

United States District Court
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

DENNIS HARRISON and SUSAN
HARRISON

v.

MEDTRONIC, INC.

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CIVIL ACTION NO. 3:20-CV-1407-S

MEMORANDUM OPINION AND ORDER

This Order addresses Defendant Medtronic, Inc.’s Motion to Dismiss Plaintiffs’ Amended Complaint (“Motion to Dismiss”) [ECF No. 37]. For the following reasons, the Court **GRANTS** Defendant’s Motion to Dismiss.

I. BACKGROUND

Following a diagnosis of aortic insufficiency, Plaintiff Dennis Harrison (“Mr. Harrison”) underwent valve replacement surgery performed by Dr. Robert Hebel, a cardiologist at Baylor University Medical Center. 2d Am. Compl. (“Complaint”) [ECF No. 32] ¶¶ 10-11. Following the procedure, Dr. Hebel placed Mr. Harrison on a temporary external pacemaker called an external pulse generator (“EPG”) which was designed, manufactured, and distributed by Defendant Medtronic, Inc. (“Defendant”). Mr. Harrison was then transferred to the intensive care unit for monitoring. *Id.* ¶ 13.

The next day, while still in the ICU, Mr. Harrison went into cardiac arrest. *Id.* ¶ 14. He was resuscitated after CPR and being “shocked.” *Id.* Mr. Harrison contends that his EPG malfunctioned, delivering an inappropriate impulse or “misfire” in-between heartbeats, resulting in an “R on T phenomenon” that caused “A fib” and induced cardiac arrest. *Id.* ¶¶ 14-16. The Complaint alleges (1) that the EPG had “a tendency for software or mechanical malfunction[;]” (2) that the battery drawer electrical contact fails to maintain a constant connection with the battery,

resulting in a failure to maintain steady power, which results in power failure, power surges, and untimely activation”; and (3) “degradation of the lead connector resulting in intermittent connection and shorting, resulting in untimely activation.” *Id.* ¶ 36.

Mr. Harrison has experienced chest pain and neurological effects he attributes to lack of oxygen during CPR, including headaches and balance and memory problems. *Id.* ¶¶ 17-18. Mr. Harrison is suing for compensatory damages for his physical injuries, mental anguish, loss of earning capacity, and medical expenses. *Id.* ¶ 82. His wife, Plaintiff Susan Harrison (“Mrs. Harrison,” and together with Mr. Harrison, “Plaintiffs”), seeks damages for loss of consortium and loss of household services. *Id.* ¶ 83. Plaintiffs allege seven causes of action: strict products liability manufacturing, marketing, and design defects; corresponding negligent manufacturing, marketing, and design; and breach of implied warranty for merchantability. *Id.* ¶¶ 23-38.

Plaintiffs filed their Original Petition in the 298th Judicial District of Dallas County, Texas, on August 19, 2019. *See* ECF No. 1 Ex. 10. Defendant timely removed the case to this Court on June 1, 2020, after non-diverse defendants were voluntarily dismissed by Plaintiffs. *See* ECF No. 1. Plaintiffs filed an Amended Complaint [ECF No. 13] on July 10, 2020, and a Second Amended Complaint [ECF No. 32] on December 1, 2020. Defendant moves to dismiss the Second Amended Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. In their Response to the Motion, Plaintiffs move for leave to amend their complaint if the Court determines that Plaintiffs have failed to state a claim. Pls.’ Resp. Br. 23-24.

II. LEGAL STANDARD

To defeat a motion to dismiss filed pursuant to Rule 12(b)(6), a plaintiff must plead “enough facts to state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *Reliable Consultants, Inc. v. Earle*, 517 F.3d 738, 742 (5th Cir. 2008). To meet this “facial plausibility” standard, a plaintiff must “plead[] factual content that allows the

court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Plausibility does not require probability, but a plaintiff must establish “more than a sheer possibility that a defendant has acted unlawfully.” *Id.* The court must accept well-pleaded facts as true and view them in the light most favorable to the plaintiff. *Sonnier v. State Farm Mut. Auto. Ins.*, 509 F.3d 673, 675 (5th Cir. 2007). However, the court does not accept as true “conclusory allegations, unwarranted factual inferences, or legal conclusions.” *Ferrer v. Chevron Corp.*, 484 F.3d 776, 780 (5th Cir. 2007) (citation omitted). A plaintiff must provide “more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Twombly*, 550 U.S. at 555 (internal citations omitted). “Factual allegations must be enough to raise a right to relief above the speculative level . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact).” *Id.* (internal citations omitted).

In ruling on a Rule 12(b)(6) motion, the court limits its review to the face of the pleadings. *See Spivey v. Robertson*, 197 F.3d 772, 774 (5th Cir. 1999). The pleadings include the complaint and any documents attached to it. *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498-99 (5th Cir. 2000). However, the court may also consider documents outside of the pleadings if they fall within certain limited categories. First, the “court is permitted . . . to rely on ‘documents incorporated into the complaint by reference, and matters of which a court may take judicial notice.’” *Dorsey v. Portfolio Equities, Inc.*, 540 F.3d 333, 338 (5th Cir. 2008) (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007)). Second, the “court may consider documents attached to a motion to dismiss that ‘are referred to in the plaintiff’s complaint and are central to the plaintiff’s claim.’” *Sullivan v. Leor Energy, LLC*, 600 F.3d 542, 546 (5th Cir. 2010) (quoting *Scanlan v. Tex. A & M Univ.*, 343 F.3d 533, 536 (5th Cir. 2003)). Third, “[i]n deciding a 12(b)(6) motion to dismiss, a court may permissibly refer to matters of public record.” *Cinel v.*

Connick, 15 F.3d 1338, 1343 n.6 (5th Cir. 1994) (internal citations omitted); *see also, e.g., Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011) (stating, in upholding district court’s dismissal pursuant to Rule 12(b)(6), that “the district court took appropriate judicial notice of publicly-available documents and transcripts produced by the [Food and Drug Administration], which were matters of public record directly relevant to the issue at hand.” (internal citations omitted)).

The ultimate question is whether the complaint states a valid claim when viewed in the light most favorable to the plaintiff. *Great Plains Tr. Co. v. Morgan Stanley Dean Witter & Co.*, 313 F.3d 305, 312 (5th Cir. 2002). At the motion to dismiss stage, the court does not evaluate the plaintiff’s likelihood of success. It only determines whether the plaintiff has stated a claim upon which relief can be granted. *Mann v. Adams Realty Co.*, 556 F.2d 288, 293 (5th Cir. 1977).

III. ANALYSIS

A. *Strict Products Liability*

In Texas, “to make out a strict liability cause of action, a party must establish that: (1) a product is defective; (2) the defect rendered the product unreasonably dangerous; (3) the product reached the consumer without substantial change in its condition from the time of original sale; and (4) the defective product was the producing cause of the injury to the user.” *Syrie v. Knoll Int’l*, 748 F.2d 304, 306 (5th Cir. 1984). A product may be unreasonably dangerous because of a defect in marketing, design, or manufacturing. *Am. Tobacco Co., Inc. v. Grinnell*, 951 S.W.2d 420, 426 (Tex. 1997). Plaintiffs allege the EPG contained all three of these defects.

(1) *Manufacturing Defect*

“A manufacturing defect exists when a product deviates, in its construction or quality, from the specifications or planned output in a manner that renders it unreasonably dangerous.” *Cooper Tire & Rubber Co. v. Mendez*, 204 S.W.3d 797, 800 (Tex. 2006) (quoting *Ford Motor Co. v. Ridgway*, 135 S.W.3d 598, 600 (Tex. 2004)); *Casey v. Toyota Motor Eng’g & Mfg. N. Am., Inc.*,

770 F.3d 322, 326 (5th Cir. 2014). To state a manufacturing defect claim, a plaintiff must plead the existence of a specific manufacturing defect. *Funk*, 631 F.3d at 782 (upholding dismissal for failure to allege a “specific defect in the [manufacturing] process that caused the personal injury,” or how the product deviated from its normal manufacturing specifications); *Carpenter v. Boston Sci. Corp.*, No. 3:18-cv-02338-L, 2019 WL 3322091, at *7 (N.D. Tex. July 24, 2019) (dismissing complaint that did not “show the device deviated from the specifications or planned output, [or] how such deviations rendered Plaintiff’s device unreasonably dangerous”). Consequently, complaints that rely on the doctrine of *res ipsa loquitur* do not state a claim for manufacturing defect under federal pleading standards. *Funk*, 631 F.3d at 782; *Elmazouni v. Mylan, Inc.*, 220 F. Supp. 3d 736, 741 (N.D. Tex. 2016).

Plaintiffs have failed to allege a plausible claim for a manufacturing defect. Plaintiffs allege that Mr. Harrison’s EPG “may have deviated, in construction or quality, from the specifications or planned output” and that it “may have had a software error, calibration error, or improper instructions for use.” 2d Am. Compl. ¶¶ 28-30. Plaintiffs do not identify how, if at all, the manufacturing process failed, nor do they explain how any defect in the manufacturing process caused Mr. Harrison’s injuries. Plaintiffs fail to specify how Mr. Harrison’s EPG departed from its intended specifications or even what the EPG’s intended manufacturing specifications were. Indeed, Plaintiffs raise only the possibility of such a deviation, without alleging that one actually occurred. As explained above, Plaintiffs’ reliance on *res ipsa loquitur* in support of their manufacturing defect claim is insufficient. *Funk*, 631 F.3d at 782. Accordingly, Plaintiffs have failed to state a claim for manufacturing defect.

(2) *Marketing Defect*

“[A] marketing defect occurs when a defendant knows or should have known of a potential risk of harm presented by the product but markets it without adequately warning of the danger or

providing instructions for safe use.” *Wright v. Ford Motor Co.*, 508 F.3d 263, 274 (5th Cir. 2007) (quoting *Sims v. Washex Mach. Corp.*, 932 S.W.2d 559, 562 (Tex. App.—Houston 1995, no pet.)); *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 382 (Tex. 1995).

Under the learned intermediary doctrine, a manufacturer can fulfill its duty to warn by providing adequate warnings to a patient’s doctor. *Ackermann v. Wyeth Pharms.*, 526 F.3d 203, 207 (5th Cir. 2008); see also *Alm v. Aluminum Co. of Am.*, 717 S.W.2d 588, 591 (Tex. 1986). Under this doctrine, “if the doctor is properly warned of the possibility of a side effect and is advised of the symptoms normally accompanying the side effect, it is anticipated that injury to the patient will be avoided.” *Id.* As a result, this doctrine excuses a manufacturer “from warning each patient who receives the product when the manufacturer properly warns the prescribing physician of the product’s dangers.” *Id.* (citing *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 467-68 (5th Cir. 1999)). The Fifth Circuit has applied the learned intermediary doctrine to medical device cases. *In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.*, 888 F.3d 753, 774 (5th Cir. 2018).

If the learned intermediary doctrine applies, “a plaintiff must show that (1) the warning was defective, and (2) the failure to warn was a producing cause of the injury.” *Ackermann*, 526 F.3d at 207. “[W]hen the prescribing physician is aware of the product’s risks and decides to use it anyway, any inadequacy of the product’s warning, as a matter of law, is not the producing cause of the patient’s injuries.” *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 170 (Tex. 2012). Likewise, a warning that “specifically mentions the circumstances complained of . . . is adequate as a matter of law.” *Hale v. Metrex Research Co.*, 963 F.3d 424, 428 (5th Cir. 2020) (quoting *Seifried v. Hygenic Corp.*, 410 S.W.3d 427 (Tex. App.—Houston 2013, no pet.)).

Plaintiffs allege that (1) Medtronic did not adequately warn the learned intermediary, Dr. Hebel, of risks associated with the EPG; and (2) if the warnings had been adequate, Mr. Harrison's injuries would have been avoided because Dr. Hebel would not have used the EPG. 2d Am. Compl. ¶¶ 32-35, 44. Specifically, Plaintiffs allege:

there was an inherent risk in the intended or reasonably foreseeable use of the product that the product could misfire, that the battery drawer electrical contact could fail to maintain a constant connection with the battery, resulting in a failure to maintain steady power, which could result in power failure, power surges, and untimely activation; or that Degradation of the lead connector could result in intermittent connection and shorting, resulting in untimely activation, have a software error, calibration error, improper instructions for use or other errors, causing serious injury.

Id. ¶ 32. Plaintiffs contend that Medtronic failed to adequately warn against these risks or instruct Dr. Hebel on how to use the EPG in a way that would have avoided these risks. *Id.* ¶¶ 32-35. Plaintiffs also allege that the warnings provided “were not placed in a location to reasonably be expected to catch the attention of the user,” and “failed to inform the user of the nature of the danger.” *Id.* ¶ 32.

Plaintiffs' allegations that the warnings were defective are conclusory and thus insufficient. Plaintiffs fail to allege with any particularity what information the EPG's warnings included. *See Id.* ¶¶ 32-35. Nor do Plaintiffs point to any specific warning that was defective, instead making only general assertions about the EPG's inadequacy. *Carpenter*, 2019 WL 3322091, at *9 (dismissing complaint that “lack[ed] sufficiently specific allegations regarding the warnings provided to the prescribing physicians . . . and the basis for the warnings being inadequate as to render the surgical implant unreasonably dangerous.”). Although Plaintiffs allege that the EPG's warnings were not placed in an adequate location on the device, Plaintiffs do not indicate where the warnings were actually placed or describe a more appropriate location.

Plaintiffs also inadequately allege that Dr. Hebeler would have changed his treatment decision had he received an adequate warning. Other than the unsupported assertion that a different product would have been used if Defendant had provided adequate warnings for the EPG, Plaintiffs do not explain how Dr. Hebeler would have changed his treatment decision. 2d Am. Compl. ¶ 35; *Centocor, Inc.*, 372 S.W.3d at 170.

Even if Plaintiffs had alleged specific defects, the warnings given for EPG (contained in its “Technical Manual”) were adequate because they specifically mention risk of the harm that Mr. Harrison allegedly suffered.¹ *See Hale*, 963 F.3d at 428. The Technical Manual states that “operational failure of the temporary pacemaker can occur as the result of battery depletion, mishandling, or random component failure.” Technical Manual 14. The Technical Manual also states that operations failures can include “loss of control of rate, output, sensitivity, or power” and warns of possible problems with the lead pacing system, including “inadvertent disconnection” and “lead fracture or displacement causing intermittent or complete loss of capture and/or sensing.” *Id.* at 14, 19. Finally, the Technical Manual warns that patients should be monitored to ensure that the EPG is working properly. *See id.* at 9, 12. These warnings address precisely the purported malfunction that Plaintiffs allege caused Mr. Harrison’s injuries. Accordingly, Plaintiffs have failed to state a marketing defect claim.

(3) *Design Defect*

“[T]o recover for a products liability claim alleging a design defect, a plaintiff must prove that (1) the product was defectively designed so as to render it unreasonably dangerous; (2) a safer alternative design existed; and (3) the defect was a producing cause of the injury for which the

¹ The Court can consider the Technical Manual [ECF No. 39] at the Motion to Dismiss stage because it was attached to Defendant’s motion to dismiss, the warnings provided in it were referenced in the Complaint, and it is central to Plaintiffs’ marketing defect claims. *Sullivan*, 600 F.3d at 546.

plaintiff seeks recovery.” *Casey*, 770 F.3d at 330 (citing *Goodner v. Hyundai Motor Co.*, 650 F.3d 1034, 1040 (5th Cir. 2011)). A product is “unreasonably dangerous when its risk outweighs its utility.” *Genie Indus., Inc. v. Matak*, 462 S.W.3d 1, 6 (Tex. 2015). Conclusory allegations which only address dangerousness or poor quality will not suffice, as design defects “are not presumed by the mere fact that an accident or injury occurred.” *Arant v. Wal-Mart Stores, Inc.*, 628 F. App’x. 237, 239 (5th Cir. 2015) (citing *Krummel v. Bombardier Corp.*, 206 F.3d 548, 551 (5th Cir. 2000).

A plaintiff must plead the existence of a safer alternative design to allege a plausible design defect claim. *Casey*, 770 F.3d at 330 (citing *Hernandez v. Tokai Corp.*, 2 S.W.3d 251, 258 (Tex. 1999)). A safer alternative design “is one that would have prevented or significantly reduced the risk of the injury, would not substantially impair the product’s utility, and was economically and technologically feasible at the time.” *Id.* at 7.

Plaintiffs allege the EPG had three design defects: (1) “a tendency for software or mechanical malfunction”; (2) “the battery drawer electrical contact fails to maintain a constant connection with the battery, resulting in a failure to maintain steady power, which results in power failure, power surges, and untimely activation”; and (3) “degradation of the lead connector resulting in intermittent connection and shorting, resulting in untimely activation.” 2d Am. Compl. ¶ 36. These allegations describe “tendencies” or “results” of perceived problems with the EPG. Plaintiffs do not articulate with any specificity defects in the design of the EPG. In other words, Plaintiffs have pleaded that the EPG malfunctions without pleading a design defect. Moreover, Plaintiffs engage in no substantive evaluation of whether these purported risks outweigh the benefits of the EPG.

Plaintiffs’ proposed safer alternative design is simply a pacemaker that does not have these three alleged design defects. *Id.* ¶ 37. Rather than identifying a particular alternative design,

Plaintiffs rely on conclusory statements that amount to a recital of the legal standard for a safer alternative design. *Id.* Plaintiffs assert that a hypothetical pacemaker without the alleged defects existed at the time the product left Defendant's control, which would have "prevented or significantly reduced the risk" of Mr. Harrison's injury without substantially impairing the product's utility and was economically and technically feasible. *Id.* Plaintiffs' proposed safer alternative design is conclusory, and, as a result, Plaintiffs have failed to allege a plausible claim for a design defect. See *Villarreal v. Navistar, Inc.*, No. 3:20-CV-02980-X, 2021 WL 1894700, at *2 (N.D. Tex. May 11, 2021) (allegations of a "seat structure that would not collapse," an "exterior structure that would not collapse inward," and "fuel system integrity that would prevent fuel escape" insufficient to plea safer alternative design).

B. Negligence

To prevail on a negligence claim, a plaintiff must establish the existence of a "duty, a breach of that duty, and damages proximately caused by the breach." *W. Invest., Inc. v. Urena*, 162 S.W.3d 547, 550 (Tex. 2005) (citing *Doe v. Boys Clubs of Greater Dallas, Inc.*, 907 S.W.2d 472, 477 (Tex. 1995)).

[A]lthough a negligence claim requires a different showing from a strict liability claim, a manufacturer logically cannot be held liable for failing to exercise ordinary care when producing a product that is not defective because: (1) if a product is not unreasonably dangerous because of the way it was manufactured, it was not negligent to manufacture it that way and (2) even if the manufacturer was somehow negligent in the design or production of the product, that negligence cannot have caused the plaintiff's injury because the negligence did not render the product "unreasonably dangerous."

Garrett v. Hamilton Standard Controls, Inc., 850 F.2d 253, 257 (5th Cir. 1988).

In support of their negligence claims, Plaintiffs recapitulate their manufacturing, marketing, and design defect allegations and provide no additional support for their claims that: (1) the EPG was negligently manufactured; (2) the EPG was negligently designed; (3) Defendant

negligently failed to warn the physician or hospital of the EPG's risks; (4) Defendant negligently failed to place a warning where it could reasonably be expected to catch the attention of the user; and (5) Defendant negligently failed to properly instruct how to safely use the EPG. 2d Am. Compl. ¶ 49. Plaintiffs again invoke the doctrine of *res ipsa loquitur* in support of their negligence claims. *Id.*

For the reasons stated above, Plaintiffs have failed to state a plausible claim for manufacturing, design, or marketing defect. This failure is fatal to Plaintiffs' negligence claims. *Garrett*, 850 F.2d at 257.

C. *Breach of Implied Warranty*

Under Texas law, a seller of goods implicitly warrants that the goods "are fit for ordinary purposes for which such goods are used." *Gen. Motors Corp. v. Brewer*, 966 S.W.2d 56, 57 (Tex. 1998). A seller of a good only breaches this warranty if a good is defective or "unfit for the ordinary purposes for which they are used because of a lack of something necessary for adequacy." *Id.* However, "a product which performs its ordinary function adequately does not breach the implied warranty of merchantability merely because it does not function as well as the buyer would like, or even as well as it could." *Id.*; see also *Plas-Tex, Inc. v. U.S. Steel Corp.*, 772 S.W.2d 442, 443-44 (Tex. 1989). In short, to state a claim successfully for breach of the implied warranty of merchantability, the goods at issue must be defective. *Id.*

Plaintiffs allege that Defendant breached the implied warranty of merchantability because of the previously alleged marketing and design defects. 2d Am. Compl. ¶¶ 58-70. Plaintiffs do not appear to allege that Defendant breached because of any manufacturing defects. *See id.*

Plaintiffs have not alleged a plausible claim for a breach of implied warranty, as they did not allege plausible claims for manufacturing, design, and marketing defects. Because Plaintiffs'

claim of breach is predicated entirely upon these insufficient allegations, Plaintiffs' claim of breach of the implied warranty of merchantability is also insufficient.

In addition, Plaintiffs' claim for breach of implied warranty of merchantability is barred because they failed to provide Defendant timely notice of this claim. Texas law requires that a plaintiff notify a seller of an alleged breach of implied warranty "within a reasonable time after he discovers or should have discovered any breach or be barred from any remedy." TEX. BUS. & COMM. CODE § 2.607(c)(1). "The notice provisions of the Texas Code are liberally construed, and whether notice is adequate depends on the reasonableness of buyers' efforts to communicate their dissatisfaction in light of all the circumstances." *Ameristar Jet Charter, Inc. v. Signal Composites, Inc.*, 271 F.3d 624, 628 (5th Cir. 2001). Reasonable notice is ordinarily a question of fact, but becomes a question of law when "there is no room for ordinary minds to differ about the proper conclusion to be drawn from the evidence." *Palmco Corp. v. American Airlines, Inc.*, 983 F.2d 681, 685 (5th Cir. 1993).

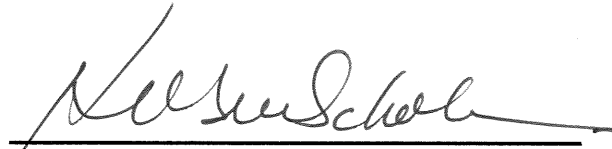
Plaintiffs informed Defendant of their potential claim for breach of implied warranty of merchantability in a letter dated July 9, 2019, nearly two years after the EPG allegedly malfunctioned. *See* ECF No. 39 at 108-10. Plaintiffs claim this was a reasonable time to give notice because "they were not aware of the malfunction of the [EPG]" until sometime after Mr. Harrison's cardiac arrest. Yet Defendant correctly points out that this "argument is inconsistent with Plaintiffs' entire case . . . that the defects in the EPG were so clear that *nothing* could explain what happened to Mr. Harrison except that the EPG was defective." Def's. Reply Br. [ECF No. 43] at 9. Accordingly, the Court finds that Plaintiffs failed to provide Defendant notice of their breach of implied warranty claims within a reasonable time.

IV. CONCLUSION

Accepting well-pleaded facts as true and viewing them in the light most favorable to Plaintiffs, the Court **GRANTS** Defendant's Motion to Dismiss Plaintiffs' Amended Complaint. Though Plaintiffs have already amended their complaint twice, this is the first time the Court has ruled on a motion to dismiss. Accordingly, the Court **GRANTS** Plaintiffs leave to file an amended complaint by October 11, 2021. If an amended complaint is not filed within such time, this action will be dismissed with prejudice

SO ORDERED.

SIGNED September 20, 2021.


KAREN GREN SCHOLER
UNITED STATES DISTRICT JUDGE