**UNITED STATES DISTRICT COURT**
**DISTRICT OF MINNESOTA**
**THIRD DIVISION**

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| In re: Guidant Corp. Implantable Defibrillators Products Liability Litigation | MDL No. 1708 (DWF/AJB) |
| *This Document Relates to All Actions* | |

# PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE MASTER COMPLAINT CLAIMS OF DEVICE RECIPIENT PLAINTIFFS

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Plaintiffs respectfully submit this memorandum in opposition to Defendants' Motion to Dismiss ("Defendants' Memorandum" or "Def Mem.") the Master Complaint ("Complaint"/"¶ _").

## I. INTRODUCTION

Plaintiffs' Complaint alleges that all Guidant medical devices at issue in this litigation are defective. *See* Appendix A (summary of allegations). Serious and palpable risks to human health have resulted in the recall of nearly every device in this MDL. Many of these recalls (Ventak Prizm 2 DR 1861, the Contak Renewal 1 & 2, AVT and pacemakers) are FDA Class I recalls, reserved for "situations in which there is a reasonable probability that the use of, or exposure to, [the] violative product will cause serious adverse health consequences or death." 21 C.F.R. § 7.3 (m)(1). *See* ¶¶ 113, 129, 144, 156. Other models at issue – the Contak Renewal 3 & 4, Insignia and Nexus models – have seen Class II recalls. ¶¶ 236, 166. A "[r]ecall means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure." 21 C.F.R. § 7.3(g) (2006).

As a direct result of implantation with a defective Guidant device, every Plaintiff herein has suffered cognizable injury.[1] Specific injuries include the alleged deaths of at least eleven Plaintiffs, physical injury resulting from non-consensual

[1] ¶ 369 ("Plaintiffs were and are injured and/or were and are directly exposed on a prolonged, repeated and continuous basis, to a significantly and substantially increased risk of injury and death from failure and malfunction of the Devices, relative to the population of cardiac patients implanted with non-defective and unrecalled devices or receiving other therapies.").

implantation of defective devices, physical injury resulting from administration of unnecessary shocks (*see, e.g.*, 16, 21), physical injury resulting from explantations of defective devices (*e.g.*, ¶¶ 13, 15, 17-19, 22-23, 25-26), physical and emotional stress resulting from knowledge that a defective and dangerous device has been placed inside one's chest in direct contact with sensitive heart tissue (*e.g.*, ¶ 16); and, in all cases, economic damages: paying substantial sums for a defective product and (in many cases) having to pay equally substantial sums for its replacement.

Despite these allegations, which are plainly asserted in the Complaint, Defendants assert that a subset of Plaintiffs "do not plead and cannot plead any present injury attributable to a manifested defect in Defendants' products." Def. Mem. 1. In so arguing, Defendants not only conveniently disregard each of the above allegations, but rely on two fundamentally flawed assumptions.

First, Defendants assume, without any basis, that non-consensual implantation of a defective and dangerous medical device, and the physical and emotional stress caused by knowledge that such a device remains implanted, do not constitute legally recognized injury. This contention essentially refutes itself, and, in all events, the degree of physical and emotional stress in any given case is not a matter to be determined on Rule 12 motion.

Second, and no less significantly, every Plaintiff who had a defective heart device implanted paid for it, and was – in layman's as well as legal terms – defrauded. After all, who would have agreed to have a Prizm 1861 device implanted in 2002 had Guidant disclosed to her that, at that very time, it had learned the devices were

misdesigned, that failures had occurred, and that it believed it could fix the devices but instead chose to sellout its inventory before changing the devices? Similarly, what rational Plaintiff would have agreed to Prizm 1861 or Contak Renewal device implantation, had he or she known that polyimide, a material that the United States military had stopped using years earlier in aircraft because of its dangerous propensity to degrade in moist environments, was a critical insulating material in these devices? Additionally, the costs of explantation and replacement constitute clear and unequivocal economic injuries.

Defendants want the Court to forget that, in most substantial measure, this litigation is about economic injury. Whether those claims sound in the legal forms of action of fraud, warranty, negligent misrepresentation, consumer fraud or unjust enrichment, the fact is that tens of thousands of recipient patients paid hundreds of millions of dollars for allegedly defective and dangerous products, and many of those paid hundreds of millions of dollars more to have them replaced.

Defendants claim "there is no manifest defect in many cases" because plaintiffs allege only that their devices "may" or "can" fail, Def. Mem. 3. In many cases, as alleged, an actual device's malfunction will not become apparent until the device is required to administer a shock, or after extensive medical monitoring is conducted (including commanding a shock in the device).[2] Further, even for Plaintiffs who may not have had explantation at the time they filed their complaint, many have since had explantation, and Defendants' blunderbuss attempt to cut out a subcategory of claims

[2] *See, e.g.*, ¶¶ 112, 129, 136, 143, 148, 154, 56, 165, 369, 370.

would foreclose them. In short, the operative facts are needed before any group of Plaintiffs' claims could be dismissed (though none should be).

Part I of Defendants' Motion is premised on the argument that a subset of Plaintiffs that is neither set forth in the Complaint nor otherwise defined by Defendants with any specificity – has not suffered cognizable injury. As shown, this is not true, and would, if anything, present a matter for determination upon a factual record, not a dismissal motion. Defendants ask this Court to ignore basic and well settled law of warranty, infliction of emotional distress, medical monitoring, and state consumer protection law. Accordingly, Part I of Defendants' Motion cannot provide a basis for dismissing any Plaintiffs' claims.

Part II fares no better: it is based on a premature attempt to impose the laws of each of the Plaintiffs' home States, regardless of whether they filed suit in this District and without a proper conflicts of law analysis – an analysis that must await a more fully developed record.

Accordingly, Defendants' motion to dismiss should be denied in its entirety.

## II. ARGUMENT

### A. Relevant Legal Standards.

When considering a motion to dismiss, the court "must accept all factual allegations as true and grant every reasonable inference in [plaintiffs'] favor." *Strand v. Diversified Collection, Inc.*, 380 F.3d 316, 317 (8th Cir. 2004). A motion may be granted only "in the unusual case in which a plaintiff includes allegations that show, on the face

of the complaint, that there is some insuperable bar to relief." *Frey v. Herculaneum*, 44 F.3d 667, 671 (8th Cir. 1995); *Booker v. City of St. Louis*, 309 F.3d 464, 467 (8th Cir. 2002) ("In reviewing a Rule 12(b)(6) motion to dismiss for failure to state a claim, 'we construe the complaint liberally, taking all allegations as true, and will affirm only if it appears beyond a doubt that [the plaintiff] cannot prove any set of facts in support of the claim'").

Defendants' Motion ignores the applicable standard, and asks the Court to accept or assume purported facts inconsistent with the Complaint's allegations.

**B. Choice-of-Law Analysis.**

Defendants conclusorily contend that no choice-of-law analysis is required to dismiss the claims of those Plaintiffs still implanted with defective devices. Def. Mem. 6. Defendants fail to cite a single case where a court has ever done what they ask the Court to do and, indeed, even the cases they cite suggest such a course would be error. *See In re St. Jude Medical, Inc., Silzone Heart Valve Prods. Liab. Litig.*, 425 F.3d 1116, 1120 (8th Cir. 2005). As Defendants acknowledge, *Erie R.R. Co. v. Tompkins*, 304 U.S. 64 (1938) provides that plaintiffs' claims are governed by State law. *Van Dusen v. Barrack*, 376 U.S. 612 (1964) requires this Court to apply the State law that would have been applied in the districts in which the cases in this MDL originated. A conflict of laws analysis is required if "the applicable law from each jurisdiction provides different substantive rules." *Finance One Public Co. Ltd. v. Lehman Bros. Special Financing, Inc.*, 414 F.3d 325, 331 (2d Cir 2005) (*quoting Curley v. AMR Corp.*, 153 F.3d 5, 12 (2d Cir. 1998)).

Defendants' approach is backwards. They do not even purport to conduct the required analysis. One cannot simply assume Defendants' proposition – that ***all*** relevant jurisdictions would reject the tort claims of certain Plaintiffs. To begin with, although Defendants acknowledge that the Complaint "implicat[es] the laws of all 50 states," Def. Mem. 1, they provide purported authority from, at most, 18; and most are non-authoritative federal cases. In addition, Defendants are repeatedly wrong about the law in those 18 jurisdictions. For instance, a number of these jurisdictions do allow recovery in negligence (or pursuant to other tort theories) for emotional distress, even though no physical injury resulted.

Critically, in this case, relevant differences in state law could easily have a "significant possible effect on the outcome of the trial." *Finance One*, 414 F.3d at 331. This Court should reject Guidant's invitation to gloss over differences in State law and avoid a proper conflict of law analysis, an invitation long rejected by courts. *See Arfons v E.I. Dupont de Nemours & Co.*, 261 F.2d 434, 436 (2d Cir. 1958) (holding that "[i]t would be premature, also, before the facts are developed, for us to express an opinion as to what the law of Ohio may be in respect to implied warranties, nor are we called upon to do so"); *Dyotherm Corp. v. Turbo Machine Co.*, 233 F. Supp. 119, 122-123 (E.D. Pa. 1964) (internal citations omitted) (since neither counsel filed an "exhaustive" analysis of relevant law, the Court was "persuaded that in the present posture of this case the third count should not be dismissed for insufficiency, since it does not appear 'to a certainty that the plaintiff would not be entitled to relief under any state of facts which could be proved in support of the claim'"); *cf. In re St. Jude Medical, Inc., supra*, 425 F.3d at

1120. As the brief contemporaneously filed in opposition to Defendants' motion to dismiss the third-party payor ("TPP") claims discusses, the appropriate juncture at which to conduct a rigorous choice-of-law analysis is the class certification stage, or, in the case of individual claims, or, with respect to the cases selected for representative trials, at the motion *in limine* stage. This analysis is not simplistic: as the Third Party Payor Plaintiffs' Memorandum in Opposition to Defendants' Motion to Dismiss Third Party Payor Claims in the Master Complaint ("TPP Mem.") discusses, the TPP claims asserted in the Complaint, and filed in the District of Minnesota, may be appropriate for class certification and trial under Minnesota law. Under the doctrine of *depecage*, as recognized in this Circuit, the law of different states may be applied to resolve different issues in the same case. *Ewing v. St. Louis-Clayton Orthopedic Group, Inc.*, 790 F.2d 682, 686 (8th Cir. 1986). This will be addressed when specific class certification motions are made or cases are set for trial, and there is a record upon which the applicability of laws can be determined and an actual choice-of-law analysis performed. Defendants' truncated choice-of-law analysis for purposes of dismissing claims, rather than properly selecting the law that will apply to them, is inappropriate.

### C. The Complaint Asserts Viable Product Liability, Negligence and Warranty Claims For Device Recipients Whose Devices Have Not Been Explanted.

#### 1. The Complaint Alleges That All Explanted Plaintiffs Have Suffered Cognizable Injuries In Tort And Warranty.

It is clear that Plaintiffs who have not had their devices explanted have adequately pleaded injury and/or alleged that the products were defective. In each of

their strict liability and negligence claims, Plaintiffs allege that "[a]s a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain *severe physical injuries and/or death, severe emotional distress*, economic losses, and other damages." ¶¶ 277, 286, 292, 297. Defendants' claim that the Plaintiffs have "no injury" ignores the express allegations of the Complaint. This alone should end the analysis on the present motion.

In addition, Defendants' claim that the device recipient Plaintiffs have suffered "no injury" ignores the fact that these Plaintiffs had to be cut open in order to have a defective device implanted in them. The physical injury represented by, and resulting from, implantation surgery itself satisfies any requirement for bodily injury for traditional tort claims, and satisfies any "impact" or "involvement" requirement for emotional distress claims. *See generally Rickey v. Chicago Transit Authority*, 457 N.E.2d 1, 4 (Ill. 1983) (discussing showing required under the "impact" rule).

Numerous courts have described the rule as permitting recovery of emotional distress damages if there is an impact "however slight." *Ortiz v. John D. Pittenger Builder, Inc.*, 889 A.2d 1135, 1139 (N.J. Super. 2004); *Brooks v. Hickman*, 570 F. Supp. 619 (W.D. Pa. 1983); *Robb v. Pennsylvania R. Co.*, 210 A.2d 709, 714 (Del. 1965) (collecting early cases). Courts have permitted emotional distress claims to proceed with impacts far less serious than those involved here. *E.g. Bader v. Johnson*, 732 N.E.2d 1212, 1222 (Ind. 2000) (bodily changes accompanying continued pregnancy was sufficient impact); *Holloway v. Bob Evans Farms, Inc.*, 695 N.E.2d 991, 996 (Ind. Ct. App. 1998) (ingestion of a portion of vegetables cooked with a worm was sufficient

impact). Indeed, in *D'Augustino v. Bristol-Myers Squibb Company*, 980 F. Supp. 1452 (M.D. Fla. 1997), the plaintiff was permitted to pursue an emotional distress claim though there was apparently no impact beyond implantation of breast implants.

Many States have wholly abandoned the requirement of an impact for emotional distress claims. "The vast majority of jurisdictions . . . have abandoned or refused to adopt the impact rule. Most jurisdictions allow a direct victim to recover for fright resulting in physical injury if he was in danger of physical injury and as a result feared for his own safety." *Williams v. Baker*, 572 A.2d 1062, 1066 (D.C. App. 1990); *accord AALAR, Ltd., Inc. v. Francis*, 716 So.2d 1141, 1145 (Ala. 1998) ("most states do not require the existence of a physical injury as a prerequisite to the recovery of damages for emotional distress.").

No one could doubt that if the operating surgeon had placed a rock inside a Plaintiff's chest, rather than a defibrillator, there would be ample injury to support a cause of action, even if the rock did not result in an infection or further bodily injury. For many Plaintiffs, Guidant's defective device is no better.

Defendants' three page reliance (Def. Mem. 7-9) on *Briehl v. General Motors Corp.*, 172 F.3d 623 (8th Cir. 1999), as well as *Briehl's* repeated citation thereafter, is misplaced. Defendants conveniently forget that in *Briehl*, the plaintiffs "affirmatively state[d] that their purported class excludes any claim for personal injury or property damage caused by brake failure." 172 F.3d at 628. The same cannot be said of Plaintiffs' allegations here, where a product was put, not on their cars, but in their bodies without their – but with Defendants' – knowledge of its defective nature. Here, *per se*

physical harm occurred, from the very beginning, to the body of each Plaintiff. Plaintiffs have expressly — and understandably — alleged that Defendants' devices have caused "severe physical injuries and/or death" and "severe emotional distress."

This case, unlike *Briehl*, is not solely a class action seeking only economic, non-personal injury damages for a product that never was put in the human body. Nor is it a case where the plaintiffs merely claim that a fully functioning product "should have" been designed differently to make it more "user-friendly." This is a case where Defendants' devices have failed, sometimes disastrously so, in a manner so well documented that the federal government was required to intervene to assure they were taken off the market.

Nor is this case comparable to *Khan v. Shiley Inc.*, 266 Cal. Rptr. 106 (Cal. App. 4 Dist. 1990) or the numerous other "heart valve" cases that Defendants cite: (a) many of those cases actually uphold various of the specific claims under specific State laws (*e.g.*, fraud claims under California law in *Shiley*); (b) many of those cases were decided on summary judgment upon a factually developed record (as Defendants must concede); and (c) claims of emotional distress or injury pursuant to physical implantation were not put forward (or, at least, not addressed) in a number of those decisions. Heart valve litigation has proven somewhat anomalous in this area; however, unlike heart valves, which either "function continuously" or exhibit obvious (sometimes disastrous) failures, a defibrillator is designed to administer a shock only when the body's conditions require it. Accordingly, while a defibrillator may have already failed, that failure may be undetected for years. Thus, many plaintiffs may have inside their chests the functional

equivalent of a rock (*i.e.*, an already manifested defect), but will not discover that until a cardiac episode occurs, possibly fatally.

Indeed, other courts have disagreed with Defendants' position on what is injury under tort and warranty law – both within the product area generally and as it specifically concerns implantable devices.

Court have rejected Defendants' blunderbuss contention that non-manifest defects are *per se* non-compensable in products defect cases. *See In re Bridgestone/ Firestone, Inc. Tires Products Liability Litigation*, 155 F. Supp. 2d 1069 (S.D. Ind. 2001) *rev'd in part on other grounds*, 288 F.3d 1012 (7th Cir. 2002). In *Bridgestone*, which Defendants themselves cite, the District Court, applying Michigan and Tennessee law, held that "there is no requirement that Plaintiffs demonstrate any injury to their person or property as a result of the breach, but only that they purchased an unmerchantable product." *Id.* at 1099. Many other States follow a similar rule. *See Kelly v. Sears Roebuck and Co.*, 720 N.E.2d 683 (Ill. App. Ct. 1999); *Stroderd v. Yamaha Motor Corp., U.S.A.*, No. Civ. A. 04-3040, 2005 WL 2037419, at *3 (E.D. La. Aug. 4, 2005) (Louisiana redhibition claim); *In re Ford Motor Co. Bronco II Prods. Liability Litigation*, No. MDL-991, 1995 WL 491155 (E.D. La. Aug. 5, 1995) (same); *Coghlan v. Wellcraft Marine Corp.*, 240 F.3d 449 (5th Cir. 2001) (Florida and Texas law); *Microsoft Corp. v. Manning*, 914 S.W.2d 602, 609 (Tex. App. 1995).

The *Bridgestone* decision succinctly explained the fallacy of an argument virtually identical to that of Defendants here: "Defendants' argument assumes that the only way Plaintiffs can prove that the Tires are defective is by tread separation and that

the only way Plaintiffs can prove that the Explorers are defective is by an active roll-over incident. However, this is a factual assumption that is inappropriate for the Court to embrace in ruling on a motion to dismiss." 155 F. Supp. 2d at 1100. Thus, "Plaintiffs allege that the Tires and the Explorers are defective, and as Defendants cannot demonstrate as a matter of law that they are not, we shall assume for purposes of this motion that they are. Therefore, Plaintiffs' claim for breach of implied warranty of merchantability will not be dismissed for failure to allege manifest injury." *Id.* at 1101.

Here, Defendants contend that the Plaintiffs can only show that the faulty devices it sold them are defective if the Plaintiffs suffer a cardiac episode and the devices fail to respond. Just as the Explorer owners did not need to plead an injurious rollover at the motion to dismiss stage, Plaintiffs here should not be required to die in order to secure the benefit of Guidant's warranty.

This issue was addressed directly in *Larsen v. Pacesetter Systems, Inc.*, 74 Haw. 1, 837 P.2d 1273 (1992), in which the Hawaii Supreme Court concluded that "neither the tort nor the warranty formulations of the test for product defectiveness heretofore enacted by the legislature or adopted by this court require that a product actually malfunction." *Id.* at 1286. Defendants' blithe contention about the laws of "all the states" is manifestly wrong.

Furthermore, as to warranty claims, the defects at issue render the devices less valuable, regardless of any propensity to cause injury, and this difference in value is compensable under a warranty theory. *Coghlan v. Wellcraft Marine Corp.*, 240 F.3d 449, 452 (5th Cir. 2001) (the measure of damages under the Uniform Commercial Code "is

neither novel nor exotic"). This common sense measure of damages is written into the Uniform Commercial Code itself: "The measure of damages for breach of warranty is the difference at the time and place of acceptance between the value of the goods accepted and the value they would have had if they had been as warranted, unless special circumstances show proximate damages of a different amount." U.C.C. § 2-714(2); *e.g.* Minn. Stat. § 336.2-714.[3]

The U.C.C. only requires a buyer to allege that goods were not as warranted; no allegation of personal injury is required. In *Muehlbauer v. General Motors Corp.*, 431 F. Supp.2d 847, 871 (N.D. Ill. 2006), for instance, the court permitted claims to go forward on behalf of plaintiffs who had "experienced the defect," even if they had not suffered personal injuries. For purposes of a warranty claim, Plaintiffs are aware of no case that requires, as Defendants claim, that the product manifest defects ***and*** cause personal injury before a claim for breach of the implied warranty of merchantability can be asserted: tort is not a prerequisite of breach of warranty, or vice versa.

### D. In A Number Of States, Damages For Emotional Harm Alone Are Recoverable In Tort And Warranty Theories.

Even putting aside the fact that Plaintiffs have adequately alleged injury and defects for purposes of their tort and warranty claims, this Court should deny Defendants' motion because the clear law in a number of states permits recovery for

[3] *Briehl*'s apparent rejection of a similarly stated measure of damages as "too speculative," reflects either the fact that proper argument based on the U.C.C. was not made to the Court, or, as suggested by the district court in *Bridgestone*, "is simply another way of saying that the products were, in fact, merchantable, and therefore there was no breach of warranty." 155 F. Supp. 2d at 1100.

purely emotional harm in a case like this pursuant to negligence, strict liability and warranty theories. For example, in *Larsen, supra*, in addition to holding that a claim for an implantable cardiac device under tort or warranty law does not require actual malfunction, the Hawaii Supreme Court also held that emotional distress damages were recoverable "in implied warranty, strict products, and negligence actions," and attributed the same views to Iowa and other States. 837 P.2d at 1294.

Likewise, while Alabama, for example, does not recognize a separate tort of negligent infliction of emotional distress, under Alabama law "[d]amages for emotional distress may be awarded in a negligence case, even in the absence of physical injury. *Flagstar Enters., Inc. v. Davis*, 709 So.2d 1132, 1141 (Ala. 1997). Indiana, a Guidant "home state," allows recovery for purely emotional injury "without regard to whether the emotional trauma arises out of or accompanies any physical injury to the plaintiff." *Bader v. Johnson*, 732 N.E.2d 1212, 1221 (Ind. 2000).[4]

Many States permit recovery of emotional distress damages in the absence of other injury, either under the independent tort of Negligent Infliction of Emotional Distress, or, if the State has not recognized an independent tort, as part of an ordinary

[4] As of this writing, Indiana law may or may not require an "impact" of some sort to permit recover for emotional distress. *See Delta Airlines v. Cook*, 821 N.E.2d 400, 403 (Ind. Ct. App. 2005) (holding that increases in heart rate and breathing were sufficient to satisfy Indiana's "modified impact" rule). The Indiana Supreme Court has granted review in *Delta Airlines*, which has the effect of vacating the Court of Appeals' decision. Oral argument was held approximately a year ago. The decision, which is expected any time, could either clarify or dispense with the impact rule. Regardless, , there is no doubt that the implantation surgery that all plaintiffs endured would be sufficient to satisfy that rule.

negligence or other tort action. A summary of some of these jurisdictions' laws are contained in Appendix B.

Even in those jurisdictions that require physical injury, it cannot be said beyond doubt that Plaintiffs can prove no set of facts that supports claims of injury. *See Hoffman v. Stamper*, 385 Md. 1, 867 A.2d 276 (Md. 2005) (real property purchaser's testimony that whenever he began thinking about the problems resulting from the fraudulent scheme, he would get headaches and would vomit, was sufficient to show some objectively ascertainable accompanying or consequential physical injury to permit recovery of non-economic damages for emotional injury).[5]

In short, inasmuch as emotional distress is alleged on behalf of all Plaintiffs, including those Defendants disparagingly claim to have suffered "no injury," Defendants have not shown – nor could they – that such plaintiffs have not set forth cognizable claims. Point III of Defendants' omnibus motion must fail.

### E. The Court Should Decline Defendants' Invitation To Fashion State Policy.

Apparently lacking confidence in their legal argument, Defendants invite the Court to apply their own notions of policy to Plaintiffs' claims. The Court should, indeed must, decline that invitation. This is a diversity case. In such cases, it is black

[5] Maryland, like a number of jurisdictions outlined above, does not recognize the separate and distinct tort of negligent infliction of emotional distress. *See Lapides v.* Trabbic, 134 Md. App. 51, 758 A.2d 1114, 1122 (Md. Ct. Spec. App. 2000). Nevertheless, "[r]ecovery may be had in a tort action for emotional distress arising out of negligent conduct. In such case, the emotional distress is an element of damage, not an independent tort." *Hamilton v. Ford Motor Credit Co.*, 66 Md. App. 46, 502 A.2d 1057, 1066 (Md. 1986).

letter law that the federal courts are "not free to develop their own notions of what should be required by the public policy of the state, but are bound to apply the state law." *Cornellier v. American Casualty Co.*, 389 F.2d 641, 644 (2d Cir. 1968). The Eighth Circuit recently identically observed: "The basis of jurisdiction in this case is diversity of citizenship, and state law, here the law of Missouri, supplies the rule of decision. Our duty is to apply Missouri law, not the rule of law that we might select if we were free to do so." *In re Popkin & Stern*, 340 F.3d 709, 716-17 (8th Cir. 2003); *accord Hall v. Wilkerson*, 926 F.2d 311, 316 (3d Cir. 1991).

Accordingly, even if the Court did believe that "public policy" should permit a manufacturer of a knowingly defective cardiac implant to use Russian Roulette as the rule of recovery (a position with which Plaintiffs do not acquiesce for a number of policy and factual reasons, including that Defendants' conclusory economic assumptions are not applicable in the slightest to a device like an implantable heart device), the Court would be obliged to follow state law.

### F. The Complaint Asserts Viable Medical Monitoring Claims

Defendants claim that so-called "no injury" Plaintiffs cannot obtain medical monitoring relief. Their 20-page argument is a mixture of generalized policy discussion with case snippets — even from jurisdictions with contrary authority — that concludes with the assertion that medical monitoring is limited to toxic tort cases. Common sense refutes that proposition: if state medical monitoring is appropriate when such monitoring might prevent or aid in the treatment of a long-term possibly illness (such as a cancer), it *a fortiori* should be permissible where monitoring might prevent the sudden failure of a

device at the very moment upon which a person's life depends on it. No case law supports the distinction Defendants put forward, landmark authority refutes it,[6] and, as we show below, many courts have indeed permitted medical monitoring claims to proceed in the area of drugs and medical devices.

As an initial matter, the most salient point is that this is a Rule 12 motion; accordingly, the Complaint allegations govern. Here, the Complaint asserts that "Guidant has also recommended that individuals implanted with the Guidant pacemakers consider increasing the frequency of medical visits to increase the likelihood of detecting a failure that has already occurred." ¶ 156. *See also* Appendix C (Allegations Regarding Monitoring). As Plaintiffs must receive additional medical monitoring in order to safeguard their lives and their health, this case presents a prototypical case for medical monitoring, logically, legal and equitably. Furthermore, because of the significantly increased risk of death and injury that Defendants have imposed on Plaintiffs with its defective implants, it is only fair – legally as well as economically – that Defendants bear the burden of their own wrongful conduct.

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[6] In the seminal decision *Friends for All Children, Inc. v. Lockheed Aircraft Corp.*, 796 F.2d 816 (D. D. Cir. 1984) (Starr, J.), the defining medical monitoring case, the triggering event was airplane cabin depressurization and emergency landing. No toxics were involved. The *Diet Drug* multi-state medical monitoring class certification decision involved prescription drugs. *In re Diet Drugs Prods. Liab. Litig.*, 1999 U.S. LEXIS 13228 (E.D. Pa.). The *Telectronics* multi-state medical monitoring class certification involved heart devices — pacemaker lead wires. *In re Telectronics Pacing Systems, Inc.*, 172 F.R.D. 271 (S.D. Ohio 1997).

### 1. Defendants Have Publicly Acknowledged That Medical Monitoring Is Necessary.

Plaintiffs allege that medical monitoring of the defective devices is necessary to guard against further injury. The Complaint alleges clearly in eight places that, at least in some instances, medical monitoring will successfully prevent further injuries and deaths. *See* Appendix C.

Somewhat incredibly, Defendants argue that they should not be liable — as a matter of law — for the cost of the increased "medical monitoring." Defendants carefully omit the fact that they themselves have repeatedly advised physicians through "Dear Doctor" letters and similar advisories that they must monitor the recipients of Guidant's defective devices with extra care in order to avert further injury. Defendants further contend that no form of monitoring would have any positive value in terms of reducing exposure to further injury. Def. Mem. 39. If so-called "device monitoring" is "pointless," why did Guidant advise doctors that they must engage in extra-monitoring of patients with Guidant implants? If there is no "efficacious monitoring method," why did Guidant propose various forms of tests and additional monitoring in its "Dear Doctor" letters? In short, Defendants' argument that Plaintiffs' medical monitoring claim should be rejected as impracticable and without benefit is contrary to not only the facts alleged in the Complaint, but to Guidant's prior admissions.

### 2. Plaintiffs Have Alleged Every Element Of A Claim for Medical Monitoring.

The recognized elements of a claim for medical monitoring have been summarized in the *Manual for Complex Litigation*:

> Exposure to a harmful substance or product that the defendant marketed or wrongfully released into the environment;
>
> Causing a significantly increased risk of developing a serious latent disease;
>
> The existence of a diagnostic test;
>
> The increased risk caused by the harmful substance or product has made testing reasonably necessary; and,
>
> Early detection can significantly improve medical treatment of the disease.

*Manual for Complex Litigation (Fourth)* § 22.74 (2004) ("MCL").

Plaintiffs satisfy each of these elements First, Plaintiffs have alleged that they are exposed to harmful products. Second, Defendants recalled these devices because they were admittedly defective and imposed increased safety risks on Plaintiffs. The FDA found that the devices are unsafe, and that they pose a "reasonable probability" of "serious adverse health consequence or death" (Class I recall devices), or that they pose a risk of further injury to Plaintiffs (Class II recall). Plaintiffs' allegations are sufficient to meet the requisite criteria. *See, e.g., Redland Soccer Club, Inc. v. Department of the Army*, 696 A.2d 137, 146 (Pa. 1997); *Petito v. A.H. Robins Co., Inc.*, 750 So.2d 103, 104 (Fla. App. 3 Dist. 1999); *In re Paoli R.R. Yard PCB Litig.*, 916 F.2d 829, 852 (3d Cir. 1990); *Hansen v. Mountain Fuel Supply Co.*, 858 P.2d 970, 979 (Utah 1993) ("First, the plaintiff must prove exposure, which we define as ingesting, inhaling, injecting, or otherwise absorbing the substance in question into the body"). Thus, Plaintiffs satisfy the second and fourth elements. *See, e.g., Day v. NLO*, 851 F. Supp. 869, 881 (S.D. Ohio 1994) ("Therefore, it is sufficient for the Plaintiffs in the case at bar to show by expert

medical testimony that they have increased risk of disease which would warrant a reasonable physician to order monitoring.").

Finally, Plaintiffs have sufficiently alleged the third and fifth elements. As discussed above, Plaintiffs have alleged that certain monitoring procedures exist that will aid in the detection and prevention of further injuries and deaths, thereby significantly improving medical treatment. As Guidant admits, these medical monitoring measures are in addition to those that the Plaintiffs would undergo if they were only receiving follow-up care for heart devices that were not defective. *See, e.g., Petito*, 750 So.2d 106-07 (to maintain a cause of action for medical monitoring plaintiff must show that "a monitoring procedure exists that makes the early detection of the disease possible . . . the prescribed monitoring regime is different from that normally recommended in the absence of the exposure; and (7) the prescribed monitoring regime is reasonably necessary according to contemporary scientific principles"); *Redland Soccer Club, Inc.*, 55 F.3d at 845-46 ("we think that a plaintiff must: 'prove that by reason of the exposure to the toxic substance caused by the defendant's negligence, a reasonable physician would prescribe for her or him a monitoring regime different from the one that would have been prescribed in the absence of that particular exposure.'"). Plaintiffs have pleaded every recognized element of a claim for medical monitoring.[7]

[7] Plaintiffs have also alleged that Guidant was negligent in the manufacture and distribution of its devices. While not a factor in the MCL formulation, it has been required by certain courts. *See Barnes v. The American Tobacco Company*, 161 F.3d 127, 138-39 (3d Cir. 1998). This allegation is supported by Guidant's recalls, its letters to physicians regarding the risks associated with these devices, and by the FDA's findings that the devices subject to Class I recalls do not comply with FDA regulations.

### 3. Numerous Federal And State Courts Have Recognized Claims For Medical Monitoring.

Defendants' motion is omnibus in attacking Plaintiffs' medical monitoring claim, not because the elements of the claim have been met, but primarily because they assert that medical monitoring is a novel legal claim that has been almost uniformly rejected by the courts. Yet, "medical monitoring" would not be a recognized matter in tort litigation across the nation were that so; nor would medical monitoring be discussed as a specific topic by the *MCL*. There would, by definition, by no recognized set of elements of the claim were if it was not, in actuality, a recognized claim.

Defendants' position that medical monitoring claims can be dismissed as a matter of law because the nation's jurisprudence rejects them is demonstrably erroneous. When numerous courts have considered claims of medical monitoring, they have recognized its viability because of the necessity of taking reasonable steps to limit the injuries caused by defective medical devices, products, hazardous substances, or disastrous events. *See, e.g., Burns v. Jaquays Min. Corp.*, 752 P.2d 28, 33 (Ariz. Ct. App. 1987) (upholding medical monitoring claim absent present physical injury because "compensation for reasonable and necessary medical expenses is consistent with well accepted legal principles. It is also consistent with the important public health interest in

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*See, e.g., Bower v. Westinghouse Elec. Corp.*, 522 S.E.2d 424, 433 (W.Va.1999) ("Liability for medical monitoring is predicated upon the defendant being legally responsible for exposing the plaintiff to a particular hazardous substance. Legal responsibility is established through application of existing theories of tort liability."); *Hansen,* 858 P.2d at 979 ("the plaintiff must prove that the exposure to the toxic substance was caused by the defendant's negligence, i.e., by the breach of a duty owed to the plaintiff.").

fostering access to medical testing for individuals whose exposure to toxic chemicals creates an enhanced risk of disease.")(internal citations omitted); *Friends for All Children*, 746 F.2d at 824 (airplane cabin depressurization) ("In light of general principles of tort law, the *Restatement (Second) of Torts*, and the law of other jurisdictions, we believe that the District of Columbia Court of Appeals would recognize [a cause of action for diagnostic examinations without proof of actual injury]"); *In re Paoli R.R. Yard PCB Litig.*, 916 F.2d at 852 ("[T]he Supreme Court of Pennsylvania would follow the weight of authority and recognize a cause of action for medical monitoring . . . Medical monitoring claims acknowledge that, in a toxic age, significant harm can be done to an individual by a tortfeasor, notwithstanding latent manifestation of that harm."), *cert. denied*, 499 U.S. 961 (1991); *Patton v. General Signal Corp.*, 984 F. Supp. 666, 674 (W.D.N.Y. 1997) (stating that there is "a growing national acceptance of . . . a claim [for medical monitoring], and [one] would be embraced by the New York Court of Appeals") (internal citations omitted); *Potter v. Firestone Tire & Rubber Co.*, 863 P.2d 795, 823 (Cal. 1993) (holding that "a reasonably certain need for medical monitoring is an item of damage for which compensation should be allowed"); *Lockheed Martin Corp. v. Superior Court*, 63 P.3d 913 (Cal. 2003), *aff'd*, 94 Cal. Rptr. 2d 652 (Cal. Ct. App. 2000) (no *per se* prohibition of class certification of medical monitoring claims); *Petito v. A.H. Robins Co.*, 750 So.2d 103, 106 (Fla. Dist. Ct. App. 1999) (holding that Florida recognizes a cause of action for medical monitoring when the party seeking relief has yet to develop any identifiable physical injuries or symptoms); *Lewis v. Lead Industries Ass'n*, 793 N.E.2d 869, 873 (Ill. App. Ct. 2003) (holding that "cost of

diagnostic testing to detect a possible injury, which testing was made necessary by a defendant's breach of duty, is in itself a present injury compensable in a tort action."); *Cook v. Rockwell Intern. Corp.*, 755 F. Supp. 1468, 1476-77 (D. Colo. 1991) (recognizing claim for medical monitoring in absence of present physical injury); *see also Ayers*, 525 A.2d at 313; *Bower v. Westinghouse Electric Corp.*, 522 S.E.2d 424, 430-31 (W.Va. 1999).

Moreover, at least 13 states, plus the District of Columbia and Guam, specifically recognize medical monitoring claims without present physical injury. *See Burns*, 752 P.2d at 33; *Potter*, 863 P.2d at 823; *Cook*, 755 F. Supp. at 1476-77; *Martin v. Shell Oil Co.*, 180 F. Supp. 2d 313, 322-23 (D. Conn. 2002); *Friends for All Children*, 746 F.2d at 824 (children who could have suffered hidden brain damage in an accident held entitled to defendant-funded diagnostic exams to determine whether injury existed); *Petito*, 750 So. 2d at 106; *Abuan v. Gen. Elec. Co.*, 3 F.3d 329, 334-335 (9th Cir. 1992), *cert. denied*, 510 U.S. 1116 (1994); *Lewis*, 793 N.E. 2d at 873; *Lamping v. Am. Home Prods., Inc.*, No. DV-97-85786 (Mont. 4th Dist. Ct. Feb 2, 2000); *Ayers*, 525 A.2d at 313; *Patton*, 984 F. Supp. at 674; *Day*, 851 F. Supp. at 879-81; *Redland Soccer Club*, 696 A. 2d at 143-46; *Hansen*, 858 P.2d at 976-77; *Bower*, 522 S.E.2d at 430-31. These courts accept that the financial, physical, and emotional burdens necessitated by participating in medical monitoring constitute an injury in and of itself. *See, e.g., Friends for All Children*, 746 F.2d at 826 ("It is difficult to dispute that an individual has an interest in avoiding expensive diagnostic examinations just as he or she has an interest in avoiding physical injury. When a defendant negligently invades this interest, the injury to which is

neither speculative nor resistant to proof, it is elementary that the defendant should make the plaintiff whole by paying for the examinations."); *In re Paoli*, 916 F.2d at 850 ("The injury in a medical monitoring claim is the cost of the medical care that will, one hopes, detect that injury.").

The courts have also recognized medical monitoring in the context of defective devices and medical products, as well as hazardous substances such as asbestos. *See, e.g.*, *In re Prempro*, 230 F.R.D. 555, 570-71 (E.D. Ark. 2005) (recognizing existence of medical monitoring claim for a hormone replacement therapy drug which was still approved by the FDA and still on the market); *Petito*, 750 So.2d at 104 (Phen-Fen; recognizing that "a cause of action for medical monitoring when the party seeking relief has yet to develop any identifiable physical injuries or symptoms"); *In re W. Va. Rezulin Litig.*, 585 S.E.2d 52, 73 (W. Va. 2003) (reversing lower court's denial of class certification of medical monitoring claims).

The holdings in the foregoing cases apply with particular force in this case, where the FDA has expressly stated that most of the devices at issue in this litigation pose a "reasonable probability" of causing serious injury or death and its own advice that physicians must conduct extra tests and/or take additional steps to monitor the condition of patients who have been subjected to the implantation of Defendants' defective devices. In summary, this case presents almost the strongest possible set of facts for permitting a claim for medical monitoring to proceed.

Not surprisingly, and contrary to Defendants' position that medical monitoring is not permissible outside of toxic tort cases, courts – including the Eighth

Circuit just last year in the *St. Jude* case – have repeatedly recognized the existence of claims for the monitoring of defective medical devices implanted into individuals. These cases include claims about defective pacemakers, *In re Telectronics Pacing Systems, Inc.*, 172 F.R.D. 271, 295 (S.D. Ohio 1997) (certifying medical monitoring subclasses in products liability case involving defective pacemakers lead wires already implanted in plaintiffs); heart valves, *In re St. Jude Medical, supra*, 425 F.3d at 1121-22 (recognizing, at least, by necessary implication, various state law claims for medical monitoring in case involving defective heart valve implanted in class of patients); stent grafts, and prosthetic hip implants, *In re Inter-Op Hip Prosthesis Liability Litigation*, 204 F.R.D. 330, 349 (N.D. Ohio 2001) (approving settlement and certifying medical monitoring class of individuals who had received hip implants but who had not yet rejected the implant or had the implant replaced). Thus, Defendants' contention that courts have not "recognized a cause of action for medical monitoring of plaintiffs with potentially defective medical devices" is simply incorrect.[8]

[8] Neither case cited by Defendants regarding medical monitoring and medical devices involves facts where the increased risk of further severe injury to the plaintiffs, and the admitted need for medical monitoring, is so clear. In *In re Orthopedic Bone Screw Products Liability Litigation*, the court rejected class certification of the medical monitoring claim, not because the claim was novel or inherently unsuitable, but because plaintiffs had "[f]ailed to show the court that medical monitoring relief is suitable under the circumstances of this case." *In re Orthopedic Bone Screw Products Liability Litigation*, MDL No. 1014, 1995 WL 273597, at *9 (E.D. Pa. Feb. 22, 1995) . In *Martin v. American Medical Systems, Inc., Pfizer, Inc.*, the court denied a medical monitoring cause of action because there was no indication that medical monitoring was needed, and because there were serious questions as to whether the device was defective. *Martin v. American Medical Systems, Inc., Pfizer, Inc.*, 1995 WL 680630, at *6 (S.D. Ind. Oct. 25, 1995).

Aside from ignoring the extensive case law that supports Plaintiffs, the cases that Defendants cite are factually inapplicable. First, while Defendants term the non-explant device recipients "no-injury plaintiffs" undoubtedly to try to squeeze this litigation into some of the prior case law, as already discussed above, the Master Complaint alleges that all Plaintiffs have suffered some injury from Defendants' defective heart implant devices. For this reason, all of Defendants' cases regarding the lack of a "present injury" are inapposite.[9]

Second, and no less importantly, those Plaintiffs who are still living and whose Guidant devices have not already been explanted are exposed to the risks of their defective Guidant devices on a continuous basis, twenty-four hours a day, seven days a week. The issue for these vulnerable Plaintiffs is not whether there is a continued risk of harm, as there is, *but rather how to minimize that risk*. None of the cases that Defendants cite as rejecting claims for medical monitoring deal with the analogous situation of a class of plaintiffs continuously exposed to a defective device placed inside their chests and into the tissues of a vital human organ. *Compare, e.g., Hinton v. Monsanto Co.*, 813 So.2d 827, 828 (Ala. 2001) (medical monitoring claim based on alleged past exposure to tortiously released PCB's and potential of future injury); *Goodall v. United Illuminating*, 1998 WL 914274, at *8 (Conn. Super. Ct. Dec. 15, 1998) (medical

[9] *See, e.g., Henry v. Dow Chemical Company,* 701 N.W.2d 684, 686-687 (Mich. 2005) (cause of action for medical monitoring exists where there is a present injury); *Wood v. Wyeth-Ayerst Labs*, 82 S.W.3d 849, 856 (Ky. 2002) ("Where there has been a physical injury requiring future medical treatment, medical monitoring damages may be a novel way of describing a remedy already employed in this jurisdiction"); *Hinton v. Monsanto Co.*, 813 So. 2d 827, 850 (Ala. 2001) (same).

monitoring claim failed; nothing to indicate that plaintiffs had suffered any injury, plaintiffs were no longer exposed to asbestos, and medical monitoring was not necessary); *Mergenthaler v. Asbestos Corp. of America*, 480 A.2d 647, 651 (Del. 1984) (medical monitoring claim rejected because there was no evidence of actual exposure to toxin; "there was no direct contact by the plaintiff-spouses with the asbestos, and no evidence was presented to show that they actually inhaled asbestos fibers"). Thus, the situation presented here is dispositively different from those in the cases upon which Defendants rely.

### G. Public Policy Supports Medical Monitoring In This Case

As already discussed, this Court applies state law and should not impose its views of what "public policy" should be. Nonetheless, as to medical monitoring, Defendants spend many pages discussing their view of the underlying policy considerations, and attempt to suggest this is a matter of federal law. They rely, in most substantial measure, on *Metro-North Commuter Railroad Company v. Buckley*,[10] 521 U.S. 424 (1997), for the proposition that the Supreme Court has held that "sound policy considerations support the rejection of medical-monitoring claims." Def. Mem. 25.

This is wrong as a matter of what the Court held and also as to what should be the law. In *Metro-North*, "the Court [narrowly] held that a lump sum award of damages for medical monitoring to an asymptomatic plaintiff was not provided for by the Federal Employers' Liability Act ("FELA")." *In re Methyl Tertiary Butyl Ether (MTBE)*

[10] Erroneously cited by Defendants as *Commuter R.R. Co. v. Metro-North.*