NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 13-1405

_____

ELOISE LABARRE,
as surviving spouse & administratix of
the Est. of Edward LaBarre, Sr.,
Appellant

v.

BRISTOL-MYERS SQUIBB COMPANY; SANOFI-AVENTIS U.S. LLC;
SANOFI-AVENTIS U.S., INC.; SANOFI-SYNTHELABO, INC.

_____

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
(D.C. No. 3-06-cv-06050)
District Judge: Honorable Freda L. Wolfson

_____

No. 13-1406

_____

PATRICIA BEGLEY,
Appellant

v.

BRISTOL-MYERS SQUIBB COMPANY; SANOFI-AVENTIS U.S. LLC;
SANOFI-AVENTIS U.S., INC.; SANOFI-SYNTHELABO, INC.

_____

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
(D.C. No. 3-06-cv-06051)
District Judge: Honorable Freda L. Wolfson

Submitted Under Third Circuit LAR 34.1(a)
November 15, 2013

Before: HARDIMAN, SHWARTZ, and SCIRICA Circuit Judges.

(Filed: November 18, 2013)

OPINION

SHWARTZ, Circuit Judge.

Eloise LaBarre, as surviving spouse and adminstratrix of the estate of Edward LaBarre, Sr., and Patricia Begley bring two products liability cases concerning the prescription drug Plavix, a blood thinner manufactured and sold by Bristol-Myers Squibb Company, Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S., Inc., and Sanofi-Synthelabo, Inc. (together, the "Defendants"). In both cases, the District Court entered an order granting summary judgment in favor of the Defendants. We will affirm both orders.

I. Background

A. Plavix

Plavix is used to treat individuals at risk for heart attack, stroke, and circulation problems. Because Plavix inhibits the formation of blood clots, it increases the risk of bleeding. The labeling disclosed this risk.[1]

[1] The label provided:

PRECAUTIONS

The FDA has approved the use of Plavix with aspirin to treat individuals suffering from acute coronary syndrome ("ACS"). Since aspirin also inhibits the formation of blood clots, using the two drugs together increases the risk of bleeding, and the Plavix label described this risk.[2]

> **General**
>
> As with other antiplatelet agents, PLAVIX should be used with caution in patients who may be at risk of increased bleeding from trauma, surgery, or other pathological conditions. If a patient is to undergo elective surgery and an antiplatelet effect is not desired, PLAVIX should be discontinued 5 days prior to surgery.
> *GI Bleeding*: PLAVIX prolongs the bleeding time. . . . PLAVIX should be used with caution in patients who have lesions with a propensity to bleed (such as ulcers).
> . . .
> **Information for Patients**
>
> Patients should be told that it may take them longer than usual to stop bleeding when they take PLAVIX, and that they should report any unusual bleeding to their physician.
> . . .
> **ADVERSE REACTIONS**
> . . .
> *Hemorrhagic:* In CAPRIE [one study] patients receiving PLAVIX, gastrointestinal hemorrhage occurred at a rate of 2.0%, and required hospitalization in 0.7%. In patients receiving aspirin, the corresponding rates were 2.7% and 1.1%, respectively. The incidence of intracranial hemorrhage was 0.4% for PLAVIX compared to 0.5% for aspirin.

App. 224-26.

[2] The label provided:

> **ADVERSE REACTIONS**
> . . .
> In [one study], PLAVIX use with aspirin was associated with an increase in bleeding compared to [a] placebo with aspirin . . . . There was an excess in major bleeding in patients receiving PLAVIX plus aspirin compared with placebo plus aspirin, primarily gastrointestinal and at puncture sites.

B. Mr. LaBarre's Medical History

Mr. LaBarre suffered from ACS. In October 2002, after a heart attack and other complications resulting from ACS, Mr. LaBarre's physicians prescribed Plavix. Shortly thereafter, in preparation for a double bypass operation, Mr. LaBarre's physicians instructed him to stop taking Plavix. In July 2003, after suffering a second heart attack, Mr. LaBarre's physicians prescribed Plavix and aspirin. Mr. LaBarre remained on Plavix and aspirin until December 2004. In December 2004, Mr. LaBarre hit his head. Two weeks later, he developed a severe headache and became unconscious. Doctors determined that Mr. LaBarre suffered a brain hemorrhage typically associated with trauma. Mr. LaBarre died on December 21, 2004 as a result of the brain hemorrhage. The death certificate indicated that the hemorrhage was a consequence of his Plavix therapy.

C. Ms. Begley's Medical History

Ms. Begley also suffers from ACS. In December 2003, Ms. Begley had a heart attack, was found to have blocked coronary arteries, and had stents implanted. To prevent blood clotting in the stents, Ms. Begley was prescribed Plavix and aspirin. With only brief interruptions, Ms. Begley took Plavix with aspirin from December 2003 through January 2006. In December 2004, Ms. Begley suffered rectal bleeding and, in January 2006, she suffered gastrointestinal bleeding.

D. Procedural History and the District Court Opinions

App. 226-27.

Ms. LaBarre and Ms. Begley (together, the "Plaintiffs") filed products liability suits against Defendants. Each asserted failure to warn, design defect, manufacturing defect, and negligence claims. Ms. LaBarre's claims were governed by Florida law, and Ms. Begley's claims were governed by Illinois law. Because the two cases involved the same product and claims, the parties conducted joint discovery.

Before expert designations were due and before Plaintiffs deposed any of the Defendants' employees—but after Plaintiffs deposed the prescribing physicians—the Defendants moved for summary judgment.[3] The District Court stayed discovery pending its decision on the Defendants' motion. Pursuant to Federal Rule of Civil Procedure 56(d), Plaintiffs filed an affidavit declaring that they sought "more information concerning the inefficacy of Plavix." The District Court denied Plaintiffs' request for additional discovery concerning Plavix's efficacy since it found that Plavix's efficacy was irrelevant, under both Florida and Illinois law, to all of Plaintiffs' claims.

The District Court the granted summary judgment in favor of the Defendants on each claim.[4]

[3] Though expert reports were not yet due, Plaintiffs submitted the expert report of Dr. Lemuel Moyé who provided opinions concerning Plavix's efficacy and risks for certain patients.

[4] According to the District Court: (1) Plaintiffs' failure to warn claims failed because, among other things, Plaintiffs failed to present expert testimony on the inadequacy of Plavix's warning label as required by both Florida and Illinois law; (2) under both Florida and Illinois law, comment k to § 402A of the Restatement (Second) of Torts precluded Plaintiffs' design defect claims; (3) as to the manufacturing defect claims, Plaintiffs presented no evidence of a defect in the manufacturing process; and (4) Plaintiffs' negligence claims were simply a restatement of the other products liability claims.

Plaintiffs now appeal.[5] Both argue that the District Court erred by denying their request for additional discovery. Further, Ms. LaBarre asserts that the District Court erred in granting summary judgment on her failure to warn and design defect claims.

II. Standard of Review

We review whether a district court prematurely granted summary judgment for abuse of discretion. Hart v. Elec. Arts, Inc., 717 F.3d 141, 148 (3d Cir. 2013). "To demonstrate an abuse of discretion, an appellant must show that the District Court's decision was arbitrary, fanciful or clearly unreasonable." Id. (alterations and quotation marks omitted).

We exercise plenary review over a District Court's order granting summary judgment. Jacobs Constructors, Inc. v. NPS Energy Servs., Inc., 264 F.3d 365, 369 (3d Cir. 2001). Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In reaching this decision, the Court must determine "whether the pleadings, depositions, answers to interrogatories, admissions on file, and affidavits show that there is no genuine issue of material fact and whether the moving party is therefore entitled to judgment as a matter of law." Macfarlan v. Ivy Hill SNF, LLC, 675 F.3d 266, 271 (3d Cir. 2012) (citing Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986)). A disputed issue is "genuine" only if there is a sufficient evidentiary basis on which a reasonable jury could find for the non-moving party. Kaucher v. Cnty. of

[5] The District Court had jurisdiction pursuant to 28 U.S.C. § 1332. We have jurisdiction pursuant to 28 U.S.C. § 1291.

Bucks, 455 F.3d 418, 423 (3d Cir. 2006) (citing Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986)). A factual dispute is "material" only if it might affect the outcome of the suit under governing law. Doe v. Luzerne Cnty., 660 F.3d 169, 175 (3d Cir. 2011) (citing Gray v. York Newspapers, Inc., 957 F.2d 1070, 1078 (3d Cir. 1992)). Further, "[w]e may affirm the District Court on any grounds supported by the record." Nicini v. Morra, 212 F.3d 798, 805 (3d Cir. 2000) (en banc).

III. Discussion

A. Discovery

A district court may grant summary judgment before discovery is completed so long as the party opposing summary judgment has had "an adequate opportunity to obtain discovery." Dowling v. City of Phila., 855 F.2d 136, 138-39 (3d Cir. 1988); see also Celotex Corp., 477 U.S. at 322. If a party opposing summary judgment "believes that s/he needs additional time for discovery, Rule 56(d) specifies the procedure to be followed." Pa. Dep't of Pub. Welfare v. Sebelius, 674 F.3d 139, 157 (3d Cir. 2012) (quoting Dowling, 855 F.2d at 139, which addressed the predecessor to Rule 56(d), Rule 56(f)). Rule 56(d) provides:

> If a nonmovant shows by affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition, the court may: (1) defer considering the motion or deny it; (2) allow time to obtain affidavits or declarations or to take discovery; or (3) issue any other appropriate order.

Fed. R. Civ. P. 56(d). The rule requires "a party seeking further discovery in response to a summary judgment motion [to] submit an affidavit specifying, for example, what particular information is sought; how, if uncovered, it would preclude summary

judgment; and why it has not previously been obtained." Dowling, 855 F.2d at 139-40. Except in rare cases, "failure to comply with [Rule 56(d)] is fatal to a claim of insufficient discovery on appeal." Bradley v. United States, 299 F.3d 197, 207 (3d Cir. 2002).

On appeal, Plaintiffs argue that the District Court abused its discretion by proceeding with summary judgment on their failure to warn claim before the expert reports were due and then granting summary judgment for failing to obtain such an expert witness. Plaintiffs, however, submitted an affidavit seeking only additional information from the Defendants about Plavix's efficacy and did not state they sought additional time to obtain expert testimony about the warnings.[6] Because Plaintiffs did not submit a Rule 56(d) affidavit requesting additional time to obtain such expert testimony, the District Court had no reason to lift the discovery stay or withhold deciding the summary judgment motion based on a potential need for expert testimony. Thus, "as a procedural matter alone, [Plaintiffs] ha[ve] failed to comply with the rule," Dowling, 855 F.2d at 140, and cannot rely on the purported lack of discovery as a basis to reverse the District Court. Accordingly, the District Court "acted within the permissible bounds of its discretion when it ruled on the [Defendants'] summary judgment motion on the record before it." Id. at 141.

[6] Plaintiffs do not argue that the District Court abused its discretion by denying their request for additional discovery concerning Plavix's efficacy.

B. Ms. LaBarre's Failure to Warn Claim

Under Florida law,[7] drug manufacturers have a duty to provide adequate warnings of the drug's dangerous side effects. Upjohn Co. v. MacMurdo, 562 So. 2d 680, 683 (Fla. 1990). If a manufacturer fails to provide an adequate warning, it may be strictly liable for any resulting harm. Buckner v. Allergan Pharms., Inc., 400 So. 2d 820, 822 (Fla. Dist. Ct. App. 1981). A manufacturer's duty to warn runs to the physician prescribing the drug rather than the patient taking the drug.[8] Felix v. Hoffmann-LaRoche, Inc., 540 So. 2d 102, 104 (Fla. 1989).[9] To prevail on a failure to warn claim under Florida law, a plaintiff must prove: "(1) that the warnings accompanying the item were inadequate; (2) that the inadequacy of the warnings proximately caused [the plaintiff's] injury; and (3) that [the plaintiff] in fact suffered an injury by using the product." Colville v. Pharmacia & Upjohn Co., 565 F. Supp. 2d 1314, 1320 (N.D. Fla. 2008).

Ms. LaBarre advances two arguments on the adequacy of Plavix's warnings. First, she contends the warnings were inadequate because Mr. LaBarre's physicians were

[7] Our role in diversity cases is to apply state law as announced by the state's highest court. Sheridan v. NGK Metals Corp., 609 F.3d 239, 253 (3d Cir. 2010). If the state's highest court has not addressed an issue, we must predict the court's position on the issue. Id. In so doing, we may look to the decisions of intermediate appellate courts. See id. at 254. Moreover, to promote "consistency of law and principles of comity," we may also look to lower state courts applying the decisions of intermediate state appellate courts. Id.

[8] Because Florida law applies, Ms. LaBarre's argument that we should follow State ex rel. Johnson & Johnson Corp. v. Karl, 647 S.E. 2d 899, 914 (W. Va. 2007), and hold that a drug manufacturer's duty to warn runs to the patient, is both contrary to Florida law and inapplicable.

[9] The Felix court explained that "the prescribing physician, acting as a 'learned intermediary' between the manufacturer and the consumer, weighs the potential benefits against the dangers in deciding whether to recommend the drug to meet the patient's needs." Felix, 540 So. 2d at 104.

not "aware of the lack of efficacy of Plavix." Appellant Br. at 47. Second, she contends the warnings were inadequate because Mr. LaBarre's physicians were not warned as to "the extent to which Plavix increased the risk of bleeding." Id. Both arguments are unavailing.

First, Plavix's efficacy is not relevant to a failure to warn claim. Under Florida law, a manufacturer's duty to warn physicians only extends to the risks or dangers posed by a drug. See MacMurdo, 562 So. 2d at 683; Felix, 540 So. 2d at 104; Buckner, 400 So. 2d at 823; see also Christopher v. Cutter Labs., 53 F.3d 1184, 1192 (11th Cir. 1995) (noting that, under Florida law, a manufacturer has a duty to provide "an adequate warning of the risks associated with a prescription product"). Thus, under Florida law this duty does not extend to a warning about a drug's efficacy and allowing Ms. LaBarre "to pursue a claim for the 'failure to warn' of the efficacy of a drug would be an expansion of liability under Florida law," In re Fosamax Prods. Liab. Litig., No. 1:06-MD-1789-JFK, 2010 WL 1257299, at *5 (S.D.N.Y. Mar. 26, 2010), which is contrary to our role when applying state law. See City of Phila. v. Lead Indus. Ass'n, 994 F.2d 112, 123 (3d Cir. 1993) (noting that a federal court sitting in diversity may not act as a "judicial pioneer" when applying state common law). In short, Plavix's efficacy is irrelevant to Ms. LaBarre's failure to warn claim, and the physicians' purported lack of information about it is of no consequence to the adequacy of the warnings.

Second, Ms. LaBarre's failure to warn claim fails because she has presented no expert opinion on the subject. To demonstrate inadequate warnings, a plaintiff must generally show through expert testimony that the warnings were not "adequate to warn a

physician of the possibility that [the drug] might be causing the condition experienced." MacMurdo, 562 So. 2d at 683; see also Colville, 565 F. Supp. 2d at 1321 (citing MacMurdo, 562 So. 2d at 683). Accordingly, summary judgment is appropriate on a failure to warn claim if a plaintiff has not proffered expert testimony on the adequacy of the warnings. See Paparo v. Ortho McNeil Pharm., No. 05-81044, 2007 WL 121149, at *4 (S.D. Fla. Jan. 11, 2007); Haggerty v. Upjohn Co., 950 F. Supp. 1160, 1168 (S.D. Fla. 1996). Here, Ms. LaBarre's expert witness provided no opinions about Plavix's label or the adequacy of its warnings. For this additional reason, Ms. LaBarre's failure to warn claim fails.[10]

C. Ms. LaBarre's Design Defect Claim

Under Florida law, a manufacturer may be strictly liable for harm resulting from a product's defective design. Jennings v. BIC Corp., 181 F.3d 1250, 1255 (11th Cir. 1999). A design is defective if it renders a product unreasonably dangerous. Id. "A product is unreasonably dangerous if the risk of danger in the design outweighs the benefits." In re Fosamax, 2010 WL 1257299, at *6 (quotation omitted). A design's defectiveness is "determined based on an objective standard." Jennings, 181 F.3d at 1255.

Florida provides an affirmative defense to strict liability for products that are "incapable of being made safe" so long as they provide a benefit that justifies their use.

[10] Ms. LaBarre's failure to warn claim also fails because she did not prove that a different warning would have changed Mr. LaBarre's physician's recommended course of treatment. See In re Fosamax Prods. Liab. Litig., 707 F.3d 189, 193 (2d Cir. 2013). Both of Mr. LaBarre's physicians testified that they still believe Plavix was an appropriate treatment for Mr. LaBarre, all things considered. Thus, Ms. LaBarre's failure to warn claim also fails as to causation.

Restatement (Second) of Torts § 402A, cmt. k (1965);[11] see also Adams v. G.D. Searle & Co., 576 So. 2d 728, 733 (Fla. Dist. Ct. App. 1991). To invoke this defense, a seller must establish that: (1) "the product's benefits must outweigh its known risks as of the date the product is distributed,"[12] id.; (2) the drug must be "incapable of being made safe," Amore, 748 F. Supp. at 854; (3) the drug must be "properly prepared and marketed," id.; and (4) the drug must be "accompanied by a proper warning." Id.

On appeal, Ms. LaBarre focuses on only the first element, arguing that the District Court erred in finding that comment k applied because there is a genuine dispute as to whether Plavix's risks outweigh its benefits.[13] The testimony of Mr. LaBarre's

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[11] Comment k provides:

> Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous.

Restatement (Second) of Torts § 402A, cmt. k (1965). Thus, comment k applies to products that are unavoidably unsafe but are nonetheless desirable to treat an affliction that has greater destructive effects. Amore v. G.D. Searle & Co., 748 F. Supp. 748, 854 (S.D. Fla. 1990). Comment k's applicability must be established by the seller on a case by case basis. Adams, 576 So. 2d at 733.

[12] Courts in Florida have looked to the testimony of treating physicians when analyzing this element. See Kunzie v. Family Med. Care, P.A., No. 03-3850-CA, 2005 WL 6317652 (Fla. Cir. Ct. Aug. 25, 2005) (applying Adams, 576 So. 2d at 731-33).

[13] Ms. LaBarre relies on In re Fosamax Prods. Liab. Litig., No. 1:06-MD-1789-JFK, 2010 WL 1257299 (S.D.N.Y. Mar. 26, 2010), but the Fosamax court addressed

physicians and Dr. Moyé's expert report supports the District Court's conclusion that no reasonable juror could find for Ms. LaBarre on her design defect claim. Mr. LaBarre's family physician testified that, considering Plavix's benefits, the risk of bleeding, and the risk of not treating a patient's ACS, Plavix with aspirin was an appropriate course of treatment for Mr. LaBarre and patients like him. Further, Mr. LaBarre's cardiologist testified that: (1) prescribing Plavix and aspirin together, in his experience, had been effective in reducing the number of heart attacks and stent blockages he sees in his patients; (2) bleeding complications from the two drugs occurred infrequently; (3) considering the risks and benefits of Plavix, he believed Plavix with aspirin was an appropriate treatment for Mr. LaBarre; and (4) he continues to prescribe Plavix and aspirin, even taking into account the risk of bleeding.

Dr. Moyé's expert report is not to the contrary. While Dr. Moyé discusses studies showing that Plavix provides only limited benefits to certain populations of patients and increases the risk of bleeding, he also states that for patients suffering from ACS, like Mr. LaBarre, Plavix provides a benefit that is "relatively small but clear," and at no point states that the risks of Plavix outweigh its benefits. Accordingly, on this record, the District Court properly granted summary judgment on this claim.

IV.

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whether the product at issue was unreasonably dangerous, which is an element of a plaintiff's design defect claim. The Fosamax court did not discuss comment k, which is an affirmative defense to a design defect claim. By attempting to rely on Fosamax, Ms. LaBarre conflates an element of her design defect claim—which she must prove—with an element of the comment k affirmative defense—which the Defendants must prove. Thus, Fosamax is not relevant to comment k's applicability in this case.

For these reasons, we will affirm the orders of the District Court.