

**UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA**

In re: GUIDANT CORP. IMPLANTABLE  
DEFIBRILLATORS PRODUCTS  
LIABILITY LITIGATION

MDL No. 05-1708 (DWF/AJB)

This Document Relates to:

Leopoldo Duron, Jr.,

Plaintiff,

v. Civil No. 06-25 (DWF/AJB)

Guidant Corporation, Guidant Sales  
Corporation, Boston Scientific Corp., and  
Cardiac Pacemakers, Inc.,

Defendants.

**MEMORANDUM OPINION  
AND ORDER**

This matter came before the Court pursuant to a Motion for Summary Judgment on Plaintiff Leopoldo Duron, Jr.'s Failure-to-Warn Claims Based on the Learned Intermediary Doctrine brought by Guidant Corporation, Guidant Sales Corporation, Boston Scientific Corp., and Cardiac Pacemakers, Inc. (collectively, "Guidant"). For the reasons set forth below, the Court grants in part and denies in part the motion.

## BACKGROUND

The factual background and procedural history of this case are fully set forth in the Court's May 22, 2007 and June 12, 2007 Orders. Briefly, in March 2002, Dr. Steven Higgins, an electrophysiologist,<sup>1</sup> surgically implanted an implantable cardioverter defibrillator ("ICD"), the VENTAK PRIZM 2 DR, Model 1861 (the "Prizm 2"), in Duron after an electrophysiology study showed that he needed an ICD. Guidant manufactured the Prizm 2. Prior to the surgery, Guidant provided Dr. Higgins with a copy of the Prizm 2's Physician Technical Manual and System Guide. In that manual and/or guide, Guidant warned that Prizm 2 devices were "subject to random component failure" and that "[s]uch failure could cause inappropriate shocks, induction of arrhythmias or inability to sense arrhythmias, and could lead to the patient's death."<sup>2</sup>

In June 2005, Guidant recalled Prizm 2 devices, including Duron's device, which were manufactured prior to April 2002. Shortly thereafter, the Food and Drug Administration classified Guidant's recall as a Class I recall. A Class I recall is reserved for devices that create a reasonable probability of serious adverse health consequence or death. On August 19, 2005, Dr. Sardul Singh explanted Duron's Prizm 2 and replaced it

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<sup>1</sup> An electrophysiologist is a cardiologist who has had additional education and training in the diagnosis and treatment of abnormal heart rhythms. Although the parties did not provide any actual numbers, the Court notes there is a relatively small number (1,000-2,000 range) of electrophysiologists in the United States.

<sup>2</sup> Guidant did not provide the Court with a copy of the manual; instead, these quotes are taken from Dr. Higgins' Affidavit. (Guidant's Summ. J. Mem., Ex. I.) Duron does contest the accuracy of the quotations.

with a different Guidant-manufactured ICD. Subsequently, Duron commenced an action against Guidant based on alleged injuries he suffered as a result of the Prizm 2.

## **ARGUMENT**

### **I. Motion for Summary Judgment**

Summary judgment is proper if there are no disputed issues of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). The Court must view the evidence and the inferences, which may be reasonably drawn from the evidence, in the light most favorable to the nonmoving party. *Enter. Bank v. Magna Bank of Mo.*, 92 F.3d 743, 747 (8th Cir. 1996). As the United States Supreme Court has stated, “[s]ummary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed ‘to secure the just, speedy, and inexpensive determination of every action.’” *Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986) (quoting Fed. R. Civ. P. 1).

The moving party bears the burden of showing that there is no genuine issue of material fact and that it is entitled to judgment as a matter of law. *Enter. Bank*, 92 F. 3d at 747. The nonmoving party must demonstrate the existence of specific facts in the record that create a genuine issue for trial. *Krenik v. County of Le Sueur*, 47 F.3d 953, 957 (8th Cir. 1995). A party opposing a properly supported motion for summary judgment may not rest upon mere allegations or denials of his pleading, but must set forth specific facts showing that there is a genuine issue for trial. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256 (1986).

Guidant moves for summary judgment on Duron’s failure-to-warn claims based on the learned intermediary doctrine. The parties agree that the learned intermediary doctrine applies to Duron’s failure-to-warn claims and on the standard used for failure-to-warn claims under California law. They disagree about the impact of that doctrine and standard on Duron’s claims.<sup>3</sup>

Under California law, it is well-settled that a manufacturer of medical devices or prescription drugs owes to the medical profession the duty of providing adequate warnings if it knows, or has reason to know, of any dangerous side effects of its devices or drugs. *See Carlin*, 13 Cal. 4th at 1112-13. California follows the learned intermediary doctrine, which provides that the duty to warn “runs to the physician, not to the patient.” *Id.* at 1116. Thus, a manufacturer discharges its duty to warn if it provides adequate warnings to the physician about any known or reasonably knowable dangerous side effects, regardless of whether the warning reaches the patient. The adequacy of a warning is controlled by comment k of the Restatement (Second) of Torts, § 402A, and it

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<sup>3</sup> It is unclear which exact counts in Duron’s Amended Complaint-by-Adoption the parties classify as the “failure-to-warn” claims. Guidant classifies the claims “as strict liability warning and negligent failure to warn, [and]. . . the consumer protection claims to the extent they are based on a failure to warn theory.” (6/19/07 Tr. at 58.) Duron classifies his failure-to-warn claims as those claims that “sound in fraud or something akin to fraud or negligence.” (*Id.* at 63.) Given this, Counts I, III, VI, and VIII are likely implicated. The standards for such claims are quite different. *See Carlin v. Superior Court*, 13 Cal. 4th 1104, 1112-13 (Cal. 1996) (discussing differences between negligent failure-to-warn claims and strict liability failure-to-warn claims). Because the focus of the parties’ briefing is on the “known or knowable” aspect of failure to warn, which is derived from strict liability cases, the focus of this Order is on that standard.

requires that a manufacturer's device be accompanied with warnings of a device's "dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution." *Brown v. Superior Court*, 44 Cal. 3d 1049, 1061 (Cal. 1988). The Court assumes, and the parties appear to agree, that under California law, a plaintiff asserting failure-to-warn claims must prove not only that no warning was provided or the warning was inadequate, but also that the inadequacy or absence of the warning caused the plaintiff's injury. *Motus v. Pfizer, Inc.*, 196 F. Supp. 2d 984, 993 (C.D. Cal. 2001) (applying California law and concluding that California courts would likely not apply a reputable presumption for causation in failure-to-warn claims).

Using these standards, Guidant asserts that it is entitled to summary judgment on Duron's failure-to-warn claims for three primary reasons. The Court will discuss each in turn.

**A. Pre-Implant Warning**

Dr. Higgins implanted the Prizm 2 in Duron on March 9, 2002. Prior to that time, Guidant had received one report on February 1, 2002, involving arcing in the header of a Prizm 2. Guidant received that device on February 12, 2002, and its engineers analyzed the device and determined that the incident was caused by a short circuit within the header. The parties dispute the result of those findings and whether, at that time or before, Guidant knew or should have known that there was a potentially systematic problem in the Prizm 2s, whether that problem is with polyimide or with the placement of the DF- feed through wire.

Guidant asserts that it had no duty to warn Duron's doctor of the February 1, 2002 incident because, at that time, it did not know the cause of the problem; therefore, it contends that it could not have given an accurate warning. And, Guidant argues that its warning about "random component failure" covers the February 1, 2002 incident. Guidant also asserts that over-warning doctors carries with it a risk that the warnings will go unheeded. In addition, Guidant contends that, at that time, the FDA precluded it from giving a warning because there was no significant medical evidence to suggest there was a possible health hazard to Prizm 2 patients. Finally, Guidant characterizes Duron's failure-to-warn claims as a back-door way to get to design defect claims, which are unavailable to him under California law.

Duron responds that Guidant did have a duty to warn of the February 1, 2002 incident because it knew or should have known that the device defect at issue was a systematic, as opposed to a random, defect that could lead to death or serious injury. He points out that Guidant's own Independent Panel concluded that reports of single events should be communicated to doctors if (a) there is a risk of death or serious injury; (b) there is a suspected or defined basis for the malfunction or failure; and (c) the failure is likely to be systematic and to occur in other patients. (Duron's Ex. 66. at 19.) Moreover, even if Guidant did not know the "root cause" of the February incident, Duron points to several scientific authorities published years before Duron's implant surgery to show that Guidant should have known of the problems created by polyimide when it is placed in contact with bodily fluids.

The Court agrees with Duron. It is true that medical device manufacturers may not have a duty to warn after receiving every single incident report, depending on the circumstances underlying the incident report and the cause of that report. Here, however, there are genuine issues of material fact with respect to what Guidant knew or should have known after receiving the February 1, 2002 report and what Guidant knew or should have known about polyimide prior to Duron's implant. The FDA's actions or inactions may be admissible to show whether these risks were known or reasonably scientifically knowable.<sup>4</sup> *Carlin*, 13 Cal. 4th at 1111. These genuine issues of material fact need to be resolved before determining whether Guidant should have issued specific warnings that the Prizm 2 may malfunction as a result of polyimide degradation. Guidant's boilerplate warnings of random failures or potential mortality due to failure to defibrillate do not cover failures caused by specific, known or knowable, causes and do not insulate Guidant from potential liability. For these reasons, the Court denies Guidant's motion with respect to whether its warnings were adequate prior to Duron's implant surgery. *See id.* at 1116-17.

### **B. Post-Implant Warning**

The parties agree that California law imposes a continuous post-sale duty to warn so long as the device remains in use. *See Valentine v. Baxter Healthcare Corp.*, 81 Cal. Rptr. 2d 252, 262 (Cal. Ct. App. 1999). Guidant moves for summary judgment on any

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<sup>4</sup> The June 29, 2007 *Daubert* Order addresses the evidentiary implications of the FDA actions or inactions.

claims involving post-implant warnings because it asserts that Duron cannot show that any post-implant warnings caused his injuries. Duron's alleged injuries stem from the June 2005 recall and his subsequent explant surgery in August 2005. Duron does not specifically respond to this argument; instead he focuses on what Guidant knew or should have known post-implant surgery. The Court agrees with Guidant that Duron's post-implant warning claims must fail because there is no causal link between those warnings and his alleged injuries. Accordingly, the Court grants Guidant's motion with respect to this aspect of Duron's failure-to-warn claims.

### **C. Causation**

As stated earlier, the Court assumes, and the parties appear to agree, that under California law, a plaintiff must show that the inadequacy or lack of warning caused the plaintiff's injury. *Motus*, 196 F. Supp. 2d at 995. In connection with its summary judgment motion, Guidant submitted Dr. Higgins' affidavit, in which he avers that his decision to implant the Prizm 2 in Duron would not have changed had Guidant warned him of the February 1, 2002 incident. Dr. Higgins further states that prior to Duron's implant surgery, he was aware that "electrical arcing and short circuiting in ICDs may occur." (Guidant's Summ. J. Mem. Ex. I, ¶ 10.) Dr. Higgins does not state if he knew why the arcing and short circuiting might occur, but he does state that "these risks have been generally known in the medical community for over twenty years." (*Id.* at ¶ 11.) He further explains that he would not want or expect to be notified every time an ICD fails. Dr. Higgins does not discuss polyimide degradation. Based on Dr. Higgins' affidavit, Guidant asserts that it is entitled to summary judgment because Duron cannot

establish causation, given that Dr. Higgins would have implanted Duron's Prizm 2 even if he had the warnings Duron says Guidant should have given.

Both before and after Duron's implant, Dr. Higgins had a long-standing relationship with Guidant. Not surprisingly, the parties characterize the Dr. Higgins-Guidant relationship differently. Guidant asserts that Dr. Higgins was simply reasonably compensated for consulting work that he performed for Guidant and for his service as a member of Guidant's Medical Advisory Board. It contends that Dr. Higgins merely "thinks Guidant is a great company because Guidant makes great devices that save people's lives." (6/19/07 Tr. at 52.) Guidant further asserts that Dr. Higgins has no bias for Guidant because many other electrophysiologists in the United States have relationships with medical device companies similar to Dr. Higgins' relationship with Guidant. According to Guidant, Dr. Higgins' "admiration for Guidant is entirely understandable and pretty typical of the vast majority of [electrophysiologists]." (*Id.* at 54.)

In response, Duron points out that, among other things, Guidant paid for Dr. Higgins, Guidant's Cardiac Rhythm Management Division President Fred McCoy, and other top Guidant executives to travel to Ireland for a golf trip to celebrate Dr. Higgins' birthday. He also points out that top Guidant executives regularly visited Dr. Higgins at his home and went on golfing trips in the United States. He notes that in e-mails to Guidant, Dr. Higgins described himself as Guidant's "alter ego" and as a "hit man." (*Id.* at 73-74.) In addition, Duron states that on-going, past-due discovery will show that Guidant paid Dr. Higgins very large sums of money for his various consulting

and study activities. Finally, Duron points to other doctors' testimony to demonstrate that other doctors would not have implanted the Prizm 2 in their patients had they been properly warned of the risks of arcing and polyimide degradation.

Guidant's causation argument is that there is no way for Duron to succeed on his failure-to-warn claims because his implanting doctor, despite his relationship with Guidant, averred that he would have implanted the Prizm 2 in Duron independent of any additional or different warnings. Guidant also argues that other doctors' opinions are irrelevant. But the law does not turn a blind eye to an implanting doctor's bias or interest. Rather, Dr. Higgins' statements must be viewed in conjunction with his ties and/or relationship to Guidant. *See, e.g., Stevens v. Parke, Davis, & Co.*, 9 Cal. 3d 51, 66-67 (Cal. 1973) (explaining that the evidence supported the jury's inference that the doctor was induced to prescribe a drug based on defendant's overpromotion); *see also Motus*, 196 F. Supp. 2d at 997 (explaining that summary judgment would not be warranted if plaintiff had presented evidence putting the physician's credibility in question).

Contrary to Guidant's assertions, the Court doubts that Guidant provides European-birthday-golfing-trips to most electrophysiologists in the United States, that top Guidant executives frequently visit electrophysiologists' homes, and that Guidant or other ICD manufacturers pay electrophysiologists the sums Guidant paid Dr. Higgins. If this is true, at a minimum, it creates an appearance of bias and interest that the jury is entitled to consider and that certainly deserves an explanation. Given this, summary judgment is inappropriate because, as discussed above, genuine issues of material fact

exist concerning Dr. Higgins' credibility and whether Duron can establish causation.

Therefore, the Court denies Guidant's motion with respect to causation.

### CONCLUSION

Based on the foregoing, it is **HEREBY ORDERED** that:

1. Guidant's Motion for Summary Judgment on Plaintiff Leopoldo Duron, Jr.'s Failure-to-Warn Claims Based on the Learned Intermediary Doctrine (MDL No. 05-1708 (DWF/AJB), Doc. No. 1458; Civ. No. 06-25 (DWF/AJB), Doc. No. 25) is

**GRANTED IN PART AND DENIED IN PART** as follows:

a. Guidant's Motion for Summary Judgment with respect to Post-Implant Warnings is **GRANTED**.

b. Guidant's Motion for Summary Judgment with respect to Pre-Implant Warnings and Causation is **DENIED**.

Dated: July 6, 2007

s/Donovan W. Frank  
DONOVAN W. FRANK  
Judge of United States District Court