27 So.3d 805
District Court of Appeal of Florida,
First District.

Wesley WEBSTER, Appellant/Cross-Appellee,
v.
BODY DYNAMICS, INC. d/b/a BDI Pharmaceuticals, The Pantry, Inc. f/k/a Lil' Champ Food Stores, Inc. and Nittany Pharmaceuticals, Inc., Appellees/Cross-Appellants.

No. 1D08-5114. | Feb. 24, 2010.

Synopsis

Background: Stroke victim brought negligence and products liability action against dietary supplement manufacturers, distributors, and retailers. Following a jury trial, the Circuit Court, Alachua County, David L. Reiman, J., entered judgment against victim, and he appealed.

[Holding:] The District Court of Appeal, Benton, J., held that trial court's error in precluding expert testimony on fact that Food and Drug Administration (FDA) had banned certain dietary supplements was harmless.

Affirmed.

Thomas, J., filed dissenting opinion.

West Headnotes (3)

[1] Appeal and Error
Particular types of evidence

Trial court's error in precluding expert's testimony to the fact that Food and Drug Administration (FDA) had banned certain dietary supplements was harmless, in stroke victim's negligence and products liability action against supplement manufactures, distributors, and retailers; jury might have concluded there was no convincing proof that chemical purported to cause strokes was in victim's system at the time he suffered stroke, and expert's testimony conveyed in great detail health and safety concerns underlaying the FDA's proposal to adulterate dietary supplements containing the chemical alleged to have caused victim's stroke.

1 Cases that cite this headnote

[2] Appeal and Error
Prejudice to Rights of Party as Ground of Review

Under the harmless error standard of review, reversal is unwarranted in a civil case unless the appellant demonstrates that it is reasonably probable that a result more favorable to the appellant would have been reached if the error had not been committed.

[3] Appeal and Error
Review of correct decision based on erroneous reasoning in general

Under the "tipsy coachman rule," when the trial court reaches the right result, but for the wrong reasons, that decision will be upheld on appeal if there is any basis which would support the judgment in the record.

1 Cases that cite this headnote

Attorneys and Law Firms

***805** Tracy Raffles Gunn of Gunn Appellate Practice, P.A., Tampa, for Appellant/Cross-Appellee.

David B. Weinstein and Kimberly S. Mello, Greenberg Traurig, P.A., Tampa, for Appellee/Cross-Appellant Body Dynamics, Inc.; Robert E. **Biasotti** of Carlton Fields, P.A., St. Petersburg, for Appellee/Cross-Appellant The Pantry, Inc.; and ***806** Elliot H. Scherker and Brigid F. Cech Samole, Greenberg Traurig, P.A., Miami, for Appellee/Cross-Appellant Nittany Pharmaceuticals, Inc.

Opinion

BENTON, J.

Wesley Webster, the plaintiff below, appeals a judgment exonerating all defendants in this negligent-failure-to-warn and products liability case. He argues the trial court erred

in denying a pretrial motion seeking to put before the jury a Food and Drug Administration (FDA) rule banning all "dietary supplements"[1] containing ephedrine alkaloids, adopted some six years after a stroke felled him. The trial court excluded the FDA rule, and perhaps other evidence of the ban on ephedrine in dietary supplements, on grounds that the ban had no bearing on Mr. Webster's claims for damages for antecedent injuries. Exclusion may have been error but we affirm because any such error was harmless. Our disposition moots the cross-appeal.

Mr. Webster sued the manufacturers and/or distributors as well as the retail seller[2] of Super Minis[3]/Mini Thin Naturals,[4] a "dietary supplement" containing ephedrine,[5] alleging that they were legally responsible for his stroke. Dr. Triggs, one of the physicians Mr. Webster-at the time of the stroke, a 26-year-old university student-called at trial as a witness testified that sometimes young people have strokes for unexplained reasons. Another of the plaintiff's medical experts, Dr. Nadeau, testified that forty percent of the time young people suffer strokes, the cause is never identified. The jury apparently concluded this was one such case.

The stroke took place on June 6, 1998, after, Mr. Webster testified, he had ingested two Super Mini/Mini Thin Natural pills, one between six o'clock and seven o'clock the evening before, and one a few hours after that. He testified that taking two pills at such intervals had been his custom approximately two days every week over the previous four months.[6] But neither Mr. Webster's blood nor his urine yielded any evidence of ephedrine present in his system at any pertinent time. A drug profile performed on the blood sample taken when he was admitted to the hospital on June 6, 1998, and a more comprehensive toxicology profile conducted on June 10, 1998, revealed no sign of ephedrine.[7] The jury returned a defense verdict, ***807** finding that no defendant had placed any ephedrine-containing dietary supplement on the market "with a defect which was a legal cause of damage" to Mr. Webster.

Before trial, Mr. Webster's trial counsel had asked the court to take judicial notice of the FDA rule "adulterating"[8] dietary supplements containing ephedrine alkaloids, issued by the FDA in 2004, six years after Mr. Webster's stroke. *See* Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk, 69 Fed. Reg. 28,6788 (Feb. 11, 2004) (to be codified at 21 C.F.R. pt. 119). In the rule-135 pages in length-the FDA premises the adulteration on its "conclusion that the risks of these products outweigh their benefits," explaining:

> We are using this rulemaking authority for dietary supplements containing ephedrine alkaloids because ... it is more efficient to declare these products adulterated as a category than to remove them from the market in individual enforcement actions in which we would have to establish, for each individual product, that they present a significant or unreasonable risk.
>
> ....
>
> The government's burden of proof for 'unreasonable risk' can be met with any science-based evidence of risk and does not require a showing that the substance has actually caused harm in particular cases.

Id. at 28,6794, 28,6798. The trial judge declined to take judicial notice of the rule and reserved ruling on its admissibility "with the understanding" that under no circumstance would he allow the entire 135-page document into evidence. The trial judge reasoned that the FDA rule in its entirety was "way more than any jury in this particular case even needs to begin to understand...." At trial, plaintiff's counsel asked the judge to "reconsider one aspect" of his pretrial ruling, arguing the FDA ban was relevant to show that the dietary supplement Mr. Webster allegedly ingested was unsafe and ineffective. The trial judge did not, however, alter his ruling.

We assume for purposes of decision that counsel's request that the trial court "reconsider one aspect" of its ruling regarding the FDA ban on ephedrine in dietary supplements is properly viewed as a request for leave to question Dr. Parisian (an FDA employee in charge of verifying that clinical trials had demonstrated the safety and effectiveness of products before they were marketed) in order to establish the fact of the FDA ban (even though no proffer was made). On this assumption, the trial court arguably[9] abused its discretion by denying the request to prove that all dietary supplements containing ephedrine were later taken off the market. As the dissent explains, evidence of a post-accident recall may be admissible in strict products liability cases to prove that the ***808** product was defective when it left the possession of the manufacturer.[10]

But Dr. Parisian testified at length about the FDA's investigation of dietary supplements containing ephedrine

during the period before Mr. Webster's stroke. In 1993, the jury learned, the Commissioner of the FDA testified before Congress regarding serious adverse incidents associated with the use of ephedra, including stroke. In 1995, after receiving reports of injuries associated with dietary supplements containing ephedrine, the FDA conducted a public meeting to discuss the risks of ephedra. In 1996, the FDA issued a press release that listed the names of dietary supplements containing ephedra and warned of the risks associated with them. In 1997, in the wake of reports of young people suffering serious adverse events such as stroke and heart attack after consuming dietary supplements containing ephedra, the FDA proposed to adulterate dietary supplements containing more than eight milligrams of ephedrine alkaloids per pill. [11] Manufacturers failed to heed the FDA's warnings and continued marketing dietary supplements containing in excess of eight milligrams per pill. Dr. Parisian informed the jury of this history in some detail, and testified to her opinion that a dietary supplement with more than eight milligrams of ephedrine alkaloids was "unreasonably dangerous for a consumer."

[1] [2] [3] On appeal, Mr. Webster asserts the judgment must nevertheless be reversed ***809** because the jury did not learn that the FDA subsequently banned all dietary supplements containing ephedrine alkaloids. But any error in this regard was harmless under the standard for harmless error applicable in civil cases. Reversal is unwarranted in a civil case unless the appellant demonstrates that "it is reasonably probable that a result more favorable to the appellant would have been reached if the error had not been committed." *In re Commitment of DeBolt,* 19 So.3d 335, 337 (Fla. 2d DCA 2009) (quoting *Damico v. Lundberg,* 379 So.2d 964, 965 (Fla. 2d DCA 1979)). Any error here in precluding Dr. Parisian's testifying to the fact the FDA banned dietary supplements containing ephedrine was harmless on at least two bases. [12]

The jury was asked to determine whether the defendants had marketed an ephedrine-laden dietary supplement "[1] with a defect [2] which was a legal cause of damage" to the plaintiff. If the jury answered in the negative because it found Super Minis/Mini Thin Naturals were not "a legal cause of damage" to Mr. Webster because he had ingested no detectable quantity of ephedrine in the pertinent time period, the trial court's failure to admit evidence of the FDA rule-which arguably tended to prove a defect, but not ingestion or other legal causation of the stroke Mr. Webster suffered-could not logically have affected the verdict. The jury may well have concluded that there was no convincing proof that ephedrine was in the plaintiff's system when he suffered the stroke.

In any event, Dr. Parisian's testimony conveyed in great detail the health and safety concerns that underlay the FDA's proposal to adulterate dietary supplements containing ephedrine alkaloids in excess of eight milligrams per pill, and ultimately led to the ban of dietary supplements (but not other over-the-counter medications) containing any ephedrine alkaloid at all. Dr. Parisian testified unequivocally that manufacturers continued to market dietary supplements containing ephedrine at levels not recognized as safe and effective by the FDA. She opined in no uncertain terms that the pills Mr. Webster allegedly consumed were "unreasonably dangerous." ***810** The testimony that strokes had been associated with ephedrine use was uncontroverted. [13]

Dr. Parisian's testimony explained to the jury the reasoning behind the eventual ban of dietary supplements containing ephedrine, and the entire rationale eventually set forth in the text of the rule effecting the ban. The appellant has not demonstrated a reasonable probability that proof of the ban itself would have led to a different result.

Affirmed.

KAHN, J., concurs; THOMAS, J., dissents with opinion.

THOMAS, J., Dissenting.

I respectfully dissent. The trial court abused its discretion in excluding evidence that the Food and Drug Administration (FDA) recalled and banned ephedrine-alkaloid containing products in 2004, six years after Appellant allegedly ingested such a product. Without question, the trial court erred as a matter of law in its view that this evidence was not relevant to prove that Appellees had notice of the dangers of these products. Notice is not an element of a strict liability claim, and this was not a basis to exclude the evidence. Thus, on this basis alone, this court could reverse, utilizing the *de novo* standard of review regarding evidentiary trial decisions based on questions of law. *Shands Teaching Hosp. v. Dunn,* 977 So.2d 594 (Fla. 1st DCA 2007). Even applying the abuse of discretion standard, however, the trial court reversibly erred in excluding the evidence.

A mandatory recall and ban is relevant evidence and demonstrates a product's design defect, even where the recall

and ban is issued after the date of the product's manufacture. Section 90.401, Florida Statutes, defines relevant evidence as "evidence tending to prove or disprove a material fact." In 2004, the FDA reported that ephedrine-containing products were so dangerous that public safety required a ban and recall of that class of products. Thus, the ban is relevant to show that the Super Mini's allegedly ingested by Appellant, which contained ephedrine alkaloids in 1998, had a defect in design. The 2004 ban does not conclusively prove that the products used in 1998 were in fact defective, but it does tend to show that ephedrine alkaloids posed a significant threat. I note that the FDA's report was not an after-the-fact determination based on new evidence of danger, but a determination that the products had to be recalled.

The date of the recall and ban is only one aspect of the value of the evidence, which goes to its weight, not its admissibility. The trial court reversibly erred by depriving Appellant of the opportunity to present evidence that the product was investigated and then recalled. *See Brantley v. Snapper Power Equip.*, 665 So.2d 241 (Fla. 3d DCA 1995); *see generally Hessen v. Jaguar Cars, Inc.*, 915 F.2d 641, 648-49 (11th Cir.1990) (trial court properly admitted recalled evidence where plaintiff's automobile was not included in recall, but its defective condition was same defect identified in recall); *Rose v. Figgie Int'l, Inc.*, 229 Ga.App. 848, 495 S.E.2d 77, 84 (1997); *Stinson v. E.I. DuPont De Nemours & Co.*, 904 S.W.2d 428, 432 (Mo.App.1995) (warning labels provided after manufacturing date relevant to show "whether [product was] unreasonably dangerous, and thus defectively designed ... at the time of [the] injury.").

***811** The case of *Toole v. McClintock*, 999 F.2d 1430 (11th Cir.1993), is distinguishable and unpersuasive. There, the district court admitted into evidence an FDA report which contained *proposed* findings that breast implants can cause cancer or autoimmune disease. *Id.* at 1433-34. Here, by contrast, the FDA *banned* all products containing ephedrine alkaloids. Had the FDA's 1997 proposed rule regarding ephedrine alkaloids been admitted into evidence, *Toole* could be persuasive.

As to the other reasons cited by the trial court, none compelled exclusion of the evidence. Appellee BDI Pharmaceutical's arguments that the FDA's 2004 report banning ephedrine alkaloids did not specifically address Super Mini's also goes to the weight and value of the evidence, not its admissibility. Had the trial court admitted the 2004 report, BDI could argue to the jury that the ban utilized a cost-benefit analysis and made no determination regarding any specific product. Certainly, BDI could inform the jury of the FDA's conclusion that it had no proof "that any substance has actually caused harm in particular cases."

A trial should be based on competing theories, with relevant and admissible evidence heard and considered by the jury. Here, the trial court abused its discretion by not permitting the jury to consider relevant evidence, based on an incorrect legal determination. Contrary to the trial court's finding under section 90.403, there was no adequate showing that unfair prejudice outweighed the probative value. Because the trial court incorrectly determined the relevance of the evidence, it could not effectively weigh any prejudice the evidence could create *vis a vis* its probative value; thus, the section 90.403 analysis was compromised. The evidence was, in fact, relevant, and its prejudicial value must be considered in that context. *Cf. Marchina v. State*, 702 So.2d 1369, 1369-70 (Fla. 1st DCA 1997) (where evidence has "little legitimate probative value," court should exclude evidence if substantially outweighed by danger of unfair prejudice).

The exclusion of this evidence left the jury with the incorrect impression that the ephedrine alkaloid products remained available to the public even after the FDA's investigation resulted in a proposed rule. The 2004 ban was so inextricably intertwined with other evidence that its exclusion left a false and misleading impression that, in my view, meets the test for harmful error. *See generally City of Ocala v. Red Oak Farm, Inc.*, 673 So.2d 86 (Fla. 5th DCA 1996) (harmfulness of evidentiary ruling highlighted by vigorous trial advocacy in support of ruling reversed by appellate court). The evidence at issue here was relevant, and its exclusion seriously prejudiced Appellant's opportunity to fairly present its own case for the jury to consider. I would reverse and remand for a new trial on this issue.

Parallel Citations

35 Fla. L. Weekly D440

Footnotes

1 Over-the-counter medicines for asthma and certain prescription medicines containing ephedrine are still on the market. The recommended maximum daily allowance for the asthma over-the-counter medicine is three times as much as Mr. Webster testified he ingested.

2 The product in question was allegedly purchased at a convenience store owned by The Pantry, Inc. f/k/a Lil' Champ Food Stores, Inc.

3 Super Minis were manufactured and/or distributed by both Body Dynamics, Inc. d/b/a BDI Pharmaceuticals, and Nittany Pharmaceuticals, Inc.

4 Mini Thin Naturals were manufactured and/or distributed by Body Dynamics, Inc. d/b/a BDI Pharmaceuticals.

5 Ephedrine alkaloids occur naturally in a species of ephedra, the Chinese herb ma huang, but can also be synthesized.

6 Mr. Webster's recitation of events was corroborated by his friend Justin Blow, who testified that the day before Mr. Webster's stroke, the two men ingested ephedra pills in the late afternoon or early evening. Each pill contained 25 milligrams of ephedrine.

7 Dr. Miller testified that the toxicology profile detects ephedrine. Dr. Miller explained that sympathomimetics, the class of drugs to which ephedrine belongs, are typically detectable for two to three days, but with prolonged, heavy use, may be detectable for up to seven days.

8 The Federal Food, Drug, and Cosmetic Act provides that a dietary supplement "shall be deemed to be adulterated" when it "presents a significant or unreasonable risk of illness or injury under (i) conditions of use recommended or suggested in labeling, or (ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use." 21 U.S.C. § 342(f)(1)(A) (2008) (boldface omitted). The FDA "adulterated" the dietary supplements in the sense of deeming them adulterated.

9 The FDA justified the rule on the basis of efficiency and made no finding that Super Minis/Mini Thin Naturals were "defective" or dangerous. The FDA allowed ephedrine-containing products other than dietary supplements to remain on the market.

10 In *Hessen in re Allstate Ins. Co. v. Jaguar Cars, Inc.*, 915 F.2d 641, 648-49 (11th Cir.1990), the Eleventh Circuit addressed the admissibility of a subsequent recall of Jaguar Cars which did not include the vehicle involved in the accident at issue. The court ruled that, "the district court properly held that if Allstate could show that the defect alleged in the [plaintiff's] vehicle was the same as the defect involved in the recall, then evidence of the Jaguar recall campaign would be admitted for jury consideration." *Id.* at 649. Likewise, in *Harley-Davidson Motor Co. v. Carpenter*, 350 So.2d 360, 361 (Fla. 2d DCA 1977), the Second District held that while evidence of a subsequent government recall was not admissible to show that a defect existed in the plaintiff's particular motorcycle, it was admissible "to show that the defect existed in the hands of the manufacturer" (citations omitted).

See also Rose v. Figgie Int'l, Inc., 229 Ga.App. 848, 495 S.E.2d 77, 84 (1997) (evidence of post-accident product recall relevant to show that defect in product was present when product left manufacturer's hands); *Pesce v. Gen. Motors Corp.*, 939 F.Supp. 160, 165 (N.D.N.Y.1996) (denying defendant's motion to preclude evidence of post-accident recall letter where plaintiff established seat belt defect through independent evidence); *Harley-Davidson Motor Co. v. Daniel*, 244 Ga. 284, 260 S.E.2d 20, 22-23 (1979) (evidence of Congressionally-mandated post-accident recall relevant on question of whether defect was present in car when it left manufacturer, and admissible so long as there was independent evidence to establish that particular product suffered from same defect); *Longenecker v. Gen. Motors Corp.*, 594 F.2d 1283, 1286 (9th Cir.1979) (evidence of post-accident recall letter stating "engine-mount separation would occur, if at all, during rapid acceleration" relevant to show a flaw in the engine mounts, even though accident caused by separation of mounts did not occur during acceleration); *Manieri v. Volkswagenwerk A.G.*, 151 N.J.Super. 422, 376 A.2d 1317, 1322 (1977) (post-accident recall letters relevant to show whether the defect arose while the vehicle was in the defendants' control); *Barry v. Manglass*, 55 A.D.2d 1, 389 N.Y.S.2d 870, 874-77 (N.Y.App.Div.1976) (post-accident recall letters mandated by federal statute relevant to show a defect existed in the product at the time it left the manufacturer, and their relevancy outweighed any possible prejudice); *Fields v. Volkswagen of Am., Inc.*, 555 P.2d 48, 57-58 (Okla.1976) (recall letter which plaintiffs had not received prior to accident admissible to show whether defect existed when product left manufacturer).

11 The pill Mr. Webster allegedly ingested in 1998 contained 25 milligrams of ephedrine alkaloids.

12 Under the "tipsy coachman" rule, when the "trial court reaches the right result, but for the wrong reasons, [that decision] will be upheld [on appeal] if there is any basis which would support the judgment in the record." *Dade County Sch. Bd. v. Radio Station WQBA*, 731 So.2d 638, 644-45 (Fla.1999).

Section 90.403, Florida Statutes (2008), affords substantial discretion to trial courts to exclude otherwise relevant evidence "if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of issues, misleading the jury, or needless presentation of cumulative evidence." *See Harris v. State*, 449 So.2d 892, 897 (Fla. 1st DCA 1984) ("[A] large measure of discretion rests in the trial judge to determine whether the probative value of the evidence is substantially outweighed by any of the enumerated reasons." (quoting C. Ehrhardt, *Florida Evidence* § 403.1 at 62-63 (1977))). We nevertheless decline to affirm on the alternative ground that the trial court appropriately declined Mr. Webster's request to admit the 135-page FDA rule on grounds it was "way more than any jury in this particular case even needs to begin to understand...."

Affirmance on this ground would be inappropriate, even though "[a]s a general rule, a trial court's ruling on the admissibility of evidence will not be reversed, absent an abuse of discretion." *McCray v. State*, 919 So.2d 647, 649 (Fla. 1st DCA 2006) (citations

omitted). The weighing contemplated by section 90.403 is for the trial court, in the first instance, and here the trial court ruled the subsequent ban altogether irrelevant, so that no weighing took place below.

On the other hand, but for this error, the trial court would necessarily have reached the question whether the probative value outweighed the danger of unfair prejudice and might have excluded the 135-page rule on that basis. The appellant has not, at least, demonstrated otherwise.

13 Dr. Olney did testify, however, that it had not been proven that ephedrine could cause strokes.