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. vs. Case No. 06-00025 Guidant Corp., et al.	**DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFF LEOPOLDO DURON, JR.'S MOTION IN LIMINE**

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I. INTRODUCTION

Guidant requests that the Court deny the following of Mr. Duron's motions in limine.

II. GUIDANT'S OPPOSITION TO PLAINTIFF'S MOTION IN LIMINE TO PRECLUDE ANY ARGUMENT THAT THE FDA DID NOT FIND REGULATORY VIOLATIONS IN CONNECTION WITH THE CLASS I RECALL OF THE PRIZM 2 AND THE PRIZM 2 PMA SUBMISSIONS

Mr. Duron seeks to preclude Guidant from arguing at trial that the FDA did not find regulatory violations in connection with its voluntary recall of the PRIZM 2. *See* Plaintiff's Omnibus Memorandum in Support of His Motion in Limine to Exclude Certain Evidence at Trial at 1 ("Memo in Support"). But this is a question of fact that the jury must decide. In this section of his Memo in Support, Mr. Duron does not cite to a single Federal Rule of Evidence or any case law to support such a blanket preclusion. At the very least, there are issues of fact for the jury to decide regarding whether Guidant made any such violations. An outright denial of Guidant's ability to defend against such accusations would mislead the jury and severely prejudice Guidant. Guidant therefore respectfully requests that this court deny Mr. Duron's motion.

A. Whether Guidant Violated Federal Regulations, Which It Denies, is a Question of Fact for the Jury.

Guidant concedes that its voluntary action related to the PRIZM 2 was classified as a Class I recall by the FDA. But Guidant denies that it violated any federal law or regulations in the design, manufacture and distribution of the PRIZM 2. Whether Guidant violated federal regulations is a justiciable issue and a question of fact for the jury to decide.

The FDA's recall classification of the PRIZM 2 "was outside the regulatory criteria for a Class I recall." Expert Report of Robert L. Sheridan at 11 (Ex. 1). A Class I recall is defined as "a situation in which there is a reasonable probability that the use of . . . a violative *product* will cause serious adverse health consequences or death." 21 C.F.R. § 7.3(m)(1) (emphasis added). The FDA was also careful to explain "that the reasonable probability of adverse health consequences or death applied, not to the entire [PRIZM 2] device population, but only to a particular device that was malfunctioning." *Id.*; see also FDA News P05-37 (July 1, 2005) (Ex. 2); FDA Advice for Patients, last updated Jan. 28, 2006 (Ex. 3). Mr. Duron's specific device never malfunctioned, and thus was outside the Class I recall criteria.

The FDA also acknowledged that the number of reported failures was "very small compared with the number of devices in use, so it's unlikely that a patient will experience one of these events." FDA Advice for Patients, last updated Jan. 28, 2006 (Ex. 3). And the FDA has stated that its determination of a Class I recall did "not necessarily mean that the device will be removed from the market or that the device needs to be removed from the patient." *Id.* The FDA has never publicly stated that Guidant violated any federal regulations, or if it did, which ones they were. Even if the FDA concluded that Guidant violated federal law or regulations, it is not conclusive proof that Mr. Duron's product was defective in any way.

To preclude wholesale any argument that Guidant did not violate federal regulations would be an overly broad prohibition. In fact, numerous courts have rejected

the FDCA-based negligence per se action that Mr. Duron claims applies in this case.[1] And Mr. Duron cites to no case law or rules of evidence to support his attempted blanket preclusion. Clearly there is a difference of opinion as to the facts underlying how the FDA classified Guidant's voluntary actions concerning the PRIZM 2 and whether Guidant violated any federal regulations. Thus, the trier of fact – the jury – should be entitled to hear Guidant's position on these matters. Guidant has a right to defend all allegations against it. Mr. Duron has the burden of proving that his interpretation of the facts establishes the elements for his causes of action. He should not be allowed to entirely preclude Guidant's position that it did not violate any federal laws or regulations simply because of the FDA's classification of the PRIZM 2 voluntary recall, especially when Guidant disagrees with the FDA's assessment.

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[1] **Fourth Circuit**: *Baraukas v. Danek Medical, Inc.*, No. 6:97CV00613, 2000 WL 223508, at *4 n.2 (M.D.N.C. Jan. 13, 2000) (applying North Carolina law)

Fifth Circuit: *Hackett v. G.D. Searle & Co.*, 246 F. Supp. 2d 591, 594 (W.D. Tex. 2002) (applying Texas law)

Sixth Circuit: *In re Meridia Prods. Liab. Liab. Litig.*, 328 F. Supp. 2d 791, 817 & n.23 (N.D. Ohio 2004), *aff'd* 447 F.3d 861 (6th Cir. 2006) (applying Ohio law)

Seventh Circuit: *Schwarz Pharma, Inc. v. Breckenridge Pharm., Inc.*, 388 F. Supp. 2d 967, 974-75 (E.D. Wis. 2005) (applying Wisconsin law);

Eighth Circuit: *Vanderwerf v. SmithKlineBeecham Corp.*, 414 F. Supp. 2d 1023, 1027 (D. Kan. 2006) (applying Kansas law); *Pulice v. Smith & Nephew Richards, Inc.*, No. 97-2080, 1999 WL 613370, at *6 (W.D. Ark. Mar. 29, 1999) (applying Arkansas law)

Ninth Circuit: *Little v. Depuy Motech, Inc.*, No. 96CV0393-L JAH, 2000 WL 1519962, at *9 (S.D. Cal. Jun. 13, 2000) (applying California law)

Tenth Circuit: *Alexander v. Smith & Nephew, P.L.C.*, 98 F. Supp. 2d 1299, 1308 (N.D. Okla. 2000) (applying Oklahoma law)

Eleventh Circuit: *Blinn v. Smith & Nephew Richards, Inc.*, 55 F. Supp. 2d 1353, 1361 (M.D. Fla. 1999) (applying Florida law)

Minnesota State Court: *In re Shigellosis Litig.*, 647 N.W.2d 1, 10 (Minn. App. 2002), *review denied* (Minn. Aug. 20, 2002).

B. The FDA Did Not Find Numerous Regulatory Violations Related to the PRIZM 2 During a Post-Recall Inspection of Guidant's Facilities

Mr. Duron refers in his motion to an FDA inspection of Guidant's facilities between August 22 and September 1, 2005, and a related warning letter sent to Guidant in December, 2005. Memo in Support at 3. He argues that such observations and the associated letter demonstrate "numerous violations" of FDA regulations. *Id*. Mr. Duron appears to be arguing that because of these alleged "numerous violations," Guidant should generally be precluded from any argument that the FDA did not find regulatory violations related to the recall of the PRIZM 2. Both the Form 483 observations and the associated letter referred to by Mr. Duron are, however, inadmissible. Furthermore, not only is Mr. Duron's argument illogical, it also misconstrues the evidence on which it is based. For all of these reasons, Mr. Duron's motion should be denied.

First, evidence of FDA observations or associated warning letters from August 22, 2005, or later, are inadmissible as irrelevant, unduly prejudicial and related to subsequent remedial measures. Fed. R. Evid. 401, 402, 403 and 407.[2] Mr. Duron's alleged injury stems from the manufacture and implantation of his PRIZM 2. All of the relevant conduct possibly contributing to that injury occurred no later than March 9, 2002. Moreover, in terms of the Form 483, it is the time of manufacture of Mr. Duron's device, which was prior to his implantation date in 2002, that is the most relevant. Thus the inspection of Guidant's facilities was conducted and the associated letter was sent long after Mr. Duron's specific device was manufactured and implanted. During the

[2] On June 15, 2007, Guidant filed a Consolidated Motion in Limine to exclude certain evidence, including the FDA Form 483 observations and the related warning letter.

period relevant to Mr. Duron's device, the FDA conducted several inspections and no violations were noted. Indeed, a separate inspection occurred in May 2005 specific to the PRIZM 2, Model 1861 devices and no action resulted from it. Thus, neither the August 22, 2005 inspection and resulting warning letter, nor any alleged regulatory violation implicated by either, can impact any fact of consequence to this litigation. Such inadmissible evidence does not justify an order precluding Guidant from presenting to the jury the facts that support its defense. Mr. Duron's motion should be denied.

Mr. Duron argues that the Form 483 and the associated warning letter detailed "numerous violations." The observations made by the FDA, however, do not relate to Mr. Duron's device. In fact, the warning letter makes no specific reference to the PRIZM 2 product line, nor do any references in the letter to devices or device components relate to device headers, which is where the potential arcing problem at issue with the PRIZM 2 is centered. Any evidence related to (1) other products manufactured by Guidant or (2) concerns unrelated to the potential arcing in the header of the PRIZM 2 is inadmissible as irrelevant and unduly prejudicial. Fed. R. Evid. 401, 402 and 403. Such inadmissible and factually irrelevant evidence does not warrant an order from this Court preventing Guidant from presenting facts of consequence to this jury. Mr. Duron's motion should be denied.

Finally, Mr. Duron's argument is simply illogical. He argues that because the FDA allegedly found post-recall regulatory violations it would be misleading for Guidant to argue that the FDA did not find violations at the time of the Recall. Memo in Support at 4. This seems to assume that because violations were allegedly identified in

September, 2005, they must have existed prior to that time. That is simply conjecture and is completely irrelevant. Guidant should have the opportunity to argue to the jury any fact that is relevant to Mr. Duron's claims, including the fact that the FDA made no finding regarding regulatory violations prior to Mr. Duron's alleged injury. Mr. Duron's motion should be denied.

C. The FDA Never Revoked the PRIZM 2 PMA, Which Further Demonstrates That Guidant Did Not Violate Federal Regulations

With no real analysis or citation to case law, Mr. Duron claims that the FDA's classification of Guidant's voluntary actions related to the PRIZM 2 as a Class I recall means Guidant *per se* violated federal regulations. Memo in Support at 5. In turn, he argues this means that Guidant's PRIZM 2 Premarket Approval (PMA) was therefore invalid. Memo in Support at 5. But as addressed above in Part II.A, whether or not Guidant violated any federal regulations, which Guidant denies, is a question of fact for the jury.

Also, the PMA of the PRIZM 2 has never been revoked by the FDA. There are strict procedures for the withdrawal of a PMA. Expert Report of Robert L. Sheridan at 7 (Ex. 1) Withdrawal of a PMA is not automatic or self-executing as Mr. Duron claims is the case. *Id.* "[T]he recall of a PMA-approved device does not have the effect of suspending, withdrawing, or invalidating the approval of a device. In the absence of any suspension or withdrawal of a PMA approval, the approval remains in effect." *Id.* It is undisputed that the FDA has never suspended, withdrawn, or invalidated the PRIZM 2 PMA. Nor has the FDA ever ordered removal of the PRIZM 2 from the market. Most

telling, the FDA has continued to approve supplemental PMA applications, including applications directly associated with the PRIZM 2. *Id.* at 12.

The PRIZM 2 PMA has never been invalidated by the FDA. And Mr. Duron can cite to no FDA precedent or case law to back up his claim that the PMA has been invalidated. The continued viability of the PRIZM 2 PMA is probative of whether Guidant ever violated any federal regulations, and Guidant should not be precluded from making this argument at trial. Thus, Mr. Duron's attempt to invalidate the PMA based on the FDA's classifying Guidant's PRIZM 2 actions as a Class I recall fails.

D. That the FDA Never Mandated Explantation of All Recalled PRIZM 2 Devices Is Evidence of the PRIZM 2's Reliability

Mr. Duron asserts that "the FDA does not make blanket, across the board explant recommendations." Memo in Support at 6. Even if this is true, the FDA does make statements regarding explants that use stronger language depending on the risk involved. If the risks of detrimental effects to patients were high, the FDA could have stated that physicians should consider replacement of the device. Robert L. Sheridan Dep. at 263:21-264:22. (Ex. 4) For example, in an advisory sent to physicians regarding Shiley heart valves, the FDA specifically noted that the risk to a certain subset of patients "may be high enough to *consider* prophylactic valve replacement." FDA, Important Information on Shiley C-C Valve Fractures at 3 (Apr. 21, 1992) (Ex. 5).

Here, the FDA could have made a stronger statement concerning the PRIZM 2, but did not. In fact, the FDA acknowledged that because the reported failure rate of the PRIZM 2 is so low, it is unlikely that a patient will experience a device

malfunction. *See* FDA, Advice for Patients, last updated Jan. 28, 2006 (Ex. 3). These facts are all probative of the reliability of the PRIZM 2. Like his other arguments, Mr. Duron cites to no authority, whether cases or evidentiary rules, to support his attempt to exclude this information at trial. Guidant should not be prohibited from presenting these relevant facts to the jury.

Mr. Duron's attempt at a wholesale preclusion of any argument by Guidant that it did not violate federal regulations is based on inadmissible evidence, is factually inaccurate and illogical, and is unsupported by law. For all of these reasons, Guidant respectfully requests that this Court deny Mr. Duron's Motion in Limine.

III. GUIDANT'S OPPOSITION TO PLAINTIFF'S MOTION IN LIMINE TO PRECLUDE THE INTRODUCTION OF ANY EVIDENCE OR ANY ARGUMENT REGARDING GUIDANT'S PURPORTED GOOD DEEDS OR REPUTATION

Mr. Duron next argues that Guidant should not be permitted to introduce evidence or argument regarding its good deeds or reputation. However, the disputed character evidence is proof of essential elements of Guidant's defenses – particularly with respect to Mr. Duron's claim for punitive damages. The evidence Mr. Duron seeks to exclude is also highly relevant to the claims he has lodged against Guidant. The Court should therefore deny this motion.

A. The Character Evidence at Issue is Admissible to Prove Elements of Guidant's Defense.

Character evidence is admissible notwithstanding Fed. R. Evid. 404(a) where "character or a trait of character of a person is an essential element of a charge, claim, or defense . . . ." Fed. R. Evid. 405(b). Guidant's character is an essential element

of Mr. Duron's claim for punitive damages. *See, e.g.*, Restatement (Second) of Torts § 908, cmt. b ("Character of defendant's conduct. Since the purpose of punitive damages is not compensation of the plaintiff but punishment of the defendant and deterrence, these damages can be awarded only for conduct for which this remedy is appropriate – which is to say, conduct involving some element of outrage similar to that usually found in crime.")

> The general rule is that the good character of the defendant is not admissible in a civil case. But there is an exception to that general rule where the nature and basis of the subject matter of a civil case involves proof of criminal intent, such as cases wherein facts giving rise to allowance of punitive damages are alleged and proved. In the latter instances evidence relating to reputation and character which would be admissible in a criminal prosecution, based on the same facts proved, may be admitted in a civil case.

Raines v. Faulkner, 48 S.E.2d 393, 402 (W. Va. 1947); see also *Spaulding v. Mingo County Bd. of Educ.*, 526 S.E.2d 525, 530 (W. Va. 1999) ("character evidence is admissible where punitive damages are sought").

Under California law, the standard for proving punitive damages is provided in the California Civil Code, which states:

> In an action for the breach of an obligation not arising from contract, where it is proven by clear and convincing evidence that the defendant has been guilty of oppression, fraud, or malice, the plaintiff, in addition to the actual damages, may recover damages for the sake of example and by way of punishing the defendant.

Cal. Civ. Code, § 3294(a).

"Within the meaning of Civil Code section 3294, above, 'malice' means a wrongful intent to vex or annoy; 'oppression' means subjecting a person to cruel and

unjust hardship in conscious disregard of his rights." *J. R. Norton Co. v. Gen. Teamsters, Warehousemen & Helpers Union*, 208 Cal.App.3d 430, 444 (1989). To establish malice, it is insufficient to show merely that the defendant's conduct was negligent, grossly negligent, or even reckless. *Gawara v. U.S. Brass Corp.*, 63 Cal.App.4th 1341, 1361 (1998) (strict product liability case reversing award of punitive damages); *Flyer's Body Shop Profit Sharing Plan v. Ticor Title Ins. Co.*, 185 Cal.App.3d 1149, 1155 (1986). Thus, "evil motive" is the central element to the malice requirement for purposes of a punitive damage award, *G.D. Searle & Co. v. Super. Ct.*, 49 Cal.App.3d 22, 30 (1975), and "despicable conduct" must be conduct so vile, contemptible, wretched or loathsome that it is looked down upon and despised by ordinary decent people. *George F. Hillenbrand, Inc. v. Ins. Co. of N. Am.*, 104 Cal.App.4th 784, 817 (2002).

In order to defend itself against plaintiff's allegations on punitive damages, Guidant must be able to introduce evidence of its good character. *Cf. Tillery v. Richland*, 158 Cal.App.3d 957, 969 (1984) (affirming trial court's admission of character evidence negating plaintiff's allegation that defendant's acts were malicious and intentional). Mr. Duron is likely to present a litany of evidence of Guidant's purported bad character in support of his claim for punitive damages. *See generally* Plaintiff Leopoldo Duron's Memorandum in Response to Defendants' Motion for Summary Judgment On Mr. Duron's Punitive-Damage Claim [Dkt # 1708]. Guidant is entitled to counter any such evidence with Guidant's good character and acts. Guidant cannot be expected to defend itself against charges of malice, recklessness, and evil motives if, for instance, it cannot demonstrate that its employees are dedicated to the quality of the products they make.

Moreover, evidence regarding the character of the individuals at Guidant must be permitted because a corporation can only act through its officers, directors, or employees. Where punitive damages are sought from a corporate entity, a plaintiff must demonstrate that the "wrongful act giving rise to the exemplary damages be committed by an 'officer, director, or managing agent.'" *White v. Ultramar, Inc.*, 21 Cal.4th 563, 572 (1999); Cal. Civ. Code § 3294(b) ("With respect to the corporate employer, the advance knowledge and conscious disregard, authorization, ratification or act of oppression, fraud, or malice must be on the part of an officer, director, or managing agent of the corporation."). Thus, the good character of Guidant's officers, directors, and employees is critical to Guidant's defense of Mr. Duron's claim for punitive damages.

The evidence highlighted in Mr. Duron's motion is also key to Guidant's defense of other claims. For instance, Guidant's extensive experience in the development of ICDs bears directly on the issue of how the PRIZM 2 was designed. When Mr. Duron asserts that the PRIZM 2 is defective, Guidant must be able to show that it, in fact, is a "lifesaving" device. Likewise, when Mr. Duron complains that Guidant misrepresented the safety and efficacy of its devices, Guidant must be able to show that it not only followed industry standards in the amount of device information it provided to physicians, but also that it led the industry in that regard. Mr. Duron has leveled some very serious allegations against Guidant in this case, and Guidant must be permitted to refute them at trial.

B. The Character Evidence at Issue is Highly Relevant to Mr. Duron's Claims.

For many of the same reasons, the evidence Mr. Duron seeks to exclude is highly relevant. As a preliminary matter, Guidant's innovations in the development of ICDs, the fact that it makes life-saving devices, its leadership in the industry, and the location of its facility in Arden Hills are all standard pieces of background information that Guidant should be able to present to the jury. Surely Mr. Duron expects to tell the jury about his family, career, and general life history. The fact that Guidant is a corporation instead of a natural person should not deprive it of the same opportunity.

This evidence also bears directly on Mr. Duron's claims in this lawsuit. The fact that Guidant is an innovative company, and has a long history of producing life-saving devices is relevant to the development of the PRIZM 2. For instance, Mr. Duron claims that the PRIZM 2 is defective because it contains polyimide. The fact that Guidant successfully used polyimide in other highly reliable products for many years is critical to its defense of this point. Likewise, Guidant's leadership role in the industry is important evidence that its policies regarding issues such as physician communications and product performance reporting were reasonable. Finally, the dedication of Guidant's employees to the quality of its products is relevant in defending claims, for instance, that Guidant (and hence its employees) failed to exercise reasonable care in manufacturing the PRIZM 2.

The character evidence that Mr. Duron seeks to exclude bears on the essential elements of Guidant's defense, and is otherwise highly relevant. Moreover,

there is simply no basis for Mr. Duron's claims that this evidence is unfairly prejudicial. Consequently, the Court should deny Mr. Duron's motion.

IV. GUIDANT'S OPPOSITION TO PLAINTIFF'S MOTION IN LIMINE TO PRECLUDE THE INTRODUCTION OF ANY EVIDENCE OR ANY ARGUMENT THAT DR. SINGH OR KAISER PERMANENTE HOSPITAL EXPLANTED MR. DURON'S DEVICE FOR FINANCIAL MOTIVES.

Mr. Duron asserts that *any* evidence demonstrating that his explanting physician, Dr. Sardul Singh, or Kaiser Permanente ("Kaiser") hospital recommended the explant of his ICD based upon financial motivations, as opposed to medical necessity, is "irrelevant" and "speculative." *See* Plaintiffs' Motion *In Limine* at 14. But as this Court pointed out in its June 12, 2007 Order, whether or not explant surgery is doctor-recommended is a critical factor in establishing the essential element of causation. *In re Guidant Corp. Litigation*, MDL No. 05-1708 (DFW/AJB), 2007 WL 1725289 at * 13 (D. Minn. June 12, 2007). Further, the expert opinion of Dr. Steven Higgins concerning the explant recommendation is amply supported. As such, Dr. Higgins' expert opinion and other admissible evidence concerning the medical basis (or lack thereof) for recommending Mr. Duron's explant should be admitted.

A. Evidence Concerning the Medical Necessity of Kaiser's and Dr. Singh's Recommendation to Explant is Relevant and, Therefore, Admissible.

Except as otherwise provided, "[a]ll relevant evidence is admissible." Fed. R. Evid. 402. **"**'Relevant evidence' means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401. In the case of expert testimony, the opinion must assist the jury in understanding the

evidence or to determine a fact in issue. Fed. R. Evid. 702. Whether Mr. Duron's explant was recommended due to medical necessity is a crucial factor in determining causation—a primary element in the determination of Mr. Duron's claims.

Causation is a hotly disputed element in this case and requires Mr. Duron to prove that the conduct of which he complains caused his alleged injuries. Significantly, this Court explained in its June 12, 2007 Order that a major factor demonstrating causation includes whether explant surgery was doctor-recommended. *See In re Guidant Corp. Litigation* at *12. In fact, this case was distinguished from *O'Brien v. Medtronic*, where the court granted summary judgment for lack of causation, by emphasizing that in *O'Brien*, surgery was not a medical necessity, but "was ultimately performed only to relieve emotional distress." *Id.* at *13.

Likewise, if Dr. Singh recommended Mr. Duron's explant for financial gain instead of medical necessity, it is of consequence in determining the outcome of Mr. Duron's claims because its existence makes causation either more or less probable. Moreover, expert testimony, such as that offered by Dr. Higgins, is necessary to assist the fact finder in understanding the different influencing factors involved in a doctor's explant recommendation—a decision that, contrary to public belief, is not always driven by the medical necessity of the patient.[3] As stated succinctly in *Olson v. Ford Motor Company*, "[t]he judge does not find facts and only then permit the jury to hear evidence regarding those facts. Rather, the judge permits all relevant evidence to be admitted, and

[3] Indeed, even this Court made the assumption that "a person generally only receives medical treatment when a doctor deems it medically necessary." *In re Guidant Corp. Litigation* at * 13.

the jury finds the facts based on that evidence." 481 F.3d 619, 625 (8th Cir. 2007) (denying plaintiff's request to bar the jury from hearing any evidence regarding whether her husband had consumed alcohol until the court first found he was intoxicated). Thus, evidence demonstrating the basis upon which Mr. Duron's doctor recommended explant surgery is relevant and, therefore, admissible.

B. Dr. Higgins Opinion Concerning Kaiser's and Dr. Singh's Recommendation to Explant is Based on Sound Facts and Data.

Mr. Duron requests this Court to bar Dr. Higgins' expert testimony concerning Kaiser's and Dr. Singh's recommendation that Mr. Duron explant his ICD because it is not based upon any facts or data and is speculative. *See* Plaintiffs' Motion *In Limine* at 14. But Dr. Higgins testimony is clearly based upon Mr. Duron's medical status, Dr. Singh's testimony, Guidant explant statistics, and his professional experience. As such, Dr. Higgins opinion is amply supported.

"An expert's opinion should be excluded only if that 'opinion is so fundamentally unsupported that it can offer no assistance to the jury." *Synergetics, Inc. v. Hurst*, 477 F.3d 949, 956 (8th Cir. 2007). Indeed, the Supreme Court has been clear about how infirmities in expert testimony should be exposed: 'Vigourous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence. '" *Olson* at 626 (citing *Daubert v. Merell Dow Pharm., Inc.*, 509 U.S. 579, 596 (1993)). Further, an expert may base his opinion on facts or data that is "perceived by or made known to the expert." Fed. R. Evid. 703. And, as noted in *Gen. Elec. Co. v.*

Joiner, trained experts commonly draw conclusions from existing data provided by others. 522 U.S. 136, 146 (1997). *See also Larson v. Kempker*, 414 F. 3d 936, 941 (8th Cir. 2005) (noting that experts are permitted to offer opinions on a wide range of topics, including those not based on their firsthand knowledge).

Dr. Higgins agrees that he can only speculate concerning the private thought processes of Dr. Singh. But he firmly anchors his expert opinion addressing whether Kaiser's and Dr. Singh's explant recommendation was based on medical necessity to Mr. Duron's medical status, Dr. Singh's testimony, Guidant explant statistics, and his professional experience. Dr. Higgins explained:

> A. . . . I think it's inappropriate to have changed all these devices with [its] documented low incidence rate and [Mr. Duron's] known infection and complication rate with these generator changes, and that [Dr. Singh] placed patients at risk by doing that, if that was his conclusion. And I know that the majority of the EP community would agree with me in that regard.[4]

And later Dr. Higgins opined:

> A. don't like to criticize doctors any more than any other physician does, but it–it bothers me to see that the average generator change rate is well less than 10 percent for the 1861 across the country, and there are selected physicians, not just Dr. Singh, who are close to 100 percent. And when patients don't cooperate with the generator change, they make them sign an AMA agreement almost as a coercion, and then that those same physicians' health plans stand to gain financially substantially by doing this generator change concerns me that patient care may have not been the only motivation.[5]

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[4] Dr. Steven Higgins Dep. Tr. 285:17- 23 (Ex. 6).

[5] *Id.* at 287:13- 24.

When challenged for questioning the actions of a fellow doctor, Dr. Higgins clearly explained his opinion and its basis as indicated in the following deposition excerpts:

> Q. You're not—you're not saying that Dr. Singh performed unnecessary and inappropriate replacement surgery and that he engaged in some kind of improper activity as a doctor, are you?
>
> A. I was quite startled when I read the deposition just this week from Dr. Singh that their policy appeared to be to schedule replacements on everyone with this device and replace them all if they could. And if they—if they couldn't replace them all to make patients sign an against-medical-advice letter about that. That's not the standard of care in the EP community and I think places patients at risk. And if asked to discuss that, I'd be happy to elaborate.[6]
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> * * *
>
> Q. [Dr. Singh] obviously made the judgment to consult with this patient; that was the appropriate thing to do, right?
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> A. You know, again, reviewing his deposition, I was disappointed to see that he didn't consult with the patient, as best I could tell, that he had the patient scheduled for generator change surgery and that there wasn't any reference in his medical records that the patient requested a generator change or had emotional instability related to concerns about the newspaper article and that his policy was to replace all these devices. That's—in the medical community, that's considered improper to replace all these devices.[7]
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> * * *

And later when asked whether Dr. Higgins considered that Dr. Singh's motivation may have been based on his loss of trust in Guidant, Dr. Higgins responded:

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6 *Id.*

7 *Id*. at 282:9-24.

> A. Yes. I find that a little incongruous with the fact that he chose to put another Guidant device in this patient. If that was his motivation, then that doesn't make a lot of sense to me.[8]
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> * * *

Dr. Higgins clearly anchors his opinions concerning the medical necessity of Mr. Duron's explant to "sufficient facts or data." Fed. R. Evid. 702. And, although Mr. Duron asserts that "impugning the integrity and motivation of medical professionals does not involve "scientific, technical or specialized knowledge,"[9] opining upon the medical necessity of an explant based upon Dr. Higgins' professional experience, Mr. Duron's medical status, Dr. Singh's testimony, and Guidant explant statistics squarely requires "specialized knowledge." Fed. R. Evid. 702. As such, Dr. Higgins' expert opinion satisfies Rule 702 and, therefore, should be admitted.

A major factor in determining whether Mr. Duron's claimed injuries were caused by Guidant's alleged conduct includes whether Mr. Duron's explant was recommended based on medical necessity. The mere announcement that Dr. Singh is a medical professional and Kaiser is a large HMO cannot, alone, prove that all of their decisions were based on medical necessity. Similar to all other persons and entities, even doctors and HMOs must be willing to place their decisions up to the light.

Dr. Higgins' opinion that recommendations to explant were wide-spread without individual patient factors taken into account is clearly based upon his evaluation of Dr. Singh's testimony, his experience, Mr. Duron's medical status and explant

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8 *Id*. at 283:22-284:1.

9 *See* Plaintiffs' Memo in Support at 15.

statistics. If the truth bears to light that the recommendation to explant was due to financial motivations, the title of doctor or HMO should not be a sufficient basis upon which to exclude this evidence. Thus, introduction of such evidence, including Dr. Higgins' expert opinion, should be admitted.

V. GUIDANT'S OPPOSITION TO PLAINTIFF'S MOTION IN LIMINE TO PRECLUDE THE INTRODUCTION OF EVIDENCE REGARDING PAYMENTS MADE TO MR. DURON BY THIRD PARTIES

Mr. Duron argues that the collateral source rule bars the introduction of evidence that third parties, such as health insurers, have paid Mr. Duron for alleged injuries in this action. The rationale behind the collateral source rule, according to Mr. Duron, is that "there is substantial danger that the jurors will take [such] evidence into account in assessing the damages." *See* Memo in Support at 17. But long before this Court addresses the damages issue, this Court must first address the fundamental question whether Mr. Duron has standing to seek any damages at all under California law, such as the California Unfair Competition Law ("UCL"). The collateral source rule is never intended to function as a device to generate a claim that should not exist. It also cannot preclude any evidence that may effectively extinguish a claimant's standing to sue.

The only possible UCL remedies available in a private-party action are injunctive relief and restitution. Cal. Bus. & Prof. Code §§ 17203, 17206; *see also Korea Supply Co. v. Lockheed Martin Corp.*, 29 Cal. 4th 1134, 1144 (2003). In this case, Mr. Duron does not seek any injunctive relief. If Mr. Duron also fails to claim for restitution, the only other possible remedy, he lacks standing to sue under the UCL. Guidant should

be allowed to prove that Mr. Duron lacks such standing through evidence that Mr. Duron has in fact suffered no direct pecuniary loss required under California law.

The California Supreme Court has denied UCL remedies for restitution to a plaintiff where the plaintiff could not establish that the money he claimed for was taken from him or that he had an ownership interest in it. *Id.* at 1149 (denying recovery of disgorgement of profits obtained through alleged unfair business practices under the UCL).

Mr. Duron cannot establish that Guidant took money or property from him. Mr. Duron did not pay for his device or any medical expenses, which were paid for by Mr. Duron's insurance carrier. Mr. Duron did not suffer any financial loss for taking time off from work, because he received paid sick time and leave time. Nor can Mr. Duron show that the money he seeks to recover from Guidant is any fund in which he had an ownership or vested interest. In sum, Mr. Duron has not suffered any out-of-pocket pecuniary loss and cannot seek restitution under the UCL. Mr. Duron, therefore, lacks standing to sue under the UCL.

That independent sources paid Mr. Duron's alleged injury so that Mr. Duron suffered no pecuniary loss and that Guidant did not take money directly from Mr. Duron are key to Guidant's argument that Mr. Duron lacks standing to bring the statutory UCL claim. Counsel for Guidant is unaware of any authority that the collateral source rule has been used to bar evidence that effectively extinguishes a claimant's claim or to generate a claim that should not exist. This Court should deny Mr. Duron's motion to

exclude evidence that third parties paid Mr. Duron for his alleged injuries when such evidence is used to prove that Mr. Duron lacks standing to sue under the UCL.

VI. GUIDANT'S OPPOSITION TO PLAINTIFF'S MOTION IN LIMINE TO THE PRECLUDE THE INTRODUCTION OF EVIDENCE REGARDING MR. DURON'S PERSONAL LIFE AND HISTORY THAT IS WHOLLY IRRELEVANT TO THESE PROCEEDINGS

The evidence Mr. Duron seeks to exclude relating to (1) his prior medical and psychological health; (2) his financial difficulties; (3) engagement of an attorney through an advertisement and (4) his history of smoking is relevant to his credibility and proper for the purpose of impeachment.[10] Although impeachment of a witness is not among "other purposes" explicitly listed under Evidence Rule 404(b), governing admissibility of evidence of other crimes, wrongs, or acts by way of example, that list is not exhaustive, and impeachment qualifies as a permissible purpose for introduction of prior acts. *U.S. v. Stockton*, 788 F.2d 210 4th Cir. 1986) *cert. denied* 479 U.S. 840. Moreover, Rule 404(b) *applies to evidence in chief, not to impeachment evidence. U.S. v. Cerro*, 775 F.2d 908 (7th Cir. 1985). Thus, it is not impermissible character evidence and, as set forth below, is relevant in this case.

A. All of Mr. Duron's Medical and Mental Health History is Probative of Causation and Mr. Duron's Credibility Regarding His Emotional Distress.

A jury should, within reason, be informed of all matters affecting a witness's credibility to aid in their determination of the truth. *U.S. v. Partin*, 493 F.2d

[10] Guidant does not intend to introduce evidence of the medical condition of Mr. Duron's family, his DUI arrest, past legal actions involving Mr. Duron's family, Mr. Duron's previous marriage or his sex life unless Mr. Duron "opens the door" to such evidence and it is necessary in cross-examination.

750, 762 (4th Cir. 1974). Evidence of the a physical or mental condition of witness at time about which he testifies is admissible on the issue of credibility. *Id*. Mr. Duron's failing health is relevant to the cause of his emotional distress and his credibility in asserting that his emotional distress stems from the recall and explant of his ICD device.

Dr. Granacher reported that in the years leading up to the explant of his device Mr. Duron suffered from aortic stenosis, low blood pressure and elevated heart rate upon his admission to the hospital in February of 2002. Report of Dr. Robert Granacher at 3 ("Granacher Report") (Ex. 7). At that time he underwent an aortic valve replacement. *Id*. During surgery he developed substantial complications, was difficult to wean from bypass and was placed on an intra-aortic balloon pump when he developed right ventricular failure. *Id*. Mr. Duron also developed acute respiratory distress syndrome and a metabolic encephalopathy. *Id*.

Moreover, in the six months *prior to learning that his device had been recalled*, Mr. Duron was hospitalized for five days due to paroxysmal atrial fibrillation. (000131-18SCP-00081-84) ("Medical Records" collectively Ex. 8). In the five months *prior to learning that his device was recalled*, Mr. Duron's sister passed away (000131-18SCP-00116-119). During the *two months prior to learning that his device was recalled* he was (1) hospitalized due to chest pain and had an abnormal ECG (000131-18SCP-00083; Pltf. 274); (2) suffered from burning in his legs at night (000131-18SCP-00081); (3) was taking Mevacor, Amiodarone, Atenolol and Pepcid daily and Coumadin three days a week. (000131-18SCP-00019); (4) was on a low sodium, low fat, low cholesterol diet (000131-18SCP-00018); and (5) complained of being tired and sluggish (000131-

21STU-00405). All of Mr. Duron's medical and psychological history is relevant to refute his assertion that the cause of his emotional distress was the recall of his device. Each of the above medical and mental traumas could have been the source of his depression and anxiety. Thus, such evidence is properly admitted.

B. Mr. Duron's Financial Difficulties, Financial Concerns, Non-Retirement; and Engagement of an Attorney Based on an Advertisement Are Relevant to His Bias and Credibility.

Guidant is entitled to introduce evidence of Mr. Duron's financial difficulties to show that this lawsuit is financially motivated. Additionally, Guidant is entitled to introduce evidence that Mr. Duron filed this suit after responding to an legal advertisement to show that this lawsuit is attorney driven, rather than plaintiff driven.

Although not directly covered by a specific rule of evidence, a witness may be impeached by showing that he or she is biased, has an interest in the outcome of the litigation, is prejudiced in some relevant way, or has a motive to testify in a particular way. *United States v. Abel*, 469 U.S. 45, 49-52 (1984) (permitting bias impeachment despite no rule of evidence specifically allowing it). "The reliability of witness recollection may be questioned because people sometimes engage in selective recall and even confabulation in order to serve their biases." 27 Fed. Prac. & Proc. Evid. § 6095 (2007).

> Impeachment by showing the witness to be biased rests on two assumptions: (1) that certain relationships and circumstances impair the impartiality of a witness, and (2) that a witness who is not impartial may, consciously or otherwise, shade his or her testimony in favor of or against a party. Since bias of a witness is always significant in assessing credibility, the trier of fact must be sufficiently informed of the underlying relationships, circumstances,

> and influences operating on the witness to determine whether a modification of testimony reasonably could be expected as a probable human reaction.

Behler v. Nanlon, 199 F.R.D. 553 (D. Md. 2001) *citing* 4 Jack B. Weinstein & Margaret A. Berger, Weinstein's Federal Evidence § 607.04[1].§ [2][a] (2d. ed.1997).

Thus, the bias of a witness is always relevant. *United States v.* Caldwell, 88 F.3d 522, 525 (8th Cir. 1996). *See also, United States v. Peltier,* 585 F.2d 314, (8th Cir. 1978) (evidence tending to show a substantial reason for bias or interest in an important witness is never collateral or irrelevant). And a successful showing of bias on the part of a witness would have a tendency to make the facts to which he testified less probable in the eyes of the jury than it would be without such testimony. *U.S. v. Abel* 469 U.S. 45, 50-51 (1984).

1. Financial difficulties.

Evidence of Mr. Duron's financial difficulties, financial concerns and refusal to retire is probative of Mr. Duron's bias and interest in the outcome of this litigation. Bias may also be proven by showing that a witness has a financial interest in the outcome of the case. *United States v. Lester,* 248 F.2d 329, 334 (2d Cir. 1957). *See also United States v. Harris,* 185 F.3d 999, 1008 (9th Cir.1999), *cert. denied* 528 U.S. 1055 (1999) (noting that financial interest of witness is probative of credibility given that "[s]ome people would lie or shade the truth for a couple of hundred thousand dollars, even against a close relative."); *United States v. Dees,* 34 F.3d 838, 844 (9th Cir.1994) (holding the district court abused its discretion in denying defendant the opportunity to inquire as to witness's financial interest in the trial outcome). *Stetson v. Caverly,* 175 A.

473 (Me. 1934) (testimony that executor's wife was chief beneficiary and the amount of the estate 'clearly admissible' over objection on cross-examination to show bias); *Domangue v. State*, 654 N.E.2d 1, 3 (Ind. Ct. App.1995) (a witness' credibility may be affected by financial considerations and thus, such considerations may be a proper subject for cross-examination).

In *People of the State of New York v. Griffin*, 242 A.D.2d 70 (N.Y. App. Div. 1998) the court held that the evidence of witness's straitened financial condition and pending ten million dollar civil suit against the defendant was a proper inquiry on cross-examination to impeachment the witness and show her monetary incentive to fabricate allegations against defendant. *Id.* at 74.

In the present case, Mr. Duron is seventy-three years old and is unable to retire for financial reasons. Duron Dep. at 58:22-59:18. (Ex. 9) Mr. Duron began working at the age of seven and has continued to work his entire life. (Franks Report at 8-11) (Ex. 10). Mr. Duron filed for bankruptcy in the early nineties and stated that he had to "start all over after that" (Franks Report at 11). Mr. Duron's financial condition and past financial problems are relevant because they affect his credibility, call into doubt his assertion that he was "injured" by a device that never failed and suggest that this lawsuit is financially motivated. A jury is entitled to consider this evidence. Thus, such evidence is admissible to attack Mr. Duron's credibility.

2. Legal advertisement.

Evidence that Mr. Duron initiated this lawsuit based on an advertisement is relevant because it shows that this lawsuit was not organic, but rather attorney driven.

This calls into question Mr. Duron's bias, and supports Guidant's assertion that his memory about the recall of his device is selective and self-serving. Thus, it is relevant and admissible impeachment evidence.

C. Mr. Duron's Past History of Cigarette Smoking and Alcohol Use is Relevant to His Credibility That He Allegedly "Feared For His Life."

Prior acts evidence is admissible to show a victim's fear and its reasonableness. *United States v. Dennis*, 625 F.2d 782, 800 (8th Cir. 1980). Evidence of a witness' fear may be presented as a means of demonstrating a witness' bias thereby tending to discredit him. *U. S. v. Cerone*, 452 F.2d 274 (7th Cir. 1971) *cert. denied* 405 U.S. 964. The prior acts may be relevant even if they are not identical to those which the victim fears. *United States v. Dennis*, 625 F.2d at 800.

Mr. Duron asserts that "as a direct and proximate cause of Plaintiff's use of Defendants' defective product, Plaintiff . . . was in fear of his life . . . ." Complaint ¶72. Mr. Duron, however, smoked cigarettes for forty-nine years. Granacher Report at 4. It is beyond peradventure that cigarette smoking is hazardous to one's health and can result in death. Mr. Duron also has a history of alcohol use. Franks' Report at 11-12.

Mr. Duron contends, however, that no risk of failure was acceptable with respect to his ICD. Duron Depo. at 106:22-107:17 (Ex. 6). Such an assertion is simply not credible. The jury should have the opportunity to consider Mr. Duron's past risk taking behavior when weighing his credibility as to his "fear of death." Thus, such evidence is proper for impeachment and goes to Mr. Duron's credibility.

Based on the foregoing, evidence of Mr. Duron's (1) prior medical and psychological health; (2) financial difficulties; (3) engagement of an attorney through an advertisement and (4) history of smoking is relevant to his credibility and proper for the purpose of impeachment.

VII. GUIDANT'S OPPOSITION TO PLAINTIFF'S MOTION IN LIMINE TO PRECLUDE THE INTRODUCTION OF ANY EVIDENCE REGARDING THE PUBLIC POLICY IMPLICATIONS OF MR. DURON'S CLAIMS

Mr. Duron also argues that Guidant should not be permitted to introduce evidence, references, testimony or argument regarding the public policy implications of Mr. Duron's claims. However, Guidant is entitled to discuss the public policy implications of these claims. In fact, much of the disputed evidence is proof that Guidant's conduct did not rise to the level necessary for an award of punitive damages under California Law, as well as proof that plaintiff is lacking necessary elements of several of their claims. Therefore, the Court should deny this motion as it relates to the evidence below.

A. Evidence Relating to the "FDA's Mission" or the "FDA's Protective Regime" is Relevant to Illustrate Guidant Satisfied Any Duty to Warn.

Plaintiff seeks to basically exclude all evidence that illustrates the FDA's role in the medical device industry. Such an exclusion would be incredibly detrimental to Guidant's ability to fully illustrate why it issued advisories when it did, as well as several other important facts regarding how these devices are regulated. Plaintiff seeks to exclude the following:

> Any comment or inference, or the presentation of any evidence, testimony or documents mentioning that state tort law undercuts the FDA's mission to provide only scientifically valid warnings.
>
> . . .
>
> Any comment, evidence, testimony, inference or document mentioning that state products liability law frustrates the FDA's protective regime.

Plaintiff's Memo in Support, p. 23-24. This evidence is obviously relevant here. "FDA action or inaction, though not dispositive, may be admissible . . . to show whether a risk was known or reasonably scientifically knowable." *Carlin v. Superior Court*, 13 Cal. 4th 1104, 1114 (Cal. 1996). The "FDA precludes . . . [device] manufacturers from warning about every conceivable adverse reaction; they may warn only if there exists significant medical evidence of a possible health hazard." *Id.* at 1114.

Even aside from arguing preemption, the fact that the FDA did not take action following being informed of the one known and reported failure significantly buttresses the conclusion that Guidant's warning at the time of Mr. Duron's implant was adequate. While this evidence is "not dispositive," it is highly relevant to show that Guidant satisfied its duty to warn under the FDA's regulations.

B. Evidence Regarding the Plaintiff's Proposed Warnings is Relevant.

Plaintiff requests that this Court exclude the following:

> Any comment or inference, or the presentation of any evidence, testimony or documents inferring that state warning defect or failure-to-warn laws pressure drug manufacturers to add unsubstantiated, false, or invalid warnings in order to avoid lawsuits.
>
> . . .

> Any comment, evidence, testimony, inference or document mentioning that too many warnings of serious injuries will dilute the effectiveness of warnings generally.

Plaintiff's Memo in Support, p. 23. Plaintiff alleges that Guidant failed to warn him. Such a claim obviously necessitates the investigation into what duty to warn existed. It is crucial that Guidant be permitted to introduce evidence to show why it had no duty to warn, above reporting, as it did, such to the FDA. When the FDA took no action, Guidant was relieved of any further duty to warn. As previously stated, the "FDA precludes . . . [device] manufacturers from warning about every conceivable adverse reaction; they may warn only if there exists significant medical evidence of a possible health hazard." *Carlin,* 13 Cal. 4th at 1114. Therefore, not only does the FDA preclude these types of warnings, but it would be foolish and highly irresponsible to issue premature and overbroad warnings. Guidant is entitled to defend its conduct by demonstrating the needless and excessive nature of the warnings Plaintiff's claim Guidant should have given. Such evidence is relevant and the jury deserves to understand Guidant's reasoning.

C. Public Policy Considerations of the Effect on the Future of the Medical Device Industry is Relevant.

Plaintiff also seeks to exclude essentially any mention of how this decision could effect the future of the medical device industry. For the jury to be fully informed, Guidant must be able to illustrate that the cost of the medical devices it manufactures is somewhat driven by the litigation surrounding those devices. These lifesaving devices manufactured by Guidant far exceed industry standards. However, they are not perfect.

"No defibrillator is perfect; they are man-made, complex, computerized systems and accordingly problems will occur." *See* Thomas Ross Expert Report, March 21, 2007 at 7. (Ex. 11).

Plaintiff demands what amounts to triple redundant perfection for these devices. Such a demand is impossible to reach, however, with these man-made systems. While the devices are highly reliable, turning a 10-15% survival rate for cardiac arrest into a 95% survival rate, they will never save 100% of the patients' lives. *See id.* at 3. This overreaching and impossible standard would simply cause these medical devices to become too expensive to be used. Guidant must be able to explain to the jury how instituting this triple redundant perfection standard, while not increasing the effectiveness of these cutting-edge devices, would result in an extreme increase in the price of the devices and extreme disincentives to the development of these state of the art devices.

D. Evidence of Similar Device Company's Conduct is Relevant to Illustrate That Guidant's Conduct Did Not Rise to the Level Necessary For an Award of Punitive Damages.

Plaintiff seeks to exclude evidence regarding recalls or advisories made by other medical device companies. *See* Plaintiff's Memo in Support, p. 24. Such evidence, however, is highly relevant to illustrate to the jury that Guidant's conduct in issuing its advisories is not uncommon in the medical device industry. As such, it would also show that Guidant's conduct did not rise to the level necessary for an award of punitive damages under California law.

Under California law, the standard for proving punitive damages is provided in the California Civil Code, which states:

> In an action for the breach of an obligation not arising from contract, where it is proven by clear and convincing evidence that the defendant has been guilty of oppression, fraud, or malice, the plaintiff, in addition to the actual damages, may recover damages for the sake of example and by way of punishing the defendant.

Cal. Civ. Code, § 3294(a).

"Within the meaning of Civil Code section 3294, above, 'malice' means a wrongful intent to vex or annoy; 'oppression' means subjecting a person to cruel and unjust hardship in conscious disregard of his rights." *J. R. Norton Co. v. Gen. Teamsters, Warehousemen & Helpers Union*, 208 Cal.App.3d 430, 444 (1989). To establish malice, it is insufficient to show merely that the defendant's conduct was negligent, grossly negligent, or even reckless. *Gawara v. U.S. Brass Corp.*, 63 Cal.App.4th 1341, 1361 (1998) (strict product liability case reversing award of punitive damages); *Flyer's Body Shop Profit Sharing Plan v. Ticor Title Ins. Co.*, 185 Cal.App.3d 1149, 1155 (1986). Thus, "evil motive" is the central element to the malice requirement for purposes of a punitive damage award, *G.D. Searle & Co. v. Super. Ct.*, 49 Cal.App.3d 22, 30 (1975), and "despicable conduct" must be conduct so vile, contemptible, wretched or loathsome that it is looked down upon and despised by ordinary decent people. *George F. Hillenbrand, Inc. v. Ins. Co. of N. Am.*, 104 Cal.App.4th 784, 817 (2002).

By demonstrating to the jury that other medical device companies have engaged in similar conduct relating to issuing advisories or recalls, it would constitute evidence which has the "tendency to make the existence of any fact that is of consequence" – whether Guidant's conduct rises to the level to be considered so vile, contemptible, wretched or loathsome – "more probable or less probable than it would be

without the evidence." *See* Fed. R. Evid. 401. Therefore, it is clear that this evidence is relevant under the Federal Rules of Evidence.

E. Guidant Should Also be Permitted to Demonstrate That the Fear Related to This Case is Mostly Generated From the Plaintiff's Attorneys.

Plaintiff seeks to exclude:

> Any mention of the purported "litigation crisis," "lawsuit crisis," "lawsuit abuse," "need for tort reform," or similar terms or phrases.

Plaintiff's Memo in Support, p. 23. Guidant should be permitted, however, to show that this is an artificial, attorney-driven litigation, where most of the fear and concern is authored by the attorneys. Such should be considered a "litigation crisis." Mr. Duron cannot illustrate any way in which this would be unfairly prejudicial. Rather, he simply claims that these terms will inflame the jury and cause him prejudice. Without such substantiation, however, Guidant should be permitted to illustrate these facts.

VIII. CONCLUSION

For the reasons set forth above, Guidant requests that the Court deny Mr. Duron's motions in limine.

Respectfully submitted,

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