\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

The "officially released" date that appears near the beginning of each opinion is the date the opinion will be published in the Connecticut Law Journal or the date it was released as a slip opinion. The operative date for the beginning of all time periods for filing postopinion motions and petitions for certification is the "officially released" date appearing in the opinion.

All opinions are subject to modification and technical correction prior to official publication in the Connecticut Reports and Connecticut Appellate Reports. In the event of discrepancies between the advance release version of an opinion and the latest version appearing in the Connecticut Law Journal and subsequently in the Connecticut Reports or Connecticut Appellate Reports, the latest version is to be considered authoritative.

The syllabus and procedural history accompanying the opinion as it appears in the Connecticut Law Journal and bound volumes of official reports are copyrighted by the Secretary of the State, State of Connecticut, and may not be reproduced and distributed without the express written permission of the Commission on Official Legal Publications, Judicial Branch, State of Connecticut.

\*\*\*\*\*\*\*\*\*\*\*\*

ECKER, J., concurring in part and dissenting in part. I agree with, and join, part I and much of parts II A and B¹ of the majority opinion. I disagree, however, with parts II C through E, in which the majority concludes that the trial court properly declined to charge the jury on the reasonable alternative design prong of the risk-utility component of the Connecticut Product Liability Act, General Statutes § 52-572m et seq., as interpreted by this court in *Bifolck* v. *Philip Morris*, *Inc.*, 324 Conn. 402, 434–35, 152 A.3d 1183 (2016). Specifically, I do not agree with the majority's conclusion that the plaintiffs, Lesly Fajardo (Fajardo) and Jairo Fajardo, "did not produce sufficient evidence . . . to warrant an instruction on reasonable alternative design." Part II E of the majority opinion.

The trial court concluded that there was insufficient evidence in the trial record to support a jury instruction on the plaintiffs' claim that the Obtryx Transobturator Mid-Urethral Sling System designed by the named defendant, Boston Scientific Corporation, was defective under the risk-utility test because there was a viable and safer reasonable alternative design to the Obtryx. For the reasons set forth at length in part II of this opinion, I am convinced that this ruling was erroneous. There was abundant evidence presented at trial from which the jury could have concluded that one particular competitor product, a retropubic tension free vaginal sling trademarked "TVT" that is produced by Gynecare, part of the Ethicon division of Johnson & Johnson,<sup>2</sup> qualified as a reasonable alternative to the Obtryx. It was undisputed that not only is this TVT commercially viable, it is the most widely used treatment for stress urinary incontinence, the condition suffered by Fajardo, and meets the recognized standard of care for treatment of that condition. The plaintiffs proffered expert testimony, including the testimony of retained experts, Fajardo's treating physicians, and articles in respected medical research journals, that, if credited by the jury, together established that (1) the Obtryx differs from Ethicon's TVT in three primary respects, namely, its transobturator approach, its heat-sealed middle section, and its detanged edges, (2) each of those departures from the design of the TVT constitutes a defect, because they each increase the risks to the patient with no offsetting benefit, (3) the injuries that Fajardo suffered were caused by those design defects, and (4) the TVT would have avoided or reduced the risk of those types of harm and been a more suitable choice for Fajardo. Nothing more is required to warrant a jury instruction on a theory of reasonable alternative design under Bifolck. For these reasons, I respectfully concur in part and dissent in part.

Before I discuss the evidence in the record that warranted a reasonable alternative design jury charge, I emphasize three important preliminary points that should be uncontroversial. First, I agree with the majority regarding the standard of review. "[A] trial court should instruct the jury in accordance with a party's request to charge if the proposed instructions are reasonably supported by the evidence. . . . We therefore review the evidence presented at trial in the light most favorable to supporting the [plaintiffs'] proposed charge." (Citation omitted; emphasis added; internal quotation marks omitted.) Godwin v. Danbury Eye Physicians & Surgeons, P.C., 254 Conn. 131, 139, 757 A.2d 516 (2000). The emphasized language carries constitutional significance. "It must always be borne in mind that litigants have a constitutional right to have issues of fact decided by the jury and not by the court." (Internal quotation marks omitted.) Larsen Chelsey Realty Co. v. Larsen, 232 Conn. 480, 499, 656 A.2d 1009 (1995). For this reason, "[a] trial court should instruct a jury on [every] issue for which there is any foundation in the evidence, even if weak . . . ." (Internal quotation marks omitted.) Henriques v. Magnavice, 59 Conn. App. 333, 336, 757 A.2d 627 (2000); see also *Curran* v. *Kroll*, 303 Conn. 845, 857, 37 A.3d 700 (2012) ("it is well established that a plaintiff has the same right to submit a weak case as he has to submit a strong one" (internal quotation marks omitted)).

Second, the essential elements of a product liability claim predicated on a design defect are well established. The plaintiff must establish each of the following elements by a preponderance of the evidence: (1) the defendant was engaged in the business of selling the product; (2) the product was, by reason of its design, in a defective condition unreasonably dangerous to the consumer; and (3) the defect caused the injury for which compensation is sought. See, e.g., Bifolck v. Philip Morris, Inc., supra, 324 Conn. 434; Connecticut Civil Jury Instructions § 3.10-1, available at https:// www.jud.ct.gov/JI/Civil/Civil.pdf (last visited December 10, 2021). When the plaintiff seeks to establish the second element—defective design—on a reasonable alternative design theory, he or she also must establish that (A) a reasonable alternative design was available (B) that would have avoided or reduced the risk of harm, and (C) the failure to use that alternative design rendered the product unreasonably dangerous. See, e.g., Bifolck v. Philip Morris, Inc., supra, 434–35; see also footnote 16 of this opinion. A reasonable alternative design instruction is required if there is sufficient evidence in the record to permit the jury to find for the plaintiff on each of these elements.

Third, although the majority correctly observes that the existence of a reasonable alternative design typically must be established, at least in part, via expert testimony;<sup>3</sup> see part II C of the majority opinion; this court never has imposed a unitary source requirement such that a single expert must provide all component parts of that expert opinion. As I discuss more fully in part III C of this opinion, no rule or principle precludes the jury from piecing together the requisite quantum of proof from multiple sources, including the testimony of one or more expert witnesses, articles or other writings containing expert opinions admitted in evidence without restriction, and other qualifying evidence, including circumstantial evidence. See, e.g., Thompson v. Ethicon, Inc., Docket No. SAG-19-03159, 2020 WL 3893253, \*5 (D. Md. July 10, 2020) (court was aware of "no authority [requiring] that a single expert witness establish each element of a claim"); Slepski v. Williams Ford, Inc., 170 Conn. 18, 22, 364 A.2d 175 (1975) (jury in product defect case may rely on combination of expert testimony, lay witnesses, and circumstantial evidence); Morgan v. Hill, 139 Conn. 159, 161–62, 90 A.2d 641 (1952) (trier was privileged to accept portions of different experts' conflicting testimony in arriving at estimate of damage); Louisiana Dept. of Transportation & Development v. Scramuzza, 673 So. 2d 1249, 1261 n.10 (La. App. 1996) ("[j]uries may even mix and match parts of several expert opinions"), rev'd in part on other grounds, 692 So. 2d 1024 (La. 1997); *Bieniek* v. *Keir*, Docket No. A-3096-06T5, 2008 WL 1848293, \*5 (N.J. Super. App. Div. April 23, 2008) (jury properly could have accepted different portions of dueling experts' conclusions).

Moreover, is well established that a jury may draw reasonable inferences from an expert's testimony no less than the testimony of any other witness and come, thereby, to a conclusion that it could not permissibly reach solely on the basis of lay knowledge. See, e.g., Procaccini v. Lawrence + Memorial Hospital, Inc., 175 Conn. App. 692, 725–27, 168 A.3d 538 (although no single expert testified that decedent died of delayed respiratory depression, jury reasonably could have inferred such from all expert testimony considered together), cert. denied, 327 Conn. 960, 172 A.3d 801 (2017); Carter v. State, 620 S.W.3d 147, 153 (Tex. Crim. App. 2021) ("At first glance, it seems irrational to expect an ordinary [fact finder] to make an inference regarding positioning of certain components in a synthetic compound. But, the mere fact that an ordinary [fact finder], prior to any evidence being presented, could not make the required inferential step, does not mean that an informed [fact finder] could not reasonably make such an inference. That is all to say that an ordinary jury could still draw a reasonable inference from an expert's testimony about technical elements as long as each inference is supported by the evidence presented at trial."), petition for cert. filed (U.S. August 24, 2021) (No. 21-269); Anderson v. Combustion Engineering, *Inc.*, 256 Wis. 2d 389, 394, 647 N.W.2d 460 (2002) ("a jury

is entitled to draw reasonable inferences from expert testimony even if, at first blush, it may appear that the jury's conclusions based on those inferences require proof by specialized expert testimony").

Likewise—and this becomes particularly important with respect to the testimony of the plaintiffs' primary design expert, Bruce A. Rosenzweig, a professor of urogynecology—the jury is free to credit one portion of an expert's testimony while rejecting a different part of that same testimony. See, e.g., State v. Leroya M., Conn. A.3d (2021) ("[t]he [fact finder] is free to accept or reject each expert's opinion in whole or in part" (internal quotation marks omitted)); Grondin v. Curi, 262 Conn. 637, 657 n.20, 817 A.2d 61 (2003) ("[I]t is the province of the jury to weigh the evidence and determine the credibility and the effect of testimony . . . . [T]he jury is free to accept or reject each expert's opinion in whole or in part." (Internal quotation marks omitted.)); In re David W., 254 Conn. 676, 693, 759 A.2d 89 (2000) ("the trier is entitled to accept in part . . . [and] disregard in part . . . the uncontradicted testimony of [an expert] witness"); Champagne v. Raybestos-Manhattan, Inc., 212 Conn. 509, 545, 562 A.2d 1100 (1989) ("the trier of fact may accept part of the testimony of an expert without being bound by all of the opinion of the expert" (internal quotation marks omitted)); Yontef v. Yontef, 185 Conn. 275, 281, 440 A.2d 899 (1981) ("[the trier of fact] is free to rely on whatever parts of an expert's opinion the [trier] finds probative and helpful"). I do not understand the majority to have intended to dispense with this indisputable rule; nor does the majority suggest any reason why it should not apply in the present case. Indeed, it applies with full force because Boston Scientific has relied—both at trial and on appeal—almost exclusively on the specious argument that the jury could not have credited Rosenzweig's testimony that the Obtryx is defective vis-à-vis the TVT because Rosenzweig also believed that all polypropylene slings are defective. I explain the many failings in this argument in part III B of this opinion, an analysis to which the majority has offered no response.

П

With these principles in mind, I turn now to the evidence that was presented at trial in support of the plaintiffs' theory that the TVT represented a reasonable alternative design at the time Boston Scientific marketed and sold Fajardo's Obtryx. It is undisputed that Boston Scientific was engaged in the business of selling the Obtryx and, therefore, that the first element of the plaintiffs' product liability claim was established. My disagreement with the majority centers on the second (defective condition unreasonably dangerous to the consumer, which includes proof of feasibility) and third (causation) elements of the claim.

Beginning with feasibility, I note that there was overwhelming evidence at trial that the TVT is a feasible design. Indeed, 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," "the standard of care," and/or the most widely used treatment for precisely the condition from which Fajardo suffered. A "gold standard," commercially available product is the paradigmatic feasible alternative.

Four different research studies entered in evidence as full exhibits, each published in respected medical journals and relied on by the plaintiffs' experts, identified the TVT-either the Ethicon TVT or another TVTtype sling—as the primary accepted treatment for the condition from which Fajardo suffered, namely, female stress urinary incontinence. Three of the studies expressly identified the TVT as the "gold standard" for treating Fajardo's condition. See 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) ("[TVT is the] widely accepted . . . gold standard for the treatment of [stress urinary incontinence]"); 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) ("TVT . . . is commonly acknowledged as the gold standard of [synthetic midurethral slings] by virtue of its extensive safety and efficacy data in the literature"); 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) (TVT is "the gold standard").4 A fourth study in evidence referred to the TVT as "the surgery of choice for treating stress urinary incontinence" and "the standard of care." S. Ross et al., "Transobturator Tape Compared with Tension-Free Vaginal Tape for Stress Incontinence: A Randomized Controlled Trial," 114 Obstetrics & Gynecology 1287, 1287-88 (2009) (Ross study).

In light of the fact that four of the studies relied on by the plaintiffs' experts expressly state that the TVT is the "gold standard" or "standard of care" for the treatment of female stress urinary incontinence, it is difficult to understand the majority's insistence that "the evidence in the record did not establish that the Ethicon branded TVT is the 'gold standard' to treat stress urinary incontinence." Footnote 20 of the majority opinion. The question is not whether the majority would have been persuaded by that evidence had they sat as jurors, or whether I am persuaded by it, but, rather, whether there was *any* evidence on the basis of which *the jury* could have reached that conclusion. Clearly there was, and the majority offers no explana-

tion why the jury could not reasonably have relied on the statements and opinions contained in medical studies admitted as substantive evidence at trial.<sup>5</sup>

In addition, the jury reasonably could have found that two of Fajardo's treating physicians, Richard Bercik, a urogynelogical reconstructive surgeon and professor of female pelvic medicine at Yale School of Medicine, and Brian Hines, a urogynecologist, specifically recommended that Fajardo consider use of the TVT to treat her condition. Bercik further testified that he and his colleagues have had negative experiences with transobturator slings such as the Obtryx and generally have stopped implanting them in favor of the TVT. This evidence would have permitted the jury to conclude not only that the TVT is, in general, a viable alternative to the Obtryx that is readily available in Connecticut, but also that it was well suited to Fajardo's individual needs.

Finally, it was clear from the evidence presented at trial that the defendant's own expert witness, Peter L. Rosenblatt, also a urogynecologist, concurred that the TVT is a feasible alternative design. In a 2004 article that was admitted into evidence, Rosenblatt wrote that, with the invention of the Gynecare TVT, "[f]or the first time, surgeons had a reproducible, highly-effective, minimally-invasive sling procedure." 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); see id. ("study after study has consistently demonstrated the procedure's safety and effectiveness"). Rosenblatt testified at trial that, of the roughly 2000 studies showing that polypropylene slings are safe and effective for the treatment of female stress urinary incontinence, most have studied the TVT. Bercik agreed with Rosenblatt that the TVT is safe and effective. The fact that a product has been shown to be safe and effective in treating a particular condition necessarily implies that it is a feasible alternative for that purpose. See, e.g., Kosmynka v. Polaris Industries, Inc., 462 F.3d 74, 80 (2d Cir. 2006) ("[p]ractical engineering feasibility can be demonstrated by expert testimony concerning either a prototype that the expert has prepared or similar equipment using an alternative design that has been put into use by other makers"); Messina v. Ethicon, Inc., Docket No. 6:20-cv-1170-Orl-40LRH, 2020 WL 7419586, \*4 (M.D. Fla. December 17, 2020) ("safe and effective" implies feasible); Wald v. Costco Wholesale Corp., Docket No. 03 Civ. 6308JSR, 2005 WL 425864, \*7 (S.D.N.Y. February 22, 2005) ("To satisfy the first and most important element, lack of reasonable safety, plaintiffs must show that it was feasible to design the product in a safer manner. . . . [The] [p]laintiff has done so in one of the most basic ways: he has identified makers of similar equipment who have already put into use the alternative

design that has been proposed." (Citation omitted; internal quotation marks omitted.)); Restatement (Third), Torts, Products Liability § 2, comment (f), pp. 23–24 (1998) ("Cases arise in which the feasibility of a reasonable alternative design is obvious and understandable to laypersons and therefore expert testimony is unnecessary to support a finding that the product should have been designed differently and more safely. . . . [O]ther 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.").

Once experts for both sides had established that the TVT represents an alternative to the Obtryx that is widely used to treat Fajardo's condition and is deemed safe and effective by the medical community, and had provided the necessary context for the jury to understand the supporting clinical studies in evidence, the jury was free to conclude that the plaintiffs had shouldered their burden of establishing feasibility under Bifolck. Although the majority takes issue with some of my analysis in this regard, I understand the majority to agree with the ultimate conclusion in this part of my opinion that the TVT, as a successful and widely commercialized product, represents a technologically and economically viable alternative to the Obtryx that would have been a feasible option for Fajardo. I believe that our disagreement, instead, is limited to whether the jury reasonably could have found that use of the TVT would have avoided or reduced the risk of harm presented by the Obtryx. I address those issues in parts II A 2 and B of this opinion.

2

The plaintiffs next needed to establish that the design of the Obtryx renders it unreasonably dangerous relative to the TVT and, hence, defective. They did this by demonstrating that, although the two slings are similar, the Obtryx has three distinguishing features, each of which renders it more dangerous than the TVT without any corresponding benefit: it has a heat-sealed middle section that makes it less flexible and more subject to contraction than other slings, it features detanged edges that hinder the integration of the sling with native tissue, and it is designed for a transobturator approach, which results in more palpable tape (a characteristic linked to tape extrusion and vaginal erosion) and paraurethral banding (linked to leading to internal dyspareunia), as well as vaginal tenderness and groin pain.

There was abundant evidence from which the jury could have found that these three design features, which undisputedly constitute the primary design differences between the TVT and the Obtryx, render the Obtryx unreasonably dangerous. With respect to heat sealing, Rosenzweig explained to the jury how the Lim and Moalli studies found that the unique heat sealing

process used by Boston Scientific renders its sling products significantly stiffer than the TVT and, therefore, potentially more likely to cause erosion, vaginal obstruction, and voiding dysfunction. See Y. Lim et al., supra, 21 International Urogynecology J. 1161; P. Moalli et al., supra, 19 International. Urogynecology J. 662.7 Rosenzweig also testified that the heat sealing process aggravates the foreign body reaction associated with the use of polypropylene mesh. He explained that the heatsealed center portion makes the Obtryx stiffer than other midurethral slings and that "stiffness of mesh is a bad property" that is associated with a higher rate of complications, such as inflammation, groin pain, scarring, urgency, overactive bladder, vaginal erosion, and dyspareunia, or pain during intercourse. Whereas Rosenzweig testified that midurethral slings such as the Obtryx can contract, causing chronic pain, Bercik testified that, in his clinical experience, significant contracture does not tend to occur with the TVT.

Similarly, with respect to detanging, the Moalli study, on which Rosenzweig relied, stated that the tanged edges of the TVT were "designed to 'grip' tissue after sling placement." P. Moalli et al., supra, 19 International. Urogynecology J. 655. Doreen Rao, a principal engineer for Boston Scientific, acknowledged that some of her colleagues thought that maintaining the tangs—rough edges where the polypropylene mesh had been cut was useful in holding the sling in place and promoting ingrowth of native tissue. Rao referred to this as the "leading theory." Rao was unable to document any offsetting benefits from Boston Scientific's decision to remove the tangs, other than that detanging "presents a smoother surface." Rosenzweig testified more definitively that detanging adds no benefit to outweigh the heightened risks associated with a lack of integration of the sling with the patient's native tissue. The jury should have been given the option to agree with Rosenzweig insofar as his testimony spoke to the shortcomings of the Obtryx relative to the TVT.

With respect to the risks associated with the transobturator design of the Obtryx, the plaintiffs highlighted the Ross study, a randomized, double blind, clinical study of nearly 200 women, which compared the Obtryx to Boston Scientific's own Advantage retropubic midurethral sling. See S. Ross et al., supra, 114 Obstetrics & Gynecology 1288–89. Because the two slings are made from the same material and share other common design features, the study was able to isolate the safety and effectiveness of using a transobturator approach vis-àvis the traditional retropubic approach. The study found no statistically significant difference in the products' cure rates. See id., 1291. The study did find, however, that the vaginal mesh was much more likely to remain palpable to the touch one year after surgery among women who received transobturator slings, an outcome that the authors deemed "concerning" due to the heightened risk of tape extrusion and vaginal erosion. Id., 1293; see id., 1287–88, 1290. More women in the transobturator group also experienced tenderness and groin pain. See id., 1290, 1292-93. The authors' final conclusion: "Compared with the [Advantage] TVT group, more women in the transobturator tape group had tape that was palpable and groin pain on vaginal examination. The presence of palpable tape is concerning; longer follow-up is needed to determine whether this outcome leads to extrusion or resolves over time. Until longterm follow-up is available from this and other trials, TVT should remain the midurethral sling procedure of choice." Id., 1293–94. The Cholhan study likewise suggested that tapes such as the TVT, which feature a retropubic design, have a more favorable risk-benefit profile than do transobturator tapes, such as the Obtryx, for the treatment of female stress urinary incontinence. See H. Cholhan et al., supra, 202 Am. J. Obstetrics & Gynecology 481.e1. That study identified a "concerning" new complication—paraurethral banding, leading to internal dyspareunia—that occurred in transobturator but not retropubic sling patients.8 Id., 481.e3.

Rosenzweig testified that he relied on each of these studies in forming his opinions regarding the product defects and injuries at issue in this case and that they are authoritative in the field. He also made crystal clear the conclusion that the jury itself easily could have drawn from the Cholhan, Lin, Moalli, Ross and other studies in evidence, namely, that these three design features render the Obtryx "defective . . . ." Rosenzweig opined that the unique detanged and heat-sealed features of the Obtryx have no benefits that outweigh the added risks. He characterized the research as demonstrating that, because the transobturator design of the Obtryx was associated with significantly higher incidences of groin pain and other complications, "the retropubic sling is better than the [Obtryx] transobturator sling." Rosenzweig specifically linked negative research findings regarding transobturator slings to Fajardo's Obtryx. He concluded, to a reasonable degree of medical certainty, that "[the Obtryx sling] is defective in design." 10

In an e-mail to Boston Scientific that also was admitted as a full exhibit, Paul Tulikangas, a urogynecologist and female pelvic medicine and reconstructive surgery specialist, likewise interpreted the medical research to mean that the Obtryx is "inferior" to other midurethral slings, with higher rates of erosion, groin pain, and voiding issues compared to the TVT. <sup>11</sup> Bercik appeared to concur, indicating that he had abandoned the use of transobturator slings, including the Obtryx, because he and other physicians experienced a high rate of complications and that he now exclusively uses the TVT.

The foregoing evidence leads me to conclude with confidence that the plaintiffs set out a prima facie case that the three design features by which the Obtryx departs from the TVT render the Obtryx defective. The majority disagrees and, deploying an argument never articulated by Boston Scientific, appears to take the position that the Obtryx could not have been defective relative to the TVT because both products present potential dangers and risks. The majority emphasizes, for example, that "there were risks and complications with the use of the [Ethicon branded] TVT"; part II E of the majority opinion; and that "the Ethicon branded TVT and each of the other products within the class of TVTs had risks and complications associated with them." Footnote 25 of the majority opinion. These observations miss the fundamental point. A design is defective if it creates a greater risk of harm than the alternative design without sufficient offsetting benefit, which means that the question is not whether the alternative is risk free, but whether it confers the same benefits with a lesser risk of harm. See, e.g., Bifolck v. Philip Morris, Inc., supra, 324 Conn. 434–35. This point is clear even in the very cases that the majority cites in support of its argument. Thus, the majority cites Casey v. Toyota Motor Engineering Mfg. North America, Inc., 770 F.3d 322, 331 (5th Cir. 2014), for the proposition that "'[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." (Emphasis altered.) Part II E of the majority opinion; see Water Pollution Control Authority v. Flowserve US, Inc., Docket No. 3:14-cv-00549 (VLB), 2018 WL 1525709, \*25 (D. Conn. March 28, 2018) (plaintiff was required to establish that reasonable alternative design "would have avoided or reduced the risk of harm without unreasonably increasing cost" (emphasis added; internal quotation marks omitted)), aff'd, 782 Fed. Appx. 9 (2d Cir. 2019).

It is, of course, true that, if an alternative design reduces certain risks but increases other risks, or raises costs, or reduces functionality, it may not be a *reasonable* alternative design. But the majority is incorrect that, if two competing medical product designs both have benefits, and both have risks, then neither can be defective, and neither can be a reasonable alternative design. *Every* medical product and procedure involve some degree of risk. The plaintiffs' task was not to demonstrate that the TVT is risk free. Rather, they had only to present evidence from which the jury reasonably could conclude that the Obtryx was unnecessarily dangerous and that the TVT reduces those dangers without sacrificing functionality and without adding other, off-setting risks or costs.

The evidence cited in the preceding paragraphs establishes precisely that. Indeed, viewing the evidence in the light most favorable to the plaintiffs, this case presents a textbook example of a reasonable alternative design, insofar as Boston Scientific, in designing the Obtryx, essentially took the TVT and altered it in three ways. <sup>12</sup>

The jury could have found that, in addition to those risks shared equally by the two products (e.g., surgical risks or risks involved in the body's reaction to foreign materials such as polypropylene), the Obtryx, by virtue of those three alterations, carries three additional sets of risks—stemming from its heat-sealed middle, detanged edges, and transobturator design—that (1) are not shared by the TVT, and (2) do not offer any significant offsetting benefits or cost savings. 13 Indeed, Boston Scientific itself acknowledges that, although Rosenzweig was of the view that all polypropylene mesh devices are defective, "Rosenzweig may believe the . . . characteristics [of the Obtryx] allegedly make it more defective/unreasonably dangerous . . . ." Under the applicable law, including the cases on which the majority relies, that showing is enough for the jury to find the Obtryx unreasonably dangerous, and hence defective, on a theory of reasonable alternative design.

F

With respect to the third element of the plaintiffs' defective design claim, which requires evidence that the defective features of the design of the Obtryx caused or contributed to Fajardo's injuries, there was sufficient evidence from which the jury reasonably could have reached that conclusion. First, as I discussed, there was extensive evidence that three specific design elements of the Obtryx increase the risk of harm to patients, including Fajardo. The heat-sealed middle section makes the sling less flexible and more subject to contraction than other slings, which, in turn, aggravates the foreign body reaction associated with the use of polypropylene mesh and results in a higher rate of complications, such as inflammation, groin pain, scarring, urgency, overactive bladder, vaginal erosion, and dyspareunia. The detanged edges hinder the integration of the sling with native tissue. The transobturator design results in vaginal tenderness and groin pain, and may be linked to tape extrusion, vaginal erosion, and internal dyspareunia. Dyspareunia, pelvic pain and swelling, and worsening incontinence are the very symptoms that Fajardo alleged.

Second, the plaintiffs' expert witnesses were of the opinion that these defective characteristics of the Obtryx were in fact responsible for Fajardo's injuries. Rosenzweig testified that the decision by Boston Scientific to heat seal the middle portion of the Obtryx stiffened the sling, which, in turn, aggravated Fajardo's incontinence and exacerbated the foreign body reaction, inflammation, scarring, and the other sequelae of her condition. He opined that "Fajardo has . . . . chronic groin pain from the Obtryx sling . . . ." He further noted that Fajardo's sling was palpable when removed, consistent with the cautions contained in the Ross study regarding the transobturator design, and that her injuries were to her obturator foramen, which

was precisely where the Obtryx was inserted. Ultimately, Rosenzweig unequivocally opined, to a reasonable degree of medical certainty, that "[t]he defects of the Obtryx sling caused the injuries to . . . Fajardo." The majority's statement to the contrary fails to acknowledge the clear significance of this evidence. 15

Finally, the jury reasonably could have concluded, on this record, that using a TVT in lieu of the Obtryx would have reduced, if not avoided altogether, the risks of harm that the Obtryx presented. Indeed, insofar as the primary design differences between the Obtryx and the TVT were also the precise defects alleged to have injured her, by far the most logical conclusion is that selecting a TVT would have reduced her risk of dyspareunia, groin pain, and incontinence, consistent with the medical studies in evidence.

As I previously discussed, it is well within the province of the jury to draw reasonable inferences from an expert's testimony and, thus, to come to a conclusion that it could not permissibly reach solely on the basis of lay knowledge. In the present case, the jury was at liberty to combine various elements of the expert evidence—Rosenzweig's testimony, the Tulikangas opinion letter, and the medical studies admitted as full exhibits<sup>17</sup>—to reach the reasonable conclusion that the elimination of three specific dangerous features of the Obtryx would reduce the risk of danger presented by that product. See, e.g., State v. Nunes, 260 Conn. 649, 675, 800 A.2d 1160 (2002) (substance of experts' testimony was held sufficient to establish causation to reasonable degree of medical certainty, despite fact that experts merely stated that "the symptoms experienced by the victim were consistent with those of chloral hydrate" (emphasis omitted)); Procaccini v. Lawrence + Memorial Hospital, Inc., supra, 175 Conn. App. 725–26 (recognizing that expert opinion is required to prove causation in medical malpractice action but holding that jury could find causation from cumulative effect of expert testimony and other evidence, including circumstantial evidence); see also Thompson v. Ethicon, Inc., supra, 2020 WL 3893253, \*5 (applying same rule in context of mesh litigation). Because the plaintiffs had only to persuade the jury that use of the TVT would have reduced the risks posed by the Obtryx, establishing that the TVT posed a lower danger to Fajardo with respect to any one of the three suspect design features would have been sufficient to warrant a reasonable alternative design instruction. Construing the evidence in the light most favorable to the plaintiffs, as we must, there was sufficient evidence of all three defects to warrant such an instruction.<sup>18</sup>

(

I have established that the plaintiffs were entitled to the requested instruction if there was evidence tending to show that a reasonable alternative design was available that would have avoided or reduced the risk of harm and the failure to use that alternative design rendered the product unreasonably dangerous. The plaintiffs claimed in particular that the unique characteristics of the Obtryx—a heat-sealed middle section, detanged edges, and a transobturator design—rendered it less safe than the TVT and that those differences caused or contributed to Fajardo's injuries. They contended that the TVT was a generally safe, effective, and widely used mesh sling product for the treatment of female stress urinary incontinence and that the Obtryx did not offer any significant advantages in safety or effectiveness visà-vis the "gold standard" TVT that would justify the increased rate of complications. They offered expert testimony, bolstered by respected clinical studies, in support of those contentions, and in support of the conclusion that the Obtryx should not be used due to its unnecessarily high rate of serious complications.

The claim as presented was not oblique or difficult to understand. The plaintiffs' counsel throughout trial directly and repeatedly referenced the foregoing body of research suggesting that TVT slings are superior in design and feature a more favorable risk-benefit profile vis-à-vis transobturator slings in general, and the Obtryx in particular. In his closing argument, the plaintiffs' counsel began by discussing this body of research at some length and by emphasizing that the TVT had been proven to be a safer product than the Obtryx, with fewer complications, and, therefore, that it should remain the midurethral procedure of choice. He specifically linked the higher incidence of complications relative to TVT with the unique design features of the Obtryx, such as the detanged edges and heat-sealed mid-portion, and the resulting increase in material stiffness, as well as the Obtryx' transobturator approach. Later, counsel analogized the Obtryx to the Ford Pinto and its proclivity to burst into flames during rear-end collisions, explaining that evidence that mesh slings are generally safe was simply irrelevant to the plaintiffs' claim that the Obtryx is specifically dangerous.

Finally, in his rebuttal, the plaintiffs' counsel argued: "[A]lmost their whole defense was saying mesh slings are good. Very, very little of what they said had to do with the Obtryx. And they said that [the] plaintiffs are here telling you all mesh slings are bad. Those words never left my mouth once. I put a lot of evidence in front of you, but there's a feasible alternative called the TVT, which is superior. And that's just not my words, that's . . . Tulikangas who told them that, that their product is inferior." A few minutes later, he returned to this theme: "So, then [the defendants' counsel] tell[s] you how great TVT is, is a complete distraction and actually supports our claim that there is a better product that doesn't have near[ly] as many problems. And they were told that." He then closed with a final reference to the Ross study: "Here's the 2009 Ross study, and let's look at the last sentence. Use TVT, don't use the Obtryx. That's th[e] conclusion." The evidence of reasonable alternative design was presented at trial as a distinct theory of product defect, the claim was argued forcefully on the basis of that evidence, and the evidence was sufficient in all respects to allow the jury to exercise its constitutional function.<sup>19</sup>

 $\Pi$ 

Despite the evidence discussed in part II of this opinion, and the requirement that we construe that evidence in the light most favorable to the plaintiffs, the majority remains unpersuaded that a reasonable alternative design instruction was appropriate, for four primary reasons. First, the majority contends that the TVT cannot qualify as a reasonable alternative design because the term "TVT," as used at trial, is ambiguous, and did not adequately identify one specific product brand. Second, the majority contends that the plaintiffs could not rely on the expert opinion of Rosenzweig to establish that the TVT represents a reasonable alternative design when Rosenzweig also opined that all polypropylene mesh products are unsafe. Third, the majority contends that the jury was precluded from considering published medical research studies, the testimony of treating physicians, and certain other testimony when evaluating whether the Obtryx was defectively designed. Fourth, the majority, having weighed the evidence presented at trial, finds that the evidence in support of the plaintiffs' reasonable alternative design theory was unpersuasive, lacked credibility, or was contradicted by other evidence of record. I consider each argument in turn.

Δ

The majority first argues that the TVT cannot qualify as a reasonable alternative design because the term "TVT" is ambiguous. The majority contends that "[t]he record demonstrates that the term 'TVT' is used both with respect to the Ethicon branded tension free vaginal tape (the specific TVT type product [Fajardo] 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, [the majority] use[s] 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 . . . . " Footnote 9 of the majority opinion. On the basis of this premise—which, as I will explain, is incorrect—the majority proceeds on the assumption that a plaintiff may not satisfy its burden of producing sufficient evidence of a reasonable alternative design by pointing to a class of products that themselves differ in material, design, safety and efficacy with some containing the very same defects of which the plaintiff complains. The majority proceeds to evaluate the expert testimony and other evidence

presented by the plaintiffs through the lens of its erroneous assumption that "the plaintiffs are claiming that the class of TVTs is a reasonable alternative design . . ."<sup>20</sup> Part II E of the majority opinion.

The flaws in the majority's position become manifest upon careful review of its reasoning. The majority elaborates: "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. 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. Finally . . . 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." (Citation omitted; footnotes omitted.) Part II E of the majority opinion. The majority also contends that, insofar as certain TVTs, such as Boston Scientific's own Advantage, have the same alleged design defects as the Obtryx—a heat-sealed, detanged center section—there is no evidence that use of the TVT would have prevented Fajardo's injuries.

The argument of the majority, in summary, relies on five propositions: (1) the term "TVT" can refer both to the Ethicon branded TVT and to the broader class of retropubic slings; (2) the plaintiffs use the term in the latter, broader sense, not with reference to any particular sling product; (3) a class of products cannot qualify as a reasonable alternative design; (4) some members of the class of TVTs, most notably Boston Scientific's Advantage retropubic sling, have the same design features as, and are no safer than, the Obtryx; and (5) the plaintiffs, therefore, did not proffer sufficient evidence to warrant a reasonable alternative design instruction.<sup>21</sup>

I agree with the first proposition, that the term "TVT" can be ambiguous. The majority is simply mistaken, however, with respect to the latter three propositions. First, the vast majority of the evidence in the record, and the focal point of the plaintiffs' reasonable alternative design argument, addressed the original, Ethicon branded TVT, rather than a generic class of retropubic slings. Second, nothing in law or logic bars the plaintiffs from arguing that all TVT-type retropubic slings are superior to the Obtryx *and* that the original, Ethicon branded TVT is especially superior. And third, the plaintiffs presented compelling evidence that the Obtryx was

less safe than both the Ethicon TVT and other TVT-type retropubic slings. Accordingly, the fact that the term "TVT" is occasionally used loosely, in the course of a ten day trial, to refer to retropubic slings generally is of no consequence; the trial court did not rely on that argument, and nothing about it justifies the court's instructional ruling.

1

The majority incorrectly suggests that the plaintiffs never compared the Obtryx to any particular TVT product and that their references were only to the class of tension free tape that is implanted in a retropubic fashion. The truth is that, with just a handful of exceptions, all of the references to "TVT" in the record were expressly to the product that bears that name, the TVTbrand sling manufactured by the Gynecare unit of Johnson & Johnson's Ethicon division. This is no surprise. As the majority acknowledges, the plaintiffs identified one particular TVT product in their complaint, and only one—the Ethicon TVT. Indeed, unless my review of the record missed contrary evidence, Ethicon's is the *only* vaginal mesh that uses the trade name "TVT." In light of these facts, I do not understand why the majority resists the reasonable assumption that the Ethicon TVT is the TVT to which the plaintiffs were referring.

The cross-examination of one of the plaintiffs' experts at trial illustrates that everyone in the court-room—including Boston Scientific's own lawyers—clearly understood that the TVT under discussion was the Ethicon TVT. Bercik testified, among other things, that Fajardo would have been a suitable candidate for the TVT. He repeatedly made clear that the TVT to which he was referring was the Ethicon TVT in particular, and not retropubic slings more generally. The following colloquies, for example, took place during his cross-examination.

"Q. And then you say [that Fajardo] may potentially benefit from repeat sling procedure, and what you left out when you read to the jury was the word TVT. You wrote TVT at the end of the sentence, right?

"A. I did.

"Q. Okay. And so what you were reporting in your note is that . . . Fajardo might benefit from a repeat sling procedure, TVT, right? That's what you wrote?

\* \* \*

- "Q. But a TVT is a polypropylene sling, right? It's made from polypropylene?
  - "A. So, it's a specific brand of a polypropylene sling.
- "Q. Sir, my . . . question is [whether] the TVT is a polypropylene sling, right?

"A. Yes, sir.

- "Q. Okay. And it's also . . . made by Johnson & Johnson and not Boston Scientific, right?
  - "A. That's correct.
- "Q. Ethicon. And you have implanted that polypropylene sling for many years. You talked . . . with . . . Fajardo's lawyers about that, right?
  - "A. Yes, sir.
- "Q. Okay. And you currently use and recommend that polypropylene sling to women with stress urinary incontinence, right?
  - "A. Yes, sir, I do.
- "Q. And you place about 100 of those polypropylene midurethral slings a year, right?
  - "A. Give or take, yeah.

\* \* \*

- "Q. Sure. . . . For the slings that . . . you have implanted . . . the TVT sling manufactured by Johnson & Johnson, those women [who] have that sling, there's a risk that their sling[s] may need to be removed?
  - "A. Oh, I see what you're saying. Yes.
- "Q. Yeah. And any time that you implant a TVT sling in the hundreds of women that you have recently, you discuss with them the potential that the sling may need to be removed as a potential risk, right?
  - "A. I do. I generally quote about a 1 percent risk.
- "Q. All right. And you continue to recommend slings as an option for women to use despite the fact that there's a risk that they may need to be . . . removed, correct?
- "A. No, I don't—I don't recommend slings, plural. I recommend a sling, a specific sling.
- "Q. You recommend a specific sling, the one that you choose to use, even with a risk of potential removal, correct?
- "A. Right. Based [on] my experience and my knowledge of—of the risk and complication rates, yes.
- "Q. And you also agree that, [with] the sling that you recommend, there is a risk of contracture with that sling, as well, agreed?
- "A. . . . With my experience, I have not seen significant contracture with that sling." (Emphasis added.)

The following additional colloquies took place on redirect examination.

- "Q. [I]s TVT made by the same manufacturer as the Obtryx sling?
  - "A. No, ma'am.

"Q. Okay.

"A. Different company.

\* \* \*

"Q. Okay. So the TVT that you use has a different approach than the Obtryx sling. Correct?

"A. Yes, ma'am." (Emphasis added.)

It could not be any clearer that Fajardo's treating physician was comparing the Ethicon TVT to the Obtryx. <sup>22</sup> He opined that the Ethicon sling was a suitable alternative for Fajardo specifically. He opined that the Ethicon sling was safer than the Obtryx in various respects, with fewer complications, less contraction, and less risk of removal. He went out of his way to emphasize that he was recommending only one particular sling, sold by one particular company. And both the plaintiffs' and the defendants' counsel repeatedly indicated that they understood that the sling at issue was the Ethicon TVT, not a general class of retropubic slings or Boston Scientific's own retropubic Advantage sling. It is impossible to read the record any other way.

Other key testimony at trial would have reinforced the fact that the term "TVT" is primarily used in reference to the Ethicon branded TVT, and not to a class of TVT-like products. Rosenblatt, the primary defense expert, testified that the first mesh sling was the TVT, which was developed in 1998. He referred to it as the "Ethicon TVT," and he explained that, unlike Boston Scientific's vaginal slings, the TVT was manufactured from Prolex branded polypropylene, rather than Marlex. Indeed, Rosenblatt repeatedly distinguished "the TVT" from "TVT-like retropubic slings," such as Boston Scientific's Advantage, making perfectly clear that he was not using the term "TVT" broadly to encompass all retropubic slings. Notably, he emphasized that the TVT—unlike the Advantage and the Obtryx—does not have the controversial detanged edges, which, he explained, is a novel development and is unique to the Boston Scientific products.<sup>23</sup>

In addition, Rao, the Boston Scientific engineer, distinguished the Advantage from the Ethicon branded TVT, making clear that the TVT, unlike Boston Scientific's products, did not have the heat-sealed center, detanged edges, and other design flaws alleged to have caused Fajardo's injuries.<sup>24</sup> I am not aware of any trial testimony, by contrast, that suggested that the TVT that was held up as an alternative to the Obtryx represented a class of products.

Most of the exhibits introduced at trial likewise used the term "TVT" in reference to the Ethicon branded product of that name, rather than as a synonym for retropubic slings generally; many expressly distinguished Boston Scientific's Advantage retropubic sling from *the* TVT. The Lim study, for example, distinguished the Advantage from the "Gynecare" TVT and postulated that the defects in the former result from the heat sealing process, which renders the Advantage stiffer and less elastic than the TVT. See Y. Lim et al., supra, 21 International Urogynecology J. 1157, 1161. Moalli compared the "Gynecare TVTTM" from Ethicon with the Advantage and four other midurethral slings. See P. Moalli et al., supra, 19 International. Urogynecology J. 655. The authors stated that the Gynecare TVT, which has unique tensile properties, is "the gold standard"; id., 656; and explained how newer slings, such as the Advantage, depart from the TVT by adding a heat-sealed middle, a tensioning suture, or a different weave pattern. See id., 662. Another study in evidence likewise distinguished the TVT from subsequent retropubic slings such as Advantage. See generally 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).

In other trial exhibits, physician consultants to Boston Scientific also used the term "TVT" to specifically reference the Ethicon product. In an e-mail, one consultant, Joseph Macaluso, referred to the "TVT™," distinguishing the actual trademarked TVT from what he refers to as "TVT-type" mesh. Similarly, in his correspondence with Boston Scientific, Tulikangas responded to an e-mail from Boston Scientific, stating: "Advantage vs TVT—Longer term follow-up—Retrospective—Multiple Institutions—Shows that [Advantage] is just as effective as TVT . . . ."<sup>25</sup> Indeed, of the scores of exhibits in evidence, only one, the Ross study, consistently used the terms "TVT" and "retropubic" interchangeably. See generally S. Ross et al., supra, 114 Obstetrics & Gynecology 1287.

In most instances, it also was apparent that counsel for both sides, when referencing the "TVT," were referring to the Ethicon product in particular. As the majority concedes, all of the plaintiffs' references to "TVT" in the operative complaint expressly referenced Ethicon's original, branded TVT. See footnote 9 of the majority opinion. In his closing argument, the plaintiffs' counsel identified the TVT as "a competitor's product," which eliminates any possibility that he was referencing the class of TVTs that includes Boston Scientific's Advantage sling. In support of his claim that the TVT is a superior product for which Fajardo would have been well suited, he discussed the Moalli study and the testimony of Bercik, both of which addressed the Ethicon TVT, in particular. Counsel explained how "the TVT people," unlike Boston Scientific, designed the TVT with tanged edges "for a functional purpose to grip tissue." Although counsel's other references to TVT, such as in the context of discussing the Ross study, were arguably ambiguous, at no point did he suggest that the TVT that he was holding up as a comparator was the class of retropubic slings, much less Boston

Scientific's own Advantage product.

We can be certain that Boston Scientific was not confused by the supposed ambiguity. In its closing, Boston Scientific continued to hew to the position that it took throughout the trial, namely, that the TVT is a particular product rather than a class. Counsel walked the jury through the historical use of polypropylene in medical devices: "You then have the first product that comes onto the market in 1998, and that's called, you've heard, the TVT. It's a polypropylene mesh sling. Five years later, Boston Scientific puts out its first polypropylene mesh sling called the Advantage . . . . "

The majority cites no examples of any instance at trial when Boston Scientific uses the term "TVT" to refer to a class of products. Indeed, even on appeal, the defendants themselves have not taken the position espoused by the majority that the term "TVT" was used at trial in reference to the class of retropubic slings. In its brief, Boston Scientific repeatedly distinguishes "the TVT," which was "first . . . marketed in 1998" and "lacks detanged edges," from retropubic slings such as the Advantage. Although Boston Scientific does fault the plaintiffs for not identifying a competitor product that, in its view, "would have reduced or avoided the risk of harm to . . . Fajardo," it is perfectly clear from its brief that Boston Scientific understands that the Ethicon TVT is among the reasonable alternative designs at issue. (Emphasis omitted.)

It is clear, then, that there was abundant evidence from which the jury reasonably could have found that the original TVT, the branded product manufactured and sold by the Gynecare unit of Johnson & Johnson's Ethicon division, represented a reasonable alternative to the Obtryx. Expert testimony and supporting scientific studies established that that particular sling (1) is widely used, (2) is safe and effective, (3) was a feasible option for Fajardo, (4) is superior to the Obtryx, and (5) does not have the design features that allegedly caused Fajardo's injuries, namely, a heat-sealed middle section, detanged edges, and a transobturator approach. If there are concerns that the jury might have been confused by Ross' looser use of the term "TVT," or ambiguities in the arguments of counsel, then the trial court could have solved the problem by instructing the jury to consider only the evidence tending to show that the Ethicon TVT in particular represented a reasonable alternative design. There was no justification for throwing out the entire claim.

2

Even were we to assume, purely for the sake of argument, that the plaintiffs intended the "TVT" to refer to a class of products rather than a particular product, the majority has provided neither authority nor argument in support of its contention that a class of products

cannot serve as a reasonable alternative design. A consumer injured by a cigarette lighter using a novel ignition device would be entirely justified in holding up the class of disposable butane lighters using a flint wheel as a reasonable alternative design, rather than, say, arbitrarily pointing to some particular BIC or Scripto model. As one federal court in Connecticut has explained, "proof of a feasible alternative design [is] a euphemism for avoidability . . . . " (Internal quotation marks omitted.) Mals v. Smith & Nephew, Inc., Docket No. 3:19-cv-01770 (VLB), 2020 WL 3270835, \*5 (D. Conn. June 17, 2020). If the defendant's product differs in some important way from all competitor products, and in a way that is demonstrably responsible for the plaintiff's injuries, then why should it matter that those various, safer alternatives are not in every respect identical?

In the present case, every sling in the class of TVTtype products lacks at least one of the three defects of the Obtryx, namely, the use of a transobturator rather than a retropubic design. Evidence in the record that was introduced and relied on by the plaintiffs' design experts and emphasized by the plaintiffs' counsel during both opening and closing arguments, such as the Ross and Cholhan studies, as well as other evidence, such as the Petri study; see footnote 8 of this opinion; indicated that the use of a transobturator approach was a defect of the Obtryx that is associated with injuries of the type suffered by Fajardo. Rosenzweig clearly summarized this body of research for the jury, stating that, because the transobturator design of the Obtryx was associated with significantly higher incidences of groin pain and other complications, "the retropubic sling is better than the [Obtryx] transobturator sling." He summed up his discussion of these and other complications associated with the Obtryx by opining that the Obtryx is defective and that its defects caused Fajardo's injuries. Accordingly, even if the majority were correct that the plaintiffs tried the case by comparing the Obtryx only to the class of retropubic slings, rather than to the Ethicon TVT in particular, there was abundant evidence from which the jury could have found that the use of any retropubic sling would have reduced the risk of the types of injuries that Fajardo suffered.

To summarize, the plaintiffs demonstrated at trial that both of the Boston Scientific products, the Advantage and the Obtryx, are inferior to the Ethicon TVT insofar as they have two unique design elements: detanged edges and a heat-sealed middle section. The plaintiffs also demonstrated that the Obtryx is worse even than the Advantage, insofar as the former sling has a third design defect: transobturator slings are more dangerous than retropubic slings, without offsetting benefits. So, the Obtryx is the worst of both worlds. Fajardo would have reduced her risks had she used any TVT-style retropubic sling, and she would have minimized her risks to the greatest extent by using

the Ethicon TVT, rather than a heat-sealed, detanged Boston Scientific TVT product. However defined, TVT was a safer product, a less defective, reasonable alternative design. At least, the jury could have so found. It should have been allowed to do so.

В

The second reason that the majority believes that a reasonable alternative design instruction was not warranted, despite the abundant evidence that the TVT was a viable, superior alternative that could have prevented Fajardo's injuries, is that the plaintiffs also presented some evidence that all polypropylene slings are unreasonably dangerous because polypropylene is not suitable for use in the human body. Specifically, the majority embraces Boston Scientific's principal argument the same argument that apparently persuaded the trial court—that the plaintiffs could not, as a matter of law, have established that the TVT is a reasonable alternative design because their own product design expert, Rosenzweig, testified that, in his opinion, all mesh products fabricated from polypropylene, including the TVT, are unsafe and unsuitable for implantation in the human body. The plaintiffs counter, and I agree, that the fact that Rosenzweig was of the view that all polypropylene mesh products are unsafe does not mean that the jury was precluded from finding that the TVT represents a reasonable alternative design to the Obtryx sling. I reach this conclusion for several reasons.

1

As I explained in part I of this opinion, the jury was not confined to the binary choice of either crediting all of Rosenzweig's opinions or rejecting them whole hog. Our law governing expert witnesses is very clear on this point. The jurors were free to credit Rosenzweig's opinion that the unique features of the Obtryx—a heatsealed center, detanged edges, and a transobturator approach—constituted design flaws that caused or contributed to Fajardo's injuries, while at the same time rejecting his more idiosyncratic view that all polypropylene mesh products are defective and, instead, crediting the trial testimony of other experts that polypropylene is a suitable material for use in medical implants and that the TVT is a safe and effective treatment for female stress urinary incontinence. Indeed, the trial court instructed the jury to that effect immediately before Rosenzweig testified.

Rosenzweig himself provided ample basis for the jury to disregard his more extreme views regarding the dangers of polypropylene. Although Rosenzweig's own opinion was that polypropylene is not a suitable material for medical implants and that the alternative Burch procedure is a preferable means of treating stress urinary incontinence, he also repeatedly acknowledged at trial that those views do not represent the prevailing opinion among urogynecologists and, indeed, are well outside the medical mainstream. For example, Rosenzweig testified that, according to the medical literature, polypropylene mesh is the "gold standard" for treating stress incontinence and that its use has been endorsed as safe and effective by every major urological association. He agreed with the defendants' counsel that polypropylene has been used in the human body for more than fifty years in millions of patients, that polypropylene slings such as the TVT are effective and widely used, and that physicians who use them do so reasonably and consistent with the prevailing standard of care. Rosenzweig acknowledged that his own colleagues at Rush University Medical Center regularly use such slings and continue to train residents in the use thereof. In short, he agreed that polypropylene slings represent the most commonly used modality for treating stress urinary incontinence and that their use is supported by extensive medical data, including more than 2000 studies.

Accordingly, the jury reasonably could have credited Rosenzweig's testimony that the unique design characteristics of the Obtryx render it especially dangerous and contributed to Fajardo's injuries while simultaneously concluding that Rosenzweig is an outlier with respect to his strident opposition to any medical use of polypropylene. The jury could have credited the testimony of various other witnesses—such as Bercik, Rosenblatt, and Boston Scientific's biomaterials expert, Stephen Badylak—that polypropylene, such as that used in the TVT, is a generally safe material that is widely used for the fabrication of medical implants and accepted by all major medical associations.

2

Another reason that Rosenzweig's beliefs regarding the dangers associated with polypropylene did not fatally taint his entire testimony is that I do not accept Boston Scientific's view, apparently shared by the majority, that an alternative product design that is unsafe, but significantly less so than the defendant's product design, cannot, ipso facto, be a reasonable design. It is noteworthy that neither Boston Scientific nor the majority has identified a single authority for the theory that a federally regulated product that is legally on the market and in widespread use cannot qualify as a reasonable alternative design if it is safer than the product at issue but, nevertheless, poses safety risks that arguably outweigh its advantages. Rather, the few courts and commentators to have considered the issue uniformly have concluded that a less unsafe product can qualify as a reasonable alternative design if that product lacks the features that caused or contributed to the plaintiff's injuries. Indeed, several federal courts have reached that very conclusion in the multidistrict vaginal mesh litigation, rejecting similar arguments.

See, e.g., Herrera-Nevarez by Springer v. Ethicon, Inc., Docket No. 17 C 3930, 2017 WL 3381718, \*7 (N.D. Ill. August 6, 2017) ("the fact that [an expert] evidently does not believe that any such devices are safe does not preclude him from ranking them on a comparative basis"); Kaiser v. Johnson & Johnson, Docket No. 2:17-CV-114-PPS, 2018 WL 739871, \*7 (N.D. Ind. February 7, 2018) (similar); Wiltgen v. Ethicon, Inc., Docket No. 12-cv-2400, 2017 WL 4467455, \*5 (N.D. Ill. October 6, 2017) (similar); see also Campbell v. Boston Scientific Corp., 882 F.3d 70, 79 (4th Cir. 2018) (rejecting argument that Rosenzweig's testimony did not support finding of reasonable alternative design).

Although those courts did not elaborate on the reasoning underlying their rulings, legal scholars have made a persuasive case. For example, Professor Douglas A. Kysar has explained that "even an unavoidably unsafe product sometimes can be made marginally less unsafe. By allowing courts to balance the risks and rewards posed by alternative product designs, the riskutility test provides manufacturers with incentives to constantly evaluate and [to] adopt such reasonable alternative designs." D. Kysar, "The Expectations of Consumers," 103 Colum. L. Rev. 1700, 1717 (2003). The Restatement (Third) is of the same view: "The requirement . . . that the plaintiff show a reasonable alternative design applies in most instances even though the plaintiff alleges that the category of product sold by the defendant is so dangerous that it should not have been marketed at all. . . . [This applies to] [c]ommon and widely distributed products such as alcoholic beverages, firearms, and [aboveground] swimming pools . . . . " (Citation omitted.) Restatement (Third), supra, § 2, comment (d), p. 20.

Consider the hypothetical of a tobacco company that develops a cigarette featuring a novel design that, while more stylish in appearance than those currently on the market, has a less effective filter that removes fewer carcinogens. A cigarette design expert might well testify that the new product is unnecessarily dangerous relative to traditional designs, which are less likely to cause cancer, while also acknowledging that she would never smoke or allow her children to smoke and that she is of the view that no cigarettes should be legal due to the well-known medical risks associated with smoking. Of course, cigarettes are legal. They are heavily regulated, but society has accepted that the health and financial costs associated with smoking related illnesses are justified by the economic benefits and the rights of adults to make their own determination that the pleasure that they derive from smoking outweighs the risks.

Moreover, this in for a penny, in for a pound theory of product liability is especially poorly suited to the medical device field. The parties, and all of the experts who testified at trial, agreed that every surgical intervention and every internally implanted medical device carry some potentially serious risks. Much of the practice of Western medicine involves the process of attempting to identify and quantify such relative risks so that clinicians and patients can make informed decisions as to whether the dangers associated with a particular intervention are justified by the potential benefits. As is clear from the present case, medical experts no less than their patients reasonably may reach different conclusions about whether, for example, it is prudent to implant a particular medical device that has a reasonable likelihood of curing an irksome but nonlethal condition, such as chronic stress urinary incontinence, but that also has the potential to cause serious pain and other side effects. So long as that device falls within the standard of care and is deemed to have some medical utility, I see no reason why the law should not incentivize manufacturers to minimize those risks, rather than pile risk upon risk, to the extent reasonably possible. The majority's holding in the present case removes that incentive and potentially disincentivizes manufacturers of certain categories of products from developing design innovations that reduce the risk of harm.

3

Finally, the majority ignores the fact that this court already has, in essence, decided this very question in the plaintiffs' favor. In Bifolck, we made clear that a plaintiff is not precluded from arguing that a class of products is inherently, manifestly unsafe while, in the alternative, also contending that the particular product at issue could have been designed to be less unsafe. See Bifolck v. Philip Morris, Inc., supra, 324 Conn. 435 ("Although the fact finder considers under either theory whether the risk of danger inherent in the challenged design outweighs the benefits of that design, these theories are not mutually exclusive. A plaintiff may consistently allege that a product had excessive preventable danger (reasonable alternative design) and that the product was too dangerous to market to the consumer irrespective of whether it could have been designed to be safer (manifestly unreasonable design)."). The majority does not appear to recognize that its holding in the present case deviates from the court's guidance in *Bifolck* and offers no rationale for this departure.

(

Third, as I have alluded to throughout this opinion, I am troubled by the majority's view that the only evidence that the jury was permitted to consider in assessing a potential reasonable alternative design claim was the testimony of the plaintiffs' primary product design expert, Rosenzweig, and that the plaintiffs' case was not established unless Rosenzweig himself recited the talismanic words that the Ethicon TVT was a reasonable alternative design, use of which would

have averted or reduced the risk of harm to Fajardo. This idea, that a jury in a product liability lawsuit is permitted to consider only a limited category of expert testimony regarding the design of medical devices and cannot take into account and draw reasonable inferences from other relevant expert evidence, such as scientific and medical studies and the testimony of treating physicians, even when that evidence was admitted without objection or limitation, is flatly inconsistent with established law. This aspect of the majority opinion encroaches on the autonomy of the jury and overlooks the realities of how expert witnesses are actually used, especially in complex civil cases.<sup>26</sup>

First, no one is arguing that expert testimony was not required in this case. The plaintiffs presented the testimony of a product design expert, Rosenzweig, whom they disclosed as an expert on safer alternatives to the Obtryx, and whom the trial court permitted to testify, over the objection of Boston Scientific. The plaintiffs also disclosed and presented the expert testimony of Richard W. Trepeta, a pathologist, who testified as to the material condition of the Obtryx that was implanted in Fajardo. As I previously discussed, Rosenzweig testified as to the design flaws in the Obtryx heat sealing, detanging, a transobturator insertion relative to the TVT, and he linked those differences to Fajardo's poor outcome. Although the majority worries that the jury was incapable of understanding the medical studies in evidence, contending that "the jury [did] not have the assistance necessary to reach an intelligent or correct decision"; footnote 20 of the majority opinion; the reality is that Rosenzweig made it about as basic as one can: "[T]he retropubic sling is better than the [Obtryx] transobturator sling."

For its part, Boston Scientific disclosed and presented experts of its own, some of whom verified that the TVT is the most well established vaginal sling and that the primary differences between the TVT and the Obtryx are the latter's heat-sealed middle, detanged edges, and transobturator approach.

As discussed, the plaintiffs also introduced the expert opinions of Fajardo's treating physicians via the testimony of Bercik, whom the plaintiffs also disclosed as an expert on product design and reasonable alternatives to the Obtryx, and the office notes of Hines. The expert opinion of a third physician, Tulikangas, was before the jury, as well. It is well established that a plaintiff's treating physicians may provide expert testimony within their realm of practice, without the need for formal expert certification or detailed disclosures. See Practice Book § 13-4 (b) (2) (defining expert disclosure requirements for treating physicians). Moreover, even physicians who are not formal product design experts may provide relevant testimony as to elements of product design to the extent that there is overlap with their

professional experience. See, e.g., Procaccini v. Lawrence + Memorial Hospital, Inc., supra, 175 Conn. App. 723 (causation testimony of physician disclosed as standard of care expert constituted "'expert'" testimony, insofar as it reflected his medical expertise and experience, and, once admitted without objection or limitation, was before jury to use for any purpose); see also Allen v. C. R. Bard, Inc., Docket No. 11-cv-2031-LRR, 2017 WL 4127765, \*2 (N.D. Iowa September 15, 2017) (treating physician may opine that product feature caused patient's injuries without offering improper opinion as to design defect). Indeed, courts in other vaginal mesh cases have concluded that surgeons who perform mesh removal procedures may thereby be qualified to opine as to the design of such devices. See, e.g., Heatherly v. Boston Scientific Corp., Docket No. 2:13cv-00702, 2018 WL 3797507, \*4, \*9 (S.D. W. Va. August 9, 2018).

So, the question is not whether expert testimony is normally required in a product liability action involving a medical device. Nor is there any question that the plaintiffs had to supply expert evidence to demonstrate that Fajardo's injuries were likely caused by certain defective design features of Boston Scientific's product and that there is some reasonable alternative design that is economically and technically feasible, use of which would have reduced the risk of harm to end-users, including Fajardo. The question, rather, is whether that evidence was required to take a very particular form. As I discussed in part I of this opinion, the majority has not pointed to any authority in support of its position that the plaintiffs' proof cannot be forged from the combined testimony of different design and materials experts, treating physicians, scientific studies, and other evidence of record, both direct and circumstantial. Nor is there some magic words requirement that an expert express his or her opinion using the precise legal jargon that an appellate court might employ. See, e.g., State v. Nunes, supra, 260 Conn. 672–73; Struckman v. Burns, 205 Conn. 542, 555, 534 A.2d 888 (1987). Truly complex design questions plainly require the testimony of design experts. The cases cited by the majority say no more, no less.<sup>27</sup> But expert testimony is required when, and only when, the specific point to be established cannot be ascertained by a lay jury. Expert testimony must not be fetishized to the point where it replaces our trust in the jurors' native intelligence and good sense.

Moreover, once the opinion testimony of a purported expert has been admitted without objection or limitation, it becomes part of the trial record, and it is inappropriate for either the trial court or this court to determine that it is off-limits for purposes of assessing the sufficiency of the evidence or an instructional request simply because that court, in hindsight, questions whether the witness was a proper expert, or the right species of

expert. See, e.g., State v. Carey, 228 Conn. 487, 496, 636 A.2d 840 (1994) ("If [inadmissible] evidence is received without objection, it becomes part of the evidence in the case, and is usable as proof to the extent of the rational persuasive power it may have. The fact that it was inadmissible does not prevent its use as proof so far as it has probative value. . . . This principle is almost universally accepted. . . . The principle applies to any ground of incompetency under the exclusionary rules . . . [including] the expertness qualification." (Internal quotation marks omitted.)); Maurice v. Chester Housing Associates Ltd. Partnership, 189 Conn. App. 754, 759 n.2, 208 A.3d 691 (2019) ("We note that it is not necessary for a party to ask that the court recognize the witness as an expert before asking the witness to provide an opinion. . . . The proponent of the expert simply must lay the necessary foundation before asking the witness a question that calls for an expert opinion. If there is no objection to the question, the witness may give the opinion. If there is an objection to the witness' qualifications or to whether the witness' testimony will assist the trier of fact, the court can then rule on the objection in the context of the specific questions asked." (Citation omitted.)).

The same principles apply with respect to research studies published in scientific and medical journals. The majority has failed to identify any authority indicating that, once a study has been admitted into evidence without objection or limitation, supported by the foundational testimony of an expert that the study is authoritative and that he or she relied on it in forming his or her opinions, the jury is barred from reading the study and drawing all reasonable conclusions therefrom. The studies at issue were admitted into evidence as full exhibits, without limitation. They contain statements of fact and opinion that the jury was entitled to consider as if the entire article had been read into the record verbatim. See Conn. Code Evid. § 8-3 (8);28 see also, e.g., Curran v. Kroll, supra, 303 Conn. 864 ("Th[e] evidence was admitted in full, without limitation. In the absence of any limiting instruction, the jury was entitled to draw any inferences from the evidence that it reasonably would support."); Procaccini v. Lawrence + Memorial Hospital, Inc., supra, 175 Conn. App. 724 ("[i]n the absence of any [limiting] instruction from the court, the evidence . . . was before the jury for it to use for any purpose").<sup>29</sup>

If the defendants wanted to limit the jury's consideration to certain portions of the articles, or wished to limit the jury's use of the contents of the articles, they should have asked to have the articles redacted or requested a limiting instruction.<sup>30</sup> See, e.g., *Filippelli* v. *Saint Mary's Hospital*, 319 Conn. 113, 135–36, 124 A.3d 501 (2015). They did not do so, and it is inconceivable to me that an appellate tribunal can now retroactively deem portions of those articles to be off-limits, or other-

wise preclude the jury from using the contents of the articles to reach any conclusions supported by them, regardless of whether supplemented by expert testimony. If the defendants believed that the opinions contained in the articles required explanation, they had their opportunity to pursue that line of examination through witnesses at trial.<sup>31</sup>

Insofar as the trial court overlooked or opted not to consider any of this evidence, and restricted its consideration of the plaintiffs' requested charge to the universe of Rosenzweig's testimony,32 that represents a legal error, rather than a factual finding to which we must defer, as the majority appears to believe. See footnote 13 of the majority opinion; see also, e.g., Brown v. Robishaw, 282 Conn. 628, 633, 922 A.2d 1086 (2007) (whether evidence presented reasonably supports particular request to charge is question of law subject to plenary review). Had the trial court excluded any of the evidence that I have cited, then that decision would be subject to deference and reviewable only for abuse of discretion. But once the evidence was admitted without limitation, the jury was free to consider it for any purpose, and it is inappropriate for the majority to direct otherwise.

D

Fourth, returning to where we began, I am concerned that the majority not only fails to construe the evidence in the light most favorable to the plaintiffs, as required by law, but also steps into the jury's role by making its own assessments of the strength of the plaintiffs' evidence and the credibility of their witnesses, ultimately downplaying any evidence that supports the requested instruction while highlighting conflicting evidence. Two examples illustrate this slippage.

First, the majority determines that Bercik cannot credibly opine as to the question of a reasonable alternative design merely because, although Bercik knew that the Obtryx was fabricated from the Marlex brand of type 1 microporous polypropylene, he was uncertain whether the TVT was made from the same brand of that material. See footnote 22 of the majority opinion. On the basis of this one statement, which a reasonable juror may deem wholly insignificant, the majority finds that Bercik "[knew] next to nothing about the design features of the Obtryx . . . . " Part II E of the majority opinion. The majority never explains why Bercik's lack of knowledge as to the brand of polypropylene used in the TVT says anything about his knowledge of the design features of the *Obtryx*; nor does it tell us why the brand of plastic used would be relevant to any of the defects under discussion. Bercik is a surgeon, who implants slings into women and removes them when they have proven to be ineffective or defective. On the basis of that experience, he testified about his and several of his colleagues' strong preference for slings,

such as the TVT, that use a retropubic approach. In combination with the other evidence of record, the jury reasonably might have found this testimony compelling and relevant, or not. But it is not this court's role to deem the testimony unimportant or unpersuasive, and certainly not on such arbitrary grounds.

Second, rather than taking at face value the medical research in evidence that indicated that the Ethicon TVT is the gold standard treatment for female incontinence, that the TVT has a lower rate of complications, and that the "TVT should remain the midurethral sling procedure of choice," the majority dwells at length on other evidence that arguably called into question whether the TVT is, in fact, a superior product. I understand that the plaintiffs did not demonstrate the superiority of the TVT or the defectiveness of the Obtryx to the satisfaction of the majority. The only question before us, however, is whether there was some minimal quantum of evidence from which the jury reasonably could have been persuaded of those allegations. Clearly there was.

It is not our role to make assessments of this nature under these circumstances. Our only proper role, given the procedural posture in which this case reaches us, is to assess whether there was sufficient evidence from which a reasonable, properly instructed jury could have found that the Obtryx is defective because its design renders it unreasonably dangerous and there is a feasible alternative design that would have reduced the risks of the types of injuries that Fajardo suffered. Before the majority upholds the trial court's instructional error, it was compelled to marshal the evidence of record in the manner that *best* supported the requested instruction, and only then to explain why that evidence, so construed, was legally insufficient. I do not believe it has done so.

IV

There is evidence in the record from which the jury reasonably could have found that (1) the Ethicon TVT is a feasible, federally approved, and widely used product that was a suitable candidate to treat Fajardo's condition, (2) the Obtryx differs from the Ethicon TVT primarily with respect to the former's heat-sealed middle section, detanged edges, and transobturator approach, (3) those particular features of the Obtryx tend to increase its stiffness and have been linked to higher incidences of the injuries that Fajardo suffered relative to the TVT, and (4) according to Rosenzweig, the plaintiffs' primary design expert, those features are defects their increased risks outweigh any benefits—that were responsible for Fajardo's injuries. If the jury had been instructed in accordance with Bifolck and had found for the plaintiffs on that theory, it is inconceivable to me that, on this record, we would have concluded that there was insufficient evidence and overturned the verdict. In my view, no more was necessary to warrant a reasonable alternative design instruction and put the issue before the jury. Accordingly, I respectfully concur in part and dissent in part.

<sup>1</sup> I agree with all of part II A except the majority's ultimate conclusion that "the trial court correctly concluded that the evidence did not support an instruction under the reasonable alternative design prong of the risk-utility test . . . ." Part II A of the majority opinion. In part II B, the majority assumes, without deciding, that the plaintiffs' instructional challenge was properly preserved at trial. For the reasons identified by the majority, I have no difficulty concluding that the issue is in fact properly preserved. Specifically, I agree with the majority that it would elevate form over substance to refuse to consider the issue on appeal when the trial court resolved it on the merits after concluding that the legal claim was timely presented. See part II B of the majority opinion.

<sup>2</sup> In part III A of this opinion, I explain why the majority is incorrect when it contends that all of the references to "TVT" at trial were to the category of TVT-type retropubic slings modeled on Ethicon's branded TVT, rather than to that market-leading product itself. See footnote 14 of the majority opinion and accompanying text. Unless otherwise noted, all references in this opinion to the TVT are to the Ethicon product.

<sup>3</sup> See, e.g., *Izzarelli* v. *R.J. Reynolds Tobacco Co.*, 321 Conn. 172, 203–204, 136 A.3d 1232 (2016).

<sup>4</sup> Two of these studies, Lim and Moalli, specifically discuss the Ethicon TVT, rather than the class of TVT-like slings, as the gold standard. See Y. Lim et al., supra, 21 International Urogynecology J. 1157; P. Moalli et al., supra, 19 International Urogynecology J. 656. To the extent that the majority faults the plaintiffs for not having identified by name the particular studies that support their reasonable alternative design claim; see footnote 24 of the majority opinion; the studies that they reference and that I discuss in this opinion were provided to us in the appendix to the plaintiffs' brief, and are the same studies that their experts discussed at length at trial and that they cited in their arguments to the judge and jury.

<sup>5</sup> None of these studies, for example, suggested that the TVT is suitable only for certain women or only under certain conditions, or only as a replacement after another sling has been removed, or that it is more expensive than other slings, or otherwise not feasible for patients such as Fajardo.

<sup>6</sup> The majority seems to take the position that we should not take Bercik's testimony into account for any purpose when considering whether there was sufficient evidence before the jury to warrant a reasonable alternative design instruction. The majority argues that (1) although Bercik was disclosed as an expert on sling design and design alternatives, and apparently recognized by the defendants' counsel as such, he purported to testify only as a "treating physician," (2) the plaintiffs do not cite to Bercik's testimony in their appellate briefs, (3) the trial court did not consider Bercik's testimony when it denied the plaintiffs' instructional request, and (4) Bercik's testimony lacked credibility. See footnotes 12, 13 and 22 of the majority opinion and accompanying text. First, Bercik's testimony is cited herein for very limited purposes, is relied on only as secondary evidence, and is not necessary or even important to my position—the testimony of Rosenzweig (who testified that he relied on Bercik's assessment and testimony in forming his own opinions) and the various studies and other documents on which he relied were sufficient to warrant a reasonable alternative design instruction. Second, and more generally, I disagree with the majority's all-or-nothing analysis with respect to the use of Bercik's testimony. As I explain in part III C of this opinion, once Bercik's testimony was admitted without objection or limitation, it was available for the jury to use for any purpose; it must be construed in the light most favorable to the plaintiffs' request, regardless of whether the trial court overlooked it or whether the majority deems it to be credible or deems Bercik to be a fitting expert. Bercik's notes recommending that Fajardo consider a TVT were before the trial court when it considered the plaintiffs' motion, and, indeed, the defendants' counsel himself solicited much of the testimony to which the majority objects. To the extent that the trial court failed or declined to consider that evidence of record, that omission was either proper or improper as a matter of law and was not, as the majority incorrectly posits, a factual "finding" to which we must defer. Footnote 13 of the majority opinion. I do agree with the majority that the plaintiffs' counsel has not relied on Bercik's testimony on appeal, and I discount its importance primarily for that reason. That said, I do not ignore this evidence altogether when it was relied on by Rosenzweig and reinforces a proposition established by other evidence.

 $^7\mathrm{I}$  disagree with the majority's statement that, "[a]t 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." Part II E of the majority opinion. The significance of the studies is not so limited. The Moalli study, for example, compared the Ethicon TVT to five more recently developed slings, including the Obtryx, and concluded that the TVT "has a unique tensile behavior" that "in theory . . . lowers the rate of erosions of a sling into the urethra or bladder." P. Moalli et al., supra, 19 International Urogynecology J. 662.

<sup>8</sup> Although the plaintiffs' counsel highlighted the Ross and Cholhan studies to make this point, that was not the only evidence before the jury indicating that the use of a transobturator design was a defect relative to the TVT. One study on which Rosenzweig relied, for example, found that "[t]he complications of persistent pain and dyspareunia were strikingly more frequent among [the transobturator] compared to [the retropubic] group." E. Petri & K. Ashok, "Comparison of Late Complications of Retropubic and Transobturator Slings in Stress Urinary Incontinence," 23 International Urogynecology J. 321, 324 (2012) (Petri study).

<sup>9</sup> The majority incorrectly states that "Rosenzweig identified only the polypropylene mesh and the heat seal as the defects that caused Fajardo's injuries" and did not consider the transobturator design of the Obtryx to be a defect. Part II E of the majority opinion. Boston Scientific itself concedes that "Rosenzweig testified that retropubic and nondetanged slings may be better" than the Obtryx. I further address this point in part III A of this opinion

<sup>10</sup> For reasons elaborated in part III B of this opinion, it is of no legal consequence that Rosenzweig also held the view that *all* polypropylene mesh devices (including the TVT) are defective. The jury was entitled to accept Rosenzweig's opinion with respect to the Obtryx in particular and reject his broader opinion regarding the entire class of products.

<sup>11</sup> The majority makes no mention of the Tulikangas opinion letter, but the plaintiffs' counsel referenced the letter three times during closing argument, highlighted the fact that Tulikangas believed that the Obtryx is an inferior product, and referenced the letter in briefing to the trial court.

<sup>12</sup> In its brief, Boston Scientific acknowledges that it "developed the Advantage mesh from which it makes the Obtryx (and all its midurethral slings) to be substantially similar to other mesh on the market, like the TVT mesh."

<sup>13</sup> The majority repeatedly contends, erroneously, that some products in the class of TVT-type slings "had the exact same defect alleged to have caused Fajardo's injuries in this case." Part II E of the majority opinion. Not so. In fact, the record demonstrates that *no* TVT-type sling has *all* of the defects alleged to make the Obtryx unreasonably dangerous. The jury reasonably could have found, on the basis of the evidence in the record, that any TVT-type sling would have reduced at least some of the risks to Fajardo, such as the risks associated with the use of a transobturator design, without any offsetting costs or risks. The plaintiffs' claim, in any event, was targeted at the Ethicon TVT in particular. See part III A of this opinion.

<sup>14</sup> Fajardo's treating physicians concurred with Rosenzweig that the Obtryx was the cause of her injuries. Bercik testified that, to a reasonable degree of medical certainty, the Obtryx had caused Fajardo's worsening incontinence and dyspareunia. This was consistent with Hines' recommendation to Fajardo that she have the mesh removed because it was "clearly . . . what's causing her pain."

<sup>15</sup> As I previously noted, the majority contends that Rosenzweig's testimony regarding the dangers created by these particular defects is of no force because Rosenzweig also believed that the Obtryx was defective because it contained polypropylene. The logic of this point escapes me. See part III B of this opinion.

<sup>16</sup> The required showing should not be misunderstood. The plaintiff is not required to show that the alternative design would have avoided or reduced the plaintiff's injuries. The legal standard requires evidence only that the alternative design could avoid or reduce the risk of harm created by the defendant's product. See footnote 3 of this opinion. This is not a causation requirement but, rather, proof that a product is defective because an alternative would present a reduced risk of harm to a user or consumer. See, e.g., Gardner v. Ethicon, Inc., Docket No. 4:20-cv-00067-SAL, 2020 WL 5077957, \*4–5 (D.S.C. August 27, 2020) (rejecting defendant's argument that plaintiff was required "to connect the reasonable alternative design to her specific

injuries" by presenting expert testimony that safer alternative design existed for defective products that would have prevented or reduced plaintiff's injuries, and holding that "the risk-utility test relates to the defectiveness of the design—not causation"); *Thompson v. Ethicon, Inc.*, supra, 2020 WL 3893253, \*6 (rejecting "hypertechnical criticism" of plaintiff's expert testimony and holding that it was enough that expert established that device was defective and tied that defect to plaintiff's injuries); *Rheinfrank v. Abbott Laboratories, Inc.*, 137 F. Supp. 3d 1035, 1040–41 (S.D. Ohio 2015) (plaintiff need only establish that use of alternative design would reduce general risk of similar harm for similarly situated patients).

<sup>17</sup> I would also add to this list the testimony of Bercik, one of the physicians who treated Fajardo for her sling related injuries and ultimately removed the Obtryx. He 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. The majority offers a different interpretation of Bercik's opinion on this subject, on the basis of other testimony of his. See footnote 16 of the majority opinion. Rather than explaining why I read that testimony differently, it will suffice to say that the jury should have been allowed to choose which of Bercik's testimony to emphasize and whether Bercik's opinions ultimately supported the plaintiffs' claims.

18 In rejecting this conclusion, the majority relies on generalities and truisms regarding the need for expert testimony in product design defect cases. See footnote 20 of the majority opinion. Those generic propositions are unhelpful here because the plaintiffs in this case presented extensive expert testimony and peer reviewed scientific research studies that permitted the jury to decide the case. The majority consistently states that expert testimony is necessary to allow the jury to conclude that there is an alternative design that is feasible, which is sufficiently safer than the product at issue to render the latter defective, and that the use of that alternative design would have reduced the risk of the types of injuries suffered by the plaintiff. Once the experts and the research studies had demonstrated that there are three primary design features that distinguish the Obtryx from the TVT, that each of those three differences makes the Obtryx unnecessarily dangerous, that those features are defects that caused or contributed to Fajardo's injuries, and that the TVT was a viable alternative, it is unclear what more the majority believes the jury needed to hear from the experts before it could reasonably conclude that the TVT was a reasonable alternative design, the use of which would have reduced the risk of the injuries caused by the defective design of the Obtrvx.

<sup>19</sup> I reject the majority's position that, although the plaintiffs (1) disclosed two experts who would testify as to safer alternatives to the Obtryx, (2) set forth abundant evidence of a reasonable alternative design, (3) referenced their "feasible alternative" theory during closing argument, and (4) requested a reasonable alternative design jury instruction, they nevertheless were not entitled to such an instruction because they "took a scattershot approach" to arguing the case. Part II E of the majority opinion. It is true that the plaintiffs and their various expert witnesses offered several different theories of liability: they argued that the TVT was a reasonable alternative design, that the Burch procedure is a better treatment option than vaginal mesh, and that polypropylene is ill-suited for use in medical devices. It is beyond dispute, however, that a plaintiff is free to present multiple alternative or even contradictory theories of liability to the jury and is entitled to an instruction on any of the theories for which there is minimally sufficient evidence to support a verdict. See, e.g., Meribear Productions, Inc. v. Frank, 328 Conn. 709, 722, 183 A.3d 1164 (2018) ("'a party may plead, in good faith, inconsistent facts and theories' "); Dreier v. Upjohn Co., 196 Conn. 242, 245, 492 A.2d 164 (1985) ("[u]nder our pleading practice, a plaintiff is permitted to advance alternative and even inconsistent theories of liability"). The question is not whether a reasonable alternative design was the plaintiffs' only or even principal theory of the case but, rather, whether there was sufficient evidence before the jury to warrant an instruction. The answer, quite clearly, in my view, is yes.

<sup>20</sup> The majority points to nothing in the record suggesting that the trial court declined to give the requested instruction for this reason or even considered the issue.

 $^{21}$  I might quibble as well with other assumptions underlying the majority's argument. Its claim, for example, that different TVTs are made from many different materials finds little, if any, support in the record. See part II E

of the majority opinion. Indeed, the defense expert, Rosenblatt, testified that, although the *brands* of polypropylene used may vary, all synthetic slings are produced from type 1 microporous polypropylene and are "about the same" and "extremely similar." Certainly, the jury could have so concluded. But, for reasons of expediency, I will focus my attention on the most prominent flaws in the majority's argument.

<sup>22</sup> Despite the majority's statement to the contrary; see footnote 16 of the majority opinion; Bercik did compare the Ethicon TVT to the Obtryx. He 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. This comparative testimony was not dwelled on at any length, but it is part of the trial transcript, and it was for the jury to determine its persuasiveness.

 $^{23}\, Rosenzweig$  was operating on the same premise, using "the TVT" as synonymous with the Ethicon branded TVT. When asked whether he "recall[ed] what the first sling—transvaginal sling, or through the vagina . . . was called," he responded, "[t]he TVT."

<sup>24</sup> Rao was examined as follows:

"Q. So, can you tell me how the Advantage project—[how] you came to work on that project?

"A. Well, the project started before I was assigned to work on it. And I was assigned to help to develop a mesh that was very similar to the TVT mesh that was currently on the market.

"Q. And what were your duties as assigned to the Advantage mesh project?

"A. To characterize the TVT mesh so we understood its structure and understood what it was made of and to find a manufacturer that could make a comparable mesh product that we could then test and see if it was indeed similar to the TVT mesh, and also to look for ways to improve [on] the existing TVT mesh that was in the field.

\* \* \*

"A. I'm not 100 percent sure. I know that, by the time I joined, we knew that the TVT mesh was made from polypropylene, and we also knew that we, Boston Scientific, had a polypropylene mesh on the market made from the same—that could be used to knit the structure that we wanted for the Advantage mesh.

\* \* \*

"Q. Okay. Now, can you describe to me your responsibilities as technical team leader for the mesh?

"A. So, my responsibility was to figure out how to make a mesh that was similar, if not better, than the TVT mesh. So, we needed to figure out what the TVT mesh was made [of], what its properties were, what its structure was, and then find a vendor that could knit and heat-set the mesh.

\* \* \*

"Q. Okay. What changes did you-all actually make to the Advantage mesh to differentiate your product from [the] TVT?

"A. So we detanged the section that would go under the urethra. If I can explain that, when you cut a knit structure, there [are] little fibers that stick out [of] the edges. We smooth those fibers through a heat process so that they wouldn't be as kind of prickly to the tissue. And we also made sure that we cut our mesh very straight.

\* \* \*

"Q. Did Boston Scientific, during the development of the Advantage mesh, do testing on the TVT product?

"A. Yes, we did.

\* \* \*

"Q. Your role, as you indicated earlier, was to basically try to develop a mesh that was substantially similar to the TVT mesh, right?

"A. Yes."

<sup>25</sup> In addition, plaintiffs' exhibit 86, a review of mesh testing data by John Lehmann, identifies the TVT tested as "Gynecare" and states that "[t]he TVT device has a significant clinical record of success . . . ." Plaintiffs' exhibit 87, another study conducted by another Boston Scientific consultant, likewise identifies "the commercially available TVT device" with Gynecare.

<sup>26</sup> In complex civil cases such as medical malpractice actions, it is not at all uncommon for plaintiffs to prove their case through the combined testimony of various experts and treating physicians. See, e.g., *Mather* v. *Griffin Hospital*, 207 Conn. 125, 136, 540 A.2d 666 (1988) (holding that causation was adequately established and that deficiencies in testimony of plaintiffs' primary expert were filled by testimony of other experts and hospital staff). To impose an artificial requirement that one single expert make one pro-

nouncement that explicitly establishes breach and causation is legally groundless and could potentially wreak havoc on litigation of this sort.

<sup>27</sup> Although the majority cites various cases—most of them from Iowa regarding the need for expert testimony, none of those cases supports the position taken by the majority, which is that, in a case such as this, one single designated product design expert must testify clearly and unequivocally as to every element of the plaintiff's claim and every step in the logical process. Rather, the cited cases qualify the need for expert testimony in all sorts of ways and largely stand only for the unremarkable proposition that some expert testimony is necessary to establish some elements of most product design defect cases. See, e.g., Water Pollution Control Authority v. Flowserve US, Inc., 782 Fed. Appx. 9, 15 (2d Cir. 2019) ("expert knowledge is often required in such circumstances" and holding that expert testimony was required as to specific technical aspects of plaintiff's particular claim (emphasis added)); Willet v. Johnson & Johnson, 465 F. Supp. 3d 895, 905 (S.D. Iowa 2020) ("Whether expert testimony is required ultimately depends on whether it is a fact issue upon 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 products 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." (Citations omitted; internal quotation marks omitted.)); 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 which 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 which cannot be fully understood by the average juror without some expert assistance . . . . " (Emphasis added; internal quotation marks omitted.)); Benedict v. Zimmer, Inc., 405 F. Supp. 2d 1026, 1032-33 (N.D. Iowa 2005) ("Although the . . . Restatement (Third) does not require expert testimony in every case, the plaintiff must rely on expert testimony in many cases. . . . Expert testimony as to the existence of a design defect is not required when the feasibility of a reasonable alternative design is obvious and understandable to laypersons. . . . 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." (Citations omitted; emphasis added.)). Critically, in each of these cases relied on by the majority, the plaintiffs had provided no admissible expert testimony whatsoever, and, so, unlike in the present case, the question before the court was simply whether the jury could identify a product defect and/or a reasonable alternative design without any expert assistance.

<sup>28</sup> Section 8-3 (8) of the Connecticut Code of Evidence provides: "To the extent called to the attention of an expert witness on cross-examination or relied on by the expert witness in direct examination, a statement contained in a published treatise, periodical or pamphlet on a subject of history, medicine, or other science or art, recognized as a standard authority in the field by the witness, other expert witness or judicial notice [is not excluded by the hearsay rule]."

<sup>29</sup> The Appellate Court discussed this principle at some length in *Procaecini*, explaining how, even if expert evidence is offered strictly for one specific purpose, once it has been admitted in full, the jury may use it for any purpose. The onus is on the opposing party to seek a limiting instruction or otherwise object. See *Procaccini* v. *Lawrence* + *Memorial Hospital*, *Inc.*, supra, 175 Conn. App. 714–15, 723–24. The majority offers no reason why the same principle should not apply in the present case.

<sup>30</sup> Similarly, if a party objects and the trial court is concerned that the jury would be confused or misled by examining the materials unaided by expert testimony, the court may decline to admit the materials. See, e.g., *Cross* v. *Huttenlocher*, 185 Conn. 390, 397, 440 A.2d 952 (1981). *Huttenlocher* is instructive because, in that case, the trial court properly declined to admit a medical study that addressed a drug similar, but not identical, to the one at issue and found side effects different from those alleged. See id., 398. The clear implication of this court's decision in *Huttenlocher* is that, had the study been more directly on point, as are the studies at issue in the present case, reading and drawing conclusions from the study would have

been well within the purview of the jury.

<sup>31</sup> It bears emphasizing in this regard that Connecticut has a more liberal rule governing the use of scientific journal articles and other learned treatises than do many of our sister states. See, e.g., *Filippelli* v. *Saint Mary's Hospital*, supra, 319 Conn. 135–36. Specifically, once an expert witness has qualified an article as admissible under § 8-3 (8) of the Connecticut Code of Evidence, that article may be admitted as a full exhibit and, if not otherwise limited by the trial court, used by the jury for any purpose during its deliberations, despite "the danger of misunderstanding or misapplication by the jury . . ." (Internal quotation marks omitted.) Id., 140; see E. Prescott, Tait's Handbook of Connecticut Evidence (6th Ed. 2019) § 7.9.1, p. 469.

 $^{32}$  Although it is impossible to know for certain what was said in chambers, the plaintiffs have represented that the trial court indicated that it was aware of but declined to consider certain potentially relevant evidence, such as the cited studies.