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## RAYMOND C. FERRARI v. JOHNSON AND JOHNSON, INC., ET AL. (AC 41170)

Alvord, Sheldon and Pellegrino, Js.

Syllabus

- The plaintiff brought this product liability action against the defendants, alleging that the defendants' product, a spinal system, was defective and that it caused him to sustain injuries. The plaintiff's surgeon, P, had used various components of the spinal system, which included titanium rods, in the fusion of the plaintiff's spine during a spinal surgery. Thereafter, the plaintiff underwent a second surgery that revealed a fracture of one of the titanium rods. The plaintiff claimed, inter alia, that the spinal system contained a design defect and that the written warnings in the product insert were not adequate when combined with the input and influence of the defendants' product representative, R, who had had discussions with P prior to the plaintiff's first surgery that were in the nature of technical assistance. The defendants filed a motion for summary judgment in which they claimed, inter alia, that because the plaintiff had failed to disclose an expert witness, he could not establish that the product was defective, and that his failure to warn claim was barred by the learned intermediary doctrine. The trial court granted the motion for summary judgment and rendered judgment thereon, determining, inter alia, that under the modified consumer expectation test, the plaintiff could not, as a matter of law, maintain a breach of warranty or strict liability design claim against the defendants without expert testimony. Held:
- 1. The trial court properly rendered summary judgment for the defendants as to the plaintiff's design defect and breach of warranty claims, as the plaintiff could not prove, without the use of expert testimony, that the defendants' product was defective or that its alleged defect caused his injury: because the ordinary consumer expectation test was inapplicable, as this was not a res ipsa type case or one in which the injury was so bizarre or unusual that the jury would not need expert testimony, the modified consumer expectation test applied, and, therefore, the court correctly held that expert testimony was required to prove the product's defect; moreover, expert testimony was required to establish that the alleged defect caused the plaintiff's injury, as the spinal system at issue is a complex product that includes titanium rods that are implanted into a patient's spine and components that consist of fifteen screws, two rods and two transverse transconnectors.
- 2. The trial court properly rendered summary judgment for the defendants as to the plaintiff's failure to warn claim on the basis of the learned intermediary doctrine; the plaintiff, who acknowledged that the defendants' product was accompanied by adequate warnings in the product insert, did not present any evidence that R said or did anything inconsistent with the product's warnings, and, thus, failed to provide a sufficient evidentiary foundation to demonstrate the existence of a genuine issue of material fact.

Argued January 17-officially released May 21, 2019

## Procedural History

Action to recover damages for personal injuries sustained as a result of an allegedly defective product manufactured and sold by the defendants, and for other relief, brought to the Superior Court in the judicial district of Hartford, where the court, *Noble*, *J.*, granted the defendants' motion for summary judgment and rendered judgment thereon, from which the plaintiff appealed to this court. *Affirmed*.

Andrew W. Skolnick, for the appellant (plaintiff).

W. Kennedy Simpson, pro hac vice, with whom was Christopher J. Lynch, for the appellees (defendants).

ALVORD, J. The plaintiff, Raymond C. Ferrari, appeals from the summary judgment rendered by the trial court in favor of the defendants, Johnson & Johnson, Inc., and Synthes, Inc. The plaintiff claims that the court erred by holding that (1) he cannot prove that the defendants' product was defective, or that the product's alleged defect caused the plaintiff's injury, without the use of expert testimony, and (2) the learned intermediary doctrine barred the plaintiff's failure to warn claim. We affirm the judgment of the trial court.

The following undisputed facts and procedural history are relevant to our resolution of this appeal. On August 17, 2012, the plaintiff underwent spinal surgery at Hartford Hospital. The procedure included a posterolateral fusion, in which the plaintiff's surgeon, Dr. Paul Schwartz, implanted various components of the defendants' product, the Synthes Matrix spinal system (product). This system included stabilizing titanium rods that were used in the fusion of the plaintiff's spine. The plaintiff's surgery required a junction of the new titanium hardware with a previously placed steel construct. On April 4, 2013, the plaintiff underwent a second surgery, which revealed a fracture of the left titanium rod at the junction of the new titanium instrumentation with the old steel construct.

On April 7, 2016, the plaintiff served a four count complaint on the defendants. The first two counts alleged product defect claims pursuant to the Connecticut Product Liability Act, General Statutes § 52-572m et seq. Specifically, the plaintiff set forth claims involving (1) a failure to warn defect<sup>1</sup> and (2) a design defect.<sup>2</sup> The third and fourth counts alleged breaches of express and implied warranties.

The deadline for the plaintiff to disclose any expert witnesses was January 15, 2017, pursuant to the parties' mutually agreed on scheduling order. The plaintiff failed to disclose any expert witnesses.<sup>3</sup>

On April 17, 2017, the defendants filed a motion for summary judgment, arguing that (1) the plaintiff had failed to disclose an expert witness, (2) the plaintiff could not establish that the product was defective, (3) comment (k) to § 402A of the Restatement (Second) of Torts barred the plaintiff's claims, (4) the learned intermediary doctrine barred the plaintiff's claims, and (5) the plaintiff could not establish causation. On July 10, 2017, the plaintiff filed an objection to the defendants' motion for summary judgment, claiming that a product defect can be inferred from the evidence without expert testimony and that genuine issues of material fact existed as to whether there were adequate warnings. A hearing on the defendants' motion for summary judgment was held on July 31, 2017.

The court issued its memorandum of decision on

November 28, 2017, granting the defendants' motion for summary judgment. This appeal followed. Additional facts and procedural history will be set forth as necessary.

Before addressing the plaintiff's claims, we set forth the applicable standard of review of a trial court's ruling on a motion for summary judgment. "Practice Book § [17-49] provides that summary judgment shall be rendered forthwith if the pleadings, affidavits and any other proof submitted show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. . . . In deciding a motion for summary judgment, the trial court must view the evidence in the light most favorable to the nonmoving party. . . . The party seeking summary judgment has the burden of showing the absence of any genuine issue [of] material facts which, under applicable principles of substantive law, entitle him to a judgment as a matter of law." (Internal quotation marks omitted.) DiMiceli v. Cheshire, 162 Conn. App. 216, 221–22, 131 A.3d 771 (2016).

"Once the moving party has met its burden [of production] . . . the opposing party must present evidence that demonstrates the existence of some disputed factual issue. . . . [I]t [is] incumbent [on] the party opposing summary judgment to establish a factual predicate from which it can be determined, as a matter of law, that a genuine issue of material fact exists. . . . The presence . . . of an alleged adverse claim is not sufficient to defeat a motion for summary judgment." (Citation omitted; internal quotation marks omitted.) Episcopal Church in the Diocese of Connecticut v. Gauss, 302 Conn. 408, 422, 28 A.3d 302 (2011), cert. denied, 567 U.S. 924, 132 S. Ct. 2773, 183 L. Ed. 2d 653 (2012). "Our review of the decision to grant a motion for summary judgment is plenary. . . . We therefore must decide whether the court's conclusions were legally and logically correct and find support in the record." (Internal quotation marks omitted.) DiMiceli v. Cheshire, supra, 162 Conn. App. 222.

The plaintiff first claims that the trial court erred by holding that he cannot prove that the defendants' product was defective, or that the product's alleged defect caused the plaintiff's injury, without the use of expert testimony. In response, the defendants argue that expert testimony was required for the plaintiff to prevail on his claims, as a matter of law. We agree with the defendants.

The following additional facts and procedural history are relevant to our resolution of this claim. The defendants submitted numerous exhibits in support of their motion for summary judgment, including Dr. Schwartz' notes, the transcript of Dr. Schwartz' deposition, and

a copy of the product insert that contained warnings with respect to the use of the defendants' product.

The product's insert explained that nonunion<sup>4</sup> could result from the product's use. The insert provided in relevant part: "These devices can break when subjected to the increased loading associated with delayed union or nonunion. Internal fixation appliances are load-sharing devices which hold a fracture in alignment until healing occurs. If healing is delayed, or does not occur, the implant could eventually break due to metal fatigue. Loads produced by weight-bearing and activity levels will dictate the longevity of the implant. The patient should understand that stress on an implant can involve more than weight-bearing. In the absence of solid bony union, the weight of the limb alone, muscular forces associated with moving a limb, or repeated stresses of apparent relatively small magnitude, can result in the failure of the implant." (Emphasis omitted.)

In its memorandum of decision, the trial court concluded that, without expert testimony to establish the existence of a defect and the element of causation, the plaintiff could not, as a matter of law, maintain a breach of warranty claim or a strict liability design defect claim against the defendants. The court concluded that, under the modified consumer expectation test,<sup>5</sup> the plaintiff could not prove that the defendants' product was defective without the use of expert testimony. With respect to causation, the trial court determined that the product was of a complex design, and that "[e]xpert testimony is thus essential, because the claims will raise and address complex and highly technical concepts and questions, which are clearly beyond the everyday experiences of the ordinary consumer."

We begin by setting forth the applicable standard of review and relevant legal principles that guide our analysis. "Our Supreme Court has described the essential elements of a strict products liability claim as follows: (1) the defendant was engaged in the business of selling the product; (2) the product was in a defective condition unreasonably dangerous to the consumer or user; (3) the defect caused the injury for which compensation was sought; (4) the defect existed at the time of the sale; and (5) the product was expected to and did reach the consumer without substantial change in the condition." (Emphasis omitted; internal quotation marks omitted.) *Theodore* v. *Lifeline Systems Co.*, 173 Conn. App. 291, 308, 163 A.3d 654 (2017).

The plaintiff first argues that, with respect to whether the product was in a defective condition and was unreasonably dangerous to the consumer or user, the ordinary consumer expectation test was applicable and, therefore, he was not required to provide expert testimony to prove the product's defect. We disagree.

Under the ordinary consumer expectation test, "[t]o

be considered unreasonably dangerous, the article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics." (Internal quotation marks omitted.) *Izzarelli* v. *R.J. Reynolds Tobacco Co.*, 321 Conn. 172, 185, 136 A.3d 1232 (2016). "Expert testimony on product design is not needed to prove the product's defect . . . ." Id., 203.

In Izzarelli, however, our Supreme Court held that the modified consumer expectation test is our primary strict product liability test. Id., 194. The court explained the limited circumstances in which the ordinary consumer expectation test applied: "The ordinary consumer expectation test is reserved for cases in which the product failed to meet the ordinary consumer's min*imum* safety expectations, such as res ipsa type cases." (Emphasis in original.) Id. "In other words, the ordinary consumer expectation test would be appropriate when the incident causing injury is so bizarre or unusual that the jury would not need expert testimony to conclude that the product failed to meet the consumer's expectations." Id., 191; see Potter v. Chicago Pneumatic Tool Co., 241 Conn. 199, 222, 694 A.2d 1319 (1997) (The court emphasized that it would "not require a plaintiff to present evidence relating to the product's risks and utility in every case. . . . There are certain kinds of accidents—even where fairly complex machinery is involved—[that] are so bizarre that the average juror, upon hearing the particulars, might reasonably think: Whatever the user may have expected from that contraption, it certainly wasn't that." [Emphasis added; internal quotation marks omitted.]).

The present case does not arise in any of the limited circumstances in which the ordinary consumer expectation test is applicable. This is not a "res ipsa type case" or a case in which the "injury is so bizarre or unusual that the jury would not need expert testimony . . ." *Izzarelli* v. *R.J. Reynolds Tobacco Co.*, supra, 321 Conn. 191.

Accordingly, the modified consumer expectation test applies in the present case. "Under the modified consumer expectation test, the jury would weigh the product's risks and utility and then inquire, in light of those factors, whether a reasonable consumer would consider the product design unreasonably dangerous." (Internal quotation marks omitted.) Id., 190. Therefore, "[t]o establish the defect, the plaintiff's case required expert testimony on [the product] design and manufacture, as well as the feasibility of an alternative design." Id., 203–204; see *White* v. *Mazda Motor of America, Inc.*, 139 Conn. App. 39, 49, 54 A.3d 643 (2012) ("[a]lthough it is true that an ordinary consumer may, under certain circumstances, be able to form expectations as to the safety of a product . . . [our courts] nonetheless con-

sistently have held that expert testimony is required when the question involved goes beyond the field of the ordinary knowledge and experience of judges or jurors" [citation omitted; internal quotation marks omitted]), aff'd, 313 Conn. 610, 99 A.3d 654 (2014). Thus, the trial court correctly held that expert testimony was required to prove the product's defect in the present case.

The plaintiff also argues that expert testimony was not required to prove that the alleged defect caused the injury for which compensation was sought. Specifically, he argues that expert testimony was not required to prove causation because "[t]here is no dispute that the defendants' product failed." We disagree.

"Proof that a defect in the product caused the injury in controversy is a prerequisite to recovery for product-caused injury in every products liability case, whether the action is grounded on negligence, breach of warranty, strict liability in tort . . . or a combination of such theories." (Internal quotation marks omitted.) *Theodore* v. *Lifeline Systems Co.*, supra, 173 Conn. App. 308. "When the causation issue involved goes beyond the field of ordinary knowledge and experience of judges and jurors, expert testimony is required." (Internal quotation marks omitted.) Id., 311.

The product at issue in the present case is a complex product: a spinal system which includes stabilizing titanium rods that are implanted into the patient's spine. The implanted product components consist of fifteen screws, two rods, and two transverse transconnectors. Accordingly, we agree with the trial court's determination that expert testimony was required to establish causation.

For the foregoing reasons, we conclude that the trial court properly rendered summary judgment in favor of the defendants, with respect to the plaintiff's design defect and breach of warranty claims, because the plaintiff could not prove that the defendants' product was defective, or that the product's alleged defect caused the plaintiff's injury, without the use of expert testimony.

II

The plaintiff next claims that genuine issues of material fact remained with respect to his failure to warn claim and, therefore, the learned intermediary doctrine did not bar this claim. Specifically, the plaintiff argues that, although the written warnings contained in the product insert were adequate, "[t]he factual circumstances of this case make the application of the learned intermediary doctrine inappropriate. The warnings were not adequate when combined with the input and influence of [the] defendants' product representative." We disagree.

The following additional facts and procedural history

are relevant to our resolution of this claim. As previously noted, the plaintiff's surgery required a junction of the new titanium hardware with a previously placed steel construct. In addition, the plaintiff alleges that he weighed 267 pounds at the time of his first surgery.

The product was sold with a package insert containing several warnings about the risk of product failure and breakage. Specifically, the warnings provided that "factors such as the patient's weight . . . have an effect on the stresses to which the implant is subjected, and therefore on the life of the implant." The warnings additionally provided that "[d]issimilar metals in contact with each other can accelerate the corrosion process due to galvanic corrosion effects," and warn against "[m]ixing titanium . . . with stainless implant components . . . for metallurgical, mechanical and functional reasons."

In his complaint, with respect to his failure to warn claim, the plaintiff alleged that the defendants' products were sold "without proper or adequate warnings, labels and instructions regarding use in patients of the plaintiff's size and history of prior spinal fusions and instrumentalities," and "without proper or adequate warnings, labels and instructions regarding the junction of titanium hardware to stainless steel hardware . . . ."

In the plaintiff's objection to the defendants' motion for summary judgment, he argued that "[t]he warnings were not adequate when combined with the input and influence of the defendant's product representative." The plaintiff claimed that, prior to his first surgery, "Dr. Schwartz had discussions and consultations with Mike Rogers, who was and still is the defendants' local sales representative. Those discussions were in the nature of technical assistance, including the product to be used in the surgery and the properties thereof, including the size and type."

Similarly, at the hearing on the defendants' motion for summary judgment, the plaintiff's counsel argued: "[Dr. Schwartz] testified that ultimately it was his decision. My argument, Your Honor . . . is that he was nonetheless influenced; and the warnings were muted by virtue of the defendants' agent's involvement. And for that, that is a question of fact as to what extent he was influenced, to what extent the warnings were muted and weakened, and that is something that the trier of fact should decide."

In its memorandum of decision, the trial court concluded: "There is no testimony or other evidence that shows that the consultant had any impact on Dr. Schwartz' decisions regarding the plaintiff's surgery. Accordingly, there is no question of fact that the learned intermediary doctrine bars the plaintiff's failure to warn claim."

We begin by setting forth the applicable standard of review and relevant legal principles that guide our analysis. A product may be defective because of inadequate warnings or instructions. See *Hurley* v. *Heart Physicians*, *P.C.*, 278 Conn. 305, 315, 898 A.2d 777 (2006); *Giglio* v. *Connecticut Light & Power Co.*, 180 Conn. 230, 236, 429 A.2d 486 (1980) ("the failure to warn . . . is, of itself, a defect").

"According to the Restatement (Second) of Torts, certain products, by their very nature, cannot be made safe. See 2 Restatement (Second), [Torts § 402A, comment (k) (1965)]. Prescription drugs generally fall within the classification of unavoidably unsafe products. . . .

"Comment (k) to § 402A of the Restatement (Second) of Torts provides that some products are incapable of being made safe for their intended and ordinary use. Nevertheless, certain unavoidably unsafe products provide such benefits to society that their use is fully justified, notwithstanding the unavoidab[ly] high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. . . . [Id.] Comment (k) provides that a manufacturer of an unavoidably unsafe product should not . . . be held to strict liability for unfortunate consequences attending their use, merely because [it] has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk. . . .

"A manufacturer of an unavoidably unsafe product can avoid strict liability if the product is properly prepared, and accompanied by proper directions and warning . . . . [Id.] Generally, a manufacturer's duty to warn of dangers associated with its products pertains only to known dangers and runs to the ultimate user or consumer of those products. . . . The learned intermediary doctrine, which is supported by comment (k) to § 402A of the Restatement (Second) of Torts, is an exception to this general rule. . . .

"The learned intermediary doctrine provides that adequate warnings to prescribing physicians obviate the need for manufacturers of prescription products to warn ultimate consumers directly. The doctrine is based on the principle that prescribing physicians act as learned intermediaries between a manufacturer and consumer and, therefore, stand in the best position to evaluate a patient's needs and assess [the] risks and benefits of a particular course of treatment." (Citations omitted; emphasis omitted; internal quotation marks omitted.) Breen v. Synthes-Stratec, Inc., 108 Conn. App. 105, 110–12, 947 A.2d 383 (2008). In Breen, this court concluded that, under Connecticut law, the learned intermediary doctrine is properly applied to cases

involving prescription implantable medical devices. Id., 109.

The plaintiff admits that the defendants' product was accompanied by adequate warnings in the product insert. What the plaintiff claims is at issue, however, is whether, notwithstanding the written warnings, the defendants' product representative, by his oral communications to Dr. Schwartz, nullified the written warnings in the insert and rendered the warnings inadequate.

In Hurley v. Heart Physicians, P.C., supra, 278 Conn. 305, our Supreme Court considered a similar argument. In Hurley, the plaintiffs appealed from the trial court's summary judgment rendered, on the basis of the learned intermediary doctrine, in favor of the defendant manufacturer on the plaintiffs' failure to warn product liability claims. Id., 307–308. Similar to the plaintiff in the present case, the plaintiff parents in Hurley and their fourteen year old daughter who used the pacemaker at issue, admitted that the product was accompanied by adequate warnings in the product's manual. Id., 321. The plaintiffs' claim before the trial court was based on the assertion that the defendant's product representative had made statements to the daughter's treating physician that nullified the warnings that had been contained in the product's manual. Id., 307. The plaintiffs presented evidence from which a jury could have found that the defendant's sales consultant had made recommendations and taken actions in a manner inconsistent with the product's warnings.9 The court concluded that "whether [the defendant's product representative's] actions were in derogation of the warnings in the technical manual was an issue of material fact sufficient to defeat the defendant's motion for summary judgment"; id., 323–24; and reversed the judgment of the trial court as to the plaintiffs' product liability claims. 10 Id., 326.

In the present case, however, the plaintiff failed to provide a sufficient evidentiary foundation to demonstrate the existence of a genuine issue of material fact. In *Hurley*, our Supreme Court noted: "If there exists an undisputed record demonstrating that [the defendant's product representative] did nothing inconsistent with the manual, then we would agree with the defendant that the trial court properly rendered judgment in its favor based on the learned intermediary doctrine." (Emphasis in original.) Id., 321. The plaintiff in the present case did not present any evidence that the defendants' representative said or did anything inconsistent with the product's warnings.<sup>11</sup> Accordingly, the trial court properly rendered summary judgment in favor of the defendants on the basis of the learned intermediary doctrine with respect to the plaintiff's failure to warn claim.

The judgment is affirmed.

In this opinion the other judges concurred.

<sup>1</sup> The plaintiff alleged that the defendants' product was sold "without

proper or adequate warnings, labels and instructions regarding use in patients of the plaintiff's size and history of prior spinal fusions and instrumentalities," and "without proper or adequate warnings, labels and instructions regarding the junction of titanium hardware to stainless steel hardware."

<sup>2</sup> The plaintiff alleged that the defendants' product was "designed, fabricated, manufactured, tested, distributed, marketed and/or sold without adequate or proper precautions to prevent the failure and fracture of components once installed in patients," and that the defendants' product was "in [a] dangerous and defective condition at the time [it] left [Johnson & Johnson, Inc.'s] possession and control and [was] placed into the stream of commerce by [the defendants] with the expectation that [it] would reach users and consumers . . . without substantial change in [its] condition."

The trial court noted that "[t]he plaintiff does not clearly allege what product defect existed but rather recites various possibilities in his allegations . . . . The plaintiff's complaint is most clearly construed to allege a design defect." (Citation omitted.) The plaintiff does not claim otherwise on appeal. Therefore, like the trial court, we construe the plaintiff's complaint to allege strict liability failure to warn and design defect claims, and a breach of warranty claim.

<sup>3</sup> Moreover, the plaintiff did not request permission to file an untimely disclosure of an expert. Rather, the plaintiff was of the view, as he is on appeal, that an expert was not needed for him to prevail.

<sup>4</sup> At his deposition, Dr. Schwartz acknowledged that nonunion, also referred to as pseudoarthrosis, is the failure of a patient's bones to heal or fuse. He stated that nonunion is the primary reason that hardware either breaks or loosens. In their memorandum of law in support of their motion for summary judgment, the defendants stated that their expert, Dr. Nicholas Theodore, a neurosurgeon, would opine that the most likely cause of the breakage of the defendants' product, in this case, was chronic pseudoarthrosis, which was exacerbated by the plaintiff's smoking.

<sup>5</sup> "Under the modified consumer expectation test, the jury would weigh the product's risks and utility and then inquire, in light of those factors, whether a reasonable consumer would consider the product design unreasonably dangerous." (Internal quotation marks omitted.) *Izzarelli* v. *R.J. Reynolds Tobacco Co.*, 321 Conn. 172, 190, 136 A.3d 1232 (2016). Therefore, "[t]o establish the defect, [a] plaintiff's case require[s] expert testimony on [the product] design and manufacture, as well as the feasibility of an alternative design." Id., 203–204.

In its memorandum of decision, the trial court refers to the modified consumer expectation test as the risk-utility test. Courts use these terms interchangeably. See id.

<sup>6</sup> Although the plaintiff argues that the ordinary consumer expectation test applies to the circumstances of the present case, he also appears to set forth an argument, on appeal, under the malfunction theory as a basis for establishing strict liability. In his brief to this court, the plaintiff argues: "Design defects can be inferred from circumstantial evidence. Under appropriate circumstances, the evidence of malfunction is sufficient evidence of a defect."

"A product liability claim under the malfunction theory is distinct from an ordinary product liability claim." White v. Mazda Motor of America, Inc., 313 Conn. 610, 622, 99 A.3d 1079 (2014). "The malfunction theory allows a plaintiff in a product liability action to rely on circumstantial evidence to support an inference that an unspecified defect attributable to a product seller was the most likely cause of a product malfunction when other possible causes of the malfunction are absent. . . . This theory does not fall squarely within either the ordinary or modified consumer expectation test, but to some extent overlaps with both tests." (Citation omitted; emphasis added; internal quotation marks omitted.) Izzarelli v. R.J. Reynolds Tobacco Co., supra, 321 Conn. 194–95 n.12.

The plaintiff in the present case, however, did not reference the malfunction theory in his pleadings, nor did he present any allegations relative to its elements. "To properly plead a product liability claim under the malfunction theory, the plaintiff was required to at least claim in the pleadings that some unspecified defect caused the plaintiff's harm and to allege facts tending to establish the malfunction theory's two basic elements, namely, that (1) the incident that caused the plaintiff's harm was of the kind that ordinarily does not occur in the absence of a product defect, and (2) any defect most likely existed at the time the product left the manufacturer's or seller's control and was not the result of the reasonably possible causes not attribut-

able to the manufacturer or seller." (Emphasis added; internal quotation marks omitted.) White v. Mazda Motor of America, Inc., supra, 313 Conn. 623. "[T]he plaintiff was not required to plead a separate malfunction theory count in his complaint, but this does not relieve him of his burden of pleading facts to raise this theory in his complaint as part of his product liability claims." Id., 625. Although the plaintiff alleged an unspecified defect, he failed to allege facts to establish the malfunction theory's two basic elements. Because we conclude that the plaintiff did not raise the malfunction theory in the trial court prior to its rendering summary judgment, we decline to consider its application on appeal.

<sup>7</sup> Rather, as the plaintiff concedes, nonunion was a possible cause of the fracture, apart from any product defect.

<sup>8</sup> Moreover, the plaintiff's failure to warn claim involves the risk associated with the mixing of dissimilar metals. See part II this opinion. This issue also goes beyond the field of ordinary knowledge and experience of jurors.

<sup>9</sup> At the product representative's deposition, he confirmed that he evaluated the defendant's product, which was the plaintiff's pacemaker, and indicated that the battery was low. *Hurley* v. *Heart Physicians*, *P.C.*, supra, 278 Conn. 309–10. He told the plaintiff's physician that the pacemaker's battery needed to be replaced as soon as possible. However, he also made a recommendation that he could lower the pacemaker rate to "'buy . . . more time'" to replace the pacemaker's battery. Id., 311. In accordance with what he believed the position of the plaintiff mother to be on the matter, the product representative chose to adjust the pacemaker down from sixty paces per minute to forty. Id. The product's manual, however, provided that rates below forty paces per minute may be used for "diagnostic purposes," and "the manual [did] not provide that rates below forty paces per minute safely may be used for diagnostic purposes *after the indicator has signaled the end of battery life.*" (Emphasis in original.) Id., 323.

<sup>10</sup> The court explained: "[A]lthough the manual provides that rates below forty paces per minute may be used for 'diagnostic purposes,' whether the discussion between [the product representative] and [the physician] and the adjustment actually made were consistent with that purpose when the electric replacement indicator on the . . . pacemaker signaled the need for immediate replacement as in this case, raised disputed factual issues meant for consideration by a fact finder at trial, not by a court deciding whether to render summary judgment." (Emphasis in original; footnote omitted.) Hurley v. Heart Physicians, P.C., supra, 278 Conn. 322–23.

<sup>11</sup> In support of his claim, the plaintiff points only to the testimony of Dr. Schwartz. Dr. Schwartz, during his deposition, stated that he consulted with the defendants' sales representative before the plaintiff's surgery, about screw size and length, and that the defendants' sales representative was available to be consulted during the plaintiff's surgery. This testimony does not support the plaintiff's bald assertion that the defendants' representative made statements which diluted the product's warnings. "Mere statements of legal conclusions . . . and bald assertions, without more, are insufficient to raise a genuine issue of material fact capable of defeating summary judgment." (Internal quotation marks omitted.) CitiMortgage, Inc. v. Coolbeth, 147 Conn. App. 183, 193, 81 A.3d 1189 (2013), cert. denied, 311 Conn. 925, 86 A.3d 469 (2014).

Moreover, the plaintiff focuses on Dr. Schwartz' use of the product despite the product's warnings regarding the risks associated with the patient's weight and the mixing of dissimilar metals. Dr. Schwartz, however, acknowledged that it was his decision to use the defendants' product. The plaintiff does not point to any statements or actions by the defendants' product representative that could have diluted the product's warning.

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