UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

Celeste Wood and Thomas Wood

v. Civil No. 13-cv-090-LM
Opinion No. 2015 DNH 099

Medtronic Xomed Inc.

O R D E R

The plaintiff, Celeste Wood, suffers from a condition known as pseudotumor cerebri ("PC"), which results in elevated intracranial pressure. To alleviate her symptoms, Mrs. Wood has undergone several surgeries to implant devices known as "shunts," which are designed to drain fluid away from her brain. During one of these surgeries, in 2009, Mrs. Wood's surgeon implanted a catheter manufactured by the defendant, Medtronic Xomed Inc. ("Medtronic"). Later, the catheter broke, and a piece became lodged in Mrs. Wood's heart. Subsequently, Mrs. Wood required surgery, and she endured a series of infections and an extended hospital stay.

Mrs. Wood and her husband, Thomas Wood, brought suit against two medical facilities at which Mrs. Wood was treated, several of her doctors, and Medtronic. The Woods have since dismissed all of the defendants with the exception of Medtronic, against which they assert claims for strict liability and loss

of consortium. Medtronic has moved for summary judgment and the Woods have objected. The court held a hearing on Medtronic's motion on May 11, 2015. For the reasons that follow, the court denies the motion for summary judgment.

Background

I. Statement of Facts[1]

Mrs. Wood has suffered from PC since 1994. The disorder is characterized by intracranial hypertension, which results in headache and vision loss, among other symptoms. PC is often treated by using shunts to divert cerebrospinal fluid ("CSF") away from the brain to another part of the body. A shunt is typically comprised of a valve with an attached catheter on either end. One catheter is surgically placed near the brain to collect CSF, and the other is placed elsewhere in the body, often in the abdomen. The draining of CSF away from the brain acts to relieve the buildup of pressure within the skull.

Mrs. Wood first underwent surgery to implant a shunt system in 1998. Due to ongoing symptoms, the shunt system was modified in 2000. Mrs. Wood underwent a further surgery to modify the shunt system on June 4, 2009. The purpose of this surgery was

[1] These facts are summarized from the summary judgment record and are not in dispute.

to convert Mrs. Wood's existing shunt system to a so-called "ventricular-atrial shunt." To complete the procedure, Mrs. Wood's surgeon attached a catheter manufactured by Medtronic, and ran the catheter from the existing shunt to Mrs. Wood's right atrium, one of the chambers of the heart. This catheter was made of silicone, and was part of a batch of Medtronic catheters bearing the lot number C37608, and the reference number 43103.

Several months after the surgery, Mrs. Wood experienced further symptoms, and surgery was scheduled to examine the modified shunt system. This surgery occurred on March 4, 2010, and it determined that the newly-installed catheter had broken into two pieces. Mrs. Wood's surgeon removed a segment measuring approximately two centimeters, but he could not locate the remaining portion of the catheter.

Mrs. Wood was transferred to the Dartmouth-Hitchcock Medical Center in Lebanon, New Hampshire, where she underwent further surgery. During this procedure, her surgeons removed a 14-centimeter portion of the catheter, which, after breaking, had migrated through a valve in Mrs. Wood's heart from the right atrium to the right ventricle. Mrs. Wood underwent yet another surgery on March 18, 2010, to address ongoing problems related to the broken catheter.

After her release from Dartmouth-Hitchcock, Mrs. Wood developed an infection in the area of the surgical incisions. Combating the infection required two surgical procedures and an extensive antibiotics regimen. Ultimately, Mrs. Wood was hospitalized for a total of 28 days, and then suffered a series of severe rashes requiring extensive dermatological treatment.

II. The Summary Judgment Record

The Woods allege that the catheter was defectively manufactured and that Mrs. Wood suffered injury as a result. The parties have each offered evidence on these issues. The Woods proffer the testimony of two witnesses whom they seek to offer as experts: Dr. Richard Sutton, and Professor John G. Webster, Ph.D.

Dr. Sutton serves as Acting Chief of the Section of Infectious Diseases at the Veterans Affairs Connecticut Healthcare System. Dr. Sutton proposes to testify regarding the infection that Mrs. Wood developed following her surgeries. He does not, however, offer any testimony regarding the manner in which the catheter broke, or whether the catheter was defectively manufactured.

Professor Webster is not a medical doctor, but has a long background in engineering and fluid mechanics. Professor Webster began his career in the 1950s in the aerospace industry,

and since 1967 has worked as a professor at the University of Wisconsin, where he studies and teaches in the field of medical devices and instrumentation. He is currently conducting funded research on the use of shunt systems to drain CSF.

Professor Webster proposes to testify regarding the manner in which the catheter malfunctioned. In Professor Webster's expert report, he concludes, without a great deal of elaboration, that the shunt system broke due to "excessive flexing." Separately, in a more detailed declaration, Professor Webster opines that "more probably than not, the subject catheter was defective . . . [and] could not withstand normal flexion stress and separated." See Decl. of John G. Webster, Ph.D. (doc. no. 69-4) ¶ 9.

The Woods have also offered in evidence a declaration by Mrs. Wood's surgeon, Dr. Joseph Phillips, who originally implanted the Medtronic catheter, and who discovered during the March 2010 exploratory surgery that the catheter had broken.[2] In relevant part, Dr. Phillips states that the catheter was not abnormally stretched during surgery, and that he is aware of one other incident involving a different patient in which a Medtronic catheter similarly malfunctioned. See Decl. of Joseph M. Phillips, M.D. (doc. no. 69-5) ¶¶ 4, 6.

[2] The Woods do not offer Dr. Phillips as an expert witness.

Medtronic has offered two experts of its own: Dr. Michael Pollay and Dr. Joseph Polak. Both Drs. Pollay and Polak would testify regarding whether the catheter was defectively manufactured. Each concludes that a malfunction due to a manufacturing defect is highly improbable, and Dr. Polak suggests that a more likely cause of the break was an error by Mrs. Wood's surgeon in implanting the catheter.

In addition, Medtronic offers the declarations of four of its employees, each of whom concludes that a manufacturing defect was highly unlikely. Jeffrey Bertrand, a Principal Scientist in Product Development, suggests based on his assessment of the two broken ends of the catheter that it was manually torn or cut, and did not fail as a result of normal stretching or flexing. Another Principal Scientist in Product Development, Drew Amery, suggests that the catheter's silicone material was strong enough to withstand extreme stretching, and that therefore a manufacturing defect would have been highly unlikely to result in a malfunction. Jason McElroy, a Senior Principal Quality Engineer, states that the catheter was manufactured in accordance with company specifications and passed a quality assurance test. Finally, Leanne Lintula, a Product Manager, states that she found no evidence of a manufacturing defect.

Standard of Review

A movant is entitled to summary judgment where he "shows that there is no genuine dispute as to any material fact and [that he] is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); see also Ponte v. Steelcase Inc., 741 F.3d 310, 319 (1st Cir. 2014). In reviewing the record, the court construes all facts and reasonable inferences in the light most favorable to the nonmovant. Kelley v. Corr. Med. Servs., Inc., 707 F.3d 108, 115 (1st Cir. 2013).

Discussion

Medtronic seeks summary judgment on the grounds that: (1) the expert witnesses offered by the Woods are not qualified under the standards articulated in Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993); and that (2) even if the experts were qualified, the Woods have failed to proffer sufficient evidence to maintain a strict liability claim. Because it is entitled to judgment on the strict liability claim, Medtronic suggests, the ancillary loss of consortium claim must be dismissed as well.

I. Expert Qualification Under Daubert

The admissibility of expert testimony is governed by Federal Rule of Evidence 702:

> 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:
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> (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;
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> (b) the testimony is based on sufficient facts or data;
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> (c) the testimony is the product of reliable principles and methods; and
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> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. "[T]his rule requires district courts to act as gatekeepers, ensuring that an expert's proffered testimony 'both rests on a reliable foundation and is relevant to the task at hand.'" Samaan v. St. Joseph Hosp., 670 F.3d 21, 31 (1st Cir. 2012) (quoting Daubert, 509 U.S. at 597). In other words, in addition to ensuring that the witness has the requisite expertise, the trial judge must "evaluate an expert's proposed testimony for both reliability and relevance prior to admitting it." Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co., 161 F.3d 77, 80 (1st Cir. 1998) (citing Daubert, 509 U.S. at 589-95).

"The requisite review for reliability includes consideration of several factors: the verifiability of the expert's theory or technique, the error rate inherent therein, whether the theory or technique has been published and/or

subjected to peer review, and its level of acceptance within the scientific community." Ruiz-Troche, 161 F.3d at 80-81 (1st Cir. 1998) (citing Daubert, 509 U.S. at 593-95). These factors do not amount to a "definitive checklist or test," but they do "form the basis for a flexible inquiry into the overall reliability of a proffered expert's methodology." Ruiz-Troche, 161 F.3d at 81 (citations omitted) (internal quotation marks omitted).

The relevancy requirement "seeks to ensure that there is an adequate fit between the expert's methods and his conclusions." Samaan, 670 F.3d at 32 (citing Daubert, 509 U.S. at 591). This "fit requirement refers to the necessity of a connection between the expert's testimony and the facts of the case." Grimes v. Hoffmann-LaRoche, Inc., 907 F. Supp. 33, 35 (D.N.H. 1995). "Thus, the results of a scientifically reliable experiment or study will fail Daubert's fit requirement and be excluded unless the results can be linked through scientifically reliable means to the expert opinion it purports to support." Id.

"The Daubert regime can play a role during the summary judgment phase of civil litigation. If proffered expert testimony fails to cross Daubert's threshold for admissibility, a district court may exclude that evidence from consideration when passing upon a motion for summary judgment." Cortes-

Irizarry v. Corp. Insular de Seguros, 111 F.3d 184, 188 (1st Cir. 1997). Nevertheless, the First Circuit has urged a cautious approach:

> The fact that Daubert can be used in connection with summary judgment motions does not mean that it should be used profligately. A trial setting normally will provide the best operating environment for the triage which Daubert demands. Voir dire is an extremely helpful device in evaluating proffered expert testimony and this device is not readily available in the course of summary judgment proceedings. Moreover, given the complex factual inquiry required by Daubert, courts will be hard-pressed in all but the most clearcut cases to gauge the reliability of expert proof on a truncated record. Because the summary judgment process does not conform well to the discipline that Daubert imposes, the Daubert regime should be employed only with great care and circumspection at the summary judgment stage.
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> We conclude, therefore, that at the junction where Daubert intersects with summary judgment practice, Daubert is accessible, but courts must be cautious - except when defects are obvious on the face of a proffer - not to exclude debatable scientific evidence without affording the proponent of the evidence adequate opportunity to defend its admissibility.

Id. (citations omitted).

Medtronic contends that both of the Woods' proffered expert witnesses, Dr. Sutton and Professor Webster, are subject to exclusion under Daubert.

A. Dr. Richard Sutton

Medtronic seeks to exclude Dr. Sutton's testimony on the grounds that it does not meet the relevancy, or "fit"

requirement under Daubert. Based on the record, it appears that Dr. Sutton's testimony would be confined solely to the manner in which Mrs. Wood acquired the bacterial infection that required her extended hospital stay. Dr. Sutton would opine that the infection resulted from Mrs. Wood's surgery on March 18, 2010, which was made necessary by complications resulting from the broken catheter. Dr. Sutton apparently will not opine on the manner in which the catheter malfunctioned, or whether any such malfunction was the result of a manufacturing defect.

The Woods do not appear to dispute that Dr. Sutton's testimony is irrelevant to the issue raised in Medtronic's motion for summary judgment: whether there is adequate evidence that the catheter was defectively manufactured. Dr. Sutton's testimony is relevant, however, to causation and damages should these proceedings reach those issues. See Pridham v. Cash & Carry Bldg. Ctr., Inc., 116 N.H. 292, 297 (1976) (recognizing that a tortfeasor is liable for damages resulting from negligently-performed medical services that are necessitated by the tortfeasor's original act of negligence). Thus, the court will not consider Dr. Sutton's testimony for purposes of the motion for summary judgment, but declines to eliminate him as a prospective expert witness at this early juncture.

B. Professor John Webster, Ph.D.

Medtronic challenges Professor Webster's testimony on the grounds that Professor Webster is unqualified, and that his opinions are unreliable and do not meet the relevancy (or fit) requirements under Daubert. The court will consider each challenge in turn.

i. Qualifications

To testify as an expert, a witness must be qualified by virtue of his "knowledge, skill, experience, training, or education . . . ." Fed. R. Evid. 702. The district courts are afforded a measure of discretion in qualifying expert witnesses, and the First Circuit has recognized that not all experts will be "blue-ribbon practitioner[s]." United States v. Mahone, 453 F.3d 68, 71 (1st Cir. 2006).

Medtronic contends that Professor Webster is unqualified to serve as an expert witness in this case because, among other reasons, he is not a medical doctor and has no experience with the surgical implantation of catheters. What is more, Medtronic contends, Professor Webster's training was largely in the field of electrical engineering.

All of this is true. Nevertheless, a review of Professor Webster's qualifications reveals that he has spent several

decades studying and designing medical devices, including shunts. He also has extensive experience in the field of fluid mechanics, and he is presently working on funded research into the use of shunts to divert CSF and relieve intracranial pressure. Professor Webster's curriculum vitae contains many examples of his work (past and present) on topics directly relevant to the issues in this case. At this preliminary stage of the case, Professor Webster appears eminently qualified to opine on the proper manufacture and use of shunts and catheters, and on the manner in which the catheter in this case malfunctioned. For this reason, the court declines to enter summary judgment for Medtronic on grounds that Professor Webster is unqualified to serve as an expert witness.

ii. Reliability

Medtronic argues that Professor Webster's opinion that the catheter was defective is unreliable because he did not adequately describe the methodology that he used to arrive at this conclusion. See Ruiz-Troche, 161 F.3d at 80-81 (describing that an expert's theory or technique should be, inter alia, verifiable and subjected to peer review). Based on Professor Webster's expert report and his declaration, it appears that he

analyzed the catheter by taking pictures of it with a camera-enabled microscope.[3]

The subject on which Professor Webster proposes to testify is the manner in which the catheter broke while inside of Mrs. Wood's body. To the court, a careful examination of the catheter by a qualified expert seems to be a reasonable methodology to use in order to arrive at a conclusion as to the cause of the malfunction. See id. at 85 ("As long as an expert's scientific testimony rests upon good grounds, based on what is known, it should be tested by the adversary process . . . rather than excluded from jurors' scrutiny . . . .") (citations omitted) (internal quotation marks omitted). Indeed, in his declaration, Professor Webster explains that despite several decades of relevant experience, he is unaware of any test other than visual examination that would be useful in determining the cause of a catheter's failure. For these reasons, the court finds that, for purposes of summary judgment, Professor Webster's testimony meets the reliability requirements under Daubert.

[3] These pictures accompanied Professor Webster's expert report.

iii. Relevancy (Fit)

Finally, Medtronic suggests that Professor Webster's testimony is inadmissible under Daubert because he does not adequately explain how his theory that the catheter broke due to "excessive flexing" is related to a purported manufacturing defect. Of the three Daubert grounds on which Medtronic challenges Professor Webster's testimony (qualifications, reliability, and relevancy), this is the closest call.

Ultimately, the question before the court is whether there exist genuine issues of material fact with regard to the manner in which the catheter malfunctioned. The Woods suggest that the malfunction was due to a manufacturing defect. Medtronic denies this allegation, and suggests that the malfunction must have been due to an error by Mrs. Wood's surgeon. Professor Webster's testimony pertains directly to this key issue.

In his declaration, Professor Webster opines that the catheter was defective because of the shape and texture of the edge of the catheter at the point of the breakage. According to Professor Webster, the shape and texture indicated that the catheter was subjected to more stress than it could withstand, which caused it to break while inside of Mrs. Wood's body.

While it would have been preferable for Professor Webster to more fully explain his conclusion that a manufacturing defect

led to the catheter's failure, the court is mindful that, at the summary judgment stage, Professor Webster has not yet had an opportunity to fully explain the methodology underlying his conclusions. This factor counsels against prematurely discounting his testimony. Cortes-Irizarry, 111 F.3d at 188. Thus, for summary judgment purposes, the court finds that Professor Webster's testimony meets the Daubert relevancy requirements.

C. Conclusion

For the reasons described, the court declines to grant summary judgment to Medtronic on the grounds that the Woods' proffered expert witnesses are unqualified under the standards articulated in Daubert. To be clear, however, this order should not be construed as certifying Dr. Sutton and Professor Webster as expert witnesses. Medtronic may, through motions in limine, seek to exclude their testimony in later proceedings.

II. Strict Liability and Loss of Consortium

Medtronic maintains that even if the court were to admit the Woods' proffered expert testimony in full, the Woods have nonetheless failed to adequately allege a strict liability claim. Because a loss of consortium claim is ancillary to the underlying tort claim, Medtronic argues that it is entitled to

summary judgment on both claims. See Guilfoy v. United Servs. Auto. Ass'n, 153 N.H. 461, 463 (2006) ("It is well settled that loss of consortium is a consequential damage derivative of the underlying bodily injury claim.").

"Under the doctrine of strict liability, 'one who sells any product in a defective condition unreasonably dangerous to the user or consumer . . . is subject to liability for physical harm thereby caused to the ultimate user or consumer.'" Kelleher v. Marvin Lumber & Cedar Co., 152 N.H. 813, 824 (2006) (quoting Restatement (Second) of Torts § 402A(1) (further citations omitted)). A strict liability claim may allege that the product in question was defectively designed, that it lacked adequate warnings to consumers, or, as here, that it was defectively manufactured. See Gianitsis v. Am. Brands, Inc., 685 F. Supp. 853, 856 (D.N.H. 1988).

Medtronic takes the position that there is no evidence in the record that the catheter was defectively manufactured. Medtronic points to the evidence offered by Drs. Pollay and Polak that a manufacturing defect was a highly improbable cause of the catheter's failure, and also points to the declarations offered by the four Medtronic employees which reach similar conclusions.

In opposing summary judgment, the Woods point to Professor Webster's expert report, in which he concludes that the catheter broke due to "excessive flexing," as well as to his declaration, in which he states his opinion that the catheter was defective because it "could not withstand normal flexion stress."[4] The Woods also point to Dr. Phillips's declaration, in which he offers evidence that the catheter was not abnormally stretched during surgery, and that another one of his patients experienced the similar malfunction of a Medtronic catheter.

The court finds that the evidence offered by Professor Webster and Dr. Phillips is adequate to raise a genuine issue of material fact regarding the cause of the catheter's malfunction. As noted above, it would have been preferable for Professor

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[4] Medtronic urges the court to disregard Professor Webster's declaration on the grounds that it is inconsistent with his expert report. See Colantuoni v. Alfred Calcagni & Sons, Inc., 44 F.3d 1, 4-5 (1st Cir. 1994) (explaining what has become known as the "sham affidavit rule" by noting that "[w]hen an interested witness has given clear answers to unambiguous questions, he cannot create a conflict and resist summary judgment with an affidavit that is clearly contradictory, but does not give a satisfactory explanation of why the testimony is changed"). The court has carefully reviewed Professor Webster's expert report and his declaration, and finds that they are not materially inconsistent. In relevant part, Professor Webster's declaration states that the catheter broke because it was subjected to "more flexion than it could withstand," and that the catheter "could not withstand normal flexion stress." The court does not view these statements as fundamentally inconsistent with Professor Webster's expert report in which he states that the catheter malfunctioned due to "excessive flexing."

Webster to more thoroughly articulate the basis for his conclusion that, based on his visual examination of the catheter, a manufacturing defect was to blame for its failure. The court finds, however, that Professor Webster's testimony credibly calls into question the conclusion offered by Medtronic that its catheter was highly unlikely to have a manufacturing defect.

The court's conclusion that there exist genuine issues of material fact regarding the cause of the catheter's malfunction is also supported by Dr. Phillips's declaration. There, Dr. Phillips states that he is "quite sure" that the catheter was not abnormally stretched during the implantation procedure, and he notes a similar occurrence involving the spontaneous fracturing of a Medtronic catheter in another one of his patients.

At this stage, the weight of the evidence likely favors Medtronic's position that the catheter failed for some reason other than a manufacturing defect. Nevertheless, viewing the record in the light most favorable to the Woods, as the court must, Kelley, 707 F.3d at 115, the evidence that Professor Webster and Dr. Phillips offer is adequate to raise a genuine dispute of material fact regarding the cause of the catheter's malfunction. See Noonan v. Staples, Inc., 556 F.3d 20, 25 (1st

Cir. 2009) (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250 (1986) (further citations omitted)) ("[T]he court's task is not 'to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial.'"). Thus, Medtronic is not entitled to summary judgment.

Conclusion

For the foregoing reasons, Medtronic's motion for summary judgment (doc. no. 43) is denied.

SO ORDERED.

Landya McCafferty
United States District Judge

May 14, 2015

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