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LESLY FAJARDO ET AL. *v.* BOSTON SCIENTIFIC CORPORATION ET AL. (SC 20455)

Robinson, C. J., and Palmer, D'Auria, Mullins, Kahn and Ecker, Js.*

Syllabus

Pursuant to this court's decision in *Bifolck* v. *Philip Morris, Inc.* (324 Conn. 402), under the risk-utility test, a product is in a defective condition that is unreasonably dangerous to the consumer if (1) a reasonable alternative design that would have avoided or reduced the risk of harm was available and the absence of that alternative design renders the product unreasonably dangerous, or (2) the product is a manifestly unreasonable design in that the risk of harm so clearly exceeds the product's utility that a reasonable consumer, informed of those risks and utility, would not purchase the product.

The plaintiffs, F and F's husband, sought to recover damages from, among others, the defendant L, who was F's gynecologist, L's medical practice, and the defendant B Co. for personal injuries that F sustained in connection with an unsuccessful surgery in which a transvaginal mesh sling designed by B Co., known as the Obtryx, was implanted in F's body for the purpose of treating F's stress urinary incontinence. During F's annual health examination, L diagnosed F with pelvic organ prolapse and recommended that he perform a surgical repair known as a colporrhaphy. L also recommended that F undergo a sling procedure to rectify her stress urinary incontinence. Because L did not perform the sling procedure, he referred F to P, a urologist. P described to F the risks and benefits of, and alternatives to, the sling procedure, and F gave P her informed consent to proceed with both the colporrhaphy and the sling procedure. The procedures were scheduled for the same day but performed consecutively. Immediately after L performed the colporrhaphy, P implanted the Obtryx in F. Thereafter, F continued to experience pain and had the Obtryx removed. The plaintiffs' complaint included claims against L and L's medical practice, alleging that L had failed to obtain F's informed consent to the sling procedure and that L made innocent, negligent or intentional misrepresentations regarding the risks and benefits of the sling procedure. The complaint also alleged a product liability claim against B Co. under the Connecticut Product Liability Act (§ 52-572m et seq.), namely, that the defective design of the Obtryx caused F's injuries. Prior to trial, L and L's medical practice, and the plaintiffs, filed separate motions for summary judgment in connection with the informed consent and misrepresentation claims. Specifically, the plaintiffs claimed that L had assumed a duty to obtain F's informed consent for the sling procedure by discussing and recommending that procedure to F. The trial court disagreed and, instead, granted the motion for summary judgment filed by L and L's medical practice, concluding that the duty to obtain informed consent rests with the physician performing the procedure, namely, P. The trial court also rendered summary judgment for L and L's medical practice on the misrepresentation claims. The plaintiffs' product liability claim subsequently was tried to a jury. The plaintiffs introduced into evidence the testimony of a product design expert, R, and various medical studies, which referred to a class of mesh slings known as tension free vaginal tapes (TVTs) that are implanted in a retropubic fashion, unlike the Obtryx, which is implanted using a transobturator approach. R testified that all slings made of polypropylene mesh, including the Obtryx and a certain TVT, are defective and unreasonably dangerous, that the polypropylene mesh caused a foreign body reaction in F and contributed to her injuries, and that a surgery known as the Burch procedure was his preferred method to treat stress urinary incontinence. He also testified regarding what he considered to be defects in the Obtryx, specifically, its heat-sealed middle section and detanged edges, which produce a stiffer mesh. Before the trial court charged the jury, the plaintiffs e-mailed the court, requesting an instruction on both prongs of the risk-utility test. The court, however, declined

to instruct the jury as to the reasonable alternative design prong and instructed the jury only with respect to the second prong regarding whether the design of the Obtryx was manifestly unreasonable. The jury returned a verdict for B Co., and the plaintiffs moved to set aside the verdict on the basis of the court's failure to give a reasonable alternative design instruction. The trial court denied that motion and rendered judgment in accordance with the jury's verdict, from which the plaintiffs appealed. *Held*:

1. The trial court properly rendered summary judgment for L and L's medical practice in connection with the plaintiffs' informed consent claim: this court previously had concluded, as a matter of law, that the duty to obtain a patient's informed consent rests solely with the physician who is to perform the procedure, and that jurisprudence was consistent with the rule recognized by most jurisdictions and legal and medical authorities that, when a physician refers a patient to a specialist for a consultation and that specialist performs the procedure, the specialist is solely responsible for educating the patient and obtaining her informed consent, even when the referring physician discussed the procedure with, or recommended it to, the patient; in the present case, the implantation of the Obtryx by P was an entirely separate procedure from the colporrhaphy performed by L, P was solely responsible for the sling procedure, even though L suggested it to F and referred her to P, and the trial court properly relied on the unanimous expert testimony presented at trial that the physician who performs a procedure, and not the referring physician, has the duty to obtain the patient's informed consent to the procedure; moreover, the plaintiffs' reliance on the lay standard of informed consent, which relates to the extent or degree of disclosure a physician must make to fulfill his duty rather than whether a physician has a duty to inform, was misplaced because L did not have a duty to obtain F's informed consent in the first instance; furthermore, even if this court were to consider the colporrhaphy and the sling procedure to be a single procedure, the plaintiffs' claim would nonetheless fail because, when more than one physician provides care to a patient in relation to a particular medical condition, the patient must prove by expert testimony which physician, if any, owes the patient a duty to obtain informed consent, and all the experts testified at trial that it was the duty of P, not L, to obtain F's informed consent to the sling procedure.
2. The trial court properly rendered summary judgment for L and L's medical practice in connection with the plaintiffs' misrepresentation claims: this court recently held that an innocent misrepresentation claim is not viable in the context of a urogynecologist's provision of medical services because such claims generally are governed by § 552C of the Restatement (Second) of Torts, which requires that the misrepresentation occur in a "sale, rental or exchange transaction with another," and the plaintiffs' innocent misrepresentation claim failed as a matter of law because the only medical services L provided to F, namely, recommending that F see a specialist and discussing the sling procedure, did not qualify as a sale, rental or exchange transaction; moreover, the plaintiffs' negligent and intentional misrepresentation claims also failed because L could not have negligently or intentionally misled, misinformed or misrepresented the quality, usefulness, risks or benefits of the Obtryx in light of the trial court's findings that L was unaware of what brand of sling P planned to implant in F and that L never discussed with F the Obtryx or any other products manufactured by B Co.
3. The plaintiffs could not prevail on their claim that the trial court improperly declined to instruct the jury on the reasonable alternative design prong of the risk-utility test:

   a. This court assumed, without deciding, that the plaintiffs preserved their challenge to the trial court's jury instruction for purposes of this appeal because, even though the plaintiffs did not take exception to the instruction until after the jury was instructed and even though their e-mail request to charge the jury did not comply with the relevant rules of practice (§§ 16-21 and 16-23) insofar as it neither constituted a written request nor cited to any supporting evidence in the record, the trial court nonetheless determined that the plaintiffs timely requested a reasonable alternative design charge and addressed the claim on the merits.

   b. In order to establish that they were entitled to an instruction on reasonable alternative design, the plaintiffs were required to present expert testimony regarding the alleged design defect of the Obtryx,

whether an alternative design was technically and economically feasible, and whether the alternative would have reduced or avoided the risk of harm to F, as those issues involved complicated medical principles that were beyond the ken of the average juror; in the present case, the trial court determined, and the plaintiffs agreed, that R was the plaintiffs' product design expert, and, because the trial court correctly concluded that R was the only witness qualified to testify concerning reasonable alternative design, it properly focused on R's testimony in considering whether the plaintiffs had produced sufficient evidence to warrant such an instruction.

c. The plaintiffs failed to produce sufficient evidence that the class of retropubic slings consisting of TVTs constituted a reasonable alternative design to the Obtryx and that B Co.'s failure to use that alternative design rendered the Obtryx unreasonably dangerous: the plaintiffs' references to TVTs did not constitute identification of a reasonable alternative design, as the evidence demonstrated that the safety data related to TVT products, which can be made of many different types of mesh material with different pore sizes and weights that alter the performance of those products, varied considerably, and, to the extent that there was evidence regarding the safety data of TVTs, the studies the plaintiffs relied on indicated merely that there were risks and complications with the use of TVT products, not that there was another product on the market that would have reduced the risk of harm to F in comparison to the Obtryx; moreover, some TVT products suffer from the same alleged defects as the Obtryx, namely, its heat seal and detanged edges, R testified that all transvaginal slings, including a specific TVT, made of polypropylene mesh are defective and unreasonably dangerous, regardless of whether they are heat-sealed or detanged, and the primary medical study on which the plaintiffs relied compared the Obtryx to a TVT manufactured by B Co., which was made of the same material and had the same heat seal as the Obtryx, and, therefore, did not support the plaintiffs' claim that there was a reasonable alternative design that would have reduced or avoided the risk of harm to F; furthermore, the plaintiffs did not point to a specific existing product and demonstrate that its use would have reduced or avoided the risk of harm to F but, rather, took a scattershot approach, pointing to different alternatives to the Obtryx, including surgical options, such as the Burch procedure, and the class of products known as TVTs, and that evidence did not demonstrate that any particular product was safer or would have reduced or avoided the risk of harm to F when compared to the Obtryx.

(*One justice concurring in part and dissenting in part*)

Argued April 27, 2020—officially released December 16, 2021*

Procedural History

Action to recover damages for, inter alia, personal injuries resulting from an allegedly defective product, and for other relief, brought to the Superior Court in the judicial district of Stamford-Norwalk and transferred to the Complex Litigation Docket, where the complaint was withdrawn as to the defendant Bridgeport Hospital; thereafter, the court, *Zemetis*, *J.*, granted the motions for summary judgment filed by the defendant Lee Jacobs et al. and rendered judgment thereon; subsequently, the case was tried to a jury before *Zemetis*, *J.*; verdict for the named defendant; thereafter, the court denied the plaintiffs' motion to set aside the verdict and rendered judgment in accordance with the verdict, from which the plaintiffs appealed. *Affirmed.*

Brenden P. Leydon and *Jacqueline E. Fusco*, for the appellants (plaintiffs).

Daniel B. Rogers, pro hac vice, with whom were *Proloy K. Das*, *Jennifer M. DelMonico* and *Eric Anielak*, pro hac vice, for the appellee (named defendant).

James F. Biondo, with whom, on the brief, was *Diana M. Carlino*, for the appellees (defendant Lee Jacobs et al.).

Opinion

MULLINS, J. This appeal arises from an action in which the named plaintiff, Lesly Fajardo (Fajardo),[1] suffered injuries related to the implantation of a transvaginal mesh sling,[2] a medical device that is implanted in women to treat stress urinary incontinence.[3] In this action, the plaintiffs alleged that the named defendant, Boston Scientific Corporation (Boston Scientific), defectively designed its Obtryx Transobturator Mid-Urethral Sling System (Obtryx),[4] a polypropylene transvaginal mesh sling, and that the product injured her in various ways after Edward Paraiso, a nonparty urologist, implanted it in her. The plaintiffs claimed, as relevant to this appeal, that Boston Scientific's sale of the Obtryx violated the Connecticut Product Liability Act, General Statutes § 52-572m et seq.

The plaintiffs also brought, inter alia, claims of negligence sounding in informed consent and misrepresentation against Fajardo's gynecologist, the defendant Lee D. Jacobs, and Jacobs' medical practice, the defendant OB-GYN of Fairfield County, P.C. (medical defendants).[5] Their claims against the medical defendants rest on the theory that Jacobs, who referred Fajardo to Paraiso for a mesh sling implant, voluntarily assumed a duty to fully and accurately educate Fajardo as to the risks and benefits of, and the alternatives to, a mesh sling implant procedure. As to the misrepresentation claims, the plaintiffs alleged that Jacobs innocently, negligently and intentionally misled and misinformed Fajardo regarding the quality, usefulness, risks and/or benefits of the Obtryx.

Prior to trial, the trial court granted the medical defendants' motion for summary judgment, concluding, as a matter of law, that Jacobs, as a referring physician, had no duty to obtain Fajardo's informed consent for a procedure that Paraiso was to perform. The court also rendered summary judgment in favor of the medical defendants on the plaintiffs' misrepresentation claims. Thus, the case proceeded to trial only against Boston Scientific, and the jury returned a verdict in its favor. The plaintiffs moved to set aside the verdict, but the trial court denied that motion and rendered judgment in accordance with the jury's verdict. This appeal followed.[6]

On appeal, the plaintiffs claim that the trial court (1) incorrectly concluded that Jacobs did not owe a duty to procure Fajardo's informed consent to the sling procedure, (2) improperly rendered summary judgment in favor of the medical defendants on the plaintiffs' misrepresentation claims, and (3) improperly failed to instruct the jury that it could find Boston Scientific liable under the Connecticut Product Liability Act if Fajardo's injuries resulted from Boston Scientific's failure to adopt a reasonable alternative design that ren-

dered the Obtryx unreasonably dangerous. We conclude that the trial court properly rendered summary judgment in favor of the medical defendants on the informed consent and misrepresentation claims and that it properly declined to instruct the jury on the reasonable alternative design prong of the risk-utility test. Accordingly, we affirm the judgment of the trial court.

I

CLAIMS AGAINST MEDICAL DEFENDANTS

A

Informed Consent Claim

The plaintiffs assert that the trial court improperly rendered summary judgment in favor of the medical defendants because it incorrectly concluded that Jacobs had not assumed a duty to obtain Fajardo's informed consent for implantation of the mesh sling and the sling procedure. Specifically, the plaintiffs argue that Jacobs assumed the duty by discussing and recommending the sling procedure to treat Fajardo's stress urinary incontinence. The plaintiffs also claim that Jacobs had a duty to obtain Fajardo's informed consent because Jacobs was involved in or maintained control over the surgical procedure performed by Paraiso. Neither claim has merit.

The following facts and procedural history are relevant to this claim. On March 26, 2010, Fajardo visited Jacobs, her gynecologist, for her annual preventative health examination. During that visit, Fajardo consulted with Jacobs about her gynecological and urological concerns. In his medical notes for this appointment, Jacobs noted that " '[the] patient complains of stress incontinence daily, very disruptive, she wants surgical repair.' "

After a physical examination, Jacobs diagnosed Fajardo with pelvic organ prolapse—a weakness in the vaginal wall that causes the bladder, colon, or rectum to herniate into the vagina. Specifically, Jacobs determined that Fajardo suffered from a grade 2 cystocele (prolapse of the bladder) and a grade 2 rectocele (prolapse of the posterior vaginal wall). Jacobs explained that a surgery to address the cystocele and rectocele probably would not rectify the incontinence issues. Consequently, given her interest in a more permanent fix to the incontinence issues, Jacobs discussed with Fajardo the option of "her see[ing] a urologist for an evaluation to see what could be offered to her [to address the incontinence]."

Also, during or as a result of this appointment, Jacobs wrote an office note, in which he stated that the " 'risks, benefits, and alternatives of sling/AP (anterior and posterior colporrhaphy)[7] discussed, all questions answered.' " (Footnote added; footnote omitted.) Then, as he had with numerous other similarly situated patients, he

referred Fajardo to Paraiso, a urologist, for consultation and evaluation regarding her stress urinary incontinence.

On April 10, 2010, Fajardo consulted with Paraiso. He diagnosed her with stress urinary incontinence and recommended that she consent to having Paraiso surgically implant a midurethral mesh sling to treat it. Paraiso described the risks and benefits of, and alternatives to, the procedure. He then obtained Fajardo's "oral 'informed consent' " to proceed with surgical repairs to both her vaginal walls (a colporrhaphy performed by Jacobs) and urethra (a mesh sling implant performed by Paraiso).

Paraiso also discussed with Fajardo that both procedures would occur on the same day in a hospital surgical setting. Fajardo thereafter signed two separate consent forms, one for the A/P repair to be performed by Jacobs, and one for the sling procedure to be performed by Paraiso. Paraiso then communicated this plan to Jacobs.

On December 15, 2010, Fajardo signed Bridgeport Hospital's informed consent form, after having read and discussed it with Jacobs. Thereafter, Jacobs surgically repaired Fajardo's vaginal walls. Paraiso was not present during Jacobs' portion of the surgery. On the same day, immediately following Jacobs' procedure, Paraiso surgically implanted the Obtryx in Fajardo to address the stress urinary incontinence. Jacobs was not present during Paraiso's procedure. Jacobs also was not aware of the type of mesh sling Paraiso implanted into Fajardo. Furthermore, Paraiso is not associated with the medical defendants and is not a party to this action. The plaintiffs also do not allege that Jacobs had any vicarious liability for Paraiso's actions.

After these surgeries, Fajardo still experienced pain. Eventually, the sling had to be removed. As a result of her continued issues, and her belief that Jacobs had assumed a duty but failed to adequately inform her of the risks associated with the sling procedure, the plaintiffs brought claims against the medical defendants, alleging, inter alia, lack of informed consent, as well as intentional, negligent and innocent misrepresentation.

Before trial, the plaintiffs moved for summary judgment. They claimed that they were entitled to summary judgment in connection with their informed consent claim against Jacobs because Jacobs "voluntarily assumed the duty to obtain informed consent from . . . Fajardo for implantation of the mesh sling and the mesh sling procedure when he recommended the sling procedure, informed her that it was mesh that would be permanently implanted into her to treat her stress urinary incontinence . . . [and that] it would fix her [stress urinary incontinence], and convinced her that

it was safe." The plaintiffs argued that the undisputed facts supported their claim.

The medical defendants also filed a motion for summary judgment on the informed consent issue. In support of their motion, the medical defendants asserted that Jacobs was not obligated to obtain Fajardo's informed consent for implantation of the mesh sling and the sling procedure because he was not the physician who performed that procedure. The medical defendants relied on testimony from both their own and the plaintiffs' experts, who all agreed that it was Paraiso's duty—as the physician performing the surgery—to obtain Fajardo's informed consent for implantation of the mesh sling and the sling procedure.

Although the plaintiffs and the medical defendants gave slightly different accounts of the conversations that occurred during the March 26, 2010 appointment, both the plaintiffs and the medical defendants agreed that there were no disputed issues of material fact relevant to the informed consent claim. They agree that the issue for the trial court was whether, on the undisputed facts that Jacobs had discussed and recommended the sling procedure to Fajardo, as a matter of law, Jacobs was obligated to obtain Fajardo's informed consent.

The trial court denied the motion for summary judgment filed by the plaintiffs and granted the motion for summary judgment filed by the medical defendants. In doing so, the trial court explained: "[The plaintiffs urge] the court to impose a duty on Jacobs to obtain [Fajardo's] informed consent for Paraiso's implant of the [Boston Scientific] mesh because Jacobs 'assumed a duty' when, according to Jacobs' . . . office note [dated March 26, 2010], [he made the notation that] the 'risks, benefits, and alternatives of sling/AP surgery discussed, all questions answered.' The court rejects this request." (Footnote omitted.) In rejecting that request, the trial court relied on *Logan* v. *Greenwich Hospital Assn.*, 191 Conn. 282, 465 A.2d 294 (1983), in which this court concluded that "[t]he principle that one who gratuitously undertakes a service [that] he has no duty to perform must act with reasonable care in completing the task assumed is not applicable to" a physician who discussed a procedure with a patient but then referred the patient to another physician to perform the surgery. Id., 305.

The trial court concluded that, in the present case, "Jacobs was a referring physician regarding the urological surgery performed by Paraiso. Jacobs is not alleged to have any vicarious liability for the conduct of Paraiso." The trial court further concluded that the duty to obtain informed consent "rests [with] the physician performing the procedure. The procedure is the mesh implant. Paraiso performed the implant. Paraiso, not Jacobs, had to obtain [Fajardo's] informed consent for the surgical implantation of the [Boston Scientific]

mesh product."

On appeal, the plaintiffs assert that the trial court misapplied *Logan* v. *Greenwich Hospital Assn.*, supra, 191 Conn. 305, in concluding that a physician can never assume a duty of obtaining informed consent. We read neither *Logan* nor the trial court's interpretation of that decision as concluding that a physician can never assume a such duty. Rather, as we explain herein, we agree with the medical defendants that, under the circumstances of the present case and without expert testimony to the contrary, the physician conducting the vaginal mesh implantation surgery was responsible for obtaining Fajardo's informed consent.

We first set forth the applicable standard of review. "Practice Book [§ 17-49] provides that summary judgment shall be rendered forthwith if the pleadings, affidavits and any other proof submitted show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. . . . In deciding a motion for summary judgment, the trial court must view the evidence in the light most favorable to the nonmoving party. . . . The party seeking summary judgment has the burden of showing the absence of any genuine issue [of] material facts which, under applicable principles of substantive law, entitle him to a judgment as a matter of law . . . and the party opposing such a motion must provide an evidentiary foundation to demonstrate the existence of a genuine issue of material fact. . . . Finally, the scope of our review of the trial court's decision to grant the plaintiff's motion for summary judgment is plenary." (Internal quotation marks omitted.) *Dougan* v. *Sikorsky Aircraft Corp.*, 337 Conn. 27, 35, 251 A.3d 583 (2020).

We begin our analysis with a brief review of the law of informed consent. "The informed consent doctrine derives from the principle that [e]very human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent . . . commits an assault, for which he is liable in damages." (Internal quotation marks omitted.) *Sherwood* v. *Danbury Hospital*, 278 Conn. 163, 180, 896 A.2d 777 (2006). "The essential elements of a cause of action based [on] a lack of informed consent are [1] a breach of [2] duty by the defendant and [3] a causal connection between that breach and [4] the harm to the plaintiff." *Lambert* v. *Stovell*, 205 Conn. 1, 6, 529 A.2d 710 (1987). Only the second element, duty, is at issue in the present appeal.

In the realm of informed consent, as throughout the law of tort, "[t]he existence of a duty is a question of law and [o]nly if such a duty is found to exist does the trier of fact then determine whether the defendant violated that duty in the particular situation at hand. . . . If the court determines, as a matter of law, that a

defendant owes no duty to a plaintiff, a verdict should be directed [or summary judgment rendered] because [i]t is merely reaching more speedily and directly a result [that] would inevitably be reached in the end." (Citation omitted; internal quotation marks omitted.) *Petriello* v. *Kalman*, 215 Conn. 377, 382–83, 576 A.2d 474 (1990).

Several of our informed consent cases have presented, in one form or another, the issue of whether a physician or institution may owe a duty to obtain a patient's informed consent to a procedure that is to be performed by a third-party physician. In each case, this court has concluded, as a matter of law, that the physician who performed the procedure was solely responsible for obtaining the patient's informed consent. See, e.g., *Sherwood* v. *Danbury Hospital*, supra, 278 Conn. 171 n.8 (treating physician, rather than hospital, is responsible for procuring patient's informed consent); *Petriello* v. *Kalman*, supra, 215 Conn. 385 ("informed consent . . . is the sole responsibility of the attending physician to obtain"); *Logan* v. *Greenwich Hospital Assn.*, supra, 191 Conn. 304–306 (internist who discussed kidney biopsy with patient and referred her to urologist to obtain biopsy did not assume duty to procure patient's informed consent). The Appellate Court has reached the same conclusion. See, e.g., *Torres* v. *Carrese*, 149 Conn. App. 596, 622–23, 90 A.3d 256, cert. denied, 312 Conn. 912, 93 A.3d 595 (2014); *Mason* v. *Walsh*, 26 Conn. App. 225, 230–31, 600 A.2d 326 (1991), cert. denied, 221 Conn. 909, 602 A.2d 9 (1992).

Those results are consistent with the rule, recognized by other jurisdictions and legal and medical authorities, that, when a physician refers a patient to a specialist for a consultation, it is the specialist—assuming that he ultimately performs the procedure at issue—who is solely responsible for educating the patient and obtaining her informed consent. See, e.g., *Brotherton* v. *United States*, Docket No. 2:17-CV-00098-JLQ, 2018 WL 3747802, *4 (E.D. Wn. August 7, 2018) ("the majority of jurisdictions that have addressed whether referring physicians have a duty to obtain a patient's informed consent have concluded that they do not" (internal quotation marks omitted)); 61 Am. Jur. 2d 314, Physicians, Surgeons, and Other Healers § 168 (2012) ("only the physician or health care provider who actually gives the treatment or performs the operation has a duty to inform the patient of the risks involved and [to] obtain the patient's informed consent").

As one federal court has explained, "[t]his makes common sense. The physician performing a procedure should advise on the risks of the procedure. When a primary care physician refers a matter to a specialist, it is not logical to impose a legal duty on the primary care physician to explain the risk of a procedure [that] the specialist may perform. Generally the reason for

the referral to a specialist is because the specialist has more training, knowledge, or experience in the particular area of medicine." *Brotherton* v. *United States*, supra, 2018 WL 3747802, *5.

In Connecticut, *Logan* v. *Greenwich Hospital Assn.*, supra, 191 Conn. 282, is the seminal case regarding the duty of a referring physician to obtain informed consent. In *Logan*, this court examined whether the plaintiff's internal medicine specialist (internist) had a duty to obtain the plaintiff's informed consent for a needle biopsy of her kidney that was performed by a different physician. See id., 304–306. The internist had informed the patient that she had lupus and recommended that she get a biopsy of her kidneys to determine to what extent the lupus had affected her kidneys. Id., 284–85. The internist explained that the procedure would involve the insertion of a needle into her back to obtain a specimen of kidney tissue. Id., 285. He further explained that it was a simple procedure in which local anesthesia would be used, that she may experience some bleeding and discomfort, and that she could leave the hospital in a day or two if there were no complications. Id.

The internist referred the plaintiff to Peter Bogdan, a urologist who would perform the operation, and told the patient that Bogdan would describe the details more fully. Id. Bogdan performed the needle biopsy and injured the plaintiff during the procedure. Id., 286–87. The plaintiff brought a claim of negligence against the internist for failure to obtain her informed consent. Id., 287. The trial court denied the internist's motion for a directed verdict, but the jury nonetheless returned a verdict in favor of the internist. The plaintiff appealed. Id., 284.

On appeal, this court concluded that the trial court should have granted the internist's motion for a directed verdict. In doing so, this court explained: "Although it is undisputed that [the internist] did discuss the kidney biopsy with the plaintiff and describe the procedure generally, there was no evidence that it was his duty to do so. In fact, the testimony indicated the contrary. The plaintiff's expert witness . . . testified that an internist . . . had no obligation to discuss the surgical procedure with the plaintiff or to obtain her informed consent. He stated unequivocally that those duties rested [with] the physician who was to perform the operation." Id., 305.

In reaching this conclusion, this court expressly rejected the voluntary assumption of duty principle on which the plaintiffs rely in the present case. In *Logan*, the plaintiff claimed that the internist, by discussing the biopsy procedure with her, assumed and therefore owed a duty to the plaintiff to obtain her informed consent. Responding to this claim, this court clarified that "[t]he principle that one who gratuitously under-

takes a service [that] he has no duty to perform must act with reasonable care in completing the task assumed is not applicable to this situation. . . . Although [the internist] did describe the general nature of the operation to the plaintiff and some of the possible complications, he also told her that a more detailed explanation would be provided by Bogdan, the urologist. There is no evidence that his reliance [on] the operating surgeon to provide the information necessary for informed consent was contrary to normal medical practice or was unreasonable under these particular circumstances." (Citations omitted.) Id.

Logan is in line with the rule followed in most jurisdictions, which is that the physician conducting the surgery is the one who owes the duty of obtaining the patient's informed consent. This rule applies even under circumstances in which the referring physician discusses the surgical procedure with the patient and recommends that the patient undergo the procedure. *Logan* teaches that it is the physician who performs the actual procedure who is responsible for obtaining the informed consent to that procedure.

In the present case, Jacobs, Paraiso and the plaintiffs all agree that the implantation of the sling, performed by Paraiso, was a separate procedure from the repair to the vaginal wall performed by Jacobs. And Paraiso was solely responsible for performing the sling procedure. Thus, like the internist in *Logan*, notwithstanding the fact that Jacobs may have mentioned the sling procedure or even suggested that Fajardo may be a good candidate for the sling procedure, the fact remains that Jacobs referred her to Paraiso, the specialist, for further consultation. The plaintiffs presented no evidence to undermine the fact that Paraiso, as the physician who performed the sling procedure, was the physician responsible for obtaining Fajardo's informed consent.

In fact, here, as in *Logan*, even the plaintiffs' experts explained that the physician who performs the surgery is required to obtain a patient's informed consent, not the referring physician. Indeed, the plaintiffs' expert, Richard Bercik, a urologist, testified: "[T]he surgeon who is doing the procedure is responsible for the evaluation of the patient for that condition, the selection of how they're going to do the surgery, what they're going to do, and informing the patient. That's all [in] the hands of the person doing the procedure." The medical defendants' expert also agreed that it was the duty of the surgeon who performed the implantation procedure to obtain the patient's informed consent for that procedure and not the referring physician.

In rendering summary judgment, the trial court relied on the fact that "all disclosed medical experts agree [that] Paraiso, not Jacobs, had to obtain [Fajardo's] informed consent for the implant[ation] of the mesh product." We conclude that the trial court properly

relied on the unanimous expert testimony to support its conclusion that Jacobs did not owe a duty to Fajardo to obtain her informed consent.

The plaintiffs also raise a similar but slightly different argument to support their claim that Jacobs had a duty to obtain Fajardo's informed consent to the sling procedure. In particular, they argue that, because Jacobs was Fajardo's gynecologist and she had established a high level of trust with him, she expected and trusted him to give her the information necessary for her to give informed consent. For support, they rely on the lay standard of informed consent adopted in *Logan*. They claim that the lay standard requires this court to determine whether a particular physician has a duty to obtain informed consent based on the patient's perspective of the interaction, instead of by relying on expert testimony regarding common practices in the medical community. We disagree.

In *Logan* v. *Greenwich Hospital Assn.*, supra, 191 Conn. 282, this court concluded that, in order to obtain informed consent from a patient, a physician must "provide the patient with that information [that] a reasonable patient would have found material for making a decision whether to embark [on] a contemplated course of therapy." Id., 292–93. This standard is referred to as the "lay standard of disclosure" because it focuses on what information a reasonable patient would want to know about a particular procedure in order to give his or her informed consent. Id.

We have made clear that "[o]ur standard of disclosure for informed consent in this state is an objective standard that does not vary from patient to patient based on what the patient asks or what the patient would do with the information if it were disclosed. . . . [T]he lay standard of informed consent requires a physician to provide the patient with that information [that] a reasonable patient would have found material for making a decision whether to embark [on] a contemplated course of therapy. . . . In adopting the objective lay standard, this court recognized that rather than impose on the physician an obligation to disclose at his peril whatever the particular patient might deem material to his choice, most courts have attempted to frame a less subjective measure of the physician's duty." (Citation omitted; emphasis omitted; internal quotation marks omitted.) *Duffy* v. *Flagg*, 279 Conn. 682, 692, 905 A.2d 15 (2006).

Contrary to the plaintiffs' assertion, the lay standard adopted in *Logan* does not speak to *whether* a physician has a duty to inform, but, rather, the standard governs how a physician who has a duty to obtain informed consent fulfills that duty. In other words, the lay standard applies only to the content of the disclosure that must be made. It is only once the duty to inform is established that the lay standard dictates how that duty

must be satisfied. See *Mason* v. *Walsh*, supra, 26 Conn. App. 230 ("[o]nce the existence of the duty to inform has been established, the degree or extent of disclosure necessary to satisfy the duty must be proven in accordance with the lay standard"). If the physician does not have a duty in the first instance, the lay standard simply does not apply. Here, Jacobs never had the duty to obtain Fajardo's informed consent for the mesh implantation procedure. Thus, for purposes of determining whether Jacobs had a duty to inform at all, the lay standard does not inform that question.

Lastly, the plaintiffs claim that, because the two surgeries here took place on the same day and Jacobs maintained control over the procedures, he thus owed a duty to obtain Fajardo's informed consent. This claim is factually and legally meritless.

First, it is undisputed that the two surgeries were separate procedures, performed by different physicians with different training and specialties. Jacobs was not present when Paraiso performed the implantation procedure. Most important, it is undisputed that it was Paraiso, not Jacobs, who decided which vaginal mesh to implant in Fajardo, consistent with normal medical practice. The plaintiffs have failed to point to any evidence to support their claim that Jacobs retained control over the implantation of the surgical mesh, which occurred during a different surgery. Thus, the fact that these distinct surgeries took place on the same day does not establish that Jacobs maintained control over the separate procedure performed by Paraiso. As a factual matter, then, this is not a scenario in which multiple physicians were performing or involved in a single surgical procedure.[8]

Second, even if we were to consider both surgeries as one surgical procedure, despite all of the evidence to the contrary, the plaintiffs' claim still fails because they provided no expert testimony to demonstrate that Jacobs had any duty to obtain Fajardo's informed consent. To be sure, this court has clarified that, when more than one physician provides care to the plaintiff, in relation to a particular medical condition, the plaintiff must prove by expert testimony which physician, if any, owes the plaintiff a duty to obtain informed consent. See *Godwin* v. *Danbury Eye Physicians & Surgeons, P.C.*, 254 Conn. 131, 144, 757 A.2d 516 (2000), citing *Mason* v. *Walsh*, supra, 26 Conn. App. 230; see also *Mason* v. *Walsh*, supra, 230 ("[When] . . . a surgeon engages one or more specialists to perform a portion of a procedure, the issue as to who has the duty to obtain the patient's consent to that portion of the procedure to be performed by the specialist arises. It was incumbent [on] the plaintiff to establish by expert testimony *which of the physicians, if any*, owed him the duty of disclosing sufficient facts to permit him to exercise an informed consent to the use of general anesthesia."

(Emphasis added.)).

In the present case, even Bercik, the plaintiffs' expert, a urogynecologist and reconstructive surgeon, and professor of female pelvic medicine, agreed with Jacobs and Paraiso that, as a general matter, it is the consulting surgeon who is going to perform the procedure who is responsible for evaluating the patient, selecting the appropriate treatment, and educating the patient regarding that procedure. Frederick Rau, the medical defendants' expert, a board certified obstetrician and gynecologist, agreed that, under circumstances such as these, "[t]he referring physician has no medical duty or responsibility to obtain a patient's informed consent for a surgical procedure he/she is not going to perform. . . . [I]n this case . . . Jacobs acted entirely reasonably in discussing a potential sling procedure with [Fajardo], but he had no duty to obtain [her] informed consent for the ultimate sling procedure that was performed." Thus, not a single expert testified that Jacobs had a duty to obtain Fajardo's informed consent to the mesh implant.

Based on the foregoing, we conclude that the trial court properly rendered summary judgment in favor of the medical defendants in connection with the informed consent claim.

B

Misrepresentation Claims

The plaintiffs also claim on appeal that the trial court improperly rendered summary judgment in favor of the medical defendants on the claims of innocent, negligent, and intentional misrepresentation. We disagree.

First, this court recently concluded that a claim of innocent misrepresentation against a urogynecologic surgeon did not lie as a matter of law. See *Farrell* v. *Johnson & Johnson*, 335 Conn. 398, 421, 238 A.3d 698 (2020). In so concluding, this court explained that the surgeon's "provision of medical services did not qualify as a 'sale, rental or exchange transaction' under § 552C of the Restatement (Second) [of Torts], and, therefore, a claim for innocent misrepresentation does not lie under our existing innocent misrepresentation precedent." Id. Similarly, in the present case, Jacobs' provision of medical services, which involved only his recommendation that Fajardo see a specialist and discuss the sling procedure, does not qualify as a "sale, rental or exchange transaction . . . ." 3 Restatement (Second), Torts § 552C, p. 141 (1977). Therefore, the plaintiffs' claim of innocent misrepresentation fails as a matter of law.

Second, we agree with the trial court that the plaintiffs' claims of negligent and/or intentional misrepresentation also fail. The trial court found that "Jacobs was unaware of what kind of a sling Paraiso planned to implant in [Fajardo]." Indeed, the trial court also found

that "the parties agree [that] Jacobs never discussed [Boston Scientific] products with [Fajardo]." Thus, because Jacobs did not know what product Paraiso would implant in Fajardo and never discussed Boston Scientific products with Fajardo, he could not have negligently or intentionally misled, misinformed or misrepresented the quality, usefulness, risks and benefits of the Obtryx.

Accordingly, we conclude that the trial court properly rendered summary judgment in favor of the medical defendants on the plaintiffs' misrepresentation claims.

II

INSTRUCTIONAL ERROR CLAIM AGAINST BOSTON SCIENTIFIC

We next turn to the plaintiffs' claim that the trial court improperly declined to charge the jury on the reasonable alternative design prong of the risk-utility test. Specifically, the plaintiffs claim that they introduced sufficient evidence that the tension free vaginal tape (TVT)[9] was a safer reasonable alternative design to Boston Scientific's device, the Obtryx, which caused Fajardo's injuries. Boston Scientific contends that the plaintiffs' instructional error claim is unreviewable because it was not timely or properly preserved. Boston Scientific argues, in the alternative, that, if we conclude that the claim is reviewable, no such instruction was warranted in light of the evidence that was presented at trial and the governing law.

Even if we assume, for purposes of this appeal, that the request for a reasonable alternative design instruction was timely and properly made, we agree with the trial court that the evidence did not support such an instruction. Accordingly, we affirm the judgment of the trial court.

A

Legal Background

Before we turn to the parties' specific contentions, it is helpful briefly to situate the dispute within its broader legal context. In 2016, we decided a pair of cases that required us to reexamine and clarify the legal standards that govern claims brought under the Connecticut Product Liability Act. See *Bifolck* v. *Philip Morris, Inc.*, 324 Conn. 402, 152 A.3d 1183 (2016); *Izzarelli* v. *R.J. Reynolds Tobacco Co.*, 321 Conn. 172, 136 A.3d 1232 (2016).

In *Izzarelli*, we sharply limited the scope of the traditional legal standard governing defective product design claims, the so-called "ordinary consumer expectation test," under which, "[t]o be considered unreasonably dangerous, the article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its charac-

teristics." (Internal quotation marks omitted.) *Izzarelli* v. *R.J. Reynolds Tobacco Co.*, supra, 321 Conn. 185. We clarified that that test "would be appropriate [only] when the incident causing injury is so bizarre or unusual that the jury would not need expert testimony to conclude that the product failed to meet the consumer's expectations." Id., 191. In other words, "[t]he ordinary consumer expectation test is reserved for cases in which the product failed to meet the ordinary consumer's minimum safety expectations, such as res ipsa [loquitur] type cases." (Emphasis omitted.) Id., 194.

In most product liability cases, by contrast, the plaintiff is required to establish a defective design under the modified consumer expectation test, pursuant to which "the jury would weigh the product's risks and utility and then inquire, in light of those factors, whether a reasonable consumer would consider the product design unreasonably dangerous." (Internal quotation marks omitted.) Id., 190; see id., 194. In applying that test, we indicated that the jury is to be instructed to consider a nonexclusive list of factors, one of which may be the availability of a feasible alternative design. See id., 190–91, 208–10.

In *Bifolck*, we further clarified *Izzarelli*'s ordinary and modified consumer expectation tests. First, we renamed them the "consumer expectation test" and the "risk-utility test," respectively. *Bifolck* v. *Philip Morris, Inc.*, supra, 324 Conn. 432. Second, we set forth two distinct prongs or methods by which the latter test may be satisfied. "Under the risk-utility test, which will govern most cases, a product is in a defective condition unreasonably dangerous to the consumer or user if:

"(1) A reasonable alternative design was available that would have avoided or reduced the risk of harm and the absence of that alternative design renders the product unreasonably dangerous. In considering whether there is a reasonable alternative design, the jury must consider the feasibility of the alternative. Other relevant factors that a jury may consider include, but are not limited to, the ability of the alternative design to reduce the product's danger without unreasonably impairing its usefulness, longevity, maintenance, and esthetics, without unreasonably increasing cost, and without creating other equal or greater risks of danger [*Bifolck 1*]; or

"(2) The product is a manifestly unreasonable design in that the risk of harm so clearly exceeds the product's utility that a reasonable consumer, informed of those risks and utility, would not purchase the product [*Bifolck 2*]." Id., 434–35.

Here, the trial court declined to give an instruction under *Bifolck 1* and gave only a *Bifolck 2* instruction. The question in the present case is whether the trial court correctly concluded that the evidence did not

support an instruction under the reasonable alternative design prong of the risk-utility test (i.e., *Bifolck 1*). We conclude that it did.

It is well established that, "[i]n determining whether the trial court improperly refused a request to charge, [w]e . . . review the evidence presented at trial in the light most favorable to supporting the . . . proposed charge. . . . A request to charge [that] is relevant to the issues of [a] case and [that] is an accurate statement of the law must be given. . . . If, however, the evidence would not reasonably support a finding of the particular issue, the trial court has a duty not to submit it to the jury. . . . Thus, a trial court should instruct the jury in accordance with a party's request to charge [only] if the proposed instructions are reasonably supported by the evidence. . . . If . . . the evidence reasonably does not support a finding on the particular issue, the trial court is duty bound to refrain from submitting it to the jury." (Citation omitted; internal quotation marks omitted.) *Brown* v. *Robishaw*, 282 Conn. 628, 633, 922 A.2d 1086 (2007).

Whether the evidence presented by a party reasonably supports a particular request to charge "is a question of law over which our review is plenary." Id. Similarly, whether there is a legal basis for the requested charge is a question of law also entitled to plenary review. See id., 633–34.

B

Reviewability of Plaintiffs' Instructional Claim

First, we must address Boston Scientific's assertion that the plaintiffs' claim is unreviewable because the plaintiffs failed to properly preserve their challenge regarding the instruction. Boston Scientific contends that the plaintiffs' *Bifolck 1* instruction claim is unpreserved because they did not submit a written request to charge on the instruction and also failed to cite evidence in the record to support such an instruction pursuant to Practice Book §§ 16-21 and 16-23. The following facts are necessary to address this contention.

Before the trial court charged the jury, the parties and the court had off-the-record discussions regarding *Bifolck 1*, the reasonable alternative design charge. Following those discussions, the plaintiffs requested the charge through an e-mail to the court and did not cite to any evidence in the record to support the request.[10] However, the plaintiffs did not formally submit a written request for the court to charge the jury as to *Bifolck 1* pursuant to Practice Book §§ 16-21 and 16-23; nor did they take exception to the court's charge on the record before the jury was instructed.[11]

It was not until the jury had been charged and dismissed for the day that the plaintiffs formally took exception to the court's design defect instruction, claiming entitlement to an instruction on *Bifolck 1*.

Although the plaintiffs' request did not technically comply with the requirements of Practice Book §§ 16-21 and 16-23, the trial court determined that the plaintiffs "did timely submit a request to charge on the 'reasonable alternative design' test . . . ." Ultimately, in response to the plaintiffs' motion to set aside the verdict, the trial court addressed the merits of the plaintiffs' claim and rejected it.

It is important to note that, in their e-mail request to the court, the plaintiffs did not cite to any evidence to support their request for a *Bifolck 1* charge. In failing to cite to any evidence in the request to charge, the plaintiffs failed to comply with Practice Book §§ 16-21 and 16-23. Accordingly, the trial court would have been warranted in denying the plaintiffs' request on the basis that the plaintiffs did not cite to evidence to support it. See, e.g., *State* v. *Bettini*, 11 Conn. App. 684, 690, 528 A.2d 1180 ("[i]n the absence of compliance with the rules of practice, the trial court is entitled to deny a request to charge"), cert. denied, 205 Conn. 804, 531 A.2d 937 (1987); see also *State* v. *Kendall*, 123 Conn. App. 625, 672, 2 A.3d 990, cert. denied, 299 Conn. 902, 10 A.3d 521 (2010).

We point this out because it is this lack of specificity in the plaintiffs' request to charge that the concurrence and dissent capitalizes on and uses as an opportunity to recast and create its own arguments that, in its opinion, the plaintiffs should have made at trial to support their request for a reasonable alternative design instruction.

Nevertheless, despite the plaintiffs' failure to comply with Practice Book §§ 16-21 and 16-23, the trial court determined that the plaintiffs timely requested a *Bifolck 1* charge and addressed the request on the merits. Therefore, for the purposes of this appeal, we assume, without deciding, that the plaintiffs have preserved their challenge to the jury instruction.

C

Plaintiffs' Instructional Claim

The plaintiffs assert that the evidence presented at trial was sufficient to support the instruction, and, as a result, the trial court improperly declined to charge the jury on the reasonable alternative design prong of the risk-utility test. In support of their claim, the plaintiffs cite to a study introduced into evidence; see S. Ross et al., "Transobturator Tape Compared with Tension-Free Vaginal Tape for Stress Incontinence: A Randomized Controlled Trial," 114 Obstetrics & Gynecology 1287 (2009) (Ross study); the testimony of their product design expert, Bruce Rosenzweig, and other studies admitted into evidence.

Our decisions in *Bifolck* and *Izzarelli* establish the framework within which a plaintiff is entitled to a reasonable alternative design instruction under the risk-

utility test. In *Bifolck*, this court explained: "In order to state a prima facie case that will permit the case to be submitted to the jury, the plaintiff must simply prove that the alternative design was feasible (technically and economically) and that the alternative would have reduced or avoided the harm." *Bifolck* v. *Philip Morris, Inc.*, supra, 324 Conn. 433. In *Izzarelli*, in which we addressed cigarette design, this court explained that, "[t]o establish the defect, the plaintiff's case required expert testimony on [product] design and manufacture, as well as the feasibility of an alternative design." *Izzarelli* v. *R.J. Reynolds Tobacco Co.*, supra, 321 Conn. 203—204.

At the outset, we must determine what type of evidence is sufficient to prove that an "alternative design was feasible (technically and economically) and that the alternative would have reduced or avoided the harm." *Bifolck* v. *Philip Morris, Inc.*, supra, 324 Conn. 433. Although we concluded in *Izzarelli* that expert testimony was required in that case, a question has arisen as to whether expert testimony is always required as a necessary component under the risk-utility test. This court has not addressed that specific question.

The issue has, however, received some attention in the federal courts. Indeed, as the United States District Court for the District of Connecticut has recognized, "[n]either *Izzarelli* nor *Bifolck* state[s] explicitly that expert testimony is required under the risk-utility test. However, both cases suggest it by juxtaposing the consumer expectation test, which does not require expert testimony, and the risk-utility test." *Frederick* v. *Deco Salon Furniture, Inc.*, Docket No. 3:16-cv-00060 (VLB), 2018 WL 2750319, *7 (D. Conn. March 27, 2018). Consistent therewith, the United States District Court for the District of Connecticut and the Second Circuit have applied the expert requirement to such claims.

For example, in deciding a motion for summary judgment for a defective design claim involving a water treatment pump, the United States District Court for the District of Connecticut concluded that "this is the type of complex case [that] requires an expert opinion as to defect and as to feasible alternative design." *Water Pollution Control Authority* v. *Flowserve US, Inc.*, Docket No. 3:14-cv-00549 (VLB), 2018 WL 1525709, *24 (D. Conn. March 28, 2018), aff'd, 782 Fed. Appx. 9 (2d Cir. 2019).

The court explained that, because the case involved the requirements of a pump for a wastewater treatment facility, the jury would not be "as capable of comprehending the primary facts and of drawing correct conclusions from them as are witnesses possessed of special or peculiar training." (Internal quotation marks omitted.) Id. The Second Circuit agreed with this analysis, explaining that, under Connecticut law, "[e]xpert evidence is necessary to satisfy the risk-utility test

[when] the nexus between the injury and the alleged cause would not be obvious to the lay juror, because expert knowledge is often required in such circumstances to establish the causal connection between the accident and some item of physical or mental injury." (Internal quotation marks omitted.) *Water Pollution Control Authority* v. *Flowserve US, Inc.*, 782 Fed. Appx. 9, 14–15 (2d Cir. 2019).

This position is consistent with the majority of other jurisdictions. "[W]hen technical issues are involved (issues beyond common knowledge and experience) in a [product] liability or a [product related] case, expert testimony is required to generate a jury issue. . . . Technical issues requiring expert testimony include engineering, metallurgical and medical principles. . . . When such principles are at issue in a design defect case, expert testimony is necessary to establish a reasonable alternative design and the ability of such design to reduce the foreseeable harm of the challenged product—that is to say, expert testimony may be needed to establish the elements of breach and causation." (Citations omitted; internal quotation marks omitted.) *Farm Bureau Property & Casualty Ins. Co.* v. *CNH Industrial America, LLC*, Docket No. C16-3122-LTS, 2018 WL 2077727, *17 (N.D. Iowa February 5, 2018).

Other jurisdictions have explained that, "[w]hen understanding the nature of the alleged defect requires knowledge . . . beyond that possessed by the average lay person . . . [the] law requires expert testimony to establish both the defect and the practical and technically feasible alternative design." (Internal quotation marks omitted.) *Buck* v. *Ford Motor Co.*, Docket No. 3:08CV998, 2012 WL 12887708, *3 (N.D. Ohio June 25, 2012), aff'd, 526 Fed. Appx. 603 (6th Cir. 2013); see, e.g., *Hilaire* v. *DeWalt Industrial Tool Co.*, 54 F. Supp. 3d 223, 252 (E.D.N.Y. 2014) ("New York law requires plaintiffs to use expert testimony as to the feasibility and efficacy of alternative designs in order to prove a design defect"). Indeed, in another product liability case involving vaginal mesh products, the United States District Court for the Southern District of Iowa explained that expert testimony was required on the issue of "whether an alternative safer design existed for a medical device, which plainly involves medical principles." *Willet* v. *Johnson & Johnson*, 465 F. Supp. 3d 895, 905 (S.D. Iowa 2020).

Thus, as we have in other contexts, we conclude that expert testimony is required in a reasonable alternative design case when the evidence regarding the defect and whether the alternative was feasible (technically and economically) and whether the alternative would have reduced or avoided the risk of harm is beyond the ken of the average juror. See, e.g., *LePage* v. *Horne*, 262 Conn. 116, 125, 809 A.2d 505 (2002) ("[e]xpert testimony is required when the question involved goes beyond

the field of the ordinary knowledge and experience of judges or jurors" (emphasis omitted; internal quotation marks omitted)). In the present case, the evidence regarding whether there was an alternative design to the Obtryx that would have reduced or avoided the risk of harm to Fajardo involved complicated medical principles. These medical principles included the material from which the products were made, how the different products were placed in the body, how each worked to treat the condition of stress urinary incontinence, how the products interacted with the human body when implanted, and the risks and potential side effects. Accordingly, in order to prove that Boston Scientific's product was unreasonably dangerous under *Bifolck 1*, the plaintiffs were required to produce expert testimony on a reasonable alternative design.

Here, the trial court determined that Rosenzweig "was [the plaintiffs'] product design expert." The plaintiffs agree that he was their design expert. In fact, in their brief to this court, the plaintiffs focus on Rosenzweig and his testimony in other cases.[12] Therefore, in evaluating the plaintiffs' motion to set aside the verdict based on the failure of the trial court to give the *Bifolck 1* instruction, the trial court reviewed Rosenzweig's testimony and the documentary evidence that came in through him.

The trial court determined: "While [Rosenzweig] was critical of several design characteristics of the Obtryx product, he offered no reasonable alternative design of a mesh product that was available to [Boston Scientific] when the Obtryx [implanted] in [Fajardo] was produced. The court rejects [the plaintiffs'] current suggestions [that] the jury might infer [that Rosenzweig] endorsed any polypropylene transvaginal mesh product, however designed or configured, as [Rosenzweig] . . . in this case . . . testified [that] transvaginal polypropylene implants are defective and unreasonably dangerous because transvaginal polypropylene mesh products provoke a foreign body rejection or reaction in women." Indeed, Rosenzweig testified that, in his opinion, all vaginal slings made of polypropylene mesh are defective. He specifically testified that a TVT produced by Gynecare, which is part of the Ethicon division of Johnson & Johnson (Ethicon branded TVT), is defective.

We agree with the trial court that Rosenzweig was the only witness qualified to opine on reasonable alternative design, and, therefore, the trial court properly focused on the testimony of Rosenzweig to determine whether the plaintiffs had produced sufficient evidence to warrant an instruction under the reasonable alternative design prong. We do the same and, as explained more fully in this opinion, conclude that the evidence was not sufficient to warrant an instruction on reasonable alternative design.[13]

D

Framing of the Issue Presented

In order to better understand the issue that is truly in dispute in this appeal, it is important to keep in mind that a plaintiff in Connecticut has two ways to establish that "a product is in a defective condition unreasonably dangerous to the consumer or user . . . ." *Bifolck* v. *Philip Morris, Inc.*, supra, 324 Conn. 434. Those two ways are: "(1) A reasonable alternative design was available that would have avoided or reduced the risk of harm and the absence of that alternative design renders the product unreasonably dangerous. . . . [*O*]*r* (2) [t]he product is a manifestly unreasonable design in that the risk of harm so clearly exceeds the product's utility that a reasonable consumer, informed of those risks and utility, would not purchase the product." (Emphasis added.) Id., 434–35. Therefore, in Connecticut, unlike in some states and in accordance with the position of the Restatement (Third) of Torts, Products Liability, proof of a reasonable alternative design is not necessary to prove that a product has a defective design. It is only one way of proving defective design.

In the present case, the jury was instructed under the second theory of liability, namely, that the risk of harm from the Obtryx so clearly exceeded its utility that a reasonable consumer would not purchase it. Accordingly, although the concurring and dissenting opinion spends considerable energy laying out how the plaintiffs demonstrated that the Obtryx was defective, it is important to remember that the jury considered whether the product was defective insofar that it was a "manifestly unreasonable design in that the risk of harm so clearly exceeds the product's utility . . . ." Id., 435. Indeed, the jury was able to consider all of the evidence presented and ultimately found that the Obtryx was not defective under *Bifolck 2*.

The issue on appeal is not whether the jury should have been able to consider the plaintiffs' claims at all. Instead, the question is whether the plaintiffs introduced sufficient evidence that the Obtryx is defective because a reasonable alternative design was available that would have reduced or avoided the risk of harm to Fajardo and Boston Scientific's failure to adopt that reasonable alternative design rendered the Obtryx unreasonably dangerous. In considering the plaintiffs' claim and the position of the concurrence and dissent, it is important to remember that "a manufacturer is not required to design the safest possible product or a safer product than the one it designed, so long as the design adopted was reasonably safe. The duty assumed by the manufacturer is to design the product for its intended use, namely, that use which could reasonably be foreseen. Stated differently, a manufacturer has a duty to avoid placing on the market a product [that], because

of its defective design, presents an unreasonable risk of harm to others." (Footnotes omitted.) 6 S. Speiser et al., American Law of Torts (2010) § 18:73, pp. 180–81.

Accordingly, in considering the plaintiffs' claim, the issue is not whether the plaintiffs have produced sufficient evidence that the Obtryx had defects and that some of those defects may have caused Fajardo's injuries, which is the claim under *Bifolck 2* that the jury considered and rejected. Rather, the issue presented by this appeal is whether the plaintiffs introduced sufficient evidence that there was a reasonable alternative design available to Boston Scientific's Obtryx and that Boston Scientific's failure to use that alternative design rendered the Obtryx unreasonably dangerous.

E

Whether an Instruction on a Reasonable Alternative Design Was Warranted

On appeal, the plaintiffs assert that Rosenzweig's testimony, the Ross study, and other studies introduced into evidence established a reasonable alternative design to the Obtryx, namely, the TVT. To the extent that the plaintiffs assert that they presented sufficient evidence that the TVT is a reasonable alternative design to the Obtryx, it appears—from the evidence on which they rely—that they must be referring to the class of tension free vaginal tape that is implanted in a retropubic fashion.[14] First, Rosenzweig does not compare the Obtryx to the Ethicon branded TVT. Second, the Ross study did not compare the Obtryx to the Ethicon branded TVT but compared the Obtryx to another retropubic sling manufactured by Boston Scientific. Third, the other studies entered into evidence did not compare the Obtryx device to the Ethicon branded TVT.[15] Finally, despite the efforts of the concurrence and dissent; see part III A 1 and footnote 22 of the concurring and dissenting opinion; Bercik did not compare the Ethicon branded TVT to the Obtryx; he notes only that he and a few other physicians with whom he works prefer the Ethicon branded TVT to other slings but that one of his superiors in his working group at Yale School of Medicine still uses the Obtryx.[16]

The class of TVTs cannot, however, be a reasonable alternative design that would have reduced or avoided the risk of harm to Fajardo. Specifically, the evidence in the record demonstrates that products that belong to the class of TVTs can be made of many different types of mesh material of various pore sizes and differing weights and that those design differences can alter performance and safety. Therefore, the plaintiffs' repeated reference to TVT does not constitute identification of a reasonable alternative design when the safety data related to that class of products vary considerably. By referring to the class of TVTs when some products within that class suffer from the same alleged

defects as the Obtryx—a point we will elaborate on shortly—the plaintiffs failed to produce sufficient evidence of a reasonable alternative design that would have reduced or avoided the risk of harm to Fajardo.

A review of Rosenzweig's testimony reveals that he testified regarding defects in the Obtryx. First, he explained that, in his opinion, all slings made with polypropylene mesh are defective. Rosenzweig explained that the use of that type of mesh caused a foreign body reaction in Fajardo and contributed to the cause of her injuries. The Obtryx is made of polypropolyene mesh, but so, too, is the Ethicon TVT.

Second, Rosenzweig testified that the mesh used in the Obtryx had a detanged or heat-sealed edge and that it made the mesh stiffer in the area that had been sealed. Rosenzweig explained: "When you seal the edge of the mesh, you increase the stiffness of the mesh. . . . But, what scientists have shown is that stiffness of mesh is a bad property. It increases the foreign body reaction . . . the inflammatory reaction, the amount of scarring, and all the sequelae that we're going to continue to talk about . . . ." Rosenzweig was later asked: "Earlier, you described some problems with the detanging or the heat sealing of the center portion of the . . . Obtryx sling. Does that detanging add any benefit that would outweigh the added risks . . . from the stiffness?" Rosenzweig responded, "[n]o."[17]

To the extent that the plaintiffs are claiming that the class of TVTs is a reasonable alternative design that would have reduced or avoided the risk of harm to Fajardo, this testimony does not support the plaintiffs' claims. First, there was evidence that other products within the class of TVTs are made of the exact same mesh as the Obtryx, and those products have the same heat seal and detanging. Rosenzweig testified that the Advantage sling has the "same heat-sealed center." The plaintiffs did not demonstrate how a TVT product with the same allegedly defective material and heat sealing as the Obtryx would have reduced or avoided the risk of harm to Fajardo. Second, even if the plaintiffs established that other TVTs do not have the heat seal and detanging, that does not prove that the use of that other product would have reduced or avoided the risk of harm to Fajardo. In fact, the plaintiffs' product design expert testified that all vaginal slings made of polypropylene mesh are defective and unreasonably dangerous. Even more to the point, Rosenzweig admitted that he considered the Ethicon branded TVT defective for that reason.

Nevertheless, the plaintiffs also rely heavily on the Ross study in support of their claim that the class of products known as TVTs is a reasonable alternative design to the Obtryx. It cannot be emphasized enough that the Ross study does not address the Ethicon branded TVT at all. Instead, it compared two products

made by Boston Scientific—the Obtryx and the Advantage branded TVT. See S. Ross et al., supra, 114 Obstetrics & Gynecology 1288. Therefore, the plaintiffs' reliance on that study undermines the claim of the concurrence and dissent that the plaintiffs pointed to the Ethicon branded TVT as a reasonable alternative design.

Furthermore, the Ross study does not even support the plaintiffs' claim that the class of TVTs was a reasonable alternative design to the Obtryx that would have reduced or avoided the risk of harm to Fajardo. Specifically, there was evidence at trial that the Obtryx and the Advantage branded TVT are made of the exact same mesh material. In explaining the Ross study, Rosenzweig stated: "This is a study that was done and published in 2009. It's a randomized control trial comparing the Obtryx sling made of Advantage mesh with the Advantage sling that goes behind the pubic bone, also made of Advantage mesh." Rosenzweig also testified that the Advantage sling is made of the exact same material as the Obtryx, including the heat seal. Because Rosenzweig identified the heat seal in the mesh that is used in the Obtryx as one of the primary defects that caused Fajardo's injury, a study that compared two products made of the same mesh with the same heat seal does not support the plaintiffs' claim that there was a reasonable alternative design that would have reduced or avoided the risk of harm to Fajardo.

The only difference between the two devices compared in the Ross study was their placement in the body. The Advantage sling was designed to be placed in a retropubic fashion, meaning behind the pubic bone. The Obtryx, on the other hand, was designed to be placed using a transobturator approach. See S. Ross et al., supra, 114 Obstetrics & Gynecology 1287. Rosenzweig did not testify that the risk of harm to Fajardo would have been reduced or avoided if a retropubic sling was used. Instead, Rosenzweig identified only the polypropylene mesh and the heat seal as the defects that caused Fajardo's injuries. Accordingly, contrary to the plaintiffs' position, the Ross study did not support their request for a reasonable alternative design instruction.

Furthermore, even if the plaintiffs were able to make a claim of reasonable alternative design by pointing to a class of products, it is important to note that Rosenzweig testified that, in his opinion, *all* mesh products fabricated from polypropylene, including the Ethicon branded TVT, as well as other products within the class of TVTs, are unsafe and unsuitable for implantation in the human body. Rosenzweig's testimony was that any vaginal sling made of polypropylene mesh is defective and not reasonably safe, and that the Burch procedure, a surgical option, was the best approach to treat stress urinary incontinence.[18]

As the Fifth Circuit has explained, "[a] design is not a safer alternative if, under other circumstances, [it would] impose an equal or greater risk of harm than the design at issue. . . . Similarly, the plaintiff must show the safety benefits from [the] proposed design are foreseeably greater than the resulting costs, including any diminished usefulness or diminished safety." (Citation omitted; emphasis omitted.) *Casey* v. *Toyota Motor Engineering & Mfg. North America, Inc.*, 770 F.3d 322, 331 (5th Cir. 2014). Accordingly, we cannot conclude that the plaintiffs produced sufficient evidence to warrant an instruction that the class of TVTs constitutes a reasonable alternative design.

We agree with the concurrence and dissent that pointing to an existing product that has been successfully commercialized can serve as evidence of the feasibility of an alternative design; see part II A 1 of the concurring and dissenting opinion; but we simply find that proposition inapplicable to the present case.

To put it simply, that is just not the way that the plaintiffs tried this case. The plaintiffs did not produce sufficient facts to support a reasonable alternative design claim. Namely, the plaintiffs did not point to a specific existing product on the market and demonstrate that its use would have reduced or avoided the risk of harm to Fajardo. At best, the plaintiffs took a scattershot approach, pointing to different alternatives to the Obtryx that included surgical options and a class of products known as TVTs. Specifically, the plaintiffs' product design expert recommended a surgical alternative known as the Burch procedure, the Ross study compared the Obtryx to an entirely different product, the Advantage tape, another study compared transobturator slings like the Obtryx to retropubic slings (the class of products known as the TVT), and another study compared mesh used in products within the class of TVTs to the mesh used in the Ethicon branded TVT. The evidence did not, however, demonstrate that any particular product was safer or, most important, would have reduced or avoided the risk of harm to Fajardo when compared to the Obtryx.

We recognize that the commentary to the Restatement (Third) provides that "other products already available on the market may serve the same or very similar function at lower risk and at comparable cost. Such products may serve as reasonable alternatives to the product in question." Restatement (Third), Torts, Products Liability § 2, comment (f), p. 24 (1998); see part II A 1 of the concurring and dissenting opinion. This court, however, has not adopted the Restatement (Third). See *Bifolck* v. *Philip Morris, Inc.*, supra, 324 Conn. 431 ("the defendant's arguments have not persuaded us that we should adopt the Restatement (Third) at this time").

Although we have not expressly adopted the

Restatement (Third), it does inform our analysis in the present case. Even if this court had adopted the Restatement (Third), and if we agreed with the concurrence and dissent that the plaintiffs pointed to a single product on the market as a reasonable alternative—namely, the Ethicon branded TVT—pointing to a product on the market alone would not have satisfied the plaintiffs' burden in this case. Although pointing to a product on the market with an alternative design may demonstrate that the alternative design is feasible, it does not by itself establish that the alternative design would have reduced or avoided the harm to Fajardo. See, e.g., *Bic Pen Corp.* v. *Carter*, 171 S.W.3d 657, 671–72 (Tex. App. 2005) (not requiring expert testimony based on counsel's concession but reviewing safety data introduced into evidence to determine whether products on market were reasonable alternative design that would have avoided injury), rev'd on other grounds, 251 S.W.3d 500 (Tex. 2008). The plaintiffs still needed to produce sufficient evidence to demonstrate that, if Boston Scientific had adopted the design of the Ethicon branded TVT, it would have reduced or avoided the risk of harm to Fajardo.

To the extent that there was information regarding the safety data of the TVT, that evidence was that there were risks and complications with the use of the TVT. For example, one study explained that "one of the primary problems in using the TVT is that as a result of its low stiffness, the mesh easily deforms when tensioning under the urethra. Specifically, pulling the sling gently results in thinning of the mesh (permanent deformation) and fraying at the tanged edges. Consequently, various companies have modified polypropylene sling meshes for easier placement by heat sealing the midportion of the sling that lays under the urethra . . . ." P. Moalli et al., "Tensile Properties of Five Commonly Used Mid-Urethral Slings Relative to the TVT," 19 International Urogynecology J. 655, 656 (2008) (Moalli study). Another study explained the complications from the TVT to "include bladder perforation, excessive blood loss, urinary retention, pelvic hematoma, and suprapubic wound infection. Later complications include exacerbation of existing or development of de novo overactive bladder, persistent suprapubic discomfort, and vaginal mesh erosion. Rare complications, such as bowel injuries and female sexual dysfunction, have been reported." H. Cholhan et al., "Dyspareunia Associated with Paraurethral Banding in the Transobturator Sling," 202 Am. J. Obstetrics & Gynecology 481.e1, 481.e1 (2010) (Cholhan study). The authors of the Ross study also explained that "the most common perioperative complications associated with TVT were bladder perforation and bleeding"; S. Ross et al., supra, 114 Obstetrics & Gynecology 1291; and that "[c]oncern about complications associated with TVT led in 2001 to the development of another minimally invasive pro-

cedure using the transobturator tape." (Footnotes omitted.) Id., 1287–88.[19] Contrary to the assertions of the concurrence and dissent; see part II A 2 of the concurring and dissenting opinion; we do not conclude that the plaintiffs had to point to a risk free product on the market to allow the jury to find that there was a reasonable alternative design for the Obtryx. Nevertheless, the plaintiffs did have to produce evidence that the other product on the market would have reduced the risk of harm to Fajardo.

Furthermore, because this case involves complex medical devices with complicated medical risks and injuries, evidence comparing their relative safety data would have had to come from an expert qualified to testify regarding the designs of the Ethicon branded TVT and the Obtryx, and qualified to explain how use of the Ethicon branded TVT would have reduced or avoided the risk of harm to Fajardo.[20] In discussing whether expert testimony was required for a reasonable alternative design in another case involving a pelvic mesh product, the United States District Court for the Southern District of Iowa explained: "Whether expert testimony is required ultimately depends on whether it is a fact issue [on] which the jury needs assistance to reach an intelligent or correct decision. . . . Although Iowa law does not appear to require expert testimony for recovery in a [product] liability action, the plaintiff must supply sufficient evidence to satisfy the trial court that the jury, with its common knowledge, could reasonably find an alternative design to be practicable and feasible. . . . Technical issues requiring expert testimony include engineering, metallurgical and medical principles. . . . When such principles are at issue in a design defect case, expert testimony is necessary to establish a reasonable alternative design and the ability of such design to reduce the foreseeable harm of the challenged product—that is to say, expert testimony may be needed to establish the elements of breach and causation. . . . Also, [e]xpert testimony regarding reasonable alternative designs is subject to the same standard as any other expert testimony. . . . *Here, the issue is whether an alternative safer design existed for a medical device, which plainly involves medical principles. . . . Indeed, this is a case well outside the common experience of jurors, such as a stuffed toy with hard plastic buttons, because it involves more technical and scientific issues.*" (Citations omitted; emphasis added; internal quotation marks omitted.) *Willet* v. *Johnson & Johnson*, supra, 465 F. Supp. 3d 905. We conclude that, under Connecticut law, the issue of whether one particular vaginal mesh sling on the market would reduce or avoid the risk of harm is an issue on which the jury needed assistance to reach an intelligent decision.[21] Therefore, we agree with the trial court that the plaintiffs' failure to produce such expert testimony on that issue was fatal to the plaintiffs' claim

under the reasonable alternative design theory of *Bifolck 1*.

To be sure, the Restatement (Third) also makes clear that "[i]t is not sufficient that the alternative design would have reduced or prevented the harm suffered by the plaintiff if it would also have introduced into the product other dangers of equal or greater magnitude." Restatement (Third), supra, § 2, comment (f), p. 23. Rosenzweig testified that a substantial contributing factor of Fajardo's injuries was the fact that she experienced a foreign body reaction to the Obtryx. Rosenzweig explained that polypropylene mesh slings can cause this type of reaction. Accordingly, Rosenzweig opined that all polypropylene mesh slings are defective and unreasonably dangerous. He specifically opined that the Ethicon branded TVT, which is made of polypropylene mesh, was defective. Given this testimony from the plaintiffs' product design expert, we cannot see how the plaintiffs could have successfully claimed that the Ethicon branded TVT or the class of TVTs was a reasonable alternative design that would have reduced or avoided the harm suffered by Fajardo. Therefore, the trial court was correct not to instruct the jury on the reasonable alternative design prong.

Even if we were to consider Bercik's testimony as expert testimony on reasonable alternative design, as the concurrence and dissent suggests; see, e.g., footnote 6 of the concurring and dissenting opinion; we cannot conclude that it supports the plaintiffs' request for a reasonable alternative design instruction. First, Bercik's testimony was not based on sufficient data to comment on reasonable alternative design. Bercik never established his qualifications regarding product design and testified that he was unaware of a key design element of the Ethicon branded TVT, namely, the type of mesh used in the product.[22] Furthermore, the fact that Bercik testified that he prefers the Ethicon branded TVT does not support a reasonable finding that it would have reduced or avoided the risk of harm to Fajardo. Beside knowing next to nothing about the design features of the Obtryx, and not remembering why he stopped using it, he also admitted that, although his preference is for the Ethicon branded TVT, his supervisor uses the Obtryx. Thus, in his testimony, he acknowledged his preference for the Ethicon branded TVT, but that testimony does not establish that it is a reasonable alternative design to the Obtryx that would have reduced or avoided the risk of harm to Fajardo.[23]

We do not agree with the concurrence and dissent that other studies and documents that were entered into evidence were sufficient to support a reasonable alternative design claim.[24] See parts II A 1 and 2 of the concurring and dissenting opinion. At most, these studies demonstrate that the Ethicon branded TVT was the first tension free vaginal tape manufactured, and

for that reason, there is more data evaluating its safety and effectiveness. Nevertheless, the evidence in the studies demonstrate that, "[a]lthough the [Ethicon branded] TVT was the first [midurethral] sling to gain widespread acceptance, numerous other [midurethral] sling systems have subsequently been introduced. While all of the meshes consist of a knitted polypropylene material, they have been altered as a marketing strategy to overcome [clinician perceived] deficiencies in the [Ethicon branded] TVT." P. Moalli et al., supra, 19 International Urogynecology J. 655.

Furthermore, also contrary to the representations of the concurrence and dissent, the evidence did not demonstrate that the class of TVTs or the Ethicon branded TVT is the "gold standard" to treat stress urinary incontinence. Part II A 1 of the concurring and dissenting opinion. The concurrence and dissent asserts that, "although the majority steadfastly resists this fact, expert witnesses and evidence from scholarly journals on which those witnesses relied repeatedly identified the TVT as the 'gold standard,' [and/or] 'the standard of care' . . . ." Id. However, no expert in the present case pointed to the TVT (either the Ethicon branded TVT or the class of products known as the TVT) as the "gold standard." Thus, no one explained what is meant by the term. Instead, the design expert in the present case testified that all slings made of polypropylene mesh are unreasonably dangerous and that a surgical procedure is the best method for treating stress urinary incontinence.[25]

In the present case, the plaintiffs simply did not introduce sufficient evidence to warrant an instruction on a reasonable alternative design. We find a recent case from the United States District Court for the District of Connecticut instructive in this regard. In granting a manufacturer's motion for summary judgment on a reasonable alternative design claim, the court explained that the plaintiff "has not established that a reasonable alternative [water treatment] pump design was available. [The expert's] report, even if admitted, does not identify a reasonable alternative. Rather, [the expert's] report opines that [the plaintiff] should have used [the competitor's] pumps, which have larger motors. However, the [competitor's] motors would have required an expensive reworking of the system as a whole, and were considered and rejected by [the plaintiff] during the bidding process. . . . [The plaintiff] has offered no evidence that a 'reasonable alternative design was available' for pumps that would meet the [plaintiff's] system specifications 'that would have avoided or reduced the risk of harm' without 'unreasonably increasing cost.' " (Citation omitted.) *Water Pollution Control Authority* v. *Flowserve US, Inc.*, supra, 2018 WL 1525709, *25.

Similarly, the plaintiffs in the present case did not produce sufficient evidence that an alternative design

was available that would have met Fajardo's needs and have avoided or reduced the risk of harm without unreasonably increasing cost. To the contrary, evidence presented at trial showed that the class of TVTs had varying degrees of safety, depending on the type of material that was used to make them, and some even had the exact same defect alleged to have caused Fajardo's injuries in this case. Furthermore, the plaintiffs' expert testified that all polypropylene mesh slings are defective, including the Ethicon branded TVT. Accordingly, we cannot conclude that the trial court incorrectly determined that the plaintiffs did not produce sufficient evidence of a reasonable alternative design that would have avoided injuries to Fajardo to warrant an instruction on reasonable alternative design.

The plaintiffs cite to *Campbell* v. *Boston Scientific Corp.*, 882 F.3d 70 (4th Cir. 2018), in support of their claim that there was sufficient evidence in the present case to warrant an instruction on the reasonable alternative design prong. We disagree. In that case, the defendant claimed that there was insufficient evidence to support the jury verdict and, specifically, to show that there was a safer alternative design. See id., 79. Based on the trial record and the expert's testimony in that case, the Fourth Circuit concluded that there was sufficient evidence to support the safer alternative design claim. As one example of evidence that supported the plaintiffs' claim in that case, the court pointed to the expert's testimony regarding the Ross study. See id. The Fourth Circuit's conclusion that, based on the particular safer alternative design claim made by the plaintiffs in that case and supported by evidence, the Ross study supported the safer alternative design claim.

The Fourth Circuit's conclusion, however, does not mean that the Ross study will always support a reasonable alternative design claim. In the present case, the Ross study does not support the plaintiffs' claim that there is a reasonable alternative design, particularly because the plaintiffs claimed and their expert testified that the heat-sealed mesh used in the Obtryx caused Fajardo's injuries. Because the Ross study compared two slings made of the exact same heat-sealed mesh, that study is not evidence of a reasonable alternative design, in light of the claim that was presented by the plaintiffs in this case.

Based on the foregoing, we conclude that the plaintiffs did not produce sufficient evidence to warrant an instruction on a reasonable alternative design. Accordingly, we conclude that the trial court properly declined their request for such an instruction.

The judgment is affirmed.

In this opinion ROBINSON, C. J., and PALMER, D'AURIA and KAHN, Js., concurred.

* The listing of justices reflects their seniority status on this court as of

the date of oral argument.

* December 16, 2021, the date that this decision was released as a slip opinion, is the operative date for all substantive and procedural purposes.

[1] Fajardo's husband, Jairo Fajardo, is also a plaintiff. We need not separately address his derivative claims for loss of consortium, insofar as they rise or fall with Fajardo's claims.

[2] The terms "mesh sling," "tape," and "sling" are used interchangeably in this opinion.

[3] Stress urinary incontinence is defined as the "leakage of urine as a result of coughing, straining, or some sudden voluntary movement, due to incompetence of the sphincteric mechanisms." Stedman's Medical Dictionary (28th Ed. 2006) p. 962.

[4] The midurethral sling is a narrow strap made of synthetic mesh or native tissue that is placed under the urethra. It acts as a hammock to lift or to support the urethra and the neck of the bladder.

[5] The plaintiffs withdrew their complaint against another defendant, Bridgeport Hospital.

[6] The plaintiffs appealed to the Appellate Court, and we transferred the appeal to this court pursuant to General Statutes § 51-199 (c) and Practice Book § 65-1.

[7] Colporrhaphy is surgical repair of the vaginal wall. An anterior colporrhaphy treats a cystocele or urethrocele (prolapse of the urethra into the vagina), whereas a posterior colporrhaphy treats a rectocele.

[8] The plaintiffs cite to cases from other jurisdictions that have concluded that a referring physician owes a duty to obtain a patient's informed consent when the referring physician maintains control over the procedure performed. See, e.g., *O'Neal* v. *Hammer*, 87 Haw. 183, 187, 953 P.2d 561 (1998). Because we conclude that the plaintiffs did not produce sufficient evidence for the jury to conclude that Jacobs maintained control over Fajardo's vaginal mesh procedure, we need not address these cases from other jurisdictions.

[9] The record demonstrates that the term "TVT" is used both with respect to the Ethicon branded tension free vaginal tape (the specific TVT type product the plaintiff identified in her complaint) and as a generic term for similar tension free vaginal tapes in the class of TVT products, such as Boston Scientific's Advantage tape. Unless otherwise noted, we use the term in that broader, generic context. Although the plaintiffs juxtaposed the Obtryx to the class of TVT products generally, they did not focus on a particular TVT product with which to compare the Obtryx and, most important, did not demonstrate how another specific product without the alleged defects of the Obtryx would have avoided her injuries, a point we discuss in more detail subsequently in this opinion. See parts II C through E of this opinion.

[10] Counsel for the plaintiffs submitted the following request by e-mail: "In further response to [the defendants'] prior comments [the] [p]laintiffs contend that both consumer expectation and risk utility . . . of *Bifolck* are all applicable."

[11] The court charged the jury in relevant part: "The plaintiff[s] [claim] the Obtryx was defectively designed. In order to prove that a product was defective, the plaintiff[s] must prove the condition [they] claimed to be a defect made the product unreasonably dangerous. A product is in a defective condition unreasonably dangerous to the consumer or user if the design of the product [was] so manifestly unreasonable in that the risk of harm so clearly exceeds the product's utility that a reasonable consumer, informed of those risks and utility, would not purchase the product."

[12] The plaintiffs do not rely on Bercik, whom the concurrence and dissent is forced to rely on to support its position. It is not surprising that the plaintiffs do not rely on Bercik because, as we explain subsequently in this opinion; see footnote 23 of this opinion and accompanying text; Bercik did not testify about the design of the Obtryx or its defects; he merely explained that he had implanted the Obtryx once or twice but usually implants the Ethicon branded TVT. He gave no opinion on whether use of the Ethicon branded TVT would have reduced or avoided the risk of harm to Fajardo.

[13] Although the ultimate determination of whether the facts supported the instruction is a legal question subject to plenary review, the facts underpinning that determination will not be overturned in the absence of a finding that they were clearly erroneous. In the present case, the trial court determined that Rosenzweig was the plaintiffs' product design expert, and the plaintiffs do not challenge that finding, let alone assert that it is clearly erroneous. The trial court further found that Rosenzweig's testimony was that all polypropylene mesh slings are defective and unreasonably dangerous

and that the Burch procedure, which is a surgical repair, was his preferred method. The plaintiffs do not challenge these findings by the trial court as clearly erroneous, and the concurrence and dissent does not find them to be unsupported by the evidence. In fact, instead of addressing why the trial court's findings are clearly erroneous, the concurrence and dissent ignores them and engages in its own fact-finding. At no point did Rosenzweig opine that use of the Ethicon branded TVT or any other TVT product would have reduced or avoided Fajardo's injuries.

[14] The concurrence and dissent asserts that it is an "erroneous assumption" that, to the extent that the plaintiffs referred to the TVT, it was the class of retropubic slings rather than the Ethicon branded TVT. Part III A of the concurring and dissenting opinion. That claim is belied by the record. Indeed, a review of the plaintiffs' memorandum in support of their motion for a new trial reveals that the plaintiffs never once identified the Ethicon branded TVT as the reasonable alternative design for which they had presented sufficient evidence to support a charge. Instead, in their memorandum in support of the motion, the plaintiffs cited to "safer alternatives" to the Obtryx, including the Burch procedure. Even in their brief to this court, the plaintiffs again referred to "safer alternatives" and the Burch procedure, and, for the first time, mentioned "TVT" as one of the safer alternatives without indicating whether it was the Ethicon branded TVT.

Furthermore, Boston Scientific's brief to this court demonstrates that it also understood the plaintiffs to be claiming that the class of TVTs was a reasonable alternative design. Boston Scientific argues specifically in its brief: "Without naming a specific product, the plaintiffs argue that other polypropylene slings, presumably without detanged portions, are reasonable alternative designs to the Obtryx." Boston Scientific further asserted that "the plaintiffs never identified at trial any specific alternative design [that] they claim [Boston Scientific] should have used with the Obtryx." (Emphasis omitted.) Boston Scientific also explained that "[t]he plaintiffs' posttrial reliance on a single clinical study for the proposition that other polypropylene slings constitute reasonable alternative designs is inconsistent with the evidence presented by the plaintiffs at trial."

[15] Although the Moalli study compared the tensile property of the mesh used in five other devices (including the mesh used in the Obtryx) to the mesh used in the Ethicon branded TVT, it did not compare how the Obtryx performed in the human body to how the Ethicon branded TVT performed in the human body; nor did it compare the risks of harm from the two devices. See P. Moalli et al., "Tensile Properties of Five Commonly Used Mid-Urethral Slings Relative to the TVT," 19 International Urogynecology J. 655, 663 (2008) ("Although it is important to understand the behavior of a sling before implantation, the behavior of these slings in vivo and after incorporation into host tissue may be inferred, but is not directly apparent from these studies. Indeed, the next logical step to the current study is the implementation of rigorous in vivo studies to determine how the textile and tensile properties of polypropylene slings relate to tissue behavior, efficacy, patient morbidity, and patient satisfaction.").

[16] The concurrence and dissent asserts that Bercik "testified that Fajardo could have been a candidate for the TVT, that the Obtryx was the cause of her injuries, and that he had begun using the TVT in favor of transobturator slings, including the Obtryx, because of his negative experience with the latter." Footnote 17 of the concurring and dissenting opinion. Bercik actually testified that, at the time Farjado came to see him in 2014 when she was experiencing pain from the Obtryx, he recommended that she could potentially benefit from the TVT. Bercik explained that he recommended the TVT at that time because the transobturator sling procedure had not worked, so he would not try that again. This clearly is not testimony suggesting that the TVT was safer or a more reasonable alternative and should have been used in 2010 when Fajardo had the Obtryx implanted, as the concurrence and dissent suggests.

Similarly, Brian Hines, a urogynecologist who did not testify at the trial in the present case, also saw Fajardo after she was having pain from the Obtryx. A review of his notes from that appointment, which were an exhibit at the trial, reveals that Hines suggested the TVT as an option for Fajardo *after* she had already tried the Obtryx, but he also notified her that it had many of the same risks of injury that she experienced with the Obtryx and that further testing was required to determine if she would be a good candidate for this procedure. Again, Hines did not opine on whether the TVT should have been used at the time of Fajardo's original surgery, only that, after she already had issues with the Obtryx, the TVT could possibly

be an alternative. Accordingly, we disagree with the concurrence and dissent that "[t]his evidence would have permitted the jury to conclude not only that the TVT is, in general, a viable alternative to the Obtryx . . . but also that it was well suited to Fajardo's individual needs." Part II A 1 of the concurring and dissenting opinion.

[17] Rosenzweig never testified that a particular TVT would have been a reasonable alternative design. At most, Rosenzweig testified that "the data [are] limited but [show] that . . . for [the] Obtryx and the Advantage mesh . . . it's inferior to the other slings that are on the market."

[18] To the extent that the plaintiffs' claim may be understood to be that the surgical procedure testified to by Rosenzweig constitutes a reasonable alternative design, we agree with the courts that have considered this issue and concluded that a surgery is not a reasonable alternative design to a particular product. See, e.g., *Mullins* v. *Johnson & Johnson*, 236 F. Supp. 3d 940, 943 (S.D. W. Va. 2017) ("[e]vidence that a surgical procedure should have been used in place of a device is not an alternative, feasible design in relation to the TVT").

[19] The authors of the Ross study also explained that "[t]wo systematic reviews have examined the evidence on effectiveness of transobturator tape compared with TVT, without finding clear differences in outcome. Objective cure [rates] after transobturator tape ranged from 84 [percent] to 98 [percent]; for TVT it ranged from 86 [percent] to 99 [percent]. The objective cure rates in [the Ross] study (81 [percent] for transobturator tape, 77 [percent] for TVT) appear lower than those previously reported, but the difference is likely because [the Ross study's] follow-up and definition of objective cure was very rigorous." S. Ross et al., supra, 114 Obstetrics & Gynecology 1291.

[20] In the present case, the concurrence and dissent asserts that the plaintiffs produced sufficient evidence for the jury to consider their claim that the Ethicon branded TVT was a reasonable alternative design to the Obtryx. The basic premise underlying that position is that the evidence at trial established that the Ethicon branded TVT is the "gold standard" to treat stress urinary incontinence, that the Obtryx differed from the Ethicon branded TVT in three ways, and that those three design differences rendered the Obtryx unreasonably dangerous. We disagree with the position of the concurrence and dissent in three fundamental ways.

First, despite the repeated protestations of the concurrence and dissent, the evidence in the record did not establish that the Ethicon branded TVT is the "gold standard" to treat stress urinary incontinence. See, e.g., part II A 1 of the concurring and dissenting opinion. To the contrary, the one product design expert who testified at trial testified that a surgical procedure, not the Ethicon branded TVT, was the best method to treat stress urinary incontinence. The product design expert also testified that all products made of polypropylene mesh are defective, including the Ethicon branded TVT. Furthermore, as we discuss subsequently in this opinion, there was evidence in the studies introduced at trial that, although the Ethicon branded TVT may have been the first such product on the market, it had several deficiencies that caused manufacturers to create alternatives. What the plaintiffs' expert never did was testify that the design of the Ethicon branded TVT would have entailed less risk of harm to Fajardo and, thus, would not have caused greater or equal injury. At best, the plaintiffs' expert testified that the Obtryx had three alleged defects, but we do not learn from Rosenzweig or any other expert how or whether the Ethicon branded TVT would have reduced or avoided the risk of harm to Fajardo.

Second, the concurrence and dissent acknowledges that the one product design expert who testified did not identify the Ethicon branded TVT as a reasonable alternative design to the Obtryx. Nevertheless, while acknowledging that expert testimony on reasonable alternative design is required in this case, the concurrence and dissent asserts that any evidence that the product design expert did not provide is supplemented by other evidence in the case, including circumstantial evidence. We disagree.

The question of whether there was a reasonable alternative design available for the Obtryx involved complex medical principles, and the jury needed qualified expert testimony about each element of the prima facie case of reasonable alternative design. Courts have repeatedly explained that "[a]ny decision [that] pertains to the design of the device involves engineering, metallurgical and medical principles beyond common knowledge and experience. Whether the device had a design defect, whether the foreseeable risks of harm the device posed could have been reduced or avoided by the adoption of a reasonable alternative design and whether the omission of

such design rendered the device not reasonably safe are technical, scientific issues that cannot be fully understood by the average juror without some expert assistance." *Benedict* v. *Zimmer, Inc.*, 405 F. Supp. 2d 1026, 1033 (N.D. Iowa 2005); see also *Neilson* v. *Whirlpool Corp.*, Docket No. 3:10-cv-00140-JAJ-RAW, 2012 WL 13018693, *11 (S.D. Iowa January 3, 2012) ("An average juror has no understanding as to the actual design of the Whirlpool washer or any alternative designs [that] might reduce the risk of foreseeable harm. This is the exact type of case in which a 'jury needs assistance to reach an intelligent or correct decision. . . . Design defect cases sometimes involve technical, scientific issues [that] cannot be fully understood by the average juror without some expert assistance.' "). If we adopt the position of the concurrence and dissent and allow other nonexpert testimony to fill in gaps left by the qualified expert in this type of case, the jury does not have the assistance necessary to reach an intelligent or correct decision.

Third, although the Obtryx may have differed from the Ethicon branded TVT in three ways, evidence of these different design elements is not enough. The plaintiffs needed to prove, through expert testimony, that use of the Ethicon branded TVT would have reduced or avoided the risk of harm to Fajardo. There simply was not sufficient evidence on this point. To the contrary, Rosenzweig testified that Fajardo suffered from a chronic foreign body reaction, that use of polypropylene mesh can cause a foreign body reaction, and that both the Ethicon branded TVT and the Obtryx were made of polypropylene mesh. Accordingly, the plaintiffs did not produce sufficient evidence to support an instruction under *Bifolck 1*.

[21] There was evidence introduced in the present case that the transobturator approach was as effective and reduced or avoided some risk of injuries to patients. For example, the authors of the Petri study explained that "numerous different types of transobturator slings like inside-out tapes and thermally annealed non-knitted, non-interwoven polypropylene tape (Obtape) were developed and tested in clinical trials. In terms of efficacy, both retropubic and transobturator tapes are found to have similar subjective and objective cure rates . . . . Only one meta-analysis showed that the occurrence of bladder perforations, pelvic hematoma, and storage lower urinary tract symptoms was significantly less common in patients treated by transobturator tapes . . . ." (Citations omitted.) E. Petri & K. Ashok, "Comparison of Late Complications of Retropubic and Transobturator Slings in Stress Urinary Incontinence," 23 International Urogynecology J. 321, 321 (2012); see id., 324 (concluding that obstructive complications seen more commonly in retropubic tapes as compared to transobturator tapes were more frequently associated with persistent pain, dyspareunia, and tape related infections). Other studies introduced at trial explained that "[p]otential advantages of the transobturator approach include fewer bladder and bowel injuries and less voiding dysfunction and urinary retention than with traditional sling procedures." P. Rosenblatt & S. Pulliam, "Update on Suburethral Slings for Stress Urinary Incontinence," Contemporary OB/GYN, April 15, 2004, available at https://www.contemporaryobgyn.net/view/update-suburethral-slings-stress-urinary-incontinence (last visited December 10, 2021). Another study concluded that, "[i]n short-term follow-up there was no obvious difference between [retropubic] and [transobturator] routes in terms of safety and efficacy." T. Tarcan et al., "Safety and Efficacy of Retropubic or Transobturator Midurethral Slings in a Randomized Cohort of Turkish Women," 93 Urologia Internationalis 449 (2014).

The studies showed that each approach had benefits and risks. The question under *Bifolck 1* is not simply whether there are other feasible designs, but whether there is a feasible design that would have reduced or avoided the risk of harm to Fajardo. This complicated medical evidence demonstrates that the jury needed the assistance of an expert qualified to testify regarding product design to enable the jury to make an intelligent decision regarding whether there was a reasonable alternative design that would have reduced or avoided the risk of harm to Fajardo. The plaintiffs failed to produce that expert evidence, and therefore, its request for an instruction under *Bifolck 1* was properly denied.

[22] At trial, Bercik testified as follows:

"Q. What kind of polypropylene is the TVT sling made of that you use?

"A. I'm not sure—I'm not sure what you're asking.

"Q. Is a TVT sling made of the same polypropylene as the Obtryx sling?

* * *

"Q. Doctor, do you know what kind of polypropylene the Obtryx sling is made of?

"A. I do know it's made of something called—I think Marlex.

"Q. Okay.

"A. It's what they use.

"Q. Okay. Do you know . . . if the TVT sling is made of the same Marlex?

"A. I don't know if it's made of the same—like, from the same manufacturer or anything like that.

"Q. Okay. Is—

"A. I don't know.

"Q. —is TVT made by the same manufacturer as the Obtryx sling?

"A. No, ma'am.

"Q. Okay.

"A. Different company."

Although the concurrence and dissent asserts that Bercik's testimony is not necessary or important to its position; see footnote 6 of the concurring and dissenting opinion; it cites to his testimony no less than thirty-seven times, refers to the fact that Bercik was disclosed as a product design expert, and relies on him as such. However, by characterizing Bercik as a product design expert, the concurrence and dissent disregards the fact that there was a motion in limine to exclude him from testifying as a product design expert. Although there is not a clear ruling on that motion in the record, there is discussion on the record about his testimony being limited, and Bercik testified that he was not aware of a key aspect of the design of the Ethicon branded TVT, namely, the type of mesh from which it is made. Moreover, in its memorandum of decision, the trial court explained that "Rosenzweig . . . was [the plaintiffs'] product design expert," and the plaintiffs neither challenge that conclusion on appeal nor cite to Bercik in support of their claim. Accordingly, we disagree with the efforts of the concurrence and dissent to cast Bercik as qualified to give expert testimony regarding whether the TVT was a reasonable alternative design for the Obtryx.

[23] The concurrence and dissent asserts that Bercik "indicated that he had tried using the Obtryx, which employs a transobturator approach, had a negative experience with it, and so began using the Ethicon TVT, which uses a different approach." Footnote 22 of the concurring and dissenting opinion. That does not accurately characterize Bercik's actual testimony. He testified that he had implanted slings using the transobturator approach in the past but that he had stopped doing that because of complications. He then clarified that he had "trialed the [Obtryx] maybe once in the operating room" and had "never used it on a regular basis . . . ." He further explained: "I think I mentioned I [tried] the Obtryx once, and I don't remember why I don't—it was something about it that I didn't like. I don't know, I don't recall, it was ten years ago. But I gave up using other obturator approach slings because of my experience." Contrary to the representations of the concurring and dissenting opinion; see footnote 22 of the concurring and dissenting opinion and accompanying text; Bercik clearly testified that his "negative experience" was with other slings implanted using the transobturator approach, not the Obtryx.

[24] The plaintiffs assert that "[t]here were also a number of other studies admitted as full exhibits [that] supported the claim that the risks of the Obtryx outweigh its benefits in comparison with safer alternatives on the market at the time." The plaintiffs did not, however, identify the studies to which they refer.

[25] One of the studies introduced into evidence explains: "The retropubic tension-free vaginal tape (TVT, Gynecare, Somerville, NJ, USA) which was introduced in [the] 1990s is commonly acknowledged as the gold standard of [midurethral slings] by virtue of its extensive safety and efficacy data in the literature." Y. Lim et al., "Do the Advantage Slings Work As Well As the Tension-Free Vaginal Tapes?," 21 International Urogynecology J. 1157, 1157 (2010) (Lim study). Although the Lim study does state that the TVT has the most extensive data and was the original vaginal sling on the market, its authors concluded: "In this study, we found that the Advantage sling appears to be as effective as the TVT. There was a trend [toward] more overactive bladder and voiding difficulty issues, which may be related to the slightly stiffer nature of the Advantage sling, thus requiring the Advantage slings to be left slightly looser than [the] TVT. Further randomized controlled trials are necessary to confirm this supposition." Id., 1161.

Thus, although the Lim study may establish that the Ethicon branded TVT was a feasible alternative to the Obtryx, it does not establish that it would have reduced or avoided the risk of harm to Fajardo. The concurrence and dissent repeatedly uses the term "gold standard" to imply that the Ethicon branded TVT was the safest product on the market. But, as we have explained previously in this opinion, there was evidence presented at trial that the

Ethicon branded TVT and each of the other products within the class of TVTs had risks and complications associated with them. In light of the fact that they were complicated medical devices with complicated safety information, the plaintiffs had to do more to demonstrate that use of the Ethicon branded TVT would have reduced or avoided the risk of harm to Fajardo.