UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

SUMMARY ORDER

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Daniel Patrick Moynihan United States Courthouse, 500 Pearl Street, in the City of New York, on the 25th day of March, two thousand eleven.

PRESENT: DENNIS JACOBS,
Chief Judge,
ROSEMARY S. POOLER,
PETER W. HALL,
Circuit Judges.

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EILEEN F. DONOVAN and TIMOTHY D. DONOVAN,

Plaintiffs-Appellants,

-v.- 10-1769-cv

CENTERPULSE SPINE TECH INC.,

Defendant-Appellee,

CENTERPULSE USA, INC.,

Defendant.
- -X

FOR APPELLANTS: HUGH M. RUSS, III (Ryan K. Cummings, on the brief), Hodgson Russ LLP, Buffalo, NY.

FOR APPELLEE: HARRY F. MOONEY (Jody E. Briandi, Tasha T. Dandridge, Hurwitz & Fine, P.C., Buffalo, NY, and Thomas G. Stayton, Baker & Daniels LLP, Indianapolis, IN, on the brief), Hurwitz & Fine, P.C., Buffalo, NY.

Appeal from a judgment of the United States District Court for the Western District of New York (Curtin, J.).

UPON DUE CONSIDERATION, IT IS HEREBY ORDERED, ADJUDGED AND DECREED that the judgment of the district court be **AFFIRMED**.

Appellants Eileen and Timothy Donovan appeal from the judgment entered on March 31, 2010 by the United States District Court for the Western District of New York (Curtin, J.), which, inter alia, granted appellee's motion for summary judgment on the Donovans' strict products liability and negligence claims under New York law relating to appellee's product, the Silhouette Spinal Fixation System ("Spinal System"). We assume the parties' familiarity with the underlying facts, the procedural history, and the issues presented for review.

A grant of summary judgment is reviewed de novo, "resolv[ing] all ambiguities and draw[ing] all permissible factual inferences in favor of the party against whom summary judgment is sought." Terry v. Ashcroft, 336 F.3d 128, 137 (2d Cir. 2003) (internal quotation marks omitted).

[1] The amended complaint alleges that Ms. Donovan was harmed by the "defective design and/or manufacture of the [fractured] screw" from the Spinal System. (Am. Compl. ¶ 11.) The parties dispute which legal claims are raised by the allegation, but any such claim* is subject to the same causation analysis: Under New York law, "whether the action is pleaded in strict products liability, breach of warranty

* The potential failure-to-warn claim is discussed separately below.

or negligence, it is a consumer's burden to show that a defect in the product was a substantial factor in causing the injury." Tardella v. RJR Nabisco, Inc., 576 N.Y.S.2d 965, 966 (3d Dep't 1991).

Although expert medical evidence of causation is not required in all products liability cases under New York law, Voss v. Black & Decker Mfg. Co., 59 N.Y.2d 102, 110-11 (1983), "[o]rdinarily, expert medical opinion evidence . . . is required, when the subject-matter to be inquired about is presumed not to be within common knowledge and experience." Fane v. Zimmer, Inc., 927 F.2d 124, 131 (2d Cir. 1991) (quoting Meiselman v. Crown Heights Hosp., 285 N.Y. 389, 396 (1941)). Here, the Spinal System was installed to help remedy a pain condition that arose from an accident that preceded installation and continued unabated after removal. Normally, when "an injury has multiple potential etiologies, expert [medical] testimony is necessary to establish causation." Wills v. Amerada Hess Corp., 379 F.3d 32, 46 (2d Cir. 2004) (requiring expert medical testimony even for Jones Act claim, which has a reduced burden for causation).

The plaintiffs have not supported their claims with expert medical opinion evidence. Their metallurgical expert considered causation only in respect of the failure of the device itself; he was not qualified to opine on medical causation, and did not so do. Plaintiffs' causation argument therefore rests on one statement from Dr. Suddaby's deposition, indicating that Ms. Donovan's pain was caused in part by the loose hardware. At the threshold, it is unclear whether Dr. Suddaby was referring to pain experienced after the removal surgery or while the Spinal System remained implanted. If the latter (which seems more likely), the comment is not probative of the "severe and permanent disabilities" alleged in the complaint.

In any event, this remark taken in context provides insufficient support of causation. "[T]he mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient [to defeat summary judgment]; there must be evidence on which the jury could reasonably find for the plaintiff." Jeffreys v. City of New York, 426 F.3d 549, 554 (2d Cir. 2005) (internal quotation marks omitted). Furthermore, an expert opinion "requires some explanation as to how the expert came to his conclusion and what methodologies or evidence substantiate that conclusion," Riegel v. Medtronic, Inc., 451 F.3d 104, 127

(2d Cir. 2006); taking one statement from a deposition out of context, without more, provides insufficient explanation.

In context, Dr. Suddaby clearly (and repeatedly) opined that the "significant component" of Ms. Donovan's pain following removal was the residual spinal instability that pre-dated the surgeries and that the embedded screw fragment would not have adverse effects. Joint Appendix at 1697, 1725.

On this record, a reasonable jury could not find that the Spinal System was a substantial factor in causing Ms. Donovan's lasting injuries.

[2] Plaintiffs argue here that they pled a failure-to-warn claim; but the plain language of the amended complaint alleged only "defective design and/or manufacture of the [fractured] screw." (Am. Compl. ¶ 11.) And plaintiffs have not moved to further amend the complaint. "[A] district court does not abuse its discretion when it fails to grant leave to amend a complaint without being asked to do so." See Greenidge v. Allstate Ins. Co., 446 F.3d 356, 361 (2d Cir. 2006). We therefore need not consider plaintiffs' failure-to-warn argument, because it was untimely raised. See Id.

In any event, a failure-to-warn claim would be futile. Under New York law, "[t]he physician acts as an 'informed intermediary' between the manufacturer and the patient; and, thus, the manufacturer's duty to caution against a [device's] side effects is fulfilled by giving adequate warning through the [treating] physician, not directly to the patient." Martin v. Hacker, 83 N.Y.2d 1, 9 (1993) (internal citations omitted); Banker v. Hoehn, 718 N.Y.S.2d 438, 440 (3d Dep't 2000) (applying informed intermediary doctrine to medical devices).

The record reflects that Dr. Suddaby was supplied product information, including specific warnings about nonunion and device component fracture, which he had read prior to the surgery; he attended courses about the device on a routine basis, which included hands-on practice on cadavers; he traveled several times to appellee's teaching facility; he reviewed workbooks that described the device and its use; and he was aware that obesity was contraindicated for the device. The plaintiffs do not

identify any particular information that Dr. Suddaby lacked that would have affected the course of treatment.

We have considered all of appellants' contentions on this appeal and have found them to be without merit. Accordingly, the judgment of the district court is hereby **AFFIRMED**.

FOR THE COURT:
CATHERINE O'HAGAN WOLFE, CLERK