

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

WILLIAM FERTIK, individually and as personal representative and successor of the ESTATE of GRETA FERTIK,  <div style="text-align: right;">Plaintiff,</div>	)	
v.	)	Civil Action No. 12-10795-PBS
WILLIAM STEVENSON, M.D.; MELANIE MAYTIN, M.D.; ABBOTT VASCULAR, INC.,  <div style="text-align: right;">Defendants.</div>	)	

**MEMORANDUM AND ORDER**

August 4, 2016

Saris, C.J.

**INTRODUCTION**

William and Greta Fertik<sup>1</sup> 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. Abbott moved for summary judgment and to exclude the opinion testimony of the plaintiff's expert, Dr. Dana Medlin, under Daubert v.

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<sup>1</sup> 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.

Merrell Dow Pharm., Inc., 509 U.S. 579 (1993). In an earlier order, this Court denied Abbott's motion for summary judgment, ruling that the plaintiff's case could proceed to trial on the doctrine of *res ipsa loquitur*. Fertik v. Stevenson, No. 12-cv-10795-PBS, 2016 WL 2851315, at \*1 (D. Mass. May 13, 2016). The Court declined to rule on Abbott's Daubert motion at that time, allowing the parties to supplement the record with any new evidence they discovered about the length of the wire remnant left in the plaintiff's chest. Id. at \*6.<sup>2</sup> The Court assumes familiarity with that opinion, which sets forth the factual record of this case. The Court held an evidentiary hearing at which the plaintiff's expert, Dana Medlin Ph.D., P.E., FASM, testified. After hearing, the defendant's Daubert motion (Docket No. 179) is **ALLOWED** in part.

#### **DISCUSSION**

Abbott argues that Dr. Medlin's theory that the guide wire separated at the hypotube junction is not supported by the measurement of the wire remnant, and that, because he could not

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<sup>2</sup> The Court did not allow the submission of a new expert report by Dr. Medlin, particularly a report based on information from a previously undisclosed consulting expert, Dr. Pilichowska. Therefore, the Court **ALLOWS** Abbott's motion to strike the June 27, 2016 Supplemental Report of Dr. Medlin (Docket No. 242). Based on this supplemental report, Abbott served a deposition notice on Dr. Medlin and a subpoena on Dr. Pilichowska. Because, the Court has struck this supplemental report, the plaintiff's motion for a protective order and to quash the defendant's deposition subpoena (Docket No. 247) is now **MOOT**.

test the actual wire remnant, he has no reliable scientific basis for claiming that it was more likely than not that the guide wire broke as a result of a manufacturing defect.

Admissibility of expert testimony is guided by Federal Rule of Evidence 702, which provides that:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

Milward v. Rust-Oleum Corp., 820 F.3d 469, 473 (1st Cir. 2016)

(quoting Fed. R. Evid. 702). The district court "serves as the gatekeeper for expert testimony by 'ensuring that it both rests on a reliable foundation and is relevant to the task at hand.'"

Id. (quoting Daubert, 509 U.S. at 597 (alterations omitted)).

The second requirement "seeks to ensure that there is an adequate fit between the expert's methods and his conclusions."

Samaan v. St. Joseph Hosp., 670 F.3d 21, 32 (1st Cir. 2012).

"This prong of the Daubert inquiry addresses the problem that arises when an expert's methods, though impeccable, yield results that bear a dubious relationship to the questions on which he proposes to opine." Id. "The party seeking to introduce

the evidence has the burden of establishing both its reliability and its relevance." Milward, 820 F.3d at 473.

The geography of the guide wire is critical to Dr. Medlin's analysis. The guide wire itself is composed of two wires—one steel and one Elastinite—which meet at the hypotube junction, and are held together by adhesive. As the two wires enter the hypotube junction, they taper, or become thinner. The parties agree that the Elastinite "distal" end of the guide wire was inserted first into the plaintiff's body and would have been the portion left inside Mr. Fertik.<sup>3</sup>

In his five expert reports, Dr. Medlin opined that it was "highly likely" that the guide wire at issue "fractured or separated at the Elastinite Hypotube junction," based on "a manufacturing defect." Docket No. 251, Ex. 1 at 9; Docket No. 251, Ex. 2 at 5. Dr. Medlin was unable to test the actual wire remnant removed from the plaintiff because it was discarded after removal, through no fault of either the plaintiff or Abbott.

The only record of any testing performed on the remnant is a one-page pathology report, dated May 14, 2009, which reported the remnant to be 39.5 centimeters (cm) long. Docket No. 240, Ex. 1 at 6. In their depositions, Drs. Brock and Agoston,

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<sup>3</sup> A diagram of the guide wire illustrating this geography is attached to this order under seal.

pathologists at Brigham & Women's Hospital, testified that a non-tissue specimen, like the guide wire at issue, was usually measured to the nearest 0.5 cm. Docket No. 241 at 3; Docket No. 242, Ex. 2 at 6-7. With this range of measuring error, the wire remnant could have measured between 39 cm and 40 cm.

Dr. Medlin advanced two theories: separation and fracture. His separation theory posits that the guide wire pulled apart at the hypotube junction because of "inadequate adhesion between the Elastinite core wire and the Hypotube." Docket No. 251, Ex. 2 at 18. At the hearing, the parties referred to this theory as the "pull-out theory." Hearing Tr. at 106. Because the pathology report is the only recorded measurement of the remnant, the specifications of the guide wire are critical to the likelihood of the pull-out theory. According to the specifications, the Elastinite end of the guide wire, including the portion inside the hypotube junction, measured 40.7 cm  $\pm$  .2 cm. Therefore, the Elastinite end could measure between 40.5 cm and 40.9 cm. For the pull-out theory to be possible, the wire remnant must measure somewhere in that range. Here is where the separation theory comes apart. Taking the best case scenario for the plaintiff, the remnant could have measured, at most, 40 cm, which is 0.5 cm less than the Elastinite end, measuring, at least, 40.5 cm. Based on this 0.5 cm gap, the pull-out theory could not have occurred. As the plaintiff and Dr. Medlin

conceded, the pull-out theory is unsupported by reliable facts, and therefore, Dr. Medlin may not testify about it at trial.

Dr. Medlin's alternative theory is that the wire fractured at or near the hypotube junction. This theory, at least as to the place of the fracture, is consistent with the measurement of the wire remnant. He further opined that, because the Elastinite wire becomes thinner as it enters the hypotube junction, it would take less than eight pounds of force to fracture the wire there. At the thickest part of the wire, he testified that it would take closer to twenty-eight pounds of force. To calculate these forces, Dr. Medlin took the minimum tensile strength of the wire from the specifications along with the wire diameter and conducted "a basic engineering calculation." Hearing Tr. at 96. As plaintiff's counsel conceded at the hearing, Dr. Medlin did not disclose these calculations in any of his expert reports. Hearing Tr. at 97. Therefore, he may not testify about these force calculations at trial.

Dr. Medlin relies largely on the operating physicians' deposition testimony that they did not experience anything unusual or feel the wire break as they conducted the surgical procedure. Because the guide wire is designed to withstand normal forces, he then concludes that it must have been defective or it would not have broken during a normal, foreseeable medical procedure. This testimony is essentially the

rationale behind the Court's *res ipsa loquitur* ruling. Therefore, he may testify that, in his opinion, there was a defect at the hypotube junction. Dr. Medlin may also testify about the specifications, measurements, and materials of the guide wire and that the wire likely broke at or near the hypotube junction based on the measurement of the wire remnant.

Dr. Medlin admitted that, because he could not test the wire remnant itself, his theories about the reason for the fracture were "based on possibility." Hearing Tr. at 109. Because Dr. Medlin admitted that he was providing possible, not probable, explanations for the wire breakage, I find that his opinion that it is more likely than not that the guide wire broke due to a defect related to the tapered wire's ability to withstand the force used lacks adequate factual support under Daubert. Therefore, Dr. Medlin may not testify about this theory at trial. Additionally, the plaintiff has waived his negligent design theory. Docket No. 192 at 2 n.2. Dr. Medlin may not testify about this now-abandoned theory.

#### **ORDER**

The Court **ALLOWS** Abbott's motion to strike the June 27, 2016 Supplemental Report of Dr. Medlin (Docket No. 242). The plaintiff's motion for a protective order and to quash the defendant's deposition subpoena (Docket No. 247) is now **MOOT**. Finally, Abbott's motion *in limine* to exclude the testimony of

Dr. Medlin (Docket No. 179) is ALLOWED in part in accordance with this order.

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