeks recovery." n163 In order to establish causation, the Reporters stress that there must be a sufficient increase in prevention or reduction of harm by adopting the alternative design. n164 Furthermore, a design is defective "only when risks were reasonably foreseeable." n165 The Reporters conclude that the design defect approach they have adopted "is based on the common sense notion that liability attaches only when harm is reasonably preventable." n166

Cognizant that non-manufacturing sellers, wholesalers and retailers are not in a good position to adopt alternative and safer designs or better warnings and instructions, the Reporters, in accordance with decisional law, state that "strict liability is imposed on a wholesale or retail seller who neither knew nor should have known of the relevant risks ... so long as a predecessor in the chain of distribution could have acted reasonably to avoid the risks." n167 Although this rule reflects the common law, the Reporters observe this rule has been neutralized by legislative statutes immunizing the non-manufacturers. n168

The Restatement (Third)'s guideline factors for a risk-utility balancing test, David Owen argues, are vague and "fail to provide specific guidance on the balancing method on just how the balance should be accomplished." n169 Owen describes the Restatement (Third)'s "overall safety[.]" terminology as macro-balancing, that is, a balancing of the aggregate risk with the product's aggregate social utility. This notion of "overall safety," according to David Owen, leads

courts to miss the actual issues that have been litigated in a design defect case. n170 The issue in a design defect case, Owen explains, is not whether the "accident-producing product was globally good or bad for society[;]" rather the issue is whether by altering the product's design, inexpensively and without seriously undermining the product's usefulness, the accident could have been avoided. n171 Relying on the Learned Hand test n172 and on Mark F. Grady's early work on the topic, n173 the "proper" test Owen advocates, is what he calls a "micro-balance test[;]" that is, a "narrow" balancing of costs of altering the design of an accident-producing product, along the lines advocated by plaintiff, against the resulting safety benefits in actually altering the design. n174 Instead of focusing on the "overall risk, utility, or quality of a product," Owen's micro-balance test, focuses on the costs and benefits of plaintiff's advocated alteration to the product's design to determine whether the omission of such an alteration made the product defective. n175

The risk-utility test, as formulated by the Reporters, to a great extent, n176 necessitates an absolute requirement of an alternative design in design defect cases. The alternative design allows the court to assess the design defect next to an alternative design from the point of view of a reasonable person. n177 If the plaintiff demonstrates that the product is not safe based on the outcome of a dangers-vs.-benefits assessment, but he does not provide an alternative design, the plaintiff will not prevail. n178 The Reporters suggest that in certain circumstances the plaintiff need not show an alternative design to prevail. These circumstances involve design defects that are "so manifestly unreasonable, in that they have low social utility and high degree of danger, that liability should attach even absent proof of a reasonable alternative design." n179 The requirements contained in sections 2 (a), (b), or (c) must be satisfied before liability would attach in these cases. The Reporters clearly state that this does not apply to inherently dangerous products such as firearms and alcohol. n180 The Reporters correctly observe that courts have not held product categories liable. n181 One commentator notes that the alternative design requirement "effectively insulates" such inherently dangerous products like cigarettes and alcohol from design-defect liability. n182

Despite Comment f's explicit reference that "subsection 2(b) does not require the plaintiff to actually produce a prototype in order to make out a prima facie case," many commentators contend that the prototype inevitably will become an absolute requirement. n183 Several commentators vehemently argue that an absolute requirement of an alternative design does not reflect the weight of authority, n184 while others believe that an alternative, safer design is part of the plaintiff's prima facie case. n185

The consumer expectations n186 standard was rejected in comment g to section 2. n187 Acknowledging that the only "rival" to the risk-utility test is the consumer expectations test, the Reporters claim that only a small minority of jurisdictions follow solely a consumer expectations test; n188 and "in most instances reference to consumer expectations is fully consistent with the rule of this section." n189 Consumer expectations, no longer "constitute an independent standard for judging the defectiveness of product design." n190 Given that the way products are marketed may influence consumer behavior and product choice, the Reporters believe that consumer expectations, although not determinative of design defectiveness, "constitute an important factor in determining the necessity for, or the adequacy of, a proposed alternative design." n191 The Reporters admit that courts frequently rely on consumer expectations when addressing liability based on other theories of liability. n192 In design defects cases, the Reporters claim that courts

"use the term 'reasonable consumer expectations' as an equivalent of 'proof of a reasonable, safer design alternative.'" n193

The Reporters argue that consumer expectations in design and warning defects are "more difficult to discern than in the case of a manufacturing defect." n194 Unlike manufacturing defect cases, where manufacturers set quality control at a certain level and are aware that some products will leave the assembly line defective and cause injury, "[a] reasonably designed product still carries with it elements of risk that must be protected against by the user or consumer since some risks cannot be designed out of the product at reasonable cost." n195 It follows, the Reporters posit, that "the element of deliberation in setting appropriate levels of design safety is not directly analogous to the setting of levels of quality control by the manufacturer." n196 Although rejected, the Restatement (Third) recognizes that consumer expectations have a special and significant role to play in injuries caused by defective food products. n197 Additionally, consumer expectations are not an "independent basis for denying recovery." n198 The Reporters assert that openness and obviousness of risks which the consumer expects does not "prevent a finding that the design is defective." In both situations, however, open and obvious risks may be relevant "but in neither are they controlling." n199

The Restatement (Third) recognizes the harsh criticism the consumer expectations test had received for its seemingly unjust outcomes in many situations, particularly in cases involving children. n200 The peripheralization of the consumer expectation test, nonetheless, attracted heated debate. n201 Some commentators argue that the Reporters have scrapped, without justification, the consumer expectations standard, which was explicitly enunciated in comment i of 402A. In response to this charge, other commentators insist that the intent of the drafters of 402A, based on the legislative history and subsequent scholarly publications by 402A drafters, in fact was to limit the applicability of comment i to manufacturing defects and not to include design and warning defects within its ambit. n202

Several commentators, n203 and a recent Connecticut Supreme Court decision, n204 take issue with the Reporters' assertion that the overwhelming majority of jurisdictions have adopted a risk-utility test to determine design defectiveness. n205 Some commentators have insisted that the risk-utility test is "useless in jury instructions." n206 Calabresi & Cooper, for example, criticize the risk-utility test as "profoundly case by case," and expensive. n207 These commentators argue that the consumer expectation test is an appropriate test in design defect cases. n208 These commentators would like the consumer expectation test to take a more prominent position in the Restatement (Third). At the very-least, some courts and commentators proffer, the risk-utility factors could be incorporated into the consumer expectations standard for ascertaining defectiveness n209 or that consumer expectations could be an alternative standard. n210 Other commentators emphasize that many courts reject the absolute requirement of an alternative, safer design enunciated in the Restatement (Third). n211 Such objections to the Reporters' restatement of design defect jurisprudence has led to charges that they have not restated the law but rather engaged in tort reform. n212

Despite the Reporters' caution that subsection 2(b) "should not be construed to create artificial and unreasonable barriers to recovery," n213 some commentators believe that section 2(b) will drastically affect plaintiff's ability to recover for injuries caused by defective design. n214 Some Courts assert that proving the alternative design is an extremely heavy burden n215 and insist that a risk-utility analysis does necessarily require an alternative design. n216 This absolutist black letter law is viewed as harsh on the plaintiff. n217 Moreover, the burden on the

plaintiff to show an alternative design "requires proof of too much detailed evidence, evidence which is more readily accessible to the defendant than the plaintiff." n218

It is true that requiring an alternative design will weed out unmeritorious claims, but the other side of the same coin is that an alternative design requirement will effectively weed out meritorious small claims. n219 Law firms will not invest their money on developing an alternative design and hiring expert witnesses where the amount of recovery will not be cost effective. n220 An alternative design should be a factor, an extremely important factor for that matter, but not an absolute requirement.

(3) Inadequate Warning Or Instruction Defect n221

Inadequate warnings or instructions are subject to the same rules applicable to design defects. n222 Section 2(c) states that a product is defective because of inadequate instructions or warnings "when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings ... and the omission of the instructions or warnings renders the product not reasonably safe." n223

A seller must provide reasonable instructions or warnings about his product's foreseeable risks. n224 The Reporters explain that instructions "inform users how to use products safely" and "warnings alert users ... to product risks." n225 In turn, instructions and warnings "can prevent harm either by appropriate conduct during use or consumption or by choosing not to use or consume." n226 In addition, the Reporters opine that warnings should "inform users and consumers of non-obvious risks that unavoidably inhere in using or consuming the product." n227 The Reporters believe that reasonably foreseeable consumers can avoid the non-obvious risk and make an "informed decision" to purchase or not to purchase the product. n228 The Reporters, however, limit warnings and instructions to where "reasonably foreseeable product users and consumers n229 would deem material significant in deciding whether to use or consume the product." n230 Unless the risks presented by the product would have been reduced by the adoption of reasonable instructions or warnings, the Reporters assert, "liability for failure to warn does not attach." n231

What risks is the manufacturer obliged to warn against? The Reporters clearly state in the black letter law that the manufacturer is liable only for foreseeable risks. They believe that unforeseeable risk "by definition cannot specifically be warned against." n232 Thus, in design and inadequate warnings defect cases, the Reporters maintain, the plaintiff bears the "burden of establishing that the risk in question was known or should have been known to the relevant manufacturing community." n233 "Of course," assert the Reporters, "the manufacturer must conduct adequate testing before marketing the product." n234

As in design defects, the Reporters acknowledge that section 2(c) "adopts a reasonableness test for judging the adequacy of product instructions and warnings." n235 To guide the courts, the Reporters enumerate several factors to be used to determine reasonableness of the inadequate warning or instruction. In assessing adequacy of the warning or instructions, the Reporters direct courts to focus "on various factors, such as content and comprehensibility, intensity of expression, and the characteristics of expected user groups." n236 The Reporters caution, however, that "it is impossible to identify anything approaching a perfect level of detail that should be communicated in product disclosures." n237

As in design defects, the Reporters state that warning defects "require determinations that the product could have reasonably been made safer by a better design or instruction or warning." n238 Sections 2(b) and 2(c), the Reporters continue, "rely on a reasonableness test traditionally used in determining whether an actor has been negligent." n239 The appropriate rules in a warning defect case, according to the Reporters, should be "some sort of independent assessment of relevant advantages and disadvantages, to which some attach the label 'risk-utility balancing.'" n240 At the outset, the Reporters acknowledge that although design and warning rules are almost identical, "the defectiveness concept is more difficult to apply in the warning context." n241 Although the Reporters maintain that the risk-utility test "nicely describes the decisional calculus that lies at the heart of products liability law," they admit that a risk-utility analysis that excessively relies on producing "right" answers may be problematic. n242

Whether a reasonably foreseeable consumer would have followed the warnings, determines if the omission thereof would result in seller's liability. The Reporters clearly state that if the consumer would have bought or used the product regardless of the lack of warning, "the lack of warnings is not a legal cause of that plaintiff's harm." n243

In the open and obvious risk arena, the Reporters assert that no duty exists to "warn or instruct regarding risks and risk avoidance measures that should be obvious to, or generally known by, foreseeable product users." n244 Unlike in design defect situations where the open and obviousness of a risk does not prevent liability, n245 the open and obvious nature of a product, according to the Reporters, is a defense to an inadequate warning claim. n246 It is the understanding of the Reporters that "when a risk is obvious or generally known, the prospective addressee of a warning will or should already know of its existence." n247 It follows, therefore, that a warning of an obvious risk "in most instances will not provide an effective additional measure of safety." n248 The issue of whether the risk was obvious or generally known is a question of fact to be decided by the trier of fact. n249

Remarking upon the intent of comment (j), n250 the Reporters admit that a manufacturer does not have a duty to warn about obvious dangers, "but reject the position that the obviousness of a danger is an automatic defense to a design defect claim." n251 The Reporters' examination of open and obvious dangers reflects the majority jurisdictions. n252 One commentator, although taking exception with most of the Restatement (Third), described the open and obvious commentary as "unexceptionable." n253 The Reporters make clear that liability attaches in design and warning claims "only when the product is put to uses that it is reasonable to expect a seller or distributor to fore see." n254 Clearly, 'foreseeable use' does not include "every conceivable mode of use and abuse." n255

The issues of misuse, modification, and alteration are dealt with in comment p to section 2. These are "forms of post sale conduct by product users" and are relevant for the determination of defect and causation. n256 Most important, misuse goes to the heart of causation. That is, the misuse may be considered an intervening cause relieving the manufacturer from liability, both in design and warning cases. n257 The Reporters emphasize that the concept of foreseeable misuse and modification "must also be considered in deciding whether an alternative design should have been adopted." n258 The Reporters note that a product may be found defective and be the cause of plaintiff's injury, but if the plaintiff misused the product, comparative responsibility doctrine would reduce his recovery. n259

Acknowledging that warnings may be ineffective due to consumer inattention or insufficient motivation to follow the instructions, the Reporters strongly assert that "when a safer design can reasonably be implemented, adoption of the safer design is preferable to a warning that leaves a residuum of risk." n260 When reasonable alternative designs cannot be reasonably implemented, the Reporters believe that "adequate instructions and warnings will suffice to render the product non-defective." n261

Although the instructions and warnings are usually from the manufacturers, "sellers down the chain of distribution must warn when doing so is feasible and reasonably necessary." n262 Whether a supplier of a product for use by others through an intermediary has a duty to warn the ultimate user directly, the Reporters concede, there is no clear-cut answer except that the standard "is one of reasonableness in the circumstances." n263 The Reporters do offer various factors to be considered in this situation: "the gravity of the risks posed by the product, the likelihood that the intermediary will convey the information to the ultimate user, and the feasibility and effectiveness of giving a warning directly to the user." n264

Finally, like in design defect claims, plaintiff bares the burden of proving that adequate instructions or warning were not provided." n265 As in the case of all three types of defect, the defective condition of the product must have caused the harm to the plaintiff. n266 Courts n267 and commentators alike have long observed that the duty to warn under negligence and strict liability are "almost indistinguishable;" n268 that is, "negligence and strict liability, doctrine, have converged." n269 The Restatement (Third)'s negligence approach, therefore, correctly restates the law and reflects the weight of authority. n270 Many commentators agree with the Restatement (Third) regarding warning law. On the other hand, several courts and many commentators vehemently contend, based entirely on public policy, n271 that the manufacturer should be strictly liable for unforeseeable risks of their products. n272 Another commentator goes as far as advocating that a strict liability regime is the appropriate liability standard in all warning and instructions cases. n273

The main flaw with the Restatement (Third)'s examination of warning law is that by implication, it suggests that a risk-utility test is applicable to warning defects, yet the Reporters do not explain how this test works. The Reporters admit that it is more difficult to apply risk-utility balancing in warning cases than it is in design cases, but they do not offer any guidance. One commentator has discerned the distinction between risk-utility analysis in design and warning defects. n274 Madden discerned that the main difference between risk-utility analysis in warning defect and design defect "pertain to the burden of precaution element of the equation" - the cost variable in the equation. n275 Unlike in warning defect cases, in design defect cases, the cost of altering the design of a product may be substantial undermining the product's economic viability or may substantially diminish the product's utility. n276 However, creating warnings or instructions for a product to improve upon an existing one is always possible. n277 Unlike the cost of an alternative design, the cost of an improved warning is often negligible. n278 As such, when a jury finds that an additional warning could have prevented the injury, the plaintiff will almost always prevail. The solution, according to one commentator, is to focus on the cost incurred based on the "time and attention" required to read and remember the various disclosures in a warning. n279 Another commentator rejects the notion that costs are negligible in warning defects and insists that design and warning defects are the same type of defect. n280 The cost variable in the risk-utility analysis, according to Davis, is determined by applying a cost concept framework that includes direct cost, n281 indirect cost, n282 opportunity cost n283 and per-

verse cost. n284 Another commentator tackles the cost problem from a pure supply and demand approach. n285 Viscusi argues that when a consumer becomes aware of more hazards to the product than earlier believed, the consumer's demand and willingness to pay for the product would drop, and the manufacturer's profits would decrease. n286 Yet, another commentator offers his algebraic spin on the cost variable arguing that to determine the associated cost of an alternative warning (R), the decrease in probability of risk minimizing behavior (P) should be multiplied "by the magnitude of harm associated with that event $L = PL$." n287 Others have rejected the applicability of the risk-utility analysis in warning defects, altogether, describing it as "misplaced" and overly pro-defendant. n288

Despite the fact that the Restatement (Third) correctly restates warning law as it stands today, it did not make it any clearer. Warning law jurisprudence in itself is flawed. Courts analyzing a warning defect claim should take into account the findings of social science research that concluded that people's cognitive abilities are limited by numerous factors such as memory, mistakes and personality. n289 The paramount significance of this research was demonstrated, quite convincingly, by Howard Latin's UCLA Law Review article. In short, inadequate warning or instruction jurisprudence must incorporate these social sciences discoveries to insure a fair and rational products liability regime.

(4) Prescription Drugs

An examination of the concept of defectiveness is not complete without examining where prescription drugs and medical devices position under the new Restatement. Since the mid 1960's, prescription drugs were treated within the ambit of 402A's comment k. n290 An overwhelming majority of jurisdictions have adopted comment k. n291 Comment k provided that a manufacturer of an "unavoidably unsafe" product was, to a great extent, immune from strict liability. Courts have almost entirely, applied comment k's concept of "unavoidably unsafe" to prescription drugs, vaccines, and medical devices. n292 This "unavoidably unsafe" cocoon reached its metamorphoses under the Restatement (Third). In accord with developing law, which has treated prescription drugs differently than other products, the new Restatement allocates a special section for prescription drugs and medical devices. Section 6 addresses liability of sellers for harm caused by defective prescription drugs and medical devices. n293 Subsection (a) sets up the liability standard as follows: "A manufacturer of a prescription drug or medical device who sells or otherwise distributes a defective drug or medical device is subject to liability for harm to a person caused by the defect." Postulating the underpinnings of any liability system, this section provides that persons harmed due to defective drugs or medical devices will have a cause of action to recover for damages. The heart of the issue is what is meant by the concept of defect as it pertains to prescription drugs and medical devices.

Subsection (b) proceeds to provide that a prescription drug or medical device is defective, "at the time of sale or other distribution," if it "contains a manufacturing defect" within the meaning of section 2(a), or "is not reasonably safe" due to its defective design within the meaning of section 6(c), or "is not reasonably safe" due to inadequate instructions or warnings within the meaning of section 6(d). The concept of defect as it pertains to prescription drugs and medical devices, like other products, is "trifurcated." While the concept of defective manufacturing falls within the parameters outlined in section 2, design and inadequate warnings are subject to new guidelines.

(a) Manufacturing defect

If a drug or medical device "departs from its intended design even though all possible care was exercised in the preparation and marketing of the product" the manufacturer is liable for harm suffered. n294 This section clearly subjects a manufacturing defect to strict liability, i.e. liability will attach "even though all possible care was exercised." n295 There is unanimous agreement favoring strict liability in the case of a manufacturing defect. n296 Given that the limitations on the liability standard in design defects are not supported in the case of manufacturing defects, claim the Reporters, liability for manufacturing defects in prescription drugs and medical devices, is the same liability standard for commercial sellers of other products. n297 This section clearly has the weight of decisional law. n298

(b) Design defect

Unlike manufacturing defects, there is more to consider regarding design defects. Section 6(c) provides that

A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients. n299

Unlike manufacturing defects, design defects conform to the manufacturer's unit specifications. The black letter law establishes a balancing test for prescription drug and medical devices - liability will attach only when "risks of harm so far outweigh its therapeutic benefits that reasonable, properly informed health care providers would not prescribe it." n300 The Reporters justify their special attention to prescription drugs and medical devices with the notion that, unlike other products, "a prescription drug or medical device entails a unique set of risks and benefits." For this reason, the Reporters explain, courts traditionally have refused to "impose tort liability for defective designs of prescription drugs and medical devices." n301 The Reporters continue, "What may be harmful to one patient may be beneficial to another." n302 Based on this observation, the Reporters emphasize that a drug is defectively designed "only when it provides no net benefit to any class of patients." n303

The Reporters also believe "that the regulatory system governing prescription drugs is a legitimate mechanism for setting the standards for drug design." n304 The Reporters explain this "deference" is due to the courts' concern "over the possible negative effects of judicially imposed liability on the cost and availability of valuable medical technology." n305 The Reporters further exhort that this deference rests on two assumptions. First, "that the prescribing health care providers, when adequately informed by drug manufacturers, are able to assure that the right drugs and medical devices reach the right patients," and second, "that governmental regulatory agencies adequately review new prescription drugs and devices, keeping unreasonably dangerous designs off the market." n306 The Reporters rightfully note that many courts find "unqualified deference to these regulatory mechanisms" as unjustified. The Reporters admit that "an approved prescription drug or medical device can present significant risks without corresponding advantages." n307

The Reporters justify their great limitation of manufacturer liability with the notion that "manufacturers must have ample discretion to develop useful drugs and devices without subjecting their design decisions to the ordinary test applicable to products generally under 2(b)." n308 Thus, prescription drug or medical device design defects are subject to "a more rigorous test for defect than does 2(b)." n309 Explaining the distinction between design defect under section 2 and section 6, the Reporters state that for prescription drugs or medical devices the drug or device must "have so little merit compared with its risks that reasonable health care providers, possessing knowledge of risks that were known or reasonably should have been known, would not have prescribed the drug or device that has usefulness to any class of patients, is not defective in design even if it is harmful to other patients." n310

The right drug or device will reach the right patient, according to the Reporters, via learned intermediaries. A design is defective, explain the Reporters, "when reasonable, informed health care providers would not prescribe it to any class of patients - then the design of the product is defective and the manufacturer should be subject to liability for the harm caused." n311 In the alternative, if the defendant establishes "one or more contexts in which its product would be prescribed by reasonable, informed health care providers" the design is not defective. n312 The Reporters caution, however, the fact that a health care provider does in fact "prescribe defendant's product does not in itself suffice to defeat plaintiff's claim." n313 The Reporters provide a general outline to make sense of this position. They maintain that the standard is an objective assessment of whether a reasonable provider, "possessing the knowledge that a reasonable drug manufacturer had or should have had about the risks and benefits attendant to the use of the drug or medical device, would prescribe it for any class of patients." n314 The Reporters concede that this standard is extremely demanding. They state that "given this very demanding objective standard, liability is likely to be imposed only under unusual circumstances." n315 Many commentators describe this demanding standard as unwarranted. n316

As with section 2, the liability standard applies only to "risks of harm that are reasonably foreseeable at the time of sale." n317 The Reporters opine that imposing liability for unforeseeable risks, in addition to the fact that such risks cannot be insured against, "can create inappropriate disincentives for the development of new drugs and therapeutic devices." n318 The responsibility of drug and medical device manufacturers is to "perform reasonable testing prior to marketing a product and to discover risks and risk avoidance measures that such testing would reveal." n319 Thus, any harm resulting from unforeseen risk will go uncompensated. n320

There are numerous problems with subsection 6(c). In addition to being a reasonable health care provider, the comments clearly suggest that the health care provider must be "properly informed." What "properly informed" encompasses, is not clear. Given the emphasis on reasonableness, it will most likely be based on a reasonableness standard. Another ambiguity is whether a "health care provider" who is not "properly informed" is liable for not being properly informed? According to the black letter law, the manufacturer is liable if the health care provider would not have prescribed the drug. What happens in the instance where the health care provider prescribed a drug, that should not have been prescribed? Is the health care provider negligent? Would a plaintiff have a cause of action directly against the health care provider, or limited to the manufacturer? Holding the manufacturer to the standard of a health care provider will result in discrepancies and confusion. The manufacturer should be held to a reasonable manufacturer standard. The health care provider's prescription practice may be relevant, but it is the manufacturer of the drug that should be liable for defectively designed drugs or medical devices.

The health care provider standard has received much criticism. Many commentators convincingly argue that there is no precedent for the "health care provider" standard. n321 Moreover, commentators cast doubt on the physician or health care provider's independent expertise regarding prescription drugs. n322 Most health care providers rely extensively on manufacturer's representations regarding the safety level of a given drug. As such, observers prefer a reasonable-manufacturer standard, proffering that the manufacturer, not the physician, is in a better position to inform health care providers of a drug's efficacy, safety and risks. n323 Interestingly, even the Reporters equate the health care provider standard with that of a manufacturer. n324

The provisions of the Restatement (Third) pertaining to defectively designed drugs and medical devices are overly harsh on plaintiffs. n325 Some have charged that the Reporters prescription drug design provisions are "contrary to developing law." n326 Although the policy of insuring innovation and incentive to develop new drugs is an important policy consideration, n327 it should not trump consumer safety. Many observers believe that a blanket-type protection of prescription drugs is not in the public's interest. The fact of the matter is that many drugs will have unavoidable risks. The consumer should be protected against these risks. The manufacturer, who may profit handsomely from placing drugs in the market, is in a better position to spread the cost than the consumer.

(c) Inadequate warning or instructions

Inadequate warnings or instructions is the quintessential defect type implicated in prescription drug and medical device cases. n328 Section (6)(d) provides that:

A prescription drug or medical device is not reasonably safe because of inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:

- (1) prescribing and other health care providers who are in a position to reduce the risks of harm in accordance with the instruction or warnings; or
- (2) the patient when the manufacturer knows or has reason to know that health care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings. n329

Section 6(e) proceeds to state that a retail seller or other distributor of a prescription drug or medical device is subject to liability for harm caused by the drug or device if:

- (1) at the time of sale or other distribution the drug or medical device contains a manufacturing defect as defined in s 2(a); or
- (2) at or before the time of sale or other distribution of the drug or medical device the retail seller or other distributor fails to exercise reasonable care and such failure causes harm to persons. n330

The Reporters note that section 6(d) sets forth the manufacturer's duty to warn of foreseeable risks to the prescribing health care provider and in certain circumstances to directly warn the patient. n331 The duty to directly warn a patient arises when the physician or other health care provider "has a much diminished role as an evaluator or decision maker." n332 The Reporters further explain that the manufacturer requires a direct warning to the patient when drugs "are dispensed or administered to patients without the personal intervention or evaluation of a health care provider." n333 Mass vaccine inoculations are an example of a manufacturer's duty to directly warn the patient. However, the Reporters note that the duty to directly warn the patient arises only if a direct warning "is feasible and can be effective." n334

Traditionally, the Reporters observe, warning has been "directed to health care providers and not to patients." n335 The Restatement (Third) retained the "learned intermediary" rule. This "learned intermediary" approach, explain the Reporters, rests on the understanding that only health care professionals are qualified to appreciate the risks of a prescription drug and weigh the relative advantages and disadvantages to advise their patients accordingly. n336 The Reporters note that courts have carved-out two exceptions to the learned intermediary rule. First, in the case of a governmental regulatory agency mandating that patients be informed of risks pertaining to the use of a drug; and second in the case of manufacturers advertising a prescription drug in the mass media. In both cases, regulations require that the drugs be accompanied by appropriate information concerning the risk. n337 The Reporters, however, state that the ALI does not sanction either exception but leaves these and other exceptions to the development of case law. n338

The Reporters rightfully observe that health care providers cannot reduce the risk of harm in instances where there are unavoidable risks inherent in the drug or medical device. In these instances, the manufacturer's duty to warn of such unavoidable risks "allow the health care provider, and thereby the patient, to make an informed choice whether to utilize the drug or medical device." n339 In addition to this duty, the Reporters emphasize that a drug or device manufacturer "may have a duty under the law of negligence to use reasonable measures to supply instructions or warnings to non-prescribing health care providers who are in positions to act on such information so as to reduce or prevent injury to patients." n340

Liability of manufacturers or learned intermediaries is limited by foreseeability. Liability of manufacturers of prescription drug or medical devices "arise only with respect to risks of harm that are reasonably foreseeable at the time of sale." n341 The Reporters limitation of liability to foreseeable risks of harm is based on two assumptions: (1) holding manufacturers liable for unforeseeable risk would "create inappropriate disincentives for the development of new drugs and therapeutic devices[;]" and (2) manufacturers could not adequately insure against such unforeseeable risks. n342 The manufacturer's responsibility, according to the Reporters, is merely "to perform reasonable testing prior to marketing a product." n343

The prescription drug and medical device section has drawn heavy criticism. Many commentators believe that the pro-defendant provisions do not take in account the welfare of consumers. n344 Although many commentators contend that the prescription provisions do not have weight of authority, n345 many others maintain that the weight of authority is on the Restatement (Third)'s side. n346 In the main, the Restatement (Third) approach to prescription drugs and medical devices is that of negligence. Indeed, commentators observed a decade ago that attempting to distinguish the duty to warn under negligence with the duty to warn under 402A "is futile, as they are practically the same." n347 Even if the Restatement (Third) reflects the majority of

jurisdictions, many jurisdictions' common-law devised rules to somewhat relieve the plaintiff from such a wanting burden. For example, some courts give the plaintiff the benefit of the hearing presumption, n348 this was rejected by the Reporters. Another example is the shifting from the plaintiff to the defendant the burden of showing the manufacturer's knowledge of the products' risks. With no doubt, recovery in prescription cases will be rare and as the Reporters themselves admit, "unusual."

(V) Proposal

The Restatement (Third) has not achieved a proper balance between manufacturer interests and consumer interests. Unlike its predecessor 402A, the Restatement (Third) is pro-manufacturer. With the minor exception of manufacturing defect, the Restatement (Third) has established an ultra-negligence liability standard for injuries caused by product defects. Again, Cordozo's words of wisdom seem appropriate:

It is but a human impulse if the framers of a restatement are tempted to declare the law not only as the past has shaped it in judgments already rendered, but as the future ought to shape it in cases yet to come. n349

It is clear that the Reporters of the Restatement (Third) have restated the decisional law as closely as they could, but, indeed, they have also restated the decisional law as they saw "the future ought to shape it in cases yet to come." The following is a proposal by the author, recommending the future direction of products liability jurisprudence.

Products liability law involves the protection of consumers and reflects the civility of a society. The proposed liability system, achieved either by federal legislation or by common law development, would hold manufacturers strictly liable, liable without fault, for harm caused to "users, consumers, and foreseeable bystanders" regardless of what they knew or should have known about product risks in long latency injuries. In such situations, how are consumers to be protected within a legal products liability formulation? According to Professor Madden, the creation of what he calls a "residual domain" of strict liability in such long latency injury settings would more adequately protect consumers:

For products that cause long latency personal physical injuries, by defective formulation and consequent toxicity by touch, ingestion, inhalation, infection or radiation, excluding alcohol, tobacco and prescriptive products, elimination of the state of the art defense or the state of scientific knowledge defense, and imposition of true strict tort liability, would preserve the progress of section 402A where anything less would not adequately protect injured individuals. n350

To Madden's proposition, I would add prescription drug related injuries. In many long latency injury cases, including those caused by prescription drugs, the operation of the state of the art defense is a miscarriage of justice and cruel. n351 Drug manufacturers are in a better position to

compensate consumers for unforeseeable injuries. They profit from putting drugs on the market. Indeed, the level of responsibility of a manufacturer in injuries due to foreseeable risks, as opposed to unforeseeable risks, is not the same. The amount of a damage award would be substantially lower in injuries due to unforeseeable risks, and punitive damages would not apply.

It is true that if manufacturers were to pay out huge awards for unforeseeable risks, this would stifle innovation. The main cause of concern is the amount of the awards. As long as punitive damages n352 are not recoverable in unforeseeable risk cases, and the manufacturer was not grossly negligent, then awards for injured consumers would be confined to prove compensatory damages and the manufacturer can spread the risk and cost more efficiently than the injured consumer. If this is not acceptable, then a special fund n353 should be established to compensate consumers injured by unforeseeable product risks. In sum, consumers injured by unforeseeable product risks should be compensated, at the least for medical expenses and lost wages.

Only with the incorporation of such a proposal in American products liability jurisprudence, will American products liability reach the level of civility we think we embody. Unfortunately, the Restatement (Third) does not adopt this position. What position will the courts take? It depends. Federal legislation in products liability is gaining popularity. Thus many issues of contention in the Restatement (Third) may be preempted by Federal legislation. Most importantly, however, the courts may choose to adopt the Restatement (Third) wholeheartedly and they may not. There is no guarantee, and it is unlikely that section 2 of the Restatement (Third) will receive the wide spread adoption that its predecessor, 402A, enjoyed.

(VI) Consumer Protection Act Part I (1987)

(A) Introduction

Any comparative analysis is bound to have a margin of error. This Comment does not compare absolute likes - U.S./U.K. There are peculiar aspects of the English legal culture that will interplay in products liability jurisprudence producing a different result than in the U.S. For example unlike in the U.S., contingency fee arrangements have only recently been permitted in England and they have a percentage cap. n354 The judge and not the jury, determines damage awards in English cases. n355 England's Consumer Protection Act does not allow punitive damages; n356 England has a National Health Care System and extensive statutory laws, many more than in the U.S., protecting consumer purchases ranging from toys to industrial equipment. n357 Although the evolution of products liability in both legal cultures is not entirely parallel, the evolution is substantially similar warranting the present study.

The Consumer Protection Act is statutory law. A Restatement, on the other hand, is not law. It is an attempt by the ALI to restate as closely as possible the law on a particular subject. n358 The Restatement (Third) is supposed to be most representative of American products liability in general. The CPA's concept of defectiveness, therefore, will be compared with the parallel Restatement (Third) sections.

For decades under English law, recovery for injury caused by a defective product was based on negligence principles. n359 All this changed in 1987 with the enactment n360 of the Consumer Protection Act 1987 Part I. British products liability law was dramatically transformed. n361 In addition to the Strasbourg Convention on Products Liability in Regard to Personal Injury and Death, n362 several U.K. Law Commission Reports n363 and the European Economic

Community Directive n364 had recommended that manufacturers be strictly liable for injuries caused by defective products. n365

(B) Who is liable under the new strict liability regime

Unlike the Restatement (Third), prescription drugs are not governed by a separate theory of liability. Injuries caused by prescription drugs were governed by negligence, n366 and since 1987 by the CPA. The nuances of negligence based prescription drug liability are not within the scope of the present Comment. n367 Prescription drugs fall within the definition of product under the CPA, n368 therefore, the discussion below applies equally to prescription drugs.

By imposing strict liability for injuries caused by defective products, the CPA changed decades of negligence based products liability. n369 Section 2(1) provides that "where any damage is caused wholly or partly by a defect in a product, n370 every person to whom subsection (2) below applies shall be liable for the damage." Section 2(2) expands the class of defendants subject to liability to include "the producer n371 of the product," owners of a "trade mark or other distinguishing mark in relation to the product[;]" and importers of products "into a member State from a place outside the member State ... in the course of his business."

Section 2(3) specifically extends liability to a supplier n372 of a defective product that caused injury. Subsection 3's extensive expansion is meant to insure the identification of the source of a product. n373 Liability attaches to the supplier only if the product source has not been identified within a reasonable time. n374 This subsection extends liability "beyond the bounds of privity." n375 With the extension of the class of defendants that are liable for defective products, it will be easier for consumers to seek redress, and most important, it insures that the injured party would always have "an identifiable target or a means of finding the identity of the manufacturer." n376

The pro-consumer extension of the class of defendants stopped when it reached game and agricultural farmers. Section 2(4) provides that unless the game or agricultural product has "undergone an industrial process[;]" n377 subsection 2 and 3 shall not apply "to a person in respect of any defect in any game or agricultural product." n378 It is not clear what exactly is an industrial process. It is believed that the British government included this exemption because: (1) other EC members chose to include the exemption, (2) "the production of agricultural produce depends very largely on factors outside the farmer's control" and (3) the perceived difficulty of "tracing back the chain of supply of agricultural produce." n379 This provision has attracted much criticism as being inconsistent with the public policy reasons for imposing a strict products liability regime. One commentator exclaimed: "It seems anomalous to leave a person who is made ill by eating poisonous fruit or shell fish without redress under the Act." n380 Given that the Sale of Goods Act would apply to agricultural produce, n381 commentators insist that the exemption of agricultural products make no logical sense. n382 With time this "misconceived" exemption will prove unworkable and detrimental to the British consumer. n383

(C) Definition of defect

Like the Restatement (Third), the CPA provides that manufacturers, among others, n384 are liable for persons injured by their defective products. Although the CPA does not explicitly divide defect into manufacturing, design, and inadequate warning or instructions defects, n385 English case law followed a "trifurcated" approach to product defect. n386 The CPA measures

defectiveness in terms of "safety," i.e., the risk of damage to persons or property. n387 Under the CPA a product is defective

if the safety of the product is not such as persons generally are entitled to expect; and for those purposes 'safety', in relations to a product, shall include safety with respect to products comprised in that product and safety in the context of risks of damage to property, as well as in the context of risks of death or personal injury. n388

Article 3(2) provides several factors to assist courts in determining what "persons generally are entitled to expect."

(a) the manner in which, and purposes for which, the product has been marketed, its get-up [presentation], the use of any market in relation to the product and any instructions for, or warning with respect to, doing or refraining from doing anything with or in relation to the product; (b) what might reasonably be expected to be done with or in relation to the product; and (c) the time when the product was supplied by its producer to another; and nothing in this section shall require a defect to be inferred from the fact alone that the safety of a product which is supplied after that time is greater than the safety of the product in question. n389

Consumer expectations may be influenced by many other factors, such as, price, alternative products, n390 appeal to target market, "its safety, style, durability, versatility, efficiency, speed, size and so on." n391 Many commentators agree that expectations should be assessed by a standard of reasonable objectivity. n392 Despite the consensus regarding the objective standard of expectations, many commentators believe that the definition of defect under the CPA is vague and does not provide a workable standard for neither court nor manufacturer. n393

What are people entitled to expect? The Law Commission's Report stated that there are two approaches to the concept of defect, (1) safety and (2) merchantability. Recommending the safety approach to defect, the Commission asserted that the "essence of the definition of 'defect' should be the lack of safety." n394 The remaining factors focus on the representation of the product as determinative of peoples' expectations. Warnings, instructions, and the get-up n395 are relevant to consumer expectations. Moreover, reasonable expectations include reasonable product use. Thus, manufacturers should take steps to guard against misuse that can reasonably be anticipated. n396

The CPA's consumer expectation language, to a certain extent, parallels the language of 402A comment i. n397 A product is defective when the risk of harm of a product is not such as persons generally are entitled to expect. British commentators have expressed dubiety regarding the effectiveness of a consumer-expectations standard in complex design and warning defects, arguing the standard in many instances can be unworkable. n398 Clark contends that the consumer expectation test in open and obvious risks would, in many instances, lead to unjust outcomes. In complex design cases, he argues, it is difficult to ascertain what the consumer expects,

if anything. Finally, injured bystanders may not have knowledge of the existence of the product, therefore, have no expectations of safety. n399 It is presumed that "all relevant circumstances" will be considered to determine what persons are entitled to expect. Some commentators have observed that the overall approach of assessing defect "incorporates a risks/benefits element into the test of defectiveness." n400 The circumstances to be considered will inevitably include reasonableness, foreseeability, and causation n401 - essentially, negligence principles. n402

Many British commentators recommend a cost-benefit approach as the superior test, n403 especially in design and warning defect cases. Others argue that a cost-benefit approach will inquire into conduct, hence, negligence based. Under a strict liability regime, it is the product, not the conduct, which is the focus of the inquiry. It is not possible to entertain liability without fault, whilst having to consider cost and benefit factors that circle back to the conduct of the manufacturer. n404 Dolding, for example, confidently contends that section 3 "uses negligence- based criteria to determine what is defective and will clearly involve the court in a cost-benefit analysis of product safety." n405 Some commentators argue that it is difficult to distinguish the inevitable cost-benefit defect standard in the CPA from that of negligence. n406 Newdick, for example, notes that the underlying rationale of a risk-utility analysis involves application of "principles most familiar to the law of negligence." n407 Other commentators agree that the consumer expectation test under the CPA could be "a semantic veneer covering what is in reality a cost- benefit test[.]" which is essentially the objective standard under negligence. n408

How would British courts deal with a cost-benefit, or risk- utility analysis? The risk-utility analysis in the U.S. originated in Judge Learned Hand's opinion in *United States v. Carroll Towing Co.* n409 Judge Hand held that to determine an owner's duty to provide against injuries caused by his vessel breaking free from her moorings, the interplay between three variables should be analyzed:

- (1) the probability that she will break away;
- (2) the gravity of the resulting injury, if she does; and
- (3) the burden of adequate precautions.

Judge Learned Hand continued: "if the probability be called P; the injury L; and the burden B; liability depends upon whether B is less than L multiplied by P" - whether $B < PL$. n410 The Reporters for the Restatement (Third) rely on Judge Learned Hand's formulation when explaining risk-utility analysis.

Morris v. West Hartlepool Steam Navigation Co. n411 is an example of a British risk-utility formulation. *Morris* involved a deckhand who fell through an open hatch and suffered injury. After balancing the obviousness of the risk, and the serious consequence of the injury, with the simple guard that would have avoided the injury, the court held that the ship captain was guilty of negligence for failing to erect the simple guard. Articulating the cost-benefit analysis, Lord Reid held that it was the duty of an employer

in considering whether some precaution should be taken against a foreseeable risk, to weigh, on the one hand, the magnitude of the risk, the likelihood of an accident happening and the possible seriousness of the consequences if an accident does happen, and, on the other hand, the difficulty and expense and any other disadvantage of taking the precaution. n412

Learned Hand's and Lord Reid's test are almost identical. Like Learned Hand's burden variable, Lord Reid, articulates the same notion of burden as expenses and other disadvantages of adopting the safety measure. Thus, if the burden (Hand) or the expense and disadvantage (Reid) are less than the probability and gravity of injury (Hand) or magnitude of risk and likelihood of consequence (Reid), then liability does not attach. n413 It appears that U.S. risk-utility analysis and U.K. cost-benefit analysis are quite similar. Moreover, although the CPA speaks of strict liability, as did 402A, courts in many cases will rely on a cost-benefit negligence analysis of product design and warning defects. In sum, if the CPA and its judicial interpretation would hold that a person is not entitled to expect the products to be any safer than reasonable care and skill make it, with minor exceptions, the Act has changed little in English law.

(D) Development risk defense

Article 4 of the CPA enumerates an elaborate list of defenses. n414 Many British commentators caution that the CPA's elaborate list of defenses is inconsistent with the CPA's pro-consumer policy. n415 Unlike the Restatement (Third), the defendant has the burden of proving any one of these defenses. n416 Section 4(1)(d) provides a defense if "the defect did not exist in the product at the relevant time." Relevant time is defined as the "time when" the manufacturer "supplied the product to another." n417 The defense under the CPA that is relevant to the present study, n418 is the "state of scientific and technical knowledge" defense n419 which provides:

that the state of scientific and technical knowledge at the relevant time was not such that a producer of products of the same description as the product in question might be expected to have discovered the defect if it had existed in his products while they were under his control. n420

The enactment of the CPA was an attempt to harmonize English products liability law in accord with a 1985 EEC products liability directive. n421 The EEC directive gave member States the option of including the state of scientific knowledge defense in their national products liability law. n422 The British government chose to include the state of scientific knowledge defense in the CPA for several alleged reasons. First, innovation would be inhibited without a state-of-the-art defense. Second insurance costs might increase, and third that the U.K. would be put at a competitive disadvantage, given that many European countries have this defense. n423 The focus in a strict liability regime should be on the defectiveness of the product rather than on the conduct of the manufacturer, thus unforeseeability of the defect would seem irrelevant. By incorporating the state of scientific knowledge defense, in essence a foreseeability inquiry, a drug manufacturer can escape liability under the CPA, if he shows that he was not expected to have known about a certain defect or side effect at the time of manufacture. n424 Strictly speaking, a development risk defense and strict liability are a contradiction in terms. Many commentators

have demonstrated that none of the underlying policy considerations of strict liability n425 are advanced by the adoption of the development risk defense. n426 Like the Restatement (Third), if a producer was not negligent in failing to discover the defect, he is not liable. n427 By implicating concepts such as foreseeability and reasonableness, the state-of-the-art defense returns products liability to a negligence standard. n428 The Restatement (Third), like the CPA, holds manufactures liable to "risks of harm that are reasonably foreseeable at the time of the sale." n429 Unlike the CPA, the development risk defense under the Restatement (Third) is not a defense, but part of the definition of defectiveness. Many British commentators eschew that the concept of "development risk" goes to the essence of the concept of defect. That is, the development risk includes industry customs and whether a feasible, safer alternative design was available at the time of sale. Thus, development risk should be part of the definition of defect rather than a defense. n430

The CPA, albeit slightly, improves the consumers' chances of bringing claims in products liability. The main improvement for the U.K. consumer is the increase of possible targets for a claim. n431 The CPA will make recovery easier for plaintiffs, but it is hardly a revolution in products liability jurisprudence. In fact, in some cases plaintiffs have better chances of recovery under the old law than under the CPA. n432 Many commentators, correctly believe that the CPA will not depart from the law of negligence, while others believe that proving that a product is defective is just as difficult as proving negligence in tort. n433 With the exception of two cases that mention the CPA in passing, n434 the Act has not produced any case law. n435 It becomes clear from the foregoing discussion that the CPA may not have departed much from current negligence law. Commenting on the CPA, Clark put it succinctly "the spirit of the reasonable man has not been fully exorcised." n436 In the final analysis, English courts, with the exception in manufacturing defect cases, will adopt a risk-utility analysis in design and warning cases, though couched in strict liability terminology.

(VII) Conclusion

The foregoing comparison between the Restatement (Third) and the Consumer Protection Act attempted, through a comparative textual analysis, to shed some light on the differences between both systems. As we have seen in part I of the paper, products liability in England was essentially negligence based. There was no comparable evolution of case law toward strict liability as there was in the United States. However, English policy trends encouraged a movement toward a United States version of strict liability. Ironically, the evolution of United States products liability indicates a retreat from strict liability and a return to a negligence-based conceptualization of products liability.

Finally, in the absence of judicial interpretation of the CPA, n437 one can not be certain of the direction U.K. products liability will take in the future. In addition to the development risk defense and hints of cost-benefit analysis, it is extremely likely that judicial interpretation of the CPA will move toward the Restatement (Third). That is, a strong negligence basis for products liability couched in strict liability terminology or strict liability linguistics.

Legal Topics:

For related research and practice materials, see the following legal topics:

FOOTNOTES:

n1. Most commentators agree that the concept of defectiveness is the pulp of products liability. Marshall Shapo, for example, intimates that, "the way we speak about the defect concept has implications across a broad spectrum of jurisprudence." See Marshall S. Shapo, A New Legislation: Remarks on the Draft Restatement of Products Liability, *30 U. Mich J. L. Reform* 215, 216 (1997). David G. Owen, insists that the first two sections of the Restatement (Third), which deal with the concept of defect, are the "heart and soul of the Third Restatement." David G. Owen, Defectiveness Restated: Exploding the "Strict" Products Liability Myth, *1996 U. Ill L. Rev* 743, 746. Alistair M. Clark states that "defectiveness is the basis of any claim." Alistair M. Clark, Product Liability 5 (1989) [hereinafter Clark].

n2. A recent search in WESTLAW's Federal and States case database, conducted by the author, retrieved almost 3,800 cases citing the *Restatement (Second) Of Torts 402A*.

n3. A small minority of products liability commentators argue that the subject of products liability is "ill-suited to restatement." Anita Bernstein, Restatement Redux: Product Liability by Jane Stapleton, *48 Vand. L. Rev.* 1663, 1678 (1995) (book review) (insisting that "products liability, somewhat amenable to restatement in the past, now resists reconciliation and centralized improvements").

n4. The American Law Institute adopted the Proposed Final Draft (April 1, 1997) with minor changes on May 20, 1997 [hereinafter Restatement (Third)].

n5. *10 M. & W.* 109, *11 L.J. Ex.* 415 (1842).

n6. Its impact on products liability has been recognized by commentators. Jerry Phillips' case book on products liability takes Winterbottom as the point of departure in the evolution of products liability. Jerry J. Phillips, Nicholas P. Terry & Frank J. Vandall, *Products Liability: Cases, Material, Problems* (1994).

n7. *11 L.J. Ex.* 415.

n8. See id.

n9. Id. at 417.

n10. Discussing privity, Cardozo elaborated, "in England the limits of the rule are still unsettled. *Winterbottom v. Wright* is often cited." *Macpherson v. Buick*, 111 N.E. 1050, 1054 (1916). See also 1 M. Stuart Madden 1.2, p. 8 (2d ed. 1988); Jane Stapleton, *Product Liability* at 17 (1993).

n11. See Phillips, Terry, & Vandall, *supra* note 6, at 1-2.

n12. See Cornelius W. Gillam, *Products Liability in a Nutshell*, 37 *Or. L. Rev.* 119 (1958) (observing that "almost as soon as the privity rule was (supposedly) formulated, the courts began to emasculate it with exceptions"). Gillam discerned 29 exceptions to the privity rule:

(1) The retailer is the consumer's agent to buy; (2) the retailer is the manufacturer's agent to sell; (3) the retailer assigns his warranty from the manufacturer to the consumer; (4) the consumer is a third-party beneficiary of the retailer's contract with the manufacturer; (5) the manufacturer's marketing of the goods is an offer to the consumer to warrant them if he will buy; (6) the manufacturer makes a unilateral offer to the consumer; (7) the manufacturer's marketing of the goods is a representation to the consumer that they are fit to buy; (8) the defendant is unable to overcome the inference of negligence from circumstantial evidence; (9) there is irrebuttable "presumption" of negligence; (10) a warranty "runs with the goods" from the manufacturer to the consumer; (11) the manufacturer's warranty to the retailer "insures to the consumer's benefit;" (12) a warranty runs with food from the manufacturer to the consumer, but not with a food container; (13) pure-food statutes makes the manufacturer a guarantor of his product as to consumers; (14) warranty is confused with negligence; (15) food cases are a special exception to the privity rule; (16) the privity rule is repudiated as contrary to public policy; (17) the privity rule is simply rejected; (18) the privity rule is simply ignored; (19) breach of implied warranty is a tort; (20) section 15(1) of the Uniforms Sales Act abolishes the privity requirement; (21) section 15(2) of the Uniform Sales Act includes the consumer as a "buyer;" (22) Section 15(2) of the Uniform Sales Act includes the manufacturer as a "seller;" (23) Section 15(2) of the Uniform Sales Act extends the implied warranty of fitness for a general purpose to the consumer; (24) implied sidesteps the privity requirement; (25) notice and opportunity to defend make adverse findings against the defendant retailer binding on the manufacturer against whom the retailer has a claim over; (26) the manufacturer's advertising is an express warranty to the consumer; (27) the manufacturer's advertising is a negligent express representation to the consumer; (28) the manufacturer's advertising is a deceit; (29) the manufacturer is estopped from denying that he has made representations to the consumer.

Id. at 154-155.

n13. 6 *N.Y.* 397 (1852).

n14. *Id. at 405.*

n15. See *id.*

n16. *Id. at 409.*

n17. *Id. at 410.*

n18. Phillips, Terry, & Vandall, *supra* note 6, at 2; see also Gillam, *supra* note 12, at 134 (stating that "ultimately the exception became the rule").

n19. *111 N.E. 1050 (1916).*

n20. *Id. at 1051.*

n21. *Id.*

n22. *Id.*

n23. *Id. at 1053.*

n24. Lester W. Freezer, Tort Liability of Manufacturers & Vendors, *10 Minn L. Rev. 1, 3 (1925)* cited in Gillam, *supra* note 12, at 134.

n25. Gillam, *supra* note 12, at 134.

n26. *50 P.2d 436 (1944).*

n27. See *id. at 437.*

n28. See *id. at 439.*

n29. *Id.*

n30. *Id. at 440.*

n31. *50 P.2d at 440.*

n32. *377 P.2d 897 (1963).*

n33. See *id.* at 897.

n34. *Id.* at P.2d at 900.

n35. See *id.* at 901.

n36. *Id.*

n37. In 1923, The Committee on the Establishment of a Permanent Organization for the Improvement of the Law, a group composed of judges, lawyers and law professors, concluded that American Law had two flaws - its uncertainty and its complexity. The Committee recommended that a lawyer's organization be established to improve American law. Thus, the American Law Institute [hereinafter ALI] was born. ALI's charter stated that its main purpose was "to promote the clarification and simplification of the law and its better adaptation to social needs, to secure the better administration of justice, and to encourage and carry on scholarly and scientific legal work." American Law Institute, About the American Law Institute, (visited Jan. 22, 1998) <<http://www.ali.org/ali/thisali.htm>>.

n38. See Herbert Wechsler, Introduction to Restatement (Second) Of Torts at viii (1965).

n39. Prosser contended that "strict liability in food cases, without privity is the present law of a clear majority of the jurisdictions;" and that strict liability has gone beyond food-stuff to include products ranging from hair dye to tires. William L. Prosser, The Assault Upon the Citadel (Strict Liability to the Consumer), 69 *Yale L.J.* 1099, 1110-1112 (1960). This, according to Prosser, revealed that "the definite impression that the dam has busted, and those in the path of the avalanche would do well to make for the hills." *Id.* at 1113.

n40. *Id.* at 1134.

n41. See *Restatement (Second) Of Torts 402A* (1965). It is interesting to note that during drafting, 402A was subject to three revisions: first, 402A was applicable only to food-stuff, second, it was extended to include "products for intimate bodily use[.]" and finally, as applicable to all products. See William L. Prosser & John W. Wade, *Torts: Cases And Materials* 707 (5th ed. 1971).

n42. (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

(a) the seller is engaged in the business of selling such a product, and

(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although

(a) the seller has exercised all possible care in the preparation and sale of his product, and

(b) the user or consumer has not bought the product from or entered into any contractual relation with the sellers.

Restatement (Second) Of Torts 402A (1965).

n43. There are two minor differences between the Greenman rule and 402A: (1) unlike 402A, Greenman required that the manufacturer know that the product would be used without inspection; and (2) unlike Greenman, 402A allowed, in the absence of personal injury, recovery for loss of property other than the defective product. See Madden, *supra* note 10, 6.1, at 192.

n44. See Owen, *supra* note 1, at 744 (lamenting that "if ever a Restatement reformulation of the law were accepted uncritically as divine, surely it is *section 402A of the Second Restatement of Torts*"); Philip 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, 1051 (1994).

n45. CLARK, *supra* note 1, at 5.

n46. See Geraint G. Howells, *Comparative Products Liability 69-70* (1993) (explaining that in addition to recognizing that "articles dangerous in themselves" as an exception to Winterbottom, the British courts recognized liability in cases where the manufacturer knew of product dangers, yet did nothing to prevent injury); see also Lord Griffiths, Peter De Val & R.J. Dormer, *Developments in English Product Liability Law: A Comparison With the American System*, 62 *TUL. L. REV.* 353, 357 (pointing out there were two exceptions to the general privity rule (1) in the case where an article is dangerous in and of itself; and (2) where the defect was known to the manufacturer).

n47. 1932 *App. Cas.* 562 (appeal taken from Scot.).

n48. See *id.*

n49. Lord Atkin: "I don't think so ill of our jurisprudence as to suppose that its principles are so remote from the ordinary needs of civilized society and the ordinary claims which it makes upon its members as to deny a legal remedy where there is so obviously a social wrong." *Id. at 583*.

n50. *Id. at 599*.

n51. See *Hill v. James Crowe, 1 All E.R. 812, 816 (1978)* (holding "if plaintiff's injuries were a reasonably foreseeable consequence of such negligence, the manufacturer's liability would be established under Donoghue").

n52. Interestingly, Lord Atkin cited Judge Cardozo's MacPherson opinion as further support for his position. Lord Atkin stated: "It is always a satisfaction to an English lawyer to be able to test his application of fundamental principles of the common law by the development of the same doctrines by the lawyers of the courts of the United States. In that country I find that the law appears to be well established in the sense in which I have indicated. The snail had emerged from the ginger beer bottle in the United States before it appeared in Scotland, but there it brought liability upon the manufacturer. I must not in this long judgment do more than refer to the illuminating judgment of Cardozo J. in *Macpherson v. Buick Motor Co.* in the New York Court of Appeals, in which he states the principles of law as I should desire to state them" *Id. 1932 App. Cas. at 598*.

n53. See, e.g., Howells, *supra* note 46, at 71; see also Griffiths, *supra* note 46, at 360, Stapleton, *supra* note 1, at 20.

n54. The reasons for this are easily explained by the English legal and political system. England has no written constitution. Unlike the U.S. Supreme Court that has the right to judicial review, i.e., reviewing the constitutionality of legislation, the final word in England does not rest with the House of Lords, but it lies with Parliament. As a result, English judges are not confident nor willing to engage in a role of law and policy making. See R.M.S. Gibson, *Products Liability in the United States and England: The Difference and Why*, 3 *Anglo-Am. L. Rev.* 493, 516-517 (1974). Moreover, the rule of stare decisis is more religiously adhered to in England than in the United States, thus, English law is slow to evolve and adapt, without legislative intervention. In fact, until recently the House of Lords was bound by its own precedent. This rigidity led to much criticism. Only since 1966 has the House of Lords agreed to depart from its own precedent, and only in rare instances. See *Practice Statement (Judicial Precedent) 1 W.L.R. 1234, 1234 (1966)*. "Their Lordships nevertheless recognize that too rigid adherence to precedent may lead to injustice in a particular case and also unduly restrict the proper development of the law. They propose, therefore, to modify their present practice and, while treating former decisions of this House as normally binding, to depart from a previous decision when it appears right to do so." *Id.* See generally Michael Zander, *The Law-Making Process* 179-225 (3rd ed. 1993) (examining the nature of binding precedent in the English court hierarchy). By na-

ture by comparison to the U.S., judicial law-making in the U.K. is severely constrained and conservative.

n55. See, e.g., Sale of Goods Act 1979 (c54) 14(2) (1995) provides "where the seller sells goods in the course of a business, there is an implied term that the goods supplied under the contract are of satisfactory quality." Section 5(1)(b) of the Unfair Contract Terms Act 1977 (c 50) (1978) provides that where injury is caused by defective product "liability for the loss or damage cannot be excluded or restricted by reference to any contract term or notice contained in or operating by reference to a guarantee of the goods; Section 6 of the Consumer Safety Act 1978 which authorized the government to regulate the sale and supply of unsafe products, provided criminal penalties, for violators (the Consumer Safety Act has been superseded by the Consumer Protection Act 1987)." See Griffiths, *supra* note 46, at 360 (listing numerous statutes dealing with consumer protection). For English safety regulations see 5(2) Halsbury's Statutes Of England, P 976 (1995).

n56. Griffith, *supra* note 46, at 360; see also Clark, *supra* note 1, at 47. "The law previously recognized no separate area of products liability." *Id.*

n57. Griffiths, *supra* note 46, at 360. See also Peter Cartwright, Defendants in Consumer Protection Statutes: A Search for Consistency, 59 *Mod. L. Rev.* 225 (discussing U.K. statues that provide for criminal penalties to protect consumers, such as the Trade Description Act 1968, the Consumer Protection Act 1987 Part II, the Food Safety Act 1990 and the Property Misdescriptions Act 1991).

n58. See *Banks v. ICI Americas, Inc.*, 450 *S.E.2d* 671, 672 (1994). "There are three general categories of product defects: manufacturing defects, design defects, and marketing/packaging defects." *Id.* Most products liability treatises and case books organize the material according to defect type. See, e.g., Phillips, Terry, & Vandall, *supra* note 6.

n59. 1 *All E.R.* 812 (1978).

n60. See *id.* at 812.

n61. *Id.* at 816.

n62. Howells, *supra* note 46, at 72. See also Clark, *supra* note 1, at 10. "The presence of a manufacturing defect ... commonly gives rise to a presumption of negligence on the part of the producer, and in some cases the application of the maxim *res ipsa loquitur* can assist the plaintiff." *Id.*

n63. 980 *F.2d* 632 (10th Cir. 1992).

n64. See *id.* at 634.

n65. *Id.*

n66. See *id.*

n67. *Id.* at 638.

n68. 980 F.2d at 636.

n69. See *id.* at 637.

n70. 1 Lloyd's Rep. 610 (1978).

n71. See *id.* at 611.

n72. *Id.*

n73. See *id.* at 612.

n74. See *id.*

n75. 1 Lloyd's Rep.

n76. See *id.*

n77. *Id.* at 621. If Judge Stockes found that there were no ways to overcome the defective design, would he have still found for plaintiffs? It is not clear from Lambert. That is, would the manufacturer still be negligent in the absence of an alternative design?

n78. 450 N.E.2d 204 (1983).

n79. See *id.* at 206.

n80. *Id.*

n81. See *id.*

n82. See *id.*

n83. *450 N.E.2d at 208.*

n84. *Id.*

n85. *See id. at 209.*

n86. *See Morris v. West Hartlepool Steam Navigation Co., 1956 App. Cas. 552* (articulating the nuances of a cost-benefit test). For a detailed examination of *Morris*, see *infra*.

n87. The fact of the matter is that U.S. strict liability does not mean liability without fault.

n88. *1 Q.B. 88 (1971).*

n89. *See id. at 94.*

n90. *See id.*

n91. *See id.*

n92. *See 1 Q.B. at 94.*

n93. *Id. at 95.*

n94. *Id. at 109.*

n95. *See id. at 109-110.*

n96. *725 P.2d 1076 (1986).*

n97. *See id. at 1078.*

n98. *See id.*

n99. *Id. at 1079.*

n100. *Id.*

n101. Id.

n102. *810 P.2d 549 (1991)*.

n103. See *supra* note 37.

n104. See Bruce Kaufman, *ALI Membership Grants Final Approval to Influential Product Liability Treatise*, *BNA Products Liability Daily*, May 23, 1997, available in Westlaw, BNA Library, BNAPLD File.

n105. See *id.* On April 20, 1993, the Reporters published their "Preliminary Draft No. 1" entitled "Liability for the Sale or Distribution of Defective Products." Since then, several preliminary drafts were discussed, and Tentative Draft No. 1 1994, Tentative Draft No. 2 1995, and Tentative Draft No. 3 1996, and Proposed Final Draft 1997, have been published.

n106. See *supra* note 1.

n107. See Restatement (Third) 2 cmt. n.

n108. See generally Oscar S. Gray, *The Draft ALI Product Liability Proposals: Progress Or Anachronism?* *61 TENN. L. REV. 1105 (1994)*. "Under the proposals, there would be no liability in negligence, or for breach of warranty, for marketing an unreasonably dangerous product unless there were a manufacturing or warning defect, or unless the plaintiff could establish the technical and economic feasibility of an alternative design that would make the product in question safer." *Id.*

n109. Prior to the ALI, May, 1997, annual meeting, both ALI and the National Conference of Commissioners on Uniform State Laws [hereinafter NCCUSL] approved in principle the following Comment to article 2-404 [2-314]:

When recovery is sought for injury to person or property that allegedly resulted from manufacturing or design defects in goods sold or inadequate instructions or warnings, the applicable state law of products liability determines whether the goods are merchantable under Section 2-404. Merchantability in the context of a claim to recover for injury to person or property is synonymous with the level of safety required for the goods as a matter of public policy adopted by the courts of this state or, if applicable, the Restatement of the Law (Third), Torts: Products Liability.

The comment further states that the implied warranty of fitness for a particular purpose and express warranties, in cases involving personal injury, are governed by article 2 of the UCC.

n110. An examination of UCC revised article 2 (May 1997 draft) illustrates the intended far-reaching implications of the Restatement (Third). Revised article 2 states that in personal injury actions, the concept of defect should follow state products liability law. In other words, if the Restatement (Third) is adopted in State X and the injured party pursues an implied warranty of merchantability action, the plaintiff must satisfy the functional definition of defect under the Restatement. That is, he may not rely on the merchantability standard as enunciated in the UCC.

It is stated by the Reporters that "claims based on product defect at time of sale or other distribution must meet the requisites set forth in Subsection (a), (b), and (c), or other provision in this chapter 1." Regardless of label, be it implied warranty of merchantability, strict liability, or negligence, the plaintiff must establish the requisites of Subsection (a), (b) or (c). 2 cmt. n. Most significantly, the Reporters assert that "failure to meet the requisites of s 2(a), (b), or (c) will defeat a cause of action under either negligence, strict liability, or implied warranty of merchantability." Reporters Notes' 2 cmt. n. Although the Reporters provide that in cases where multiple theories are alleged by plaintiff, they leave to "local law the question of the procedural stage in a tort action at which plaintiff must decide under which theory to pursue the case," the Reporters recommend State procedures to limit the theories upon which a plaintiff may pursue his action. "This Restatement contemplates that a single tort definition of defect will emerge regardless of the characterization of the claim as sounding in tort or in implied warranty of merchantability," the Reporters predict. Reporters' Notes' 2 cmt. n. The Reporters advocate that a plaintiff may not allege multiple claims, where one or more of the claims are "factually identical." It seems that the Reporters are suggesting that, what they perceive as duplicative claims, such as implied warranty of merchantability, strict liability and negligence, should be abolished in cases of products liability in favor of a new products liability system based solely on a functional definition of defect. The Reporters note that since design and warning defect are subject to a risk-utility analysis, bringing a claim under negligence, strict liability, or warranty of merchantability would be duplicative. This the Reporters exhort "would generate confusion and may well result in inconsistent verdicts." However, the Reporters emphasize that the plaintiff can choose the more advantageous theory. Moreover, the Reporters state that "claims based on misrepresentation, express warranty, and implied warranty of fitness for particular purpose, in particular, are not within the scope of this chapter and thus are unaffected by it." Limiting the applicability of negligence, the Reporters claim that "negligence retains its vitality as an independent theory of recovery for a wide range of product-related, harm-causing behavior. This Restatement includes several such topics in later Chapters, including post-sale failure to warn (see s 10); post-sale failure to recall (see s 11); and a successor's liability for its own failure to warn (see s 13)." Id. 2 cmt. n.

From the forgoing, it would seem that the Reporters effectively advocate that since the new regime is a functional regime, negligence should be allowed in limited instances, product defect not being among them. This position could also have far reaching consequences on contract law. Does this mean that a plaintiff injured by a defective product can

only pursue his claim under a functional tort liability system? It may well be the case. See generally Gray, *supra* note 108, at 1111 (calling comment j (now cmt. n) "a proposition of breathtaking audacity" and void of precedent).

n111. See *id.*

n112. Duty, breach, causation, and damages.

n113. See Oscar S. Gray, *supra* note 108, at 1108 (describing Restatement (Third) proposals as "a truncated negligence test"); see also Teresa Moran Schwartz, The Impact of the New Products Liability Restatement on Prescription Products, *Food & Drug L.J.* 399, 458 (1995) (lamenting that the standard for recovery under Restatement (Third) has been elevated to "super negligence"); Frank J. Vandall, Constructing A Roof Before the Foundation is Prepared: The Restatement (Third) of Tort: Products Liability Section 2(b) Design Defects, 30 *U. Mich. L.J. Reform* 261, 262 (1997) (calling the Restatement (Third) proposal "radical negligence").

n114. The New York Court of Appeals rejected the position that implied warranty of merchantability and strict products liability, causes of action, are identical. *Denny v. Ford Motor Co.*, 662 *N.E.2d* 730 (1995). The Denny court asserted that strict products liability and breach of implied warranty of merchantability "are not identical in New York and that the latter is not necessarily subsumed by the former." *Id.* In contrast, the Michigan Supreme Court held that, whether based on implied warranty or negligence, Michigan follows a "pure negligence ... risk-utility" balancing in design defect cases. See *Gawenda v. Werner Co.*, 932 *F.Supp.* 183, 187 (*E.D. Mich.* 1996).

n115. M. Stuart Madden, Strict Product Liability Under *Restatement (Second) of Torts 402A*: 'Don't Throw the Baby Out with the Bathwater,' 10 *Touro L. Rev.* 123, 125 (1993); see also William A. Dreier, Design Defects Under the Proposed *Section 2(b) of the Restatement (Third) of Torts: Products Liability* - A Judge's View, 30 *U. Mich. J. L. Reform* 215, 226-228 (1997) (noting that although differences between strict liability and negligence regarding burden of proof and defenses exist, in practice, "analysis under strict liability did not differ much, if at all, from analysis under negligence").

n116. *Id.* 1 cmt. a.

n117. *Id.* Many commentators observe that the black letter law tends to appear strict while the comments explain the rule in terms of negligence. See, e.g., David Owen, *supra* note 1, at 762 (describing the paradox as "a pig-is-a-mule definition").

n118. Benjamin N. Cardozo, *Law And Literature: And Other Essays And Addresses*, 123-124 (1986).

n119. See Dreier, *supra* note 115, at 238 (stating that "under the proposed Restatement (Third) the law has not changed" but has been "explained more precisely"); see also Michael Prince, Law Panel Offers New Rule for Design Defect Cases: Plaintiffs Attorney Fear Product Liability Harder to Prove, *Business Insurance*, June 16, 1997 (quoting Madden describing the Restatement (Third): "[It is] a refinement of the law and not a changing of the law"); Sheila L. Birnbaum and J. Russell Jackson, In the New Restatement On Torts, the Reporters Distinguishes Manufacturing Defects from Design and Warning defects, *Nat'l L.J.*, August 4, 1997, B5 (opining that the Restatement (Third) "more accurately articulates the current state of products liability law, and does so in a more comprehensive fashion, than its predecessor").

n120. Guido Calabresi & Jeffrey O. Cooper, New Direction in Tort Law, *30 Val. U. L. Rev.* 859, 866 (1996). See also Vandall, *supra* note 113, at 267 (lamenting that the Reporters failed to truthfully Restate Products Liability and instead they "announced a new concept for design defect cases - 'radical negligence,' i.e., in addition to failure to exercise reasonable care, an alternative design must be shown"); Angela C. Rushton, Comment, Design Defects Under the Restatement (Third) of Torts: A Restatement of Strict Liability and the Goals of a Functional Approach, *45 Emory L.J.* 389, 436 (1996) (claiming that the Restatement (Third) does not "represent the current state of the law nor satisfactorily states what the law should be"); Michael Prince, *supra* note 119 (quoting John Vargo describing the Restatement (Third): "It has no academic integrity whatsoever if they want to follow what the states say[;] ... this is written to protect corporations and insurance companies and prevent consumers from recovering in suit." *Id.*; and quoting Professor Phillips describing the Restatement (Third): "It's an attempt to change the law in a regressive fashion").

n121. *Restatement (Third) Of Torts: Products Liability 1* (P.F.D. 1997).

n122. *Id.* 1(a).

n123. All major treatises and case books on Products Liability organize the material according to defect type. See, e.g., Phillips, Terry & Vandall *supra* note 6.

n124. See, e.g., *Banks v. ICI Americas, Inc.*, 450 S.E.2d 671, 672 (1994). "There are three general categories of product defect: manufacturing defects, design defects, and marketing/packaging defects." *Id.* But see, e.g., *Cronin v. J.B.E. Olson Corp.*, 501 P.2d 1153, 1163 (1973) (refusing to distinguish between manufacturing and design defect in order "to avoid providing ... a battle ground for clever counsel"). Five years later, the California Supreme Court in *Barker v. Lull Engineering Co.*, 573 P.2d 443 (Cal. 1978), however, recognized the three types of defect. John Wade's criticism of Cronin seems appropriate: "Indeed, the position of the California court in Cronin, in limiting the requirement to a defective product, would be much more sustainable if the strict liability for products which it applies were confined to the product which has its 'defect' developed unintentionally in the manufacturing process, thus leaving the design and warning cases to be handled under the negligence techniques." John Wade, On the Future of Strict Tort Liability for Products, 44

Miss. L.J. 825, 837 (1973). Other commentators oppose this trifurcation. See e.g., Douglas E. Schmidt, Mark R. Kosieradzki and Carol Lynn O'Gara, A Critical Analysis of the Proposed Restatement (Third) of Tort: Products Liability, 21 *Wm. Mitchell L. Rev.* 411, 414 (1995). "Various commentators have expressed the view that the distinction between manufacturing and design defect is 'an illusion,' 'slippery,' and 'no longer tenable.'" (footnotes omitted). *Id.*

n125. Owen, *supra* note 1, at 747.

n126. See David Owen, *supra* note 1, at 748 (noting that the express division of a defect into three types inherently "provides a mechanism for stripping away the great bulk of strict liability from products liability law and returning it to negligence, more or less").

n127. See Jerry J. Phillips, The Unreasonably Unsafe Product And Strict Liability, 72 *Chi-Kent L. Rev.* 129, 129-136 (1996) (illustrating that design and warning defects overlap with manufacturing defect and arguing that "[a] distinct-category analysis is artificial, and contrary to the fact-specific approach of tort law"); see also Vandall, *supra* note 113 at 267 (criticizing the trifurcation of defect and illustrating examples where depending on approach to product determines whether the defect is a manufacturing or a design defect); see also Rebecca Korzec, Dashing Consumer Hopes: Strict Products Liability and the Demise of the Consumer Expectations Test, 20 *B.C. Int'l & Comp. L. Rev.* 227, 244 (1997) (arguing that trifurcation of defect "often proves a futile and ineffective analytical exercise" and that "design and warning flaws may overlap," and that "design and production defects also may overlap or coincide").

n128. Jerry Philips for example, contends that misrepresentation "cannot be artificially separated from design, manufacturing, and warning defects, since misrepresentation by advertising, product appearance, and otherwise is often a substantial factor in determining product defectiveness on any basis." Phillips believes that the Reporters intentionally excluded misrepresentation "as an integral element for determining defectiveness" because "the representational aspect of products liability is an essential part of the consumer expectation test, which is the underlying basis for strict liability under the *Restatement (Second) of Torts section 402A* and which the Reporters are particularly anxious to reject." See Jerry J. Phillips, Achilles' Heel, 61 *Tenn. L. Rev.* 1265, 1268 (1994); see also *Phillips, supra* note 127, at 139-142 (discussing same).

n129. See *Restatement (Third) Of Torts: Products Liability 2(a)*.

n130. *Id.* 2(a) cmt. b.

n131. "As early as 1266, criminal statutes imposed liability upon ... brewers, butchers, cooks, and other persons who supplied contaminated food and drink." *Restatement (Third) 1 cmt. a* (1997).

n132. Id. 2 cmt. a

n133. See, e.g., *Phillips v. Kimwood*, 525 P.2d 1033 (Or. 1974). See also, David G. Owen, *supra* note 1, at 748 (opining that strict liability for manufacturing defect, embodied in the Restatement (Third) is "where almost all agree that it belongs"). See also Madden, *supra* note 10, 9.6, at 330-332. (stressing that the "distinction between negligence and strict tort liability" in manufacturing defect instances "are most readily discernible and the principles of strict tort liability most readily applied").

n134. Marshall S. Shapo, In Search of the Law of Products Liability: The ALI Restatement Project, 48 *Vand. L. Rev.* 631, 659-660 (1995) (expressing "dubiety about casting the distinction as ironclad," and arguing that sellers engage in analogous decision making and in both cases, "they are aware of the level of statistical risk to which they expose the consumer"). See also Shapo, 1 *The Law Of Products Liability* P 9.01(2) (emphasizing same); *Phillips*, *supra* note 128, at 1269-1270 (contending that most policy consideration supporting strict liability in a manufacturing defect situation also support the application of strict liability in a design defect situation).

n135. Restatement (Third) 2(a) cmt. b. "The rule for manufacturing defects stated in 2(a) imposes liability whether or not the manufacturer's quality control efforts satisfy standards of reasonableness." Id. The comment provides several objectives supporting strict liability in the case of a manufacturing defect, among others, strict liability is said to "encourage greater investment in product safety" than does a negligence regime, that it "reduces the transaction costs involved in litigating" the issue of manufacturer fault, that it is fairer to the plaintiff in the sense that it functions like the "concept of *res ipsa loquitur*, allowing deserving plaintiffs to succeed notwithstanding what would otherwise be difficult or insuperable problems of proof," and that a manufacturing defect may not live up to the consumer's reasonable expectations because manufacturer's choice of quality control is reflected in the manufacturing defect level and "their knowledge that a predictable number of flawed products will enter the marketplace entails an element of deliberation about the amount of injury. Id. Most commentators agree that the policy reasons behind strict liability can be summarized into six: "(1) compensation through loss spreading; (2) deterrence; (3) encouraging useful conduct; (4) amelioration of expensive and time consuming problems of proof; (5) protection of consumer expectations; and (6) cost internalization." See Madden, *supra* note 115, at 127.

n136. See *Caterpillar Tractor Co. v. Beck*, 593 P.2d 871, 880 (Alaska 1979) (recognizing that design defects "present the most perplexing problems in the field of strict products liability because there is no readily ascertainable external measure of defectiveness).

n137. See Larry S. Stewart, *The ALI and Products Liability: 'Restatement' or 'Reform'?*, *Trial*, September 1994, at 28, 29 (describing the alternative design issues as being "the most hotly debated proposal made by the reporters").

n138. See, e.g., Shapo, *supra* note 134, at 688-691; Comment, *supra* note 120, at 419; Frank J. Vandall, *The Restatement (Third) of Torts, Products Liability, Section 2(b): Design Defect*, 68 *Temp. L. Rev.* 167, 168 (1995); John F. Vargo, *The Emperor's New Clothes: The American Law Institute Adorn A "New Cloth" for Section 402A Products Liability Design Defects - A Survey of the States Reveal a Different Weave*, 26 *U. Mem. L. Rev.* 493 (1996). See generally Symposium, *On The ALI's Proposed Restatement (Third) of Torts, Products Liability*, 21 *Wm. Mitchell L. Rev.* 369 (1995); Symposium, *Review of the System of Products Liability Law*, 36 *S. Tex. L. Rev.* 227 (1995).

n139. See, e.g., William A. Dreier, *supra* note 115, at 221 (arguing that criticisms of 2(b) are "unfounded" and that when "section 2(b) is read together with the Reporters' extensive comments ... it becomes clear that this perception is largely incorrect"); Richard L. Cupp, *Rethinking Conscious Design Liability for Prescription Drugs: The Restatement (Third) Standard Versus a Negligence Approach*, 63 *Geo. Wash. L. Rev.* 76, 108 (1994) (stating that the "new Restatement's non-drug design liability test - which is much closer to a true restatement of existing case law than its prescription product design standard").

n140. Restatement (Third) 2 cmt. c.

n141. *Id.* 2 cmt. a. See also Reporters' Notes on cmt. a: "Since the degree of risk or safety in every product design is counterbalanced by considerations such as cost, utility, and aesthetics, the basis of responsibility for design defect logically should be based on the principle of optimality inherent in the philosophical notion of utility and in the economic concept of efficiency." See also Owen, *supra* note 1, at 754 (rejecting strict liability and advocating negligence in design defect cases claiming that "the goal of both design engineers and the law should be to promote in products an ideal balance of product usefulness, cost, and safety"). See also Richard C. Ausness, *Product Category Liability: A Critical Analysis*, 24 *N. Ky. L. Rev.* 423, *1 (observing that "since no single definition of defect is broad enough to cover every type of dangerous condition, courts have employed a variety of tests to determine if a product is defective" and that risk-utility balancing is usually used in design defects).

n142. Restatement (Third) 2(b).

n143. *Id.* 2 cmt. a.

n144. *Id.*

n145. The manufacturing defect rationale is not applicable to design defect cases, according to the Reporters, because "the element of deliberation in setting appropriate levels of design safety is not directly analogous to the setting of levels of quality control by the manufacturer." *Id.* cmt. a. That is, when a manufacturer reasonably designs a product, "the

responsibility for product risks that cannot be designed out of the product at acceptable cost is appropriately transformed to a user population that is in a better position than the manufacturer to manage those risks efficiently." Id. cmt. a.

n146. Restatement (Third) 1 cmt. a.

n147. Id. 1 cmt. a.

n148. See generally the Reporters' Notes on cmt. (d). A recent article takes issue with this contention. See Vargo, *supra* note 138, at 554 (finding after a detailed survey of the jurisdictions that only seven states apply a "pure risk-utility test"); see also Vandall, *supra* note 138, at 168; Roland F. Banks and Margaret O'Connor, Restating the Restatement (Second), Section 402A - Design Defect, 72 *Or. L. Rev.* 411, 413 (finding only seven states that solely follow a risk-utility test); Howard Klemme, Comments to the Reporters and Selected Members of the Consultative Group, Restatement of Torts (Third): Products Liability, 61 *Tenn L. Rev.* 1173, 1174-1175 (criticizing the Reporters assertion that the majority of states follow a risk-utility test claiming that "more than half the cases cited fail to provide anything but the most fanciful support for those statements"); But see MADDEN, *supra* note 10, 8.3, at 299 (observing that "the majority rule posits that plaintiff cannot establish a prima facie case of defective design without evidence of a technologically feasible, and practicable, alternative to defendant's product that was available at the time of manufacture"); see also James T. O'Reilly & Nancy C. Cody, Products Liability Resource Manual 66 (1993) (asserting that "risk/utility is the dominant method of deciding 'design defect' cases, though in rare circumstances, it is rejected in favor of the consumer expectation standard").

n149. Restatement (Third) 2 cmt. a.

n150. Id. cmt. a. The Reporters state: "For the liability system to be fair and efficient, most courts agree that the balancing of risks and benefits in judging product design and marketing must be done in light of the knowledge of risks and risk-avoidance techniques reasonably attainable at the time of distribution. To hold a manufacturer liable for a risk that was not foreseeable when the product was marketed might foster increased manufacturer investment in safety. But such investment by definition would be a matter of guesswork." Id.

n151. See *United State v. Carroll Towing Company*, 159 *F.2d* 169, 173 (2nd Cir. 1947) (creating a risk-utility test to determine breach of duty of care by focusing on the interplay between probability, gravity and injury - B<PL). John Wade's seven factor inquiry is a more developed application of the B<PL formula:

(1) The usefulness and desirability of the product - its utility to the user and to the public as a whole.

(2) The safety aspects of the product - the likelihood that it will cause injury and the probable seriousness of the injury.

(3) The availability of a substitute product which would meet the same need and not be as unsafe.

(4) The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.

(5) The user's ability to avoid danger by the exercise of care in the use of the product.

(6) The user's anticipated awareness of the dangers inherent in the product and their availability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions.

(7) The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.

John Wade, *supra* note 124, at 837-838.

n152. Restatement (Third) 2 cmt. a. Over two decades ago it was recognized that liability for a design defect sounded in negligence. John Wade stated: "There is little difference here between the negligence action and the action for strict liability." See John Wade, *supra* note 124, at 841.

n153. Reporters' Notes on cmt. a. See, e.g., Theodore S. Jankowski, Focusing on Quality and Risk: The Central Role of Reasonable Alternatives in Evaluating Design and Warning Decisions, *36 S. Tex. L. Rev.* 283, 351 (1995).

"Risk-utility analysis remains the only judicial method for scrutinizing product decisions in a way that rationally balances the societal goals at stake enables fair compensation for those injured as a result of unreasonable decisions made concerning product safety." *Id.*

Commentators have conceptualized risk-utility into two versions: economic version and the reasonableness version. For an analysis of both version as they relate to design defects under the Restatement (Third), see generally Michael D. Green, The Schizophrenia of Risk-Benefit Analysis in Design Defect Litigation, *48 Vand. L. Rev.* 609 (1995). The economic version of risk-utility postulates that, to borrow Richard Posner's formulation, "if the cost of safety measures or of curtailment - - whichever cost is lower - - exceeds the benefit in accident avoidance to be gained by incurring that cost, society would be better off, in economic terms, to forgo accident prevention." Richard A. Posner, A Theory of Negligence, *1 J. Legal Studies*, 29, 32 (1972), cited in Green, *supra* note 153, at 616. Thus, if foregoing a certain safety feature which would cost the manufacturer \$ 100 million and only result in injury to persons, like losing an arm or finger, totaling 20 million, then the design is not defective under the risk-utility balance. This economic version is rigid and seemingly heartless. On the other side, the reasonableness version is basically represented

by John Wade's seven factors enunciated in his famous 1973 Mississippi Law Review article. The reasonableness version is less rigid and includes both economic and reasonableness variables, though it has its flaws. Where does the Restatement (Third) place within these two versions? Green feels that the Restatement (Third) places it in the middle. The requirement of an alternative design acknowledges the need for a yardstick for an economic version comparison and by adding 'reasonable' to the alternative design, the Restatement acknowledged the reasonable person of the softer version. *Id.* at 623. Green's main criticism of the Restatement is that it "fails to address the most difficult, perhaps intractable, problem posed by the economic version of risk-benefit analysis, that conundrum, identified earlier, is making comparisons between incommensurable. Specifically, risk-benefit analysis entails comparing injuries and death, on the one hand, and the costs -- often in dollars - of additional safety features on the other." *Id.* at 624-625.

n154. Restatement (Third) 2 cmt. f. The Reporters emphasize "when evaluating the reasonableness of a design alternative, the overall safety of the product must be considered". *Id.*

n155. *Id.* 2 cmt. c.

n156. See *Id.* 2 cmt. f. "The factors include, among others, the magnitude and probability of the foreseeable risks of harm, the instructions and warnings that accompany the product, and the nature and strength of consumer expectations regarding the product. The relative advantages and disadvantages of the product as designed and as it alternatively could have been designed may also be considered. Thus, the likely effects of the alternative design on production costs; the effects of the alternative design on product longevity, maintenance, repair, and esthetics; and the range of consumer choice among products are factors that may be taken into account." *Id.*

n157. Restatement (Third) 2 cmt. f.

n158. *Id.*

n159. *Id.* 2 cmt. d. "Under prevailing rules concerning allocation of burden of proof, the plaintiff must prove that such a reasonable alternative was, or reasonably could have been, available at time of sale or distribution." *Id.* For minority view that allocates burden of proof on defendant see, e.g., *Barker v. Lull Engage Co.*, 573 P2d 443, 458 (Cal. 1978) (stating that a product is not defective in design if "the defendant fails to prove ... that on balance the benefits of the challenged design outweigh the risk of danger inherent in such design") (emphasis added).

n160. Restatement (Third) 2 cmt. c. Interestingly the Reporters contend that the same policy reasons supporting a negligence regime are applicable in the design defect case. *Id.*

n161. Id.

n162. Id.

n163. Id.

n164. See Restatement (Third) 2 cmt. c. See also, 2 cmt. e. "It is not sufficient that the alternative design would have reduced or prevented the harm suffered by the plaintiff if it would also have introduced into the product other dangers of equal or greater magnitude". Id.

n165. Id. 2 cmt. a. The Reporters claim that if a manufacturer is liable for a non foreseeable risk that would translate into huge investment in insurance that is not easy to estimate and is not equitable. "Thus, with respect to unforeseeable or incalculable risks, manufacturers would find it inherently impossible to adequately protect themselves with insurance." Id. See *Grzanka v. Pfeifer*, 694 A.2d 295 (N.J. 1997). Grzanka involved an alleged defective traffic light signal. Id. Comparing with approval 2(b) of the Restatement (Third) with New Jersey law, the court rejected plaintiffs products liability claim noting that in a risk-utility analysis, in addition to an alternative design, the plaintiff must prove that the manufacturer could have reasonably foreseen the risk and that "the omission of the alternative design renders the product not reasonably safe." Id. The court held that the plaintiffs "alternative design fails to meet the full test of Restatement (Third) 2(b)." *Id. at 304.*

n166. Restatement (Third) 2 cmt. f.

n167. Id. 2 cmt. o. Comment o further explains that "once it is determined that a reasonable alternative design or reasonable instructions or warnings could have been provided at or before the time of sale by a predecessor in the chain of destruction and would have reduced plaintiff's harm, it is no defense that a nonmanufacturing seller of such a product exercised due care." Id. See also id. cmt. (a), and 1 cmt. e.

n168. See Restatement (Third) 2 cmt. o.

n169. David G. Owen, Toward A Proper Test for Design Defectiveness: "Micro-Balancing" Costs and Benefits, 75 *Tex. L. Rev.* 1661, 1662 (1997) (examining risk- utility balancing in detail and concluding that the term cost-benefit is more appropriate and that a micro-balancing approach will clear the confusion on what a cost- benefit test should address).

n170. Owen, *supra* note 169, at 1662.

n171. David G. Owen, Risk-Utility Balancing Design Defect Cases, *30 U. Mich. J.L. Reform*, 239, 244-245 (1997).

n172. For the Hand test enunciated in *Carroll Towing* see *supra* note 151. See also Owen, *supra* note 169, at 1685 (stressing that "the Hand formula by nature implies a micro-balance of the costs and benefits of adopting a particular rejected precaution, and the formula works as well in strict products liability as it does in negligence").

n173. See Mark F. Grady, *Untaken Precautions*, *18 J. Legal Stud.* 139 (1989); see also Mark F. Grady, *A New Positive Economic Theory of Negligence*, *92 Yale L.J.* 799 (1983).

n174. Owen, *supra* note 171, at 241. Owen proposed the following micro-balance test: "A product is defective in design if the safety benefits from altering the design as proposed by plaintiff were foreseeably greater than the resulting costs, including any diminished usefulness or diminished safety." *Id.* at 247.

n175. See *id.* at 245.

n176. The Reporters did provide for a narrow exception in the case of a manifestly unreasonable design. See *Restatement (Third) 2 cmt. e.*

n177. See *id.* 2 cmt. d. "Assessment of a product design requires a comparison between an alternative design and the product design that caused the injury, undertaken the view point of a reasonable person." *Id.*

n178. Shapo observes that "the Draft simply does not allow for the possibility that a seller might be liable if it sells a product whose configuration is such that the only feasible way to avoid its dangers would be to adopt a substitute, rather than an "alternative design," or to forego manufacture of that product." Shapo, *supra* note 138, at 663. Later on in his article, Shapo uses several examples to illustrate his point, for example "the Dalkon Shield certainly was a bad IUD. Suppose it were the only IUD. Should that immunize it from suit;" does the Draft mean "that the use of a product for cosmetic purposes on a limited population should be immunized from litigation because there is no other way to achieve the same result?" *Id.* at 673.

n179. *Restatement (Third) 2 cmt. e.* "Several courts have suggested that the designs of some products are so manifestly unreasonable, in that they have low social utility and high degree of danger, that liability should attach even absent proof of a reasonable alternative design. In large part the problem is one of how the range of relevant alternative design is described." *Id.* Applying above formulations to a toy gun that shoots pellets and causes injury to children, the Reporters explain that a toy that shoots Ping-Pong balls that do not cause injury would be an alternative design, however, if the main character of this gun is its capacity to injure, then there are no alternative designs. As such, the Reporters state that

a court "would declare the product design to be defective and not reasonably safe because the extremely high degree of danger posed by its use or conception so substantially outweighs its negligible social utility that no rational, reasonable person, fully aware of the relevant facts, would choose to use, or to allow children to use, the product." *Id.* The Reporters claim that only several courts adopt this approach, thus the Reporters relegate this formulation to the periphery. But see *McCarthy v. Olin Corp.*, 1997 WL 395339 (2nd Cir N.Y.) (holding that bullets intended to rip and tear upon impact "were not in defective condition nor were they unreasonably dangerous for their intended use because the Black Talons were purposely designed to expand on impact and cause severe wounding").

n180. Tobacco was included as an inherently dangerous product in earlier drafts of the Restatement. Tobacco was considered outside the traditional products liability rules. However, the references to tobacco in the Restatement (Third) were deleted in the final vote approving the Restatement (Third) on May 20, 1997. The ongoing negotiations between tobacco companies and the States regarding a lump sum settlement for health injuries caused by cigarette smoke prompted the deletion. See Kaufman, *supra* note 104.

n181. See Restatement (Third) 2 cmt. a. "Products are not generically defective merely because they are dangerous." *Id.* The Reporters assert that an alternative design is required even if it is alleged that the product "is so dangerous that it should not have been marketed at all." They continue: "Common and widely distributed products such as alcoholic beverages, tobacco, firearms, and above-ground swimming pools may be found to be defective only upon proof of the requisite conditions in Subsections (a), (b), and (c)." Moreover, "absent proof of defect under those Sections, however, courts have not imposed liability for categories of products that are generally available and widely used and consumed, even if they pose substantial risks of harm." See *id.* cmt. d. For a recent examination of category liability see generally Ausness, *supra* note 141.

n182. See Ausness, *supra* note 141, at *3.

n183. See, e.g., Richard L. Cupp, Jr., Defining the Boundaries of 'Alternative Design' Under the Restatement (Third) of Torts: The Nature and Role of Substitute Products in Design Defect Analysis, 63 *Tenn. L. Rev.* 329, 336 (1996) (expressing concern that a prototype will more likely become an absolute requirement, predicting that "if a court instructs a jury a reasonable alternative design is necessary, it may be difficult for a plaintiff to prevail in a lawsuit without actually presenting the alternative to the jury").

n184. See, e.g., Schwartz, *supra* note 113, at 403 (conceding that risk-utility test is "widely used" in design cases, but positing that "the additional requirement of a reasonable alternative design is not universal"); see also Potter, 1997 WL *8 (Conn) (asserting that the majority of jurisdictions do not require an alternative design). But see Mary J. Davis, Design Defect Liability: In Search of a Standard of Responsibility, 39 *Wayne L. Rev.* 1217, 1245 (1993) (finding that the risk-utility inquiry in a design defect claim always circles back to conduct and claiming that "most jurisdictions require evidence of the availability

of a feasible, practical alternative at the time of manufacture before liability is imposed, specifically evaluating the manufacturer's decision to reject that alternative").

n185. See, e.g., Madden, *supra* note 10, 8.3, at 299 ("Indeed," Madden emphasizes, "the majority rule posits that plaintiff cannot establish a prima facie case of defective design without evidence of a technologically feasible, and practicable, alternative to defendant's product that was available at the time of manufacture").

n186. See *Restatement (Second) Of Torts 402A* cmt. i (1965). "The article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge will be unreasonably dangerous to him." *Id.*

n187. See *Restatement (Third)* cmt. c of the Reporters' Notes where the Reporters argue that "an overwhelming majority of American jurisdictions rely on risk utility balancing in design cases." Similarly, Madden observes that "courts and legislators throughout the country have increasingly abandoned exclusive resort to a consumer expectations standard, and adopted, de jure or de facto, a risk utility approach." Stuart M. Madden, *Products Liability, Products for use by Adults, and Injured Children: Back to the Future*, 61 *Tenn. L. Rev.* 1205, 1225 (1994). See also Owen, *supra* note 1, at 761 (noting that the consumer expectations test derives from contract and that contract law primarily operates in a strict fashion, thus, "by banishing consumer expectations as a formal test of product defect, the Reporters exploded the final obstacles to the complete and final victory of negligence principles in shaping the defect concept in design and warnings cases"). But see Philips, *supra* note 128, at 1265 (warning that the Reporters attempt to "eradicate" the consumer expectation standard will not be easy because the consumer expectation standard "underpins" the Uniform Commercial Code and that the European Community has adopted a consumer expectation standard as well).

n188. See Madden, *supra* note 10, 6.23 (observing that several states "doggedly retain" the consumer expectations test, however, in cases involving children, many of these jurisdictions consider foreseeability and feasible alternative design to favor plaintiffs).

n189. *Restatement (Third)*, cmt. d, Reporters' Notes. The Reporter's analysis of decisional law citing consumer expectations revealed the following observations.

(1) An alternative design is a predicate to a case, however, the court formulate the jury instruction generally and coached in consumer expectations terms.

(2) Many courts talk of reasonable consumer expectations, yet define consumer expectations within risk-utility language.

(3) Many courts rely on consumer expectations as a factor in risk utility balancing.

(4) In cases where *res ipsa loquitur* inference is used, the courts find that the products failed to meet the consumer's expectations.

(5) In food product cases courts rely on consumer expectations.

Id.

n190. Restatement (Third) 2 cmt. g. "Courts often use the term 'reasonable consumer expectations' as an equivalent of 'proof of a reasonable, safer design alternative,' since reasonable consumers have a right to expect product designs that conform to the reasonableness standard in 2(b)." Id. Although the consumer expectations standard is not relevant to section 2(b) because it does not take into account "whether the proposed alternative design could be implemented at reasonable costs," the Reporters emphasize that consumer expectations "about product performance and the dangers attendant to product use affect how risks are perceived and relate to foreseeability and frequency of the risks of harm, both are relevant under 2(b)." Id. But see, 2 cmt. g: "Although consumer expectations are not adequate to supply a standard for defect in other contexts, assessments of what consumers have a right to expect in various commercial food preparations are sufficiently well-formed that judges and triers of fact can sensibly resolve whether liability should be imposed using this standard." See James A. Henderson, Jr. and Aaron D. Twerski, *Arriving at Reasonable Alternative Design: The Reporters' Travelogue*, 30 *U. Mich J. L. Reform* 563, 569 (1997) (proffering that "although they are an important factor in risk utility balancing, consumer expectations are too amorphous to operate as an independent test for design defect").

But See Shapo, *supra* note 134, at 667 (suggesting "that the reporter are insufficiently cognizant of the power of this idea [of consumer expectations] beyond the narrow compass of chicken bones in enchiladas"); see also Korzec, *supra* note 127, 277, 249 (insisting that "the abandonment of the consumer expectations test may be shortsighted and imprudent" and apparently ignores "the fact that a central and paramount purpose of products liability law is the protection of legitimate consumer safety expectations").

n191. Restatement (Third) cmt. g. See also Shapo, *supra* note 134, at 669 (describing the Reporters' conceptualization of consumer expectation test as only an "overshadowed" factor not recognizing "the centrality of product promotion in creating and conditioning consumer choices").

n192. See Restatement (Third) 2 cmt. g.

n193. Id.

n194. Id. cmt. a. See also *Potter*, 1997 WL 265206 *9 (Conn) (recognizing that consumer expectation may not be appropriate in complex design case); *Soule v. General Motors Corp.* 882 P.2d 298 (Cal. 1994).

n195. See Shapo, *supra* note 134, at 660 (insisting that "the Reporters' refusal to recognize the close parallel between these two kinds of deliberation and choice renders their justification an ipse dixit"); see also Korzec, *supra* note 127, at 244. "Deciding the design defect on a negligence-based risk/utility analysis and the manufacturing defect on the consumer expectation standard becomes unworkable and doctrinally indefensible." *Id.*

n196. Restatement (Third) 2 cmt. a. For a contrary view see Shapo, *supra* note 134, at 659-660 (maintaining that "sellers engage in analogous decision making when they choose levels of product risk for the purposes of both design and quality control" and that "in both cases, they are aware of the level of statistical risks to which they expose the consumer").

n197. See Shapo, *supra* note 134, 668 (applauding the Reporters recognition but complaining that the Reporters "are insufficiently cognizant of the power of this idea beyond the narrow compass of chicken bones in enchiladas").

n198. Restatement (Third) 2 cmt. f (1997).

n199. *Id.* 2 cmt. f. "The mere fact that a risk presented by a product design is open and obvious, or generally known, and that the product thus satisfies expectations, does not prevent a finding that the design is defective." *Id.* See also 2 cmt. c which explicitly states that the "obviousness of a design related risk" does not preclude a finding of defectiveness.

n200. Many commentators, most notably Dean John W. Wade, have criticized the consumer expectation test, primarily for the injustice in situations where the consumer knew about the product danger and was barred from recovery under the consumer expectation test. See Wade, *supra* note 124, at 825; see also Madden, *supra* note 187, at 1240 (elaborating, although addressing injury to children, that the harsh effects of the consumer expectation test and the open and obvious defense can be neutralized by the Third Restatement and "in their stead," "the Reporters promote exclusive resort to a risk-utility evaluation, fortified by concepts of reasonable foreseeability, which increases the likelihood liability for manufacturer who put into household use products nominally intended for adults, but which foreseeably invite misadventure with children").

n201. See Vargo, *supra* note 138, at 518 (contending that "this 'so-called' consumer expectation factor is so overshadowed by section 2(b) black-letter rule for design defects, which clearly makes proof of alternative design an absolute requirement, that the consumer expectation factor exists in name only"). Shapo believes that "[a] lamentable defect in the Reporters' analysis lies in its downgrading of consumer expectations as a factor in judging design defect issues." Shapo bases this charge on two observations: (1) that the Reporters failed to recognize the "the centrality of product promotion in consumer choice"; and (2) that the weight of authority does not support the Reporters claims - citing several articles taking issue with Reporters' case analysis. See Shapo, *supra* note 134, at 666.

n202. Claiming that the drafters of 402A "did not contemplate strict liability based on consumer expectations test for design defects," Henderson insists that the consumer expectations test was intended for manufacturing defects. They note that in 1963 the focus was on abolishing the privity rule and imposing strict liability in manufacturing defects. See Henderson & Twerski, *supra* note 190, 572-573. "Other scholars have made this observation," intimate Henderson and Twerski, referring to the writings of Dean Prosser, in particular to his *Hornbook* (4th ed.), where Prosser basically admitted that design defect cases are subject to negligence doctrine clothed in strict language. See William L. Prosser Et Al., *Handbook On The Law Of Torts* 96, at 644-645 (4th ed. 1971).

n203. See, e.g., Shapo, *supra* note 134, at 666 (finding that out of the fourteen cases cited by the Reporters to support their position that the risk-utility in design defects reflect the majority, only one to three decisions supported the sole risk- utility test); see also Vargo, *supra* note 138, at 493 (contending after extensive jurisdictional survey that only three states' common law have adopted the alternative design requirement in design defect cases); see also Stewart, *supra* note 137, at 29-30 (noting that the consumer expectations test as an equal alternative to risk-utility is "widely used" by courts, referring to a compilation of pattern jury instruction from around the country, presented to the Reporters, which "indicate that at least 28 jurisdictions currently instruct juries that they may find a product defective if it fails to perform as a reasonable consumer would expect," and concluding that some 37 jurisdictions use or make references to the consumer expectation test").

n204. See *Potter v. Chicago Pneumatic*, 1997 WL 265206 *7-8 (Conn) (holding that "contrary to the rule promulgated in the Draft Restatement (Third), our independent review of the prevailing common law reveals that the majority of jurisdictions do not impose upon plaintiffs an absolute requirement to prove a feasible alternative design" (footnote omitted)); but see *Banks et al. v. ICI Americas, Inc.*, 450 S.E.2d 671, 734 (Ga. 1994) (adopting risk-utility balancing in design defect cases after court conducted "an exhaustive review of foreign jurisdictions and learned treatises" that revealed that a risk-utility test reflects the "general consensus" [citations omitted]).

n205. See Jankowski, *supra* note 153, at 327 (observing that "the gravitational pull in design defect cases has been toward the risk-utility balance and its concomitant, the reasonable alternative design").

n206. See Joseph W. Little, The Place of Consumer Expectations In Product Strict Liability Action For Defectively Designed Products, 61 *Tenn. L. Rev.* 1189, 1192, and n. 24 (1994) (claiming the risk-utility test "is utterly useless in jury instructions").

n207. See Calabresi & Cooper, *supra* note 120, at 865. The authors propose a "better" approach. This new approach reintroduces the consumer expectation test in least cost avoider language: "to try to decide what categories of people, buyers or sellers, users or producers - are in a better position to decide whether, and to what degree, avoidance is

worth it, and place the cost of non-avoidance on those categories." *Id.* For a survey of the scholarly formulations of an appropriate standard in design defect cases, see generally Shapo, *supra* note 134, at PP 9.02-9.06(1) (surveying scholarly formulations of tests for design defect cases).

n208. See *Phillips, supra* note 127, at 167 ("A standard of consumer expectations certainly comes nearer to achieving fairness than does a restrictive standard that requires plaintiffs to prove that a reasonably safer alternative design exists as a prerequisite to recovery for product design defectiveness"); see also Little, *supra* note 206, at 1195-1198, 1204 (proposing test for design defects modeled on the House of Lords' *Rylands v. Fletcher* decision, where "what consumers expect should weigh heavily").

n209. See *Potter, 1997 WL 265206 *9* (Conn). "We find persuasive the reasoning of those jurisdictions that have modified their formulation of the consumer expectation test by incorporating risk-utility factor into the ordinary consumer expectation analysis." (footnotes omitted). *Id.* In his concurring opinion, Justice Berdon expressed great concern, and cautioned that the majority's dicta regarding the incorporation of risk-utility factor into the consumer expectation test in complex design cases, "sounds dangerously close to requiring proof of the existence of a reasonable alternative design, a standard of proof that the court properly rejects today." (footnotes omitted). *Id.* at *30; see also Shapo, *supra* note 134, at 668 (stressing "that there is no reason that a court cannot blend 'consumer expectations' or 'consumer contemplation' analysis with a 'risk-utility' concept" and that "some courts have, in fact done this").

n210. See *Saratoga Fishing Co. v. Marco Seattle Inc., 69 F.3d 1432, 1441 (9th Cir 1995)*. In *Saratoga*, the court noted that their adoption of a risk-utility balancing for design defects in admiralty cases does not "necessarily preclude future admiralty plaintiffs from showing a design defect using the consumer expectations test." *Id.* Basically, the court concluded that giving the plaintiff a choice of either risk-utility or consumer expectations "is appropriate." In a side note, the defect was to a great extent obvious. The court engaged in manipulative justice by relying on a risk-utility analysis to overcome the open and obvious defense. See generally *Barker v. Lull Engineering Co., 573 P.2d 443, 457-458 (Cal. 1978)* (holding that "a judge may properly instruct the jury that a product is defective in design" based on a consumer expectations theory or a risk-utility theory). For jurisdictions that adhere to this alternative approach see Madden, *supra* note 10, 6.7, at 101 (1995 Supp.) "In some states, the consumer expectations test is employed as one half of a dual standard permitting a finding of defect if the product either falls short of reasonable consumer expectations or its risk outweighs its utility." *Id.*

n211. See Shapo, *supra* note 134, P 9.15(2)(b) (citing authority that "some courts refuse to require a showing of a safe alternative design to prove a design defect").

n212. See Stewart, *supra* note 137, at 30 (expressing concern regarding the Reporters citations of reform statutes in support of their positions, arguing that such reliance on stat-

utes cannot serve as authority for a Restatement and describing the Reporters position as consonant with "tort reform").

n213. Restatement (Third) 2 cmt. f.

n214. See Schwartz, *supra* note 113, at 403. "Thus, for design claims, the new Restatement fails to include any current rules that would reduce plaintiff's evidentiary burdens." *Id.* See also Bill Wagner, *Reviewing the Restatement*, *Trial* at 44, 45 (Nov. 1995) (listing several issues that will make it harder for plaintiffs under the new Restatement, such as, hiring an expert in small cases will not be cost effective, in severe injuries recovery will be reduced, and if plaintiff fails to develop a better product his injury will not be compensated).

n215. See *Potter*, 1997 WL 265206 (Conn) (holding that "the feasible alternative design requirement imposes an undue burden on plaintiffs that might preclude otherwise valid claims from jury consideration"). See also Shapo, *supra* note 134, P 9.15(2)(a). "Hurdles for plaintiffs on this issue include requirements that they show what injuries would have resulted had an allegedly safer alternative design been used and that they prove the extent of enhanced injuries caused by the alleged defect." *Id.*

n216. See *Banks et al. v. ICI Americas, Inc.*, 450 S.E.2d 671, 674-675 (Ga. 1994). In *Banks* the court adopted a risk-utility balancing test for design defects but relegated the alternative design to a factor. The court stated that "the trier of fact may consider evidence" pertaining to an alternative safer design. (emphasis added) *Id.* The factors to be considered in an alternative safe design, according to the court include: "the feasibility of an alternative design; the availability of an effective substitute for the product which meets the same need but is safer; the financial cost of the improved design; and the adverse effects from the alternative." See *id.* at 675 n.6. Interestingly, in his concurring in part and dissenting in part opinion, Justice Fletcher expressed his opposition to the majority relegating of the alternative design to a factor rather than an absolute requirement. See *Id.* at 676; see also *Phillips*, *supra* note 127, at 149 ("the courts tend to use a risk-benefit analysis without requiring proof of an alternative design. Such proof is permissible, by either side, but not required. Consumer expectations considerations blend into this analysis"). But see *Smith v. Keller Ladder Co.*, 645 A.2d 1269,1271 (N.J. 1994) (noting that NJ statutory products liability law, which requires the proof of a feasible alternative design, is in accord with the Restatement (Third)).

n217. See Vargo, *supra* note 138, at 517. See also *Banks & O'Connor*, *supra* note 148, at 417 (positing that if the consumer expectations are not ascertainable then negligence and an alternative design kick in, but this approach should be a factor in the comments and not part of the black letter law).

n218. Vargo, *supra* note 138, at 517.

n219. See Cupp, *supra* note 183, at 336 (expressing concern that "the RAD requirement may, in effect, immunize seller from all but relatively substantial claims"); see also Frank J. Vandall, *The Restatement (Third) of Torts: Products Liability Section 2(b): The Reasonable Alternative Design Requirement*, 61 *Tenn. L. Rev.* 1407, 1426 (1994) (noting that unless injury was substantial "the expenses involved in proving a reasonable alternative design far outweigh his potential award of damages").

n220. See Cupp, *supra* note 183, at 336 (insisting that "the prospect of costly expert witness fees likely will prevent many meritorious cases from being filed"); see also Corboy, *supra* note 44, at 1095-96; Vandall, *supra* note 219, at 1426 (elaborating that if injury was not so serious the cost of an alternative design would outweighs the worth of pursuing the case).

n221. Some commentators take issue with the classification of warning under the concept of product defect. Shapo opposes this description of a category of cases and argues that it is bad English and that it is "confusing to the law." Shapo vehemently argues that "equating the actual product with its image is to confuse image and reality." "It is, indeed," stresses Shapo, "to befog the recognition that the representational basis of products liability inheres not only in express warranties and various kinds of misrepresentations but in the more general ways in which products are promoted to the public." Marshall S. Shapo, *Should Courts Buy the Proposed Restatement?*, *Trial*, November 1996, at 23, 28. See also Mark McLaughlin Hager, *Don't Say I Didn't Warn You (Even Though I Didn't): Why the Pro-Defendant Consensus On Warning Law is Wrong*, 61 *Tenn. L. Rev.* 1125, 1134 (1994) (arguing that the description of "failure to warn" inevitably suggests conduct, i.e., negligence, the recommending that warning law should be renamed to "hidden danger," reorienting attention away from conduct and back to a product conceptualization that is intact with manufacturing defect).

n222. That the black letter law in both the design and inadequate warning formulations is almost identical. The Reporter throughout the comments and notes of the Restatement (Third) remark that design and warning defects are similar in many aspects. Discussing the relationship between design and warning, defects, the Reporters believe that "both aim at achieving higher levels of safety in the use and consumption of products." Restatement (Third) 2 cmt. l. Moreover, the Reporters highlight the fact that product instructions and warnings "are relevant to the question of defective design." *Id.* cmt. (l). The Reporters explain that although a product may be found to be nondefective because of adequate warning and instruction, the same product may be found defective in design. See *id.* 2 cmt. k. They continue that "when a safer design can reasonably be implemented, adoption of the safer design is preferable to a warning that leaves a residuum of risk." *Id.* 2 cmt. k. Thus, in the unavailability of a reasonable alternative design situation, adequate warnings or instructions will suffice to render the product reasonably safe. See *id.* The Reporters also stress, on the one hand, that an open and obvious risk "often serves the same function as a warnings", and on the other hand, the obviousness of a risk "does not necessarily obviate a duty to provide a safer design." Therefore, the Reporters concluded their premise, "just as warnings may be ignored, so many obvious or generally known risks may be ignored,

leaving a residuum of risk great enough to require adopting a safer design." Restatement (Third) 2 cmt. k. It is repeatedly noted throughout the Reporter Comments and Note's that most of the applicable observations pertaining to design defects apply to warning defects. Thus, the reader will notice similarities in my examination of design and warning defect, whilst the differences will be exemplified.

n223. Restatement (Third) 2c.

n224. See id. 2 cmt. i. For a comprehensive review regarding duty to warn see M. Stuart Madden, *The Duty To Warn In Products Liability: Contours and Criticism*, 89 *W. Va. L. Rev.* 221, 234 (1987) (conceptualizing warning law as a correction to the "imbalance between the product-related information available to the consumer and that available to the manufacture," following this imbalance or asymmetry methodology, finding that "identification of a material disparity in germane safety-related information known to the seller as opposed to that known to the injured claimant will, with only limited exceptions, predict seller liability for inadequate warnings or instructions").

n225. Restatement (Third) 2 cmt. i.

n226. Id. 2 cmt. i, see also David Owen, *supra* note 1, at 762 (explaining that safety information promotes two objectives: (1) "individual autonomy," that is consumer choice in purchasing or not purchasing a product in light of information about the product's risks; and (2) "optimal" safety, that is, the available information helps the consumer to reduce or minimize risks accordingly).

n227. Id. 2 cmt. i.

n228. Id. But see Howard Latin, "Good" Warnings, Bad Products, and Cognitive Limitations, 41 *U.C.L.A. L. Rev.* 1193 (1994) (examining warning law from a behavioral discourse, Rational Risk Calculator (holds that consumers can weight the personal benefits and costs of risky activity and chose the level of risk to accept) with Mistake and Momentary Inattention (holds that consumer's cognitive capacity is limited and as such is not able to assess the risk in a "rational" manner, i.e., there is an "intrinsic limitations on people's capacity to make optimal choices"), concluding that "reasonable behavior" is incompatible with actual consumer behavior and as such "good" warning are not a substitute for safer design and marketing strategies); see also Howard Latin, Behavioral Criticisms of the *Restatement (Third) of Torts: Products Liability*, 16 *J. Prod. Liab. & Toxic* 209, 211 (1994) (arguing that social science research has convincingly demonstrated that accident causing behavior is, to a great extent, unavoidable due to the "inherent cognitive limitations and from intrinsic physical or personality attributes").

n229. See Restatement (Third) 2 cmt. j (acknowledging that "warnings concerning risks of allergic reactions that are not reasonably foreseeable at the time of sale need not be provided").

n230. Restatement (Third) 2 cmt. (h) (1997). Interestingly, the Reporters stress that "if it is determined that a particular user or consumer would have decided to use or consume even if warned, the lack of warnings is not a legal cause of that plaintiff's harm." *Id.*

n231. *Id.* 2 cmt. p.

n232. *Id.* 2 cmt. m.

n233. *Id.*

n234. Restatement (Third) 2 cmt. m.

n235. *Id.* 2 cmt. i. The Reporters acknowledge that "although the liability standard is formulated in essentially identical terms ... the defectiveness concept is more difficult to apply in the warnings context." *Id.*

n236. *Id.* cmt. i. See, e.g., Madden, *supra* note 224, at 223, 311 (listing five factors to be evaluated to determine adequacy of warning: "(1) the dangerousness of the product; (2) the form in which the product is used; (3) the intensity and form of the warnings given; (4) the burdens to be imposed by requiring warnings; and (5) the likelihood that the particular warnings will be adequately communicated to those who will foreseeably use the product").

n237. Restatement (Third) 2 cmt. i.

n238. *Id.* 1 cmt. a.

n239. *Id.* 1 cmt. a. See also 2 cmt (a) (noting that the "risk-utility balancing" approach "achieves the same general objectives as does liability predicted on negligence")

n240. *Id.* 2 cmt. a. See also *id.* 2 cmt. f. The main factors are "magnitude and probability of the foreseeable risks of harm" "strength of consumer expectations," and the "relative advantages and disadvantages" of the alteration considering "production costs, product longevity, maintenance, repair, and esthetics." *Id.* Many commentators have observed that risk-utility analysis is applied to warning defect cases. See Mark Geistfeld, *Inadequate Product Warnings and Causation*, 30 U. Mich. L.J. Reform 309 (1997) at 327 (examining the Restatement (Third), stating that "the standard for evaluating a warning is based on the risk-utility test" and to recover "the plaintiff must show that the seller did not provide a

specific warning or instruction that satisfies this test"); but see Paul D. Rheingold and Susan B. Feinglass, Risk-Utility Analysis in the Failure to Warn Context, 30 U. Mich L.J. Reform 353, 355-356 (1997) (responding to the argument that risk-utility is applicable by association to warning defect: "Not only is the black letter statement devoid of such language, neither the comments nor the Reporter's Notes indicates that a judge or jury should consider such an analysis in determining whether a warning was adequate").

n241. Restatement (Third) 2 cmt. i.

n242. Id. Reporters Notes on 2 cmt. a.

n243. Id. 2 cmt. i.

n244. Id. 2 cmt. j. See *Maneely v. General Motors Corporation*, 108 F.3d 1176, 1179 (Cal. 1997) (citing with approval the Restatement provision regarding the non-existence of a duty to warn or instruct regarding open and obvious risks).

n245. See id. 2 cmt. f. The Reporters point out that the open and obviousness of a risk which the consumer expects does not "prevent a finding that the design is defective." Id. "The mere fact that a risk presented by a product design is open and obvious, or generally known, and that the product thus satisfies expectations, does not prevent a finding that the design is defective." Id. See also 2 cmt. c which explicitly states that the "obviousness of a design related risk" does not preclude a finding of defectiveness.

n246. See id. 2 cmt. j. "The obviousness of risk may bear on the issues of design defect rather than failure to warn." Id. Unlike in the case of design defect where open and obvious risks are not a defense, open and obvious risks are a defense in an inadequate warning defect case. See also, 2 cmt c. Commentators agree. See, e.g., Madden, supra note 224, at 253 ("The majority rule is that there exists no duty to warn of certain obviously hazardous conditions"); see also Owen, supra note 1, at 779 (stating that "the obviousness of a product danger often properly continues to play a decisive no-duty role, as many courts have held"). But see Rheingold & Feinglass, supra note 240, 362 (arguing the concept of obviousness is relative, and, as such, "the product supplier should be required to issue warnings to all types of persons, even if the risks would be apparent to some" opining that "after all, the warnings serve as reminder to all users"); Latin, supra note 228, at 217 (criticizing the Reporters' positions on open and obvious, arguing that "the Reporters offer no guidance on just how obvious a risk must be before courts should hold as a matter of law that warnings need not mention the risk").

n247. Restatement (Third) 2 cmt. j. See also Owen, supra note 1, at 779 (claiming the Restatement view "makes good sense," noting if one already is aware of the danger or risk, the "informational goals of a warning have been fulfilled").

n248. Id. 2 cmt. j. The Reporters claim that "requiring warnings of obvious or generally known risks reduces the efficacy of warnings generally." Id. See also Madden, *supra* note 224, 253 (discussing obviousness of a risk, opining that "there exists in most instances an equilibrium between the safety-related information held by the seller and that known by the buyer or user, and there should be no duty to warn").

n249. See id. 2 cmt. j.

n250. Id.

n251. Id. Reporters Notes 2 cmt. i. See also id. 2 cmt. i. "The fact that a risk is obvious or generally known often serves the same function as a warning. However, obviousness of risk does not necessarily obviate a duty to provide a safer design. Just as warnings may be ignored, so may obvious or generally known risks be ignored, leaving a residuum of risk great enough to require adopting a safer design." Id. See also *Caterpillar, Inc. v. Shears et al*, 911 S.W.2d 379, 383-384 (Tx. 1995) (describing, in dicta, their holding that liability for a design defect "may attach even if the defect is apparent" as consistent with the position taken under the Restatement (Third)). Commentators agree. See Madden, *supra* note 224, at 222 (insisting that "if there is shown a manufacturer's duty to redesign, that duty should not be discharged merely by providing warnings concerning the misdesign"); see also Lat-in, *supra* note 228, at 1279-1280 ("even if the obvious nature of the risk should insulate manufacturers from liability in failure-to-warn cases, a "good" warning about an obvious risk should not shield a badly designed product from liability on a design theory").

n252. See Shapo, *supra* note 134, P 9.14(1) ("there are many decisions that would subscribe to the proposition that 'injuries are not compensable if they are caused by inherent propensities of a product which are obvious to all who come into contact with them ... ' " (footnotes omitted)). For an interesting survey of the application of the open and obvious defense in numerous product see id. at PP 19.11(1)-19(11)(2)(a) (among the products surveyed, swimming pools, automobiles, motorcycles, low ceilings, football helmets electricity, slipperiness of ice, slow cooker appliance, refrigerated trailer, lawnmower, industrial machines).

n253. Shapo, *supra* note 134, at 681.

n254. Id. 2 cmt. m. (stating that the duty to warn "extends to all risk-creating misuse that is reasonably foreseeable").

n255. Id. The Reporters indicate that a manufacturer has no duty to design or warn against the post sale conduct of a user when such post sale conduct "may be so unreasonable and costly to avoid." Id. 2 cmt. o. See also id. cmt. m. It is not required, the Reporter emphasize, for manufacturers to increase "the costs of designing and marketing products in order to avoid the consequences of unreasonable modes of use." Id. See also Madden, *su-*

pra note 224, at 270 (arguing that "the informational duty should not require one to warn about what cannot be imagined").

n256. Restatement (Third) 2 cmt. p. (1997). "It follows that misuse, modification, and alteration are not discrete legal issues. Rather, when relevant, they are aspects of the concepts of defect, causation, and plaintiff's fault." Id.

n257. Id. 2 p. See also 15 on causation and 17 comparative responsibility.

n258. Id. 2 cmt. p. See Shapo, supra note 134, P 21.02(3)(a). "For many courts, 'foreseeability' of 'misuse' is sufficient to overcome defenses constructed on the foundation that a plaintiff did not use a product in the intended way." Id.. See Madden, supra note 10, 8.4, at 307. "The contemporary view is that a manufacturer has a duty to design a product reasonably safe for reasonably foreseeable misuse." Id.

n259. See Restatement (Third) 2 cmt. p.

n260. Id. 2 cmt. 1.

n261. Id.

n262. Id. 2 cmt. i.

n263. Id.

n264. Restatement (Third) 2 cmt. i.

n265. Id.

n266. See id. 2 cmt. p.

n267. See, e.g., *Feldman v. Lederle Labs*, 479 A.2d 374 (N.J. 1984); *Brown v. Superior Court*, 751 P.2d 470 (Cal. 1988); *Anderson v. Owens-Coming Fiberglass Corp.*, 810 P.2d 549 (Cal. 1991).

n268. See Madden, supra note 224, 242-243 (illustrating that both under negligence and strict liability the focus is on the extent the product poses an unreasonable danger to the user (or bystander), i.e., the "degree of risk," "severity of injury" and the "number of people to be injured" by the product, concluding that "the functional characteristics of strict liability and negligence theories are almost indistinguishable"). See also Shapo, supra note 134, at P 19.09(2)(c) & (d). "One should observe that judicial opposition to employ-

ing strict liability for failure to warn leaves considerable running room for a straight negligence action on that basis. Some courts have gone so far as to contrast explicitly the duty to warn as it exists under section 402A - characterizing the main issue under the formulation as whether the product is unreasonably dangerous - with section 388 of the Second Restatement, which articulates a conventional negligence duty to warn based on the supplier's knowledge or reason to know of the risk." Id. But see Hager, supra note 221, at 1131-1132 (claiming the view that negligence and strict liability are the same is "ill founded" and that such a view is based on three reasons: (1) a "false analogy" that warning law is like design defects, where negligence principles prevail; (2) that the term "failure to warn" suggests "faulty conduct" and as such "negligence logic is deemed intrinsic to the concept 'failure to warn;'" and (3) "thoughtless repetition of previous authority insisting that strict liability has no meaning for warning law distinct from negligence").

n269. John Wade recognized long ago that there is no difference between negligence and strict liability in warning cases. See John Wade, supra note 124, at 842. For decisional law grappling with warning law, is it negligence or strict liability? See generally Shapo, supra note 134, PP 19.09(3)(a) - 19.09(3)(e) (describing an Illinois Supreme Court decision as "an important attempt to harmonize the theories, canted in the direction of negligence ... ").

n270. See Owen, supra note 1, at 763. "And the Restatement agrees with the nearly universal view that manufacturers should not be obligated to warn of risks that cannot be foreseen. What is left of warning "defectiveness" is only negligence, nothing more." Id. But see generally Hager, supra note 221, at 1125 (1994) (acknowledging the consensus view that in design defects cases the "deficiency circles back to conduct deficiency," but claiming this position is "ill founded").

n271. It is believed that manufactures are in a better position to spread the cost and compensate those injured from their products, although not negligent. For policy considerations favoring a strict liability regime see, e.g., *Sternhagen v. Dow Company*, 935 P.2d 1139, 1143-1144 (Mo. 1997).

n272. See, e.g., *Sternhagen*, 935 P.2d at 1147 (rejecting the Restatement (Third)'s foreseeable risks limitation of liability holding that "in a strict liability case, knowledge of any undiscovered or undiscoverable dangers should be imputed to the manufacturer" and concluding that "in a strict products liability case, state-of- the-art evidence is not admissible to establish whether the manufacturer knew or through the exercise of reasonable human foresight should have known of the danger").

n273. See generally Hager, supra note 221 (renaming "failure to warn" to "hidden defect" and advocating strict liability by shifting the focus from conduct to product).

n274. See Madden, supra note 224, at 241.

n275. *Id.* This refers to Learned Hand's B < PL equation.

n276. See Jankowski, *supra* note 153, at 329. "A commonly held judicial assumption is that all additional warnings effectively reduce the risk of harm to the user while not causing a material decrease in the product's utility." *Id.*

n277. See Madden, *supra* note 224, at 241-242.

n278. See, e.g., *Eagle-Pitcher Indus, Inc. v. Balbos*, 578 A.2d 228, 255 (MD 1990) (asserting that if adequate warning would require more printing on a label, favor weighs on plaintiff); *Dambacher v. Mallis*, 485 A.2d 408, 427 n. 7 (PA. 1984) (stating that risk-utility analysis, unlike in design defects, is not suitable for warning defect because "the utility of a product will remain constant whether or not a warning is added, but the risk will not"). For a survey of decisional law on the issue of cost see SHAPO, *supra* note 138, at P 19.08.

n279. Geistfel, *supra* note 240, at 322.

n280. See generally Ralph D. Davis, Different Treatment of Marketing and Design Defects in Pure Risk-Utility Balancing: Who's the Villain?, 27 *Am. Bus. L.J.* 41 (1989) (arguing that design and warning defects are the same and the belief that the cost of warning is cheap and easy is a "myth").

n281. Direct cost "are costs that flow uninterrupted to and from the product and any element of the product." *Id.* at 58.

n282. Indirect costs "are costs that flow circuitously to and from the product and any element of the product." *Id.* at 59.

n283. Opportunity costs "include foregone beneficial alternatives that the implementation of safety necessarily precludes." *Id.* at 59.

n284. Perverse costs "safety measure-related costs that result in outcomes which not only fail to advance, but are actually adverse to, manufacturer, consumer/user, and societal interests." *Id.* at 58-62.

n285. See Kip W. Viscusi, Wading Through the Muddle of Risk-Utility Analysis, 39 *Am. U. L. Rev.* 573, 602-606 (1990).

n286. See *id.* at 603-604.

n287. Janowski, *supra* note 153, at 336 (proposing in design and warning defect cases a risk-utility analysis that first "qualifies the alternative as reasonable" in the context of technological and practical feasibility and then engages in a "risk- utility balancing accomplished through a consideration of the level of increase or decrease in risk posed by the proffered alternative").

n288. See, e.g., *Dambacher*, 485 A.2d 408, 427 (1984) (risk-utility is not appropriate for warning). See also Rheingold & Feinglass, *supra* note 240, at 353 (concluding that warning law requires a "straight-forward legal standard" and that risk- utility is not such standard nor would it "function as an effective tool in the warnings area because it provides no guidelines for manufacturers on how to increase the quality of warnings"); see also Schwartz, *supra* note 113, at 402 (complaining of Reporters' pro-defendant bias in section 2(c) on two grounds: (1) the Reporters' rejection of the "heeding presumption," and (2) the Reporter shifting of the burden of proof to the defendant on the issue of the manufacturer's knowledge of risk).

n289. See Latin, *supra* note 228, at 211. "If cognitive mistakes, confusion, momentary inattention, illiteracy, excessive optimism, forgetfulness, clumsiness, and other forms of sub-optimal user behavior occur very frequently and are largely unavoidable and inevitable, products liability doctrine should be tailored in light of realistic behavioral characterizations." *Id.* see also generally Latin, *supra* note 228.

n290. Restatement (Second) 402A cmt. k (1964).

Unavoidably unsafe product. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Id.

n291. See, e.g., *Brown v. Superior Court*, 751 P.2d 470 (1988). "We are aware of only one decision that has applied the doctrine of strict liability to prescription drugs ... most cases have embraced the rule of comment k". Id. See also Madden, supra note 10, 23.11, at 113-114 (finding that the majority of jurisdictions have adopted comment k); but see *Shanks v. Upjohn Co.*, 835 P.2d 1189 (Alaska 1992) (refusing to adopt comment k); see also *Hill v. Searle Lab.*, 884 F.2d 1064 (8th Cir 1989) (refusing to extend IUD, comment k protection, holding that comment k's unavoidably unsafe "exception would only apply upon a showing of exceptional social need").

n292. See *Brook v. Medtronic, Inc.* 750 F.2d 1227 (4th Cir. 1984) (pace maker); *Racer v. Utterman*, 629 S.W.2d 387 (Mo. 1992) (anti bacterial surgical drape); *Hufft v. Horowitz*, 5 Cal. Rptr. 2d 377 (Cal. 1992) (penal implants). See also Shapo, supra note 134, at P 19.07(9)(b). "There is specific authority on the proposition that no significant distinction exists between prescription devices and drugs with respect to the duty to warn." Id. See also Cupp, supra note 139, at 78, 82 (1994) (citing authority to the effect that courts "most often" and "most frequently" apply comment k to prescription drugs, vaccines, and medical devices).

n293. See Restatement (Third) 6. For purpose of section 6 a prescription drug or medical device "is one that may be legally sold or otherwise distributed only pursuant to a health care provider's prescription." Id. 6(a).

n294. Id. 2(a).

n295. Id. 2(a) cmt. b. "The rule for manufacturing defects stated in 2(a) imposes liability whether or not the manufacturer's quality control efforts satisfy standards of reasonableness." Id.

n296. See, e.g., *Phillips v. Kimwood*, 525 P.2d 1033 (1974). See also Owen, supra note 1, at 748 (contending that strict liability for manufacturing defects, embodied or incorporated in the Restatement (Third), is "where almost all agree that it belongs").

n297. See id. 6 cmt. c.

n298. See Madden, supra note 10, 23.3, at 353. Madden lists the following examples where manufacturer liability was found to attach: wrong formula; wrong ingredient; omission of ingredient(s); incorrect process; incorrect label; "in all these cases the product is truly defective, and liability attaches to the manufacturer under all of the usual rules including that of Restatement (Second), 402A." Id. It appears as "truly defective" is synonymous to "manufacturing defect." Id.

n299. Restatement (Third) 6(c).

n300. Id. 6 cmt. a.

n301. Id. 6 cmt. b.

n302. Id.

n303. Id.

n304. Restatement (Third) 6 cmt. 6.

n305. Id.

n306. Id.

n307. Id.

n308. Id. 6 cmt. b.

n309. Restatement (Third) 6 cmt. b. Because of the special nature of prescription drugs and medical devices, the determination of whether such products are not reasonably safe is to be made under Subsections (c) and (d) rather than under 2(b) and 2(c)." Id. But see Vandall, *supra* 113, at 271 (explaining that not all drugs and medical devices are "worthy of blanket protection" and that some drugs do save lives while others like thalidomide, chloromycetin, MER/29, DES or Oraflex cause damage, opining that the difference between prescription drugs and other products, pertaining to design defects, "is artificial and arbitrary").

n310. Id. 6 cmt. b. See also 6 cmt. f: The Reporters further emphasize that section 6(c) stands for the proposition that "as long as a given drug or device provides net benefits for a class of patients, it should be available to them, accompanied by appropriate warnings and instructions." Id.

n311. Restatement (Third) 6 cmt. f.

n312. Id.

n313. Id.

n314. Id.

n315. Id.

n316. See Schwartz, *surpa* note 113, at 407 (charging that this standard has no "precedent in case law" and calling the standard "super" negligence); Comment, *supra* note 120, at 426. "Section 8(c) hinders the consumer's ability to show that a drug is defective and increases the burden of proving that the manufacturer was negligent in its decision to place the drug on the market." Id.

n317. Restatement (Third) 6 cmt. g.

n318. Id. The Reporters continue: "Nor could such liability be adequately insured against prior to the discovery of the products' harm-causing propensities, given the fact that actuaries cannot accurately assess unknown and unknowable risks." Id. See *Brown v. Superior Court*, 751 P.2d 470 (Cal. 1988).

n319. Id. 6 cmt. g.

n320. See also id. 2 cmt (m) (stating that as long as reasonable testing was conducted, "the harms that result from unforeseeable risks - - for example, in the human body's reaction to a new drug, medical device, or chemical - - are not a basis of liability"); see, e.g., *Carlin v. Superior Court*, 920 P.2d 1347 (Cal. 1996) (holding manufacturer liable for failure to warn of risks of injury only to the extent that the risks were either known or should have been known at the time of sale or manufacture) ; see also *Brown v. Superior Court*, 751 P.2d 470 (Cal. 1988) (concluding that "a manufacturer is not strictly liable for injuries caused by a prescription drug so long as the drug was properly prepared and accompanied by warnings of its dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution").

n321. See generally Jeffrey D. Winchester, Comment, Section 8(c) of the Proposed Restatement (Third) of Torts: Is It Really What the Doctor Ordered?, 82 *Cornell L. Rev.* 644, 671-693 (1997) (finding no prescription drug case referring to the "reasonable physician" or to the "reasonable health care provider" and demonstrating that commentators and courts, alike, support a reasonable manufacturer standard); see also Teresa Moran Schwartz, Prescription Products and The Proposed Restatement (Third), 61 *Tenn. L. Rev.* 1357, 1380 (1994) (arguing that the reasonable physician standard has no precedent).

n322. Schwartz sheds doubt on the physicians' independent expertise pertaining to prescription drugs. In fact, she correctly emphasizes that "most health care providers rely on manufacturer's extensive advertising, promotional programs, and sales representatives to learn about products - - sources that do not always convey a complete, or even an accurate,

picture of products risk. Another problem is that doctors do not always stay up-to-date on available information." Schwartz, *supra* note 113, at 408.

n323. For an in-depth critique of the reasonable "health care provider" standard see Comment, *supra* note 321, at 675.

n324. See Restatement (Third) 6 cmt f. Discussing the liability standard in design defect cases, the Reporters state: "The issue is whether, objectively viewed, reasonable providers, possessing the knowledge that a reasonable drug manufacturer had or should have had about the risks and benefits attendant to the use of the drug or medical device, would prescribe it for any class of patients." (emphasis added). *Id.*

n325. See Schwartz, *supra* note 113, 408. "Not only does this standard increase the already difficult evidentiary burden for plaintiffs who bring design claims involving prescription products, it may pose initial problems of interpretation for the courts." *Id.*

n326. This charge is correct and incorrect. The problem the Reporters faced in the design defect formulation is that courts have shied away from design defect liability in prescription drug cases and only recently have begun to rely on this theory. See *Grunberg v. Upjohn Co.* 813 P.2d 89, 92 (Utah 1991). See for an argument that the Reporters design defect provision is contrary to law, Jerry J. Phillips, *supra* note 127, at 142 (opining that prescription provision is contrary to developing law, and "would essentially eliminate design liability for prescription drugs and medical devices"); Vandall, *supra* 113, 272 (exclaiming the Reporters did not consider important case law but "instead, they take a clean sheet of paper and virtually grant immunity to all drug and medical device manufacturers for defective design cases[,] and because of these omissions section 8(c) is void of precedent"). See also Schwartz, *Regulatory Standards and Products Liability: Striking the Right Balance Between the Two*, 30 *U. Mich. J.L. Reform* 431, 457-458 (1997) (asserting that the prescription drug design defect standard has "no precedent in case law, though agreeing that the Restatement (Third)'s standard for manufacturing and warning in prescription drug defects reflect the majority jurisdiction"). But see *Brown*, 751 P.2d 470 (exempting design defect drugs from liability based on policy considerations for encouraging prescription drug development).

n327. See e.g., *Brown*, 751 P.2d 470 (asserting in design defect case, "if a manufacturer could not count on limiting its liability to risks that were known or knowable at the time of manufacture or distribution, it would be discouraged from developing new and improved products for fear that later significant advances in scientific knowledge would increase its liability ... ").

n328. Failure to instruct or warn is the major basis of liability for See manufacturers of prescription drugs and medical devices. See Restatement (Third) 6 cmt. d. See also Madden, *supra* note 224, at 222. "The duty to warn is perhaps the most widely-employed claim in modern products liability litigation." *Id.*

n329. Restatement (Third) 6d.

n330. Restatement (Third) 6e.

n331. See *id.* 6 cmt. a. Section 6 "sets forth situations when a prescription drug or medical device manufacturer is required to warn the patient directly of risks associated with consumption or use of its products." *Id.* The manufacturer has a duty to directly warn the patient when the "manufacturer knows or has reason to know that health care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings." *Id.* 6(d)(2).

n332. *Id.* 6 cmt. b.

n333. *Id.* 6 cmt e.

n334. *Id.*

n335. *Id.* 6 cmt. b. See, e.g., Shapo, *supra* note 134, P 19.07(9)(a)(ii). "Indeed, the general rule on warnings about hazards associated with prescription drugs is that they need only be communicated to the prescribing physician." See also Madden, *supra* note 10, 23.12, at 371 (noting that the rule that the physician is the person to be warned "has been followed in a large number of cases").

n336. See Restatement (Third) 6 cmt. b. "When prescribing health care providers are adequately informed of the relevant benefits and risks associated with various prescription drugs and medical devices, they can reach appropriate decisions regarding which drug or device is best for specific patients." 6 cmt. d. Thus the Reporters contend, "the duty then devolves on the health care provider to supply to the patient such information as is deemed appropriate under the circumstances so that the patient can make an informed choice as to therapy." *Id.* cmt b.

n337. See Restatement (Third) 6 cmt. e.

n338. See *id.*

n339. *Id.* 6 cmt. d.

n340. *Id.*

n341. Id. 6 cmt. d. See, e.g., Madden, *supra* note 10, 23.11, at 365. "The manufacturer's duty then is to warn of (1) Dangers of which he knows, and (2) Dangers of which he should in the exercise of reasonable care know, if (3) Those dangers are reasonably to be foreseen in the use of the drug." Id.

n342. Restatement (Third) 6 cmt. g.

n343. Id.

n344. See, e.g., Vandall, *supra* note 113, at 270. "This proposal ignores the well-developed common law policies regarding products liability: the consumer lacks sophistication with regard to drugs; the loss should be placed on the manufacturer; the seller/manufacturer can spread the loss; and the seller is the cheapest cost avoided." Id.

n345. See, e.g., *Phillips*, *supra* note 127, 142, (stating that prescription provision is contrary to developing law and predicting it "would essentially eliminate design liability for prescription drugs and medical devices"); see also Vandall, *supra* note 113, 270 (arguing that section 8(c) is "void of precedent"); Comment, *supra* note 120, 424 ("The Tentative Draft approach to prescription drugs is a new position that differs substantially from any case law"); Cupp, *supra* note 139, at 108 ("The new Restatement's non-drug design liability test - which is much closer to a true restatement of existing case law than its prescription product design standard").

n346. See, e.g., Schwartz, *supra* note 113, at 404 (1995) (taking exception with the new standard for design defect but stating that "the new standards generally follow current common law rules for the first two categories of claims [manufacturing and warning defects], but depart significantly from current rules for design claims").

n347. Madden, *supra* note 10, 23.4, at 356.

n348. See, e.g., Schwartz, *supra* note 113, at 404 (citing case law supporting the hearing presumption).

n349. Cardozo, *supra* note 118, at 136-137.

n350. Madden, *supra* note 115, at 149.

n351. Incorporation of Madden's "residual domain" concept would rescue courts from confronting a situation like that in *Beshada v. Johns-Manville Products Corp.*, 90 N.J. 191, 447 A.2d 539 (1982), where the court had to twist and manipulate precedent to arrive at a just judgment. The court later confined its decision to asbestos related injury. Although the

court's decision was the morally correct one, the unleashing of a series of cases with similar situations will undermine the logic of the law.

n352. The Restatement (Second) provides that "punitive Damages may be awarded for conduct that is outrageous, because of the defendant's evil motive or his reckless indifference to the rights of others." Restatement (Second) 908(2) Punitive damages are recovered only where the defendant's conduct was reckless, willful or malicious. This is a heavy burden on the plaintiff to prove. Thus, punitive damages are not routinely awarded. See, e.g., Harry Steinberg, *Oh, Those Dastardly Trial Lawyers*, N.Y. ST. B.J., Feb. 1998, at 41. (claiming that "the simple fact is that punitive damages are as rare as hen's teeth and are a virtual nonentity in tort litigation").

n353. A federal fund or even an insurance fund established by manufacturers to compensate injured consumers for unforeseeable risks.

n354. See Courts and Legal Services Act (1990 c 41) 58 (Conditional Fee Agreements), reprinted in 11 Halsbury's Statutes Of England 1211. Section 58(5) provides that: "Any such order shall prescribe the maximum permitted percentage for each description of specified proceedings." *Id.* In 1995 legislative order was published providing that: "For the purpose of section 58(5) of the Courts and Legal Services Act 1990 the maximum permitted percentage by which fees may be increased in respect of each description of proceedings specified in article 2 is 100%." Conditional Fees Agreements Regulations, 1995, S.I. 1995, Nos. 1674-75. Recently Lord Chancellor, Lord Irvine of Lairg, the chief legal administrator in England and Wales has proposed expanding the contingency fee system further to include all civil cases, except family cases. See, Robert O'Connor, Blimey, *What's Legal Aid Coming To ?*, 48 A.B.A.J. A.J. Feb. 1998, at 22.

n355. See Griffiths, *supra* note 46, at 393 n. 158.

n356. [Hereinafter CPA] See *infra* notes 436-437 and accompanying text.

n357. To name a few: The Factories Act 1961 (requires the factory employer to provide a safe lift, if not, employer is liable for damages); The Employer Liability (Defective Equipment) Act 1969 (if employee is injured during work due to defective equipment, he can recover damages strictly); The Defective Premises Act 1972 (requires any person carrying out work to a dwelling to see that work is done with proper materials); Vaccine Damage Payment (although not a cause in tort, pays money award for those who react adversely to a vaccine); Consumer Protection Act Part II (makes it a criminal offense to supply, offer or agree to supply or expose or possess for supply "consumer goods" which fail to comply with the "general safety requirement"); Food Safety Act 1990 (regulation control quality, composition, packing and labeling of food).

n358. See, e.g., William A. Dreier, *supra* note 115, at 222. "In Putting forth a Restatement, we as members of the ALI basically invent nothing. Rather, we attempt to find a better way to describe an existing area of the law so that attorney can advice clients, judges can charge juries, and professors can instruct students, all with more precision. In my opinion, the proposed Restatement (Third) does not make functional changes in the law. Rather, it makes existing law more comprehensible and usable." *Id.*

n359. See 1 Royal Commission On Civil Liability And Compensation For Personal Injury, Report, Vol. 1, 1978, Cmnd. No. 7054-I, P 1216. "The term 'products liability' is an American invention. It does not designate a distinct category of law in the United Kingdom." *Id.* See also, Griffiths, De Val & Dormer, *supra* note 46, at 355 (1987) (explaining that England has no products liability law "but only laws relating to liability for defective products").

n360. On July 25, 1985, the Council of the European Communities adopted the Directive on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States concerning Liability for Defective Products. (No. 85/374/EEC) 28 O.J. Eur. Comm. (No. L 210) 29 (1985). The United Kingdom was among the first to pass legislation (Consumer Protection Act Part I (1987)) to comply with the EEC Directive.

n361. Consumer Protection Act Part I (1987), reprinted in 39 Halsbury's Statutes Of England 150 (4th ed. 1995 Reissue). The CPA became effective March 1988. [hereinafter all cites to General Note are to Halsbury's Statutes Of England General Notes].

n362. In 1977 the Council of Europe's "Strasbourg Convention on Products Liability in Regard to Personal Injury and Death" was opened for signature.

n363. The Royal Commission on Civil Liability and Compensation for Personal Injury (the Pearson Committee) produced its report in 1976 (Cmnd. 7054). The Law Commissions produced their report "Liability for Defective Products" in 1977 (Cmnd. 6831). For a short commentary on these Reports, see generally Gayle M. Plummer, Products Liability in Britain, 9 *Anglo-Am. L. Rev.* 65 (1980).

n364. [Hereinafter EEC] 25 July, 1985, (No. 85/374/EEC) on the approximation of the laws, regulations and administrative provision of the member states concerning liability for defective products.

n365. See General Note at 153. See also Liability For Defective Products, 1977, Law Comm'n No. 82, Scot. Law Comm'n No. 45, Cmnd. No. 6831, at 1-3.

n366. See, e.g., *Vacwell Engineering v. BDH Chemicals Ltd.*, 3 *All E.R.* 1681 (1969) (a negligence drug case).

n367. For a comprehensive examination of liability for prescription drug injuries in Britain see generally Pamela R. Ferguson, *Drug Injuries And The Pursuit Of Compensation* (1996).

n368. See Consumer Protection Act Part I (c 43) (1987) 2(1). Section 1(2) defines a product as "any goods or electricity and ... includes a product which is comprised in another product, whether by virtue of being a component part or raw material or otherwise." *Id.*

n369. The CPA is intended to supplement existing tort and contract remedies. Section 2(6) provides that "this section shall be without prejudice to any liability arising otherwise than by virtue of this part." CPA 2(6) Unlike the CPA, the Restatement (Third) may have the effect of prejudicing liability based on contract and negligence theory. See 2 cmt. n; see supra notes 107-113 and accompanying text.

n370. Consumer Protection Act Part I (c 43) (1987) 2(1). Section 1(2) defines a product as "any goods or electricity and ... includes a product which is comprised in another product, whether by virtue of being a component part or raw material or otherwise." *Id.*

n371. Section 1(2) defines producer as " (a) the person who manufactured it [product]; (b) in the case of a substance which has not been manufactured but has been won or abstracted, the person who won or abstracted it; (c) in the case of a product which has not been manufactured, won or abstracted but essential characteristics of which are attributable to an industrial or other process have been carried out (for example, in relation to agricultural produce), the person who carried out the process." CPA 1(2).

n372. Section 46(1) of the CPA provides that supplying goods is "(a) selling, hiring out or lending the goods (b) entering into a hire-purchase agreement to furnish the goods; (c) the performance of any contract for work and material to furnish the goods; (d) providing the goods in exchange for any consideration (including trading stamps) other than money; (e) providing the goods in or in connection with the performance of any statutory function; or (f) giving the goods as a prize or otherwise making a gift of the goods; and, in relation to gas or water, those references shall be continued as including references to providing the service by which the gas or water is made available for use." CPA 46(1).

n373. See, e.g. J.R. Bradgate & Nigel Savage, *The Consumer Protection Act 1987 - II*, 137 *New L.J.* 953, 953, (Oct. 9, 1987), (acknowledging that "this is potentially the most far reaching extension of liability[.]" but noting that the prime target of the CPA is the manufacturer).

n374. See CPA 2(2). According to 2(3), the supplier is liable for damages if the person who suffered the damage, "within a reasonable period after the damage occurs[.]" requests the supplier to identify "one or more of the persons" included in subsection 2, and "the supplier fails, within a reasonable period after receiving the request, either to comply with

the request or to identify the person who supplied the product to him." Id. 2(3) This change in English law is best illustrated, although in dicta, in a recent English Court of Appeal case. In *Hayes v Leo Scaffolding Ltd*, (1996) (C.A.) (Lexis, U.K. Library, ALLCAS File), the plaintiff suffered injury due to a defective scaffold. The plaintiff sued both his employer and the manufacturer and recovered under negligence. The manufacturer and the employer each contributed 50% to plaintiff's award. On appeal, the manufacturer was able to show that the employer had a duty to inspect the scaffold before allowing plaintiff to use it. The court reversed, holding the employer liable for the entire award; and the manufacturer effectively escaped liability. The court noted at the outset that the employer would have had an "impregnable argument" under the CPA. For whatever reason, it is not clear why neither the plaintiff nor the employer relied on the CPA. Under the CPA, as long as the employer identified the manufacturer of the defective product to the plaintiff within a reasonable time, the plaintiff would have a direct claim against the manufacturer under the new strict liability provisions, and the employer would not have been liable for any damages.

n375. *Bradgate & Savage*, supra note 373, at 953.

n376. *Bradgate & Savage*, *The Consumer Protection Act 1987 - Part I*, 137 *NEW L.J.* 929, 932, Oct. 2, 1987; see also Rodney Nelson-Jones & Peter Stewart, *Product Liability: The New Law Under The Consumer Protection Act 1987*, 43 (1987) (noting that subsection 3 was intended to address the problem of the "unknown defendant[,] that is, subsection 3 "protects the victim from anonymous or counterfeit products" allowing the plaintiff to go "back along the chain of supply until he ... gets back to the original source).

n377. Although the term was not defined by the Act, it is believed that canning, freezing and drying are covered.

n378. During the debate on the EEC products liability directive, the issue of agricultural produce was one of the main points of contention. The Directive, however, left it to member states to extend liability to include agricultural producers or not. The preamble to the Directive says "it is appropriate to exclude liability for agricultural products and game, except where they have undergone processing of an industrial nature which could cause a defect in those products." EC Directive No. 85/374/EEC (1985).

n379. *Bradgate & Savage*, supra note 376, at 931.

n380. Lesley Dolding, *Product Liability Reform: One Step Forward, One Step Back?*, 20 *Bracton L.J.* 26, 27 (1988).

n381. Section 14 of the Sale Of Goods Act provides:

14(2): Where the seller sells goods in the course of a business, there is an implied term that the goods supplied under the contract are of satisfactory quality." The Act further defines satisfactory quality as that which "a reasonable person would regard as satisfactory." Appropriate aspects of the quality are, among other, the following:

(a) fitness for all the purposes for which goods of the kind in question are commonly supplied; (b) appearance and finish; (c) freedom from minor defects; (d) safety and (e) durability.

Sale Of Goods Act 14 (1979 c 54) (as amended 1995), reprinted in 39 Halsbury's Statutes Of England 68 (4th ed. 1995 Reissue).

n382. See, e.g., Bradgate & Savage, *supra* note 376, at 931. "Since agricultural produce and foodstuffs are not excluded from the ambit of the sale of Goods Act, that objection seems to have little force." *Id.* In the U.S., the birthplace of modern strict products liability, the first exception to the privity rule was foodstuff. The first product to be subject to strict liability was food. The first draft of 402A strict liability was limited to food. See Prosser & Wade, *supra* note 41, at 707.

n383. CLARK, *supra* note 1, at 55 (opining that "problems with misuse of fertilizers, pharmaceuticals and pesticides are becoming increasingly apparent and it is suggested that time will show this exemption to have been misconceived").

n384. "Manufacturer" includes all possible defendants, unless otherwise specified.

n385. Unlike the Restatement (Third), but like 402A, the CPA treats defect as a single concept. Judicial interpretation of 402A, however, classified defect into three types. Although the judicial interpretation of defect under the CPA is yet unknown, English case law has classified defect into manufacturing, design and warning defects. Interestingly, the editors of Halsbury's Statutes Of England (1988 4th ed.) explained in the General Notes to the CPA, that proving a manufacturing defect will be the easiest because of the "yardstick of comparison[.]" the defective product will clearly "deviate from the norm of production." As to design defect, the General Note indicated that utility factors, similar to those considered in negligence, might be most appropriate for evaluating a design defect case. The General Note suggested that in design defect cases, issues such as whether the risk was known at the time of manufacture and the cost to eliminate the risk, should be considered. In the most recent Halsbury's Statutes Of England (1995 Reissue), the editors did not include any of the above comments in the General Notes to the CPA. Actually, there is scant commentary on the CPA in way of General Notes.

n386. See *supra* Part III.

n387. See General Note at 155.

n388. CPA 3. Most commentators have described article three to embody the consumer expectation test. See, e.g., Alistair Clark, *Legislation: The Consumer Protection Act 1987*, 50 *Mod. L. Rev.* 615, 617 (1987). Like the Restatement (Third), a plaintiff under the CPA would need to prove that the product (i) contained a defect; (ii) that plaintiff suffered damage; (iii) that the damage was caused by the defect; (iv) and that the defendant was in the class of liable persons. See *id.*

n389. CPA 3(2), reprinted in *Halsbury's Statutes Of England* (4th ed. 1995 Reissue). These factors mirror the factors recommended in the 1977 Law Commission Report, see *supra*, note 365.

n390. See Hodges, *Product Liability: Law And Insurance* 2.25, at 2-8 (MARK MILDRED ed., 1997).

n391. Christopher Newdick, *The Future of Negligence in Product Liability*, 103 *L.Q. Rev.* 288, 300 (1987).

n392. See Law Commissions, *supra* note 366, P 48, at 17. "[A] product should be regarded as defective if it does not comply with the standard of reasonable safety that a person is entitled to expect of it; and ... the standard of safety should be determined objectively having regard to all the circumstances in which the product has been put into circulation, including, in particular, any instructions or warnings that accompany the product when it is put into circulation, and the use or uses to which it would be reasonable for the product to be put in these circumstances." *Id.* See also Hodges, *supra* note 390, 2.23, at 2-8 "A person should not be entitled to have expectations over and above the general level of public knowledge." *Id.*

n393. See Clark, *supra* note 1, at 29-30 (stating that the main flaw of the definition of defect under the CPA is that "it fails to provide a readily ascertainable objective standard against which a manufacturer, or indeed a court, can make the criterion of the 'safety which persons generally are entitled to expect?'").

n394. *Liability For Defective Products*, 1977, Law Comm'n No. 82, Scot. Law Comm'n No. 45, Cmnd. No. 6831, at 16.

n395. Get-up refers to the styling, packaging and leaflets of the product. See Jones & Stewart, *supra* note 376, at 49.

n396. See General Note at 155 ("sub-s(2)(b), in referring to 'what might reasonably be expected to be done' rather than merely 'reasonable use' of the product, imposes an obligation on a producer to consider the misuse to which his product may be put. In such a case, however, the provisions of the Act concerned with contributory negligence might come into play").

n397. The Restatement (Third) explicitly rejected consumer expectations as an independent test to determine defectiveness. See *supra* notes 186-210 and accompanying text.

n398. See, e.g., Clark, *supra* note 1, 35 (stressing that products today "are too complex for a consumer to form any rational impression of the safety to be expected," especially in complex design and warning defects).

n399. See Clark, *supra* note 1, at 35-36.

n400. Ferguson, *supra* note 367, at 120.

n401. Development risk raises the issue of foreseeability; the expectation of the general consumer is another way of saying reasonable expectations.

n402. See Robin H. Crockett, Pt. I of the Consumer Protection Act 1987: Civil Liability for Products, 84 L. Soc'y Gazette 3163, 3164 (1987) (considering the overall environment of the product to determine safety will implicate "use of reasonable foresight and the concept of causation in the tort of negligence").

n403. See, e.g., Clark, *supra* note 1, at 41 (concluding that "a cost-benefit approach seems to be a sensible way to do this"). See also Jane Stapleton, Product Liability Reform - Real or Illusory?, Cambridge L.J. 392, 405 (1986) ("what reformers really mean when they say that a product meets 'expectations of safety' is that on balance its benefits outweigh its costs ... It would have made much greater sense simply to couch the liability criterion in terms of costs and benefits as such and drop the concept of expectations altogether").

n404. See, e.g., Newdick, *supra* note 391, at 300 (exclaiming whether a purported strict liability regime is "capable of imposing liability irrespective of fault[,] " when courts are to consider factors such as price, style, efficiency etc.).

n405. Dolding, *supra* note 380, at 28.

n406. See Newdick, *supra* note 391, at 301 ("it is by no means clear, however, how the test is to be distinguished from its present use in the law of negligence.") See also Clark, *supra* note 1, at 37 ("Indeed, any liability test short of absolute liability could be perceived as ultimately cost-benefit approach and a consumer expectations approach may really be one of style rather than substance").

n407. Newdick, *supra* note 393, at 304.

n408. Clark, *supra* note 1, at 37.

n409. *159 F.2d 169 (2nd Cir. 1947)*.

n410. *Id. at 173*.

n411. *1956 App. Cas. 552*.

n412. *Id. at 574*.

n413. Lord Reid's formulation would qualify under Owen's rubric of a "micro balance." In fact, Lord Reid's formulation focuses on the cost of the alternative action, or the alternative design that would have reduced or prevented the injury, more explicitly than Learned Hand's test.

n414. Section 6(4) of the CPA states that where the damage caused by a product was partly the fault of the user, the Law Reform (Contributory Negligence) Act 1945 applies. See CPA 6(4). This act has been recently interpreted as not to result in an absolute bar of recovery. See *Pitt v. Hunt*, 3 *All E.R. 344 (1990)*. Compare 17(a) & (b) of the Restatement (Third):

(a) A plaintiff's recovery of damages for harm caused by a product defect may be reduced if the conduct of the plaintiff combines with the product defect to cause the harm and the plaintiff's conduct fails to conform to generally applicable rules establishing appropriate standard of care.

(b) The manner and extent of the reduction under Subsection (a) and the apportionment of plaintiff's recovery among multiple defendants are governed by generally applicable rules of apportioning responsibility.

Restatement (Third) 17.

n415. See The Pearson Commission Report 7054, P 1259 (1978) (stressing that "to exclude development risks from a regime of strict liability would be to leave a gap in the compensation cover through which, for example, the victims of another Thalidomide disaster might easily slip") (quoted in Alistair Clark, *supra* note 388, at 619); see also Jones & Stewart, *supra* note 376, at 78 (noting that there is a total of sixteen defenses under the CPA, "this abundance demonstrates that Part I has not imposed absolute products liability"); see also Dolding, *supra* note 380, at 30 (lamenting "it is difficult to see what benefit a plaintiff could derive from the inclusion in the Act of the controversial 'development risks' ... defense"). Dolding correctly observes that the Thalidomide crisis in the 1970's that

resulted in hundreds of deformed children was the catalyst to the strict liability movement in the U.K. As such, the inclusion of the 'development risk' defense would relieve the manufacturer of Thalidomide from liability and becomes an effective obstacle to plaintiffs to recover in drug side effect cases. *Id.* at 30.

n416. Section 4 of the CPA states that in any civil suit "against any person in respect of a defect in a product it shall be a defense from him to show -" CPA 4.

n417. CPA 4(2)(a).

n418. Products liability defenses are not within the scope of this Comment. Under the Restatement (Third), the "state-of-the-art" concept is inextricably linked to the concept of defect. Under the CPA, the "state of the art" is treated as an affirmative defense. For the purposes of this study, therefore, "state-of-the-art" or state of scientific knowledge defense will be the only defense examined closely.

n419. This defense was controversial during debates on the EEC products liability Directive.

n420. CPA 4(1)(e) (1987). Compare 7(e) of the ECC Directive 7(e) which provides, in pertinent part, " that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered." No. 85/374/EEC. The ECC Directive provides that if there is any knowledge anywhere that the defect could have been discovered at the time the product was put into circulation the defense fails. Unlike the ECC, the CPA indicates that the defense is sustained if the producer could not reasonably be expected to have discovered the defect in light of scientific knowledge. Many commentaries have criticized the CPA's manipulation of 7(e) on the grounds that it reduced the defense to a variant of negligence and thus England failed to properly implement 7(e). But see, Christopher Newdick, *The Development Risk Defense of the Consumer Protection Act 1987*, 47 *Cambridge L.J.* 455 (1988) (arguing that the CPA correctly interpreted article 7(e) of the EEC Product Liability Directive). Recently, the Court of Justice of the European Communities held that the CPA's Development Risk defense was in accord with the 1985 Directive. See *European Commission v. United Kingdom*, 1997 *All E.R. (EC)* 481.

n421. See *supra* note 361.

n422. See Geraint Howells & Thomas Wilhelmsson, *EC Consumer Law* 41 (1997) ("Member States were free to exclude the defense, but we have seen that few chose to do so").

n423. See Bradgate & Savage, *The Consumer Protection Act 1987 - IV* 137 *New L.J.*, Nov. 6, 1987, at 1049, 1049. But see Law Commission, *supra* note 365, at 19- 20 (refuting

the above argument and recommending strict liability in prescription drugs even if the producer was not negligent); for a general discussion regarding innovation, insurance, trial process, risk spreading arguments, see CLARK, *supra* note 1, at 180-182.

n424. See CLARK, *supra* note 1, at 193.

n425. For a general discussion of policy considerations favoring strict liability, see Law Commission, *supra* note 365, at 6-7 (e.g., risk spreading; manufacturer in better position; manufacture can insure).

n426. See Clark, *supra* note 1, at 183 (concluding, after citing the policy consideration for a strict liability regime, "it is difficult to see how the inclusion of a development risks defense furthers any of these aims," and that "each could be taken to support the exclusion of the defense"); see also Aubrey L. Diamond, *New Trends In Product Liability Legislation In The United Kingdom: The Consumer Protection Act*, 16 *J. of Legis.* 15, 25 (1989) (referring to the policy consideration holding that the manufacturer is in a better position to insure against injuries caused by his product's defect, concluding that "the arguments for narrowing the operation of the state of the art defense seem strong").

n427. The CPA's position is contrary to the 1977 Law Commission recommendation that all products including prescription drugs should be subject to strict liability. The Commission rejected the claim that prescription drugs are unique and deserve special treatment, insisting that the underlying policy considerations favoring strict liability for injury caused by defective product, equally apply in the case of prescription drugs. Referring to the Thalidomide disaster, the Law Commissions stated: "The producer of defective pharmaceuticals creates the risk; he is the person best able to control the quality of the product; he is the person best able to insure against claims; and public expectation that drugs on the market will be safe is raised by advertising and by the promotional material with which the pharmaceutical industry supply the medical profession." Law Commission, *supra* note 368, at 19-22

n428. See JONES & STEWART, *supra* note 376, at 68 ("so far as discovery of a defect is concerned, s.4(1)(e) effectively preserves the principles of negligence law. Only the onus of proof is different"); see also Bradgate & Savage, *supra* note 423, at 1050 ("the existence of the development risks defense open up a serious loophole in the protection afforded by the Act, and the wording of the defense, coupled with the reference in the definition of 'defect' to what 'persons generally are entitled to expect' seems uncomfortably similar to the language of negligence"). See also Clark, *supra* note 1, 155; Newdick, *supra* note 391, at 293-297 (asserting that with the exception of the burden of proof, the state-of-the-art defense maintain a negligence standard).

n429. Restatement (Third) 8 cmt. g. The Reporters contend that "imposing liability for unforeseeable risks can create inappropriate disincentives for the development of new drugs and therapeutic devices." *Id.*

n430. See Clark, *supra* note 1, at 184-185.

n431. See Bradgate & Nigel, *supra* note 423, at 1050 (predicting that "by increasing the number of possible targets for a claim, the Act will increase the protection of consumer").

n432. See Diamond, *supra* note 426, at 25 (concluding that "producer's liability under the 1987 Act will in some cases be a lesser liability than is imposed upon sellers by the earlier law - the Sale of Goods Act - and, accordingly, the most serious of the anomalies remains").

n433. See Ferguson, *supra* note 368, at 122 (lamenting that "the need to establish that a product was defective may be as much a hurdle for the plaintiff under the strict liability regime as the requirement to prove negligence under tort law").

n434. See *AB v. South West Water Services Ltd.*, 1 All E.R. 609 (1993); and, *Hayes v. Leo Scaffolding Ltd*, Court of Appeal (Civil Division 1996) (LEXIS, U.K. Library, ALL-CAS File). *AB South* is primarily a punitive damages case. The *AB South* court held that punitive damages are not recoverable in products liability actions brought under the CPA. The court announced a test that allows punitive damages only in causes of action where punitive damages were awarded prior to 1964. See 1 All E.R. (1993), at 620. Applying this test to the present case, the court found that "the statutory duty relied upon in this case is created by the Consumer Protection Act 1987 and the Water Act 1945; in the former case there could not have been, and in the latter case there was not, an award of exemplary damages before 1964." *Id.* In the second case, *Hayes v. Leo Scaffolding*, *supra*, plaintiff was injured when, a defective scaffold he was standing on broke. The plaintiff brought a claim in negligence against his employer and manufacture. He recovered damages. The court then apportioned plaintiff's award, half on employer and half on manufacture. The manufacturer appealed. The court allowed the appeal on the basis that the employer had a duty to inspect the scaffold before giving the scaffold to plaintiff. The Court of Appeal noted that plaintiff and employer would have had an impregnable case under the CPA. But they did not plead under the CPA. The reason is not clear.

n435. See, e.g., The All England Law Reports Annual Review (1993), at 91 ("*AB v. South* was primarily concerned with the circumstances in which exemplary damages might be awarded. Although the point was really noted only in passing, it also appears to be the first case on the products liability provisions of the Consumer Protection Act (1987) to be reported in the All English Reports"). This can be explained by the fact that many products liability causes of action continue to be brought under statutory violations or under implied warranties. For a list of product related statutes see *supra* note 55. See also Clark, *supra* note 1, at 24 ("[a] further uncertainty is that many product-related accidents involving injury occur at the workplace. Most of these will trigger liability under statutes such as the

Factories Acts or the Employers' Liability (Defective Equipment) Act 1969, and it is not expected that injured employees will pursue the producer under the new Act").

n436. Clark, *supra* note 1, at 21.

n437. See Clark, *supra* note 1, at 45 (noting that the 'strictness' of the new CPA standard "will depend partly upon how the courts address the problem").