2005

Strictly Speaking about Ephedra: A Baseball Tragedy Helping to Define the Dynamic between Warning Defect and Design Defect

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Recommended Citation
Michael Kane, Strictly Speaking about Ephedra: A Baseball Tragedy Helping to Define the Dynamic between Warning Defect and Design Defect, 12 Jeffrey S. Moorad Sports L.J. 97 (2005). Available at: https://digitalcommons.law.villanova.edu/mslj/vol12/iss1/4

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STRICKLY 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. 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.

Just several months earlier, Steve Bechler reported to the Baltimore Orioles spring training camp ten pounds overweight. To lose weight for the upcoming baseball season, Bechler took an over-the-counter dietary supplement called Xenadrine RFA-1 ("Xenadrine"), which contains ephedra. Bechler reportedly took three Xenadrine capsules each morning, one capsule over the recommended dosage printed on the bottle. On Friday, February 14,

1. See Thomas Loverro, Bechler has an eternal presence at Camden, WASH. TIMES, Aug. 18, 2003, at C1 (describing how Kiley Bechler spread her husband’s ashes on Camden Yards’ main pitcher’s mound and two other pitching mounds located in ballpark’s bullpen after Sunday’s Baltimore Orioles-New York Yankees game).

2. See id. ("I think this is where he would want to be,’ Kiley Bechler said. ‘It adds a little closure to everything that has been going on and brings a little bit of joy to a pretty sad situation.").

3. See Gary Washburn, Ephedrine cited in Bechler’s death, at http://baltimore.orioles.mlb.com/NASApp/mlb/bal/news/bal_news.jsp?ymd=20030226&content_id=204807&vkey=spt2003news&ext=.jsp (Feb. 26, 2003) (explaining Bechler’s physical condition was not as it was in past seasons). Bechler was listed at 239 pounds and reported to spring training weighing approximately 249 pounds. See id.

4. See id. (discussing how Xenadrine is used for weight-loss by increasing metabolism speed and heart rate). Xenadrine is manufactured by both Cytodyne Technologies and Phoenix Laboratories. See id.; see also Ex parte Gen. Nutrition Corp., 855 So. 2d 475, 478 (Ala. 2003) (describing how woman’s use of Xenadrine, which contains ephedra, may have contributed to her sudden cardiac death). While Steve Bechler was taking Xenadrine with ephedra, it must be noted that an ephedra-free version of the dietary supplement Xenadrine-EFX ("EFX") was on the market and available for consumption. See Issues Relating to Ephedra-containing Dietary Supplements: Hearings Before the Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce, 108th Cong. (2003) [hereinafter Hearings] (prepared statement of Robert Chinery) (describing how Cytodyne Technologies launched ephedra-free Xenadrine-EFX in early 2002), available at http://energy commerce.house.gov/108/Hearings/07232003hearing1021/Chinery1640.htm.

For a further discussion of ephedra, see infra notes 23-27 and accompanying text.

5. See Murray Chass, Pitcher’s Autopsy Lists Ephedra as One Factor, N.Y. TIMES, Mar. 14, 2003, at D5 (stating Xenadrine’s recommended dosage as two tablets per morning and two tablets per afternoon).
2003, Bechler reported to training camp and passed a routine physical examination. Later that day, Bechler completed the Orioles’ first day of drills at spring training without incident. Two days later, however, Steve Bechler suddenly collapsed on the practice field from heat exhaustion.

Orioles’ trainers examined the twenty-three year-old pitcher at the training facility, but were unable to help him. 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. At 10:10 a.m., on Monday, February 17, 2003, Steve Bechler died.

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

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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-

\textsuperscript{14} See Peter Schmuck, \textit{Bechler’s widow sues companies for $600M; Lawsuit alleges ephedra killed Orioles pitcher}, BALT. SUN, July 18, 2003, at D1 (stating Kiley Bechler filed her lawsuit in United States District Court in Fort Lauderdale). Kiley Bechler filed her lawsuit against Cytodyne Technologies, Phoenix Laboratories, and Cytodyne president Robert Chinery on Wednesday, July 16, 2003. \textit{See id.} The lawsuit also named an unidentified company which sold the dietary supplement to Steve Bechler. \textit{See id.}

\textsuperscript{15} \textit{See id.} (alleging defendants disregarded safety of consumers in order to bolster profits).

\textsuperscript{16} \textit{See Complaint of Kiley Bechler at 11-16, Kiley Bechler v. Cytodyne Techs., Inc. (S.D. Fla, July 16, 2003) (No. 03-61369) [hereinafter \textit{Complaint}]} (claiming negligence, breach of express warranty, breach of implied warranty, and three counts of strict liability for inherently, unreasonably dangerous product, failure to warn, and misrepresentations).

\textsuperscript{17} For a discussion of design defect, see \textit{infra} notes 47-86 and accompanying text. For a discussion of warning defect, see \textit{infra} notes 87-115 and accompanying text.

\textsuperscript{18} For a discussion of the relationship between warning defect and design defect, see \textit{infra} notes 156-74 and accompanying text.

\textsuperscript{19} For a discussion of pertinent Florida strict products design defect case law, see \textit{infra} notes 47-86 and accompanying text. For a discussion of pertinent Florida strict products warning defect case law, see \textit{infra} notes 87-115 and accompanying text.

\textsuperscript{20} For a discussion of the application of the consumer expectations test to the circumstances surrounding Steve Bechler’s death, see \textit{infra} notes 119-32 and accompanying text. For a discussion of the application of the risk-utility test to the circumstances surrounding Steve Bechler’s death, see \textit{infra} notes 133-44 and accompanying text.

\textsuperscript{21} For a discussion of Florida’s policy-driven view of strict products liability law, see \textit{infra} notes 179-86 and accompanying text.
ments, including recent FDA action, and the grim future of ephedra.\textsuperscript{22}

II. BACKGROUND

A. The Attack on Ephedra

Ephedra, also known as ma huang, is a natural substance derived from plants.\textsuperscript{23} In China, ephedra has been used for thousands of years to treat various respiratory ailments.\textsuperscript{24} Today, the plant is crushed and formulated into pills, teas, and other forms, and sold as dietary supplements.\textsuperscript{25} Dietary supplements are promoted by the industry as diet aids, muscle builders, and energy boosters.\textsuperscript{26} These claims, however, have never been substantiated.\textsuperscript{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.\textsuperscript{28} Instead, before a dietary supplement can be removed from the market, the Federal Drug Administration ("FDA") must prove that the supplement is unsafe.\textsuperscript{29} Under this regulatory system, dangerous products,

\textsuperscript{22} For a discussion of current events regarding ephedra, see infra notes 187-95 and accompanying text.


\textsuperscript{24} See Supplement, supra note 23, at A14 (describing origins and medical uses of ephedra in China). "Ephedra contains two alkaloids, ephedrine and pseudoephedrine. These compounds can combat congestion and ease breathing in some conditions." Id.

\textsuperscript{25} See id. (finding some form of ephedra in nearly 200 different dietary supplements). All of these supplements were sold without a prescription. See id.

\textsuperscript{26} See id. ("Manufacturers and retailers have claimed the herb is good for weight control, building muscle and boosting energy.").

\textsuperscript{27} See Mark B. McClellan, Remark of the Commissioner of Food and Drugs, 58 FOOD & DRUG L.J. 191, 200 (2003) (describing how manufacturers of ephedra products make unsubstantiated claims about enhancing athletic performance).

\textsuperscript{28} See Lauren J. Sloane, Comment, Herbal Garden of Good and Evil: The Ongoing Struggles of Dietary Supplement Regulation, 51 ADMIN L. REV. 323, 326-27 (1999) (defining obligations of FDA when regulating dietary supplements); see also Donald G. McNeil, Jr., Sometimes, the Labels Lie, N.Y. TIMES, Sept. 9, 2003, at F7 (discussing dietary supplement manufacturers do not have to prove their products work). "That’s how products like ephedra end up on shelves and in magazine advertisements before it’s discovered that they can kill people." Id.

\textsuperscript{29} See Sloane, supra note 28, at 326 (showing difficulties with regulating dietary supplements after imposition of DSHEA).
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...

\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. \textit{See id.} "The Food and Drug Administration has reported 129 deaths associated with ephedra since 1993. Dietary supplements, unlike drugs, do not need the agency’s approval before going on the market." \textit{Id.}

\textsuperscript{31} See Ford Fessenden, \textit{Studies of Dietary Supplements Come Under Growing Scrutiny}, N.Y. TIMES, June 29, 2003, at A1 (explaining how industry research is less than scientific and frequently misleading to consumers).

\textsuperscript{32} \textit{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. Syn said in ruling on a class action suit, but [Cytodyne] had also cajoled some researchers into judging results in published scientific articles." \textit{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).}

\textsuperscript{33} \textit{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.” \textit{Id.}

\textsuperscript{34} \textit{See Register, 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. \textit{See id.}

\textsuperscript{35} \textit{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. \textit{See id.}
husband's heat stroke and death in 2001.\textsuperscript{36} 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.\textsuperscript{37}

B. Strict Products Liability\textsuperscript{38}

In \textit{West v. Caterpillar Tractor Co.},\textsuperscript{39} the Florida Supreme Court adopted the doctrine of strict liability as set out in the Restatement (Second) of Torts Section 402A.\textsuperscript{40} 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."\textsuperscript{41} A plaintiff does not need to prove that a manufacturer was negligent to succeed in a strict products liability action.\textsuperscript{42} The policy

\begin{itemize}
\item \text{36. See Chris Williams, Vikings raise ephedra as 'causal link' to Stringer's fatal heat-stroke, USA TODAY.COM, Feb. 25, 2003 (commenting on Kelci Stringer's 100 million dollar wrongful death lawsuit against Vikings), available at http://www.usatoday.com/sports/football/nfl/vikings/2003-02-25-stringer-ephedra_x.htm. Ripped Fuel, a dietary supplement containing ephedra, was found in Stringer's locker on the day of his death. See id. The examining doctors did not find any direct evidence that Stringer took Ripped Fuel on the morning of his death. See id. The National Football League banned ephedra after Stringer's death. See id.}
\item \text{37. See Complaint, supra note 16, at 11-14 (detailing Kiley Bechler's strict liability claims).}
\item \text{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.}
\item \text{39. 336 So. 2d 80 (Fla. 1976).}
\item \text{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:}
\item \text{(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}
\item \text{(a) the seller is engaged in the business of selling such a product, and}
\item \text{(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.}
\item \text{(2) The rule stated in Subsection (1) applies although}
\item \text{(a) the seller has exercised all possible care in the preparation and sale of his product, and}
\item \text{(b) the user or consumer has not brought the product from or entered into any contractual relation with the seller.}
\item \text{Id.}
\item \text{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.}
\item \text{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]..."}
\end{itemize}
surrounding strict products liability is premised on the manufacturer's ability to better bear the costs of injuries resulting from defective products.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.44 The three theories used when considering a product's defectiveness are design defect, manufacturing defect, and warning defect.45 Because this Comment focuses on the relationship between design defect and warning defect, manufacturing defect will not be discussed.46

1. Design Defect

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

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

43. 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.”); see also West, 336 So. 2d at 92 (stating similar rationale for holding manufacturers liable for defective products).

44. 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].” Id. at 1143.

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

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

47. 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).

48. See id. at 272 (stating either test is acceptable, or even both); see also Spencer H. Silverglate, 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 [. however,] . . . consumer expectations . . . may be considered as part of the risk-utility balancing test.” 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.* An attorney should make a timely objection when he or she is faced with a general verdict, and the jury has been instructed on both the consumer expectation test and the risk-utility test. *See 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 1255 (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.*
ida. 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.

57. See id. at 1253 (discussing procedural history).
58. See Jennings, 181 F.3d at 1253 (explaining facts and procedural history). Originally, the lawsuit was filed in Florida state court, but the defendant removed it to federal court. See id. While the court granted BIC's motion for summary judgment, the jury rendered verdicts in favor of the other defendants. See id. at 1253-54.
59. See id. at 1254 ("Jennings appeals the trial court's grant of summary judgment to BIC, its denial of leave to amend, and its evidentiary rulings. Jennings also appeals the jury verdict on the ground that the trial court gave erroneous instructions.").
60. See id. (arguing BIC should have designed lighter with child-proof features).
61. Id. at 1255 (emphasis in original) (determining design defectiveness by using objective standards, not subjective standards).
62. See Standard Jury Instructions-Civil Cases (99-1), 778 So. 2d 264, 271 (Fla. 2000) (articulating Florida Supreme Court's jury instructions for strict liability, 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 when used as intended or in a manner reasonably foreseeable by the manufacturer] [or] [the risk of danger in the design outweighs the benefits]." Id. (alterations in original). The jury instructions for design defect give Florida courts flexibility to define "unreasonably dangerous" by using the consumer expectation test, the risk-utility test, or both. See id. at 272. The Florida Supreme Court does not prefer either test. See id. Therefore, trial courts must determine what test is appropriate on a case-by-case basis. See id.
63. See Jennings, 181 F.3d at 1255 (applying consumer expectation test).
64. See id. (differentiating between two tests). "The consumer expectation test requires consideration of the ordinary consumer's expectations." Id.
65. See id. (finding lighter could be defective by three year-old child's subjective standard).
66. See id. at 1255-56 (declaring neither consumer expectation test or risk-utility test use subjective "child's-perspective standard" to find defectiveness); see also Standard Jury Instructions, 778 So. 2d at 271 (using ordinary consumer standard
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

for consumer expectation test). The ultimate burden of persuasion is on the plaintiff to prove the manufacturer's product is unreasonably dangerous. See id. at 272.

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

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}

\textsuperscript{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").

\textsuperscript{75} See \textit{id.} (predicting different result if majority had applied reasonable foreseeability standard).

\textsuperscript{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.

\textsuperscript{77} See 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).

\textsuperscript{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.}

\textsuperscript{79} See \textit{id.} (explaining risk-utility test).

\textsuperscript{80} See 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:

(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 avoidability, because of general public knowledge of the
The risk-utility test is another way to determine whether a product design is unreasonably dangerous to consumers.\(^{81}\) Over the last decade, the national judicial trend has been to apply the risk-utility test instead of the consumer expectation test.\(^{82}\) Courts have recognized that the risk-utility test provides a useful balance, protecting both consumers and manufacturers.\(^{83}\)

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.\(^{84}\) 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.\(^{85}\) Inevitably, certain consumer expectations will creep into the risk-utility balancing formula.\(^{86}\)

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\(^{81}\) Id. at 256 n.3 (quoting John W. Wade, *On the Nature of Strict Tort Liability for Products*, 44 Miss. L.J. 825, 837 (1973)).

\(^{82}\) 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:

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.

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

\(^{84}\) See *Cassisi v. Maytag Co.*, 396 So. 2d 1140, 1144-45 (Fla. Dist. Ct. App. 1981) (mentioning risk-utility balancing approach may include consumer expectations of product utility).

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

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.

\(^{86}\) 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 product..."
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.


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.96

Ferayorni’s estate sued Hyundai for failing to warn of the risk associated with improper use of the seatbelt.97 At trial, the jury found for the defendant Hyundai.98 The estate appealed, claiming the trial court improperly instructed the jury on the strict liability failure to warn claim.99 On appeal, the court remanded the case for a new trial only on this claim.100 In doing so, the court clarified strict liability failure to warn law in Florida.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.”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.103

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

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

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.”).

98. See id. (noting estate’s complaint included claims of design defect and inadequate warning).

99. See id. (stating Ferayorni’s alleged improper jury instructions were given to jury at trial).

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

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

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.”).

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.

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

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

In Anderson, the Supreme Court of California reasoned that completely eliminating the knowledge requirement would turn strict liability failure to warn into absolute liability.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 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."110 Therefore, the reasonableness of a manufacturer's failure to warn is irrelevant in a strict products liability failure to warn case.111

After 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 'generally recognized and prevailing best' knowledge available."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.113 If a warning is required, the adequacy of the warning is usually a question left to the jury.114 Nevertheless, when a warning is "'accurate, clear and unambiguous'" a judge may decide the warning is adequate as a matter of law.115

106. See id. (holding strict liability failure to warn claims do not require proving negligence).
108. See Ferayorni, 711 So. 2d at 1172 (claiming correct balance was established in Anderson).
109. See 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 id. at 556.
110. Id. at 558 (emphasis added).
111. See id. at 558-59 (describing main difference between strict liability failure to warn and negligent failure to warn).
112. Ferayorni, 711 So. 2d at 1172 (quoting 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 id.
115. See id. (quoting 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 WKLY., 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 websites in this study contained advertisements claiming no adverse side effects from the dietary supplement.” Id.
Xenadrine. 122 Cytodyne may assert this defense by utilizing the majority’s reasoning in Jennings. 123 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. 124 The majority found the child to be an unintended user primarily because the packaging warned consumers to keep the lighter away from children. 125 Because the child in Jennings was an unintended user, the court held that the lighter was not defective in design. 126 Like the child in Jennings, Bechler may be considered an unintended user because he suffered from contraindications listed on the Xenadrine label. 127

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. 128 Kiley Bechler could argue the dissent’s position in Jennings. 129 She can claim that her husband was a foreseeable user, or misuser, of Xenadrine. 130 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_steve_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.131 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.132

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.133 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.134 Xenadrine-EFX, the ephedra-free version of Xenadrine, could be a reasonable alternative design to Xenadrine.135 In fact, the President of Cytodyne Technologies touted Xenadrine-EFX as a “better-ephedra free product” when comparing it to Xenadrine, which contains ephedra.136 This evidence suggests that an alternative design was available to Cytodyne at the time of Bechler’s death.137

131. See Chass, supra note 5, at D5 (describing Steve Bechler’s use of Xenadrine in 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.\(^{138}\) Obesity in the United States is a growing concern.\(^{139}\) Every year, more and more Americans are categorized as overweight or obese.\(^{140}\) 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.\(^{141}\)

If the court performs a risk-utility test it will consider other factors as well.\(^{142}\) 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.\(^{143}\) All of these factors will play a role in determining Cytodyne's liability under the risk-utility test.\(^{144}\)

\(^{138}\) See Wade, \textit{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." \textit{Id.}


\(^{140}\) See \textit{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." \textit{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 \textit{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, \textit{supra} note 80, at 837 (describing factors used when evaluating defective and unreasonably dangerous products).

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

\(^{144}\) See Wade, \textit{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.145 Manufacturers and sellers may not avoid liability simply by placing warnings on their products.146 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.”147 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.148

Xenadrine’s warning label did not communicate that death or serious injury could result from taking the dietary supplement.149 The label did, however, suggest consulting a physician or licensed health care professional if the user suffered from an assortment of ailments.150 Steve Bechler did not heed this suggestion, as he did not consult a health care professional before using Xenadrine.151

An adequate warning must make the danger of a product apparent to the consumer.152 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

145. 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.

146. See Flynn, supra note 90, at 269 (“[T]he mere existence of a warning is not dispositive of the adequacy of the warning.”).

147. 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.

148. See Flynn, supra note 90, at 269-70 (noting both manufacturer and seller may be liable).


150. 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.

151. See Chass, supra note 5, at D5 (noting Bechler had abnormal liver functions and mild hypertension prior to taking Xenadrine).

152. 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.
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

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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 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

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158. See id. at 14-16 (describing results in cases where product designs and product warnings are balanced to assess defectiveness).

159. See West v. Caterpillar Tractor Co., 336 So. 2d 80, 87 (Fla. 1976) (following trend of states adopting § 402A). For a further discussion of West, see supra notes 39-40 and accompanying text.

160. Silverglate, supra note 48, at 14. “Even today, considerable confusion and disagreement exist in Florida as to the present state of products liability law.” Id.

161. See Standard Jury Instructions-Civil Cases (99-1), 778 So. 2d 264, 272 (Fla. 2000) (listing applicable jury instructions for strict products claims); see also Flynn, supra note 90, at 272 (positing Florida should provide standard jury instructions on strict liability duty to warn).

162. See Flynn, 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.” Id. at 268.

163. See Silverglate, supra note 48, at 12 (highlighting case law that describes relationship of product warnings to design defect).

164. 999 P.2d 930 (Kan. 2000).

165. See id. at 946 (holding “an adequate warning does not foreclose a finding that a product is defectively designed”). The court in 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 1 of the Restatement (Third) of Torts § 2, which provides that an adequate warning does not foreclose a finding that a product is defectively designed?

Id. at 940.
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.


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).

172. Silverglate, supra note 48, at 14 (claiming Florida law provides appropriate balance between manufacturer and consumer rights).
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 ephedra-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 huang.” 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.\textsuperscript{180} 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.\textsuperscript{181}

Precedent highlights the difficulties of finding a product defective in design after establishing that an adequate warning existed on the product.\textsuperscript{182} The current approach of the Florida courts, while somewhat complex, is a flexible and reasonable alternative.\textsuperscript{183} The hard-line approach of the Third Restatement, emphasizing product design over the use of warnings, seems harsh to manufacturers.\textsuperscript{184} On the other hand, the Second Restatement’s approach seems to foreclose many legitimate consumer claims.\textsuperscript{185} 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.\textsuperscript{186}

After several high profile deaths, the FDA finally intervened and began taking drastic measures to warn consumers of the dangers associated with ephedra.\textsuperscript{187} 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.\textsuperscript{188} Next, on December 30, 2003, the

\textsuperscript{180} See generally Bowbeer, supra note 154, at 441 (indicating strict liability failure to warn claims may find otherwise safe products defective).


\textsuperscript{182} For a discussion of the difficulties the Jennings court had in finding defectiveness, see supra notes 53-75 and accompanying text.

\textsuperscript{183} See Silverglate, supra note 48, at 17 (stating Florida courts should continue using “common sense approach”).

\textsuperscript{184} See Restatement (Third) of Torts: Products Liability § 2 cmt. 1 (1997) (emphasizing safer design requirements over mere warnings about dangerous attributes).

\textsuperscript{185} See Restatement (Second) of Torts § 402A cmt. j (1965) (foreclosing design defect claim if adequate warning is present on product).

\textsuperscript{186} See Silverglate, supra note 48, at 17 (depicting reasonable balance in Florida’s approach to balancing product design and product warning).

\textsuperscript{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.

\textsuperscript{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. Finally, on February 11, 2004, the FDA issued a ruling that bans all 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.

Id. 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).


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

191. 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.

Id.

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

193. 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 Chinerv'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.