UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
THIRD DIVISION

In re: Guidant Implantable Defibrillators Products Liability Litigation	**MDL No. 1708 (DWF/AJB)**
This Document Relates to: **Leland H. Braund** **v. Case No. 05-2035** **Guidant Corporation, et al.**	**DEFENDANTS' CONSOLIDATED MEMORANDUM IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT**

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I. INTRODUCTION

Guidant has received this Court's June 12, 2007 Memorandum Opinion and Order ruling on Guidant's motions for summary judgment in the *Leopoldo Duron* case. Guidant respectfully disagrees with some aspects of that ruling, and for purposes of preserving the record, Guidant maintains that this case should be dismissed for many of the same reasons set forth in its *Duron* briefing.

Nevertheless, this Court should dismiss Mr. Braund's claims because it differs in three critical respects from the *Duron* case. First, Mr. Braund's device was implanted *before* Guidant received a single report of arcing failure. Thus, Guidant was wholly unaware of this potential failure mode at the time of Mr. Braund's implant.

Second, there is simply no evidence that Mr. Braund's explantation was "medically necessary." In *Duron*, this Court stressed the fact that Dr. Singh, Mr. Duron's explanting physician, recommended explant as "medically necessary based on the FDA Class I recall." Memorandum Opinion and Order, June 12, 2007, at 30 (Dkt. # 1927). In this case, however, the record demonstrates that none of Mr. Braund's doctors recommended explant. Rather, Mr. Braund's decision was entirely his own. Moreover, Mr. Braund's decision to have his device explanted was based on his unfounded concern over *device shocks*, not the potential arcing failure that was the subject of the FDA recall.

Third, there is simply no evidence that Mr. Braund's device was defective in any way. In *Duron*, this Court found that a genuine issue of material fact existed as to whether there was evidence of a malfunction in Mr. Duron's device because it "contained polyimide, which malfunctioned over time by degrading, which in turn necessitated Mr.

Duron's explant surgery." *Id.* at 31. In this case, however, device testing after explant revealed that there was no cracking of the polyimide insulation on the DF- wire of Mr. Braund's device, and there was a space between the DF-wire and the backfill tube. *See* Device Evaluation Summary (Ex. 1). Mr. Braund's own engineering expert, Randolph Armstrong, concedes that "insulation breaching and arcing were not evident" in Mr. Braund's device. *See* Supplemental Expert Report of Randolph Armstrong ("Supplemental Armstrong Report") at 2 (Ex. 2). Unlike in *Duron*, each of the triple-redundant features - wire-spacing, medical adhesive, and insulation - was present in Mr. Braund's device. Even if there was evidence of polyimide degradation in Mr. Braund's device (there was not), these redundancies eliminated the potential for arcing.

Moreover, there is simply no evidence that the shocks that Mr. Braund received were the result of a device defect. Indeed, Mr. Braund's expert offered no opinion as to the cause of Mr. Braund's allegedly inappropriate shocks – in fact, he does not address the shocks at all. *See* Supplemental Armstrong Report. Rather, the record indicates that Mr. Braund's device delivered shocks in accordance with its preprogrammed settings.

Mr. Braund's device did not exhibit any polyimide degradation, had spacing between the DF- wire and the backfill tube, and delivered shocks in accordance with its preprogrammed settings. There is simply no evidence of any defect.

As set forth in this Motion, many other key differences separate this case from Mr. Duron's. Regardless of whether this Court's conclusions in the *Duron* case are ultimately correct, Mr. Braund is asking this Court to step well beyond any threshold of

previous liability sanctioned by any Court anywhere. Mr. Braund asks this Court to allow him to recover under a broad battery of legal theories for the manufacture and sale of a device that never malfunctioned, worked perfectly for four years, and attained reliability figures that far exceed those of competitors' devices and the expectations of the FDA.

Not every individual complex medical device can be expected to function perfectly; these devices are simply too complex, their scale so miniaturized, and the demands placed upon them so profound that they must be engineered with redundant safety features. *See* Report of John E. Moalli, Sc.D. ("Moalli Report") at 8 (Ex. 3). What Mr. Braund's experts assail as a "defect" is at most nothing more than an inevitable and inconsequential compromise of one internal aspect of the PRIZM 2's triple-redundant design.

What Mr. Braund conclusively labels as a defect or breach of warranty or an unfair practice is nothing more than an effectless imperfection. Under Mr. Braund's theory of recovery, any manufacturer anywhere is subject to open-ended liability not only under strict liability standards, but as an absolute guarantor of the perfect performance of all of their products as well as the perfection of all aspects of their products' internal design and manufacturing. No product no matter how simple can escape liability if the only standard is whether, after functioning perfectly, it must be submitted to a litany of plaintiffs' expert witnesses who are allowed to dissect its internal parts and identify any internal design or manufacturing flaw or potential flaw that did not manifest in a malfunction. Certainly no complex medical device, no matter how well-designed or

constructed, regardless of FDA approval or performance statistics, can ever meet this counterintuitive standard.

Triple-redundant, internal design and manufacturing perfection is the standard of liability that Mr. Braund asks this Court to impose. But such a standard is not the law in Michigan, or in any other jurisdiction. This Court must draw the line and dismiss these meritless claims.

II. DEFENDANTS' CONSOLIDATED STATEMENT OF FACTS

A. The PRIZM 2 1861.

For purposes of brevity, Guidant hereby incorporates the Consolidated Statement of Facts from the *Clasby* Memorandum in Support of Summary Judgment Part II. A-I. According to the most recent Product Performance Report, *actual* confirmed malfunctions from all causes have occurred in less than one-half of one percent of the entire PRIZM 2 product line. *See* CRM Product Performance Report at 26 (Q2 Summary Edition), Boston Scientific, June 8, 2007 (Ex. 16). Only 37 arcing malfunctions out of approximately 27,000 (0.14%) pre-April 2002 PRIZM 2s worldwide have been confirmed. *Id.* Only 38 arcing malfunctions out of all 60,000 (0.0061%) PRIZM 2s worldwide have been confirmed. *Id.* at 132.

B. Leland Braund.

1. Background.

Mr. Braund was born in Royal Oak Michigan on May 1, 1944. Plaintiff Fact Sheet for Leland Braund at 4 (Ex. 4). He continues to reside in Michigan and was the owner of Major Homes & Construction Co., Inc. in Fowlerville, Michigan for

approximately nineteen (19) years. *Id.* He has obtained a journeyman's license, master's plumber's license, state boiler's license and an unlimited building license, all in Michigan. Dep. Tr. of Leland Braund at 79:9-83:20 (Ex. 5).

In the Summer of 2001, shortly after his 57th birthday, Mr. Braund suffered a heart attack. *See* Medical Record of Leland Braund, PLTF 0260-0262 (heart attack noted on June 10, 2001) (Ex. 6). Dr. Marlo Leonen with the Michigan Heart Group in Brighton, Michigan, prescribed the implantation of an ICD. Plaintiff Fact Sheet for Leland Braund at 6. On August 24, 2001, Mr. Braund was implanted with a Guidant PRIZM 2 by Dr. James Kappler at St. Joseph's Hospital in Ann Arbor, Michigan. *Id.* Mr. Braund's implant occurred *before* the first reported incident of arcing. *See* CPI 35 00000016 (Dkt. # 1745, Ex. 13).

Mr. Braund was in no way involved in the selection of his ICD as indicated by his deposition testimony:

> Q [D]id they explain to you what various defibrillators were on the market?
>
> A No.
>
> ***
>
> Q [D]id you play any role in selecting the defibrillator that was implanted in you?
>
> A Absolutely not.
>
> ***
>
> Q When you received your first Guidant defibrillator, did you believe that there was any chance that it might fail?
>
> A I knew nothing what a pacemaker/defibrillator was or did.

Dep. Tr. of Leland Braund at 98:14-16; 100:16-18; 119:8-12.

Mr. Braund's medical records indicate that his implanting physician, Dr. Kappler, warned him of the risks and benefits of an ICD. *See* MAL 104-105; SJMHS 00024-75 (medical records). Moreover, the Patient Handbook distributed to Mr. Braund himself describes what defibrillation shocks feel like and advises that such shocks can upset patients. AICD Patient Handbook at 13 (Ex. 7). Mr. Braund admits that he read this handbook. Dep. Tr. of Leland Braund at 109:11-110:20.

2. Mr. Braund's device functioned properly.

Mr. Braund's device functioned appropriately at all times until he elected to have it explanted after four years of use. Mr. Braund's nurses and doctors routinely checked his device's performance. These visits occurred frequently right after Mr. Braund's implant procedure and then every 60 days thereafter. *Id.* at 20:12-24. At no time did the doctors or nurses tell Mr. Braund that his device was not functioning properly. *See id.* at 122:19-123:10.

The shocks that Mr. Braund received from his device were appropriate for his device's setting. Mr. Braund received shocks on two occasions – once while he was visiting a casino in Canada in October 2001 and once while he was at home in Michigan in January 2002. Dep. Tr. of Leland Braund at 53:3-15; 61:11-20. Doctors and nurses tested Mr. Braund's device in Michigan after both episodes, and they gave no indication that Mr. Braund's device had malfunctioned or needed to be explanted:

> Q While you were at the hospital [after the first event], did you have any discussions with Dr. Kappler or Dr. Leonen about whether or not you should have your device explanted?

A. At that time, no.

***

Q Okay. Did you have any discussions with Dr. Kappler or Dr. Leonen after this [second] event about whether or not you needed to have your device replaced?

A There was never any mention of replacement at those times.

Q Okay, did they tell you what they thought was going on with your device?

A Nobody – no.

***

Q Okay. Did any of your nurses talk to you about anything going on with your device?

A Not that I can recall.

Id. at 60:7-61:10; 65:3-10, 65:14-16. In fact, Mr. Braund's medical records indicate that these shocks were delivered in accordance with the device's settings, which were simply set too low. *See* Medical Records of Leland Braund, PLTF 0131-0134 ("[d]evice was interrogated with programming to reduce risk of subsequent inappropriate discharge"); PLTF 00128 ("Mr. Braund recently had an inappropriate ICD shock . . . [h]is defibrillator has been reprogrammed and hopefully this will not happen again."); PLTF 0293-0295; 0289-0291; 0285-0287; 0281-0282; and 0284 ("Evaluation shows normal ICD function with excellent sensing and capture thresholds").

Mr. Braund's own expert offers no opinion as to the cause of these allegedly inappropriate shocks – in fact, he does not address the shocks at all. *See* Supplemental Armstrong Report. Further, "[f]alse shocks, also known as inappropriate shocks, do not indicate abnormal function . . . . They typically occur due to [a]

combination of a fast heart rhythm for which the device was not intended and the programmed setting of the device." Report of Thomas Ross ("Ross Report") at 5 (Ex. 8). In this case, as Mr. Ross opined, Mr. Braund's alleged inappropriate shocks "were secondary to sinus tachycardia and atrial fibrillation and were related to programming issues and rapid conduction and are not indicative of device malfunction." *Id.* at 12. Indeed, after the reprogramming, he never received any additional shocks. Moreover, the fact that Mr. Braund's device delivered shocks indicates that his device had not experienced an arcing failure or a short-circuit. *Id.* at 4; Expert Report of Charles Swerdlow at 5 (Ex. 9).

Device testing after explant revealed that there was no cracking of the polyimide insulation on the DF- wire of Mr. Braund's device, and there was a space between the DF-wire and the backfill tube. *See* Device Evaluation Summary. Mr. Braund's own engineering expert, Randy Armstrong, concedes that "insulation breaching and arcing were not evident" in Mr. Braund's device. *See* Supplemental Armstrong Report at 2. Mr. Braund himself admits that his device never short-circuited. Pl.'s Resp. to First Set of Requests for Admissions at 1 (Ex. 10).

3. Mr. Braund voluntarily chose to have his device explanted.

The decision to replace Mr. Braund's device was entirely his own. Mr. Braund learned of the recall on TV or through a friend or family member while he was in Michigan. Dep. Tr. of Leland Braund 135:6-16. His device was ultimately explanted on September 7, 2005, at St. Joseph Mercy Hospital in Ann Arbor, Michigan. Plaintiff Fact Sheet for Leland Braund at 8. Guidant paid for Mr. Braund's replacement device and

issued $2500 in unreimbursed medical expenses. *See* Credit Memo for Leland Braund (Ex. 11); Letter from Guidant to Leland Braund (Mar. 8, 2006) (Ex. 12).

Mr. Braund's doctors, however, never recommended that his device should be replaced, as Mr. Braund testified during his deposition:

> Q Okay. Did Dr. Tappler – Kappler tell you it was your choice whether or not you would have the device explanted?
>
> A Yes.
>
> Q Did Dr. Kappler recommend to you that you should have it explanted?
>
> A I can't answer yes or no, but in the way that would make me feel more of a man and resume my normal life, but I don't want to say that yes, he did say get it replaced.
>
> Q. Is it fair to say that his concern about having your device replaced was related to your concerns about the device shocking you and how it was affecting your life?
>
> A. Yes.

Dep. Tr. of Leland Braund at 142:15-143:4. As indicated, Mr. Braund elected to replace his perfectly functioning device out of misplaced concern that device shocks were caused by a problem with his device, when, in reality, the setting simply needed to be reprogrammed.

4. Mr. Braund's allegations center around inappropriate shocks, not an arcing failure.

Mr. Braund's claims center on allegedly inappropriate shocks he received, not the potential arcing failure that was the subject of the recall. *See* Pl. Original Compl. at ¶ 4. Indeed, Mr. Braund alleges that his physical injuries were caused by "device malfunction resulting in shocks." Plaintiff's Fact Sheet at 15; *see also* Pl. Original

Compl. at ¶ 56. Mr. Braund's own psychiatric expert states that Mr. Braund "has difficulty, intellectually, and more so emotionally, separating out the cause of the shocks, a setting error, with also being notified of" the potential arcing failure that was the subject of the recall. Psychiatric Evaluation of Leland Howard Braund by Dr. Harold M. Ginzburg ("Ginzburg Report") at 5, 12 (Ex. 13). Moreover, in this same psychiatric evaluation, Mr. Braund admits that he attributed his alleged emotional distress to his heart condition, and it was only after learning of the recall that he attributed it to the shocks he had received from his PRIZM 2. *Id.* at 11.

III. SUMMARY JUDGMENT IS WARRANTED BASED ON FEDERAL PREEMPTION

Guidant hereby incorporates its arguments from Defendant's Consolidated Reply to Plaintiff's Opposition to Defendant's Motion for Summary Judgment in *Duron* to preserve the appellate record.

IV. DEFENDANTS' CHOICE-OF-LAW ARGUMENTS

Minnesota's choice-of-law factors dictate the application of Michigan law to Mr. Braund's product-liability claims (Counts I-VII), consumer-protection claims (Count VIII and IX), and emotional distress claims (Counts X and XI).

A. Minnesota's Choice-of-Law Rules Apply.

The Court has already ruled that Minnesota's choice-of-law rules apply to Mr. Braund's claims. *See* Memorandum Opinion and Order, May 22, 2007 (Dkt. # 1827). Under Minnesota law, the first issue to resolve is whether an actual conflict of law exists. *See Nodak Mut. Ins. Co. v. Am. Family Mut. Ins. Co.*, 604 N.W.2d

91, 94 (Minn. 2000). "A conflict exists if the choice of one forum's law over the other will determine the outcome of the case." *Id.* If a conflict does not exist, Minnesota law applies.[1] *See Nesladek v. Ford Motor Co.*, 46 F.3d 734, 736 (8th Cir. 1995). If a conflict does exist, Minnesota applies the "significant contacts test" to determine which state's law applies, Minnesota's or Michigan's. *Nodak*, 604 N.W.2d at 94.

"The significant contacts test consists of five choice-influencing factors":

(1) Predictability of results;

(2) Maintenance of interstate and international order;

(3) Simplification of judicial task;

(4) Advancement of the forum's governmental interest; and

(5) Application of the better rule of law.

Id. Importantly, "when all other relevant choice-of-law factors favor neither state's law, the state where the accident occurred has the strongest governmental interest; accordingly, the law of the state where the accident occurred should be applied." *Id.* at 96.

Here, Mr. Braund's allegations underlie "accidents" that occurred exclusively in Michigan (and Canada), not Minnesota. Mr. Braund received his device in Michigan from a Michigan doctor in a Michigan hospital. *See supra* Part II.B.1. Mr. Braund attended regular follow-up appointments with a Michigan doctor in a Michigan

[1] There is no conflict between Minnesota and Michigan law with respect to unjust enrichment (Count XVII). As such, Minnesota law applies to this claim. Neither Minnesota nor Michigan recognize gross negligence/malice (Count XVII). Summary judgment is warranted with respect to this claim. *See infra* Part XI.

hospital. *See supra* Part II.B.2 Mr. Braund's episodes of allegedly inappropriate shocks occurred once in Michigan and once in Canada. *Id*. Mr. Braund reported to a Michigan hospital after both of these episodes. *Id*. Mr. Braund learned of the recall in Michigan, and Mr. Braund's device was ultimately explanted in Michigan. *See supra*, Part II.B.3. Thus, even if the balance of Minnesota's choice of law factors favors neither state, Michigan law applies to Mr. Braund's claims. *See In re Baycol Prods. Liab. Litig.*, 218 F.R.D. 197, 207 (D. Minn. 2003) (finding that the accident occurred in plaintiff's state of residence because the drug "was prescribed and ingested" there).

B. Minnesota's Choice-of-Law Factors Favor the Application of Michigan Law to Mr. Braund's Product-Liability Claims (Counts I-VII).

1. An outcome-determinative conflict exists with respect to Mr. Braund's product-liability claims.

An outcome-determinative conflict exists with respect to Mr. Braund's product-liability claims (Counts I-VII). Unlike in Minnesota, the Michigan legislature has carefully devised a comprehensive framework to address product-liability claims like those at issue here. The MPLA applies broadly to any cause of action "based on a legal or equitable theory of liability brought for the death of a person or for injury to a person or damage to property caused by or resulting form the production of a product." MICH. COMP. LAWS § 600.2945(h); *see Mut. Ins. Co. of Am. v. Royal Appliance Mfg.*, 112 Fed. Appx. 386, 389 (6th Cir. 2004) (commenting on the broad reach of the MPLA); *see also Gootee v. Colt Indus., Inc.*, 712 F.2d 1057, 1066-67 (6th Cir. 1983) (noting that the MPLA combines "all products liability cases under a single rubric"). Moreover, the statutory definition of the term "production" expands the MPLA's scope of coverage to

include any injury resulting from the "manufacture, construction, design, formulation, development of standards, preparation, processing, assembly, inspection, testing, listing, certifying, warning, instructing, marketing, selling, advertising, packaging, or labeling" of a product. MICH. COMP. LAWS § 600.2945(i).

In light of its broad scope, the MPLA governs Mr. Braund's claims in Counts I through VII – which sound in strict liability, negligence, warranty, and fraud – because these claims unequivocally involve allegations of "injury to a person or damage to property caused by or resulting from the production" of Mr. Braund's device. MICH. COMP. LAWS § 600.2945(h); *see* First Am. Master. Compl. ¶¶ 277, 286, 292, 297 (claiming negligence and strict liability in Counts I-IV for "severe physical injuries and/or death, severe emotional distress, economic losses and other damages"); *id*. ¶ 303 (claiming breach of implied warranty in Count V for "economic losses and other damages"); *id*. ¶¶ 309, 315 (claiming fraud and constructive fraud in Counts VI-VII for "personal injuries and/or pecuniary losses and economic damages"); *see also Duronio v. Merck & Co., Inc.*, No. 267003, 2006 WL 1628516, at *3 (Mich. Ct. App. June 13, 2006) (noting that a court is not bound by a plaintiff's choice of labels and the "mere allegation that he is not pursuing a product liability action is not controlling").

Indeed, courts applying Michigan law have routinely concluded that claims like Mr. Braund's fall within the broad scope of the MPLA. *See, e.g., Lesho v. Textron, Inc.*, 408 F. Supp. 2d 329, 331 (E.D. Mich. 2005) (negligent design and manufacture); *Frankenmuth Mut. Ins. Co. v. Ace Hardware Corp*., 899 F. Supp. 348, 353 (W.D. Mich. 1995) (warranty); *Royal Appliance*, 112 Fed. Appx. at 389 (design defect, failure to warn,

and warranty); *Duronio*, 2006 WL 1628516, at *6 (fraud); *Lavin v. Child Craft Indus., Inc.*, No. 245386, 2004 WL 840230, at *2 (Mich. Ct. App. Apr. 20, 2004) (design defect and warranty).

Among the MPLA's generally applicable provisions is a rebuttable presumption against liability if the product at issue "was in compliance with regulations or standards . . . promulgated by, a federal or state agency responsible for reviewing the safety of the product." MICH. COMP. LAWS § 600.2946(4). The purpose of this provision is no mystery. The Michigan "Legislature intended to 'cut off liability in a wide range of product cases.'" *Toledo v. Gateway Precision Tech., LLC*, No. 263836, 2005 WL 3481436, at *5 (Mich. Ct. App. Dec. 20, 2005) (quoting trial court). Indeed, "[t]he essential point of the legislation is to make it more difficult for claimants to prevail when they bring a product-liability action concerning a product that complies with pertinent federal or state safety standards." *Royal Appliance*, 112 Fed. Appx. at 398. Michigan courts guard this presumption vigilantly. *See e.g., Lesho v. Textron, Inc.*, 408 F. Supp. 2d 329, 335 (E.D. Mich. 2005) (holding that plaintiff's expert testimony failed to rebut the presumption, noting that "simply because the product does not incorporate features that would make it safer, does not mean that the product is necessarily unsafe").

Minnesota law does not have a statutory presumption that serves to "cut off" product-liability claims sounding in strict liability, negligence, warranty, or fraud. Accordingly, there is an outcome-determinative conflict between Michigan and Minnesota law with respect to each of these claims.

2. The significant contacts test favors the application of Michigan law to Mr. Braund's products liability claims.

On balance, the significant contacts test favors the application of Michigan law to Mr. Braund's product-liability claims (Counts I-VII).

a. Predictability of results (first factor).

The first factor, predictability of results, favors the application of Michigan law. This factor has little, if any, importance in non-contract cases involving "accidents," such as Mr. Braund's case here *See Nodak*, 604 N.W.2d at 94 (stating that predictability of results "'applies primarily to consensual transactions where the parties desire advance notice of which state law will govern in future disputes'") (quoting *Myers v. Gov't Employees Ins. Co.*, 225 N.W. 2d 238, 242 (Minn. 1974)); *see also Hughes v. Wal-Mart Stores, Inc.*, 250 F.3d 618, 620 (noting that "predictability of results is not implicated when an action arises out of an accident") (interpreting identical choice-of-law factors under Arkansas law); *In re Baycol*, 218 F.R.D. at 207 (noting that predictability of results has "generally not been applied in tort cases").

Nevertheless, to the extent that this factor does apply, it unquestionably favors Michigan law. Mr. Braund could not have "predicted" that Minnesota law would apply to his claims. Mr. Braund resides in Michigan, and his device was prescribed, implanted, monitored, and explanted in Michigan. *See supra* Part II.B.1-3. Moreover, there is simply no evidence that Mr. Braund was even aware that Guidant was located in Minnesota (and Indiana) during the relevant time period.

As the court in *In re Vioxx Products Liability Litigation* astutely observed, "it is highly unlikely that a plaintiff residing outside of [the manufacturer's state] could have reasonably expected that his or her personal injury claims would be governed by [the law of the manufacturer's state]." 239 F.R.D. 450, 454 (E.D. La. 2006) (holding that "plaintiff's home jurisdiction has a stronger interest in deterring foreign corporations from personally injuring its citizens and ensuring that its citizens are compensated than [the manufacturer's state] does in deterring its corporate citizens' wrongdoing"). Moreover, Guidant would not have predicted that the law of the state in which Guidant sold the product would not apply to claims involving that same product. Predictability of results favors the application of Michigan law.

b. Maintenance of interstate and international order (second factor).

The second factor, the maintenance of interstate and international order, favors Michigan law. The Minnesota Supreme Court explained the significance of the maintenance of interstate and international order in *Nodak*:

> [It] is primarily concerned with whether the application of Minnesota law would manifest disrespect for [another state's] sovereignty (or vice versa) or impede the interstate movement of people and goods. An aspect of this concern is to maintain a coherent legal system in which the courts of different states strive to sustain, rather than subvert, each other's interests in areas where their own interests are less strong.

604 N.W.2d at 95 (quoting *Jepson v. Gen. Cas. Co. of Wis.*, 513 N.W.2d 467, 472 (Minn. 1994)). Based on this analysis, the Minnesota Supreme Court, which was considering two states' no-fault laws, concluded that the second factor favored neither state: "both

states have an equal interest as evidenced by the fact that both have laws directly pertaining to no-fault benefits recovery." *Id.*

Here, the Michigan Legislature has carefully crafted the MPLA to address product-liability claims. Minnesota, however, has not adopted a statutory framework "directly pertaining" to product-liability claims. In light of this disparity, Minnesota's interests must yield to Michigan's "to maintain a coherent legal system in which the courts of different states strive to sustain, rather than subvert, each other's interest in areas where their own interests are less strong." *Id.*

Interpreting this same factor, the District of Minnesota in *In re Baycol* relied on the Eighth Circuit's view that "this factor weighs in favor of the state which has the most significant contacts with the facts relevant to the litigation." 218 F.R.D. at 207 (citing Hughes, 250 F.3d 618).

> In [*Hughes*], the court held that the state in which the accident occurred, and in which the plaintiff lived, had the more significant contact compared to the state in which the defendant corporation had its headquarters.

Id. The District of Minnesota applied this analysis and concluded that "it is *clear* that this factor supports application of the state law in which the plaintiff resides, as [the drug] was prescribed and ingested in the state of the plaintiff's residence, and the alleged injury occurred in the state of the plaintiff's residence." *Id.* (emphasis added).

Here, Michigan unquestionably has "the most significant contacts" because it is the state in which Mr. Braund resides and where his device was prescribed, implanted, and explanted. *See supra* Part II.B.1-3. Moreover, Michigan has developed a

statutory framework directly addressing product-liability claims against the manufacturers of regulated products; Minnesota has not. This factor favors the application of Michigan law.

c. Simplification of the judicial task (third factor).

The third factor, simplification of the judicial task, favors neither forum. The Minnesota Supreme Court has stated that this factor "has not been given much weight in [the court's] precedent." *Nodak*, 604 N.W.2d at 95. In any event, the Eighth Circuit has held that, when faced with the choice of applying the law of one state or another, "the judicial task is not simplified by application of either state's law." *Hughes*, 250 F.3d at 620. "A federal district court is faced almost daily with the task of applying some state's law other than that of the forum state, and it is equally capable of resolving the dispute [under either state's law]." *Id.*; *see also Nodak*, 604 N.W.2d at 95 (holding that simplification of the judicial task favors neither state's law if the conflicting laws are "relatively clear").

The presence of Mr. Braund's case in an MDL does not affect this conclusion. *See In re Baycol*, 218 F.R.D. at 207 (giving no weight to the simplification of the judicial task factor in an MDL setting and holding that "the law of the state in which the plaintiff resides will govern the claim"). Indeed, this Court has already determined in *Duron* that it will consider choice-of-law issues individually and apply different states' laws where appropriate. (Dkt. # 1827)

d. Advancement of the forum's governmental interest (fourth factor).

The fourth factor, the advancement of the forum's governmental interest, overwhelmingly favors Michigan law. Minnesota's interest in having its own laws enforced against a resident corporation in a case involving a nonresident who was injured in another state is miniscule. The Eighth Circuit addressed the (in)significance of this interest in *Hughes*. *See Hughes*, 250 F.3d at 621. There, plaintiffs argued that a state has "an important governmental interest in having its product liability laws enforced against its own corporate residents when the products they sell to others injure the residents of other states." *Id.* The Eighth Circuit was not persuaded:

> We agree that a state has at least some interest in protecting nonresidents from tortious acts *committed within the state*, but even then, courts have recognized that the state's interest is only slight and does not support application of its law to the litigation. The governmental interest asserted by plaintiffs is even *far more tenuous*.

250 F.3d at 621 (emphasis added). On the other hand, Michigan's interest in applying Michigan law, and specifically the MPLA, to cases involving Michigan residents injured in Michigan is considerable.

Other courts have agreed. For example, in *Rowe v. Hoffman-La Roche, Inc.*, 917 A.2d 767 (N.J. 2007), a Michigan resident filed a failure-to-warn claim against prescription-drug manufacturer in the manufacturer's home state, New Jersey. The New Jersey Supreme Court ruled that Michigan's MPLA applied because "[New Jersey's] interest in deterring local manufacturing corporations from providing inadequate product

warnings, within the context of an FDA approved drug, must yield to Michigan's interest [in applying the MPLA]." *Id.* at 776.

> "To allow a life-long Michigan resident who received an FDA-approved drug in Michigan and alleges injuries sustained in Michigan to by-pass his own state's law and obtain compensation for his injuries in [New Jersey's] courts completely undercuts Michigan's interests, while overvaluing [New Jersey's] true interest in this litigation."

Id. at 776; *see also Norris v. Pfizer*, No. 109847/06, 2007 WL 969431 (N.Y. Sup. Ct. Mar. 14, 2007) (choosing to apply Michigan's MPLA in a product-liability lawsuit involving a Michigan resident who had filed suit in New York). Michigan's governmental interest in applying the MPLA to Mr. Braund's claims simply outweighs Minnesota's, and, as such, this factor favors the application of Michigan law.

e. Better rule of law (fifth factor).

With respect to the fifth factor, application of the better rule of law, the Minnesota Supreme Court has stated that it "has not placed any emphasis on this factor in nearly 20 years." *Nodak*, 604 N.W.2d at 96. This factor favors neither forum.

* * *

On balance, the significant contacts test favors the application of Michigan law to Mr. Braund's product-liability claims (Counts I-VII). While the third and fifth factors favor neither state, the second, third, and fourth factors favor the application of Michigan law. At best, Mr. Braund could only argue that these factors favor neither state, in which case Michigan law applies nonetheless because it is "the state where the accident occurred." *See Nodak*, 604 N.W.2d at 96.

C. Minnesota's Choice-of-Law Factors Favor the Application of Michigan Law to Mr. Braund's Consumer-Protection Claims (Counts VIII and IX).

1. Outcome-determinative conflicts exist with respect to Mr. Braund's consumer-protection claims.

Outcome-determinative conflicts exist with respect to Mr. Braund's consumer-protection claims (Counts VIII and IX). First, the only available remedy under Minnesota's Uniform Deceptive Trade Practices Act (UDTPA) is an injunction. MINN. STAT. § 325D.45(1). Michigan's Consumer Protection Law (CPL), however, permits injunctive relief *and* actual damages. MICH. COMP. L. § 445.911.

Second, Minnesota's False Statements in Advertising statute expressly limits claims to those involving false statements made in advertising distributed *within the state of Minnesota*. MINN. STAT. § 325F.67. Michigan's Pricing and Advertising of Consumer Items statute does not have such a limitation. MICH. COMP. L. § 445.360.

Finally, under Minnesota's Senior Citizen and Handicapped Person Consumer Fraud act, Minnesota awards a supplemental penalty of up to $10,000 when a consumer-protection violation impacts a senior citizen. MINN. STAT. § 325F.71. Michigan, on the other hand, proscribes "taking advantage" of a consumer's "inability reasonably to protect his or her interests" as an independent violation. MICH. COMP. L. 445.903(1)(x). Thus, under Michigan law, a senior citizen or handicapped person may seek *all* remedies available under the Michigan Consumer Protection Act, not just a supplemental penalty of $10,000.

2. The significant contacts test favors the application of Michigan law to Mr. Braund's consumer-protection claims.

On balance, the significant contacts test favors the application of Michigan law to Mr. Braund's consumer-protection claims (Counts VIII and IX). The third and fifth factors, simplification of the judicial task and application of the better rule of law, favor neither state for the same reasons discussed above. *See supra* Part IV.B.2. The first factor, predictability of results, favors the application of Michigan law because Mr. Braund simply could not have predicted that Minnesota law would apply to his claims. *See supra* Part IV.B.2.a. The remaining factors also favor the application of Michigan law.

a. Maintenance of interstate and international order (second factor).

The second factor, maintenance of interstate and international order, favors Michigan law. As the District of Minnesota in *In re Baycol* noted, "this factor weighs in favor of the state which has the most significant contacts with the facts relevant to the litigation." 218 F.R.D. at 207 (citing Hughes, 250 F.3d 618). Michigan unquestionably has "the most significant contacts." Mr. Braund's device was marketed in, shipped into, prescribed in, sold in, implanted in, and explanted in Michigan. *See id.* at 207. This factor favors the application of Michigan law.

b. Advancement of the forum's governmental interest (fourth factor).

The fourth factor, advancement of the forum's governmental interest, also favors the application of Michigan law. Michigan has an overwhelming governmental

interest in applying its own consumer-protection laws to a Michigan resident who was allegedly injured in Michigan as a result of a product purchased in Michigan. On the other hand, Minnesota's primary interest in enforcing its consumer-protection laws centers around protecting Minnesota consumers and policing conduct that occurs within Minnesota. Indeed, Minnesota's False Statements in Advertising statute expressly signals that Minnesota has no interest in policing allegedly false statements seen or heard outside of Minnesota. MINN. STAT. § 325F.67. Here, the only statements that Mr. Braund could have seen or heard are statements in Michigan, his home state. Minnesota simply has no significant governmental interest in protecting nonresidents injured in other states. *See Hughes*, 250 F.3d at 621.

On balance, the significant contacts test favors the application of Michigan law to Mr. Braund's consumer protection claims (Counts VIII-IX).

D. Minnesota's choice-of-law factors favor the application of Michigan law to Mr. Braund's emotional-distress claims (Counts X and XI).

1. Outcome-determinative conflicts exist with respect to Mr. Braund's emotional-distress claims.

Outcome-determinative conflicts exist with respect to Mr. Braund's emotional-distress claims (Counts X and XI). First, unlike Minnesota, Michigan has not adopted the independent tort of negligent infliction of emotional distress ("NIED"). *See Roberts v. Auto-Owners Ins. Co.*, 422 Mich. 594, 374 N.W.2d 905 (1985); *McCahill v. Commercial Union Ins. Co.*, 179 Mich. App. 761, 768, 446 N.W.2d 579, (1989). Second, the Michigan Supreme Court has never formally recognized intentional infliction of

emotional distress (IIED), and thus, it is doubtful whether such a claim is even actionable in Michigan. *See infra* Part XIII.A.2. Minnesota, however, has adopted IIED.

2. The significant contacts test favors the application of Michigan law to Mr. Braund's emotional-distress claims.

The significant contacts test favors the application of Michigan law to Mr. Braund's emotional-distress claims (Counts X and XI). Again, the third and fifth factors, simplification of the judicial task and application of the better rule of law, favor neither state for the same reasons discussed above. *See supra* Part IV.B.2.c, e. The first factor, predictability of results, again favors the application of Michigan law. *See supra* Part IV.B.2.a. The remaining factors also favor the application of Michigan law.

a. Maintenance of interstate and international order (second factor).

The second factor, maintenance of interstate and international order, favors Michigan law. The Eighth Circuit has held that, [i]n determining the relevance of the maintenance-of-interstate-order factor in a given case, 'the court may also consider whether or not application of Minnesota law will encourage forum shopping.'" *Nesladek*, 46 F.3d at (quoting *Hague v. Allstate Ins., Co.*, 289 N.W.2d 43, 49 (Minn. 1979)). Here, Mr. Braund is foreclosed from pursing independent causes of action for NIED and IIED in Michigan. The application of Minnesota law, which permits these causes of action, to a case involving a Michigan resident who was allegedly injured in Michigan would unquestionably promote forum shopping.

The Minnesota Supreme Court has acknowledged that any interest it has in protecting nonresidents must yield to its interest in deterring forum shopping:

> Minnesota does not have an interest in encouraging forum shopping, particularly where we would be sending a message to those people living on our borders to take advantage of the benefits our neighboring states offer . . ., and then, if they are injured, take advantage of Minnesota's greater willingness to compensate tort victims. Minnesota does not have an interest in encouraging that conduct.

Jepson, 513 N.W.2d at 471-72. Here, Minnesota's interest in deterring forum shopping and Michigan's interest in applying its own emotional-distress laws align, favoring the application of Michigan law.

b. Advancement of the forum's governmental interest (fourth factor).

The fourth factor, advancement of the forum's governmental interest, favors the application of Michigan law. Michigan has an overwhelming governmental interest in applying its own emotional-distress laws. Michigan courts have balanced the competing interests of compensating individuals and preventing speculative verdicts and, accordingly, determined that recovery for emotional distress must be connected to an underlying tort, not a stand-alone action. *See infra* Part XIII.A. Minnesota simply has no significant governmental interest in altering the balance struck by Michigan courts as it applies to Michigan residents injured in Michigan.

The significant contacts test favors the application of Michigan law to Mr. Braund's emotional distress claims (Counts VIII-IX).

On balance, Minnesota's choice-of-law factors dictate the application of Michigan law to Mr. Braund's product-liability claims (Counts I-VII), consumer-protection claims (Count VIII and IX), and emotional distress claims (Counts X and XI).

Even if these choice-of-law factors were neutral, Michigan law would apply because Michigan is the state in which Mr. Braund's alleged injuries occurred. *Nodak*, 604 N.W.2d at 96.

V. MICHIGAN PRODUCT LIABILITY ACT APPLIES TO MR. BRAUND'S PRODUCT LIABILITY CLAIMS

Michigan places a "heavy burden upon plaintiffs" in product liability cases. *Fleck v. Titan Tire Corp.*, 177 F. Supp. 2d 605, 613 (E.D. Mich. 2001). As discussed above, the Michigan Product Liability Act ("MPLA"), as amended by tort reform amendments in 1995, provides a comprehensive framework of procedural, evidentiary, and substantive standards that includes, among other things: (A) a presumption against liability for manufacturers whose products complied with extant federal or state laws, MICH. COMP. LAWS § 600.2946(4); (B) stringent requirements for a finding of liability in production defect cases, MICH. COMP. LAWS § 600.2946(2); and (C) limits on a manufacturer's duty to provide warnings, MICH. COMP. LAWS § 600.2948.

Although not labeled a "product liability action," Mr. Braund's claims in Counts I through VII—which sound in strict liability, negligence, fraud, and warranty—are governed by the MPLA because they involve allegations of "injury to a person or damage to property caused by or resulting from the production" of his PRIZM 2. *See supra* Part IV.B.1. Indeed, courts applying Michigan law routinely conclude that such claims fall within the broad scope of the MPLA. *See id.*

A. Mr. Braund Must Rebut the Presumption of No Liability Under the MPLA.

As noted, the "[Michigan] Legislature intended to 'cut off liability in a wide range of product cases'" by including a rebuttable presumption of no liability in the MPLA. *Toledo v. Gateway Precision Tech., LLC*, No. 263836, 2005 WL 3481436, at *5 n.22 (Mich. Ct. App. Dec. 20, 2005).

> In a product liability action brought against a manufacturer or seller for harm allegedly caused by a product, there is a rebuttable presumption that the manufacturer or seller is not liable if, at the time the specific unit of the product was sold or delivered to the initial purchaser or user, the aspect of the product that allegedly caused the harm was in compliance with standards relevant to the event causing the death or injury set forth in a federal or state statute or was approved by, or was in compliance with regulations or standards relevant to the event causing the death or injury promulgated by, a federal or state agency responsible for reviewing the safety of the product.

MICH. COMP. LAWS § 600.2946(4). Such statutory presumptions generally are designed to provide "refuge" to the manufacturer who operates in good faith and in compliance with the law. *Tuggle v. Raymond Corp*., 868 S.W.2d 621, 625 (Tenn. Ct. App. 1992).

The rebuttable presumption in the MPLA "plainly" applies to Mr. Braund's product liability claims. *Royal Appliance*, 112 Fed. Appx. at 389. First, there is no dispute that the FDA approved the PRIZM 2 on August 4, 2000, after ensuring that the device was safe and after reviewing its design structure and manufacturing process. *See* First Am. Master. Compl. ¶¶ 86, 87 (acknowledging that the PRIZM 2 was approved). The FDA was aware, prior to approval, that the device incorporated polyimide insulation—the material that Mr. Braund claims contributes to short-circuiting in PRIZM

2 devices. *See supra* Part II.A. In fact, the FDA has been aware of Guidant's use of polyimide since 1992, having approved numerous earlier generations of devices based upon Guidant's extensive polyimide qualification testing. *Id*. Second, Mr. Braund's PRIZM 2 complied with all relevant FDA standards at the time it was purchased and implanted. *Id*. Even if Mr. Braund's PRIZM 2 differed from design specifications, as he claims, it was nonetheless in full compliance with all existing FDA laws and regulations governing the safety and manufacture of ICDs. *Id*. Finally, Guidant issued all warnings required by the FDA before marketing and selling the PRIZM 2. *Id*. In fact, the FDA specifically approved the issuance of a System Guide and Physician Technical Manual for the PRIZM 2, which expressly warn ICD recipients of potential complications associated with the use of the device. *Id*.

Because the rebuttable presumption applies, Mr. Braund bears a considerable evidentiary burden on Guidant's motion for summary judgment. *See Lesho*, 408 F. Supp. 2d at 334 (noting that the rebuttable presumption applies on summary judgment because it "'goes not only to the jury's assessment of these claims but also to whether these claims should go to a jury in the first instance'" (citation omitted)); *see, e.g.*, *Michal v. PDK Labs.*, No. 234943, 2003 WL 22160438, at *5 (Mich. Ct. App. Sept. 18, 2003) (applying presumption on state equivalent of summary judgment). To overcome summary judgment, he "must point to admissible evidence in the record which, if believed by the jury would rebut the presumption." *Lesho*, 408 F. Supp. 2d at 334. This requires more than a simple showing of "a triable issue of fact" because the "essential point of the legislation is to make it more difficult for claimants to prevail

when they bring a product-liability action concerning a product that complies with pertinent federal or state safety standards." *Royal Appliance*, 112 Fed. Appx. at 398. According to the Michigan Legislature, the presumption may be "rebutted only by clear and convincing evidence proving that, regardless of compliance, the product was not reasonably safe at the time the specific unit of the product left the control of the manufacturer or seller." S.B. 344 (S-4) Summary SFA Bill Analysis at 3 (Mich. May 23, 1995); *accord* TEX. CIV. PRAC. & REM. CODE ANN. § 82.008(b) (stating that the presumption in a similar statute may only be rebutted by showing that the standards were inadequate to protect the public or that the manufacturer withheld or misrepresented information or material relevant to the government's determination).

B. Mr. Braund Must Establish the Statutory Requirements For a "Production Defect" Under the MPLA.

Under the MPLA, a manufacturer is "not liable" for harm allegedly caused by a "production defect" unless

> the plaintiff establishes that [1] the product was not reasonably safe at the time the specific unit of the product left the control of the manufacturer or seller and that, [2] according to generally accepted production practices at the time the specific unit of the product left the control of the manufacturer or seller, a practical and technically feasible alternative production practice was available that would have prevented the harm without significantly impairing the usefulness or desirability of the product to users and without creating equal or greater risk of harm to others.

Allstate Ins. Co. v. Icon Health & Fitness, Inc., 361 F. Supp. 2d 673, 676 (E.D. Mich. 2005) (quoting MICH. COMP. LAWS § 600.2946(2)). Although "production defect" is not defined under the statute, "production" is defined broadly and courts have found that this

subsection governs claims involving design and manufacturing defects. *Allstate Ins.*, 361 F. Supp. 2d at 677-78; *Torno v. 2SI, LLC.*, No. 03-74091, 2006 WL 1284924, at *5 (E.D. Mich. May 10, 2006); *accord Ghrist v. Chrysler Corp.*, 547 N.W.2d 272, 275 (Mich. 1996) (noting that the "definition of 'defective' is not limited to manufacturing defects, but also includes design defects"). Accordingly, Mr. Braund bears the evidentiary burden of proving these statutory elements.

C. Mr. Braund Must Establish the Various Statutory Requirements That Apply to Failure-to-Warn Claims Under the MPLA.

The MPLA limits a manufacturer's duty to warn in various sections. Among other things, subsection 600.2948(3) provides:

> In a product liability action brought against a manufacturer or seller for harm allegedly caused by a failure to provide adequate warnings or instructions, a manufacturer or seller is not liable unless the plaintiff proves that the manufacturer knew or should have known about the risk of harm based on the scientific, technical, or medical information reasonably available at the time the specific unit of the product left the control of the manufacturer.

MICH. COMP. LAWS § 600.2948(3); *see Irrer v. Milacron, Inc.*, No. 04-72898, 2007 WL 1300747, at *11 n.9 (E.D. Mich. May 2, 2007) (noting that, through tort reform, Michigan has provided "that the manufacturer's knowledge about the risk of harm based on scientific, technical, or medical information is to be evaluated at the time each allegedly defective product left the manufacturer's control"). Mr. Braund bears the evidentiary burden of proving these statutory elements as well.

VI. DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF SUMMARY JUDGMENT ON PLAINTIFF'S DESIGN-DEFECT CLAIM

In design-defect cases, a plaintiff must establish that a product is defective, which requires proof that the manufacturer failed to do what a reasonably prudent person would have done under the circumstances. *Prentis v. Yale Mfg. Co.*, 365 N.W.2d 176, 186 (Mich. 1984); *Miller v. Ingersoll-Rand Co.*, 148 Fed. Appx. 420, 423 (6th Cir. 2005). A plaintiff must also establish the traditional common-law elements of negligence, including causation and injury. *Abel v. Eli Lilly & Co.*, 289 N.W.2d 20, 23-25 (1979); *see* 1 MICHIGAN MODEL CIVIL JURY INSTRUCTIONS § 25.32 (2d ed. Supp. 2006) (stating that, in addition to the requirements of subsection 600.2946(2), a plaintiff has the burden of proving injury and proximate cause).

Mr. Braund alleges that "Defendants breached their duty of reasonable care to Plaintiffs by incorporating a defect into the design of the [PRIZM 2]." First Am. Master. Compl. ¶ 288. This claim rests principally upon the allegation that PRIZM 2 devices are prone to short circuit due to "deterioration of electrical insulation." *Id*. ¶ 90. More specifically, the substance used to insulate the wires—polyimide—allegedly cracks when exposed to bodily fluids. *Id*. ¶ 109. This Court should grant summary judgment in favor of Guidant because Mr. Braund cannot (A) rebut the presumption against liability by providing clear and convincing evidence of design defect or (B) provide any evidence of causation.

A. Mr. Braund Cannot Provide Clear and Convincing Evidence of a Design Defect.

Prior to the 1995 tort-reform amendments, Michigan courts applied a "pure negligence, risk-utility test" to evaluate whether a manufacturer had behaved reasonably in the design of a product. *Peck v. Bridgeport Mach., Inc.*, 237 F.3d 614, 617 (6th Cir. 2001). Under this test, the trier-of-fact evaluated the reasonableness of the manufacturer's conduct based upon: (1) the magnitude of the risk; (2) the reasonableness of the alternative design proposed; and (3) other factors concerning the reasonableness of the risk of a particular design. *Prentis*, 365 N.W.2d at 182-85; *Owens v. Allis-Chalmers Corp.*, 326 N.W.2d 372 (Mich. 1982). The 1995 tort reforms escalated the burden of proof for establishing a defective design, imposing the more "stringent" statutory requirements of subsection 600.2946(2). LINDA MILLER ATKINSON, HON. HELENE N. WHITE, & NOREEN L. SLANK, TORTS MICHIGAN LAW AND PRACTICE § 8.7 (2d ed. Supp. 2006); *see Greene v. A.P. Prods., Ltd.*, 717 N.W.2d 855, 859 (Mich. 2006) (noting that tort reform legislation displaced the common law in product liability actions).

Although courts have stated the elements variously after the tort-reform amendments, the Sixth Circuit Court of Appeals has endorsed a six-part test in design-defect cases. This test blends subsection 600.2946(2) and the "risk utility" approach traditionally followed by Michigan courts.

> Under this test, to survive a motion for summary judgment, the plaintiff must produce evidence showing:
>
> (1) that the severity of the injury was foreseeable by the manufacturer;

> (2) that the likelihood of occurrence of her injury was foreseeable by the manufacturer at the time of distribution of the product;
>
> (3) that there was a reasonable alternative design available;
>
> (4) that the available alternative design was practicable;
>
> (5) that the available and practicable reasonable alternative design would have reduced the foreseeable risk of harm posed by defendant's product; and
>
> (6) that omission of the available and practicable reasonable alternative design rendered defendant's product not reasonably safe.

Peck, 237 F.3d at 617-18 (quoting *Hollister v. Dayton Hudson Corp.*, 201 F.3d 731, 738 (6th Cir. 2000)).[2] As most relevant here, Mr. Braund cannot establish a defective design because he cannot present clear and convincing evidence that: (1) the likelihood of injury was foreseeable; (2) a reasonable and practicable alternative design was available; and (3) that omission of the alternative design rendered the PRIZM 2 not reasonably safe.

1. Mr. Braund cannot present clear and convincing evidence that the likelihood of injury was foreseeable.

"[T]he dispositive focus [in design defect cases] is on the manufacturer's conduct, not just the product" and requires the "plaintiff to prove 'that the manufacturer knew or should have known of the design's propensity for harm.'" *Gregory v. Cincinnati Inc.*, 538 N.W.2d 325, 329-30(Mich. 1995) (citation omitted); *see Estate of Triplett v. Gen. Elec. Co.*, 954 F. Supp. 149, 152 (W.D. Mich. 1996) (similar). "In offering

[2] The *Peck*/*Hollister* test is the most coherent restatement of Michigan law after the 1995 tort-reform amendments. *See* 20 MICH. CIV. JUR. *Products Liability* § 10 (discussing the *Peck*/*Hollister* test).

evidence that the risk of injury due to an alleged defect was foreseeable, a plaintiff must present evidence that the risk was foreseeable at the time that the product was designed, not at the time of trial." *Gross v. Consol. Aluminum Corp.*, 951 F.2d 349, at *6 (6th Cir. 1991).

Guidant received FDA approval for the PRIZM 2 after rigorous and thorough testing of the device. *See* CPI 2 00000001 (PRIZM 2 approval letter). Using a triple-redundant design, the PRIZM 2 reduces the possibility of arcing or short circuiting through a combination of tube spacing, medical adhesive, and state-of-the-art insulation. CPI 46 00497209, CPI 46 00497212 (Dkt. # 1745, Ex. 54); Original Expert Report of Randolph Armstrong ("Original Armstrong Report") at 6 ("As submitted to the FDA, the Model 1861 was designed to prevent arcing between DF- wire and the backfill tube using spacing per the Design Document routing, an insulator on the DF-wire, and medical adhesive as a supplemental insulator within the spacing.") (Dkt. # 1745, Ex. 65). Guidant specifically incorporated polyimide into the design of the device because, among other things, the substance had proven uniquely capable of insulating high-energy applications in more than 200,000 other devices. *See* Williams Report at 11; CPI 539 0000043898 (PRIZM 2 documents) (Dkt. # 1745, Ex. 53); *see also* MICH. COMP. LAWS § 600.2946(1) (allowing the admission of evidence that the production of a product was in accordance with generally recognized and prevailing standards in existence at the time the specific unit of the product was sold or delivered by the defendant to the purchaser or user). After extensive testing, Guidant determined that the triple-redundant design protocol

substantially reduced the likelihood of any improper shocks or other malfunctions. *See supra* Part II.A.

Mr. Braund cannot establish forseeability because he concedes that Guidant first learned of a possible problem with the PRIZM 2 devices in February 2002 – months *after* Mr. Braund had his PRIZM 2 implanted and years *after* the device was designed, tested, and approved by the FDA. *See supra* Part II.A., B.1. Given the success of polyimide in previous devices and Guidant's extensive FDA-approved testing of the PRIZM 2, Guidant would have had no reason to believe, before February 2002, that the polyimide (as alleged by Mr. Braund) could degrade or otherwise cause a short circuit under any conditions or wire configurations. *See Snider v. Stanley Works*, 28 F.3d 1214, at *3 (6th Cir. 1994) (noting that there was no evidence concerning the likelihood of an accident where "[t]here was no evidence, for example, that such an accident or one like it had ever occurred before").

Because evidence based upon "what is *now* known" about a product is insufficient as a matter of law, Mr. Braund cannot establish that Guidant should have foreseen the likelihood of his injury. *Gross*, 951 F.2d at *6.

2. Mr. Braund cannot present clear and convincing evidence that a reasonable and practicable alternative was available in 2001.

"An alternative production practice is practical and feasible only if the technical, medical, or scientific knowledge relating to production of the product, at the time the specific unit of the product left the control of the manufacturer or seller, was developed, available, and capable of use in the production of the product and was

economically feasible for use by the manufacturer." MICH. COMP. LAWS § 600.2946(2). This alternative production practice must have been available, "according to generally accepted production practices at the time the specific unit of the product left the control of the manufacturer or seller." *Id*.

Mr. Braund has presented no independent expert testimony or other competent evidence establishing that, at the time Guidant designed and distributed the PRIZM 2, technical, medical, or scientific knowledge provided an available and feasible alternative to the use of polyimide and the configuration of wires as employed by Guidant in the PRIZM 2. *See Peck*, 237 F.3d at 618 (noting that a plaintiff must provide informed expert testimony that a device could have been designed differently). Rather, he appears to rely completely upon the fact that Guidant undertook remedial measures in 2002 to suggest that an effective alternative design was available earlier. *See* First Am. Master. Compl. ¶¶ 95-96; Original Armstrong Report at 3.

Using remedial measures to prove the prior existence of an alternative design is both logically infirm and problematic as a matter of public policy. As an initial matter, changes in 2002 do not establish that an alternative was practicable, reasonable, or even known when Mr. Braund's PRIZM 2 left Guidant's control in 2001, let alone when it was initially designed in 1997. Moreover, as a matter of policy, such a hindsight standard would stifle development and reduce incentives for the redesign of existing products. *See* LINDA MILLER ATKINSON, HON. HELENE N. WHITE, & NOREEN L. SLANK, TORTS MICHIGAN LAW AND PRACTICE § 8.39 (2d ed. Supp. 2006) ("Generally, evidence of subsequent remedial measures is inadmissible as evidence of negligence because its

admission tends to discourage defendants from making necessary repairs."). For these reasons, the Michigan Legislature has determined that such remedial measures cannot be used to prove the merits of a production defect claim. *See* MICH. COMP. LAWS § 600.2946(3) (evidence of philosophy, theory, knowledge, technique, or procedure learned, placed in use, or discontinued after the event resulting in injury to the person or property may only be used to prove the feasibility of precautions if controverted or for impeachment).

Because Mr. Braund has not met his burden of producing independent evidence establishing the existence of a useful, safe, and cost effective alternative, Mr. Braund cannot establish this element.

3. Mr. Braund cannot present clear and convincing evidence that the omission of the alternative design rendered the PRIZM 2 not reasonably safe.

Even if he could prove that during at the relevant time period there as an available and practicable alternative design, Mr. Braund cannot demonstrate that the omission of that design rendered the PRIZM 2 not reasonably safe. The PRIZM 2 is one of the most reliable ICDs ever marketed. The confirmed malfunction rate for the entire product line is only 0.44%. The confirmed malfunction rate linked to short circuiting is a mere 0.14%. *See supra* Part II.A. This malfunction rate is far below the anticipated failure rate for similar devices and industry expectations. *Id.*; *see also Petto v. Raymond Corp*, 431 N.W.2d 44, 47 (Mich. Ct. App. 1988) (noting that plaintiffs in design defect cases must present compelling evidence that accidents were frequent). The simple fact that an alternative design might have reduced an already small number of malfunctions

even further is not sufficient to prove that a product is not reasonably safe under the law. *See Lesho*, 408 F. Supp. 2d at 335 ("[S]imply because the product does not incorporate features that would make it safer, does not mean that the product is necessarily unsafe." (citing *Fisher v. Kawasaki Heavy Indus., Ltd.*, 854 F. Supp. 467, 471-72 (E.D. Mich. 1994))). After all, Michigan courts have long held that manufacturers need not make their "mechanical devices 'accident proof'." *Owens v. Allis-Chalmers Corp.*, 268 N.W.2d 291, 293 (Mich. Ct. App. 1978); *see Zettle v. Handy Mfg. Co.*, 998 F.2d 358, 361 (6th Cir. 1993) (noting that manufacturers are not insurers for injury resulting from the use of their products).

A final, critical, point bears mentioning: Mr. Braund's expert does not opine that the PRIZM 2 was designed unsafely. To the contrary, he merely states that the "the root cause of the Model 1861 arcing failures was a manufacturing defect caused by operator variability." Original Armstrong Report at 12. Without expert evidence, Mr. Braund cannot, as a matter of law, establish a defective design. *See Caswell v. Air Prods. and Chems., Inc.*, 59 F. Supp. 2d 684, 689 (E.D. Mich. 1999) ("Plaintiff is required to produce expert testimony demonstrating that the product at issue constituted an unreasonable risk to users."); *see also Peck*, 237 F.3d at 294 (noting that "an expert who testifies that a product could have been designed differently, but who has never made or seen the alternative design he proposes, and therefore has no idea of its feasibility, utility or cost, does not make out a *prima facie* case that a reasonable, practicable, and available alternative design was available").

Because Mr. Braund cannot present clear and convincing evidence that—despite the approval by the FDA of the PRIZM 2 design—the failure to apply any alternative production practice rendered the PRIZM 2 not reasonably safe, he cannot establish this element.

B. Mr. Braund Cannot Provide Any Evidence That the Alleged Design Defect Caused an Injury.

"The plaintiff must plead and prove causation between the defect in the product and the injuries sustained regardless of the nature of the claim on which he or she is proceeding." LINDA MILLER ATKINSON, HON. HELENE N. WHITE, & NOREEN L. SLANK, TORTS MICHIGAN LAW AND PRACTICE § 8.7 (2d ed. Supp. 2006). Causation requires evidence of a cause in fact and legal or proximate cause. *Skinner v. Square D Co.*, 516 N.W.2d 475, 481 (Mich. 1994); *see Auto Club Ins. Ass'n v. Gen. Motors Corp*., 552 N.W.2d 523, 527 (Mich. Ct. App. 1996) ("A court must determine whether it is reasonable to infer from the evidence that the accident was probably caused by the design defect."). Because Mr. Braund cannot establish causation, Guidant is entitled to summary judgment.

ICDs are complex devices composed of thousands of electrical components. Inserted near the heart, these ICDs are designed to be small but functional, administering shocks and otherwise regulating cardiac function through electrical activity. Because of their small size and complex nature, physicians are well aware that ICDs may function improperly if not properly calibrated and operated. *See supra* Part II.A. Indeed, Guidant obtained FDA approval to issue a System Guide and Physician

Technical Manual for the PRIZM 2, which expressly warned of potential complications and adverse events, including "inappropriate shocks" and other alleged injuries upon which Mr. Braund bases his complaint. *Id*.

Guidant has produced evidence demonstrating that Mr. Braund's shocks were caused because his device needed recalibration in the months after implantation—not by any alleged design defect. *See supra* Part II.B.2. Further, Mr. Braund's own expert establishes that his injuries were not caused by the design defect he alleges, stating that "insulation breaching and arcing were not evident" in his device. *Id*. Thus, even if the device had a design flaw that could (theoretically) result in injury, there is no evidence that the alleged flaw produced an injury in this case. *See Am. & Foreign Ins. Co. v. Gen. Elec. Co.*, 45 F.3d 135, 140 (6th Cir. 1995) ("Where the evidence indicates that it is as likely that the incident was caused by factors other than those asserted, a verdict for the defendant is mandated since otherwise a verdict would be based on speculation and conjecture."); *Skinner*, 516 N.W.2d at 481 (noting that a plaintiff must establish "that the conduct of the defendant was a cause in fact of the result" and the "when the matter remains one of pure speculation or conjecture, or the probabilities are at best evenly balanced, it becomes the duty of the court to direct a verdict for the defendant").[3]

[3] *See infra* at Part XI (establishing that Mr. Braund suffered no actionable injury).

VII. DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF SUMMARY JUDGMENT ON PLAINTIFF'S MANUFACTURING DEFECT CLAIM

To establish a manufacturing defect, a plaintiff must show: (1) the product was defectively manufactured; (2) the product reached the plaintiff in the same condition as it was when it left the manufacturer; and (3) the defect was the proximate cause of the person's injuries or damages. *Prentis*, 365 N.W.2d at 182. "[A] manufacturing defect alleges that a product's defect or malfunctioning was caused by some imprecision in the manufacturing process, rather than from any negligent conduct of the manufacturer in designing the product." *Johnson v. Black & Decker (U.S.), Inc.*, 408 F. Supp. 2d 353, 357 (E.D. Mich. 2005) (citation omitted); *Gregory*, 538 N.W.2d at 329 n.10 (noting that such claims involve an "examination of the product itself rather than the manufacturer's conduct").

To establish a production defect, Mr. Braund must also satisfy the statutory requirements of subsection 600.2946(2) of the MPLA and "show that the manufacturer 'failed to manufacture its product so as to eliminate any unreasonable risk of foreseeable injury.'" LINDA MILLER ATKINSON, HON. HELENE N. WHITE, & NOREEN L. SLANK, TORTS MICHIGAN LAW AND PRACTICE § 8.7 (2d ed. Supp. 2006) (quoting *Lagalo v. Allied Corp.*, 554 N.W.2d 352, 354 (Mich. Ct. App. 1996)).

Mr. Braund alleges that Guidant "manufactur[ed] and assembl[ed] the [PRIZM 2] in such a manner that they could short circuit and/or otherwise fail to operate and malfunction." First. Am. Master Compl. ¶ 289. Through his expert, Mr. Braund argues that his PRIZM 2 was defective because it did not meet design specifications.

This Court should grant summary judgment in favor of Guidant because Mr. Braund cannot (A) rebut the presumption against liability by providing clear and convincing evidence of manufacturing defect that rendered the device unsafe or (B) provide any evidence of causation.

A. Mr. Braund Cannot Provide Clear and Convincing Evidence of a Manufacturing Defect That Rendered the Device Unsafe.

Mr. Braund bears the burden of establishing a manufacturing defect. Although he presents evidence that his PRIZM 2 did not conform to design specifications, such variations do not, *ipso facto*, establish a manufacturing defect. *See Landberg v. Ricoh Int'l, a Div. of Ricoh Co., Ltd*., 892 F. Supp. 938, 944 (E.D. Mich. 1995) ("Merely citing to a condition of the product that differs from manufacturing specifications is not enough to establish a *prima facie* case of a manufacturing defect."). Absent evidence that this deviation rendered the device not reasonably safe, there is no actionable manufacturing defect. *See Gregory*, 538 N.W.2d at 329 n.10 (product itself must be unsafe). He has produced no such evidence. *See Prentis*, 365 N.W.2d at 182 (noting that a product is evaluated against the "manufacturer's other like products"). Given his considerable burden to rebut the presumption of no liability, as well as his obligation to provide evidence under subsection 600.2946(2), Mr. Braund cannot establish this element of his *prima facie* case. Moreover, Guidant has affirmative proof that there is no evidence of a manufacturing defect here. Specifically, testing and inspection results of Mr. Braund's device show that there is space between the polyimide and the backfill tube. Thus, there is no evidence of a manufacturing defect. Mr.

Armstrong's observations regarding the bending of the DF-wire do not constitute a manufacturing defect due to the triple-redundant design features of the PRIZM 2.

B. Mr. Braund Cannot Provide Evidence That the Alleged Manufacturing Defect Caused an Injury.

In addition, Guidant is entitled to summary judgment on Mr. Braund's manufacturing defect claim because he has not produced evidence establishing that the alleged defect caused an injury. Other than the shocks caused by failure to properly calibrate and manage Mr. Braund's device in the months after initial implantation, there is no evidence of any injury whatsoever. *See Johnson*, 408 F. Supp. 2d at 357 (noting that the simple fact that a device malfunctioned is not sufficient evidence to support a claim of manufacturing defect). Indeed, although Mr. Armstrong opines that Mr. Braund's PRIZM 2 contained a manufacturing defect, he does not claim that the defect caused (or could have caused) an injury. *See Skinner*, 516 N.W.2d at 481 (plaintiff must prove "but for" causation). In fact, Mr. Armstrong acknowledges that insulation breaching and arcing were not evident, proving that Mr. Braund's PRIZM 2 had never short circuited. Absent such insulation breaching and arcing, there is no evidence that the alleged manufacturing defect in wire placement and bending caused an injury. *See Landberg*, 892 F. Supp. at 944 (defect must have contributed to injury).[4] Guidant has put on affirmative evidence that the DF- wire was placed correctly, and that other factors must present before any arcing could occur. On these facts, based on the triple-redundant

[4] *See infra* at Part IX (establishing that Mr. Braund suffered no actionable injury).

design features, Mr. Braund has no evidence that any manufacturing defect did (or ever could) cause him injury.

VIII. DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF SUMMARY JUDGMENT ON PLAINTIFF'S STRICT LIABILITY CLAIMS

Mr. Braund pursues a strict liability theory in Counts I and II of the Amended Master Complaint, alleging that: (1) Defendants' device contained manufacturing or design defects; and (2) Defendants failed to warn him of those defects. First Am. Master. Compl. ¶¶ 271-86. These claims fail as a matter of law because, unlike most states, Michigan does not recognize strict liability as a viable cause of action. *Toth v. Yoder Co.*, 749 F.2d 1190, 1193 (6th Cir. 1984) (citing *Johnson v. Chrysler Corp.*, 254 N.W.2d 569, 571 (Mich. Ct. App. 1977)); *see Pelc v. Bendix Mach. Tool Corp*., 314 N.W.2d 614, 620 (Mich. Ct. App. 1981) (stating that "Michigan has not yet openly embraced strict liability as a theory of recovery for products liability"); *see also* ELMER E. WHITE, MICHIGAN TORTS § 9.1 (2d ed. 1996) (noting that the "danger in searching the jurisprudence of the other 49 states is that the researcher will see frequent reference to 'strict liability'" while "Michigan does not recognize 'strict liability'"). Courts and commentators alike recognize that, by legislative design, "products liability claims are based on a single statute and are fault-based." 20 MICH. CIV. JUR. *Products Liability* § 1 (citing *Ryan v. Brunswick Corp.*, 557 N.W.2d 541 (Mich. 1997)). Indeed, because it is "well established under Michigan law [that] there is no strict liability for product liability claims," *Irrer v. Milacron, Inc.*, No. 04-72898, 2007 WL 677899, at *2 (E.D. Mich. Mar. 6, 2007), courts steadfastly refuse to extend product liability law to add such a theory of

liability by judicial fiat, *Fire Ins. Exch. v. Electrolux Home Prods.*, No. 05-70965, 2006 WL 2925286, at *10 (E.D. Mich. Oct. 11, 2006).[5]

IX. DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF SUMMARY JUDGMENT BASED ON LACK OF INJURY CAUSED BY ARCING OR SHORT-CIRCUITING

Mr. Braund concedes that his PRIZM 2 did not short circuit. Testing data revealed that there was no cracking on the polyimide insulation on the DF- wire, and that there was a space between the DF- wire and the backfill tube. As Mr. Braund's engineering expert, Randy Armstrong concedes, "insulation breaching and arcing were not evident" in Mr. Braund's device. *See supra* Part II.B.2. Indeed, the short-circuiting or arcing failure at issue in this MDL never manifested in Mr. Braund's PRIZM 2.

Instead, Mr. Braund claims that his device inappropriately shocked him on numerous occasions. Mr. Braund alleges that his PRIZM 2 is defective because it "experienced electrical malfunctions . . . resulting in random and inadvertent electrical shock when no shock was medically warranted." Pl. Compl. at ¶ 4. Setting aside that Guidant adequately warned of the risk of inappropriate shock, *see* Part X (Failure-to-Warn), Mr. Braund has no evidence that the alleged inappropriate shocks are attributable to a *defect* in his PRIZM 2. To the contrary, the device-detection levels needed to be readjusted. In his expert report, Randy Armstrong offers no opinion as to the cause of the alleged inappropriate shocks. In fact, he does not address inappropriate shocks at all.

[5] Under certain circumstances, the elements for a traditional cause of action based upon strict liability in tort resemble those for breach of warranty. *Owens*, 268 N.W.2d at 293.

Under both Michigan and Minnesota law, Mr. Braund's product-liability claims must be dismissed absent evidence of injury caused by a defect in his device.

A. Mr. Braund's Product-Liability Claims Must be Dismissed Absent Evidence That His Alleged Injuries Were Caused by a Malfunction in His PRIZM 2.

The Court should dismiss Mr. Braund's product-liability claims in their entirety because Mr. Braund has no evidence that any of his alleged injuries were caused by a malfunction in his PRIZM 2. Specifically, he has no evidence to dispute that his PRIZM 2 exhibited no arcing. Moreover, there is no evidence of insulation breaching or lack of wire spacing. Nor does he have any evidence that the alleged inappropriate shocks were caused by a *defect* in his PRIZM 2. Without a causal connection between injury and malfunction, his product-liability claims must be dismissed.

Merely because an injury results from the use of a product does not *ipso facto* mean that the product is defective. *Owens v. Allis-Chalmers Corp*., 268 N.W.2d 291, 293 (Mich. App. 1978). The burden of establishing proximate cause always rests with the complaining party, and no presumption of it is created by the mere fact of an accident. *Howe v. Michigan C.R. Co*., 211 N.W. 111 (Mich. 1926).

Thus, a plaintiff bringing a products-liability action must show that the defendant supplied a defective product and that the defective product *caused* the injury. *Bramble v. Hormel Foods Corp*., 2000 WL 33538512, at *1 (Mich. App. Jan. 28, 2000) (citing *MASB-SEG Property/Casualty Pool, Inc. v. Metalux*, 586 N.W.2d 549 (Mich. App 1998). In other words, a prima facie case for products liability requires proof of a *causal connection* between an established *defect* and *injury*. *Skinner v. Square D Co*., 516

N.W.2d 475, 478 (Mich. 1994). As the Michigan Supreme Court noted, the causal connection must be based on "substantial evidence" as opposed to impermissible conjecture:

> A causation theory must have some basis in established fact. However, a basis in only slight evidence is not enough. Nor is it sufficient to submit a causation theory that, while factually supported, is, at best, just as possible as another theory. Rather, the plaintiff must present substantial evidence from which a jury may conclude that more likely than not, but for the defendant's conduct, the plaintiff's injuries would not have occurred.

Skinner v. Square D Co., 516 N.W.2d 475, 480 (Mich. 1994). Minnesota law is similar. *See, e.g., J & W Enters. Inc. v. Economy Sales, Inc.*, 486 N .W.2d 179, 181 (Minn. App. 1992) (under "any theory of products liability, the plaintiff must show a causal link between the alleged defect and the injury").

In the medical-device context, federal and state courts throughout the country have consistently rejected claims by individuals who cannot show a physical injury attributable to a manifest defect in a medical device. As New York's highest court explained:

> [a]n implanted or inserted device intended to perform a continuing function . . . causes no injury until the product malfunctions. Until that time the recipient . . . has no cause to complain. If through malfunction the product is thought to have caused harm, it can in most cases be removed and examined to ascertain whether in fact it malfunctioned and, if so, whether that was the cause of the harm.[6]

[6] *Martin v. Edwards Labs*, 457 N.E.2d 1150, 1155 (N.Y. 1983) (superceded on unrelated grounds by N.Y. C.P.L.R. 214-c(2), which provides that the statute of limitations in toxic-exposure cases begins to run on date of discovery of latent injury, not on date of "impact" with toxic substance).

Numerous courts considering such medical-device cases have followed this logic to dismiss a variety of product-liability claims, including those based on warranty, tort, strict liability, fraud and consumer-protection statutes:

- *Pfizer v. Farsian*, 682 So. 2d 405, 407 (Ala. 1996) (in case involving allegedly defective heart valve, holding plaintiff's belief that a product could fail in the future is not, without more, a legal injury sufficient to support plaintiff's fraud claim).

- *Willett v. Baxter Int'l, Inc*., 929 F.2d 1094, 1097 (5th Cir. 1991) (applying Louisiana law and precluding claims where plaintiffs, whose heart valves carried a 0.08% failure rate, "provided no evidence that their particular [heart] valves . . . were not performing as designed").

- *Spuhl v. Shiley, Inc.*, 795 S.W.2d 573, 580 (Mo. App. 1990) (in a case involving an allegedly defective heart valve with 0.02% failure rate, holding that product malfunction or failure is an essential element of a claim for negligent- or strict-liability-based failure to warn).

- *Bravman v. Baxter Healthcare Corp.*, 794 F. Supp. 96, 100 (S.D.N.Y. 1992) (in case involving heart valve with 0.1% failure rate, "New York generally does not recognize a cause of action for a faulty heart valve until the valve actually fails and causes a physical harm"), *aff'd in part and rev'd in part,* 984 F.2d 71 (2d Cir.1993).

- *Rall v. Medtronic, Inc*., 1986 WL 22271 at * 2 (D. Nev. Oct. 15, 1986) (noting that "plaintiff's contention that the mere presence of a polyurethane lead in the body, with or without any malfunction, establishes a basis for liability, and a question common to all members, defies reality" and denying class certification).

- *Walus v. Pfizer, Inc*., 812 F. Supp. 41, 44 (D.N.J. 1993) (in case involving allegedly defective heart valve, noting that "[n]o provision in [New Jersey's product liability statute] authorizes a cause of action based on a claim that a normally functioning product might fail at some unknown time").

- *Keath v. Shiley, Inc*., 1991 U.S. Dist. LEXIS 21872, at *7 (N.D. Ohio 1991) (in case involving allegedly defective heart valve and strict liability, negligence, and warranty claims, noting that "[a] product is considered defective only if it causes an injury; it cannot be considered defective simply because it is capable of producing injury").

- *Lauterbach v. Shiley, Inc*., No. CIV. A H-87-3208, 1991 WL 148137, at *9 (S.D. Tex. March 29, 1991) (in case involving allegedly defective heart valve and claims based on strict liability, negligence, warranty, fraud, and intentional infliction of emotional distress, noting that "[t]here is no cause of action under Texas law where a plaintiff's product is and has been functioning without incident. Texas law does not recognize a claim seeking to recover for alleged concern or anxiety that a functioning product might fail at some future unknown time").

- *Murphy v. Shiley, Inc*., 1991 U.S. App. LEXIS 17190, at *1 (9th Cir. 1991) (holding that Washington Product Liability Act law does not allow recovery "absent product failure, malfunction, or product-caused accident").

Here, Mr. Braund concedes that his device never short-circuited or arced. *See supra* Part II.B.2. Indeed, Mr. Braund's engineering expert concedes that "breaching and arcing were not evident." *Id.* Moreover, there is a space between the DF- wire and the backfill tube. *Id.* In short, the factors required for arcing were not present in Mr. Braund's PRIZM 2 and more importantly, his device never arced. Thus, he has no evidence to support his claim.

Instead, Mr. Braund alleges that his device inappropriately shocked him. Indeed, inappropriate shocks are the only alleged defect in Mr. Braund's device. But Mr. Braund has no evidence that the alleged inappropriate shocks were attributable to a defect in his device. He has no testing data and no expert testimony to support his flawed notion that the alleged inappropriate shocks were caused by a defect or malfunction in his device. *Id.* His doctors noted in Mr. Braund's medical records that he received "inappropriate shocks" on several occasions, because the device's settings were too low. *Id.* Nowhere are inappropriate shocks mentioned in the expert report of Mr. Braund's engineering expert, Randy Armstrong. *Id.* The only expert opinion regarding inappropriate shocks is that of Dr. Thomas Ross, who opined that Mr. Braund's alleged

inappropriate shocks "were secondary to sinus tachycardia and atrial fibrillation and were related to programming issues and rapid conduction and are not indicative of device malfunction. With no evidence of defect, on one hand, and with the more plausible scenario that that his shocks were caused by his device settings, on the other, Mr. Braund has no substantial evidence of defect-caused injury essential to his product-liability claims.

Mr. Braund's case is distinguishable from *Duron*, and more akin to *O'Brien* and *Khan*. The fact that Mr. Braund's device delivered numerous shocks provided him and his doctors with assurance that his device was capable of delivering therapy. Further, Mr. Braund's engineering expert, Randy Armstrong, found no evidence of polyimide breaching or degradation. In fact, Mr. Armstrong's report regarding Mr. Braund's device does not address whether and to what extent Mr. Braund's device would have ever developed polyimide degradation. Thus, unlike *Duron*, there is no factual dispute regarding potential polyimide degradation – whether denominated as a "defect" or a "malfunction" – in Mr. Braund's case. Indeed, Mr. Braund's device was not capable of arcing since all aspects of the triple-redundant design were present. Finally, the basis for explant was Mr. Braund's subjective belief that the device was inappropriately shocking him. *See* supra Part IIB.3. As in *O'Brien*, the chain of causation is broken when a patient requests an otherwise medically unnecessary procedure, and here, there is no evidence that Mr. Braund's doctor recommended explant based on the recall. *Id*. Thus, Mr. Braund's case is distinguishable from *Duron*.

In short, there is no genuine factual dispute that Mr. Braund did not suffer any injuries resulting from short-circuiting or arcing defect in his PRIZM 2. Accordingly, the Court should dismiss all of Mr. Braund's product-liability claims to the extent they are premised on short-circuiting or arcing. Further, the Court should dismiss Mr. Braund's product-liability claims in their entirety because Mr. Braund has no evidence that the alleged inappropriate shocks were caused by a defect in his PRIZM 2 or that his doctors recommended explant based on the recall. Accordingly, the Court should dismiss the following claims:

- Negligence (Count I – Complaint)
- Strict Liability: Design and Manufacturing Defect (Count II – Complaint)
- Strict Liability: Failure to Warn (Count III – Complaint)
- Breach of Implied Warranty (Count IV – Complaint)
- Breach of Express Warranty (Count V – Complaint)
- Misrepresentation by Omission (Count VI – Complaint)
- Constructive Fraud (Count VII – Complaint)
- Fraud (Count VI – Master Complaint)
- Violation of Minnesota False Statement in Advertisement Act (Count VII – Complaint)
- Violation of Minnesota Prevention of Consumer Fraud Act (Count VIII – Complaint)
- Negligence Per Se (Count IV – Complaint by Adoption)
- Unfair and Deceptive Trade Practices Under Michigan Law (Count VIII – Complaint by Adoption)

- Negligent Infliction of Emotional Distress (Count X – Complaint by Adoption)
- Intentional Infliction of Emotional Distress (Count XI – Complaint by Adoption)
- Gross Negligence / Malice (Count XII – Complaint by Adoption)
- Medical Monitoring (Count XVI – Complaint by Adoption)[7]
- Unjust Enrichment (Count XVII – Complaint by Adoption)

X. DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF SUMMARY JUDGMENT ON MR. BRAUND'S STRICT-LIABILITY FAILURE-TO-WARN CLAIM

In Count III of his Complaint, Mr. Braund asserts that Guidant failed to warn him of the potential for arcing in the PRIZM 2 devices. Mr. Braund's assertion fails as a matter of law. First, a manufacturer only has a duty to warn of known defects. There were no reports of arcing at the time Mr. Braund's device was implanted. Second, Mr. Braund cannot prove that a warning of the potential for arcing would have altered his doctor's conduct. Mr. Braund's physician was aware that the device could deliver inappropriate shocks and still implanted the PRIZM 2. Thus, Mr. Braund's failure-to-warn claim fails as a matter of law, entitling Guidant to summary judgment on Counts I, VI, VII and VIII of the Master Complaint.

[7] Plaintiffs' Counsel has agreed that Mr. Braund is not bringing a claim for medical monitoring as an independent cause of action, but rather as an element of damages. Accordingly, the Court should dismiss such claim and treat any request for medical monitoring as an element of damages.

A. Under Michigan Law, A Manufacturer Only Has a Duty to Warn of Known Defects.

Guidant is only required to warn about known risks of harm at the time the device left Guidant's control. Pursuant to Mich. Comp. Laws. Ann. § 600.2948(3):

> In a product liability action brought against a manufacturer or seller for harm allegedly caused by a failure to provide adequate warnings or instructions, a *manufacturer or seller is not liable unless the plaintiff proves that the manufacturer knew or should have known about the risk of harm based on the scientific, technical, or medical information reasonably available at the time the specific unit of the product left the control of the manufacturer.*

Id. (emphasis added). Mr. Braund's device was implanted on August 24, 2001. *See supra* Part II.B.1. Approximately five months later, the first reported incident of arcing was on February 1, 2002. *See supra* Part II.B.2. Thus, at the time Mr. Braund's ICD was implanted, there were no known or reported arcing incidents with respect to the PRIZM 2. Therefore, Guidant could not have warned Mr. Braund of the potential arcing problem and Mr. Braund's failure to warn claim fails as a matter of law.[8]

B. Guidant Had No Duty to Warn Mr. Braund Under the Learned Intermediary Doctrine.

To establish a prima facie case of negligent failure to warn in a products liability action, the plaintiff must show that (1) the defendant owed the plaintiff a duty to warn of the danger, (2) the defendant breached that duty, (3) the defendant's breach was the proximate and actual cause of the plaintiff's injury, and (4) the plaintiff suffered

[8] Even if there is a continuing duty to warn, any future warning of the potential for arcing is in no way related to Mr. Braund's alleged injuries. As set forth below, Mr. Braund's alleged injury was related to a setting error of his device.

damages as a result. *Tasca v. GTE Products Corp.,* 438 N.W.2d 625, 627 (Mich. Ct. App. 1988).

Guidant owed no duty to Mr. Braund. Pursuant to Mich. Comp. Laws. Ann. § 600.294(7):

> Except to the extent a state or federal statute or regulation requires a manufacturer to warn, a manufacturer or seller is not liable in a product liability action for failure to provide an adequate warning if the product is provided for use by a sophisticated user.

Id. The rationale behind the doctrine is that, in making the determination as to whether the treatment of a patient should include the prescription of a manufacturer's drug, the physician, acting as a learned intermediary, is in a better position not only to weigh the risks and benefits of the particular drug for the particular patient, but also to explain these risks and benefits to the patient herself. The presumption is that use of the learned intermediary to convey the necessary warnings and recommendations is more effective and safe than would be any communication directly between a manufacturer and the consumer. *Nichols v. McNeilab, Inc.*, 850 F. Supp. 562, 564 (E.D. Mich. 1993). The learned intermediary doctrine also applies to prescriptive devices. *Brown v. Drake-Willock Int'l, Ltd.*, 530 N.W.2d 510 (Mich. Ct. App. 1995)(applying doctrine to dialysis machines).

In the present case, Mr. Braund's physician is a learned intermediary. *Nichols v. McNeilab, Inc.*, 850 F. Supp. at 564; *Smith v. E.R. Squibb & Sons, Inc.*, 273 N.W.2d 476. Thus, Guidant owed no duty to Plaintiff, and, hence, could not have breached the duty to Plaintiff.

Moreover, Guidant did not breach its duty to warn Mr. Braund's physician. The technical manual, accompanying each device states the following: "The AICD pulse generator is subject to random component failure. Such failure *could cause inappropriate shocks*, induction of arrhythmia's, and could lead to the patients death." *See supra* Part A. The technical manual also states the risk of "mortality due to inability to defibrillate or pace. . . ." CPI 34 00000218 (Dkt. # 1745, Ex. 4). Section 9.1 of the technical manual, entitled "Patient Manual" states:

> A copy of the patient manual is provided with each device for the patient, patient's relatives, and other interested people. Discuss the information in the manual with concerned individuals both before and after pulse generator implantation so they are fully familiar with operation of the device . . . .

CPI 34 00000221 (Ex. 14). Identical language is contained in the physicians manual distributed to doctors implanting the PRIZM 2 devices. CPI 34 00001469 (Dkt. # 15). Thus, Mr. Braund's physician was warned that the device could result in inappropriate shocks and random component failures, and his physician was instructed to discuss the information in the manual with Mr. Braund.[9] Therefore, Guidant fulfilled its duty to warn Mr. Braund's physician and there is no breach of that duty.

C. Mr. Braund Cannot Prove that A Failure to Warn of the Arcing is the Proximate Cause of His Alleged Injury.

Even if Guidant arguably breached such duty, Mr. Braund cannot prove that a failure to warn of the arcing is a proximate cause of his alleged injury. He must

[9] Providing the warning to the doctor, even if the doctor fails to read it is sufficient to fulfill a manufacturers duty to warn. *See Dunn v. Lederle Laboratories*, 328 N.W.2d 576, 582-83 (Mich. Ct. App. 1982)(noting that a doctor's failure to read the warning is an intervening force that destroys causation and liability).

show that an adequate warning *would have prevented the injury by altering the doctor's conduct*. *Dunn v. Lederle Laboratories*,328 N.W.2d 576, 582 (Mich. Ct. App. 1982). Otherwise, the failure to warn is not the proximate cause of injury. *Id.*

Mr. Braund cannot prove his doctor's conduct would have been altered.[10] First, there were no reported arcing incidents prior to Mr. Braund's PRIZM 2 implant. Thus, even if it were arguably relevant to Mr. Braund's injuries, there was nothing to warn Mr. Braund's physician of, and thus his conduct could not have been altered.

Second, Mr. Braund's alleged injury – inappropriate shocks – *would not have been prevented* by warning Mr. Braund's physician about the potential for arcing, because Mr. Braund's alleged injury was the result of a setting error in his device.[11] Third, Mr. Braund's physician was warned of the risk of inappropriate shocking and still choose to implant the PRIZM 2. Thus, Mr. Braund cannot prove that a failure to warn of arcing would have prevented his alleged injury, and his claim fails as a matter of law.

Based on the foregoing, Mr. Braund's failure to warn claim fails as a matter of law, entitling Guidant to summary judgment on Count I, VI, VII, VIII, and IX of the Master Complaint.

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[10] Notably, Mr. Braund's physician has not been deposed.

[11] Mr. Braund's medical records indicate that the inappropriate shocks were the result of a setting error. See supra Part II.B.2. Interestingly, Mr. Braund's expert admits that "Mr. Braund has difficulty, intellectually, and more so emotionally, separating out the cause of the shocks, a setting error, with also being notified of the inherent defect in the defibrillator unit itself." *See supra* Part II.B.4.

XI. DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF PARTIAL SUMMARY JUDGMENT ON PLAINTIFF'S UNJUST ENRICHMENT CLAIMS

Mr. Braund seeks equitable relief in the form of an unjust enrichment claim, alleging that Guidant has wrongfully "profited and benefited from the purchase and implementation" of his PRIZM 2 "at the expense of Plaintiff[]." First Am. Master. Compl. ¶¶ 372, 374. Mr. Braund is not entitled to such relief because: (A) he has pled numerous adequate legal theories which foreclose the availability of equitable relief; and (B) Guidant has not unjustly profited from the sale of his allegedly defective device because Guidant replaced Mr. Braund's device and reimbursed him for $2,500 in medical expenses.

A. Mr. Braund Has an Adequate Legal Remedy.

Mr. Braund's unjust enrichment claim fails as a matter of law because he has pled adequate legal remedies. "It is blackletter law that the theory of unjust enrichment is equitable in nature and is, therefore, not available where there is an adequate legal remedy." *In re Managed Care Litig.*, 185 F. Supp. 2d 1310, 1337 (S.D. Fla. 2002) (dismissing claims because lack of adequate remedy not specifically pled) (internal quotation marks omitted). "Equity will not take jurisdiction where there is a full, complete, and adequate remedy at law, unless it is shown that there is some feature of the case peculiarly within its jurisdiction." *ECCO Ltd. v. Balimoy Mfg. Co.*, 446 N.W.2d 546, 548 (Mich. Ct. App. 1989); *see also Servicemaster of St. Cloud v. Gab Bus. Servs., Inc.*, 544 N.W.2d 302, 305 (Minn. 1996) ("A party may not have equitable relief where there is an adequate remedy at law available.").

Mr. Braund asserts that he is entitled to relief under numerous statutory and common-law theories of liability. He does not allege that he lacks an adequate legal remedy. Because such remedies are available, equity "will not take jurisdiction." This conclusion is consistent with Minnesota law and a substantial number of other jurisdictions throughout the country. *See, e.g., Brown v. Sandimo Materials*, 250 F.3d 120 (2d Cir. 2001); *Adamson v. Ortho-McNeil Pharm., Inc.*, 463 F. Supp. 2d 496 (D. N.J. 2006); *Underwriters Ins. Co. v. Offshore Marine Contractors, Inc.*, 442 F. Supp. 2d 325 (E.D. La. 2006); *Brumbelow v. Law Offices of Bennett and Deloney, P.C.*, 372 F. Supp. 2d 615 (D. Utah 2005); *Ethypharm S.A. France v. Bentley Pharms., Inc.*, 388 F. Supp. 2d 426 (D. Del. 2005); *Harold ex rel. Harold v. McGann*, 406 F. Supp. 2d 562 (E.D. Pa. 2005); *Taylor Woodrow Blitman Const. Corp. v. Southfield Gardens Co.*, 534 F. Supp. 340 (D. Mass. 1982); *Farmers Nat'l Bank v. Wickham Pipeline Constr.*, 759 P.2d 71 (Idaho 1988); *Guinn v. Hoskins Chevrolet*, 836 N.E.2d 681 (Ill. App. Dist. 2005); *Baker v. Maclay Props. Co.*, 648 So.2d 888 (La. 1995); *Santagate v. Tower*, 833 N.E.2d 171 (Mass. App. Ct. 2005); *Robinson v. Southerland*, 123 P.3d 35 (Okla. Civ. App. 2005).

That Mr. Braund is unlikely to succeed as to some of his legal claims is of no moment. "Equitable remedies are designed to give relief where justice demands, but law fails to so provide." *Coastal Masonry, Inv. v. Reliance Ins. Co.*, 297 B.R. 34, 41 (E.D. Va. 2003). They are not available to give another remedy simply because existing legal remedies prove difficult to maintain. *J.C. Penney Co. v. United States Treasury Dep't*, 439 F.2d 63, 68 (2d Cir. 1971). In fact, where a claim is not cognizable, creating an equitable remedy would be an impermissible expansion of the common law. *Henry v.*

Dow Chem. Co., 701 N.W.2d 684, 701-02 (Mich. 2005). Mr. Braund is seeking such an extension of law in this case. Here, Mr. Braund has access to legal remedies; thus, an action in equity should not be permitted.

B. Defendants Did Not Inequitably Receive or Improperly Retain Profits or Benefits.

Even if this Court were to find that Mr. Braund can, as a matter of law, pursue an unjust enrichment claim, his claim would fail on its merits because he cannot demonstrate that Guidant has been enriched, unjustly or otherwise. "To establish an unjust enrichment claim, the claimant must show that the defendant has knowingly received or obtained something of value for which the defendant 'in equity and good conscience' should pay." *Servicemaster*, 544 N.W.2d at 307. "'[U]njust enrichment claims do not lie simply because one party benefits from the efforts or obligations of others, but instead it must be shown that a party was unjustly enriched in the sense that the term 'unjustly' could mean illegally or unlawfully.'" *Id.* (quoting First Nat'l Bank v. Ramier, 311 N.W.2d 502 (Minn. 1981)).

As an initial matter, Mr. Braund cannot establish that Guidant engaged in unjust conduct. Mr. Braund alleges that Guidant "benefited from the purchase and implementation" of the devices, accepting profits and benefits with "full knowledge and awareness" that Mr. Braund did not receive "a product of the quality, nature or fitness that had been represented by Defendants." First Am. Master. Compl. ¶¶ 372, 373. Allegations aside, however, there is no dispute that Mr. Braund received his PRIZM 2 in August 2001, Compl. by Adoption ¶ 5, after the device was approved for sale by the

FDA, First Am. Master. Compl. ¶ 86, and at least six months *before* Guidant first learned of a possible malfunction involving their PRIZM 2 devices, *id*. ¶¶ 92, 104. There is simply no evidence that, in 2001, Guidant knew that the PRIZM 2 device was anything other than the most reliable and technically capable ICD available to purchasers like Mr. Braund.[12]

Furthermore, Guidant has not retained a benefit that properly belongs to Mr. Braund. Guidant *paid* for Mr. Braund's replacement device and issued $2500 in unreimbursed medical expenses despite the fact that Mr. Braund's original device functioned appropriately for roughly four years and never manifested a defect. *See supra* Part II.B.2. As such, there is simply no evidence that Guidant was unjustly enriched from the sale of Mr. Braund's device.

Summary judgment is warranted on Mr. Braund's unjust enrichment claim (Count XVII).

XII. DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF SUMMARY JUDGMENT REGARDING CLAIMS FOR UNFAIR AND DECEPTIVE TRADE PRACTICES AND CONSUMER FRAUD

Guidant did not engage in any conduct that violated either Michigan or Minnesota consumer protection statutes nor statutes protecting senior citizens. Moreover, Mr. Braund's device never arced nor can it be established that it was defective in any

[12] The absence of facts to the contrary may explain why Mr. Braund, one of many plaintiffs now proceeding under the Amended Master Complaint, did not plead an unjust enrichment claim when he filed his individual complaint in Minnesota state court.

way. Nonetheless, Mr. Braund is seeking damages under Michigan and Minnesota law proscribing unfair trade practices.

Mr. Braund lacks standing to assert his claims under the Michigan consumer protection statutes (1) because his claims are exempted by the Michigan Consumer Protection Act (MCPA); and (2) because his device is not a consumer good or item as contemplated under the MCPA or the Pricing and Advertising of Consumer Items Act (PAA). Additionally, Mr. Braund is unable to establish that he suffered loss as a result of a violation of either the MCPA or the PAA.

Mr. Braund also lacks standing to assert his claims under the Minnesota consumer protection statutes (1) because Mr. Braund does not allege that an injunction is necessary to prevent Guidant's alleged conduct under the Deceptive Trade Practices Act (DTPA); (2) because he does not allege that any false statement made in Minnesota caused him damage as required under Minnesota's False Statements in Advertising statute (MFSA); and (3) because his DTPA, MFSA, and Prevention of Consumer Fraud Act (PCFA) claims are beyond the statutory authority of the Minnesota Attorney General.

Finally, Mr. Braund cannot prove that Guidant violated any provision of either Michigan's or Minnesota's consumer protection statutes. Accordingly, the Court should dismiss the following claims:

- Unfair and Deceptive Trade Practices Under Michigan and Minnesota State Law (Count VIII – Complaint By Adoption)
- Senior Citizen And Handicapped Person Consumer Fraud Act under Michigan and Minnesota State law (Count IX – Complaint By Adoption).

A. Mr. Braund's Michigan Unfair Trade Practices Claims Fail as a Matter of Law.

1. Mr. Braund lacks standing to bring claims under Michigan's unfair trade practices law.

a. Mr. Braund lacks standing under the MCPA because the actions about which he complains are specifically authorized under laws administered by a regulatory agency and are therefore exempt from MCPA liability.

Mr. Braund's MCPA claims are barred under the express language of the MCPA exempting from liability a "transaction or conduct specifically authorized under laws administered by a regulatory board . . . acting under statutory authority of this state or the United States." Mich. Comp. L. § 445.904(1)(a). This provision is a complete defense to Mr. Braund's MCPA claims because Guidant's design, manufacture, labeling, advertisement, and distribution of his device were at all times specifically regulated by the FDA.

The exemption for transactions and conduct authorized by administrative agencies is far reaching. As the Michigan Supreme Court held in *Smith v. Globe*, the exemption applies whenever a "general transaction is specifically authorized by law, regardless of whether the specific misconduct is prohibited." 597 N.W.2d 28, 38 (Mich. 1999). *See also Kraft v. Detroit Entm't, L.L.C.*, 683 N.W.2d 200, 205 (Mich. Ct. App. 2004) ("[w]hether the specific misconduct alleged . . . is illegal or prohibited by the [agency] is irrelevant to the determination whether the transaction or conduct was specifically authorized by the [agency].").

Under this standard, Michigan courts have consistently held that the MCPA does not apply where a defendant acted under the authority of an administrative agency. For example, in *Braundio v. Merck & Company, Inc*., the court considered an MCPA claim brought by a user of the prescription pain medication Vioxx alleging its manufacturer concealed cardiovascular risks and falsely implied it was superior to over-the-counter medications. No. 267003, 2006 WL 1628516 at *1 (Mich. Ct. App. June 13, 2006). The court held that "[t]he focus of [the MCPA exemption] is not the specific misconduct alleged by a plaintiff, but whether the general transaction is authorized by law." *Id.* at *6. The court exempted plaintiff's claims from the MCPA because the marketing, manufacturing, and distribution of drugs is governed by the Food, Drug and Cosmetic Act (FDCA) and regulated under laws administered by the FDA. *Id*. at * 7.

Mr. Braund fails to specifically identify how Guidant violated the Michigan Act. Presumably, the alleged violating conduct mirrors that which is claimed under his Minnesota Unfair Trade Practices claims. Even if Guidant's conduct conformed to all of those allegations, Mr. Braund's MCPA claims must still fail as a matter of law because the general transaction was authorized. *See Hartman v. Eichhorn Bldg. Co. v. Dailey*, 701 N.W.2d 749, 753 (Mich. Ct. App. 2005) (stating *Smith v. Globe* liberally interpreted the MCPA exemption "to include any activity or arrangement permitted by statute"). Here, as in *Braundio,* the FDA extensively regulates the design, manufacture, labeling, advertisement and distribution of Mr. Braund's device through the rigors of the pre-

market approval (PMA) process and post-reporting requirements.[13] The scope of these regulations subsume every allegation asserted by Mr. Braund in his unfair trade practices claims. *See Kemp v. Pfizer*, 835 F. Supp. 1015, 1021 (E.D. Mich. 1993) (the MDA has imposed extensive regulation upon class III device manufacturers).

Where the general transaction is authorized, the conduct is exempt, regardless of whether the legality of that conduct is in dispute. Because Guidant's design, manufacture, labeling, advertisement and distribution of Mr. Braund's device was authorized under federal law as administered by the FDA, the MCPA does not apply and Mr. Braund's MCPA claim is barred.

b. Mr. Braund lacks standing under the Michigan Consumer Protection Act because implantable heart devices are not "goods" as defined by the act.

The focus of the MCPA is to prohibit certain "[u]nfair, unconscionable, or deceptive methods, acts or practices in the conduct of trade or commerce." *Chimenti v. Apple Vacations, Inc*., No. 208446, 2000 WL 33401822, *2 (Mich Ct. App., Nov. 17, 2000); *See also* M.C.L. § 445.903(1). "[T]rade or commerce" is defined as "the conduct of a business providing goods, property, or service primarily for personal, family or household purposes . . . ." *Id*. *See also* M.C.L. § 445.902(g). Implantable cardiac

[13] *See* 21 C.F.R. § 814.20 (stating the requirements for a PMA application). *See also* 21 C.F.R. § 814.80 ("[a] device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions specified in the PMA approval order for the device."). *See also* 21 C.F.R. § 803.50 (manufacturers must continue to report "any information, from any source" suggesting malfunction or that the device may have caused or contributed to death or serious injury).

medical devices, such as Mr. Braund's device, are clearly not used primarily for personal, family, or household purposes as required under the Act.

There are no Michigan cases applying the MCPA in the prescription medical device context. But fifteen other states have similar statutory provisions limiting the availability of private rights of action to those who buy goods "primarily for personal, family, or household purposes."[14] Courts in these states hold that because products used in medical services are selected and used by medical professionals for their services, such products are not consumer goods.[15] In fact, a survey of *all* state consumer protection statutes reveals that products like the one at issue here do not fall within the ambit of covered transactions under state consumer protection statutes. *See generally* Michelle L. Evans, Annotation, *Who Is a "Consumer" Entitled to Protection of State Deceptive Trade Practice and Consumer Protection Acts*, 63 A.L.R. 5th 1 (1998).

Also relevant are federal statutory interpretations excluding medical devices from the definition of a consumer product. *See Cleveland Inst. of Elecs., Inc. v. United States*, 787 F. Supp. 741, 745 (N.D. Ohio 1992) (courts can look to other laws for guidance in construing statutory definitions). The Eastern District of Michigan's analysis

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[14] *See* Ala. Code § 8-19-3; Cal. Civ. Code § 1761 (a)-(b) & (d) ; Ga. Code § 10-1-392(a)(3); Haw. Rev. Stat. § 480-1; Ky. Rev. Stat. § 367.220(1); Me. Rev. Stat. tit. 5, § 213(1); Miss. Code § 75-24-15; Mo. Rev. Stat. § 407.025(2); Mont. Code § 30-14-133(i); Ohio Rev. Code § 1345.01; Pa. Stat. tit. 73, § 201-9.2; R.I. Gen. Laws § 6-13.1-5.2; Utah Code § 13-11-3(2); Va. Code § 59.1-148; Wyo. Stat. § 42-12-102.

[15] *See, e.g., Hogan v. Maryland State Dental Ass'n.*, 843 A.2d 902, 906 (Md. App. 2004) (finding that dental fillings are not purchased by consumers as a good); *Herzog v. Arthrocare Corp.*, No. 02-76-P-C, 2003 U.S. Dist. LEXIS 5224, at *38-39 (D. Maine March 21, 2003) (holding that Maine's consumer-protection statutes do not "extend protection to individuals who pay the bill for a medical service provider's acquisition of a medical device, even though that device is 'used' on them for 'personal purposes'").

in *Kemp v. Pfizer, Inc*., concerning whether a heart valve constitutes a consumer product under the Magnuson-Moss Warranty Act (MMA) and the Consumer Product Safety Act (CPSA) is instructive. *See* 835 F. Supp. at 1024. The court noted that the MMA defines consumer products as those "'used for personal, family, or household purposes'"—similar to the MCPA—but excludes products that are considered "uncommon." *Id*. at n. 8 (citing 16 C.F.R. § 700.1(a)). The court also noted that the CPSA, which casts a greater net than the MMA concerning what constitutes a consumer product, specifically excludes medical devices from its definition. *Id*. at 1025.

Kemp concluded that under the MMA, a heart valve was "not the type of product normally used for consumer purposes by the general public" and that "[g]oods that are not customarily available to the ordinary person are not consumer products."[16] Significantly, the court explained that "[m]edical devices that are surgically implanted are not consumer products" noting that such devices "are not sold to unsuspecting consumers relying on the warranties of unscrupulous retailers." *Id.* This rings especially true in Mr.

[16] The exclusion of medical devices as consumer products under the MMA is especially persuasive given that several other courts have followed suit. *See*

First Circuit: *Goldsmith v. Mentor Corp.*, 913 F. Supp. 56, 63 (D.N.H. 1995) (applying New Hampshire law) (testicular prosthesis not a consumer product under the MMA because it is not "tangible personal property . . . normally used for personal, family, or household purposes").

Eight Circuit: *In re Minnesota Breast Implant Litig.*, 36 F. Supp. 2d 863, 876 (D. Minn. 1998) (applying Minnesota law) (silicone breast implants not consumer products under the MMA because they are not readily accessible to all consumers).

District of Columbia Circuit: *Williams v. Purdue Pharma Co.*, 297 F. Supp. 2d 171, 174-75 (D.D.C. 2003) (applying District of Columbia law) (holding that there is no consumer transaction if the product promoted is solely to physicians).

Braund's circumstances as Mr. Braund freely admits that he played no part in the selection of his Guidant device:

> Q . . . [D]id they explain to you what various defibrillators were on the market?
>
> A No.
>
> Q . . . [D]id you play any role in selecting the defibrillator that was implanted in you?
>
> A Absolutely not.

See supra Part II.B.1. Because the implantation of a complex cardiac medical device is heavily regulated by the FDA, it is simply not the type of consumer transaction covered or intended to be covered under the MCPA. These devices are made available to patients only through physicians.

The intent of the MCPA is to "protect consumers in their purchases of goods which are primarily used for personal, family or household purposes." *Noggles v. Battle Creek Wrecking Inc.*, 395 N.W.2d 322, 324 (Mich. Ct. App. 1986). Clearly not all "goods" are swept under the purview of the Act. Given the influence of federal statutes and exclusion of such devices as consumer goods under similar state statutes, this Court should hold that Mr. Braund's medical device is not a "good" as defined by the Michigan statute. Thus, Mr. Braund lacks standing to sue under the MCPA, and the Court should dismiss any such claim.

c. Mr. Braund lacks standing under The Pricing and Advertising of Consumer Items Act (PAA) because his implantable heart device is not a "consumer item" as defined by the act.

The purpose of the PAA is to "regulate the pricing of consumer items and the advertising of consumer items [and] …goods . . . ." *JFN, Inc., v. Haynes Real Estate, Inc*., No. 272067, 2007 WL 517378, at *2 (Mich. Ct. App., Feb. 20, 2007). The PAA defines a "[c]onsumer item" as "an article of tangible personal property used or consumed, or bought for use or consumption, primarily for personal, family, or household purposes." Mich. Comp. L § 445.351(d) (2007). As such, violations alleged under the PAA must concern a "consumer item" as defined by the PAA. *Id*. (denying a PAA claim based upon an ad to sell a business because the preamble to the Act "makes clear that the Legislature's intent in enacting the PAA was to regulate the advertising of "'consumer items.'").

Mr. Braund's device is not a consumer item as defined by the Act. Similar to the definition of a consumer good under the MCPA, a "consumer item" under the PAA is also limited to those items used or consumed primarily for personal family or household purposes. For the same reasons discussed above addressing Mr. Braund's MCPA claims, an implantable heart device is not the type of consumer item contemplated under the PAA. Thus, because Mr. Braund's device is not a consumer item, he lacks standing to sue under the PAA and any such claim should be dismissed.

2. Guidant did not engage in any unfair, unconscionable, or deceptive methods, acts or practices under Michigan Unfair Trade Practices Law.

a. Guidant did not engage in any proscribed provisions under The Michigan Consumer Protection Act (MCPA).

Guidant did not engage in any conduct prohibited by the MCPA. The MCPA proscribes thirty-eight specific "unfair, unconscionable, or deceptive methods, acts or practices in the conduct of trade or commerce." Mich. Comp. L. § 445.903(1)(a)-(kk) (2007). Only six of those thirty-eight provisions are potentially relevant in this case including:

- "Representing that goods . . . have . . . characteristics . . . that they do not have . . . ." *Id*. § 445.903(c).
- "Representing that goods . . . are of a particular standard, quality, or grade . . . if they are of another. *Id*. § 445. 903(e)
- "Advertising or representing goods . . . with intent not to dispose of those goods or services as advertised or represented." *Id*. § 445.903(g)
- "Failing to reveal a material fact, the omission of which tends to mislead or deceive the consumer, and which fact could not reasonably be known by the consumer." *Id*. § 455.903(s).
- "Making a representation of fact or statement of fact material to the transaction such that a person reasonably believes the represented or suggested state of affairs to be other than it actually is." *Id.* § 455.903(bb)
- "Failing to reveal facts that are material to the transaction in light of representations of fact made in a positive manner." *Id.* § 455.903(cc).

Mr. Braund cannot offer any evidence that Guidant violated any of these provisions. Plaintiff fails to satisfy Mich. Comp. L. §§ 445.903(1)(c), (e), and (g) because Guidant never represented that Mr. Braund's device had any characteristics or was of a standard or quality that it did not possess. Plaintiff has also failed to satisfy

Mich. Comp. L. §§ 445.903(1)(s), (bb) and (cc) because the FDA-approved labeling informed physicians of all information the FDA considers *material* to the prescribing physician's decision. Representations of safety, effectiveness, conditions of use, hazards, or other information are all included in such labeling. Novak Aff. at ¶ 31. Under the learned intermediary doctrine, the implanting physician is in the best position to relay such warnings to Mr. Braund.[17]

Mr. Braund's device conformed to Guidant's representations. First, there is no evidence that Mr. Braund's alleged "inappropriate shocks" resulted from a defect in the device. Instead, Mr. Braund's medical records indicate that the therapy, i.e. shocks, he received were rendered based upon the device's programming. *See supra* Part II.B.2. Nonetheless, even if the shocks were "inappropriate," Guidant fully warned Mr. Braund's physician that ICDs are "subject to random component failure" and that "[s]uch failure could cause inappropriate shocks . . . ." *See supra* Part II.A.

Second, Mr. Braund's device never manifested a short-circuit or arcing failure, which is the very reason for this MDL litigation. Testing data revealed that there was no cracking of the polyimide insulation on the DF- wire of Mr. Braund's device, and there was a space between the DF-wire and the backfill tube. *See supra* Part II.B.2. Mr. Braund's engineering expert, Randy Armstrong, concedes that "insulation breaching and

[17] In Michigan, under the learned-intermediary doctrine, a medical-device manufacturer fulfills its duty to warn by providing warnings of the potential dangers of the product to the learned intermediary – i.e. hospital or physician. There is no duty to warn the patient when the manufacturer can expect that the sophisticated intermediary has "a mastery of the product and would adequately warn/inform the consumer of the applicable dangers." *Gillett v. Sofamor*, S.N.C., No. 96-75541, 2001 WL 1135304, at * 7 (E.D. Mich. Spt. 13, 2001); *see also Brown v. Drake-Willok Int'l, Ltd*., 209 Mich. App. 136, 147 (1995).

arcing were not evident" in Mr. Braund's device. *See id.* at II.B.2. Significantly, Mr. Braund admits that his PRIZM 2 did not short circuit. *See id.*

Third, Mr. Braund cannot provide any evidence that Guidant misrepresented the safety and reliability of the device. To date, *actual* confirmed malfunctions from all causes have occurred in less than one-half of one percent of the entire PRIZM 2 product line. *See* CRM Product Performance Report at 26 (Q2 Summary Edition), Boston Scientific, June 8, 2007 (Ex. 16). Only 37 arcing malfunctions out of approximately 27,000 (0.14%) pre-April 2002 PRIZM 2s worldwide have been confirmed. *Id.* Only 38 arcing malfunctions out of all 60,000 (0.0061%) PRIZM 2s worldwide have been confirmed. *Id.* at 132. No implantable heart device can ever be 100% effective, nor does the FDA require such perfection. Guidant never represented to Mr. Braund that his device was 100% effective, nor can Mr. Braund offer any evidence that they did. Despite the potential for some VENTAK PRIZM 2, Model 1861 devices to malfunction, it is still one of the most reliable devices ever put on the market. *See id.* at 26 (noting that only 0.14% of PRIZM 2s subject to recall have ever exhibited confirmed malfunctions).

Finally, Guidant warned Mr. Braund's physician, Dr. James Kappler, of all information considered material by the FDA concerning Mr. Braund's device. Guidant provided Dr. Kappler an FDA-approved System Guide that contained numerous warnings. As mentioned earlier, the Guide specifically warned that such devices are "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." *See supra* Part II.A. The manual further warned about the "[p]otential for mortality due to inability to defibrillate or pace" and that some patients may suffer from "[f]ear that shocking capability may be lost." *Id*. Physicians are also aware that devices such as Mr. Braund's are occasionally subject to recalls.

In sum, Mr. Braund cannot show that Guidant represented that the device at issue had any characteristics that it did not possess, misrepresented its quality, or omitted any material information. As such, Mr. Braund cannot establish that Guidant violated the MCPA and these claims must be dismissed.

b. Guidant did not engage in any proscribed violations under the Pricing and Advertising of Consumer Items Act (PAA).

Guidant did not engage in any conduct prohibited by the PAA. The PAA proscribes specified pricing and advertising violations concerning consumer items. *See* Mich. Comp. L. § 445.356 (2007). The only provisions that are potentially relevant to the case at hand include:

- "A person shall not knowingly make, publish, disseminate, circulate, or place before the public an advertisement which contains a statement or representation which is untrue, deceptive or misleading. Mich. Comp. L. § 445.356(1).

- "A person shall not advertise . . . the sale of goods . . . which are known to be substantially defective." Mich. Comp. L § 445.356(5).

Under the PAA, there is no duty to "disclose" in a product's advertisement dangers that are already well known. *See Overton v. Anheuser-Busch Co.*, 517 N.W.2d 308, 310 (Mich. Ct. App. 1994) Nonetheless, as discussed above addressing claims under the MCPA, Guidant fully warned Mr. Braund's physician of all material dangers

known to Guidant and approved by the FDA including random component failure causing inappropriate shocks, possible mortality due to inability to defibrillate or pace, and fear that shocking capability may be lost. Guidant never made any representations that Mr. Braund's device had any characteristics or qualities that it did not possess. As such, Guidant never made any representations that were "untrue, deceptive or misleading" under the PAA.

Guidant also never advertised the sale of any device "known to be substantially defective." First, for the reasons discussed in Part IX, Mr. Braund's PRIZM 2 DR 1861 device was not defective. Second, even if Mr. Braund's device was defective, Guidant was not in the position to know of any alleged defect concerning short circuiting or arcing during the time period prior to Mr. Braund's implantation. Mr. Braund's PRIZM 2 DR 1861 obtained regulatory approval from the FDA in August 2000. *See supra* Part II.A. Mr. Braund was implanted with his device in August 2001. *Id*. at II.B.1. There were absolutely no reported incidents involving arcing in the header of the PRIZM 2 until February 1, 2002. *See id.* at II.A. As such, any advertisements made by Guidant prior to Mr. Braund's implantation were made prior to any report of an alleged defect due to arcing and, therefore, were not known.

In short, Mr. Braund cannot establish that Guidant made any untrue, deceptive or misleading representations concerning his device. Nor can Mr. Braund prove that his device was defective, much less that Guidant knew of any alleged defect prior to Mr. Braund's implantation. As such, Mr. Braund cannot prove a violation of the PAA and these claims should be dismissed.

3. Mr. Braund did not suffer loss as a result of a violation of the Michigan Consumer Protection Act or the Pricing and Advertising of Consumer Items Act.

Mr. Braund's Michigan Unfair Trade Practices claims should fail as a matter of law because he cannot establish that he suffered "loss as a result of a violation" of either the Michigan Consumer Protection Act (MCPA) or the Pricing and Advertising of Consumer Items Act (PAA). *See* Mich. Comp. L. § 445.911(3) (2007); Mich. Comp. L. § 445.360 (2007). In *Zine v. Chrysler Corp*., the Michigan Court of Appeals held that if representations addressed by the MCPA affected only the transaction at issue or should be construed with reference to common-law fraud requiring a material representation, then the representation or omission must be made prior to the transaction and affect the consumer's decision to enter into the transaction. *See* 600 N.W.2d 384, 397-98 (Mich. Ct. App. 1999).

Mr. Braund's MCPA and PAA claims either involve conduct that should be construed with reference to common-law fraud requiring a material representation or clearly only affects the decision to enter into the transaction—that is implantation. *See Mayhall v. A.H. Pond Co.,* 341 N.W.2d 268, 270 (Mich. Ct. App.1983) (holding that a "great majority" of the MCPA provisions involve fraud and that PAA provisions may also involve fraud). Indeed, any loss alleged by Mr. Braund is contingent upon his decision to have his device implanted based upon the alleged concealment, misrepresentation or omission of material information by Guidant. Consequently, Mr. Braund must prove that the representations or omissions at issue were both material and made prior to his implantation. But for the reasons discussed in Part X, addressing the

learned intermediary doctrine, Mr. Braund cannot prove these essential requirements. As such, Mr. Braund has not suffered loss *as a result of* a violation of either the MCPA or the PAA and any such claim should be dismissed.

4. Mr. Braund's Michigan senior citizen status claim fails because Mr. Braund cannot establish that he was unable to protect his own interests.

Michigan does not provide protection from unfair trade practices based solely on the consumer's age. Instead, the MCPA proscribes the following conduct:

> "[t]aking advantage of the consumer's inability reasonably to protect his or her own interests by reason of disability, illiteracy, or inability to understand the language of an agreement presented by the other party to the transaction who knows or reasonably should know of the consumer's inability. Mich. Comp. L. § 445.903(x)(2007).

This statute is expressly linked to the transaction at issue. In this case, that is Mr. Braund's implantation.

Mr. Braund's senior citizen status claim fails because he cannot establish his inability to protect his interests at the time his device was implanted. Quite the contrary, Mr. Braund was only 57-years-old at the time of implantation, owned and ran his own business, was licensed in several trades and was working full time. *See supra* Part II.B.1. Moreover, Guidant's representations were directed towards Mr. Braund's physician who solely selected the device at hand. Thus, not only was Mr. Braund fully able to protect his own interests, but he demonstrated that ability by delegating decision-making power to his physician who was educated concerning implantable devices and qualified to protect Mr. Braund's interests.

Because Mr. Braund was capable of protecting his own interests, he is not the type of consumer this statute was meant to protect. As such, this claim should be dismissed.

B. Mr. Braund's Claims Fail Under Minnesota Consumer Fraud and Unfair Trade Practices Statutes.

As set forth earlier in Part IV discussing conflicts of law, Michigan law clearly governs Mr. Braund's consumer protection claims. But even if Minnesota law is applied, Mr. Braund's unfair trade practices claims must still fail as a matter of law.

1. Mr. Braund lacks standing to bring his claims under Minnesota Consumer Protection Statutes.

a. Mr. Braund does not have standing to bring his claim under the Minnesota Deceptive Trade Practices Act because he does not allege that an injunction is necessary to prevent Guidant's alleged conduct.

The Minnesota Deceptive Trade Practices Act (MDTP) provides that "[a] person likely to be damaged by a deceptive trade practice of another may be granted an injunction against it under the principles of equity and on terms that the court considers reasonable." Minn. Stat. § 325D.45(1) (2006). The statute provides standing only to plaintiffs who are seeking an injunction. *See Simmons v. Modern Aero, Inc.*, 603 N.W.2d 336, 339 (Minn. App. 1999) ("the sole statutory remedy for deceptive trade practices is injunctive relief"). Nowhere in Mr. Braund's Complaint does he seek injunctive relief. Consequently, Mr. Braund's MDTP claims should be dismissed.

b. Mr. Braund does not have standing to bring his claim under the Minnesota False Statements in Advertising Statute because he does not allege that any false statement made in Minnesota caused him damage.

The language of Minnesota's False Statements in Advertising statute (MFSA) expressly limits claims to those regarding false statements made in advertising distributed within the state of Minnesota. Minn. Stat. § 325F.67 (2006) (prohibiting false statements made in advertising that are "to be made, published, disseminated, circulated, or placed before the public *in this state*"); *Parkhill v. Minn. Mut. Life Ins. Co.*, 995 F. Supp. 983, 996-97 (D. Minn. 1998) (stating that "the plain language of the statute requires that any statements be made in Minnesota"); *Force v. ITT Hartford Life & Annuity Ins. Co.*, 4 F. Supp. 2d 843, 857-58 (D. Minn. 1998) (stating that "the plain language of the statute requires that the statements be made in Minnesota").

Nowhere does Mr. Braund—a resident of Michigan—allege that Guidant made false statements to him in Minnesota. Nor does Mr. Braund allege that he has ever even visited Minnesota. Here, Mr. Braund's alleged damages have no connection to any false statements that might have been made in Minnesota. Because the statutory language of the MFSA applies only to false statements made in Minnesota, Mr. Braund's MFSA claim fails and should be dismissed.

c. Mr. Braund does not have standing to bring his claim under the Minnesota Prevention of Consumer Fraud Act or the Minnesota False Statements in Advertising Statute because his claim derives from Michigan transactions that are beyond the statutory authority of the Minnesota Attorney General.

Private plaintiffs have standing to bring claims for damages under the Prevention of Consumer Fraud Act (PCFA) and the False Statements in Advertising statute (MFSA) pursuant only to the Minnesota private-attorney-general statute, Minnesota Statutes section 8.31(3)(a). A party suing as a "private attorney general" pursuant to this statute, may bring a claim only if the Minnesota Attorney General could bring that same claim. *Ly v. Nystrom*, 615 N.W.2d 302, 313 (Minn. 2000) ("Since the Private AG Statute grants private citizens the right to act as a 'private' attorney general, the role and duties of the attorney general with respect to enforcing the fraudulent businesses practices laws must define the limits of the private claimant under the statute."). The Minnesota Attorney General's duties are to protect the rights of the Minnesota public in the interest of Minnesota. *Id.* "It is not the responsibility of the attorney general to protect private or individual interests independent of a public purpose." *Id.*

Here, Mr. Braund lacks standing to bring his claims as a private attorney general because the claims involve no benefit to the Minnesota public. According to the Minnesota Supreme Court, the right to bring claims under the private-attorney-general statute is restricted to "those claimants who demonstrate that their cause of action benefits the public." *Ly*, 615 N.W.2d at 314; *see also Schaaf v. Residential Funding*

Corp., 2006 WL 2506974, at *15-*17 (D. Minn. Aug. 29, 2006); *Evangelical Lutheran Church in Am. Bd. of Pensions v. Spherion Pac. Workforce LLC*, 2005 WL 1041487, at *3 (D. Minn. May 4, 2005); *Zutz v. Case Corp.*, 2003 WL 22848943, at *3-*4 (D. Minn. Nov. 21, 2003); *Berczyk v. Emerson Tool Co.*, 291 F. Supp. 2d 1004, 1019-20 (D. Minn. 2003); *Antioch Co. v. Scrapbook Borders, Inc.*, 291 F. Supp. 2d 980, 1003-04 (D. Minn. 2003). Here, Mr. Braund asserts only an individual action. In Minnesota, "where recovery is sought for the exclusive benefit of the plaintiff, there is no public benefit." *Zutz*, 2003 WL 22848943, at *4; *see also Evangelical Lutheran Church in Am. Bd. of Pensions*, 2005 WL 1041487, at *4.

Furthermore, to the extent that this lawsuit might have accomplished a public benefit prior to Guidant's voluntary recall of the device and the FDA's subsequent classification of Guidant's action as a Class I recall, that public benefit has been removed by those actions. *Behrens v. United Vaccines, Inc.*, 228 F. Supp. 2d 965, 970-71 (D. Minn. 2002) (holding that plaintiffs' lawsuit might have achieved a public benefit by preventing future false representations about a product, but because the lawsuit was brought after a product recall, such public benefit no longer existed). Because Mr. Braund's consumer-protection claims will not benefit the public, Mr. Braund has no standing to bring them under Minnesota's private-attorney-general statute. Consequently, any claims Mr. Braund may make under the PCFA and MFSA fail and these claims should be dismissed.

In addition, Mr. Braund is a resident of Michigan. *See supra* Part II.B.1. Both his implant and explant surgery were performed in Michigan. *Id.* at B.1, 3.

Nowhere does Mr. Braund allege that he engaged in any consumer transaction or received any false statements related to his device in Minnesota. Absent such allegations, there is no basis to assert that the PCFA or the MFSA should apply to Plaintiff's claim. The authority to protect the rights of the Minnesota public in the interest of the state of Minnesota is simply not broad enough to allow the Minnesota Attorney General to regulate Michigan consumer transactions or alleged false statements made in Michigan solely because a Minnesota corporation is a party to the transactions.[18]

Because the Minnesota Attorney General does not have the authority to use Minnesota law to regulate Michigan consumer transactions, Plaintiff does not have the authority to bring a claim relating to the purchase of his device under the Minnesota private-attorney-general statute. *Id.* ("The sweep of the statute can be no broader than the source of its authority – that of the attorney general . . ."). Similarly, because the Minnesota Attorney General does not have the authority to use Minnesota law to regulate false statements in advertising made in Michigan, Mr. Braund lacks the authority to bring a claim relating to false statements made in relation to his device under the Minnesota private-attorney-general statute. *Id.* Because Mr. Braund falls outside the standing provided by the Minnesota private-attorney-general statute, he lacks standing to bring his claims under the PCFA or the MFSA. Consequently, these claims should be dismissed.

[18] A finding that the Minnesota Attorney General could use Minnesota law to regulate consumer transactions throughout the nation merely because a Minnesota resident was a party to those transactions would raise serious constitutional issues.

2. Mr. Braund lacks standing to bring his claim under the Minnesota Senior Citizen and Handicapped Person Consumer Fraud Act because he was not 62 while implanted and he lacks standing under any of the statutes for which the act was meant to provide a supplemental civil penalty.

The Minnesota Senior Citizen and Handicapped Person Consumer Fraud Act imposes a supplemental civil penalty for deceptive acts when that "conduct is perpetrated against one or more senior citizens." Minn. Stat. § 325F.71 (2006). Under this statute, a senior citizen is defined as "a person who is 62 years of age or older." *Id*. § 325F.71(1)(a). Mr. Braund was born on May 1, 1944. *See supra* Part II.B.1. As such, he was 57-years-old when his device was implanted and only 61-years-old when it was explanted. *Id*. Clearly, the conduct Mr. Braund complains of could not possibly extend beyond the date of his explant. Thus, Guidant's alleged conduct was not perpetrated against a senior citizen as defined by the Act.

Moreover, the senior citizen supplemental penalty is only applicable when the claimed conduct violates the Minnesota Deceptive Trade Practices Act (MDTP), the Minnesota False Statements in Advertising statute (MFSA), or the Minnesota Prevention of Consumer Fraud Act (PCFA). *Id.* The Minnesota Senior Citizen and Handicapped Person Consumer Fraud Act merely provides a supplemental penalty for violations to other Minnesota consumer-protection statutes—it does not create an independent cause of action. *See Hollywood Healthcare Corp. v. Deltec, Inc.*, No. Civ.04-1713, 2004 WL 1118610, at *7 (D. Minn. May 17, 2004). Because Mr. Braund lacks standing to bring his claim under the MDTP, the MFSA, or the PCFA, he lacks standing under the Minnesota Senior Citizen and Handicapped Person Consumer Fraud Act.

Mr. Braund was not a senior citizen during the entire time he was implanted with his device and he lacks standing under any Minnesota unfair trade practices claim. Thus, his Minnesota senior citizen status claim should be dismissed.

3. Guidant committed no unfair or deceptive acts under Minnesota law.

a. Guidant engaged in no conduct that violated Minnesota's Deceptive Trade Practices Statute.

Minnesota proscribes thirteen specific deceptive trade practices. Minn. Stat. § 325D.44 (2006). Only four of the thirteen provisions could potentially be relevant. They include when a person during the course of business:

- "represents that goods . . . have . . . characteristics, . . . uses, [or] benefits . . . that they do not have" *Id*. § 325D.44(5).
- "represents that goods . . . are of a particular standard, quality, or grade . . . if they are of another" *Id.* § 325D.44(7).
- "advertises goods . . . with intent not to sell them as advertised" *Id*. § 325D.44(9).
- "engages in any other conduct which similarly creates a likelihood of confusion or misunderstanding" *Id*. § 325D.44(13).

These provisions mirror the applicable provisions asserted under the Michigan Consumer Protection Act (MCPA). *See* Mich. Compl. L. § 445.903(1) (c), (e), (g), and (s) (2006). For the same reasons above discussing those MCPA provisions, Mr. Braund's Minnesota Deceptive Trade Practices claims must fail.

As discussed at length above, Mr. Braund cannot offer any evidence that Guidant violated these Minnesota provisions. Guidant never represented that Mr. Braund's device had any characteristics, benefits or uses that it did not possess and Mr.

Braund's device has never arced, nor can he prove that it has any defect. *See supra* Part X. Moreover, Guidant never represented that the device was of a quality or standard that it does not possess and, in all respects, Mr. Braund's device complies with Guidant's advertised criteria. As such, Minnesota's Deceptive Trade Practices statute has not been violated and any such claim should be dismissed.

b. Guidant engaged in no conduct that violated Minnesota's False Statement in Advertisement Statute.

The Minnesota False Statement in Advertisement statute proscribes corporations with the intent to sell or increase consumption from disseminating advertisements "which contain[] any material assertion, representation, or statement of fact which is untrue, deceptive or misleading" Minn. Stat. § 325F.67 (2006). This provision mirrors the proscribed conduct asserted under Michigan's statute regarding the pricing and advertising of consumer items. As discussed in Part X (Failure-to-Warn), Guidant fully warned Mr. Braund's physician of all material information concerning Mr. Braund's device and never made any untrue statements. Moreover, Mr. Braund's device conformed with all of Guidant's representations. Thus, for the same reasons discussed above addressing Michigan advertisements, Minnesota's False Statement in Advertisement claims should be dismissed.

c. Guidant engaged in no conduct that violated Minnesota's unlawful practices statute.

Minnesota's Unlawful Practices statute proscribes the use "of any fraud, false pretense, false promise, misrepresentation, misleading statements or deceptive practice, with the intent that others rely thereon in connection with the sale of any

merchandise." Minn. Stat. § 325F.69 (2006). Guidant never violated this provision because Guidant never made any false or misleading representations, omissions or promises.

Despite the fact that Mr. Braund's Complaint is riddled with extraneous assertions regarding the Ancure Endograft System and an alleged design flaw in the lead wires of the PRIZM 2, Mr. Braund admits that his device never short-circuited or arced and is unable to establish any defect in his particular device. *See* Pl. Compl. at ¶¶ 10-14, 25-53; *see supra* Part II.B.2.

Moreover, Mr. Braund has no evidence that, Guidant never made any false or misleading representations, omissions or promises toward him. Instead, Guidant fully warned Mr. Braund's physician of all material information concerning Mr. Braund's device. Thus, for all the reasons discussed in Part X, Mr. Braund cannot establish that Guidant's conduct in the sale of his device was in any way fraudulent, misleading or deceptive nor that Guidant made any false representations or promises. Thus, his Unlawful Practices claim should be dismissed.

* * *

For the reasons discussed above, Guidant asks this Court to grant summary judgment in its favor and to dismiss Mr. Braund's unfair and deceptive trade practices and consumer fraud claims *with prejudice*.

XIII. DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF SUMMARY JUDGMENT REGARDING CLAIMS FOR NEGLIGENT AND INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

Whether Michigan or Minnesota law applies, Guidant is entitled to summary judgment as a matter of law on Mr. Braund's claims for both negligent infliction of emotional distress (NIED) and intentional infliction of emotional distress (IIED).[19] Under either state's law, Mr. Braund has failed to meet essential elements to assert either theory of recovery.

A. Mr. Braund's Emotional Distress Claims Fail Under Michigan Law.

1. NIED is not an independent cause of action under Michigan law.

Under Michigan law, the tort of NIED is purely one involving bystander recovery. *See Duran v. The Detroit News*, 504 N.W.2d 715, 720 (Mich. Ct. App. 1993) ("[W]e decline to apply the tort of negligent infliction of emotional distress beyond the situation where a plaintiff witnesses negligent injury to a third person and suffers mental disturbance as a result.") (citing *Deitz v. Wometco West Michigan TV, Inc.*, 407 N.W.2d 649, (Mich. Ct. App. 1987)). Rather than creating a separate cause of action outside of bystander recovery, Michigan "merely allow[s] damages for emotional distress when the plaintiff has prevailed on a negligence cause of action." *McNeil ex rel. McNeil v. Metinko*, 1998 WL 2016585 at *3 (Mich. Ct. App. Mar. 13, 1998). Mr. Braund is not asserting bystander recovery. As addressed in Part IX, Mr. Braund's negligence claim fails because he can offer no proof that his PRIZM 2 was defective, nor can he offer any

[19] Mr. Braund did not assert claims for NIED or IIED in his Original Complaint. Mr. Braund first asserted these claims when he adopted the MDL Master Complaint. *See* Compl. by Adoption at ¶ 8 (adopting Count X (NIED) and Count XI (IIED) of MDL Master Complaint).

proof that the alleged inappropriate shocks he received were in any way related to a defect in his PRIZM 2 or conduct committed by Guidant. Because his negligence claim fails, he cannot recover damages for his alleged emotional distress. Therefore, under Michigan law, his claim for NIED must be dismissed as a matter of law. *See Deitz*, 407 N.W.2d at 381 (upholding summary judgment because NIED was not asserted as a bystander recovery claim).

2. Under Michigan law, Mr. Braund's claims for IIED should be dismissed as a matter of law.

Neither the Michigan Supreme Court nor the Legislature has expressly recognized the tort of IIED. *See Eaton Pine Village v. Jackson*, 2002 WL 1360397 at * 6-7 (Mich. Ct. App. 2002) (discussing history of IIED and uncertainty as to whether this tort exists under Michigan law). The Supreme Court of Michigan has held that if this cause of action were recognized, the elements of IIED are: (1) extreme and outrageous conduct; (2) intent or recklessness; (3) causation; and (4) severe emotional distress. *Roberts v. Auto-Owners Ins. Co.*, 374 N.W.2d 905, 908 (Mich. 1985); *see also Linebaugh v. Sheraton Michigan Corp.*, 497 N.W.2d 585, 588 (Mich. Ct. App. 1993). But even if IIED is recognized under Michigan law, Mr. Braund fails to meet essential elements recited by Michigan courts, and his IIED claim fails.

a. Mr. Braund cannot prove that Guidant caused his alleged emotional distress.

Mr. Braund cannot offer any proof that his alleged emotional distress was caused in any way by Guidant. Mr. Braund mistakenly believes that the advisory issued in June 2005 regarding the PRIZM 2 is related to allegedly inappropriate shocks he

received. But as addressed above in the Part IX, Mr. Braund has no evidence that the alleged inappropriate shocks are attributable to a defect in his PRIZM 2; in fact the shocks were related to programming and stopped after reprogramming. Testing data shows that Mr. Braund's device never exhibited the failure mode that was the subject of the recall. *See* Part IX. Mr. Braund's own expert, Randolph Armstrong, also concedes this. *See* Part IX. And Mr. Braund admits that his device never short-circuited. *See supra* Part II.B.2.

Nor can Mr. Braund present any evidence that his alleged inappropriate shocks were attributable in any way to any conduct on behalf of Guidant. Mr. Braund's expert, Randolph Armstrong, offers no opinion on the cause of the alleged inappropriate shocks. Also, none of Mr. Braund's doctors ever opined that his alleged inappropriate shocks resulted from a device malfunction or were attributable to any conduct committed by Guidant. Additionally, there is simply no evidence that the shocks Mr. Braund allegedly received were actually caused by a defect in the device as opposed to inappropriately low settings.

Mr. Braund's claims center on allegedly inappropriate shocks he received. *See* Pl. Compl. at ¶ 4 (alleging that his PRIZM 2 was defective because it "experienced electrical malfunctions . . . resulting in random and inadvertent electrical shock when no shock was medically warranted"). In his psychiatric evaluation, Mr. Braund admits that he attributed his alleged emotional distress to his heart condition, and it was only after learning of the recall that he attributed it to the shocks he had received from his PRIZM 2. *See* Ginzburg Report at 11 ("For all those years, I thought it was my heart. That is

why I was walking on egg shells, then I find out they had a recall."). But the potential failure mode that was the subject of the recall is completely unrelated to Mr. Braund's alleged inappropriate shocks. In fact, had his PRIZM 2 exhibited the failure mode that was the subject of the recall, his device could not have shocked him at all. *See* Part X (Failure-to-Warn). Moreover, Mr. Braund's own psychiatric expert states that Mr. Braund "has difficulty, intellectually, and more so emotionally, separating out the cause of the shocks, a setting error, with also being notified of" the potential failure mode that was the subject of the recall. Ginzburg Report at 5, 12.

Mr. Braund can offer no evidence that his alleged inappropriate shocks were attributable to a malfunction of his PRIZM 2 or any act by Guidant. Mr. Braund is only basing his claims on a mistaken belief that the PRIZM 2 recall was somehow related to shocks he received a few years before, which have not repeated once the device was reprogrammed. Because Mr. Braund has no evidence that his alleged inappropriate shocks were in any way attributable to a device malfunction or to conduct by Guidant, he can offer no proof that his alleged emotional distress was caused by Guidant, and his IIED claim fails.

b. There is no evidence that Guidant committed any extreme or outrageous conduct.

Under Michigan law, to assert a claim for IIED, a plaintiff must prove that the conduct complained of was extreme and outrageous. *Roberts*, 374 N.W.2d at 908; *Linebaugh*, 497 N.W.2d at 588. Liability may be found only where the conduct in question is so outrageous in character, and so extreme in degree, as to exceed all bounds

of common decency, and to be regarded as atrocious and utterly intolerable in a civilized society. *Deitz*, 407 N.W.2d at 656. This is a very high standard for plaintiffs to meet, and it is not "enough that the defendant has acted with an intent which is tortious or even criminal, or that he has intended to inflict emotional distress, or even that his conduct has been characterized by 'malice,' or a degree of aggravation that would entitle plaintiff to punitive damages for another tort." *Roberts*, 374 N.W. 2d at 908 (quoting Restatement (Second) of Torts § 46 cmt. d). Simply stated, Plaintiff cannot offer any evidence that Guidant committed such conduct.

As shown above, Mr. Braund cannot even prove that Guidant was negligent. Lacking proof of at least negligence, Mr. Braund is clearly unable to meet the higher standard necessary for an IIED claim of extreme and outrageous conduct. The conduct that Mr. Braund alleges is essentially that Guidant provided him with an allegedly defective device that provided "inappropriate shocks" on several occasions and that Guidant "never told [him] about the risks associated with the design and/or manufacturing defects associated" with his device.[20]

But as addressed above in Part IX, Mr. Braund can offer no proof that his device ever malfunctioned. The short-circuiting or arcing failure at issue in this MDL never manifested in Mr. Braund's PRIZM 2. Mr. Braund can also offer no evidence that the alleged inappropriate shocks are attributable to (1) a defect in his PRIZM 2 or (2) any conduct on behalf of Guidant. Inappropriate shocks are a common risk associated with ICDs. Guidant's Physician Manual and AICD System Guide both warn physicians of the

[20] Original Compl. at ¶¶ 54-62.

risk of inappropriate shocks and to discuss this and other information with their patients. *See supra* Part II.A. Under the learned intermediary doctrine, the implanting physician is in the best position to relay such warnings to Mr. Braund. *See* Part X. Mr. Braund's medical records indicate that his implanting physician, Dr. Leonen, warned him of the risks and benefits of an ICD. *See supra* Part II.B.1.

Also, the Patient Handbook described what defibrillation shocks feel like and advises that such shocks can upset patients. *Id.* Mr. Braund admits that he read his Patient Handbook. *Id.* Thus, even if he did not read that specific section of his manual, he was adequately warned.

Although Mr. Braund alleges that he received inappropriate shocks, he has no evidence that such shocks were attributable to a defect in his device or any conduct on Guidant's part. His own expert, Randolph Armstrong, offers no opinions on what could have caused the alleged inappropriate shocks. Therefore, Mr. Braund is unable to prove that Guidant was negligent in its conduct relating to his device. As Mr. Braund cannot satisfy the lower standard of negligence, he clearly cannot illustrate that Guidant's alleged conduct is "so extreme that it goes beyond all possible bounds of decency." As a matter of law, Guidant's alleged conduct cannot be deemed extreme or outrageous or beyond all possible bonds of decency, or to be regarded as atrocious, or utterly intolerable in a civilized community. Mr. Braund fails to meet the first element of and IIED claim under Michigan law.

c. There is no evidence that Guidant intentionally or recklessly committed any of the alleged conduct.

To be found intentional, conduct must be perpetrated for the purpose of inflicting emotional distress. *Haverbush v. Powelson*, 551 N.W.2d 206, 210 (Mich. Ct. App. 1996). Because Mr. Braund never asserted a claim for IIED in his Original Complaint, he has never set forth the parameters of his IIED claim other than the vague allegations contained in the MDL Master Complaint. *See* Amended MDL Master Compl. at ¶¶ 343-347. The record is devoid of any statement by Mr. Braund that Guidant intentionally caused him any alleged emotional distress. Indeed, as written above, Mr. Braund's device never exhibited the failure mode that was the subject of Guidant's voluntary recall of the PRIZM 2. Guidant warned both Mr. Braund and his physician that inappropriate shocks may occur and may upset a patient. Moreover, Mr. Braund has no evidence that the alleged inappropriate shocks were in any way related to a defect in his device or conduct on the part of Guidant.

Likewise, Guidant did not commit any reckless conduct. Under Michigan law, conduct is deemed reckless if the circumstances are such that any reasonable person would know emotional distress would result. Again, Mr. Braund's device never exhibited the malfunction that was the subject of the voluntary recall. Also, Guidant warned that inappropriate shocks could occur and could upset a patient. And there is no evidence that the alleged inappropriate shocks were a result of a device malfunction or in any way caused by Guidant. Guidant's conduct can hardly be deemed reckless when it warned Mr. Braund, as it does all patients, that inappropriate shocks may occur. As an

ICD patient, Mr. Braund and others assume certain risks that are inherent in these highly complex medical, manmade medical devices. These patients cannot be allowed to assert as a claim a risk about which they are warned just because the risk allegedly manifests, especially when they have no proof that the shocks are attributable to a device malfunction or company conduct.

B. Mr. Braund's Emotional Distress Claims Fail Under Minnesota Law.

1. Mr. Braund's NIED claim fails under Minnesota law.

Under Minnesota law, to recover for NIED, Mr. Braund must prove the four elements of a negligence claim – duty, breach, causation, and damages – as well as three additional elements: (1) presence within the zone of danger; (2) reasonable fear for his safety; and (3) severe emotional distress with attendant physical manifestations. *Engler v. Ill. Farmers Ins. Co.*, 706 N.W.2d 764, 767 (Minn. 2005). As addressed in Part IX, Mr. Braund has failed to prove that Guidant was negligent under either Michigan or Minnesota law, and thus his NIED claim fails. Even if Mr. Braund's negligence claim were able to survive summary judgment, he still fails to meet additional essential elements required under Minnesota law to prove his NIED claim.

a. Mr. Braund was not within a zone of danger.

Mr. Braund cannot prove the first of the three additional elements under Minnesota law required to support a NIED claim. First, he must show that he was within the "zone of danger." *Stadler v. Cross*, 295 N.W.2d 552, 553 (Minn. 1980). "[A] remote possibility of personal peril is insufficient to place plaintiff within a zone of danger for

purposes of a claim of negligent infliction of emotional distress." *K.A.C. v. Benson*, 527 N.W.2d 553, 559 (Minn. 1995).

Mr. Braund was not within the "zone of danger." The "zone of danger" test is for situations where a plaintiff is in imminent peril. *See Masepohl v. American Tobacco Co.*, 974 F. Supp. 1245, 1252 (D. Minn. 1997) (tracing the 100 year history of the "zone of danger" test and citing examples such as an impending cable car collision, proximity to a collapsed wall, and a 34,000-foot plunge by an out-of-control commercial aircraft) (citations omitted). Mr. Braund claims that his physical injuries were caused by "device malfunction resulting in shocks." *See also* Braund Complaint ¶ 56. But like all ICD patients, Mr. Braund was warned of the potential for inappropriate shocks. *See supra* Part II.A., B.2. As stated above, his PRIZM 2 did not malfunction, nor did it exhibit the conditions necessary to malfunction. *See supra* Part B.2. And Mr. Braund has no evidence that his alleged inappropriate shocks were related in any way to conduct by Guidant.

Even if Mr. Braund were able to attribute the alleged inappropriate shocks to some conduct by Guidant, such shocks also did not place Mr. Braund in imminent peril. For arrhythmias that are very fast and irregular, defibrillation shocks can return the heart to its normal rhythm. Thus, shocks cannot be described as the "zone of danger" when in fact, they are therapeutic. Also, inappropriate shocks are a common complication of ICD therapy about which Guidant warns implanting physicians, who in turn are instructed to warn patients. *See* Part X (Failure-to-Warn). Although they may be

uncomfortable and upsetting to patients, they are not physically harmful,[21] and thus do not place patients in any imminent peril. Guidant's AICD Patient Handbook describes what a defibrillation shock feels like and how it may upset the patient. *See supra* Part II.B.1. But such shocks cannot qualify as placing Mr. Braund within the "zone of danger."

Unlike bellwether plaintiff Leopoldo Duron, Jr., whose device never delivered defibrillation shocks, here the shocks that Mr. Braund received actually show that his device did not exhibit the potential arcing failure that was the subject of the PRIZM 2 recall. Thus, it was clear that Mr. Braund's device was working and that he was not in any "zone of danger." In addition, all tests performed on Mr. Braund's device show that is never exhibited the failure mode that was the subject of the recall. *See* Part IX. Even Mr. Braund's own expert, Randolph Armstrong, also grants this fact. *See id*.

Nor can Mr. Braund's elective replacement surgery qualify as the "zone of danger." As Mr. Braund's own psychiatric expert concedes, Mr. Braund is unable to differentiate the reason for the recall, which is the potential for a device to not deliver a defibrillation shock when needed, from the alleged inappropriate shocks he received—shocks he could not have received had his device exhibited the failure mode by arcing. Thus, Mr. Braund's fear that his device may have failed, which led to his replacement surgery, is based on a fundamental misunderstanding of the recall. In this respect, Mr. Braund's case is more analogous to *O'Brien v. Medtronic*, 439 N.W.2d 151 (Wis. Ct.

[21] Medscape Today, St. Jude Announces Publication of OPTIC Clinical Study Results in JAMA; Study May Hold Key to Reducing Shocks in Patients (Jan. 10, 2006), *available at* http://www.medscape.com/pages/editorial/pressreleases/pr-crm-sjm69.

App. 1989), where plaintiff's replacement surgery was performed to alleviate emotional distress related to a recalled pacemaker. Mr. Braund was not in the "zone of danger" and thus fails to meet this essential element.

b. Mr. Braund's fear for his own safety was not reasonable.

Mr. Braund's fear of receiving further shocks by Guidant's device is not reasonable. He was warned through his physician of the possibility of inappropriate shocks. The alleged inappropriate shocks have not occurred for several years ago. *See supra* Part II.B.2 Moreover, Mr. Braund decided to replace the PRIZM 2 device electively. Thus, any fear of future shocks is unfounded. Mr. Braund was not within the "zone of danger" because he was not in any imminent peril. Because Mr. Braund was not in the "zone of danger," any fear that he felt for his own safety was not reasonable.

While shocks from a device may be upsetting, it is not unusual that an AICD patient reacts this way when he receives them. *See supra* Part II.B.1. But there is no evidence that they may be deemed as placing an individual within the "zone of danger" within the meaning of Minnesota law. Inappropriate shocks are clearly not the equivalent to an imminent cable car collision or a 34,000-foot plunge toward the Earth in a commercial airliner. Thus, Mr. Braund fails the second element of NIED under Minnesota law.

2. Under Minnesota law, Mr. Braund's claims for IIED should be dismissed as a matter of law.

Under Minnesota law, to recover for IIED, a defendant's conduct must (1) be extreme or outrageous; (2) be intentional or reckless; and (3) cause severe emotional

distress. In the *Duron* case, this Court ruled that summary judgment was not proper for this cause of action, with which Guidant respectfully disagrees. Here, the alleged misconduct is based primarily on allegedly inappropriate shocks that Mr. Braund received, not the potential for the device to arc that was the subject of the recall. Guidant warned of inappropriate shocks; Mr. Braund has no basis or evidence to claim that providing FDA-approved warnings about a potential adverse event constitutes extreme or outrageous behavior. Because of this, Mr. Braund fails to prove essential elements of his IIED claim, which fails under Minnesota law.

a. There is no evidence that Guidant caused Mr. Braund's alleged emotional distress.

As shown in Part II.B.1, Mr. Braund has no evidence to show a causal connection between conduct by Guidant and his alleged emotional distress. There is no proof that Mr. Braund's inappropriate shocks were related to a malfunction in his device or attributable to any actions by Guidant. Because the record is devoid of any proof that Guidant caused Mr. Braund's alleged emotional distress, his IIED claim fails.

b. There is no evidence that Guidant committed any extreme or outrageous conduct.

Under Minnesota law, to assert a claim for IIED, a plaintiff must prove that the conduct complained of was extreme and outrageous. *Kelly v. City of Minneapolis*, 598 N.W.2d 657, 663 (Minn. 1999). The conduct must be "so atrocious that it passes the boundaries of decency and is utterly intolerable to the civilized community." *Haagenson v. National Farmers Union Property & Casualty Co.*, 277 N.W.2d 648, 652 n. 3 (Minn.1979). The conduct must cause emotional distress that is so severe that no

reasonable person can be expected to endure it. *Hubbard*, 330 N.W.2d at 439 (citing Restatement (Second) of Torts § 46 cmt. (1965)). Because mental distress damages claims are disfavored, only egregious facts satisfy the requirements of extreme or outrageous conduct. *Id.* at 437. For the reasons addressed in Part II.A.1, Mr. Braund cannot show that Guidant committed any extreme or outrageous conduct because the record is devoid of any evidence that his alleged inappropriate shocks are attributable to any actions by Guidant. In fact, Mr. Braund cannot even prove negligence on the part of Guidant. Because Mr. Braund cannot prove the first element of IIED under Minnesota law, his claim fails as a matter of law.

c. There is no evidence that Guidant committed any intentional or reckless conduct.

For Mr. Braund to prevail on a claim for IIED, he must show that any alleged conduct on the part of Guidant was directed at him and that Guidant knew of his presence so that the mental effect on Mr. Braund was anticipated by Guidant. *Domfeld v. Oberg*, 503 N.W.2d 115, 119-20 (Minn. 1993). Simply put, Mr. Braund can offer no evidence to support this element. *See* Part II.B.2. In the absence of such a showing, Guidant's conduct cannot be deemed intentional or reckless. *Id.* Mr. Braund fails the second element of IIED under Minnesota law.

For the reasons set forth above, Guidant respectfully requests that the Court dismiss Mr. Braund's NIED and IIED claims with prejudice.

XIV. DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF SUMMARY JUDGMENT ON MR. BRAUND'S NEGLIGENCE-PER-SE CLAIM

The Court should dismiss Mr. Braund's claim based on Negligence Per Se (Count IV – Complaint by Adoption) under Minnesota and Michigan law.

Michigan has rejected negligence per se in product-liability actions. The Michigan Product Liability Act, which applies to Mr. Braund's action, provides:

> Noncompliance with a standard relevant to the event causing the death or injury set forth in a federal or state statute or lack of approval by, or noncompliance with regulations or standards relevant to the event causing the death or injury promulgated by, a federal or state agency does not raise a presumption of negligence on the part of a manufacturer or seller. Evidence of compliance or noncompliance with a regulation or standard not relevant to the event causing the death or injury is not admissible.

M.C.L.A. § 600.2946(4). Accordingly, under Michigan law, the Court should dismiss Mr. Braund's claim based on negligence per se.

Even applying Minnesota law, the Court should dismiss Mr. Braund's claim based on negligence per se. Minnesota recognizes claims for negligence per se. *Whiteford v. Yamaha Motor Corp.,* 582 N.W.2d 916, 920 (Minn. 1998). However, for a statute to establish a duty, however, the person who is injured must be the person the statute is intended to protect and the person must suffer the injury the statute was intended to avoid. *Anderson v. Anoka Hennepin Indep. School Dist. 11,* 678 N.W.2d 651, 662-62 (Minn. 2004). In negligence per se cases, the statutory standard substitutes for the ordinary prudent person standard of care generally applied to negligence causes of

actions. *Anders v. State, Dept. of Natural Resources*, 693 N.W.2d 181, 189-90 (Minn. 2005).

Here, Mr. Braund has identified no violation of any statute. Mr. Braund generically alleges – by adopting Count IV in the Master Complaint – that Guidant's sales of the PRIZM 2 "constitute an adulteration, misbranding, or both, as defined by the Federal FDCA, 21 U.S.C. § 331(a) and 333(a)(2)." First Am. Master Compl. at ¶ 295. Mr. Braund has no evidence, however, that the FDA has determined that Mr. Braund's device was misbranded or adulterated at the time of implant (or at any other time). To the contrary, the FDA has never revoked its approval of Mr. Braund's PRIZM 2. *See supra* Part II.A. Thus, an essential element of a negligence-per-se claim – the violation of a statute – is missing here.

Nor has Mr. Braund identified any injury he suffered that a statute was intended to avoid. Mr. Braund alleges that he was inappropriately shocked by his PRIZM 2. But he has no evidence that the inappropriate shocks are the type of harm that the statute was designed to avoid. As explained in Part IX, Mr. Braund has no evidence that the alleged inappropriate shocks are attributable to any defect in his PRIZM 2. Without any evidence of harm that a statute was intended to avoid, Mr. Braund's negligence-per-se claim must be dismissed.

XV. DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF SUMMARY JUDGMENT ON MR. BRAUND'S "GROSS NEGLIGENCE / MALICE" CLAIM

The Court should dismiss Mr. Braund's claim based on Gross Negligence / Malice (Count XII – Complaint by Adoption).

Gross negligence is not a separate cause of action in Michigan. "With the introduction of comparative negligence in place of contributory negligence . . . it appeared that the concept of 'gross negligence' was unnecessary in Michigan tort law." Elmer E. White, Michigan Torts § 1.8; *see also Jennings v. Southwood*, 521 N.W.2d 230, 233 (Mich. 1994) ("[G]ross negligence is really the doctrine of last clear chance in disguise; accordingly, its usefulness is dubious at best in light of our holding in *Petrove*. While we recognize that *Gibbard*'s gross negligence is a seventy-year-old doctrine, we must nevertheless discard it because it has outlived its usefulness.").

Likewise, under Minnesota law, gross negligence and malice are antiquated, inapplicable requisites for punitive damages. Only cases dating back to the early 1900's involve gross negligence and malice; those cases state that gross negligence is means of showing malice in support of entitlement to punitive damages. *See, e.g.*, *Anderson v. International Harvester Co. of America*, 116 N.W. 101, 102 (Minn. 1908) ("The authorities very generally permit recovery when the tort is committed with cruelty, oppression, insult, or such gross negligence as to justify the inference of malice as a matter of law."); *Vine v. Casmey*, 90 N.W. 158, 158 (Minn. 1902) ("To justify such [exemplary] damages the tort must have been committed wantonly or maliciously, or with such insult, cruelty, oppression, or gross negligence, or such other aggravating circumstances, as to establish malice in fact.").

Minn. Stat. § 549.20 now provides appropriate standard for entitlement to punitive damages, displacing the concepts of malice and gross negligence. *See, e.g.*, *Kalema v. U.S. Oil Co., Inc.*, 2006 WL 2289849, at *5 (D. Minn. Aug. 8, 2006)

("Punitive damages are allowed where there is clear and convincing evidence that the defendant acted with deliberate disregard for the rights of the plaintiff.") (applying Minn. Stat. § 549.20). In short, malice and gross negligence are not stand-alone claims. Nor do they provide the correct standard for entitlement to punitive damages. Accordingly, the Court should dismiss Mr. Braund's claim based on Gross Negligence / Malice (Count XII – Complaint by Adoption).

XVI. DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF SUMMARY JUDGMENT ON PLAINTIFF'S REQUEST FOR PUNITIVE OR EXEMPLARY DAMAGES

Mr. Braund did not seek punitive or exemplary damages in his original state court complaint. He also failed to adopt Count XXXI of the First Amended Master Complaint, which asserts that Guidant's conduct warrants the imposition of punitive or exemplary damages. Nevertheless, he requests leave to seek such damages in his prayer for relief in his Complaint by Adoption. Compl. by Adoption at 4.

This Court should reject his request for leave to seek punitive damages. "It is well established that generally only compensatory damages are available in Michigan and that punitive sanctions may not be imposed." *McAuley v. Gen. Motors Corp.*, 578 N.W.2d 282, 285 (Mich. 1998). Indeed, "awarding punitive damages is 'plain error' under Michigan law.'" *Thompson v. Paasche*, 950 F.2d 306, 312 (6th Cir. 1991).

This Court should also reject his request for leave to seek exemplary damages. Although Michigan does, under limited circumstances, permit an award of "exemplary" damages, such damages are only appropriate "to compensate the plaintiff 'for the humiliation, sense of outrage, and indignity resulting from injuries maliciously,

willfully and wantonly inflicted by the defendant.'" *Morganroth & Morganroth v. DeLorean*, 123 F.3d 374, 385 (6th Cir. 1997) (quoting *Kewin v. Mass. Mutual Life Ins. Co.*, 295 N.W.2d 50, 55 (Mich. 1980)). Where, as here, a plaintiff pleads multiple claims based upon mental distress and anguish, a plaintiff may not be "doubly compensate[d] . . . for the same injury." *Veselenak v. Smith*, 327 N.W.2d 261, 265 (Mich. 1982).

XVII. CONCLUSION

For the reasons set forth above, this Court should grant Guidant's Summary Judgment Motion and dismiss all Mr. Braund's claims with prejudice.

Respectfully submitted,

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