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STRICTLY SPEAKING ABOUT EPHEDRA: A BASEBALL TRAGEDY HELPING TO DEFINE THE DYNAMIC BETWEEN WARNING DEFECT AND DESIGN DEFECT

I. INTRODUCTION

On August 17, 2003, Kiley Bechler spread the ashes of her recently deceased husband, Steve Bechler, on the pitcher's mound at Camden Yards.1 This solemn gesture marked an end to one chapter of the tragic saga that began with the twenty-three year-old pitcher's unexpected death.2

Just several months earlier, Steve Bechler reported to the Baltimore Orioles spring training camp ten pounds overweight.3 To lose weight for the upcoming baseball season, Bechler took an over-the-counter dietary supplement called Xenadrine RFA-1 ("Xenadrine"), which contains ephedra.4 Bechler reportedly took three Xenadrine capsules each morning, one capsule over the recommended dosage printed on the bottle.5 On Friday, February 14,
2003, Bechler reported to training camp and passed a routine physical examination.6 Later that day, Bechler completed the Orioles’ first day of drills at spring training without incident.7 Two days later, however, Steve Bechler suddenly collapsed on the practice field from heat exhaustion.8

Orioles’ trainers examined the twenty-three year-old pitcher at the training facility, but were unable to help him.9 Bechler was rushed to the hospital where his temperature reached a staggering 108 degrees, causing his body to overheat, leading to “cell death” and ultimately multiple system organ failure.10 At 10:10 a.m., on Monday, February 17, 2003, Steve Bechler died.11

Bechler’s autopsy revealed that ephedra was a significant factor in the pitcher’s death.12 Later investigation revealed that Bechler suffered from a history of abnormal liver functions and mild hypertension prior to the day of his collapse.13

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6. See Becky Dubin Jenkins, Physician explains Bechler’s death, at http://baltimore.orioles.mlb.com/NASApp/mlb/bal/news/bal_news.jsp?ymd=20030217&content_id=201272&vkey=spt2003news&fext=.jsp (Feb. 17, 2003) (“Bechler did not report any problems to the doctor who examined him and was deemed ‘fit to go’ and ‘fit to play.’ Bechler did have a routine EKG in 1999, and it, too, was normal.”).

7. See Becky Dubin Jenkins, O’s Notes: Bechler taken to hospital, at http://baltimore.orioles.mlb.com/NASApp/mlb/bal/news/bal_news.jsp?ymd=20030216&content_id=200789&vkey=spt2003news&fext=.jsp (Feb. 16, 2003) (discussing how Orioles’ manager, Mike Hardgrove, commented that Bechler finished Friday’s first day drills, but he finished them tired). The very next day, Saturday, Bechler finished most of the team drills, but was taken out of practice for disciplinary reasons. See id.

8. See id. (describing Bechler’s participation in running drills before he collapsed).

9. See id. (running through various events taking place during thirty-seven minute time period from when trainers brought Bechler to Orioles’ training room at 11:35 a.m. until emergency personnel transported Bechler from field at 12:12 p.m.).

10. See Jenkins, supra note 6 (explaining Bechler’s multiple organ failure was due to heatstroke).

11. See id. (describing events surrounding Bechler’s death at North Ridge Medical Center in Fort Lauderdale, Florida). “Bechler’s pregnant wife, Kiley, was at his bedside when he died.” Id.

12. See Chass, supra note 5, at D5 (attributing Bechler’s death, in part, to ephedra found in his system). “Releasing the toxicology report, Dr. Joshua Perper, the Broward County medical examiner, said, ‘It is my professional opinion that the toxicity of ephedra played a significant role in the death of Mr. Bechler, although it’s impossible to define mathematically the contribution of each one of the factors in his unfortunate death due to heatstroke.’” Id. Dr. Perper revealed his findings during a press conference and in a detailed thirteen page report on Bechler’s death. See id.

13. See id. (explaining how interviews and previous medical examinations revealed other risk factors which may have contributed to Bechler’s death).
In response to her husband’s death, Kiley Bechler sued the makers of Xenadrine in a Florida federal court.\textsuperscript{14} She is asking for 600 million dollars in a products liability lawsuit for wrongful death.\textsuperscript{15} The complaint sets forth six claims against the defendants.\textsuperscript{16}

This Comment focuses on two of Kiley Bechler’s strict products liability claims, specifically design defect and warning defect.\textsuperscript{17} By addressing the circumstances surrounding Steve Bechler’s death, this Comment explains the relationship between a product’s warning and its design in a strict products liability lawsuit.\textsuperscript{18} Section II provides a general background of Florida strict products liability law for design defect and warning defect.\textsuperscript{19} Section III applies Florida law to the facts surrounding Steve Bechler’s death.\textsuperscript{20} Section IV discusses certain practical considerations concerning Bechler’s case and the policy-driven ramifications of Florida’s stance on strict products liability law.\textsuperscript{21} Section IV also highlights new develop-
ments, including recent FDA action, and the grim future of ephedra.22

II. BACKGROUND

A. The Attack on Ephedra

Ephedra, also known as ma huang, is a natural substance derived from plants.23 In China, ephedra has been used for thousands of years to treat various respiratory ailments.24 Today, the plant is crushed and formulated into pills, teas, and other forms, and sold as dietary supplements.25 Dietary supplements are promoted by the industry as diet aids, muscle builders, and energy boosters.26 These claims, however, have never been substantiated.27

The federal government, through the Dietary Supplement and Health Education Act of 1994 ("DSHEA"), does not require manufacturers of dietary supplements to prove product safety or effectiveness before placing them on the market.28 Instead, before a dietary supplement can be removed from the market, the Federal Drug Administration ("FDA") must prove that the supplement is unsafe.29 Under this regulatory system, dangerous products,
like ephedra, are pulled off the shelves only after the damage is done.\textsuperscript{30}

The eighteen billion dollar-per-year dietary supplement industry has recently come under attack because of its deceptive marketing practices.\textsuperscript{31} In fact, Cytodyne Technologies, Inc., the makers of Xenadrine, recently lost a 12.5 million dollar lawsuit for false advertising practices.\textsuperscript{32} In addition, the commissioner of the FDA has publicly professed that the agency is chasing down the makers of ephedra products for their "unsubstantiated claims."\textsuperscript{33}

The FDA is not alone; plaintiffs nationwide are attacking the manufacturers of dietary supplements containing ephedra, claiming their products are unsafe and should be removed from the market immediately.\textsuperscript{34} For instance, the family of a woman who recently died while exercising on a high school track sued the makers of Xenadrine for her unexpected death.\textsuperscript{35} In addition, Kelci Stringer, the widow of former Minnesota Vikings pro-bowler Korey Stringer, has made accusations that ephedra contributed to her

\begin{itemize}
\item \textsuperscript{30} See Winnie Hu, \textit{Albany Leaders Reach Accord On Ephedra Ban}, N.Y. TIMES, June 11, 2003, at B6 (stating New York state legislators agreed to ban ephedra sales statewide). With approval from Governor Pataki, New York would join Illinois as only the second state banning over-the-counter sales of ephedra after Steve Bechler's death. See id. "The Food and Drug Administration has reported 123 deaths associated with ephedra since 1993. Dietary supplements, unlike drugs, do not need the agency's approval before going on the market." Id.
\item \textsuperscript{31} See Ford Fessenden, \textit{Studies of Dietary Supplements Come Under Growing Scrutiny}, N.Y. TIMES, June 23, 2003, at A1 (explaining how industry research is less than scientific and frequently misleading to consumers).
\item \textsuperscript{32} See id. (describing how makers of ephedra and other dietary supplements misuse data in scientific studies). "Cytodyne . . . exaggerated the findings of clinical trials it commissioned, Superior Court Judge Ronald L. Styn said in ruling on a class action suit, but [Cytodyne] had also cajoled some researchers into fudging results in published scientific articles." Id.; see also Ephedra: Cytodyne to Pay $12.5 Million in 'Xenadrine' case, at http://www.legalnewswatch.com/news_208.html (May 30, 2003) (describing both sides' reactions to court's decision).
\item \textsuperscript{33} See McClellan, supra note 27, at 200 (discussing need for stronger warning labels on any ephedra products still marketed). The commissioner stated: "We are also executing a series of actions against ephedra products making unsubstantiated claims, for example about sports performance enhancement, and against manufacturers that in effect are marketing alternatives to street drugs." Id.
\item \textsuperscript{34} See Register, \textit{Big Class Action}, at http://www.bigclassaction.com/class_action/ephedra2.html (last visited Nov. 14, 2004) (indicating first nationwide class action against leading ephedra makers was filed). Plaintiffs to this class action lawsuit are seeking monetary compensation for injuries and death, reimbursement of payments made for ephedra containing products, a recall of all dietary supplements containing ephedra, a medical monitoring fund, and a public statement by the makers of ephedra regarding the dangers of their products. See id.
\item \textsuperscript{35} See Ex parte Gen. Nutrition Corp., 855 So. 2d 475, 478 (Ala. 2003) ("The autopsy report stated, among other things, that 'her death is consistent with a sudden cardiac death.'"). The woman allegedly purchased the Xenadrine at a local General Nutrition Center ("GNC") retail store in Newport News, Virginia. See id.
\end{itemize}
husband's heat stroke and death in 2001. Kiley Bechler is leading the attack on the ephedra industry through her 600 million dollar lawsuit, and her weapon of choice is strict products liability.

B. Strict Products Liability

In *West v. Caterpillar Tractor Co.*, the Florida Supreme Court adopted the doctrine of strict liability as set out in the Restatement (Second) of Torts Section 402A. A manufacturer will be held strictly liable if the plaintiff proves that: "(1) a product (2) produced by a manufacturer (3) was defective or created an unreasonably dangerous condition (4) that proximately caused (5) injury." A plaintiff does not need to prove that a manufacturer was negligent to succeed in a strict products liability action. The policy


38. This Comment focuses on Florida tort law because the federal court hearing Kiley Bechler's lawsuit will apply Florida law. For further discussion on the application of Florida law, see supra note 14 and accompanying text.

39. 336 So. 2d 80 (Fla. 1976).

40. See id. at 87 (indicating Florida followed trend of numerous states by adopting doctrine of strict liability); see also Restatement (Second) of Torts § 402A (1965). Section 402A provides:

(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 brought the product from or entered into any contractual relation with the seller.

Id.

41. Edward M. Chadbourne, Inc. v. Vaughn, 491 So. 2d 551, 553 (Fla. 1986) (finding insufficient proof of proximate cause, and therefore, manufacturer could not be held strictly liable). If the plaintiff proves all five points, the manufacturer of the defective product is strictly liable. See id.

42. See Ferayorni v. Hyundai Motor Co., 711 So. 2d 1167, 1170-71 (Fla. Dist. Ct. App. 1998) (noting Florida strict products liability law does not require negligence). "In fact [manufacturers] can be found liable even though [they were]
surrounding strict products liability is premised on the manufacturer's ability to better bear the costs of injuries resulting from defective products.\textsuperscript{43}

In a products liability action based on strict liability, a product is considered defective if it is in a condition unreasonably dangerous to the consumer.\textsuperscript{44} The three theories used when considering a product's defectiveness are design defect, manufacturing defect, and warning defect.\textsuperscript{45} Because this Comment focuses on the relationship between design defect and warning defect, manufacturing defect will not be discussed.\textsuperscript{46}

1. Design Defect

When determining whether a product is defectively designed, a court may choose between two tests.\textsuperscript{47} Under Florida law, trial courts are given wide discretion to use either the consumer expectation test or the risk-utility test.\textsuperscript{48} In some instances, Florida courts have even applied both tests concurrently.\textsuperscript{49} As a result, all litigants

utterly non-negligent.” \textit{Id.} at 1171 (quoting \textit{Moorman v. Am. Safety Equip.}, 594 So. 2d 795, 800 (Fla. Dist. Ct. App. 1992)).

\textsuperscript{43.} \textit{See} Cassisi v. Maytag Co., 396 So. 2d 1140, 1150 (Fla. Dist. Ct. App. 1981) (“[T]he purpose of strict liability is to ensure that the costs of injuries resulting from defective products be borne by their makers who put them into the channels of trade rather than by injured persons who ordinarily are powerless to protect themselves.”); \textit{see also} West, 336 So. 2d at 92 (stating similar rationale for holding manufacturers liable for defective products).

\textsuperscript{44.} \textit{See} Cassisi, 396 So. 2d at 1143-44 (stating products are not required to be both defective and unreasonably dangerous). “On first impression, the [Second] Restatement may seem to require proof that the product be both defective and unreasonably dangerous. That, however, is not the case [in Florida].” \textit{Id.} at 1143.

\textsuperscript{45.} \textit{See} Jennings v. BIC Corp., 181 F.3d 1250, 1255 (11th Cir. 1999) (applying Florida law); \textit{see also} Ferayorni, 711 So. 2d at 1170 (noting three distinct theories that define defective products).

\textsuperscript{46.} For a discussion of the relationship between warning defect and design defect, see \textit{infra} notes 156-74 and accompanying text.

\textsuperscript{47.} \textit{See} Standard Jury Instructions-Civil Cases (99-1), 778 So. 2d 264, 271 (Fla. 2000) (stating two tests for design defect are consumer expectation and risk-utility tests).

\textsuperscript{48.} \textit{See id.} at 272 (stating either test is acceptable, or even both); \textit{see also} Spencer H. Silverglate, \textit{The Restatement (Third) of Torts: Product Liability-The Tension Between Product Design and Product Warnings}, 75 FLA. B.J. 10, 14 (2001) (describing confusion that exists with Florida’s standard jury instructions in design defect cases). “In contrast, the Third Restatement adopts the risk-utility balancing test to determine design defect [. . .] . . . consumer expectations . . . may be considered as part of the risk-utility balancing test.” \textit{Id.}

in design defect cases must be keenly aware of the ramifications of both tests in design defect claims.50

a. Consumer Expectation Test

The consumer expectation test provides that "[a] product is unreasonably dangerous because of its design if the product fails to perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable by the manufacturer."51 While the consumer expectation test is easily applied to manufacturing defect claims, the test is generally more difficult to apply to design defect claims.52

In Jennings v. BIC Corp.,53 a three year-old boy accidentally lit his brother’s pajamas on fire with a BIC lighter.54 The boys’ mother sued BIC for her son’s personal injuries.55 Her lawsuit alleged BIC’s failure to provide a child proof feature rendered the lighter defective in design.56 The case was to be tried before a jury in the United States District Court for the Middle District of Flor-

50. See Zimmer, 758 So. 2d at 715 (describing how appellate review may be precluded in cases where both consumer expectation test and risk-utility test were used in jury’s general verdict). In Zimmer, the plaintiff was precluded from appealing his case because the court could not decipher which test the jury applied in coming to its verdict. See id. The plaintiff claimed that the trial court erred when instructing the jury on the consumer expectation test. See id. Affirming the jury’s ruling for the defendant, the court stated:

The jury charge gave the jury two standards for determining whether the product was unreasonably dangerous - the ordinary consumer test and the risk benefit test. Zimmer concedes that the risk benefit test was appropriate to use in this case. The verdict form did not require the jury to identify its basis for deciding that the product was defective. Zimmer did not object at trial to the use of the verdict form. The jury might properly have decided that the rods were defective based on a risk benefit analysis. Even if we found error in the definition of the ordinary consumer test or in its submission to the jury, under the two issue rule, Zimmer is unable to demonstrate prejudice to justify a reversal. Id.

51. Standard Jury Instructions, 778 So. 2d at 271 (setting forth specific jury instruction for consumer expectation test).


53. 181 F.3d 1250 (11th Cir. 1999).
54. See id. at 1253 (observing lighter did not have child-proof feature).
55. See id. (stating mother’s response to son’s injury).
56. See id. (alleging design defect because lighter was unreasonably dangerous). The lawsuit also alleged that 7-Eleven was liable for selling the defective lighter and the store that sold the flammable pajamas was liable for distributing flammable pajamas. See id.
The court, however, granted BIC’s motion for summary judgment and Jennings’ case was dismissed. Jennings appealed the district court’s summary judgment. She contended the court erred in finding that BIC had no duty to child-proof its lighters. The issue on appeal was “limited to whether the alleged design defect of the lighter, i.e., its lack of childproof features, render[ed] it unreasonably dangerous.”

Florida courts utilize both the consumer expectation test and the risk-utility test to decide whether a product is unreasonably dangerous. In Jennings, the court focused on the consumer expectation test. Both tests require the jury to use an objective standard to determine whether the product is defective. Using the consumer expectation objective standard, the court judged the defectiveness of the lighter from an ordinary consumer’s standpoint, rather than from an ordinary three year-old child’s standpoint. As a matter of law, the court held that lighters lacking child-proof features are not defective.
In a vigorous dissent, Judge Barkett posited that the case should be sent to the Florida Supreme Court for clarification on the existing state of Florida strict products liability law, specifically design defect. The dissent suggested a jury could find BIC lighters without child-proof features defective in design under the objective ordinary consumer standard. This objective standard requires contemplating the "consideration of the ordinary consumer's expectations." Ordinary consumer expectations reasonably include the expectation of young children playing with lighters. The dissent asserted that "in light of the high casualty rate and the obviousness of the danger, a jury could well find BIC lighters to be defectively designed under an objective, ordinary consumer standard."

Furthermore, the majority in Jennings limited a manufacturer's liability to situations where a product is used only as intended. The Florida standard jury instruction for the consumer expectation test allows a jury to find a defendant liable when a product is used in a foreseeable manner or as intended. By limiting liability to

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67. See Jennings, 181 F.3d at 1260 (Barkett, J., dissenting) (explaining there is no binding precedent on point to support majority's holding).

68. See id. at 1261 (agreeing with majority that objective analysis was proper).

69. See id. at 1260 (considering "normal public expectation of danger" is another way to phrase ordinary consumer expectations). The dissent believed that the majority was erroneous in finding that the "normal public expectation of danger" of lighters did not include the probability that children could set fires. See id. at 1261.

70. See id. at 1260-61 (noting majority puts forth evidence of apparent dangers involved when children play with lighters). The dissent stated: However, given that, by the majority's own admission, "140 people, including 125 children, are killed each year in fires caused by children playing with lighters," it is hard to credit the conclusion that the "normal public expectation of danger" would not include the risk of fires so caused, and that expectation of such a risk would arise only if one adopted "a subjective, child's-perspective standard." Id. (citations omitted).

71. Id. at 1261 (arguing summary judgment in favor of BIC was inappropriate).

72. See Jennings, 181 F.3d at 1261 (Barkett, J., dissenting) (stating majority misinterpreted previous precedent set forth in High v. Westinghouse Elec. Corp., 610 So. 2d 1259 (Fla. 1992)). "The majority posits that a 'manufacturer is strictly liable only when the product is used as intended,' and asserts, on the basis of High, that a child's use of a cigarette lighter to set fire to things that are not intended to be burned is an unintended use under Florida law." Id. at 1261 (alterations in original).

73. See Standard Jury Instructions-Civil Cases (99-1), 778 So. 2d 264, 271 (Fla. 2000) (allowing jury to find liability for any foreseeable use or intended use of products).
only intended uses, the majority excluded any reasonably foreseeable use, or misuse, as a basis to find BIC liable for design defect.\textsuperscript{74} Accordingly, had the majority in \textit{Jennings} applied the reasonably foreseeable use standard, it may have reached a different result.\textsuperscript{75} The reasonably foreseeable use standard will ultimately play a role in Bechler’s case.\textsuperscript{76}

b. Risk-Utility Test

\textbf{Florida courts also apply the risk-utility test to decide whether a product is defectively designed.}\textsuperscript{77} The risk-utility test requires balancing the utility of the product against the risk it creates.\textsuperscript{78} If a product’s risk outweighs its utility, then the product’s design is defective.\textsuperscript{79} When applying the risk-utility test, courts find Professor Wade’s seven factors helpful.\textsuperscript{80}

\begin{itemize}
  \item \textbf{74. See \textit{Jennings}, 181 F.3d at 1261 (Barkett, J., dissenting) (concluding that \textit{High} provides no support for majority’s finding that “manufacturers are not strictly liable for injuries caused by reasonably foreseeable uses of their products”).}
  \item \textbf{75. See \textit{id.} (predicting different result if majority had applied reasonable foreseeability standard).}
  \item \textbf{76. See \textit{Standard Jury Instructions}, 778 So. 2d at 271 (noting foreseeable use, or misuse, will not preclude jury from entering verdict for plaintiff). For a discussion of Steve Bechler’s foreseeable misuse, see \textit{infra} notes 128-32 and accompanying text.}
  \item \textbf{77. See \textit{Radiation Tech., Inc. v. Ware Constr. Co.}, 445 So. 2d 329, 331 (Fla. 1983) (applying risk-utility test to determine whether product was unreasonably dangerous); see also \textit{Restatement (Third) of Torts: Products Liability} § 2 reporter’s note, cmt. d, § II(B) (1998) (stating Florida law does not explicitly require proof of alternative design in design defect cases, however, it may be implicit that proof of alternative design is needed to prove design defect).}
  \item \textbf{78. See \textit{Restatement (Third) of Torts: Products Liability} § 2 reporter’s note, cmt. d, § II(B) (1998) (discussing importance of reasonable alternative design in design defect cases where risk-utility test is applied). “Under risk-utility balancing the likelihood and magnitude of foreseeable harm is balanced against the burden of precaution against the anticipated harm.” \textit{Id.}}
  \item \textbf{79. See \textit{id.} (explaining risk-utility test).}
  \item \textbf{80. See \textit{Sperry-New Holland v. Prestage}, 617 So. 2d 248, 256 (Miss. 1993) (recommending trial courts apply Professor Wade’s seven factors). Professor Wade’s seven factors are:}
    \begin{itemize}
      \item (1) The usefulness and desirability of the product – its utility to the user and to the public as a whole.
      \item (2) The safety aspects of the product – the likelihood that it will cause injury, and the probable seriousness of the injury.
      \item (3) The availability of a substitute product which would meet the same need and not be as unsafe.
      \item (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.
      \item (5) The user’s ability to avoid danger by the exercise of care in the use of the product.
      \item (6) The user’s anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the}
    \end{itemize}
\end{itemize}
The risk-utility test is another way to determine whether a product design is unreasonably dangerous to consumers.\textsuperscript{81} Over the last decade, the national judicial trend has been to apply the risk-utility test instead of the consumer expectation test.\textsuperscript{82} Courts have recognized that the risk-utility test provides a useful balance, protecting both consumers and manufacturers.\textsuperscript{83}

While the risk-utility test is separate and distinct from the consumer expectation test, the risk-utility test may encompass some consumer expectations in its balancing approach.\textsuperscript{84} For instance, in design defect claims, the risk-utility test may allow for consumer expectations to be balanced against the gravity of harm that could result from the product, the availability of a safer design, and the economic feasibility of a safer design.\textsuperscript{85} Inevitably, certain consumer expectations will creep into the risk-utility balancing formula.\textsuperscript{86}

\begin{itemize}
  \item obvious condition of the product, or of the existence of suitable warnings or instructions.
  \item The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.
\end{itemize}

\textit{Id.} at 256 n.3 (quoting John W. Wade, \textit{On the Nature of Strict Tort Liability for Products}, 44 Miss. L.J. 825, 837 (1973)).

81. \textit{See Radiation Tech.}, 445 So. 2d at 331 (applying risk-utility test and not consumer expectation test to determine design defect). The Supreme Court of Florida stated:

\begin{quote}
  The term "unreasonably dangerous" more accurately depicts liability of a manufacturer or supplier in that it balances the likelihood and gravity of potential injury against the utility of the product, the availability of other, safer products to meet the same need, the obviousness of the danger, public knowledge and expectation of the danger, the adequacy of instructions and warnings on safe use, and the ability to eliminate or minimize the danger without seriously impairing the product or making it unduly expensive.
\end{quote}

\textit{Id.}

82. \textit{See Sperry-New Holland}, 617 So. 2d at 255 (recognizing risk-utility test "has become the trend in most federal and state jurisdictions").

83. \textit{See id.} at 256 (pointing out consumers and manufacturers benefit from courts applying risk-utility test).


85. \textit{See id.} at 1145-46 (explaining burden shift to defendant to prove product's design is not defective). The court holds:

\begin{quote}
  Once the plaintiff establishes a prima facie case showing that his injuries were caused by the product's design, the burden is shifted to the defendant to prove the design was not defective by presenting evidence of factors, such as gravity of the danger posed by the challenged design, the feasibility of a safer design, the financial cost of the improved design, etc.
\end{quote}

\textit{Id.} (emphasis in original).

86. \textit{See Wade, supra} note 80, at 837 (accounting for certain factors in risk utility analysis that are similar to consumer expectations). Wade's sixth factor accounted for "[t]he user's anticipated awareness of the dangers inherent in the
2. Warning Defect

The Supreme Court of Florida has not explicitly adopted a standard jury instruction for strict liability failure to warn. \(^{87}\) In fact, the court chose not to develop a standard jury instruction. \(^{88}\) It decided to await "further development of Florida law" before taking a specific position on strict liability failure to warn. \(^{89}\) Therefore, Florida courts are free to adopt their own jury instructions for claims of strict liability warning defect, which has created considerable confusion throughout the legal community. \(^{90}\)

In *Ferayorni v. Hyundai Motor Co.*, \(^{91}\) a seventeen year-old girl was killed in a car accident. \(^{92}\) She was driving a 1990 Hyundai Excel equipped with an automatic shoulder belt and a manual lap belt. \(^{93}\) At the time of impact, the decedent was not properly utilizing the vehicle's restraint system. \(^{94}\) Specifically, she was not wearing the lap belt and she improperly placed the shoulder harness under her arm, not over her shoulder. \(^{95}\) The improperly placed shoulder har-

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\(^{87}\) See Standard Jury Instructions-Civil Cases (99-1), 778 So. 2d 264, 271-72 (Fla. 2000) (declining to adopt standard jury instruction for strict liability failure to warn). There are, however, standard jury instructions for strict liability design defect and manufacturing defect. See id. at 271.

\(^{88}\) Id. at 272 (describing explicitly that Florida does not have standard jury instruction for strict liability warning defect). Because Florida does not have a uniform jury instruction, the lower courts are free to come up with their own jury instructions for strict liability failure to warn. See id.

\(^{89}\) Id. (noting Supreme Court of Florida is awaiting further developments in Florida law before creating standard jury instruction for warning defect). The court is offering a flexible approach until an adequate standard jury instruction is adopted. See id.

\(^{90}\) See Michael Flynn, *The Healthy Debate: A Proposal for the Addition of Negligent Failure to Warn and Strict Liability Failure to Warn Jury Instructions to the Florida Standard Jury Instructions for Product Liability Cases*, 25 Nova L. Rev. 267, 268 (2000) (finding confusion among attorneys and judges throughout Florida's legal community). "Absent this guidance from the supreme court, trial lawyers and trial judges scramble to put together jury instructions of which neither the lawyers, nor the judges, can be confident will hold up on appeal." Id. Flynn describes this as a needless debate. See id.

\(^{91}\) 711 So. 2d 1167 (Fla. Dist. Ct. App. 1998).

\(^{92}\) See id. at 1169 (mentioning decedent's car was struck by another vehicle).

\(^{93}\) See id. (describing Hyundai Excel's restraint system). "A 'manual' seatbelt must be applied by the occupant, while a 'passive' seatbelt is one which automatically moves into place around the occupant." Id. at 1169 n.1.

\(^{94}\) See id. at 1169 (noting improper use of seatbelt).

\(^{95}\) See id. (illustrating decedent's misuse of vehicle's restraint system).
ness caused internal injuries, which were the undisputed cause of her death.\textsuperscript{96}

Ferayorni's estate sued Hyundai for failing to warn of the risk associated with improper use of the seatbelt.\textsuperscript{97} At trial, the jury found for the defendant Hyundai.\textsuperscript{98} The estate appealed, claiming the trial court improperly instructed the jury on the strict liability failure to warn claim.\textsuperscript{99} On appeal, the court remanded the case for a new trial only on this claim.\textsuperscript{100} In doing so, the court clarified strict liability failure to warn law in Florida.\textsuperscript{101}

Traditionally, the negligence of a manufacturer was irrelevant when dealing with strict products liability claims; "[h]owever, a claim of strict liability arising specifically from a failure to warn may be an exception to the generally recognized distinction between negligence and strict liability."\textsuperscript{102} Courts have struggled over whether proof of manufacturers' knowledge of their products' dangerous tendencies should be a consideration in strict liability failure to warn claims.\textsuperscript{103}

In Ferayorni, the court employed a hybrid approach.\textsuperscript{104} It maintained the knowledge requirement to support a claim of strict liability for failure to warn.\textsuperscript{105} The court, however, did not go as far as equating strict liability failure to warn with negligent failure to

\textsuperscript{96.} Ferayorni, 711 So. 2d at 1169 (deeming decedent's death to be direct result of her internal injuries).

\textsuperscript{97.} See id. ("The estate's theory of the case was that Hyundai was aware that smaller drivers experience 'neck-cutting' from the shoulder harness and respond by wearing the shoulder harness under their arms.").

\textsuperscript{98.} See id. (noting estate's complaint included claims of design defect and inadequate warning).

\textsuperscript{99.} See id. (stating Ferayorni's alleged improper jury instructions were given to jury at trial).

\textsuperscript{100.} See id. at 1173 (declaring trial court incorrectly failed to instruct jury on strict liability failure to warn).

\textsuperscript{101.} See Ferayorni, 711 So. 2d at 1173 (instructing lower court to apply jury instructions for strict liability failure to warn).

\textsuperscript{102.} Id. at 1171; see also West v. Caterpillar Tractor Co., 336 So. 2d 80, 90 (Fla. 1976) ("Strict liability means negligence as a matter of law or negligence per se, the effect of which is to remove the burden from the user of proving specific acts of negligence.").

\textsuperscript{103.} See Ferayorni, 711 So. 2d at 1170 (deciding whether to incorporate negligence principles into strict liability failure to warn claims). "The issue, specifically, is whether a claim of strict liability failure to warn requires, like its counterpart in negligence, proof that the manufacturer knew or should have known of the product's dangerous propensities." Id. at 1171.

\textsuperscript{104.} See id. at 1172 (deciding to adopt neither negligence based nor pure strict liability approach in failure to warn claims).

\textsuperscript{105.} See id. (finding it unnecessary to completely dispose of actual knowledge or constructive knowledge requirements in strict liability failure to warn claims).
warn.\textsuperscript{106} By following the Supreme Court of California’s decision in \textit{Anderson v. Owens-Corning Fiberglass Corp.},\textsuperscript{107} the \textit{Ferayorni} court seemed to find a middle ground.\textsuperscript{108}

In \textit{Anderson}, the Supreme Court of California reasoned that completely eliminating the knowledge requirement would turn strict liability failure to warn into absolute liability.\textsuperscript{109} Strict liability failure to warn “require[s] a plaintiff to prove only that the defendant did not adequately warn of a particular risk that \textit{was known or knowable} in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.”\textsuperscript{110} Therefore, the reasonableness of a manufacturer’s failure to warn is irrelevant in a strict products liability failure to warn case.\textsuperscript{111}

After \textit{Ferayorni}, Florida courts recognized that “manufacturers are not required to warn of every risk which might be remotely suggested by any obscure tidbit of available knowledge, but only of those risks which are discoverable in light of the ‘\textit{generally recognized and prevailing best}’ knowledge available.”\textsuperscript{112} Aside from knowability, manufacturers have a duty to warn about the dangers associated with their products when these hazards are not obvious or well known to consumers.\textsuperscript{113} If a warning is required, the adequacy of the warning is usually a question left to the jury.\textsuperscript{114} Nevertheless, when a warning is “‘accurate, clear and unambiguous’” a judge may decide the warning is adequate as a matter of law.\textsuperscript{115}

\textsuperscript{106} See \textit{id.} (holding strict liability failure to warn claims do not require proving negligence).
\textsuperscript{107} 810 P.2d 549 (Cal. 1991).
\textsuperscript{108} See \textit{Ferayorni}, 711 So. 2d at 1172 (claiming correct balance was established in \textit{Anderson}).
\textsuperscript{109} See \textit{Anderson}, 810 P.2d at 552 (finding absolute liability contrary to public policy). If manufacturers were held liable for unknowable dangers, they would be discouraged from developing new products for fear of liability. See \textit{id.} at 556.
\textsuperscript{110} \textit{id.} at 558 (emphasis added).
\textsuperscript{111} See \textit{id.} at 558-59 (describing main difference between strict liability failure to warn and negligent failure to warn).
\textsuperscript{112} \textit{Ferayorni}, 711 So. 2d at 1172 (quoting \textit{Anderson}, 810 P.2d at 558) (emphasis in original) (recognizing strict liability failure to warn standard is higher threshold to meet when compared to negligent failure to warn). Yet, the court did not go as far as making manufacturers the insurers of their products. See \textit{id.}
\textsuperscript{113} See \textit{Thursby v. Reynolds Metals Co.}, 466 So. 2d 245, 251 (Fla. Dist. Ct. App. 1984) (explaining when manufacturers have duty to warn).
\textsuperscript{114} See \textit{Ragans v. Miriam Collins-Palm Beach Labs. Co.}, 681 So. 2d 1173, 1174 (Fla. Dist. Ct. App. 1996) (discussing whose duty it is to decide adequacy of product’s warning).
\textsuperscript{115} See \textit{id.} (quoting \textit{Felix v. Hoffmann-LaRoche, Inc.}, 540 So. 2d 102, 105 (Fla. 1989)) (observing general requirements for adequate warnings).
III. Analysis

A. Application of Design Defect Tests

For Kiley Bechler's design defect claim to prevail, she must prove Xenadrine fails either the consumer expectation test or the risk-utility test. Both tests play a significant role in assessing whether Xenadrine's design is defective because Florida courts do not specify a preference for either test. This Section highlights the critical aspects of design defect litigation by applying each test to the facts surrounding Steve Bechler's death.

1. Application of the Consumer Expectation Test

A product fails the consumer expectation test when it "fails to perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable by the manufacturer." Steve Bechler was an ordinary consumer, taking Xenadrine to lose excess weight. Kiley Bechler can argue that Xenadrine failed to perform as safely as an ordinary consumer would expect because ordinary consumers typically expect to lose weight from taking Xenadrine; they do not expect to develop serious health problems or ultimately die.

Cytodyne, the manufacturer of Xenadrine, might argue that Steve Bechler was an unintended user because he suffered from abnormal liver functions and mild hypertension prior to taking

116. For a discussion of tests courts may apply to prove a design defect, see supra notes 47-86 and accompanying text.
117. See Standard Jury Instructions-Civil Cases (99-1), 778 So. 2d 264, 271 (Fla. 2000) (describing how trial courts may apply both tests).
118. For a discussion of the application of the consumer expectation test, see infra notes 119-32 and accompanying text. For a discussion of the application of the risk-utility test, see infra notes 133-44 and accompanying text.
119. Standard Jury Instructions-Civil Cases, 778 So. 2d at 271 (indicating proper jury instruction for consumer expectation test).
120. See Washburn, supra note 3 (recounting Bechler’s reason for taking Xenadrine).
121. See Complementary and Alternative Medicine: Study calls for major reforms in marketing of ephedra, HEART DISEASE WKLv., Sept. 7, 2003, at 17 (on file with author) (claiming marketers have made “misleading statements about the safety, use, and efficacy” of ephedra supplements). A study found forty-one percent of websites marketing ephedra did not disclose the adverse effects or contraindications relating to supplement use. See id. Fifty-three percent of the websites marketing ephedra did not describe the proper dosage. See id. Thirty-four percent of the websites marketing ephedra contained misleading statements “which could result in serious harm to consumers” taking ephedra. Id. “Many of the web-sites in this study contained advertisements claiming no adverse side effects from the dietary supplement.” Id.
Xenadrine. Cytodyne may assert this defense by utilizing the majority’s reasoning in Jennings. In Jennings, the court found that cigarette lighters “are not to be used as children’s playthings” and held that a child was an unintended user of a lighter. The majority found the child to be an unintended user primarily because the packaging warned consumers to keep the lighter away from children. Because the child in Jennings was an unintended user, the court held that the lighter was not defective in design. Like the child in Jennings, Bechler may be considered an unintended user because he suffered from contraindications listed on the Xenadrine label.

Even though Cytodyne has a strong argument that Steve Bechler was an unintended user, this fact alone does not foreclose the possibility that Xenadrine is defectively designed. Kiley Bechler could argue the dissent’s position in Jennings. She can claim that her husband was a foreseeable user, or misuser, of Xenadrine. Steve Bechler used Xenadrine in a manner inconsistent with the label because he exceeded the manufacturer’s recom-

122. See Chass, supra note 5, at D5 (describing how Bechler suffered from ailments that may have contributed to his death); see also Did Xenadrine Kill Baltimore Orioles’ Steve Bechler?, at http://ultimatefatburner.com/xenadrine_steven_bechler.html (last visited Nov. 15, 2004) (explaining Bechler suffered from contraindicated symptoms). Bechler not only suffered from contraindicated symptoms, he also exceeded the recommended dosage. See id. “[Steve Bechler] was not a candidate for safe ephedra use. Simply put, Mr. Bechler should never have used Xenadrine.” Id. (emphasis in original).

123. See Jennings v. BIC Corp., 181 F.3d 1250, 1256 (11th Cir. 1999) (finding no design defect because of unintended use). For a discussion of the Jennings majority opinion, see supra notes 53-66 and accompanying text.

124. Jennings, 181 F.3d at 1256 (describing children playing with lighters as unintended users of lighters). “[L]ighters are intended to be used to set fire to things that are intended to be burned: cigarettes, cigars, candles, etc.” Id.

125. See id. (stating warning on package said to “‘[k]eep out of reach of children’”).

126. See id. (illustrating unintended users may be barred from claiming strict liability design defect).

127. For a discussion of unintended users, see supra notes 72-76 and accompanying text.

128. See Standard Jury Instructions-Civil Cases (99-1), 778 So. 2d 264, 271 (Fla. 2000) (allowing foreseeable use or misuse in strict products liability claim of design defect). “A product is unreasonably dangerous because of its design if [the product fails to perform as safely as an ordinary consumer would expect used as intended or in a manner reasonably foreseeable by the manufacturer] . . . .” Id. (emphasis added).

129. See Jennings, 181 F.3d at 1261 (Barkett, J., dissenting) (maintaining foreseeable use is distinct from unintended use).

130. See Standard Jury Instructions-Civil Cases, 778 So. 2d at 271 (leaving option available to argue foreseeable use or misuse when product is not used as intended).
mended dosage and suffered from hypertension and liver problems. Nevertheless, Bechler’s use of Xenadrine may have been “reasonably foreseeable by the manufacturer,” and the product could still be found unreasonably dangerous, and therefore, defective in design.

2. Application of the Risk-Utility Test

Xenadrine would fail the risk-utility test if “the risk of danger in the design outweighs the benefits” of the dietary supplement. In Florida, a reasonable alternative design is not explicitly required to prove a design defect; however, it is a very important factor in persuading the jury. Xenadrine-EFX, the ephedra-free version of Xenadrine, could be a reasonable alternative design to Xenadrine. In fact, the President of Cytodyne Technologies touted Xenadrine-EFX as a “better-ephedra free product” when comparing it to Xenadrine, which contains ephedra. This evidence suggests that an alternative design was available to Cytodyne at the time of Bechler’s death.

131. See Chass, supra note 5, at D5 (describing Steve Bechler’s use of Xenadrine as inconsistent with product’s label).
132. See generally Standard Jury Instructions-Civil Cases, 778 So. 2d at 272 (noting plaintiff has burden of persuasion).
133. Id. at 271 (describing proper way to apply risk-utility analysis). The plaintiff will put forth evidence to support the proposition that the risks of Xenadrine outweigh the benefits of Xenadrine. See id. The defendant will put forth evidence that Xenadrine’s benefits outweigh any risks or dangers associated with the product. See id.
134. See Radiation Tech., Inc. v. Ware Constr. Co., 445 So. 2d 329, 331 (Fla. 1983) (illustrating how Supreme Court of Florida finds reasonable alternative design important factor when applying risk-utility test).
135. See Hearings, supra note 4 (indicating Xenadrine-EFX was available in early 2002).
136. See id. (maintaining Cytodyne’s position regarding safety and efficacy of Xenadrine). In his prepared witness testimony to the House Committee on Energy and Commerce, Cytodyne Technologies President Robert Chinery acknowledged that he thought Xenadrine-EFX was a “better-ephedra free product.” See id. Chinery also noted that Cytodyne Technologies began phasing out advertising and promotion of Xenadrine in early 2002, and they completely stopped selling Xenadrine in early 2003 – coincidentally, just a short while after Steve Bechler’s death. See id.
137. See id. (admitting better alternative to Xenadrine existed at time of Bechler’s death).
When analyzing the utility of Xenadrine under a risk-utility balancing test, the "usefulness and desirability" of the product must be assessed. Obesity in the United States is a growing concern. Every year, more and more Americans are categorized as overweight or obese. Combating obesity is of the utmost importance in maintaining an individual's health, and a safe and effective dietary supplement is undoubtedly a useful product.

If the court performs a risk-utility test it will consider other factors as well. These factors include: the serious nature of Steve Bechler's injury, the availability of alternative dietary supplements, Cytodyne's ability to eliminate the ephedra found in Xenadrine while maintaining the utility of its product, Bechler's ability to avoid the dangerous propensities of Xenadrine by properly using the product, and Bechler's awareness of the dangers associated with dietary supplements containing ephedra. All of these factors will play a role in determining Cytodyne's liability under the risk-utility test.

138. See Wade, supra note 80, at 837 (depicting importance of product's utility in balancing approach). Professor Wade's first factor in assessing defectiveness is: "The usefulness and desirability of the product — its utility to the user and to the public as a whole." Id.


140. See Defining Overweight and Obesity, at http://www.cdc.gov/nccdphp/dnpa/obesity/defining.htm#Adults (last visited Nov. 15, 2004) (stating statistics for obese and overweight Americans). "Results of the National Health and Nutrition Examination Survey (NHANES) 1999-2000 indicate that an estimated 64 percent of U.S. adults are either overweight or obese, defined as having a body mass index (BMI) of 25 or more." Id.; see also Obesity Trends, at http://www.cdc.gov/nccdphp/dnpa/obesity/trend/prev_char.htm (last visited Nov. 15, 2004) (finding recent obesity trends across America). "In 2000, 38.8 million American adults met the classification of obesity, defined as having a body mass index, BMI score of 30 or more. Between 2000 and 2001 obesity prevalence climbed from 19.8 percent of American adults to 20.9 percent of American adults." Id.

141. See Hearings, supra note 4 (stating Cytodyne has received responses from thousands of people who have "lost weight and have improved their quality of life").

142. See Wade, supra note 80, at 837 (describing factors used when evaluating defective and unreasonably dangerous products).

143. See id. (illustrating seven factors used in risk-utility analysis). For a discussion of Professor Wade's seven factors, see supra note 80 and accompanying text.

144. See Wade, supra note 80, at 837 (noting factors may be used when assessing potential liability).
B. Application of the Warning Defect Test

Under strict liability failure to warn, a product may be defective because of an inadequate warning.\footnote{See Ferayorni v. Hyundai Motor Co., 711 So. 2d 1167, 1170 (Fla. Dist. Ct. App. 1998) (observing products may still be rendered defective if warning is inadequate). "[A] product may be defective by virtue of a design defect, a manufacturing defect, or an inadequate warning." Id.} Manufacturers and sellers may not avoid liability simply by placing warnings on their products.\footnote{See Flynn, supra note 90, at 269 ("[T]he mere existence of a warning is not dispositive of the adequacy of the warning.").} The warning "should contain some wording directed to the significant dangers arising from failure to use the product in the prescribed manner, such as the risk of serious injury or death."\footnote{Brown v. Glade & Grove Supply, Inc., 647 So. 2d 1033, 1036 (Fla. Dist. Ct. App. 1994) (describing how inadequate wording may render product defective). "The mere existence of warnings . . . is not dispositive of the adequacy of the warning for several reasons. A warning may be defective not only by virtue of inadequate warning, but as a result of its location and the manner in which the warning is conveyed." Id. at 1035.} If a warning does not convey the actual risk associated with the use of the product, the warning is inadequate and that product is defective.\footnote{See Flynn, supra note 90, at 269-70 (noting both manufacturer and seller may be liable).}

Xenadrine’s warning label did not communicate that death or serious injury could result from taking the dietary supplement.\footnote{See Gary Mihoces, USA TODAY.COM, Ephedrine under baseball’s microscope, at http://www.usatoday.com/sports/baseball/2003-02-20-cover-ephedrine-baseball_x.htm (Feb. 20, 2003) (explaining contents of Xenadrine’s warning).} The label did, however, suggest consulting a physician or licensed health care professional if the user suffered from an assortment of ailments.\footnote{See id. (describing warning on Xenadrine bottle). Xenadrine’s warning label reads: “Consult a physician or licensed health professional before using this product if you are at risk of, have a family history of, or are being treated for” assorted conditions, including high blood pressure (hypertension) and liver problems.” Id.} Steve Bechler did not heed this suggestion, as he did not consult a health care professional before using Xenadrine.\footnote{See Chass, supra note 5, at D5 (noting Bechler had abnormal liver functions and mild hypertension prior to taking Xenadrine).}

An adequate warning must make the danger of a product apparent to the consumer.\footnote{See Am. Cyanamid Co. v. Roy, 466 So. 2d 1079, 1082 (Fla. Dist. Ct. App. 1984) (stating product’s warning label should clarify any dangerous consequences). “To warn adequately, the product must make apparent the potential harmful consequences.” Id.} Kiley Bechler could argue that Xenadrine’s warning label did not convey a sufficiently forceful message that would adequately warn a reasonable person of the
product's serious dangers. If the wording of Xenadrine’s warning label was not sufficiently frightening, then the warning may be deemed inadequate and the product defective. Ultimately, the issue of adequacy is reserved for the finder of fact.

C. The Relationship Between Warning Defect and Design Defect

Distinguishing a design defect from a warning defect is critical when assessing a manufacturer’s potential liability in a strict products liability lawsuit. These two areas of strict products liability law frequently overlap and require manufacturers to strike a balance between a product’s design and warning. Therefore, a

153. See id. ("The warning should be of such intensity as to cause a reasonable man to exercise for his own safety caution commensurate with the potential danger.").

154. See id. (describing failure to give adequate warning may result in awarding punitive damages); see also Hildy Bowbeer et al., Warning! Failure to Read this Article May Be Hazardous to Your Failure to Warn Defense, 27 WM. MITCHELL L. REV. 499, 453 (2000) (noting adequate warnings clearly describe potential dangers to consumers).

155. See Bowbeer, supra note 154, at 453 ("Ordinarily, the question of whether a given warning is adequate is left to the finder of fact."). One may find James Sales’ seven factors helpful when determining the adequacy of a warning. See id. These factors provide:

First, a warning must be conspicuous. It must be printed in such a manner as to assure that a user’s attention will be attracted to its message. Second, it should use symbols when appropriate. For example, a skull and crossbones device may be necessary in addition to written warnings if the product can cause death. Third, it must sufficiently communicate the risk of danger associated with the product. In that regard, the warning must be qualitatively sufficient to impart the particular risk of harm. Fourth, the warning must be located where the user is likely to encounter it. In some cases, placement of the warning in an owner’s manual or package insert will be sufficient; in others, placement on the product itself may be required. In the latter case, the warning must be placed where it will catch the user’s eye. Fifth, the warning must be clear and unambiguous. Its content must not be vague or otherwise minimize the likelihood of the very harm it is seeking to put the user on guard of. Sixth, the warning must be sufficiently broad and encompassing and not unduly limited in scope. If the product can reasonably be put to a number of uses, the warning should address each. Seventh, the warning must be undiluted. That is, the manufacturer cannot engage in marketing or promotional activities, which tend to negate the very dangers the warning speaks of.

Id. at 453-54 (footnotes omitted).

156. See, e.g., Silverglate, supra note 48, at 14 (explaining relationship between product warnings and product design).

157. See id. (balancing need for product warnings and product design under Florida law).
court's application of the law plays a significant role in assessing a manufacturer's or seller's liability for defective products.\textsuperscript{158}

In 1976, Florida adopted strict liability as set forth by the Restatement (Second) of Torts section 402A.\textsuperscript{159} "Since then, Florida [strict] products liability law has proceeded in anything but a straight line."\textsuperscript{160} To provide some clarity, Florida courts have adopted specific jury instructions for strict product liability claims of design defect and manufacturing defect.\textsuperscript{161} The courts, however, have not provided standard jury instructions for strict liability duty to warn, which has created considerable confusion.\textsuperscript{162}

Striking the proper balance between the manufacturer's obligation to design safe products and holding consumers responsible for adhering to product warnings is a problem that has been addressed in other jurisdictions.\textsuperscript{163} In \textit{Delaney v. Deere & Co.},\textsuperscript{164} the Kansas Supreme Court considered that adequate warnings do not always save a product from being defective in design.\textsuperscript{165} While analyzing the effects of placing an adequate warning on a product that

\begin{itemize}
  \item \textsuperscript{158} See \textit{id.} at 14-16 (describing results in cases where product designs and product warnings are balanced to assess defectiveness).
  \item \textsuperscript{159} See \textit{West v. Caterpillar Tractor Co.}, 336 So. 2d 80, 87 (Fla. 1976) (following trend of states adopting § 402A). For a further discussion of \textit{West}, see \textit{supra} notes 39-40 and accompanying text.
  \item \textsuperscript{160} Silverglate, \textit{supra} note 48, at 14. "Even today, considerable confusion and disagreement exist in Florida as to the present state of products liability law." \textit{Id.}
  \item \textsuperscript{161} See Standard Jury Instructions-Civil Cases (99-1), 778 So. 2d 264, 272 (Fla. 2000) (listing applicable jury instructions for strict products claims); \textit{see also} Flynn, \textit{supra} note 90, at 272 (positing Florida should provide standard jury instructions on strict liability duty to warn).
  \item \textsuperscript{162} See Flynn, \textit{supra} note 90, at 267-68 (indicating need for standard jury instructions for strict liability failure to warn claims). "Absent this guidance from the supreme court, trial lawyers and trial judges scramble to put together jury instructions of which neither lawyers, nor the judges, can be confident will hold up on appeal." \textit{Id.} at 268.
  \item \textsuperscript{163} See Silverglate, \textit{supra} note 48, at 12 (highlighting case law that describes relationship of product warnings to design defect).
  \item \textsuperscript{164} 999 P.2d 930 (Kan. 2000).
  \item \textsuperscript{165} See \textit{id.} at 946 (holding "an adequate warning does not foreclose a finding that a product is defectively designed"). The court in \textit{Delaney} clearly stated the issue as:

Does Kansas follow the portion of Comment j of the Restatement (Second) of Torts § 402A, which provides that a product bearing an adequate warning is not in defective condition, or instead, would Kansas now adopt Comment l of the Restatement (Third) of Torts § 2, which provides that an adequate warning does not foreclose a finding that a product is defectively designed?

\textit{Id.} at 940.
\end{itemize}
could have been better designed, the court in *Delaney* described the conflicting positions of the Second and Third Restatements.166

Comment j of the Restatement (Second) of Torts section 402A provides that “a product bearing an adequate warning is not in [a] defective condition.”167 On the other hand, comment l of the Restatement (Third) of Torts section 2 “provides that an adequate warning does not foreclose a finding that a product is defectively designed.”168 In *Delaney*, the court declined to adopt either Restatement's interpretation of the effect of an adequate warning on a design defect and instead chose to adopt its own view.169 The Kansas Supreme Court held that an adequate warning does not foreclose finding a product defective in design; however, the court did not flatly adopt comment l of the Third Restatement either.170

Florida courts have not explicitly stated their position on whether an adequate warning precludes a claim for design defect.171 Their reluctance in adopting a steadfast view has been described as establishing “a reasonable balance between the manufacturer’s obligation to design safe products and its right to have its warnings and instructions heeded.”172 By not clearly rejecting or accepting either comment j of Restatement (Second) of

166. See id. at 940 (deciding whether Kansas follows comment j of Restatement (Second) of Torts § 402A or comment l of Restatement (Third) of Torts § 2).

167. Id. (explaining Second Restatement's view on warnings). “Where warning is given, the seller may reasonably assume that it will be read and heeded; and a product bearing such a warning, which is safe for use if it is followed, is not in defective condition, nor is it unreasonably dangerous.” *Restatement (Second) of Torts* § 402A cmt. j (1965).

168. *Delaney*, 999 P.2d at 940 (interpreting Third Restatement's view). The Third Restatement provides:

_Relationship between design and instruction or warning._ Reasonable designs and instructions or warnings both play important roles in the production and distribution of reasonably safe products. In general, when a safer design can reasonably be implemented and risks can reasonably be designed out of a product, adoption of the safer design is required over a warning that leaves a significant residuum of such risks. *Restatement (Third) of Torts: Products Liability* § 2 cmt. 1 (1997) (emphasis in original).

169. See *Delaney*, 999 P.2d at 946 (choosing not to adopt either Restatements' position).

170. See id. (refusing to adopt Third Restatement's point of view and holding adequate warnings do not preclude design defect claims).

171. See Silverglate, *supra* note 48, at 14 (maintaining Florida law "has proceeded in anything but a straight line" since adopting strict products liability doctrine in *West*); see also Standard Jury Instructions-Civil Cases (99-1), 778 So. 2d 264, 272 (Fla. 2000) (declining to give instruction on strict liability failure to warn claims).

Torts section 402A or comment l of Restatement (Third) of Torts section 2, Florida is taking a Delaney-like approach to strict product liability claims by combining warning and design defect. This case-by-case approach will have a direct impact on the court's assessment of Kiley Becheler's claims against Cytodyne Technologies.

IV. CONCLUSION

Dietary supplements containing ephedra are a danger for certain people, namely athletes. Individuals suffering from any one of fourteen ailments listed on the warning label should not take Xenadrine. Steve Bechler suffered from two such ailments, which rendered him an unfit candidate to take Xenadrine. On the other hand, Xenadrine's warning label did not indicate the serious risks associated with product misuse.

The tragic events surrounding Steve Bechler's death highlight a murky area of Florida strict products liability law. For example, if the warning label on the bottle of Xenadrine is defective, then

173. See generally Delaney, 999 P.2d at 940-46 (rejecting rigid approach that products with adequate warnings are immune from claims of design defectiveness).

174. See Silverglate, supra note 48, at 14-16 (analyzing various Florida cases where adequate warnings precluded defective design claims).

175. See Metabolife Int'l, Inc. v. Wornick, 264 F.3d 832, 852 (9th Cir. 2001) (claiming over 800 Adverse Event Reports were associated with ephedrine-based products in 1997). "In 1997, for example, the FDA proposed a rule establishing a dosage regimen and labeling requirements for dietary supplements containing ephedrine alkaloids such as ma haung." Id. The proposed rule was in response to known serious health risks, such as stroke and death. See id. See generally Proceed With Caution: How Safe Is Weight Loss Supplement Xenadrine?, ABC NEWS.com, at http://abcnews.go.com/sections/GMA/GoodMorningAmerica/GMA011121Xenadrine_risks.html (last visited Sept. 24, 2004) [hereinafter Proceed With Caution] (highlighting dangers of Xenadrine). Since 1994, the FDA has received over 1,400 complaints of health problems associated with dietary supplements containing ephedra. See id. These consumer complaints included high blood pressure, strokes, and heart attacks. See id.

176. See Proceed With Caution, supra note 175 (listing fourteen ailments that preclude Xenadrine use). The fourteen ailments include: "high blood pressure, liver problems, thyroid problems, diabetes, pernicious anemia, nervousness, anxiety, depression, seizure disorder, cardiac arrhythmias, stroke, pheochromocytoma, prostate enlargement and psychiatric disease." Id. The Xenadrine label also cautions "not to exceed the recommended dosages." Id.

177. See Chass, supra note 5, at D5 (noting Bechler suffered from abnormal liver functions and mild hypertension).

178. See generally id. (noting warning does not explicitly mention that death could result from taking Xenadrine). Dietary supplements containing ephedra have been advertised as natural and safe products. See id.

179. See Silverglate, supra note 48, at 17 (finding Florida law unclear). For a discussion of the unsettled areas of Florida Strict Liability failure to warn, see supra notes 159-62 and accompanying text.
Cytodyne Technologies will be held strictly liable. If the label is adequate, the warning is not defective, and the court’s application of the consumer expectation and the risk-utility tests take center stage.

Precedent highlights the difficulties of finding a product defective in design after establishing that an adequate warning existed on the product. The current approach of the Florida courts, while somewhat complex, is a flexible and reasonable alternative. The hard-line approach of the Third Restatement, emphasizing product design over the use of warnings, seems harsh to manufacturers. On the other hand, the Second Restatement’s approach seems to foreclose many legitimate consumer claims. By sitting on the fence between the two Restatements, Florida appears to be striking a reasonable balance for both plaintiffs and defendants in warning and design defect cases.

After several high profile deaths, the FDA finally intervened and began taking drastic measures to warn consumers of the dangers associated with ephedra. First, the FDA suggested that labels of dietary supplements containing ephedra should warn consumers about serious adverse reactions such as heart attacks, seizures, strokes, and death. Next, on December 30, 2003, the

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180. See generally Bowbeer, supra note 154, at 441 (indicating strict liability failure to warn claims may find otherwise safe products defective).
182. For a discussion of the difficulties the Jennings court had in finding defectiveness, see supra notes 53-75 and accompanying text.
183. See Silverglate, supra note 48, at 17 (stating Florida courts should continue using “common sense approach”).
185. See Restatement (Second) of Torts § 402A cmt. j (1965) (foreclosing design defect claim if adequate warning is present on product).
186. See Silverglate, supra note 48, at 17 (depicting reasonable balance in Florida’s approach to balancing product design and product warning).
187. See Christopher Drew, Official Urges Ban Of Ephedra By Baseball, N.Y. Times, July 25, 2003, at D1 (reporting FDA commissioner urged major league baseball to ban ephedra). “The FDA has been scrutinizing dozens of deaths, including some high school athletes, that might be linked to ephedra.” Id. at D3. The FDA reviewed more than 17,000 consumer complaints relating to ephedra-based dietary supplements. See id.
188. See generally HHS Acts to Reduce Potential Risks of Dietary Supplements Containing Ephedra, at http://www.fda.gov/bbs/topics/NEWS/2003/NEW00875.html (Feb. 28, 2003) (announcing series of actions aimed at protecting consumers from dietary supplements containing ephedra). Based on new medical evidence, the FDA became increasingly concerned about the implications of potentially serious
FDA announced plans to prohibit the sale of dietary supplements containing ephedra. In its ruling, the FDA publicly announced that dietary supplements containing ephedra "present an unreasonable risk of illness or injury." This ruling became effective on April 12, 2004.

The FDA's ruling sent shockwaves throughout the dietary supplement industry, and companies like Cytodyne are heading for the hills. Cytodyne has already changed its name to Nutraquest and health risks associated with ephedra-based dietary supplements. See id. The FDA took a proactive approach by proposing a warning label for all ephedra-containing dietary supplements. See id. The FDA noted:

The proposed label [for ephedra containing dietary supplements] warns about the risks of serious adverse events, including heart attack, seizure, stroke, and death; cautions that the risk can increase with the dose, with strenuous exercise, and with other stimulants such as caffeine; specifies certain groups (such as women who are pregnant or breast feeding) who should never use these products; and lists other conditions, such as diseases and the use of certain medications, that rule out the use of ephedrine alkaloids.

As Kiley Bechler's argument goes, had Steve Bechler been informed of the possibility that he could die from taking Xenadrine, he might still be alive today. See Complaint, supra note 16, at 13 (stating warning label did not warn that use of Xenadrine could lead to death). Kiley Bechler's complaint claims the warning was inadequate because it failed to warn of the possibility of death. See id. "Nowhere does it warn on the label that reducing food intake or engaging in exercise while also consuming ephedra or Xenadrine RFA-1 can be harmful or even fatal; to the contrary, the label encourages use of the product in conjunction with dieting and exercise." Id. (emphasis in original).


See Dietary Supplements that Present a Significant or Unreasonable Risk: Dietary supplements containing ephedrine alkaloids, 21 C.F.R. § 119.1 (2004).

Id. Stating that:

Dietary supplements containing ephedrine alkaloids present an unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in labeling, under ordinary conditions of use. Therefore, dietary supplements containing ephedrine alkaloids are adulterated under section 402(f)(1)(A) of the Federal food, Drug, and Cosmetic Act.

See id. (stating date that final rule goes into effect).

See Michael O'Keeffe, QUEST FOR THE TRUTH: Lawsuits, creditors have supplement company on the defensive, N.Y. DAILY NEWS, Nov. 3, 2003, at 62 (stating recent developments in bankruptcy litigation have garnered media attention). "Some fear Nutraquest filed for bankruptcy to duck court judgments, protect president Bob Chinery's personal assets and thwart future lawsuits." Id.
filed for chapter eleven bankruptcy protection. Nevertheless, both lawyers and creditors are chomping at the bit to get a piece of the estimated 350 to 600 million dollars in Xenadrine proceeds alone. In the meantime, with her case only in the pretrial litigation phase, Kiley Bechler waits for another painful chapter in her life to come to a close.

Michael Kane

194. See id. (describing how Cytodyne sold Xenadrine to another company and then changed its name to Nutraquest).

195. See id. (stating seventy lawsuits are currently pending against Cytodyne, a.k.a. Nutraquest). Most of the pending lawsuits are products liability cases. See id.