United States Court of Appeals
For the First Circuit

No. 15-1128

BARBARA J. BRADLEY and MICHAEL BRADLEY,

Plaintiffs, Appellants,

v.

DAVID J. SUGARBAKER, M.D.,

Defendant, Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. George A. O'Toole, U.S. District Judge]

Before

Torruella, Lynch, and Kayatta,
Circuit Judges.

Ilyas J. Rona, with whom Jin-Ho King and Milligan Rona Duran & King LLP, were on brief, for appellants.

Carol Ann Kelly, with whom Philip E. Murray, Jr., James L. Wilkinson, and Murray, Kelly & Bertrand, P.C., were on brief, for appellee.

December 16, 2015

TORRUELLA, **Circuit Judge**. In this medical malpractice action, Plaintiffs-Appellants Barbara and Michael Bradley appeal the district court's decision to grant summary judgment as to their medical battery claim. Following a jury trial as to their informed consent claim, they also assert that the district court erred by excluding expert testimony that a fine-needle aspiration ("FNA") biopsy was a viable non-surgical alternative to a surgical biopsy. After careful review of the record, we affirm the district court's dismissal of the Bradleys' battery claim but vacate and remand with respect to the excluded expert testimony.

I. Background

A. The Surgery

After experiencing shortness of breath and persistent pain in her right arm and wrist following a 2002 car accident, Mrs. Bradley underwent magnetic resonance imaging ("MRI") in November 2004. The MRI revealed a mass at the top of Mrs. Bradley's right lung that her physician feared was cancer. After learning the results of the MRI, Mrs. Bradley was scheduled for a positron emission tomography ("PET") scan and FNA biopsy.[1] On

[1] An FNA biopsy is an outpatient procedure in which a radiologist inserts a long, hollow needle through the skin and into the mass to extract cells. A pathologist then examines the specimen under a microscope. The diagnostic yield -- or "the positive yield rate" -- is between ninety to ninety-five percent.

December 1, 2004, Mrs. Bradley received her PET scan results, which suggested that the mass was benign, "although malignancy [could not] be entirely ruled out."

Mrs. Bradley met with Dr. David Sugarbaker, the Defendant-Appellee, a thoracic surgeon at Brigham & Women's Hospital, in Boston on December 7, 2004. During the appointment, Dr. Sugarbaker took Mrs. Bradley's medical history and learned that she had scarring on her right lung from the 2002 car accident. Dr. Sugarbaker stated that he was "more than 50 percent sure [Mrs. Bradley had] cancer," and that Mrs. Bradley would need to undergo a biopsy. Dr. Sugarbaker's notes from that day indicated that "[a] malignancy needs to be ruled out. We will see whether an FNA can be done to secure a diagnosis." Later that same day, Mrs. Bradley met with Dr. Lambros Zellos, another thoracic surgeon at Brigham & Women's, to review her MRI results. Mrs. Bradley explained to Dr. Zellos that she had an FNA biopsy scheduled and asked whether she should proceed with that procedure. Dr. Zellos said it was necessary "to check with the radiologist first to see if the biopsies could be done that way."

As recounted in more detail herein, Mrs. Bradley never received an FNA biopsy. After a second PET scan, Dr. Sugarbaker again met with the Bradleys on December 14, 2004. The scan indicated that the mass was unlikely to be cancerous. After

reviewing the scan, Dr. Sugarbaker advised the Bradleys that "[t]his looks like it might not be cancer" and recommended scheduling a surgical biopsy to remove and test tissue samples. Dr. Sugarbaker did not discuss the next steps once he determined whether the mass was benign or malignant.

Mrs. Bradley proceeded to surgery, which took place on December 17, 2004. The informed consent form that she signed indicated that she would undergo a bronchoscopy,[2] mediastinoscopy,[3] and minithoracotomy[4] and described the risks associated with these procedures. During the operation, Dr. Sugarbaker took six samples, all of which tested negative for cancer. To obtain a sixth sample, Dr. Sugarbaker performed a pulmonary wedge resection, during which he excised a larger sample including portions of healthy lung tissue. This section measured 8 x 3.5 x 3.5 centimeters, which was larger than each of the other samples.

Following surgery, Mrs. Bradley was dismayed to wake up in the surgical intensive care unit. At that time, she discovered

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[2] During trial, Dr. Sugarbaker described a bronchoscopy as a procedure in which a camera is used to "examine the airway passages to look for signs of cancer."

[3] One of Dr. Sugarbaker's colleagues, Dr. Christopher Ducko, described a mediastinoscopy as a procedure to "sample and biopsy the lymph nodes."

[4] A minithoracotomy is a procedure whereby doctors biopsy a mass to remove tissue samples.

"that during the surgery they actually removed a piece of my lung when they removed the mass." Her admission notes indicate that the procedure had become "more extensive [secondary] to significant scarring from prior trauma and surgery." The notes also indicate that Mrs. Bradley suffered "multiple air leaks" as a result of the wedge resection. She was not discharged until approximately a week later, on December 25, due to the air leaks.

Subsequent X-rays revealed a pneumothorax, otherwise known as a collapsed lung, where the mass was removed. In the intervening months, Mrs. Bradley developed a cough and worsening arm pain. A PET scan revealed what resembled an empyema -- a collection of pus -- near her lung. Samples from Mrs. Bradley's right upper chest area tested positive for a fungus known as aspergillus fumigatus, and Mrs. Bradley was diagnosed with a bronchopleural fistula, a leak which allowed the space where her right upper lobe was removed to be infected with aspergillus. Persistent infections have led to years of complications and pain.

In March 2006, Mrs. Bradley stopped working in her position as a law librarian because she was "too sick to go to work." During the summer of 2006, she received intravenous treatments containing antifungals and antibiotics to treat the infection. When these remedies proved unsuccessful, Mrs. Bradley underwent additional surgeries in 2006 and 2009 to treat her

ongoing infections. Mrs. Bradley still takes pain medications and an expensive antifungal medication to prevent further aspergillus infections.

B. District Court Proceedings and Jury Trial

On December 17, 2007, the Bradleys filed a complaint against Dr. Sugarbaker in the United States District Court for the District of Massachusetts. A second amended complaint was filed on June 27, 2011, alleging claims based on medical negligence, Dr. Sugarbaker's failure to obtain informed consent, and battery. The second amended complaint asserted, among other things, that Dr. Sugarbaker "negligently performed a major surgery to acquire tissue to submit to pathology when . . . obtaining tissue should and could have been done by less intrusive means, including a fine needle aspirated biopsy." The Bradleys alleged that Mrs. Bradley did not have enough information to "ma[k]e an informed choice [as to] whether to undergo less intrusive methods for obtaining biopsy tissue than an open surgical biopsy." The Bradleys also claimed that Mrs. Bradley neither consented to nor was informed "that [Dr. Sugarbaker] intended to take tissue of any significant size" and, as a result, the wedge resection constituted battery.

Following discovery, Dr. Sugarbaker filed a motion for summary judgment as to all of the Bradleys' claims. The district court denied the motion as to the informed consent claims,

explaining that "there are material facts in dispute about what Dr. Sugarbaker told Barbara Bradley about her alternatives and the associated risks." Summary judgment was granted as to the medical battery claim because, according to the district court, "the common-law tort of battery is based on the absence of consent to a particular treatment rather than the lack of informed consent." So long as Mrs. Bradley consented to surgery, "whatever the dispute about its parameters," the district court reasoned, her battery claim must fail.

The case proceeded to trial in February 2014. As described in more detail below, Dr. Sugarbaker filed a motion in limine seeking to exclude testimony from the Bradleys' expert witness, Dr. Joe Putnam, which the district court judge allowed in part. At the end of the trial, the jury returned a verdict for Dr. Sugarbaker. The jury found that Mrs. Bradley was not provided sufficient information to make an informed judgment as to whether to consent to the procedure, but that she failed to prove "that neither she nor a reasonable person in her situation would have consented to the surgery had the material information been provided."

II. Discussion

On appeal, the Bradleys assert two arguments. First, they claim that the district court erred in granting the motion

for summary judgment as to the battery claim. Second, they fault the district court for excluding portions of Dr. Putnam's testimony. We address each argument in turn.

A. Battery Claim

1. Standard of Review

Orders granting or denying summary judgment are subject to de novo review. Loubriel v. Fondo del Seguro del Estado, 694 F.3d 139, 142 (1st Cir. 2012). We view "the facts in the light most favorable to the non-moving party," Román v. Potter, 604 F.3d 34, 38 (1st Cir. 2010), and "affirm only if the record reveals 'that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.'" Avery v. Hughes, 661 F.3d 690, 693 (1st Cir. 2011) (quoting Fed. R. Civ. P. 56(a)).

2. Battery Under Massachusetts Law

A diversity suit such as this is governed by Massachusetts substantive law. See Nett v. Bellucci, 269 F.3d 1, 5 (1st Cir. 2001). In Massachusetts, battery is defined as "an intentional offensive touching of a person done without consent." Moore v. Eli Lilly & Co., 626 F. Supp. 365, 368 (D. Mass. 1986) (citing Belger v. Arnot, 183 N.E.2d 866, 869 (Mass. 1962)). In the medical context, battery qualifies as "medical treatment of a competent patient without his consent." In re Spring, 405 N.E.2d

115, 121 (Mass. 1980). The Bradleys contend that Dr. Sugarbaker committed battery by failing to obtain consent to remove a large section of Mrs. Bradley's lung before performing the wedge resection procedure.

For medical battery claims, Massachusetts courts distinguish "lack of consent" from "a lack of informed consent." Moore, 626 F. Supp. 2d at 368. Accordingly, while an allegation that there was no consent may be brought as a battery claim, where the question of consent touches on the appropriate standard of care -- for example, whether a patient was informed of the risks accompanying a procedure -- the action is better understood as sounding in negligence. See, e.g., id. ("While early cases treated lack of informed consent as vitiating the consent to treatment so there was liability for battery, the modern view is that the action is in reality one for negligence in failing to conform to the proper standard." (quoting Mink v. Univ. of Chi., 460 F. Supp. 713, 716 (N.D. Ill. 1978))); Feeley v. Baer, 679 N.E.2d 180, 182 n.4 (Mass. 1997) ("Most authorities prefer to treat informed consent liability solely as an aspect of malpractice or negligence." (internal citation omitted)). The reasoning in Heinrich v. Sweet sheds light on the difference between battery claims and medical malpractice claims premised on a lack of informed consent. Dismissing a medical battery claim, the

district court explained, "[t]he Plaintiffs do not contend that [they] gave no consent at all"; rather, the district court noted, they claimed that relevant risks had not been disclosed. Heinrich v. Sweet, 49 F. Supp. 2d 27, 38 (D. Mass. 1999) (emphasis added). As a result, the claim "should be treated as a claim for medical malpractice." Id.

The Bradleys identify documents leading up to the surgery as evidence that she never consented to a wedge resection procedure. For example, while Mrs. Bradley's consent form explicitly refers to a bronchoscopy, mediastinoscopy, and minithoracotomy, it contains no mention of a wedge resection. Similarly, while bronchoscopy, mediastinoscopy, minithoracotomy, and biopsy are marked on Mrs. Bradley's surgical booking form, the box for wedge resection is not marked. Mrs. Bradley essentially argues that she consented to certain enumerated procedures, and that the lack of references to a wedge resection before surgery indicates that there was no consent for that procedure. But Mrs. Bradley's focus on nomenclature is unavailing.

To be sure, Mrs. Bradley identifies critical differences between the first five samples and the final sample. She asserts that the timing of the test results for the first five samples suggests that Dr. Sugarbaker confirmed that the mass was not malignant before he performed the wedge resection, and that --

whereas the other samples were tested in their entirety -- only a small portion of the wedge resection was tested. As a result, Mrs. Bradley's argument appears to be that she only consented to diagnostic procedures, whereas the removal of scar tissue (the wedge resection) was a treatment to which she did not consent. While the record is "viewed in the light most favorable to the nonmovant" on summary judgment, Casas Office Machs., Inc. v. Mita Copystar Am., Inc., 42 F.3d 668, 679 (1st Cir. 1994), the evidence here simply does not support the contention that the wedge resection had no diagnostic purpose. To the contrary, the mass was tested for malignancies and those results were incorporated into Dr. Sugarbaker's conclusion that Mrs. Bradley did not have cancer.

Mrs. Bradley consented to surgery for the purpose of diagnosing an irregular mass on her lung. And there is no genuine dispute that Dr. Sugarbaker's surgery furthered that purpose. The dispute concerns, instead, whether Dr. Sugarbaker adequately described the extent of the cutting and the tissue removal that would be involved depending on the results of initial biopsies during the surgery. Massachusetts law distinguishes between "touching without consent which all concede is a battery," and "a consented touching for which consent was induced by inadequate information," which is addressed under the malpractice rubric.

Erikson v. Garber, No. 1511, 2003 WL 21956025, at *3 (Mass. App. Div. Aug. 13, 2003). The circumstances here do not quite fall into either category because the inadequacy of the information included a failure to describe the extent of the cutting. Nevertheless, where a surgery and its purpose were agreed to, and where the actual extent of the surgery was in keeping with the purpose, we would expect Massachusetts courts to treat the inadequacy under a theory of malpractice. See Feeley, 679 N.E.2d at 183 (quoting approvingly from a treatise discussing the policy reasons for funneling claims of this type into the malpractice rubric).

We do not foreclose the possibility that a question as to the scope of consent may sustain a medical battery claim in some instances. See Reddington v. Clayman, 134 N.E.2d 920, 922 (Mass. 1956) (recognizing a battery claim where a doctor removed the uvula after only receiving consent to remove the adenoids and tonsils); 14C Mass. Prac., Summary of Basic Law § 17.151 ("[I]f the patient has consented to one type of treatment and the physician performs another, a case of battery is also established."). But there was a logical nexus between the wedge resection and the other five samples: the wedge resection came from the general area for which Mrs. Bradley had consented to surgery, and samples from the wedge resection were tested for

cancer. As Mrs. Bradley contends, questions remain as to whether she was adequately apprised of the potential scope of the surgery beforehand. But, because this claim ultimately centers on the standard of care used by Dr. Sugarbaker, it should be treated as an action in negligence, not battery. Feeley, 679 N.E.2d at 183 (stating that "the problem of informed consent is essentially one of professional responsibility, not intentional wrongdoing, and can be handled more coherently within the framework of negligence law than as an aspect of battery" (internal quotation marks omitted)).

The Bradleys also focus on the relative size of the samples, contending that Mrs. Bradley understood that Dr. Sugarbaker would only be extracting much smaller samples of tissue. The Bradleys explain, "if [Mrs. Bradley] had asked Dr. Sugarbaker to . . . avoid major surgery, her battery claim would succeed because the wedge resection, which was major surgery, would have fallen outside the scope of her narrow consent." But even were we to accept Mrs. Bradley's contention that a wedge resection qualified as a "major surgery," there is no evidence in the record that Mrs. Bradley ever asked Dr. Sugarbaker to remove only small samples. During her deposition, Mrs. Bradley stated that Dr. Sugarbaker did not indicate how many samples he would take or how large those samples would be. Rather, Mrs. Bradley assumed that

the surgery would only consist of "little snippets of the mass." Viewed in the light most favorable to Mrs. Bradley, such testimony does not support the inference that Dr. Sugarbaker ever affirmatively represented that he would take only small samples; at worst, it suggests that Dr. Sugarbaker failed to provide adequate information as to the size of the samples that would be removed.

B. Negligence and Informed Consent Claims

1. Informed Consent Under Massachusetts Law

Massachusetts law recognizes the right of a competent adult to forgo treatment, and the "[k]nowing exercise of this right requires knowledge of the available options and the risks attendant on each." Harnish v. Children's Hosp. Med. Ctr., 439 N.E.2d 240, 242 (Mass. 1982). For a plaintiff to prevail on a theory of informed consent, "(1) the physician must have a duty to disclose the information at issue to the patient, and (2) the breach of that duty must be causally related to the patient's injury." Halley v. Birbiglia, 458 N.E.2d 710, 715 (Mass. 1983). Under the duty inquiry,

> (a) a sufficiently close doctor-patient relationship must exist; (b) the information subject to disclosure must be that which the doctor knows or reasonably should know; (c) the information must be of such a nature that the doctor should reasonably recognize that it is material to the patient's decision; and (d) the doctor must fail to disclose the subject information to the patient.

Id. In turn, for the causation inquiry, the plaintiff must demonstrate "that had the proper information been provided neither he nor a reasonable person in similar circumstances would have undergone the procedure." Harnish, 439 N.E.2d at 244.

A physician need only disclose information "that is material to an intelligent decision by the patient whether to undergo a proposed procedure." Id. at 243. Materiality is defined as "the significance a reasonable person, in what the physician knows or should know is his patient's position, would attach to the disclosed risk or risks in deciding whether to submit or not to submit to surgery or treatment." Id. (internal citation omitted); accord Precourt v. Frederick, 481 N.E.2d 1144, 1146 (Mass. 1985). In addition to encompassing the risks associated with a particular procedure, material information also includes "the available alternatives, including their risks and benefits." Harnish, 439 N.E.2d at 243.

2. Medical Negligence Under Massachusetts Law

The Bradleys also assert claims of medical negligence. To show medical negligence, the "plaintiff must show (1) the existence of a doctor or nurse-patient relationship, (2) that the performance of the doctor or nurse did not conform to good medical practice, and (3) that damage resulted therefrom." St. Germain v. Pfeifer, 637 N.E.2d 848, 851 (Mass. 1994). To establish the

appropriate standard of care, a plaintiff typically must present expert testimony to that effect. Pagés-Ramírez v. Ramírez-González, 605 F.3d 109, 113 (1st Cir. 2010) ("In order to determine the applicable standard of care in a medical malpractice action and to make a judgment on causation, a trier of fact will generally need the assistance of expert testimony.").

3. Admissibility of Expert Testimony

Rule 702 of the Federal Rules of Evidence governs the admission of expert testimony. Fed. R. Evid. 702. Rule 702 requires that the "testimony be (1) 'based upon sufficient facts or data,' (2) 'the product of reliable principles and methods,' and (3) that the witness apply 'the principles and methods reliably to the facts of the case.'" Pagés-Ramírez, 605 F.3d at 113 (quoting Fed. R. Evid. 702). When determining whether such evidence is admissible, "the judge must determine: 'whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue.'" Mitchell v. United States, 141 F.3d 8, 14 (1st Cir. 1998) (quoting Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 592–93 (1993)). A district court enjoys broad discretion when making such evidentiary determinations, id. at 15, and its decision to admit or exclude testimony is reviewed for an abuse of discretion, Pagés-Ramírez, 605 F.3d at 115. But "[t]he standard

is not monolithic: within it, embedded findings of fact are reviewed for clear error, [and] questions of law are reviewed de novo." Milward v. Acuity Specialty Prods. Grp., Inc., 639 F.3d 11, 13–14 (1st Cir. 2011) (quoting Ungar v. Palestine Liberation Org., 599 F.3d 79, 83 (1st Cir. 2010)). We affirm where the lower court's "error [does] not affect the parties' substantial rights and likely [does] not affect the outcome of the case." Martínez v. Cui, 608 F.3d 54, 59 (1st Cir. 2010).

4. Analysis

The Bradleys contend that the district court erred in excluding Dr. Putnam's testimony related to the availability of an FNA biopsy, explaining that such testimony was relevant to the standard of care for both their informed consent and medical negligence claims.[5] The expert disclosure report identified three opinions that subsequently were excluded:

> 1. The surgeon departed from the standard of care by failing to perform a less invasive procedure (such as needle biopsy or bronchoscopy), rather than thoracotomy as the first diagnostic procedure.
> 2. If the surgeon dissuaded the patient from consideration of needle biopsy, an alternative to diagnosis of the superior sulcus tumor and which would modify the patient's treatment options, the surgeon departed from the standard of care.

[5] The parties do not dispute Dr. Putnam's professional qualifications on appeal. Rather, their dispute is limited to the relevance of his testimony.

3. If the surgeon did not do so, the surgeon departed from the standard of care by failing to discuss with the patient and family the alternative diagnostic options to wedge resection (such as needle biopsy or bronchoscopy) as part of informed consent.[6]

The Bradleys contend that Dr. Putnam's testimony regarding Dr. Sugarbaker's failure to discuss the availability of the FNA biopsy was relevant to the available alternatives and the standard of care for the informed consent claims. During the trial, the Bradleys expanded upon Dr. Putnam's expected testimony, which would touch on the "general approach of getting informed consent which involves a general discussion of what you're going to do, the risks, the benefits, the reasonable alternatives and the risks and benefits of those." The Bradleys acknowledged that this was not a situation where an FNA biopsy had never been offered -- indeed, one had been scheduled, with another hospital, prior to the PET scan. Nevertheless, the Bradleys contend that Dr. Sugarbaker did not satisfy the standard of care articulated in Harnish by failing to engage in a discussion of "the alternate routes of obtaining a biopsy" after her PET scan: "[Mrs. Bradley] can't possibly have understood that something she was told was not

[6] The district court did admit portions of Dr. Putnam's testimony pertaining to Dr. Sugarbaker's failure to discuss Mrs. Bradley's increased risk of complications in light of her previous chest trauma.

going to be pursued anymore would have given her the alternate means of obtaining the information she wanted on December 14th [the date of the PET scan]."

As to Dr. Sugarbaker's failure to perform a less invasive procedure, Dr. Putnam would have testified that performing an FNA biopsy was relevant to the standard of care for purposes of the medical negligence claim.[7] In this respect, the Bradleys intended to have Dr. Putnam testify that an FNA biopsy "is less invasive and . . . safer than doing surgery." Dr. Putnam would explain that an FNA biopsy "is a standard initial diagnostic procedure" that would provide "crucial" information "before an operation would be performed."

As to causation, the Bradleys also intended for Dr. Putnam to testify that "what happened to Barbara Bradley would not have happened had the standard of care been followed." Dr. Putnam would have explained that, where an FNA biopsy returns negative results, the doctor should discuss with the patient the likelihood that the mass is nevertheless cancerous. In the case of Mrs.

[7] During trial, the Bradleys' counsel referred to this testimony as Dr. Putnam's "second specific opinion." As listed on the disclosure report, the "second" opinion concerns whether Dr. Sugarbaker, having allegedly dissuaded Mrs. Bradley from undergoing an FNA biopsy, deviated from the standard of care. The discussion that follows, however, touches on the failure to perform the procedure, which is in fact the first opinion listed on the disclosure report.

Bradley, who had suffered previous chest trauma, the doctor would then explain the "greater than average risk" posed by surgery and query whether other therapy options are available.

a. Federal Rule of Evidence 103(a)(2)

Dr. Sugarbaker first contends that the Bradleys did not preserve their evidentiary issue as they failed to comply with Rule 103(a)(2) of the Federal Rules of Evidence, which requires one "claim[ing] error in a ruling to admit or exclude evidence" to "inform[] the court of its substance by an offer of proof, unless the substance was apparent from context." Dr. Sugarbaker contends that "the Bradleys did not make an offer of proof with respect to the specifics of the relevant opinion testimony that they sought to elicit from Dr. Putnam."

This assertion is unsupported by the record. The Bradleys' proffer included a detailed Disclosure Report from Dr. Putnam as well as a deposition. Indeed, when determining which sections of Dr. Putnam's disclosure report were admissible, the district court methodically analyzed each paragraph of the disclosures. Such specificity is a strong indication that the Bradleys' proffer satisfied Rule 103's requirements.

Turning to the merits, we address each of Dr. Putnam's three opinions in turn.

b. Opinion 3: Dr. Sugarbaker Failed to Discuss the Alternative Diagnostic Options

The district court excluded Dr. Putnam's testimony regarding Dr. Sugarbaker's failure to discuss alternatives. It reasoned that, while the FNA biopsy theoretically was an alternative, it was not an alternative in this instance: "[the FNA biopsy] was . . . considered an alternative until it stopped being one." The district court noted that this decision was based on "the facts of the case," which indicate that an FNA biopsy "was not a practical alternative."

Dr. Sugarbaker contends that Dr. Putnam's testimony improperly spoke to the materiality of the availability of the FNA biopsy. Under Massachusetts law, "[t]he materiality determination is one that lay persons are qualified to make without the aid of an expert." Harnish, 439 N.E.2d at 243. As a threshold matter, a judge will consider the "severity of the injury" as well as the "likelihood that it will occur." Precourt, 481 N.E.2d at 1148. The determination of whether that information is "material" is then left to the factfinder. Id. at 1148–49. As a matter of law, a negligible risk is not material and need not be submitted to the jury. Id. at 1149.[8] In Precourt, the Supreme Judicial Court

[8] In Harrison v. United States, 284 F.3d 293 (1st Cir. 2002), we expanded upon Precourt, noting that "the caselaw stands for the proposition that there is no duty to disclose negligible risks, not that all non-negligible risks are actionable if not revealed."

("SJC") of Massachusetts cautioned, "[t]he development of our law concerning risks that as a matter of law may be considered remote, and those that may be left to the determination of a fact finder, must await future cases." Id.

As discussed herein, Opinion 3 would have included testimony touching on the "general approach to getting informed consent." Dr. Putnam would have explained that Dr. Sugarbaker failed to inform Mrs. Bradley of an FNA biopsy, which would "be the easiest, most straightforward, [and] carry the greatest benefit of a diagnostic with the least risk, of any procedure." Contrary to Dr. Sugarbaker's assertions, Dr. Putnam's testimony does not infringe on the jury's materiality analysis. Rather, it would explain the general category of risks and alternatives that a physician must disclose to his patient and the factors relevant to whether an FNA biopsy should have been disclosed as an alternative in this instance. In this way, Dr. Putnam's testimony was relevant to what the standard of care requires when a physician engages in a discussion of alternatives with his patient. In Harnish, the SJC explained, "[w]hat the physician should know involves professional expertise and can ordinarily be proved only through the testimony of experts." 439 N.E.2d at 243.[9] Likewise,

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Id. at 300.

[9] The Bradleys contend that the district court improperly excluded

the manner that a physician discusses a procedure with a patient and the types of information he must include in that conversation are areas where an expert may be necessary to aid the jury. The fact that Harnish does not require expert testimony on what is material does not mean that expert testimony on the available choices that doctors in the exercise of standard care offer to their patients is not relevant.

Further, the district court's determination that an FNA biopsy was not available as an alternative is not supported by the evidence adduced at trial.[10] Mrs. Bradley recounted a call from

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this evidence on the theory that it embraced an ultimate issue. See Fed. R. Evid. 704(a) ("An opinion is not objectionable just because it embraces an ultimate issue."). To the contrary, the district court stated that "the ultimate question of evaluating severity and likelihood is one for the jury," which is an accurate restatement of the law that the issue of materiality is for the jury. Harnish, 439 N.E.2d at 243.

[10] The Bradleys contend that the district court improperly usurped the jury's function by deciding this issue of fact. Under Daubert, however, when determining the admissibility of expert testimony, "the trial judge must determine at the outset, pursuant to [Federal Rule of Evidence] 104(a), whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue." Daubert, 509 U.S. at 592; cf. Fed. R. Evid. 104(b) ("When the relevance of evidence depends on whether a fact exists, proof must be introduced sufficient to support a finding that the fact does exist."). Dr. Putnam's testimony as to whether dissuasion or non-discussion of available alternatives (Opinions 2 and 3, respectively) satisfies the standard of care is only relevant insofar as the Bradleys demonstrated that non-discussion and dissuasion of available alternatives are facts at issue here, and the district court did not err in making this preliminary factual determination. See Bogosian v. Mercedes-Benz of N. Am., Inc., 104 F.3d 472, 476 (1st

Dr. Sugarbaker's physician assistant, William Hung, in which he explained that an FNA biopsy was not possible as they would be unable to access the mass using that procedure. In light of that conversation, Mrs. Bradley cancelled her previously scheduled FNA biopsy. Hung does not recall this conversation and his notes from that day do not mention the FNA procedure. At trial, Hung explained that he spoke with a radiologist, Dr. Francine Jacobsen, and that Dr. Jacobsen had recommended against an FNA biopsy. But Hung's notes contain no mention of Dr. Jacobsen's suggestions regarding the procedure. In addition, Dr. Sugarbaker recalled having a conversation with either Hung or Dr. Jacobsen in which they agreed not to proceed with an FNA biopsy "given the location of the mass." As Bradley's trial counsel noted, there were no records of these conversations, and Dr. Sugarbaker's testimony regarding his conversation with Dr. Jacobsen is inconsistent with

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Cir. 1997) ("[T]he court performs a gatekeeping function to ascertain whether the testimony is helpful to the trier of fact, i.e., whether it . . . is relevant to the facts of the case.").

The Bradleys' reliance on Milward is unavailing. There, this Court determined that, "[w]hen the factual underpinning of an expert's opinion is weak, it is a matter affecting the weight and credibility of the testimony -- a question to be resolved by the jury." Milward, 639 F.3d at 22 (internal citation omitted). But Milward concerned the district court's extensive evaluation of the reliability of the scientific theories underscoring the expert's testimony, and not the threshold issue of factual relevance.

earlier statements that he did not recall discussing the availability of the FNA biopsy with another medical professional.

Moreover, the district court's determination that an FNA biopsy was not an available alternative is further undercut by its decision to admit the testimony of expert Dr. Mark Edelman, Mrs. Bradley's interventional radiologist, who testified to the benefits of the FNA biopsy. At trial, he explained that an FNA biopsy "could have been safely performed with respect to Barbara Bradley" and opined that the location of the mass did not render it inaccessible by FNA biopsy. He also remarked on the benefit of this non-surgical alternative due to the "complications of surgery and difficulty recovering from surgery." Contrary to the district court's determination, such testimony suggests that the FNA biopsy was a viable alternative here.[11]

Nor can it be said that the risks associated with a surgical biopsy were so minimal that, as a matter of law, Dr. Sugarbaker was not obligated to disclose less invasive alternatives. At trial, Dr. Putnam testified that the risk of complications arising from surgery were heightened due to Mrs. Bradley having "sustained significant thoracic trauma just 18

[11] In addition, during his deposition, Dr. Ralph Reichle, an interventional radiologist and expert for Dr. Sugarbaker, testified that he could have performed an FNA biopsy on Mrs. Bradley without complication.

months or so previously." Dr. Putnam explained that scarring from a previous trauma may increase the risk of bleeding or otherwise complicate the surgery -- potentially requiring a longer procedure or adversely affecting the surgeon's "ability to do the operation as efficiently as [he] could without it." Furthermore, Mrs. Bradley's scarring from her chest trauma likely contributed to the apical space[12] that formed following surgery. While a physician is not required to disclose all non-negligible risks, Harrison v. United States, 284 F.3d 293, 300 (1st Cir. 2002), Dr. Putnam's testimony demonstrated that the likelihood that complications might arise was far from remote, see Harnish, 439 N.E.2d at 243 (suggesting that a surgeon need not disclose "remotely possible risks") and, further, that these risks were not "inherent in any operation," id. On the contrary, they were specific to Mrs. Bradley's medical situation.

At trial, the jury heard testimony from Dr. Gary Strauss, an oncology expert, that an FNA biopsy, even if negative, would not rule out the possibility of cancer, especially where a patient had a particularly high risk of cancer, and that Mrs. Bradley's computed tomography ("CT") and PET scans indicated that she was at

[12] An apical space refers to an area where there is no lung immediately after surgery. It can also be described as a non-expansion of the lung.

a high risk. Dr. Strauss also testified that "it would not be reasonable for Dr. Sugarbaker to rely upon a negative FNA in this setting where everything else really points to it being cancer to say she didn't have a cancer." This testimony indicated that, under the appropriate standard of care, Dr. Sugarbaker was not required to present an FNA biopsy as an alternative prior to the surgical biopsy. By excluding Dr. Putnam's testimony, the district court effectively prevented Mrs. Bradley from presenting evidence that Dr. Sugarbaker's "duty to disclose in a reasonable manner all significant medical information," Harnish, 439 N.E.2d at 243, necessitated a discussion of non-surgical alternatives and therefore from rebutting Dr. Strauss's testimony to the contrary, see Pagés-Ramírez, 605 F.3d at 116 (finding that the district court abused its discretion by refusing to allow an expert to testify in a medical malpractice case where, "without [the expert]'s testimony on causation and the standard of care, the plaintiffs were unable to present evidence on two elements of their case").

Dr. Sugarbaker argues that the Bradleys cannot demonstrate causation because Dr. Putnam conceded in his deposition that, if the results of an FNA biopsy had been negative, the mass would nevertheless have needed to be removed. But Dr. Putnam made no such cut-and-dried statement. While he acknowledged that removal of the mass was a possibility, he also

stated that a discussion of next steps was necessary in light of Mrs. Bradley's previous chest trauma. In particular, Dr. Putnam's testimony would have supported the view that a non-surgical alternative such as "watchful waiting" was a reasonable option following a negative FNA biopsy. "It would make little sense to expand the law of informed consent such that a plaintiff, in addition to demonstrating that she would have chosen an alternate course of treatment, must also delineate the precise plan of action that she would have followed to obtain that treatment . . . ." Harrison v. United States, 233 F. Supp. 2d 128, 135 (D. Mass. 2002). Accordingly, we conclude that the district court abused its discretion by excluding Opinion 3.

c. Opinion 2: Dr. Sugarbaker Dissuaded Mrs. Bradley from Considering an FNA Biopsy

The district court excluded Opinion 2, noting that, at most, there was "evidence of nonperformance and perhaps . . . non-discussion," but not evidence of "dissuasion." But there was clear evidence of dissuasion: as described herein, Mrs. Bradley testified that Dr. Sugarbaker's assistant, Hung, told her that surgery likely would be necessary as the mass would be inaccessible by an FNA biopsy. Moreover, Mrs. Bradley's conversation with Hung in fact dissuaded her from undergoing an FNA biopsy. Following the conversation, she cancelled her previously scheduled FNA biopsy at Hartford Hospital because she did not "want to go to

Hartford to have an FNA done only to find out they couldn't access [the mass] with an FNA."

The fact that Dr. Sugarbaker did not personally dissuade Mrs. Bradley does not change the result. Hung served as Dr. Sugarbaker's assistant, and Dr. Sugarbaker's testimony at trial suggested that he was aware of Hung's views that an FNA biopsy would not be feasible for Mrs. Bradley. See Mass. Gen. Laws ch. 112, § 9E ("If a physician assistant is employed by a physician or group of physicians, the assistant shall be supervised by and shall be the legal responsibility of the employing physician or physicians."). Nevertheless, Dr. Sugarbaker never recanted Hung's initial recommendations regarding the FNA biopsy. In such an instance, a jury reasonably could attribute the relevant dissuasive statements to Dr. Sugarbaker. Cf. Santos v. Kim, 706 N.E.2d 658, 661–62 (Mass. 1999) (evaluating instances where a physician may be liable for "his failure to institute practices and procedures"). Accordingly, the district court's factual finding that there was no evidence of dissuasion was clearly erroneous, and the district court abused its discretion by excluding Opinion 2.

d. Opinion 1: Dr. Sugarbaker Failed to Perform an FNA Biopsy

The district court excluded Dr. Putnam's testimony regarding Dr. Sugarbaker's failure to perform an FNA biopsy because it found that this testimony was not related to "an informing obligation but a performing obligation." The district court reasoned that, because Dr. Sugarbaker would not have been the doctor to perform the procedure, "the failure [could] have . . . no legal significance." Insofar as this ruling pertained to the informed consent claim, the district court is correct: the informed consent inquiry focuses on the physician's disclosure obligations, rather than how a medical procedure was performed. Harnish, 438 N.E.2d at 154 (describing the informed consent doctrine as relating to "a physician's failure to divulge in a reasonable manner to a competent adult patient sufficient information to enable the patient to make an informed judgment"). The Bradleys contend that this Court has "emphasized that a duty to disclose, if it exists . . . does not necessarily indicate any duty to offer or to perform" the procedure at issue. Harrison, 284 F.3d at 301 n.8. But they misconstrue our precedents. It is true that the fact that a physician would not perform a particular procedure will not immunize him from an informed consent claim. Harrison, 233 F. Supp. 2d at 134 ("[A] doctor cannot 'save' himself from liability for breach of informed consent by merely arguing

that . . . causation is lacking because he himself would have been unwilling to perform that procedure upon the patient's request."). But this legal analysis does not imply that the converse is true, i.e., that the non-performance of a specific procedure will sustain an informed consent claim. Again, informed consent is about disclosure, not performance.

The Bradleys also contend that this testimony is relevant to their medical negligence claim, which was brought "independent of any of [Mrs. Bradley's] informed-consent claims." Dr. Sugarbaker does not address this argument. The Bradleys assert that the standard of care required that Dr. Sugarbaker perform a less invasive procedure to obtain tissue for the surgical biopsy. As the Bradleys contend, the fact that Dr. Sugarbaker himself would not have performed the procedure will not foreclose a claim in the medical negligence context. Santos, 706 N.E.2d at 663 (explaining that the fact that a doctor would not personally treat a patient does not "automatically absolve him of liability"). Moreover, a physician's failure to perform a less invasive procedure may speak to whether he deviated from the standard of care. See Emerson v. Bentwood, 769 A.2d 403, 409 (N.H. 2001) (reversing a trial court's directed verdict where "[t]he expert's testimony was sufficient for a rational trier of fact to conclude that the defendant should have employed less invasive measures

. . . and that said deviation from the standard of care resulted in the plaintiff's injury"). Accordingly, the non-performance testimony in Opinion 1 may be relevant to the Bradleys' medical negligence claim.

That said, the negligence claim does not appear ever to have reached the jury: the verdict form only references Mrs. Bradley's informed consent claim, and the jury instructions were limited to the elements of informed consent. Indeed, the jury was told that "[t]his [case] is about whether there was an adequate consent to the surgery that followed," and not about the manner in which the surgery was performed. Neither party addresses whether these facts support a finding of waiver as to the medical negligence claim. In light of the poorly developed record on this issue, we leave for the district court the question of Opinion 1's relevance to the Bradleys' medical negligence claim.

III. Conclusion

For the foregoing reasons, the judgment is vacated, and the case is remanded for further proceedings consistent with this opinion.

Vacated and Remanded. No costs are awarded.