UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

WILLIAM FERTIK, individually and as personal representative and successor of the ESTATE of GRETA FERTIK, Plaintiff, v. WILLIAM STEVENSON, M.D.; MELANIE MAYTIN, M.D.; ABBOTT VASCULAR, INC., Defendants.	Civil Action No. 12-10795-PBS

MEMORANDUM AND ORDER

May 13, 2016

Saris, C.J.

INTRODUCTION

William and Greta Fertik[1] filed this action against two physicians and the manufacturer of a surgical guide wire, Abbott Vascular, Inc. (Abbott), after the guide wire broke and was left inside William Fertik's heart during cardiac surgery. The plaintiff's sole claim against Abbott is that the Hi-Torque Balanced Heavyweight cardiac guide wire failed due to Abbott's

[1] On June 12, 2015, Greta Fertik's attorney filed a suggestion of death. Docket No. 86. Her estate, through William Fertik, is now a plaintiff in this case. Because William Fertik is representing himself and the estate, I will refer to him as the plaintiff.

negligence in manufacturing the wire. Abbott has moved for summary judgment claiming that the plaintiff has failed to provide reliable evidence that the wire broke as a result of Abbott's negligent manufacturing.[2] The plaintiff responds that the doctrine of *res ipsa loquitur* defeats summary judgment. Neither party contends that the physicians were negligent in the placement of the wire. After hearing, this Court **DENIES** the defendant's motion for summary judgment (Docket No. 173).

FACTUAL BACKGROUND

The facts are taken from the record and are undisputed unless otherwise noted. On May 6, 2009, the plaintiff, William Fertik, underwent a radiofrequency cardiac ablation procedure[3] at Brigham & Women's Hospital in Boston to treat his cardiac rhythm irregularities and periodic atrial fibrillation.[4] Dr. William Stevenson, who had previously performed more than 3,000 similar

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[2] The plaintiff has waived his negligent design theory and conceded that he no longer intends to pursue a claim against Abbott Laboratories, Inc., the parent company of Abbott Vascular, Inc. Docket No. 192 at 2 n.2.

[3] Ablation usually uses long, flexible tubes (catheters) inserted through a vein in the groin and threaded to the heart to correct structural problems in the heart that cause an arrhythmia. Cardiac Ablation, Mayo Clinic, http://www. mayoclinic.org/tests-procedures/cardiac-ablation/basics/ definition/prc-20022642 (last visited April 5, 2016).

[4] "Atrial fibrillation is an irregular and often rapid heart rate that can increase [the] risk of stroke." Atrial Fibrillation, Mayo Clinic, http://www. mayoclinic.org/diseases-conditions/ atrial-fibrillation/home/ovc-20164923 (last visited March 11, 2016).

procedures without incident, and Dr. Melanie Maytin, a fellow at the hospital, performed the procedure.

During the cardiac ablation procedure, Dr. Stevenson removed the guide wire from its sterile packaging and observed no damage or evidence of any tampering. He then threaded the wire through Mr. Fertik's vasculature up to his heart. The wire served as a guide for a needle that the physicians used to puncture the internal wall of the heart and gain access to the left atrium. This procedure is known as a trans-septal puncture.

During the surgery, unnoticed by either physician, a portion of the guide wire broke off inside the plaintiff's body. The physicians experienced nothing unusual during the procedure and neither saw nor felt the wire break. After the surgery, the plaintiff was discharged from the hospital. Later he demonstrated symptoms of a stroke and hospital personnel discovered that the wire had been left coiled up inside his heart.

The plaintiff then returned to the hospital and, on May 10, 2009, Dr. Eisenhauer, a non-party, removed the wire remnant. Dr. Eisenhauer, who had performed over 15,000 procedures similar to the cardiac ablation procedure, had experienced guide wire breakage fewer than six times. Each time that the wire broke, he felt it break and immediately realized something had gone wrong. After the procedure, it is disputed whether Dr. Eisenhauer gave

the wire remnant directly to the hospital's pathology department or to Dr. Stevenson, but the remnant ultimately ended up in the possession of the hospital's pathology department for testing. After testing, through no fault of either Abbott or Mr. Fertik, the wire was mistakenly discarded.

DISCUSSION

I. Summary Judgment Standard

Faced with a summary judgment motion, the Court must assess all facts in the record, and all reasonable inferences drawn from the facts, in favor of the non-moving party. Perry v. Roy, 782 F.3d 73, 77 (1st Cir. 2015). A summary judgment motion succeeds "only where 'there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.'" Showtime Entm't, LLC v. Town of Mendon, 769 F.3d 61, 69 (1st Cir. 2014) (quoting Fed. R. Civ. P. 56(a)). Genuine disputes arise when the evidence would allow "a reasonable jury [to] return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). "A genuine issue of material fact must be built on a solid foundation—a foundation constructed from materials of evidentiary quality." Perry, 782 F.3d at 78 (internal quotation marks omitted).

II. The Doctrine of *Res Ipsa Loquitur*

A plaintiff in a product liability case must prove at least two elements: (1) the defendant produced or sold a defective product and (2) the product caused the plaintiff's injury. See Smith v. Ariens Co., 377 N.E.2d 954, 958 (Mass. 1978). A manufacturing defect exists when a product "deviates in its construction or quality from specifications or planned output in a manner that renders it unreasonably dangerous." Brown v. Husky Injection Molding Sys., Inc., 751 F. Supp. 2d 298, 300-01 (D. Mass. 2010) (internal quotation marks omitted). In manufacturing defect cases, "a particular product rather than a line of products, is alleged to be defective because of negligence in the manufacturing process." Ariens, 377 N.E.2d at 958.

Here, the plaintiff is pressing a manufacturing defect claim caused by Abbott's negligence under the doctrine of *res ipsa loquitur*. There is no present dispute over the cause of the plaintiff's injury. The defendant contends that the doctrine of *res ipsa loquitur* is inapplicable because Abbott did not have exclusive control over the guide wire, the use of the guide wire was "off-label," and the guide wire—which is delicate—has a risk of breakage even in "on-label" uses without any physician or manufacturer negligence. The plaintiff responds that the doctrine of *res ipsa loquitur* saves his case even with the loss of the wire because there is no evidence of any damage to the

wire prior to the surgery, and neither party claims the physicians were negligent. The plaintiff argues that, given the rare incidence of guide wire failures, a genuine issue of fact exists about whether the wire broke due to a manufacturing defect caused by Abbott's negligence.

Under Massachusetts law, the doctrine of *res ipsa loquitur*:

> permits a trier of fact to draw an inference of negligence in the absence of a finding of a specific cause of the occurrence when an accident is of the kind that does not ordinarily happen unless the defendant was negligent in some respect and other responsible causes including conduct of the plaintiff are sufficiently eliminated by the evidence.

Enrich v. Windmere Corp., 616 N.E.2d 1081, 1085 (Mass. 1993) (citing Restatement (Second) of Torts § 328D(1)(a) (1965)). "The jury must be able to find either by expert evidence or by their own common knowledge that the mere occurrence of the accident shows negligence as a cause." Id.

A jury can apply the doctrine if they find, by a preponderance of the evidence, that: "(1) the instrumentality causing the accident was in the sole and exclusive control and management of the defendant; and (2) the accident is of the type or kind that would not happen in the ordinary course of things unless there was negligence by the defendant." Wilson v. Honeywell, Inc., 569 N.E.2d 1011, 1013 (Mass. 1991) (internal quotation marks omitted). "Even where absolute exclusivity in

use is not evident, a jury may be reasonable in finding that the defendant's control was sufficient to warrant an inference that the defendant was more likely responsible for the incident than someone else." Id. at 1013-14; see also Restatement (Second) of Torts § 328D cmt. f (1965) ("[T]he plaintiff is not required to exclude all other possible conclusions beyond a reasonable doubt, and it is enough that he makes out a case from which the jury may reasonably conclude that the negligence was, more probably than not, that of the defendant.").

Laspesa v. Arrow International, Inc., is a products liability case on point involving a broken epidural catheter lodged in a woman's back during the delivery of her baby. No. CIV. 07CV12370-NG, 2009 WL 5217030, at *1 (D. Mass. Dec. 23, 2009). With respect to the first element in Wilson, the Laspesa court ruled that the requirement of exclusive control was met when the catheter was "out of the box" and new prior to surgery. Id. at *8. For the second element, the court ruled that *res ipsa loquitur* was appropriate when "the hospital reported the event to the FDA, the incident [was] unusual, and there [was] evidence that the patient's doctor was not negligent." Id.; see also Parkinson v. Guidant Corp., 315 F. Supp. 2d 741, 750 (W.D. Pa. 2004) (denying summary judgment because of *res ipsa loquitur* theory where the guide wire broke inside the plaintiff based on evidence that the operating physician had not been negligent and

that tip separation of a guide wire is not an incident that ordinarily occurs in the absence of negligence).

In this case, Abbott has produced no evidence that the wire used in the plaintiff's surgery was mishandled from the time it left Abbott's control to the time the defendant physicians removed it from the package during surgery. Dr. Eisenhauer, the physician who removed the guide wire remnant, testified that guide wires, like the one used in the plaintiff's surgery, are packaged in a sterile pouch by the manufacturer and the pouch is only opened by a technician in a sterile field during surgery. The defendant physicians provided testimony that neither they, nor any member of the surgical team, mishandled the guide wire prior to the surgery. They also testified that the guide wire appeared undamaged when it was removed from the packaging. This evidence is sufficient to satisfy the first prong of exclusive control for *res ipsa loquitur* under Wilson.

With respect to the second prong, the plaintiff has presented evidence that the guide wire would not have broken in the absence of manufacturer negligence. The plaintiff points to Dr. Stevenson's testimony that he had performed more than 3,000 similar procedures without a guide wire breaking. Dr. Eisenhauer testified that, in 15,000 similar procedures, he had experienced guide wire failure fewer than six times. In rebuttal, Abbott points to the Food and Drug Administration (FDA) website which

states: “The most common adverse event associated with guide wires that is reported to the FDA is breakage of the tip or wire, most commonly because of handling use error.” Docket No. 178, Ex. 24 at 2. In the circumstances of this case, however, all parties agree there was no negligence or misuse by the doctors or other third parties handling the guide wire.[5] Cf. Ryba v. LaLancette, 417 F. Supp. 2d 199, 208 (D. Mass. 2006) (rejecting *res ipsa loquitur* where plaintiff had not eliminated third parties as probable causes).

Abbott also points to evidence that the wire is described as “delicate” and Abbott contends there is a risk of breakage even in the ordinary course without negligence or misuse. However, when all reasonable inferences are drawn in the plaintiff’s favor, given the testimony of the doctors, a jury could find the wire broke as a result of a defect, and not in the ordinary course of this kind of medical procedure.

III. “Off-Label” Use

Abbott’s primary argument rests on evidence that the physicians were using the guide wire in an “off-label” manner, and that its guide wires were manufactured with sufficient

[5] Instead, the plaintiff asserts that his “negligence theory against the physician defendants is not that their negligence caused the wire to fail, but rather that they were negligent in their failure to ensure that once broken, they recognized the problem.” Docket No. 192 at 17 n.21 (emphasis in original).

strength for the uses approved by the FDA. The plaintiff responds that the defendant has overstated the level of scrutiny the FDA applied in clearing the guide wire for use, has misstated the actual "on-label" uses of the guide wire, and has failed to provide any controlling authority for the proposition that a manufacturer in a product defect case is immune from suit if its product was used in an "off-label" manner.

The Medical Device Amendments of 1976 (MDA) classify medical devices in "three categories based on the risk that they pose to the public." Medtronic, Inc. v. Lohr, 518 U.S. 470, 476 (1996). Class III devices must go through the Premarket Approval Process (PMA) and "submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission." Id. at 477. Class II devices, such as the guide wire in this case, are subject to a more limited form of review known as the § 510(k) process; "in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours." Id. at 478-79. "If the FDA concludes on the basis of the § 510(k) notification that the device is substantially equivalent to a pre-existing device, it can be marketed without further regulatory analysis." Id. at 478 (internal quotation marks omitted). Section "510(k) notification requires little information, rarely elicits a negative response

from the FDA, and gets processed very quickly." Id. at 479. Devices that "enter the market through § 510(k) have never been formally reviewed under the MDA for safety or efficacy." Riegel v. Medtronic, Inc., 552 U.S. 312, 323 (2008) (internal quotation marks omitted).

"Use of a device (or a drug) in a way not approved by the FDA—called 'off-label use'—is a widespread practice in the medical community." Holland v. Smith & Nephew Richards, Inc., 100 F. Supp. 2d 53, 55 (D. Mass. 1999). "The FDA has recognized that it cannot regulate the medical judgments that lead to off-label use." Id. "Off-label" usage of medical devices is an "accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 350 (2001).

"A manufacturer always has a duty when designing products to consider the environment in which the product will be used and must design against all reasonably foreseeable uses which could arise from that environment." Cigna Ins. Co. v. Oy Saunatec, Ltd., 241 F.3d 1, 15 (1st Cir. 2001) (applying Massachusetts law). On the other hand, a "defendant is not liable for the consequences of the unforeseeable misuse of a product." Back v. Wickes Corp., 378 N.E.2d 964, 969 (Mass. 1978). Whether or not a misuse is foreseeable is an issue of

fact for the jury. See Gillespie v. Sears, Roebuck & Co., 386 F.3d 21, 28 (1st Cir. 2004).

As a threshold matter, the plaintiff disputes Abbott's claim that the physicians used the guide wire in an "off-label" manner, and contends that the use of the guide wire in the cardiac ablation procedure was within the scope of uses cleared by the FDA. According to Janet Benson,[6] Abbott's director of regulatory affairs, the wire has four approved and labeled uses: (1) to facilitate the placement of balloon dilation catheters during percutaneous transluminal coronary angioplasty and (2) percutaneous transluminal angioplasty,[7] (3) for the placement of intravascular stents,[8] and (4) intravascular directional atherectomy devices.[9] Docket No. 178, Ex. 1 at 1-2. Abbott relies on Dr. Stevenson's affidavit in which he admits that the use of

[6] The plaintiff has moved to strike this affidavit because Ms. Benson was not identified as an expert on device labeling and has asserted a legal conclusion in her affidavit. Docket No. 197. The motion is denied with respect to the challenge to her qualifications as to this information.

[7] A guide wire with a balloon at the tip is inserted into the artery to the site of the blockage. The balloon is inflated flattening the blockage against the artery walls. Percutaneous Transluminal Angioplasty, Johns Hopkins Medicine, http://www.hopkinsmedicine.org/healthlibrary/test_ procedures/cardiovascular/_22,PercutaneousTransluminalAngioplasty/ (last visited April 5, 2016).

[8] Slender thread, rod, or catheter, lying within the interior of a tubular structure, such as an artery, and used to provide support. Stedman's Medical Dictionary 998, 1674 (26th ed. 1995).

[9] Removal of coronary device with an instrumented catheter. See Stedman's Medical Dictionary 162 (26th ed. 1995)

the guide wire "was an off-label use of the device." Docket No. 178, Ex. 3 at 2.[10] The plaintiff retorts that even though the cardiac ablation procedure is not specifically listed in the guide wire labeling as a cleared use, the product classification, submitted by Abbott and cleared by the FDA, states: "The wire is also intended to facilitate the placement of equipment such as atherectomy and compatible stent devices during other diagnostic and therapeutic procedures." Docket No. 193, Ex. 4 at 6. Without providing any expert testimony on FDA labeling, the plaintiff contends that a plain reading of this broader statement covers the facilitation of the placement of a transseptal needle (stent device) during a cardiac ablation (therapeutic) procedure.

Assuming the use of the guide wire here, a cardiac ablation procedure, is "off-label," the plaintiff has produced evidence that this use was foreseeable. Leading surgeons in a prominent Harvard-teaching hospital have used the Abbott guide wire in this manner thousands of times and Abbott has provided no evidence that this use was an unforeseeable misuse of the wire. There is also no evidence that the stress incurred by the guide

[10] The plaintiff has moved to strike this affidavit because Dr. Stevenson has no basis from which to draw this legal conclusion as he is not an expert on FDA labelling or "off-label" uses. Docket No. 196. The motion is denied because of his expertise in this medical procedure.

wire in this "off-label" procedure was greater than in the "on-label" procedures enumerated in the guide wire's label.

Abbott insists it is not liable for manufacturing defect claims relating to "off-label" uses of its products. The defendant unsuccessfully attempts to turn the screws on the plaintiff relying on cases largely involving surgical screws. To be sure, while a physician may use any device legally on the market in any way the physician deems appropriate, including in an "off-label" use, courts have held that a seller is not liable for the physician's decision to use the device "off-label" absent a defect. See Cox v. Depuy Motech, Inc., No. 95-CV-3848-L(JA), 2000 WL 1160486, at *8-9 (S.D. Cal. Mar. 29, 2000) (case involving a broken spinal screw). Moreover, a seller is not liable even if it knows of the "off-label" use of a product unless there is a product defect. Id. at *8; Little v. Depuy Motech, Inc., No. 96CV0393-L JAH, 2000 WL 1519962, at *9 (S.D. Cal. June 13, 2000) (holding that the manufacturer cannot be held liable for the doctor's decision to implant a device in an "off-label" manner even if it knows of the "off-label" use); Holland, 100 F. Supp. 2d at 56 (even if the seller improperly promoted screws for "off-label" uses, the fact that the defendant promoted the product without permission does not tend to establish that the product was defective or unfit for its intended use, even if the intended use was forbidden by the

regulatory authorities). However, there is no controlling authority that immunizes Abbott from a product defect claim based on a foreseeable "off-label" use. Therefore, Abbott's motion for summary judgment is denied.

IV. Daubert Motion

Abbott argues that the testimony of the plaintiff's expert, Dana J. Medlin, Ph.D., an engineering and metallurgy expert, should be excluded because his theory of how the guide wire broke is not consistent with the pathologist's measurement of the wire remnant removed from the plaintiff. Dr. Medlin believes that the failure of the wire is more likely due to a defect in the wire than some other cause. The plaintiff responds that the pathologist's measurement was inaccurate and Dr. Medlin's theory is still applicable to the specifics of this case. Because the wire was discarded and the pathologist remains out of the country and has not been deposed, the record contains no other alternative measurement for the guide wire remnant.

The Abbott guide wire consists of a longer Elastinite wire and a shorter steel wire. These two wires are joined at the hypotube junction, which is a sleeve 1.6 inches long with a slightly wider diameter than the wires. Both wires are inserted into the hypotube junction and are bonded with adhesive. The end of the wire that is inserted into the body, the distal end, is 15.7 inches long from the distal tip to the beginning of the

hypotube junction. Therefore, if the wire were to separate at the hypotube junction, the remnant would measure at least 15.7 inches. Dr. Medlin opines that "it is much more likely than not that failure of the subject guide wire . . . [1] resulted from inadequate adhesion between the Elastinite core wire and the Hypotube, [2] inadequate hypotube wall strength, and/or [3] defects induced into the hypotube junction." Docket No. 181, Ex. 1 at 17. All of Dr. Medlin's theories involve the wire separating or fracturing at the hypotube junction.

The pathologist's report states that the wire remnant was 39.5 centimeters (15.55 inches) long. The plaintiff disputes the accuracy of this measurement since the report notes that the "specimen is for gross diagnosis only." Docket No. 178, Ex. 18 at 2. Additionally, the report identifies the wire as a "pacemaker wire," which it is not, and gives only a rough approximation for the measurement of the wire's diameter. Id. The defendant's expert, Dr. Eager, testified that he interpreted the report to mean that the wire remnant was between 39 and 40 centimeters or 15.35 and 15.75 inches based on the precision of the measurement. If the measurement were at the high end of this range, 15.7 inches or greater, Dr. Medlin's opinion that it separated at the hypotube junction would be reliable.

The Court need not decide the admissibility of the expert's opinion now because, under the plaintiff's *res ipsa loquitur*

theory, he has provided evidence, sufficient to survive summary judgment, from the medical experts that fracture of the wire was not an ordinary occurrence during similar medical procedures even in the absence of Dr. Medlin's expert testimony. See Laspesa, 2009 WL 5217030, at *8; Parkinson, 315 F. Supp. 2d at 750. The Court will allow the parties to supplement the record with any new evidence they discover with respect to the measurement of the wire remnant by June 30, 2016. The Court will address the Daubert motion in a separate proceeding.

ORDER

This Court **DENIES** the defendant's motion for summary judgment (Docket No. 173).

/s/ PATTI B. SARIS
Patti B. Saris
Chief United States District Judge