

2016 WL 1128256

Only the Westlaw citation is currently available.

United States Court of Appeals,
First Circuit.

Michael J. TERSIGNI, Plaintiff, Appellant,

v.

WYETH, a/k/a Wyeth, LLC, f/k/a American Home Products Corp.; American Home Products, Inc.; Wyeth Ayerst Laboratories; Wyeth Pharmaceuticals, a/k/a Wyeth Pharmaceuticals, Inc., f/k/a Wyeth–Ayerst Pharmaceuticals, Inc.; f/k/a [Ayerst Laboratories, Inc.](#); Wyeth–Ayerst Pharmaceuticals, Inc.; AHP Subsidiary Holding Corporation, f/k/a [Wyeth–Ayerst Laboratories Company](#), a division of Wyeth; [Ayerst Laboratories, Inc.](#), a division of Wyeth, Wyeth–Ayerst Pharmaceuticals, Inc., Defendants, Appellees.

No. 14–1927.

|

March 23, 2016.

Synopsis

Background: Consumer brought action against seller of weight loss drug, asserting claims for negligent design and negligent failure to warn based on allegations that the drug caused consumer to develop primary pulmonary hypertension. The United States District Court for the District of Massachusetts, [Richard G. Stearns, J.](#), granted summary judgment in favor of seller on negligent design claim and denied consumer's motions to exclude evidence. Consumer appealed.

Holdings: The Court of Appeals, [Stahl](#), Circuit Judge, held that:

[1] even if claim for negligent design of prescription drug was cognizable under Massachusetts law, seller did not negligently design drug, absent showing that alternative design existed;

[2] district court's error, if any, in admitting evidence of consumer's past incarceration for non-payment of child support was harmless; and

[3] district court's admission of evidence of consumer's prior cocaine use did not merit reversal.

Affirmed.

West Headnotes (10)

[1] Federal Courts

The Court of Appeals reviews a district court's order granting summary judgment on plaintiff's negligent design claim law de novo, assessing the record in the light most favorable to plaintiff and resolving all reasonable inferences in his favor.

[Cases that cite this headnote](#)**[2] Federal Courts**

In reviewing a district court's order granting summary judgment, the Court of Appeals is not bound by the district court's decisional calculus but, rather, may affirm the decision on any ground made manifest by the record.

[Cases that cite this headnote](#)**[3] Products Liability**

Even if claim for negligent design of prescription drug was cognizable under Massachusetts law, seller of weight loss drug did not negligently design the drug, absent showing that reasonable alternative design existed which would have made the drug less likely to cause primary pulmonary hypertension.

[Cases that cite this headnote](#)**[4] Products Liability**

Massachusetts courts recognize claims predicated on the negligent design of a variety of consumer products and goods.

[Cases that cite this headnote](#)

[5] **Products Liability**



Under Massachusetts law, the reasonable alternative design inquiry in a negligent design claim requires the plaintiff to show that the product in question could have been more safely designed, not that a different product was somehow safer.

[Cases that cite this headnote](#)

[6] **Federal Courts**



As a federal court applying Massachusetts law, the Court of Appeals is bound to apply state law as it exists, not as it may become, or as the plaintiff wishes it to be.

[Cases that cite this headnote](#)

[7] **Federal Courts**



The Court of Appeals' review of a district court's denial of a motion to exclude evidence is for abuse of discretion.

[Cases that cite this headnote](#)

[8] **Federal Courts**



The Court of Appeals may affirm a district court's denial of a motion to exclude evidence in spite of an erroneous evidentiary ruling if the error was harmless, meaning that it is highly probable that the error did not affect the outcome of the case.

[Cases that cite this headnote](#)

[9] **Products Liability**



District court's error, if any, in admitting evidence of consumer's past incarceration for non-payment of child support was harmless

in consumer's action under Massachusetts law against seller of weight loss drug, alleging that seller negligently failed to warn consumer's doctor of risks associated with the drug; jury was given verdict form to determine whether seller negligently failed to warn doctor, answered question in the negative, and did not reach causation issue to which incarceration was arguably relevant. [Fed.Rules Evid.Rule 403, 28 U.S.C.A.](#)

[Cases that cite this headnote](#)

[10] **Products Liability**



District court's admission of evidence of consumer's prior cocaine use in consumer's action under Massachusetts law against seller of weight loss drug, alleging that seller negligently failed to warn consumer's doctor of risks associated with the drug, did not merit reversal; district court denied consumer's motion to exclude evidence pending its evaluation of expert testimony, and consumer's counsel chose to raise the cocaine use herself in her opening statement and during direct examination of two of consumer's witnesses.

[Cases that cite this headnote](#)

Appeal from the United States District Court for the District of Massachusetts, [Richard G. Stearns](#), U.S. District Judge.

Attorneys and Law Firms

[Louis M. Bograd](#), with whom Center for Constitutional Litigation, P.C., [Gregory J. Bubalo](#), [Paula S. Bliss](#), and Bubalo Goode Sales & Bliss, PLC were on brief, for appellant.

[Theodore V.H. Mayer](#), with whom [William J. Beausoleil](#), [Michael D. Tiger](#), Hughes Hubbard & Reed LLP, [Peter L. Welsh](#), [Jesse M. Boodoo](#), and Ropes & Gray LLP were on brief, for appellees.

Before [LYNCH](#), Circuit Judge, [SOUTER](#), Associate Justice, * and [STAHL](#), Circuit Judge.

Opinion

STAHL, Circuit Judge.

*1 For a period of time in 1997, the appellant, Michael Tersigni, was prescribed [Pondimin](#), a weight loss drug developed and sold by the appellee, Wyeth.¹ Tersigni later sued Wyeth, alleging that [Pondimin](#) caused him to develop a dangerous condition known as [primary pulmonary hypertension](#) (“PPH”). The district court entered summary judgment for Wyeth on most of Tersigni's claims, including his claim for negligent design, and allowed only a single claim for negligent failure to warn to go to trial. In separate rulings, the district court denied a pair of motions *in limine* in which Tersigni sought to exclude reference at trial to his past incarceration and use of cocaine.

The jury returned a verdict for Wyeth on Tersigni's surviving negligent failure to warn claim. In this appeal, Tersigni claims that the district court erred by entering summary judgment for Wyeth on the negligent design claim and by denying his motions *in limine*. After careful consideration, we AFFIRM.

I. Facts and Background

From 1989 until 1997, Wyeth marketed [Pondimin](#) as a medication to promote weight loss. In the mid-1990s, however, clinical research began to emerge linking [Pondimin](#) to an elevated risk for [valvular heart disease](#) and PPH.² Eventually, in July 1997, the Food and Drug Administration (“FDA”) required Wyeth to warn doctors of these risks and to add a so-called “Black Box” warning to [Pondimin's](#) label. Soon thereafter, the FDA ordered that Wyeth withdraw [Pondimin](#) from the market entirely.

Tersigni was one of millions of Americans to receive a prescription for [Pondimin](#). He was prescribed (and apparently took) the drug for an approximately six-month period beginning in early 1997, and ending in July 1997, when Tersigni's doctor learned of the FDA's required Black Box warning.

In 2011, several years after Tersigni stopped taking [Pondimin](#), he was diagnosed with PPH. Thereafter, he sued Wyeth in federal district court in Massachusetts, asserting claims for, *inter alia*, negligent design³ and negligent failure to warn. In effect, Tersigni's negligent design claim alleged

that Wyeth knew, or should have known, that [Pondimin](#) was unreasonably dangerous, but nonetheless continued to market it.

Wyeth moved for summary judgment on most of Tersigni's claims. The district court granted this motion, reasoning in relevant part that Massachusetts courts would not recognize a cause of action for the negligent design of a prescription drug. *See Tersigni v. Wyeth–Ayerst Pharm., Inc.*, No. 11–10466–RGS, 2014 WL 7464759, at *1 (D.Mass. June 25, 2014). Following the entry of summary judgment, only Tersigni's claim for negligent failure to warn remained for trial.

Separately, Tersigni moved to preclude reference at the trial both to his previous incarceration in 2008 for non-payment of child support, and to his occasional use of cocaine several decades earlier. Wyeth opposed both motions, arguing that this evidence was relevant to the defense's theory that cocaine use and the stress associated with Tersigni's incarceration contributed to his cardiopulmonary symptoms. The district court denied Tersigni's motions, ruling that, subject to certain restrictions, evidence of the cocaine use and incarceration could be offered.

*2 Following an eleven-day trial on Tersigni's negligent failure to warn claim, the jury found in Wyeth's favor, concluding that Wyeth had not negligently failed to warn Tersigni's doctor of the risks posed by [Pondimin](#). Consequently, the jury did not reach the separate question of whether [Pondimin](#) caused Tersigni to develop PPH. This appeal followed.

II. Analysis

A. Negligent Design

[1] [2] We review the district court's order granting summary judgment on Tersigni's negligent design claim *de novo*, assessing the record in the light most favorable to Tersigni and resolving all reasonable inferences in his favor. *Bingham v. Supervalu, Inc.*, 806 F.3d 5, 9 (1st Cir.2015). “In so doing, ‘we are not bound by the district court's decisional calculus but, rather, may affirm the decision ... on any ground made manifest by the record.’ “ *Ocasio–Hernández v. Fortuño–Burset*, 777 F.3d 1, 7 (1st Cir.2015) (quoting *Ruiz v. Bally Total Fitness Holding Corp.*, 496 F.3d 1, 5 (1st Cir.2007)). The entry of summary judgment is appropriate where “there is no genuine dispute as to any material fact

and the movant is entitled to judgment as a matter of law.” *Bingham*, 806 F.3d at 9 (quoting *Fed.R.Civ.P.* 56(a)).

By way of background, Section 402A of the *Restatement (Second) of Torts* subjects to strict liability certain sellers of products which are “in a defective condition unreasonably dangerous to the user or consumer.” *Evans v. Lorillard Tobacco Co.*, 465 Mass. 411, 990 N.E.2d 997, 1011 (Mass.2013) (quoting *Restatement (Second) of Torts* § 402A (1965)). However, Comment K to Section 402A (“Comment K”) offers an exception and exempts from strict liability the manufacturer of certain products (including drugs) that are highly beneficial but may carry known risks:

There are some products which ... are quite incapable of being made safe for their intended and ordinary use.... The seller of such products, ... with the qualification that they are properly prepared and marketed, and proper warning is given, ... is not to be held to strict liability ... merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts § 402A cmt. k.

[3] In granting summary judgment to Wyeth on Tersigni's negligent design claim, the district court reasoned that because the Supreme Judicial Court (“SJC”) had previously adopted Comment K, Massachusetts courts would not recognize a negligent design claim where the product in question is a prescription drug. See *Payton v. Abbott Labs*, 386 Mass. 540, 437 N.E.2d 171, 189–90 (Mass.1982) (adopting Comment K).

[4] As both parties acknowledge, Massachusetts courts do recognize claims predicated on the negligent design of a variety of consumer products and other goods. For example, in *Smith v. Ariens Co.*, 375 Mass. 620, 377 N.E.2d 954 (Mass.1978), the SJC permitted a claim to go forward where the plaintiff sought to prove that the negligent design of a snowmobile had caused her to sustain injury. *Id.* at 957; see also *Evans*, 990 N.E.2d at 1010 (cigarettes); *Vassallo v. Baxter Healthcare Corp.*, 428 Mass. 1, 696 N.E.2d 909, 912 (Mass.1998) (silicone breast implants); *McDonough v. Whalen*, 365 Mass. 506, 313 N.E.2d 435, 440–41 (Mass.1974) (septic system).

*3 The parties dispute, however, whether Massachusetts courts would recognize a negligent design claim involving a prescription drug. This is a seemingly straight-forward question, but it lacks an obvious answer. On the one hand, as Wyeth points out, Massachusetts courts have yet to formally recognize such a claim.⁴ But, on the other hand, as Tersigni fairly argues, neither has the SJC expressly ruled the claim out. In fact, in the context of claims for the negligent design of other products, the SJC has repeatedly cited not to Section 402A, involving strict liability, but to *Restatement (Second) of Torts* Sections 395 and 398, which pertain to the negligent design and manufacture of chattel. See *Smith*, 377 N.E.2d at 957–58; *McDonough*, 313 N.E.2d at 439 n. 7. At a minimum, this raises the possibility that Massachusetts courts might consider a negligent design claim related to a prescription drug, notwithstanding the SJC's embrace of Comment K. See *Toner v. Lederle Labs.*, 112 Idaho 328, 732 P.2d 297, 311 (Idaho 1987) (“[C]omment [K] does not shield sellers of products from negligence claims.”); see also *Restatement (Second) of Torts* § 402A cmt. a (“[Section 402A] does not preclude liability based upon the alternative ground of negligence”).

It is thus quite uncertain whether Massachusetts courts would recognize Tersigni's negligent design claim. We need not decide this issue, however, because even if we were to assume that such a claim is cognizable under Massachusetts law, the claim would nonetheless fail based on Tersigni's inability to proffer evidence of a reasonable alternative design.⁵ See *Evans*, 990 N.E.2d at 1024 (“In claims alleging negligence in the design of a product, ... the plaintiff must show an available design modification which would reduce the risk without undue cost or interference with the performance of the product” (alterations, citations, and internal quotation marks omitted)); *Gillespie v. Sears, Roebuck & Co.*, 386 F.3d 21, 26 (1st Cir.2004) (applying Massachusetts law and finding that “[a]n essential element of ... a design flaw claim is that there be a safer alternative design”); 1 *Mass. Super. Ct. Civil Practice Jury Instructions* § 11.2.3 (Mass. Continuing Legal Educ. 3d ed. 2014) (requiring plaintiffs to show an available design modification as an element of a negligent design claim).

[5] Tersigni does not contend here, nor did he contend before the district court, that there exists a reasonable alternative design which would have made *Pondimin* less likely to cause PPH or otherwise safer. Rather, he argues first that Wyeth may be held liable because, at the time *Pondimin*

was marketed, there were other, safer methods of weight loss available. This argument, however, misconstrues the focus of the reasonable alternative design inquiry, which requires the plaintiff to show that the product in question could have been more safely designed, not that a different product was somehow safer. See *Evans*, 990 N.E.2d at 1016, 1024 (noting that the plaintiff must offer proof of an available design modification of “the product” (emphasis added) (alteration omitted)); *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 385 (Tex.1995) (“A motorcycle could be made safer by adding two additional wheels and a cab, but then it is no longer a motorcycle.”).

*4 Tersigni also argues that Massachusetts courts would, on the basis of *Restatement (Third) of Torts: Products Liability* § 6(c) (1998)—which Massachusetts courts have not yet adopted—find that proof of a reasonable alternative design is not required where the product in question is a prescription drug. Thus, in effect, Tersigni asks us to assume, in the absence of any applicable precedent, that Massachusetts courts would recognize his negligent design claim, and that having done so, those same courts would grant a heretofore unrecognized exception to the general requirement of proof of a reasonable alternative design. This is a bridge too far, and we decline to cross it.

[6] As a federal court applying Massachusetts law, we are bound to apply state law as it exists, not as it may become, or as the plaintiff wishes it to be. See *Ryan v. Royal Ins. Co. of Am.*, 916 F.2d 731, 744 (1st Cir.1990). Here, we need not attempt to foretell whether Massachusetts courts will one day embrace a claim for the negligent design of a prescription drug. Rather, even assuming that they would, Tersigni's claim fails because he cannot offer proof of a reasonable alternative design, as Massachusetts law plainly requires. Thus, summary judgment properly entered in Wyeth's favor.⁶

B. Evidentiary Rulings

[7] [8] We turn next to Tersigni's claim that the district court erred by denying his motions *in limine* seeking to exclude evidence of his prior incarceration and cocaine use. Our review is for abuse of discretion. See *Fryar v. Curtis*, 485 F.3d 179, 182 (1st Cir.2007). We may affirm in spite of an erroneous evidentiary ruling if the error was harmless, meaning that “it is highly probable that the error did not affect the outcome of the case.” *McDonough v. City of Quincy*, 452 F.3d 8, 19–20 (1st Cir.2006).

i. Incarceration

[9] Tersigni moved to exclude reference to his past incarceration for non-payment of child support, evidence Wyeth argued was relevant to prove that Tersigni had undergone a stressful event which contributed to his cardiopulmonary symptoms. The district court denied Tersigni's motion, allowing testimony “limited to the fact of incarceration, the effect on [Tersigni's] blood pressure, and that the incarceration was based on a child support issue and not any crime of violence.” During the ensuing eleven-day trial, the jury heard a total of four sporadic references to Tersigni's incarceration. Tersigni argues that this evidence should have been excluded because its prejudicial effect of undermining his character substantially outweighed its probative value. See *Fed. R. Evid.* 403.

We need not decide whether the district court abused its discretion by admitting this evidence because any error—if indeed there was one at all—was harmless. The jury was given a verdict form in which it was first asked to determine whether Tersigni had established that Wyeth negligently failed to warn his doctor of the risks associated with *Pondimin*. The jury answered this question in the negative. Consequently, the jury did not reach the second question, which asked whether Tersigni had established that he developed PPH as a result of taking *Pondimin*, a causation issue to which Tersigni's incarceration was arguably relevant.

*5 In our view, evidence of Tersigni's incarceration likely had no effect on the jury's consideration of whether Wyeth negligently failed to warn physicians of *Pondimin*'s risks, the only issue on which the jury was required to pass. See *McDonough*, 452 F.3d at 19–20. The nature of this inquiry simply left no room for consideration of Tersigni's reliability as a witness or his overall character. Thus, if an error occurred, it was harmless.

ii. Cocaine Use

[10] Tersigni also sought to exclude evidence that, several decades earlier, he had occasionally used cocaine. Again, Wyeth claimed that this evidence was relevant to show alternative causes of Tersigni's symptoms. The district court denied Tersigni's motion, pending its “evaluation of expert testimony that the abuse of cocaine ... is related to the issue of specific causation.” The district court, however, was not required to conduct any such evaluation because Tersigni's counsel chose to raise the cocaine use herself, referencing it

twice during her opening statement and again during direct examination of two of Tersigni's witnesses.

We have previously held that a party which seeks to “remove the sting” by preemptively introducing damaging evidence thereby waives the right to appeal the admission of that evidence. See *Gill v. Thomas*, 83 F.3d 537, 541 (1st Cir.1996); see also *Ohler v. United States*, 529 U.S. 753, 760, 120 S.Ct. 1851, 146 L.Ed.2d 826 (2000). Tersigni tries to circumvent our holding in *Gill* by noting that it predated the amendment, in 2000, of [Federal Rule of Evidence 103](#), which governs the manner by which parties must preserve claims of evidentiary error. This attempt cannot succeed, however, because the Advisory Committee Notes accompanying that amendment provide that the amendments “do[] not purport to answer whether a party who objects to evidence that the court finds admissible in a definitive ruling, and who then offers the

evidence to ‘remove the sting’ of its anticipated prejudicial effect, thereby waives the right to appeal the trial court's ruling.” [Fed. R. Evid. 103](#) advisory committee's notes to 2000 amendment (citing, *inter alia*, *Gill*, 83 F.3d at 540). Thus, *Gill* remains good law and the admission of evidence of Tersigni's cocaine use does not merit reversal.⁷

III. Conclusion

The judgment of the district court is AFFIRMED.

All Citations

--- F.3d ----, 2016 WL 1128256

Footnotes

- * Hon. David H. Souter, Associate Justice (Ret.) of the Supreme Court of the United States, sitting by designation.
- 1 “Wyeth” refers collectively to Wyeth and its many subsidiaries and other affiliates (and their current and former pseudonyms) listed in the case caption above.
- 2 Valvular heart disease refers to a group of conditions which cause a disruption in the normal structure and function of the heart valves. PPH is a disease affecting pulmonary circulation and is characterized by scarring and fibrosis of the pulmonary arteries. PPH is “relentlessly progressive” and “leads to death in virtually all circumstances.” See *Brown v. Am. Home Prods. Corp.*, (*In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.*), Nos. 1203, 99–20593, 2000 WL 1222042, at *16 (E.D.Pa. Aug.28, 2000).
- 3 Tersigni's negligent design claim has taken on many guises. For example, in his opening brief, Tersigni refers to this claim interchangeably as one for “negligent marketing,” “negligent failure to discontinue marketing,” and “negligent design.” When pressed at oral argument, counsel clarified that Tersigni is, in fact, pursuing a claim for “negligent design.”
- 4 Tersigni reaches far into the annals of Massachusetts jurisprudence and directs our attention to [Norton v. Sewall](#), 106 Mass. 143 (1870), where an apothecary was found liable for the negligent sale of a deadly poison, which he had mistaken for a harmless medicinal tincture. *Id.* at 144. *Norton*, however, tells us little about how Massachusetts courts would treat a claim for the negligent design of a prescription drug. As an initial matter, the apothecary's liability was premised merely on his negligent sale, rather than his design or manufacture, of the poison. *Id.* Beyond that, *Norton* was decided more than a century prior to the SJC's adoption of Comment K, leaving open the question of whether Comment K would bar the claim Tersigni seeks to bring.
- 5 For the same reason, we acknowledge but need not consider the parties' dispute as to whether Tersigni's negligent design claim under state law is preempted by federal regulation of pharmaceutical drugs.
- 6 Tersigni urges that we certify to the SJC the question of whether his claim for negligent design is cognizable under Massachusetts law. See Mass. S.J.C. R. 1:03. We decline to do so. Tersigni chose to bring suit in federal court despite obvious uncertainty as to whether Massachusetts courts would recognize his cause of action. This undermines his request for certification. See [Cantwell v. Univ. of Mass.](#), 551 F.2d 879, 880 (1st Cir.1977) (“[O]ne who chooses the federal courts in diversity actions is in a peculiarly poor position to seek certification. We do not look favorably, either on trying to take two bites at the cherry by applying to the state court after failing to persuade the federal court, or on duplicating judicial effort.”).
- 7 Tersigni argues that the cumulative effect of admitting evidence of both his incarceration and cocaine use requires reversal. See [United States v. Stokes](#), 124 F.3d 39, 43 (1st Cir.1997) (discussing the cumulative error doctrine). Here, we have found that there was, at worst, one arguable error, and thus we need not consider its potential cumulative effect.