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## Gregory Kline v. Zimmer Holdings Inc

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## UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

No. 15-2854

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GREGORY KLINE, and CHERRIE KLINE, husband and wife,
Appellants

v.

ZIMMER HOLDINGS, INC.; ZIMMER, INC.; ZIMMER U.S., INC.

\_\_\_\_\_

On Appeal from the United States District Court for the Western District of Pennsylvania
District Court No. 2-13-cv-00513
District Judge: The Honorable Joy Flowers Conti

Submitted Pursuant to Third Circuit L.A.R. 34.1(a) September 29, 2016

Before: AMBRO, SMITH\*, and FISHER, Circuit Judges

(Filed: October 7, 2016)

OPINION\*\*

SMITH, Circuit Judge.

<sup>\*</sup> Honorable D. Brooks Smith, United States Circuit Judge for the Third Circuit, assumed Chief Judge status on October 1, 2016.

<sup>\*\*</sup> This disposition is not an opinion of the full court and pursuant to I.O.P. 5.7 does not constitute binding precedent.

On January 13, 2010, Gregory Kline underwent a total hip replacement. His surgeon implanted a Femoral Stem with Kinectiv Technology. On April 6, 2011, Kline's hip replacement broke; the stem fractured at the neck. Kline sued Zimmer Holdings Inc., Zimmer Inc., and Zimmer United States Inc. (collectively, "Zimmer"), alleging several state-law product liability claims. By the time the case reached summary judgment, Kline's only remaining claims were negligent design defect and negligent failure to warn. The District Court granted summary judgment to Zimmer on all counts. Because Kline failed to show that a reasonable jury could find that any unreasonable act or omission by Zimmer caused him harm, we will affirm the judgment of the District Court.

The District Court had jurisdiction under 28 U.S.C. § 1332, and we have jurisdiction pursuant to 28 U.S.C. § 1291.

We review the District Court's disposition of a summary judgment motion de novo, applying the same standard as the District Court. *Doe v. Luzerne County*, 660 F.3d 169, 174 (3d Cir. 2011). "[W]hen the nonmoving party is the plaintiff, he

<sup>&</sup>lt;sup>1</sup> Kline's wife, Cherrie Kline, also sued for lack of consortium. Because Cherrie Kline's claims are entirely derivative of Kline's claims and because we will affirm the grant of summary judgment as to Kline's claims, we need not perform any separate analysis relating to Cherrie Kline or her loss of consortium claim. *See*, *e.g.*, *Darr Const. Co. v. Workers' Compensation Appeal Bd.*, 715 A.2d 1075, 1080 (Pa. 1998) ("It is well-settled that the [loss of consortium] claim is derivative . . . ."); *Banks v. Int'l Rental & Leasing Corp.*, 680 F.3d 296, 300 n.6 (3d Cir. 2012) ("The District Court dismissed his claim for loss of consortium because that claim was derivative and therefore must rise or fall with his wife's claims.").

must produce sufficient evidence to establish every element that he will be required to prove at trial." *J.S. ex rel. Snyder v. Blue Mountain Sch. Dist.*, 650 F.3d 915, 925 (3d Cir. 2011) (en banc).

Under Pennsylvania law, a plaintiff must show four elements to establish a negligence claim: duty, breach, causation, and damages. See Phillips v. Cricket Lighters, 841 A.2d 1000, 1008 (Pa. 2003); Morena v. S. Hills Health Sys., 462 A.2d 680, 684 n.5 (Pa. 1983). Demonstrating breach requires showing that the defendant acted unreasonably. See, e.g., Phillips, 841 A.2d at 1008 (holding that negligence claims require an inquiry "into the reasonableness of the manufacturer's conduct in creating and distributing such a product"). Reasonableness requires comparing the risk and the utility of the alleged acts or omissions. See, e.g., Benson v. Penn Cent. Transp. Co., 342 A.2d 393, 397 (Pa. 1975) ("A risk is unreasonable if it is of such magnitude as to outweigh what the law regards as the utility of the act or of the particular manner in which it is done." (citing Restatement (Second) of Torts § 291)); see also Metzgar v. Playskool, Inc., 30 F.3d 459, 462 (3d Cir. 1994) (conducting risk-utility analysis in a negligent design case). Then, a plaintiff "must demonstrate 'the causal connection between the breach of a duty of care and the harm alleged: that the increased risk was a substantial factor in bringing about the resultant harm." Green v. Pa. Hosp., 123

A.3d 310, 316 (Pa. 2015) (quoting *Scampone v. Highland Park Care Ctr., LLC*, 57 A.3d 582, 596 (Pa. 2012)).

Thus, to survive summary judgment, Kline has to show that there is a genuine issue of material fact that Zimmer acted unreasonably in designing the stem or failing to warn about the stem and that any unreasonable act was the cause of the harm to Kline. Kline failed to do so.<sup>2</sup>

On appeal, Kline primarily contends the District Court erred because the District Court did not fully consider two affidavits filed after the Magistrate Judge first recommended granting Zimmer's summary judgment motion. Because these affidavits do not advance Kline's reasonableness or design causation arguments, they do not affect summary judgment. Therefore, this Court need not address Kline's arguments that the sham affidavit doctrine was improperly applied<sup>3</sup> or that certain portions of the affidavit of Klein's surgeon were admissible.

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<sup>&</sup>lt;sup>2</sup> Because the parties primarily addressed whether the District Court should or should not have considered certain evidence, there was little briefing on reasonableness. However, Zimmer briefed the causation issue, and the record is clear. *See Disability Rights N.J., Inc. v. Comm'r, N.J. Dep't of Human Servs.*, 796 F.3d 293, 300–01 (3d Cir. 2015) ("We may affirm a district court for any reason supported by the record." (quoting *Brightwell v. Lehman*, 637 F.3d 187, 191 (3d Cir. 2011))).

<sup>&</sup>lt;sup>3</sup> For the same reason, this Court does not need to determine whether the standard of review with regard to the sham affidavit doctrine is de novo or abuse of discretion. *See Galvin v. Eli Lilly & Co.*, 488 F.3d 1026, 1030 n.\* (D.C. Cir. 2007) (identifying national confusion over this issue).

Kline argues that the failure of the Zimmer device in another patient treated by Kline's doctor—an issue raised in both affidavits—is important here. Evidence about the other patient's device failure is not admissible, however, because it did not "involv[e] the same product under similar circumstances," nor did it (1) "show notice to the defendant of the danger," (2) "show [the] existence of the danger," or (3) "show the cause of the accident." Gumbs v. Int'l Harvester, Inc., 718 F.2d 88, 97 (3d Cir. 1983). Here, the other patient's device failure could not show notice of the danger because the allegedly related device failure occurred after the Zimmer device already had been implanted in Kline. The other patient's device failure also does not prove the "existence of the danger" or "cause of the accident" because Kline fails to offer any sort of causation theory regarding the prior accident—let alone one related to any unreasonable act that affected his own device. There is no reason to believe that whatever latent danger allegedly harmed the other patient had any relationship to Kline. Kline's lack of a causation theory for the other patient's device failure means Kline failed to show that there were relevant "similar circumstances." Gumbs, 718 F.2d at 97.

With regard to the negligent design defect claim, the District Court held that Plaintiffs' experts, Mari Truman and Dr. Donald Koss, had waived Kline's design defect claims in their depositions.

In fact, Truman and Koss did raise design defect theories in their expert reports. Although these theories were not waived, they fail at summary judgment. Truman and Koss's design defect theories were that: Zimmer should have conducted more stringent tests; Zimmer could have used a different surface treatment; Zimmer should not have used the particular type of titanium it used; the device should not have been multimodular; the offset or size of the device was dangerous; or the device is inherently flawed.

Kline failed to produce record evidence showing any of these design choices were unreasonable, thus causing his device to fail. With regard to unreasonableness, Kline failed to provide record evidence from which a jury could find that the allegedly faulty design changes increased risk more than they increased utility. See Metzgar, 30 F.3d at 462 (conducting risk-utility analysis in a negligent design case). See generally Tincher v. Omega Flex, Inc., 104 A.3d 328, 389–91 (Pa. 2014) (discussing risk-utility analysis). Instead, for instance, Truman refers to a "NEW and foreseeable risk." Whether a new risk is unreasonable can only be determined based on a comparison with alternative risks and benefits, cf. Peter Huber, Safety and the Second Best: The Hazards of Public Risk Management in the Courts, 85 Colum. L. Rev. 277, 309 (1985) ("[T]he rejection of one risk is always the acceptance of another."), or proof that the new risk was of such magnitude and likelihood that it was facially unreasonable, see Lance v. Wyeth, 85

A.3d 434, 458–59, 458 n.36 (Pa. 2014) (discussing the common use of an alternative design and approving plaintiff's theory that defendant "tender[ed] into the market a drug which it knows or should know is so dangerous that it should not be taken by anyone"). Here, there is neither sufficient record evidence about the relative risks of an alternative design nor sufficient record evidence that the stem is so dangerous that a jury could find Zimmer's design choices were unreasonable.

Moreover, to the extent Kline presented admissible causation evidence, that evidence does not support any of Kline's theories of unreasonable design. For example, Truman failed to show how increased testing would have resulted in a design change; Truman admitted that she did not have "information" to conclude that different surface treatment would have prevented the stem fracture; and Kline's metallurgy expert admitted he was not aware of a better material to use for the stem.

Summary judgment also must be granted to Zimmer on Kline's failure to warn claim. Kline's theory, supported by Zimmer's experts, was that an individual of Kline's weight or body mass index who engaged in vigorous activity was at a higher risk of device failure. As Kline acknowledged, a package insert for Zimmer's device warned about those risks, at least in general terms.<sup>4</sup> Truman

<sup>&</sup>quot;Complication or failure of any total hip prosthesis are more likely to occur in heavy patients."

opined that there were two defects with these warnings: (1) Zimmer should have contraindicated the device and (2) done so for use at specific weights, body mass indexes, and/or activity levels. Truman based her opinion on the fact that one of Zimmer's competitors contraindicated specific combinations of weights and activity levels on the competitor's device. However, to the extent Truman opined that the weaker warning was unreasonable, that opinion is unsubstantiated and therefore fails to create a genuine issue of material fact. See Advo, Inc. v. Phila. Newspapers, Inc., 51 F.3d 1191, 1198 (3d Cir. 1995) ("[E]xpert testimony without . . . a factual foundation cannot defeat a motion for summary judgment."); see also Thomas v. Hoffman-LaRoche, Inc., 949 F.2d 806, 815 (5th Cir. 1992) (describing contraindication). Truman did not indicate, among other things, that the competitor's device was sufficiently analogous to Zimmer's device, that the competitor's warning was reasonable, that there were any particular weights or

"Complications and/or failure of total hip prostheses. [sic] are more likely to occur in patients with unrealistic functional expectations, heavy patients, physically active patients, and/or with patients who fail to follow through with the required rehabilitation program. Physical activity can result in loosening, wear, and/or fracture of the hip implant. The prospective implant patient must be counseled about the capabilities of the implant and the impact it will have on his or her lifestyle. The patient must be instructed about all postoperative restrictions, particularly those related to occupational and sports activities . . . ."

activity levels at which excessive risk existed, or that the likelihood of fracture was high enough to warrant the contraindication. Accordingly, there is no evidence in the record that the risk was of a magnitude to require a contraindication at any specific weight, body mass index, or activity level, except that the device broke in Kline. For the reasons set forth above, we will affirm the judgment of the District Court.