****

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. In no event will any such motions be accepted before the ''officially released'' date.

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 electronic version of an opinion and the print version appearing in the Connecticut Law Journal and subsequently in the Connecticut Reports or Connecticut Appellate Reports, the latest print version is to be considered authoritative.

****

NICOLE HURLEY ET AL. *v.* THE HEART PHYSICIANS, P.C., ET AL.
(SC 17463)

Norcott, Katz, Palmer, Vertefeuille and Zarella, Js.

Argued March 14—officially released May 23, 2006

Antonio Ponvert III, with whom was *James D. Horwitz*, for the appellants (plaintiffs).

Lori G. Cohen, pro hac vice, with whom were *James H. Rotondo* and *Victoria Woodin Chavey*, for the appellee (defendant Medtronic, Inc.).

Opinion

KATZ, J. The plaintiffs, Nicole Hurley (Nicole), who was permanently brain damaged by a cardiac event allegedly caused by a downward adjustment to the rate of her pacemaker, and her parents, Lucinda Hurley and Navarro Hurley, brought the underlying action against the defendant Medtronic, Inc. (defendant), maker of the pacemaker, pursuant to the Connecticut Product Liability Act, General Statutes § 52-572m et seq., and the Connecticut Unfair Trade Practices Act (CUTPA), General Statutes § 42-110a et seq., claiming, inter alia, that one of the defendant's representatives had made statements to Nicole's treating physician and had engaged in conduct that nullified the warnings contained in the defendant's technical manual for Nicole's pacemaker (manual).[1] The defendant asserted as a special defense that, under the learned intermediary doctrine, it had no duty as a matter of law to provide a warning directly to the ultimate consumer regarding the product. That doctrine, based on the principle that prescribing physicians act as '' 'learned intermediaries' '' between a manufacturer and the 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, provides, in general terms, that, ''adequate warnings to prescribing physicians obviate the need for manufacturers . . . to warn ultimate consumers directly.'' (Internal quotation marks omitted.) *Vitanza* v. *Upjohn Co.*, 257 Conn. 365, 376, 778 A.2d 829 (2001). The principal issue in this appeal is whether the trial court properly rendered summary judgment for the defendant based on the learned intermediary doctrine.[2] We conclude that the record reflects

a material question of fact as to whether the warnings given by the defendant's representative were consistent with the manual and, therefore, the trial court improperly determined that the defendant was entitled to prevail under the learned intermediary doctrine as a matter of law. We further conclude that the trial court properly rendered summary judgment for the defendant on the plaintiffs' CUTPA claim. Accordingly, we reverse in part the trial court's judgment.

The record discloses the following undisputed facts. Nicole was born with a congenital complete heart block condition that interfered with her heart's capacity to produce a safe heart rhythm. When she was seven days old, her physicians implanted a cardiac pacemaker manufactured by the defendant. Every few years, Nicole received a new pacemaker manufactured by the defendant, allowing her to grow and live a normal life.

On September 14, 1998, when Nicole was fourteen years old, her pacemaker's elective replacement indicator signaled that the pacemaker battery was nearing the end of its life cycle and was wearing down. Nicole's cardiologist, Richard Landesman, asked Frank Kling, a representative of the defendant, to attend an examination of Nicole and to test the battery in her pacemaker. Kling often was called in by physicians to evaluate pacemakers, looking at the mode, rate, amplitude, pulse width and sensitivity of the device, and to make adjustments at the direction of the physicians.[3] The intent of Kling's visit to Landesman's office, however, was for Kling to assess whether the plaintiff's pacemaker was at its end of life.

During the visit, based on information he had gathered from Kling, Landesman concluded that Nicole needed a new pacemaker. Because, however, according to Landesman, Lucinda Hurley had refused to have the pacemaker replaced, Landesman decided to adjust downward the rate of the pacemaker in an effort to evaluate Nicole's ability to function with the pacemaker operating at a lower rate. Landesman testified that, because Nicole's ''heartbeat had been previously demonstrated in Yale-New Haven [Hospital] to be in the [fifty to sixty paces per minute][4] range without the pacemaker . . . [he] was actually trying to obtain some additional information which [he] hoped would eventually convince [Nicole's] mother that she needed to have the battery replaced.'' Landesman further explained that he hoped that by adjusting the rate, he could gather information about new symptoms that Nicole might experience in a further effort to convince her mother of the need for a replacement. Finally, Landesman was interested in obtaining information about a different type of pacemaker, one with two wires that Nicole's physicians at Yale-New Haven Hospital had suggested.

In his deposition, Kling confirmed that his ''interrogation'' or evaluation of Nicole's pacemaker indicated that

the battery was low and that, although it ''was still very much operating,'' he had relayed to Landesman that the pacemaker battery needed to be replaced as soon as possible. Kling testified, however, that Lucinda Hurley had been adamant about wanting her daughter's pacemaker removed altogether. In exploring the possible responses to the situation, Kling stated that his role was to present options and that, in ''trying to understand and assess'' Nicole's condition, he had presented to Landesman the option of lowering the rate.[5] Kling explained that, ''[b]y taking the rate from [sixty to forty paces per minute], just like you take amplitude from eight volts to four volts, you are also giving yourself more time before a device would, you know, hit that end point. So you know, in this whole realm of consideration, it's giving us more time to work this situation and maybe [Lucinda] Hurley would come around and wake up and say jeez, I've got to get this done. Leaving it at [sixty] would keep it on its present course'' but lowering the rate from sixty paces per minute would ''buy us more time, just as it would changing the other three parameters.'' According to Kling's testimony, ''[t]he only other option which was there from the beginning to the end was that this pacemaker needs to be replaced. And that was impressed over and over and over again.'' In light of what he understood Lucinda Hurley's position to be on the matter, Kling adjusted the pacemaker down from sixty paces per minute to forty.

In addition to the deposition testimony regarding Nicole's care and treatment, the trial court had an abundance of documentary evidence regarding the defendant's pacemaker. According to the pacemaker's Food and Drug Administration (FDA) approved warnings and the device's technical manual, the ''[e]lective [r]eplacement [i]ndicator . . . signals when battery voltage is [less than] 2.5 [volts]. The physician should schedule an immediate replacement of the pacemaker once the [elective replacement indicator] signal is exhibited.'' The manual further provides that, ''[i]f the battery voltage should temporarily fall to or below 2.5 [volts], the pacemaker paces at a 10 [percent] decrease from the programmed rate . . . .'' It was undisputed, and, indeed the trial court expressly found, that these warnings had been ''specified by the FDA's prescription device labeling regulations and . . . reviewed and approved by [the] FDA in the course of its review of the [defendant's] . . . [premarket approval] submissions.'' Additionally, as the trial court noted, it was undisputed that ''failure to comply with the conditions of approval invalidates [the FDA's] approval order and that [c]ommercial distribution of a device that is not in compliance with these conditions is a violation of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 301 et seq.].'' (Internal quotation marks omitted.) Finally, the trial court also noted the defendant's concession that the FDA's ''Conditions of Approval . . . prohibited [the defen-

dant] from making any changes to the . . . labeling affecting the safety or effectiveness of the device without supplementing the . . . [premarket approval application].'' (Internal quotation marks omitted.) See *Goodlin* v. *Medtronic, Inc.*, 167 F.3d 1367, 1370 (11th Cir. 1999) (''The manufacturer may not change the approved labeling . . . in any way that would affect the safety or effectiveness of the device. See 21 C.F.R. § 814.80.'').

In addition to its findings that the ''pacemaker was accompanied by adequate warnings in the [manual] . . . [and that the manual] warned of the need for replacement when the battery voltage fell below 2.5 volts,'' the trial court also found that Landesman ''knew the battery to [Nicole's] pacemaker was nearing end of life, knew the pacemaker 'absolutely' needed to be replaced soon, and knew the consequences of not replacing the pacemaker were potentially very serious, even life-threatening. This is precisely what the labeling accompanying the . . . pacemaker warned about and what Kling confirmed with . . . Landesman.'' Landesman and Kling also testified that they *believed* that Lucinda Hurley would not authorize the procedure to replace the pacemaker, and it was only when they reached that conclusion that they explored the other options.[6] In reliance on a section in the manual that allows for rate reduction below forty paces per minute for diagnostic purposes,[7] the trial court rejected the plaintiffs' claim that Kling's statement that the rate could be slowed down, along with his adjustment, nullified the warnings in the manual. Furthermore, the trial court concluded that, because Landesman, who was a learned intermediary, knew of the need for pacemaker replacement, the plaintiffs could not, as a matter of law, prove that inadequate warnings had caused Nicole's injuries.[8] Finally, based on the exclusivity provisions of § 52-572m (b) of the Connecticut Product Liability Act, the trial court rejected the plaintiffs' claim that the defendant had violated CUTPA. Accordingly, the trial court granted the defendant's motion for summary judgment and rendered judgment thereon. The plaintiffs then appealed from that judgment, claiming that the trial court improperly had rendered summary judgment for the defendant based on the learned intermediary doctrine.[9]

Before addressing the merits of the plaintiffs' claim, we set forth the applicable standard for our review. ''Practice Book [§ 17-49] provides that summary judgment shall be rendered forthwith if the pleadings, affidavits and any other proof submitted show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. . . . In deciding a motion for summary judgment, the trial court must view the evidence in the light most favorable to the nonmoving party. . . . The party seeking summary judgment has the burden of showing the

absence of any genuine issue [of] material facts which, under applicable principles of substantive law, entitle him to a judgment as a matter of law . . . and the party opposing such a motion must provide an evidentiary foundation to demonstrate the existence of a genuine issue of material fact. . . . A material fact . . . [is] a fact which will make a difference in the result of the case. . . . Finally, the scope of our review of the trial court's decision to grant the [defendant's] motion for summary judgment is plenary.'' (Internal quotation marks omitted.) *Ace Equipment Sales, Inc.* v. *Buccino*, 273 Conn. 217, 226–27, 869 A.2d 626 (2005).

I

In *Vitanza* v. *Upjohn Co.*, supra, 257 Conn. 373–74, we explained the legal underpinnings of the learned intermediary doctrine. ''A product may be defective due to a flaw in the manufacturing process, a design defect or because of inadequate warnings or instructions. See, e.g., *Hill* v. *Searle Laboratories*, 884 F.2d 1064, 1067 (8th Cir. 1989) (defect need not be a matter of errors in manufacture . . . a product is defective when it is . . . not accompanied by adequate instructions and warnings of the dangers attending its use); *Koonce* v. *Quaker Safety Products & Mfg. Co.*, 798 F.2d 700, 716 (5th Cir. 1986) ([t]he absence of adequate warnings or directions may render a product defective and unreasonably dangerous, even if the product has no manufacturing or design defects); *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. See *Lindsay* v. *Ortho Pharmaceutical Corp.*, 637 F.2d 87, 90 (2d Cir. 1980) ([u]nlike most other products . . . prescription drugs may cause untoward side effects despite the fact that they have been carefully and properly manufactured); *Wolfgruber* v. *Upjohn Co.*, 72 App. Div. 2d 59, 61, 423 N.Y.S.2d 95 (1979), aff'd, 52 N.Y.2d 768, 417 N.E.2d 1002, 436 N.Y.S.2d 614 (1980) (prescription drugs are [u]navoidably unsafe products . . .).

''A manufacturer of an unavoidably unsafe product can avoid strict liability if the product is properly prepared, and accompanied by proper directions and warning . . . . 2 Restatement (Second), supra, § 402A, comment (k). 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. See *Tomer* v. *American Home Products Corp.*, [170 Conn. 681, 689–90, 368 A.2d 35 (1976)]; 2 Restatement (Second), supra, § 388 (c). 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. . . . *Guevara* v. *Dorsey Laboratories, Division of Sandoz, Inc.*, 845 F.2d 364, 367 (1st Cir. 1988) (warning should be sufficient to appraise a general practitioner . . . of the dangerous propensities of the drug . . .); *Brooks* v. *Medtronic, Inc.*, 750 F.2d 1227, 1231 (4th Cir. 1984) ([t]he restriction of the duty to warn to physicians alone in ethical drug cases stands as an exception to the general duty of manufacturers to warn ultimate consumers in products liability cases); *Davis* v. *Wyeth Laboratories, Inc.*, 399 F.2d 121, 130 (9th Cir. 1968) ([o]rdinarily in the case of prescription drugs warning to the prescribing physician is sufficient)." (Citations omitted; internal quotation marks omitted.) *Vitanza* v. *Upjohn Co.*, supra, 257 Conn. 373–76.

In *Vitanza*, we adopted comment (k) to § 402A of the Restatement (Second) of Torts, concluding that the policy considerations set forth therein are persuasive and in accord with this state's product liability jurisprudence. Id., 376. Although we adopted the learned intermediary doctrine in the context of prescription drugs, we did not decide whether the policies behind the rule equally were applicable to prescription medical device cases. Numerous courts have determined that they are applicable to prescription medical device cases.[10] See, e.g., *Brooks* v. *Medtronic, Inc.*, 750 F.2d 1227, 1231–32 (4th Cir. 1984) (applying South Carolina law to defendant's cardiac pacemaker); see also *Vitanza* v. *Upjohn Co.*, supra, 257 Conn. 378 (recognizing that "[f]ederal courts sitting in diversity have applied the learned intermediary doctrine as a matter of Connecticut law for more than thirty years" and citing *Desmarais* v. *Dow Corning Corp.*, 712 F. Sup. 13, 17 [D. Conn. 1989], which involved implantable medical device). The parties have not pointed us to any case that has held that the learned intermediary doctrine does not apply in this context, and we can see no principled reason to distinguish between a prescription implantable medical device like a pacemaker and a prescription drug.

Nonetheless, the plaintiffs claim that, for several reasons, the trial court improperly applied the intermediary doctrine to this case.[11] First, the doctrine bars only inadequate warning claims, not claims involving *conduct*, like Kling's adjustment to Nicole's pacemaker. In their amended complaint, the plaintiffs alleged that the defendant was negligent, inter alia, by "*causing the*

rate of the pacemaker to be set to an improper and dangerous level'' and by failing to provide adequate instructions and warnings. (Emphasis added.) Second, as an exception to the rule of strict liability inherent in a product's liability claim, the doctrine applies only to cases wherein a manufacturer otherwise would owe a direct duty to warn an ultimate consumer of an unavoidably unsafe product. According to the plaintiffs, because the pacemaker at issue was ''not unavoidably unsafe and . . . [they] do not seek to impose strict liability against the defendant on the grounds that it owed a direct duty to warn . . . the ultimate user . . . of any unavoidably unsafe product characteristics, there is no need for an exception to this non-existent direct duty to warn . . . .''[12] (Internal quotation marks omitted.) Third, the doctrine applies only to products that are distributed in such a way that consumers might not see the product's warnings, which, because of the defendant's meticulous record keeping and monitoring of recipients of their pacemakers was not a risk in this case. Fourth, the doctrine only applies, by definition, when there is a meaningful intermediary between the manufacturer and the ultimate user of the product, and in this case because Kling physically made the adjustment, no such intermediary existed. Fifth, the doctrine applies only when the manufacturer is justified in assuming that the intermediary understands and will prescribe and administer the product in strict compliance with the warnings, and based on the evidence in this case, Kling could not have held such a reasonable expectation.

The plaintiffs alternatively contend that, even if the doctrine does apply, the trial court improperly decided questions regarding the adequacy of the warnings and causation as a matter of law when those issues were for a jury to decide, particularly when there were genuine disputes about material facts relating to those issues. Finally, the plaintiffs contend that the trial court improperly rejected the application of the exceptions to the learned intermediary doctrine set forth in *Vitanza* v. *Upjohn Co.*, supra, 257 Conn. 394.

In response to the plaintiffs' specific contentions as to why the doctrine has no application to this case, the defendant makes the following assertions: the pacemaker is a complex medical device and, therefore, falls within the protection of the doctrine; the doctrine applies to prescription devices regardless of whether the manufacturer has an opportunity to communicate directly with the patient because physicians, as learned intermediaries, still ''stand in the best position to evaluate a patient's needs and assess [the] risks and benefits of a particular course of treatment''; (internal quotation marks omitted) id., 376; Landesman was a learned intermediary, even if he was only one of the patient's treating physicians; unlike with the sophisticated user doctrine, application of the learned intermediary doctrine does

not depend on whether the manufacturer is justified in assuming that the learned intermediary, the physician, did indeed understand and appreciate the warnings; see id., 390–91; and the doctrine applies independent of whether the manufacturer knew or should have known of the physician's inferior medical care because, "[w]hen the physician-patient relationship does exist . . . we hesitate to encourage, much less require, a drug manufacturer to intervene in it." *Swayze* v. *McNeil Laboratories, Inc.*, 807 F.2d 464, 471 (5th Cir. 1987). Additionally, the defendant contends that the learned intermediary doctrine applied under the facts of this case because the pacemaker manual's written warnings concededly were adequate, and Kling's advice to Landesman was consistent with those written warnings, specifically, as it related to diagnostic evaluation purposes. See footnote 7 of this opinion (setting forth pertinent manual provision). Finally, the defendant contends that the pacemaker at issue in this case is governed by the Medical Device Amendments of 1976 to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360c et seq., and that, accordingly, any state law claim that would act to impose a requirement that was different from, or in addition to, the applicable federal requirements would be preempted.[13]

Despite the detailed record in this case and the complex considerations involved in the learned intermediary doctrine, we conclude that this case distills to a routine analysis consistent with our long-standing summary judgment jurisprudence. The dispositive issue in this appeal is whether the trial court properly determined *as a matter of law* that Kling's oral advice and his rate reduction to the pacemaker were for *diagnostic* purposes, were consistent with the technical manual and, therefore, did not nullify the warnings in the manual. If there exists an *undisputed* record demonstrating that Kling 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. We agree with the plaintiffs that they provided a sufficient evidentiary foundation to demonstrate the existence of a genuine issue of material fact—as to whether Kling behaved in a manner in derogation of the technical manual—sufficient to have precluded the trial court from determining as a matter of law that the learned intermediary doctrine shielded the defendant.

The plaintiffs admit that the pacemaker was accompanied by adequate warnings *in the manual.* What is at issue, however, is whether, notwithstanding the FDA approved written pacemaker replacement warnings, Kling, by his *oral* communications to Landesman that turning down the pacemaker was an option, accompanied by his *physical* adjustment of the pacemaker to forty paces per minute, actually contradicted the manual, thereby vitiating and nullifying the manual's warn-

ings, and rendered the pacemaker essentially ineffective.[14] Whether Kling behaved in a manner consistent with the technical manual is a question of fact because such an inquiry entails a more complicated analysis than merely comparing the words; it requires a fact finder to examine the written words, the oral communication and the context in which they were provided. See *Sharp* v. *Wyatt, Inc.*, 31 Conn. App. 824, 834, 627 A.2d 1347 (1993) ("[w]hether a product is defective under [General Statutes §] 52-572q[15] is a question of fact"), aff'd, 230 Conn. 12, 644 A.2d 871 (1994). In other words, although the manual provides that rates below forty paces per minute may be used for "diagnostic purposes,"[16] whether the discussion between Kling and Landesman and the adjustment actually made were consistent with that purpose when the electric replacement indicator on Nicole's 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. As the plaintiffs point out, the manual does 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*. Although adjustments for diagnostic purposes properly could be used in a variety of circumstances, Kling's testimony strongly suggested that no diagnostic testing should take place at a time when the pacemaker's battery is on the verge of expiration.[17]

Whether, based on the testimony before the court, Kling acted in response to questions from Landesman about diagnostic options either to assess functional capabilities, to extend the life of the battery in an attempt to buy more time in which to convince Lucinda Hurley to allow the pacemaker replacement or to gather information to assess whether Nicole needed a different type of pacemaker were all possible conclusions, not all of which were consistent with the manual. Although the evidence indicated that pacemaker adjustment *can* be performed for purposes of a diagnostic assessment, whether that was the operative reason *in this case* is something about which reasonable minds can differ. Therefore, we cannot conclude as a matter of law that the defendant established that the adjustment was done for diagnostic purposes. Accordingly, we conclude that whether Kling'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.

II

The trial court also granted the defendant's motion for summary judgment as to the plaintiffs' CUTPA claim, concluding that, because the allegations contained in that count had asserted either that the defendant's product was defectively designed or that the

defendant, in a deceptive manner, failed to warn properly about the functioning of the pacemaker, it was barred by the exclusivity provision of the Connecticut Product Liability Act (liability act). We agree that the liability act bars the plaintiffs' CUTPA claim.

In *Gerrity* v. *R.J. Reynolds Tobacco Co.*, 263 Conn. 120, 126, 818 A.2d 769 (2003), we reiterated that the exclusivity provision of the liability act makes it the exclusive means by which a party may secure a remedy for an injury caused by a defective product. See General Statutes § 52-572n (a) (''[a] product liability claim as provided in sections 52-240a, 52-240b, 52-572m to 52-572q, inclusive, and 52-577a may be asserted and shall be in lieu of all other claims against product sellers, including actions of negligence, strict liability and warranty, for harm caused by a product''). The issue in this case, as in *Gerrity*, therefore, is whether the plaintiffs' CUTPA claim falls within the scope of the liability act. ''If it does, then it is precluded and may not be asserted in conjunction with the [liability act] claim. If, however, the CUTPA claim falls outside the purview of the [liability act], it may be asserted and the exclusivity provision will not serve as a bar.

''As noted previously, the legislature defined a product liability claim to include all claims or actions brought for personal injury, death or property damage caused by the allegedly defective product. General Statutes § 52-572m (b). The legislature also provided that the damages are caused by the defective product if they arise from the manufacture, construction, design, formula, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging or labeling of any product. General Statutes § 52-572m (b). In addition, a product liability claim is defined broadly to include, but not be limited to, all actions based on [s]trict liability in tort; negligence; breach of warranty, express or implied; breach of or failure to discharge a duty to warn or instruct, whether negligent or innocent; misrepresentation or nondisclosure, whether negligent or innocent. General Statutes § 52-572m (b). Finally, the legislature defined [h]arm for purposes of the act to include damage to property, including the product itself, and personal injuries including wrongful death. General Statutes § 52-572m (d). These definitions must be read together, with the understanding that the [liability act] was designed in part to codify the common law of product liability, and in part to resolve, by legislative compromise, certain issues among the groups interested in the area of product liability. The [liability act], however, was not designed to eliminate claims that previously were understood to be outside the traditional scope of a claim for liability based on a defective product. Given this contextual framework, we conclude[d] that a product liability claim under the [liability] act is one that seeks to recover damages for personal injuries, including wrongful death, or for property damages,

including damage to the product itself, caused by the defective product.

''Therefore, the language of the exclusivity provision makes clear that the [liability act] was intended to serve as the exclusive remedy for a party who seeks recompense for those injuries caused by a product defect. The language of the exclusivity provision, however, suggests that it was not designed to serve as a bar to additional claims, including one brought under CUTPA, either for an injury not caused by the defective product, or if the party is not pursuing a claim for personal injury, death or property damage . . . . General Statutes § 52-572m (b).'' (Internal quotation marks omitted.) *Gerrity* v. *R.J. Reynolds Tobacco Co.*, supra, 263 Conn. 126–28.

After reviewing carefully the allegations in the plaintiffs' CUTPA count in the present case, we agree with the trial court that the plaintiffs are pursuing a claim for personal injuries to Nicole and are seeking recompense for those injuries caused by the defendant's pacemaker that was implanted in Nicole. Accordingly, the plaintiffs' claim falls within the scope of the liability act and thus is barred by the exclusivity provision under § 52-572n (a).

The judgment is reversed as to the product liability counts and the case is remanded to the trial court for further proceedings according to law.

In this opinion the other justices concurred.

[1] The complaint was brought on Nicole's behalf by her parents, who also each asserted claims in their individual capacities. In addition to Medtronics, Inc., the complaint initially named as defendants Richard Landesman, Nicole's cardiologist, and The Heart Physicians, P.C., the facility at which Landesman provided services to Nicole. The plaintiffs ultimately withdrew their claims as to these defendants. Medtronics, Inc., is the only remaining defendant.

[2] The defendant contends in its brief to this court that, although the trial court did not reach this special defense, the trial court's judgment should be affirmed on the ground that the plaintiffs' claims are preempted by federal law, specifically, the preemption clause of the Medical Device Amendments of 1976 to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360c et seq. The defendant has acknowledged before this court, however, that, if the warnings of the defendant's representative, Frank Kling, were indeed not consistent with the technical manual, as the plaintiffs have alleged, then the defendant cannot receive the benefit of the preemption doctrine. Because, in addressing the learned intermediary doctrine, we conclude that there was an issue of material fact as to whether the warnings were consistent with the manual, the preemption defense is similarly unavailing at this stage of the proceedings.

The defendant also contends that the trial court's judgment should be affirmed on the basis of its third special defense that its conduct did not cause Nicole's injuries. Specifically, the defendant had asserted that the plaintiffs had actual knowledge of the hazard of not replacing the battery and that its failures, if any, did not cause her injuries. Although the evidence reflects that, prior to the meeting at Richard Landesman's office when Kling made the adjustment to the pacemaker, Lucinda Hurley was aware of the risks associated with failing to timely replace the battery in Nicole's pacemaker, there is evidence in the record demonstrating that, as a result of conversations between Kling and Landesman in Lucinda Hurley's presence, her understanding was altered. Accordingly, because there is an issue of material fact regarding causation, we conclude that this special defense also cannot support the trial court's decision to render summary judgment for the defendant.

[3] In his deposition, Kling described at length the actions he typically would undertake to program a new pacemaker when a physician or hospital notified

him that a patient needed to have a ''battery change'' (synonymous with pacemaker change): he would go to the site with his laptop computer, programmer (a device used to receive information from the pacemaker by telemetry—a radio frequency exchange) and a pacing system analyzer (a device used to measure the characteristics of the lead—the wire that goes from the patient's heart to the pacemaker); he would program the new pacemaker with basic operating parameters to ensure its functioning; and he would make all the necessary adjustments to specific parameters, as instructed by the physician.

[4] See footnote 7 of this opinion.

[5] Kling explained in his deposition testimony that, although some patients are completely pacemaker dependent, Nicole had a heart rate of her own underneath the pace rate on the day that her pacemaker was adjusted. According to Kling, in attempting to respond to Lucinda Hurley, who had wanted Nicole's pacemaker removed altogether, Landesman had suggested to Kling decreasing the pacemaker's amplitude so that it would not be effective, but Kling did not offer his opinion on that option because he was not involved with Nicole's medical care and his role was confined to offering options still providing pacing support. Kling accordingly suggested the option of reducing the rate.

[6] Lucinda Hurley testified in her deposition that she never had told Landesman that she did not want Nicole's pacemaker changed. According to her testimony, neither she nor Nicole ever discussed with Landesman the idea of not replacing the pacemaker. She further explained that, at some point during the September, 1998 office visit, Landesman had led her to believe that there was no urgency in replacing Nicole's pacemaker.

[7] Section 6-8 of the manual for the defendant's pacemaker provides in relevant part: ''Inhibited and Activity Mode Pacing for Diagnostic and Pediatric Uses

''Carefully monitor the patient when using pacing rates less than 40 or greater than 100 ppm [paces per minute] in the demand mode. Rates less than 40 [paces per minute] are intended primarily for diagnostic purposes. Programmed rates of 120 to 130 [paces per minute] in the inhibited mode are intended for pediatric applications only.

''NOTE: Lower Rates in the Activity mode are 40, 50, 60, 70, 80 . . . and 120 paces per minute]. The physician should consider the rate requirements of a pediatric patient when considering the use of the Activity mode. With some very young children, the physician may elect to use the [non-rate responsive] mode to achieve higher pacing rates; then as the child becomes older, program the device to the [rate responsive] mode at a lower base rate.''

Neither the manual nor the parties have explained the significance of ''ppm,'' but we presume that this abbreviation refers to paces per minute.

[8] The trial court also rejected the plaintiffs' claim that it should recognize and apply exceptions to the learned intermediary doctrine. Because those exceptions do not control this case, we leave their discussion for another day.

[9] The plaintiffs appealed from the judgment of the trial court to the Appellate Court, and we granted the plaintiffs' motion to transfer the appeal to this court pursuant to General Statutes § 51-199 (c) and Practice Book § 65-2.

[10] The following jurisdictions also have recognized the application of the learned intermediary doctrine to implantable medical devices: *Grenier* v. *Medical Engineering Corp.*, 243 F.3d 200, 205 (5th Cir. 2001) (applying Louisiana law); *Figueroa* v. *Boston Scientific Corp.*, 254 F. Sup. 2d 361, 370 (S.D.N.Y. 2003); *Skerl* v. *Arrow International, Inc.*, 202 F. Sup. 2d 748, 753 (N.D. Ohio 2001); *Mozes* v. *Medtronic, Inc.*, 14 F. Sup. 2d 1124, 1130 (D. Minn. 1998); *Uribe* v. *Sofamor, S.N.C.*, United States District Court for the District of Nebraska, Docket No. 8:95CV464, 1999 WL 1129703, *14 (August 16, 1999); *Langehennig* v. *Sofamor, Inc.*, United States District Court for the District of Kansas, Docket No. Civ. A. 95-1299-MLB, 1999 WL 1129683, *6 (May 28, 1999); *Wilson* v. *Danek Medical, Inc.*, United States District Court for the Middle District of Florida, Docket No. 96-2460-CIV-T-17B, 1999 WL 1062129, *3–5 (March 29, 1999); *Moses* v. *Danek Medical, Inc.*, United States District Court for the District of Nevada, Docket No. CV-S-95-512, 1998 WL 1041279, *5 (December 11, 1998); *Morguson* v. *3M Co.*, 857 So. 2d 796, 801–802 (Ala. 2003); *Hansen* v. *Baxter Healthcare Corp.*, 309 Ill. App. 3d 869, 881, 723 N.E.2d 302 (1999), aff'd, 198 Ill. 2d 420, 764 N.E.2d 35 (2002); *Vaccariello* v. *Smith & Nephew Richards, Inc.*, 94 Ohio St. 3d 380, 384, 763 N.E.2d 160 (2002); *Rosci* v. *Acromed, Inc.*, 447 Pa. Super. 403, 423, 669 A.2d 959 (1995).

[11] Other than their misplaced reliance on certain language in *Vitanza* v. *Upjohn Co.*, supra, 257 Conn. 377; see footnote 12 of this opinion; the

plaintiffs cite no authority in support of any of their contentions as to why the learned intermediary doctrine does not apply in the present case.

[12] We stated in *Vitanza* v. *Upjohn Co.*, supra, 257 Conn. 376–77: "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 unavoidable 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.' . . . 2 Restatement (Second), supra, § 402A, comment (k). 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 he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.' Id. As this court has stated: 'Products liability law has thus evolved to hold manufacturers strictly liable for unreasonably dangerous products that cause injury to ultimate users. Nevertheless, strict tort liability does not transform manufacturers into insurers, nor does it impose absolute liability.' *Potter* v. *Chicago Pneumatic Tool Co.*, 241 Conn. 199, 210, 694 A.2d 1319 (1997)." (Emphasis in original.)

To the extent that the plaintiffs rely on this passage to suggest that a pacemaker does not carry inherent risks so as to fall within comment (k) to the Restatement (Second) of Torts, their reliance is misplaced. Rather, it means that when a manufacturer of an unavoidably unsafe product, whose benefits to society are such that the product is not deemed to be unreasonably dangerous, provides adequate warnings and directions, it will not be held strictly liable.

[13] The defendants acknowledge, however, that, if the plaintiffs have demonstrated an issue of material fact regarding whether Kling's warnings were inconsistent with the technical manual, that issue relates both to the learned intermediary doctrine and the federal preemption defense. See footnote 2 of this opinion.

[14] According to the deposition testimony of one of Nicole's physicians, Charles Kleinman, "turning the rate down to [forty paces per minute] is really essentially turning the rate down to [thirty-six] . . . ." Frank Checchin, a physician at Children's Hospital in Boston, Massachusetts, explained in his deposition that "there's a big difference between . . . [forty] and [thirty-six] because . . . the slower you get, you set up more scenarios for ventricular arrhythmias."

[15] General Statutes § 52-572q provides: "(a) A product seller may be subject to liability for harm caused to a claimant who proves by a fair preponderance of the evidence that the product was defective in that adequate warnings or instructions were not provided.

"(b) In determining whether instructions or warnings were required and, if required, whether they were adequate, the trier of fact may consider: (1) The likelihood that the product would cause the harm suffered by the claimant; (2) the ability of the product seller to anticipate at the time of manufacture that the expected product user would be aware of the product risk, and the nature of the potential harm; and (3) the technological feasibility and cost of warnings and instructions.

"(c) In claims based on this section, the claimant shall prove by a fair preponderance of the evidence that if adequate warnings or instructions had been provided, the claimant would not have suffered the harm.

"(d) A product seller may not be considered to have provided adequate warnings or instructions unless they were devised to communicate with the person best able to take or recommend precautions against the potential harm."

[16] Indeed, the parties agree that the only way that Kling's advice could be deemed consistent with the manual is if the rate had been reduced for diagnostic purposes.

[17] Kling testified that, when the electronic replacement indicator is exhibited, the pacemaker must be replaced "as soon as possible. That's my conservative approach to every patient. I don't care what the condition is. As soon as possible."