UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
THIRD DIVISION

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

DEFENDANTS' MEMORANDUM BRIEF IN SUPPORT OF ITS MOTION TO DISMISS THE MASTER COMPLAINT CLAIMS OF DEVICE RECIPIENT PLAINTIFFS

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INTRODUCTION

On April 24, 2006, Plaintiffs filed a sprawling Master Complaint comprising 133 pages and 470 paragraphs, implicating the laws of all 50 states, and alleging 30 counts on behalf of three categories of plaintiffs: (1) Device Recipient Plaintiffs; (2) Third Party Payor Plaintiffs; and (3) Medicare Secondary Payor Plaintiffs. This ambitious document not only fails to plead the required elements of the claims it asserts, but also attempts to plead broad claims that, if left unchecked, threaten to explode products liablity beyond any previously-recognized frontiers.

This Motion to Dismiss addresses the claims brought by the Device Recipient Plaintiffs. Motions to dismiss Third Party Payor Plaintiffs and Medicare Secondary Payor Plaintiffs are filed separately. As the bellwether-selection process has revealed, the Device Recipient Plaintiffs include four categories of plaintiffs: (1) those who allege death as injury, (2) those who claim complications from explant surgery as an injury, (3) those who claim explant surgery itself as an injury, and (4) those who have not explanted their devices but claim fear of future device failure as injury ("no-injury" plaintiffs).

This Motion is divided into two main parts. In the first part, Defendants demonstrate that the Court should dismiss the claims of this last sub-category of individuals. These are plaintiffs who do not plead and cannot plead any present injury attributable to a manifested defect in Defendants' products. In fact, these plaintiffs' devices continue to function flawlessly. Hence, this last sub-category of individuals are aptly termed no-injury plaintiffs. These plaintiffs cannot state products-liability, medical-

monitoring, or statutory consumer-protection claims without alleging a present injury attributable to a manifested defect in their devices.

In the second part of this Motion, Defendants address the claims of Device Recipient Plaintiffs generally and show that these plaintiffs cannot state implied warranty, statutory consumer-protection, or unjust-enrichment claims and that their fraud-based claims are not stated with the necessary particularity.

PART ONE: THE NO-INJURY PLAINTIFFS

Defendants respectfully request that this Court begin the process of eliminating invalid claims by dismissing Counts I-VIII and XVI with respect to no-injury plaintiffs.

For example, three of the plaintiffs in Plaintiffs' Master Complaint -- Peleg, Shreiner, and Urich -- bring such no-injury claims. These plaintiffs are individuals whose devices have been functioning perfectly and continue to function perfectly. They do not allege a product defect or a breach of warranty, but merely the potential of a product defect and the possibility of a breach of warranty. Such claims are nothing more than emotional distress claims, yet plaintiffs have indiscriminately pleaded claims for strict liability (Counts I and II), negligence (Counts III and IV), breach of warranty (Count V), fraud (Counts VI and VII), violations of every state's consumer-protection statute (Count VIII), and medical monitoring (Count XVI) on behalf of <u>all</u> types of plaintiffs, including no-injury plaintiffs. Like many plaintiffs in this MDL, these are individuals who cannot as a matter of law assert such product-liability claims in the absence of a manifested product defect and present injury tied to device malfunction,

regardless of whether such claims are denominated as negligence, strict liability, warranty, consumer-protection, or medical monitoring.

Beyond the named plaintiffs in the Master Complaint, Plaintiffs' proffered class and subclass definitions reveal that there is no manifest defect in many cases. For example, the "short-circuit defect subclass" includes individuals with devices that "may short-circuit;" the "hermetic seal defect subclass" includes individuals with devices with a hermetic seal that "can leak;" the "magnetic switch defect subclass" includes individuals with devices that "may become stuck in the closed position." In each of these subclasses, the plaintiffs allege only that their devices "may" or "can" fail but include no allegation that they have, in fact, failed and that this failure has caused injury. A significant portion of the cases currently pending in this MDL are brought by similar no-injury plaintiffs who improperly seek to assert the same type of products-liability claims without alleging manifested defect and present injury.

Even at this early stage of the litigation, before Defendants have had the opportunity to conduct meaningful discovery and before any meaningful choice-of-law analysis is possible, it is apparent that plaintiffs, through their Master Complaint, ask this Court to countenance two things that no other state or federal court has ever countenanced:

- First, they ask this Court to allow plaintiffs to assert product-liability claims in the absence of any alleged product malfunction and physical injury.
- Second, they ask this Court to take the unprecedented step of expanding the theory of medical monitoring beyond the bounds of toxic-exposure cases and into the realm of fully functional medical devices.

Defendants are unaware of any court that recognizes product-liability claims in the absence of a manifested product defect and present physical injuries. Tort-based negligence and strict-liability theories require physical injury caused by product malfunction. Warranty theory requires economic loss caused by product malfunction. Most states require ascertainable or pecuniary loss to state a claim under their respective consumer-protection regimes. But no-injury plaintiffs claiming simple fear of failure plead none of these requirements.

Many no-injury plaintiffs seek to plead around their lack of manifest defect and physical injury by asserting claims for medical monitoring. Medical monitoring provides no exception to the requirement that plaintiffs prove a defect-caused injury. Defendants are unaware of any jurisdiction that recognizes a cause of action for medical monitoring of a currently functioning medical device in the absence of a present physical injury. The courts that have addressed the subject of medical monitoring have either flatly rejected medical-monitoring claims in the absence of a present physical injury or have recognized such claims only in cases involving plaintiffs who have been exposed to toxic substances that carry a risk of latent disease subject to early detection and efficacious treatment. There is no authority or discernable logic for allowing plaintiffs to extend the already controversial cause of action for medical monitoring beyond the current narrow confines in which it is presently recognized.

Finally, plaintiffs summarily invoke the consumer-protection laws of all 50 states. But these claims fail because plaintiffs do not and cannot allege the requisite injury -- whether denominated as "pecuniary loss," "actual loss," or "property or monetary loss" --

because their devices continue to function flawlessly and have provided plaintiffs exactly what they bargained for.

For these reasons, Defendants respectfully request that this Court begin the process of eliminating invalid claims by dismissing Counts I-VIII and XVI with respect to all no-injury plaintiffs who seek to recover damages for fear of failure without device malfunction, and without explant, death, or some form of present physical injury.

I. THE LEGAL STANDARD.

For purposes of this motion, "the court must accept the allegations contained in the complaint as true and draw all reasonable inferences in favor of the nonmoving party." *Coons v. Mineta*, 410 F.3d 1036, 1039 (8th Cir. 2005) (citation omitted). However, "the plaintiff must allege facts - not mere legal conclusions - that, if true, would support the existence of the claimed torts." *Moses.com Sec., Inc. v. Comprehensive Software*, 406 F.3d 1052, 1062 (8th Cir. 2005); *see also Wiles v. Capitol Indem. Corp*., 280 F.3d 868, 870 (8th Cir. 2002) ("While the court must accept allegations of fact as true when considering a motion to dismiss, the court is free to ignore legal conclusions, unsupported conclusions, unwarranted inferences and sweeping legal conclusions cast in the form of factual allegations."). A plaintiff's "allegations are not acceptable, however, where no facts are alleged to support the conclusion or where the allegations are contradicted by the facts themselves." *Moore v. Johnson*, 826 F. Supp. 1106, 1108 (W.D. Mich. 1993) (citation omitted).

II. NO-INJURY PLAINTIFFS' CLAIMS MAY BE DISMISSED WITHOUT UNDERTAKING A CHOICE-OF-LAW ANALYSIS.

While no choice-of-law analysis is possible at this early stage of litigation, none is required to dismiss the product-liability, medical-monitoring, and consumer-protection claims of no-injury plaintiffs. As the transferee MDL Court, this Court must apply the substantive laws of the transferee fora, including their choice-of-law rules. *See Van Dusen v. Barrack,* 376 U.S. 612, 639 (1964).[1] But no state-by-state legal analysis is required to dismiss plaintiffs' no-injury claims. Defendants are unaware of any jurisdiction that permits the assertion of products-liability claims for a perfectly functioning device that has caused no present injury. Defendants are unaware of any jurisdiction permitting uninjured recipients of a functioning medical device to seek costs for "medical monitoring."

The expansive claims alleged in plaintiffs' Master Complaint effectively ask this Court to expand product-liability law beyond all recognized limits. This Court, sitting in diversity, must analyze whether the state law permits the claims plaintiffs assert. *Erie R.R. Co. v. Tompkins,* 304 U.S. 64 (1938). But "it is not the role of a federal court to expand state law in ways not foreshadowed by the state precedent." *City of Phila. v.*

[1] The Eighth Circuit Court of Appeals recently reaffirmed in *St. Jude* that both due process under *Phillips Petroleum Co. v. Shutts,* 472 U.S. 797 (1985) and Minnesota choice-of-law rules demand "an individualized choice-of-law analysis must be applied to each plaintiff's claim in a class action," requiring an analysis of the laws of the different jurisdictions before an MDL Court can render a constitutionally-supportable choice-of-law analysis. *In re St. Jude Medical, Inc*., 425 F.3d 1116, 1120 (8th Cir. 2005).

Beretta U.S.A. Corp., 277 F.3d 415, 421 (3d Cir. 2002). Yet this is precisely what Plaintiffs demand through the claims indiscriminately pleaded in the Master Complaint.

III. NO-INJURY PLAINTIFFS' PRODUCT-LIABILITY CLAIMS MUST BE DISMISSED ABSENT ALLEGATIONS OF PRESENT INJURY CAUSED BY PRODUCT MALFUNCTION. (COUNTS I – VII)

A. Courts have consistently rejected no-injury claims under all products-liability theories, including tort, strict liability, and warranty.

Product-liability claims require an allegation of injury caused by actual product malfunction. "The threat of future harm, not yet realized, is not enough." W. Page Keeton, *et al.,* Prosser and Keeton on the Law of Torts, 30, at 165 (5th ed. 1984) (footnotes omitted). This principle applies no matter what causes of action plaintiffs pursue (*e.g.,* claims for negligence, breach of warranty, strict liability, or violation of consumer-protection statutes fail alike) or what relief plaintiffs seek *(e.g.,* equitable claims and legal claims are equally barred). *Id*. Likewise, comments n. and r. of the Restatement (Third) of Torts: Prod. Liab. § 2 (1998) acknowledge that "the tort definition of product defect" should be used in "cases involving defect-caused harm to persons or property" whether the theory relied upon is warranty, strict liability, or negligence (emphases added).

In *Briehl*, the Eighth Circuit Court of Appeals squarely held that the absence of an actual product malfunction is fatal to plaintiffs' product-liability claims:

> Where, as in this case, a product performs satisfactorily and never exhibits an alleged defect, no cause of action lies. Since the Plaintiffs have failed to allege any manifest defect and their vehicles perform in a satisfactory manner, the District Court was correct when it dismissed the Plaintiffs' Original Complaint.

Briehl v. Gen. Motors Corp., 172 F.3d 623, 628 (8th Cir. 1999). In *Briehl*, the Eighth Circuit affirmed the District Court's dismissal of a putative class action asserting claims for violation of consumer-protection statutes, express warranty, implied warranty, and fraudulent concealment under the laws of the states of Missouri, Florida, Mississippi, New York, and Texas. The proposed class sought to recover damages for an alleged unmanifested design defect that rendered General Motors' anti-lock braking systems "inferior." *In re General Motors Corp. Anti-Lock Brake Litig.*, 966 F. Supp. 1525 (E.D. Mo. 1997). The plaintiffs, like Plaintiffs here, alleged that all the ABS systems "suffer from the defects," *id.* at 1530, and sought, among other things, "an order directing defendants to recall or repair the ABS systems." *Id*. at 1529.

The District Court categorically rejected the proposition that unmanifested design defects that do not cause actual damages state a valid injury:

> Plaintiffs' statement that their vehicles "suffer from the defects" is not a sufficient allegation of damages. . . . In fact, plaintiffs state that "at the time of the sale of each automobile, the GM owner (and general public) was exposed to potential brake failure." . . . It is clear from Plaintiffs' Complaint that they believe the vehicles were defective from the moment they came off the assembly line and that this fact, in and of itself, is behind their claims of damage. Manifestation of the defect in the vehicle, however, is a prerequisite to recovery.

Id. at 1530. This is, of course, the precise type of proposed class and theory of recovery that the no-injury plaintiffs advance in this case. Plaintiffs are claiming that each device recipient was or continues to be exposed to potential device failure, although such failure was manifested in very few instances.

The District Court then rejected the plaintiffs' allegations of economic injury from the unmanifested design defect:

> Plaintiffs have also failed to allege economic harm with any sufficiency. They have merely alleged that they have suffered a loss of resale value and that they paid more for their vehicles than they are worth. There are no details surrounding these claims, as it appears no plaintiff has attempted to sell his or her vehicle. Plaintiffs cannot go forward with such speculative claims.

Id. The Court noted that this failure to adequately plead damages alone warranted dismissal of all of plaintiffs' claims, and went on to dismiss the putative class claims in full, including all consumer-protection and warranty claims.

On appeal, the Eight Circuit affirmed dismissal of all claims for failure to plead injury:

> The plaintiffs' conclusory assertions that they, as a class, have experienced damages (and the method plaintiffs use to calculate the damages) are simply too speculative to allow this case to go forward. The plaintiffs' assertion that their ABS-equipped vehicles are defective is insufficient as a matter of law to plead a claim under any theory the plaintiffs advanced. Even construing the allegations in favor of the plaintiffs, we find that the District Court was correct when it dismissed the Original Complaint for failure to state a claim.

Briehl, 172 F.3d at 629.

Other courts are in accord. The Eastern District of Louisiana dismissed the claims of plaintiffs who alleged that their "air bags are dangerously defective because they are designed to deploy with sufficient speed and force to seriously injure or kill front seat occupants (although no plaintiff maintain[ed] they have done so)." *In re Air Bag Prods. Liab. Litig.,* 7 F. Supp. 2d 792, 794 (E.D. La. 1998). In that case, plaintiffs conceded

"that the air bags have not in any way manifested the defect of which they complain." *Id*. at 805. Under the case law of numerous jurisdictions, the court concluded that "manifest injury or defect" are "both central tenets of [plaintiffs'] tort and implied warranty claims." *Id*. "[T]he common thread of the[se] cases" is always the same: "the absence of manifest injury is so fundamental a deficiency in tort or implied warranty claims that such claims are more appropriately dismissed than preserved." *Id*. at 804. Accordingly, the court granted defendants' motion to dismiss because "plaintiffs' failure to demonstrate or, even allege, manifest injury or defect shatters an essential element of all their tort and implied warranty claims." *Id*. at 806.

Like the *Briehl* and *In re Air Bag Prods.* courts, federal and state courts have consistently held that claims without any actual injury or claims based simply on the alleged propensity of a product to fail or to potentially cause injury do not present an actual, compensable injury -- repeatedly rejecting no-injury, propensity-to-fail cases -- whether based on tort, fraud or warranty theories, or on state consumer-protection statutes.

Specifically, in the medical-device context, federal and state courts have consistently rejected claims by individuals who do not plead and cannot plead any present physical injury attributable to a manifest defect in a medical device. Such claims are premature and speculative. As one court has 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.

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 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).
- *Khan v. Shiley, Inc*., 266 Cal. Rptr. 106, 110 (Cal. Ct. App. 1990) (in case involving allegedly defective heart valve with a 1.1% failure rate, noting that "[n]o matter which theory is utilized [including negligence, warranty, strict liability, or infliction of emotional distress], where a plaintiff alleges that a product is defective, proof that the product has malfunctioned is essential to establish liability for an injury caused by the defect"; however, fraud claim does not require product malfunction).
- *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. Ct. 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").
- *Kent v. Shiley, Inc*., No. CIV. 87-6554-E, 1989 WL 88307, at *2 (D. Or. Jan. 24, 1989) (granting motion to dismiss in case involving allegedly defective heart valve and strict liability and negligence claims and holding that Oregon's product liability statute required product to cause physical harm in order to subject manufacturer to liability).
- *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").

Although several of the above cases were dismissed on summary judgment, in this case, dismissal on the pleadings would be appropriate. The Court need not conduct fact-intensive analysis to dismiss the claims of the no-injury plaintiffs. There is no factual issue as to whether the devices of no-injury plaintiffs have failed -- they have not, and plaintiffs do not allege otherwise. Indeed, those plaintiffs, as a matter of law, have not

suffered any cognizable injuries. Their devices continue to function as intended. These plaintiffs have not been injured by a device malfunction. Nor have their devices been explanted.

The requirement that the alleged defect actually manifest and cause malfunction that results in actual injury has been broadly applied in cases involving all types of products:

- *In re Bridgestone/Firestone, Inc. Tires Prod. Liab. Litig.*, 155 F. Supp. 2d 1069, 1087 (S.D. Ind. 2001) (dismissing on the pleadings claims of plaintiffs who sought to recover for the possibility that their tires will suffer a tread separation in the future because of a defect and for the possibility their vehicles will roll over in the future, or for the lower resale price they might receive resulting from those possibilities, because "[t]hese simply are not cognizable tort injuries").
- *Ford Motor Co. v. Rice*, 726 So. 2d 626, 631 (Ala. 1998) (affirming dismissal of class-action fraud lawsuit for SUV design defect alleged to cause a "rollover" tendency where defect did not manifest itself and plaintiffs' vehicles did not roll over).
- *Wallis v. Ford Motor Co.*, No. 04-506, 2005 WL 1120218 (Ark. May 12, 2005) (dismissing on the pleadings fraud and consumer-protection claims where the only injury complained of was diminution in value of Ford Explorers that had a tendency to roll over, but no allegation that the roll-over defect had occurred).
- *Zamora v. Shell Oil Co*., 55 Cal. App. 4th 204, 208 (1997) (holding in the absence of a product malfunction in case involving allegedly defective pipes, plaintiff cannot establish a defendant breached any duty under negligence theory).
- *Barbarin v. General Motors Corp*., No. CIV. A. 84-0888, 1993 WL 765821 *2 (D.D.C. Sept. 22, 1993) (dismissing on the pleadings warranty claims "of all plaintiffs whose X-cars never experienced the phenomenon of 'premature rear wheel lock-up'" and refusing to "entertain any class claims in which an allegation of actual product failure is absent").
- *Verb v. Motorola, Inc*., 672 N.E.2d 1287, 1295 (Ill. 1996) (dismissing on the pleadings strict liability, negligence, warranty and consumer-protection claims against cellular telephone manufacturers alleging potential safety defects because "plaintiffs' future personal injury and damages claims constitute conjecture and speculation").

- *Yu v. Int'l Bus. Mach. Corp.*, 732 N.E.2d 1173, 1177-78 (Ill. 2000) (affirming dismissal on the pleadings of class-action fraud, negligence, and deceptive-trade-practices lawsuit for allegedly potentially defective computer software where there was no allegation of actual product failure).
- *Jarman v. United Industries Corp.*, 98 F. Supp. 2d 757, 767 (S.D. Miss. 2000) (dismissing on the pleadings warranty and fraud claims because plaintiffs failed to allege that their pesticides actually failed to perform as intended, where instructions stated that results would take 1 to 4 months, but plaintiff brought lawsuit within a week of using product).
- *Freeman v. Hoffman – La Roche, Inc.*, 618 N.W.2d 827, 845 (Neb. 2000) (dismissing on the pleadings plaintiff's cause of action for fear of future product failure resulting from the use of prescription acne medicine and noting that Nebraska does not recognize a separate cause of action or theory of recovery for fear of future product failure).
- *Yost v. General Motors Corp*., 651 F. Supp. 656, 657-58 (D.N.J. 1986) (dismissing on the pleadings warranty and fraud claims because complaint alleged only that design defect in engine was "likely to cause" damage).
- *Weaver v. Chrysler Corp*., 172 F.R.D. 96, 99-100 (S.D.N.Y. 1997) (granting motion to dismiss and noting in case involving warranty and fraud claims based on allegedly defective child-safety seats, "[i]t is well established that purchasers of an allegedly defective product have no legally recognizable claim where the alleged defect has not manifested itself in the product they own").
- *Martin v. Ford Motor Co*., 914 F. Supp. 1449, 1453 (S.D. Tex. 1996) (stating that where plaintiffs admittedly have not sustained any personal injuries relating to seat belt restraint system, plaintiffs cannot succeed on their warranty, fraud, or consumer-protection claims).
- *Tietsworth v. Harley-Davidson, Inc.*, 677 N.W.2d 233 (Wis. 2004) (dismissing on the pleadings for failure to state a claim a class action alleging fraud and deceptive-trade-practices-act claims relating to concealment of engine defect: "[A]n allegation that a product is diminished in value because the product line has demonstrated a propensity for premature failure such that the product might or will at some point in the future fail prematurely is too uncertain and speculative to constitute a legally cognizable tort injury and is therefore insufficient to state damages in a tort claim for fraud.").

In this case, no-injury plaintiffs cannot state product-liability claims. They merely state potential future claims. These claims must be dismissed because federal and state court cases -- including cases involving medical devices -- have consistently required that

recovery under product-liability and tort theories are viable only when a plaintiff alleges present injury caused by product malfunction. Short of such allegations, no-injury plaintiffs' product-liability and tort claims -- whether pleaded as negligence, strict liability, or warranty -- must be dismissed.

Nor can no-injury plaintiffs plead around their lack of present injury by asserting warranty claims or fraud claims for pecuniary loss. As cases such as *Briehl* make clear, there can be no claims for pecuniary loss of the value of the product itself where the product performs precisely as warranted. *Briehl v. Gen. Motors Corp*., 172 F.3d 623, 628 (8th Cir. 1999). No-injury plaintiffs also fail to state a claim for breach of implied warranty of merchantability because they have not alleged any manifestation of the alleged defect in the devices. Numerous courts have recognized that a plaintiff cannot allege a breach of warranty based on a speculative injury. *See Briehl v. Gen. Motors Corp.*, 172 F.3d 623, 628 (8th Cir. 1999) (dismissing implied warranty claim because no cause of action lies where product performs satisfactorily and the alleged effect never manifested itself); *Carlson v. Gen. Motors Corp.*, 883 F.2d 287, 296-98 (4th Cir. 1989) (claim for breach of implied warranty of merchantability dismissed when claim was for diminished resale value, not failure of the product); *In re Air Bag Prods. Liab. Litig.*, 7 F. Supp. 2d 792, 803 (E.D. La. 1998) (plaintiffs' failure to allege that the product functioned improperly under normal use barred recovery under theory of implied warranty of merchantability). For this reason alone the implied warranty claims of these no-injury plaintiffs fail.

The sole exceptions to this rule are diminution-in-value claims, where a known but unmanifested defect or propensity of the product results in economic loss by reducing the product's resale value in a measurable secondary market.[2] But this is not the case pleaded by plaintiffs, since there is no allegation of diminished resale value on the (non-

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[2] *Briehl v. General Motors Corp.*, 172 F.3d 623, 627-29 (8th Cir. 1999) (affirming dismissal of class claims for fraudulent misrepresentation, fraudulent concealment, breach of implied and express warranties, and violation of state consumer protection statutes alleging diminished value for latent unmanifested defect in anti-lock braking system where no member of the class alleged selling their vehicle at a reduced value due to the alleged defect); *Frank v. DaimlerChrysler Corp.,* 292 A.D.2d 118, 128 (N.Y. App. Div. 2002) (dismissing on the pleadings putative class claims for negligence, strict liability, breach of implied and express warranties, fraud, concealment, unfair business practices, and conspiracy for failure to disclose a design choice that rendered an automobile backrest "unstable and susceptible to rearward collapse in the event of an accident" where plaintiffs failed to allege that seats had been retrofitted or repaired, or that plaintiffs had attempted to sell, or had sold an automobile at a financial loss due to the alleged defect); *Ziegelman v. DaimlerChrysler Corp.*, 649 N.W.2d 556, 560-61 (N.D. 2002) (dismissing on the pleadings negligence, fraud, and deceit claims alleging diminution in value where plaintiff did not allege that he sold his vehicle at a loss due to the alleged defect or incurred any costs to repair the vehicle); *In re General Motors Type III Door Latch Litig*, No. 98 C 5836, MDL 1266, 2001 WL 103434, at *3, 5 (N.D. Ill. 2001) (granting summary judgment for defendant on class warranty and fraud claims for allegedly defective automobile doors that were allegedly prone to open during collisions, citing *Perona v. Volkswagen of America, Inc.*, 684 N.E.2d 859 (Ill. Ct. App. 1997) (denying recovery for automobiles that never exhibited alleged latent defect of unintended acceleration absent proof of widespread knowledge of the defect in the marketplace leading to "lost resale value")); *Coghlan v. Aquasport Marine Corp.*, 73 F. Supp. 2d 769, 772-74 (S.D. Tex. 1999), aff'd, 240 F.3d 449 (5th Cir. 2001) (dismissing on the pleadings Magnuson Moss warranty claims by boat owners who purchased boats with hulls containing plywood as well a fiberglass as "purely hypothetical" where plaintiffs "do not claim they have, in fact, attempted to resell their boat, nor do they allege that their [boat] has a current resale price disproportionately lower than comparable fishing boats"); *Weaver v. Chrysler Corp.,* 172 F.R.D. 96, 99-100 (S.D.N.Y. 1997) (dismissing on the pleadings class claims for fraud, negligence, and breach of warranty based on unmanifested defect in integrated

existent) secondary market for used implantable defibrillators or pacemakers. To the extent plaintiffs allege out-of-pocket expenses attributable to fear of device failure, such allegations do not state any independent injury capable of sustaining a warranty claim, but merely reflect a potential element of damages in what these no-injury claims truly are -- emotional-distress claims.

B. Strong public policy reasons urge against recognizing no-injury claims.

In addition to judicial precedent, important policy reasons dictate that only those persons who incur tangible injury should be allowed to bring product-liability and contract-based lawsuits.

First, allowing an uninjured plaintiff to recover compensation for the mere potential risk of physical or financial injuries that may never materialize would invariably result in a windfall to plaintiffs.[3] Instead, courts require plaintiffs to wait until they are injured either physically or financially by a product's failure before allowing them to sue for damages. Otherwise, product prices would likely rise, and truly injured litigants would be less likely to receive full compensation. Judge John Minor Wisdom of the Fifth Circuit discussed this reality in *Willett v. Baxter Int'l, Inc.* 929 F.2d 1094 (5th Cir. 1991).

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child car seats creating a potential to unlatch because plaintiffs suffered no manifest injury and failed to adequately plead claims of economic loss).

[3] For example, as explained by the Seventh Circuit in *In re Bridgestone/Firestone, Inc.*, since the tort system fully compensates those who are injured by a defective product, allowing "no injury" recoveries of the type sought here would result in windfall compensation to purchasers who have obtained full use of the products they bought, as well as a distortion of the economic incentives on manufacturers. *In re Bridgestone/Firestone, Inc.*, 288 F.3d at 1017-1018 & n.1.

In that case, plaintiffs sought compensation because they were allegedly at risk of a potentially fatal defect in implanted heart valves. *Id.* at 1096. Among the 19,000 patients who received similar heart valves, only 17 had failed. *See id.* As the court explained, "[t]he damages of the seventeen are presumably incorporated into the price of the product and spread among the nineteen thousand who have purchased the valve." *Id.* at 1100 n.20. But the Court concluded that to allow 19,000 individuals, all contending that they are at risk of someday experiencing the malfunction, even though only a few had experienced the malfunction, would be premature and unwise:

> Because [under a regime permitting no-injury lawsuits] no loss-spreading occurs, the money flows in a circle, from each patient (in the form of a higher price) to the company back to the same patient (in the form of a fear recovery), with a substantial portion of the higher price skimmed off for attorneys' fees. In addition, the higher price will place the product beyond the economic reach of at least some of the patients, forcing them to turn to the next best (affordable) alternative. We see little reason to adopt such a system.

Id. Or as another federal court observed:

> Liability [for a functioning product] is a rather novel, and dubious theory . . . . [R]ecognition of such a cause of action could have the marketplace result of increasing the price of many everyday objects to compensate all those, *i.e.*, all consumers, who fear that the objects might fail. Taken to its logical extreme, fear claims could eventually swallow claims for physical injuries, depriving the traditional plaintiff of adequate compensation.

Bravman v. Baxter Healthcare Corp., 794 F. Supp. 96, 101 (S.D.N.Y. 1992).

As these courts recognized, if no-injury lawsuits are permitted, some consumers may gain in the short run. But in the long run, all consumers will lose. Consumers would bear the burden of higher prices to cover the increased business costs and defense

of these claims. *See Schweitzer v. Consol. Rail Corp.,* 758 F.2d 936, 942 (3d Cir. 1985) (stating that unless "manifest injury" is required, "windfalls [will be awarded to] . . . those who never take ill" and those who suffer will receive "insufficient compensation").

Second, a host of negative practical effects would flow from a decision to open the door to no-injury lawsuits. Courts across the country would be overwhelmed with lawsuits seeking to redesign products to alleviate the possibility of future accidents. Courts (and juries) would find themselves making prospective decisions about what product designs would best protect the public safety, a role with which they are unfamiliar and for which they are ill-equipped.

Not only are courts and juries ill-suited for a product-design role, allowing lawyers to bring product-liability lawsuits on behalf of no-injury purchasers invites inconsistent and unviable results. It is one thing for a jury to find in favor of an individual plaintiff who was injured by a defective product, and to order the manufacturer to compensate that plaintiff for his injuries (*i.e.*, pay his medical bills and lost wages). It is quite another to empower a jury to pronounce an entire family of products "defective" in the abstract, and effectively order them off the market.

Few defendants would possess the capacity to comply with constantly shifting product-improvement ideas devised by courts and juries. Moreover, innovation would be brought to a halt, since, once those judicial product-design determinations were made, product manufacturers would be discouraged from developing new, improved designs that may differ from those already "court approved." *Cf.* Richard A. Posner, *A Theory of Negligence,* 1 J. LEGAL STUD. 29, 32-33 (1972) (explaining how traditional principles of

negligence law enable manufacturers to internalize costs). Courts requiring that causes of action be predicated upon real injury prevent this chaos and preserve the judiciary's role as arbiter of actual cases and controversies. Conversely, were this Court to recognize plaintiffs' no-injury claims as valid products liability and warranty claims, such a decision would significantly change products-liability law, and vastly expand the liability of exposure of product manufacturers everywhere.

* * *

For the foregoing reasons, Defendants respectfully request that the Court dismiss the following claims as to no-injury plaintiffs because each such claim requires a plaintiff to allege actual injury caused by manifest device malfunction:

- Strict Liability – Failure to Warn (Count I)
- Strict Liability – Design and/or Manufacturing Defect (Count II)
- Negligence (Count III)
- Negligence Per Se (Count IV)
- Breach of Implied Warranty (Count V)
- Fraud (Count VI)
- Constructive Fraud (VII)

IV. NO-INJURY PLAINTIFFS CANNOT STATE A CLAIM FOR MEDICAL MONITORING OF A MEDICAL DEVICE THAT IS FUNCTIONING AND HAS FUNCTIONED AS INTENDED. (COUNT XVI)

In Count XVI of the Master Complaint, Plaintiffs request payment of expenses for the medical monitoring of their devices based on Defendants' alleged negligence in designing, manufacturing, and promoting their devices. Strangely, plaintiffs do not limit their request for medical monitoring to any particular type of plaintiff. Plaintiffs' claims,

apparently encompass both patients whose devices have been explanted and those whose devices have not been explanted. Plaintiffs do not limit their medical-monitoring claim to those individuals whose devices have malfunctioned, but also seek medical-monitoring expenses on behalf of individuals who do not allege that their devices have malfunctioned and caused injury.

But Plaintiffs misapprehend the fundamental limits and nature of medical-monitoring claims. While some jurisdictions may allow the recovery of future costs of medical monitoring as an element of damages for individuals who have suffered present injury caused by exposure to toxic substances, no case in any jurisdiction countenances the recovery of medical-monitoring costs for recipients of currently functioning medical devices. Because the majority of states have either flatly rejected or have narrowly limited medical-monitoring claims in the absence of physical injury, it is useful to begin with a discussion of what medical monitoring is and is not.

A. "Medical monitoring" is different from a claim for future medical expenses.

Medical monitoring -- as that term is used in this lawsuit and commonly understood today -- does not involve personal-injury plaintiffs with an existing physical injury who also seek to recover the cost of future medical expenses. The law has always permitted personal-injury plaintiffs with an existing physical injury to recover the cost of future medical expenses, which could include medical-screening tests as an item of special damages. Nor are victims of a sudden traumatic impact in a plane crash or motorbike accident properly viewed as medical-monitoring plaintiffs. Instead, the

"traumatic physical impact" under existing law is sufficient to constitute a physical injury, and such persons are already permitted to recover the cost of any diagnostic testing that may be necessary to evaluate the extent of their present physical injuries. Nor does medical monitoring encompass no-injury cases, which are usually treated: (1) under a state's emotional-distress law requiring a physical impact or severe emotional distress; or (2) as a stand-alone fear-of-disease claim requiring proof that the plaintiff is more likely than not to develop the feared disease in the future.

Genuine "medical monitoring" refers to a relatively new theory of tort liability that under specific conditions permits healthy and wholly asymptomatic individuals -- with no physical injury or traumatic impact -- to obtain medical-screening tests based solely on the concepts of "exposure" and "increased risk." The Manual for Complex Litigation § 22.74 (4th Ed.) observes that medical monitoring is typically recognized only in toxic-exposure cases involving latent diseases that are capable of early detection and treatment:

> In cases involving exposure to allegedly toxic substances in which resulting injury might be latent, plaintiffs may seek certification of a class to provide medical monitoring for the members. . . . The elements of state law claims for medical monitoring typically include exposure to a harmful substance or product that the defendant marketed or wrongfully released into the environment and that has significantly increased the plaintiffs' risk of developing a serious latent disease. Plaintiffs must show that the defendant caused the exposure to the substance and the consequent increase in risk. Courts generally require plaintiffs to show that diagnostic tests exist, that the increased risk has made testing reasonably necessary, and that early detection can significantly improve medical treatment of the disease. (Emphasis added.)

As currently framed by most courts, tort liability for medical monitoring (whether styled as a separate cause of action or a form of remedy) supposedly arises when a person is involuntarily exposed to a toxic substance, due to a defendant's negligence, thereby creating an increased risk of his or her developing some future disease, for which there is a cost-effective and medically efficacious screening test that will assist in the early detection and effective treatment of the targeted disease.[4] By definition, a medical-monitoring plaintiff has no existing physical injury, disease, or symptom of disease. Nonetheless, the exposed person may be deemed to have suffered an "injury" based on his or her exposure and increased risk. As such, medical monitoring is a rare and controversial exception to the physical-injury requirement and subverts traditional tort law by substituting the speculative concepts of exposure and risk for the concrete and verifiable requirement of a physical injury.

B. Medical monitoring is a novel theory.

A claim for medical monitoring absent any allegation of present physical injury caused by product failure is precisely the type of novel, non-traditional theory of recovery that this Court should hesitate to recognize absent clear state court authority embracing it. "[T]he tort of medical monitoring is still novel and considered a non-traditional tort." *Thompson v. Am. Tobacco Co.,* 189 F.R.D. 544, 552 (D. Minn. 1999). Medical monitoring is a "novel" and "drastic" tort because it contravenes the basic principle that a

[4] *See*, *e.g.*, *Hansen v. Mountain Fuel Supply Co.,* 858 P.2d 970, 979-80 (Utah 1993); *Bourgeois v. A.P. Green Indus., Inc*., 716 So. 2d 355, 360-61 (La. 1998), *superceded by statute*, La. Civ. Code Ann. Art. 2315(B)(West 1999).

plaintiff cannot state a tort claim absent an allegation of present injury. *Badillo v. Am. Brands, Inc.,* 16 P.3d 435 (Nev. 2001); *Parker v. Brush Wellman, Inc.,* 377 F. Supp. 2d 1290 (N.D. Ga. 2005). As other federal courts have recognized, "[n]o injury, no tort is an ingredient of every state's law." *In re Bridgestone/Firestone Inc.,* 288 F.3d 1012, 1017 (7th Cir. 2002). *See also Parker v. Brush Wellman, Inc.*, 377 F. Supp. 2d 1290, 1301 n.10 (N.D. Ga. 2005) ("providing relief to persons who have suffered no cognizable 'harm' is a *drastic and fundamental departure* from traditional tort doctrine") (emphasis added). Here, "[i]t is not the role of a federal court to expand state law in ways not foreshadowed by the state precedent." *City of Phila. v. Beretta U.S.A. Corp.,* 277 F.3d 415, 421 (3d Cir. 2002).

As explained below, the vast majority of states have either categorically rejected claims for medical monitoring in the absence of any present injury or have never addressed the issue so as to indicate they would recognize such claims. The few states that do recognize medical monitoring have done so only in cases involving toxic-tort exposure capable of causing latent diseases. But no state's law recognizes plaintiffs' request for medical monitoring of currently-functioning medical devices. The reality is that there is no state that recognizes medical monitoring of individuals with medical devices -- injury or not. Defendants respectfully submit that "it would be both imprudent and improper" to permit a medical-monitoring claim where "recognition of such a cause of action would . . . expand substantive liability under [state] law." *Trimble v. Asarco, Inc.,* 232 F.3d 946, 963 (8th Cir. 2000), abrogated on other grounds by *Exxon Mobil Corp. v. Allapattah Servs.*, 125 S. Ct. 2611 (2005).

Further, as the United States Supreme Court demonstrated in *Commuter R.R. Co. v. Metro-North,* 521 U.S. 424, 443-44 (1997), sound policy considerations support the rejection of medical-monitoring claims. *Metro-North* surveyed the likely effects of recognizing medical monitoring under the Federal Employers' Liability Act and held, by a 7-2 vote, that "the potential systemic effects of creating a new, full-blown, tort law cause of action" were too severe to tolerate the new tort. The same policy concerns addressed in *Metro-North* also militate against recognizing plaintiffs' medical-monitoring claims here.

In *Metro-North*, the Supreme Court expressed concern with a medical-monitoring claim on the ground that refusing to require plaintiffs to demonstrate a present physical injury underlying the claim would lead to a "'flood' of less important cases," *id.* at 442, or "unreliable and relatively trivial claims." *Id.* at 444. Here, Plaintiffs claim they are at some unspecified risk of suffering future injury as a result of device malfunction and request that Defendants be ordered to pay until the device is explanted or deactivated, despite the remote risk of failure in these devices. A medical-monitoring claim would provide a vehicle for every individual implanted with a device carrying a risk of failure greater than zero to bring an action based upon a speculative increased risk of device failure in an effort to recover potentially enormous monitoring costs. These claims exemplify the trivial and unreliable claims that concerned the *Metro-North* Court.

Metro-North further recognized that a medical-monitoring action is also problematic because of the "systemic harms that can accompany 'unlimited and unpredictable liability.'" *Id.* at 442. A medical-monitoring action would make any

device with a risk of failure greater than zero legally actionable and, as such, would impose severe burdens on the judiciary and upon the public with little corresponding social gain. Were this Court to uphold the medical-monitoring claims of uninjured medical device recipients, such a decision would effectively invite a flood of similar no-injury medical-monitoring claims by the purchasers of any product that could malfunction or fail, which would include all manufactured products, needlessly diverting limited judicial resources from plaintiffs who are truly injured.

Also, *Metro-North* observed that medical-monitoring claims present intractable medical and scientific difficulties for courts that must decide whether, when, and how the medical monitoring will be administered. *See id.* at 441-42 (explaining that "these difficulties in part can reflect uncertainty among medical professionals about just which tests are most usefully administered and when"). Here, the Court would face the unenviable task of deciding what type of medical monitoring regime would be appropriate for individuals who fear that their devices might fail in the future. Plaintiffs openly plead, however, that there is no test in existence capable of determining "if and when devices will fail in the future," begging the question of precisely what, how, and why they intend to monitor. (Master Compl. ¶ 152). Plaintiffs do not and cannot allege that they suffer from any type of progressive disease caused by Defendants' conduct that is amenable to early detection or capable of being "monitored." Once again, these difficulties in the current litigation confirm the concerns of the *Metro-North* Court.

Finally, *Metro-North* recognized that the resources required by medical-monitoring lawsuits would inevitably impose costs upon third parties. The "flood" of

speculative medical-monitoring lawsuits would "potentially absorb[] resources better left available to those more seriously harmed." 521 U.S. at 442. In proposed actions like this one, medical monitoring would threaten to exhaust judicial resources as well as Defendants' financial resources, leaving correspondingly less available to those suffering actual injuries. Moreover, by establishing "vast testing liability" in advance of the need for actual medical treatment, a medical-monitoring action would "adversely affect[] the allocation of scarce medical resources." *Id.* Here, Defendants respectfully suggest that this Court should dismiss the claims of uninjured plaintiffs, which will consume finite judicial and financial resources, and instead focus on whether and how to compensate people who allege actual injury caused by product malfunction.

C. The trend among state supreme courts is to reject medical monitoring.

While medical monitoring was initially recognized by a handful of state supreme courts, those cases usually involved a limited number of plaintiffs who were unknowingly and involuntarily exposed to asbestos or contaminated landfills/water as a direct result of the defendant's negligence.[5] But this potential tide has been checked and

[5] *Ayers v. Township of Jackson*, 525 A.2d 287 (N.J. 1987); *Potter v. Firestone Tire & Rubber Co*., 863 P.2d 795 (Cal 1993); *Bower v. Westinghouse Elec. Corp*., 522 S.E.2d 424 (W.Va. 1999); *Bourgeois v. A.P. Green Indus., Inc*., 716 So.2d 355, 360-61 (La. 1998), *superceded by statute*, La. Civ. Code Ann. Art. 2315(B)(West 1999); *Redland Soccer Club, Inc. v. Dep't of the Army,* 696 A.2d 137 (1997); *Hansen v. Mountain Fuel Supply Co*., 858 P.2d 970, 979-80 (Utah 1993); *see also* Henderson & Twerski, Asbestos Litigation Gone Mad: Exposure-Based Recovery For Increased Risk, Mental Distress, And Medical Monitoring, 53 S.C. L. R. 815, 850 (2002) ("[P]laintiffs have sought to convince courts that they should be compensated for present suffering. They have argued that even though they are asymptomatic, they are entitled to recover for mental distress arising from their present fear that they will

reversed. The most recent state supreme courts to confront the question have refused to expand their tort law by adopting a claim for medical monitoring.

In 2005, the Michigan Supreme Court refused to recognize medical monitoring, stating that "[b]ecause Plaintiffs do not allege a *present* injury, plaintiffs do not present a viable claim under Michigan's common law." *Henry v. Dow Chemical Company*, 701 N.W.2d 684, 686 (2005). In so holding, the court reasoned:

> Plaintiffs have asked us to recognize a cause of action that departs drastically from our traditional notions of a valid negligence claim. Beyond this enormous shift in our tort jurisprudence, judicial recognition of plaintiffs' claim may also have undesirable effects that neither we nor the parties can satisfactorily predict. For example, recognizing a cause of action based solely on exposure – one without a requirement of a *present* injury – would create a potentially limitless pool of plaintiffs.

Id. at 694.

In 2002, the Kentucky Supreme Court likewise rejected medical-monitoring claims by plaintiffs alleging no past or present physical injury. *Wood v. Wyeth-Ayerst Labs*, 82 S.W.3d 849 (Ky. 2002). The *Wood* court looked at recent Kentucky precedent addressing toxic tort cases which found that "until such time as the plaintiff can prove some harmful result from exposure . . . his cause of action has yet to accrue." *Id*. at 852 (quoting *Capital Holding Corp. v Bailey,* 873 S.W.2d 187, 195 (Ky. 1994)). "To find

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develop future injury and that they are entitled to medical monitoring awards so that they can determine whether they will need to be treated for some disease that may develop in the future. The huge majority of claims made under both of the above theories have been made on behalf of plaintiffs who have been exposed to asbestos or have developed some minor changes in their lungs evidenced by pleural plaque or pleural thickening.").

otherwise would force us to stretch the limits of logic and ignore a long line of legal precedent." *Wood*, 82 S.W.3d at 853-54.

In 2001, after reviewing Alabama and nationwide precedent, the Alabama Supreme Court refused to recognize a medical monitoring cause of action. Finding that state law "has long required a manifest, present injury before a plaintiff may recover in tort," the court found that recognizing a medical-monitoring claim "would require [it] to completely rewrite Alabama's tort-law system, a task akin to travel in uncharted waters, without the benefit of a seasoned guide." *Hinton v. Monsanto Co.*, 813 So. 2d 827, 850 (Ala. 2001). The court then weighed the public policy arguments both for and against adopting a medical-monitoring action for uninjured plaintiffs, and concluded that it could not so fundamentally alter Alabama's tort law:

> [W]e find it inappropriate . . . to stand Alabama tort law on its head in an attempt to alleviate these concerns about what **might** occur in the future. We believe that Alabama law, as it currently exists, must be applied to balance the delicate and competing policy considerations presented here. That law provides no redress for a plaintiff who has no present injury or illness.

Id. at 832 (emphasis in original).

In 2001, the Nevada Supreme Court rejected a cause of action for medical monitoring for persons with no present physical injury. *Badillo v. American Brands, Inc.*, 16 P.3d 435 (Nev. 2001). After surveying the law and recognizing that "creating new causes of action, and providing new remedies for wrongs is generally a legislative, not

judicial function," the *Badillo* court declined to create a cause of action for medical monitoring. *Id*. at 440.[6]

D. Only a handful of courts recognize medical monitoring and only in cases involving toxic-tort exposure; the majority of cases reject or do not recognize medical monitoring at all.

No jurisdiction in the United States has recognized a cause of action for medical monitoring of plaintiffs with allegedly defective medical devices. Indeed, a number of states have explicitly rejected claims for medical monitoring altogether:

- *Hinton v. Monsanto*, 813 So.2d 827, 829 (Ala. 2001) (refusing to allow a cause of action for monitoring when Plaintiff could not show the traditional tort law requirement of present injury).
- *Goodall v. United Illuminating*, No. X04 CV 95 0115437S, 1998 WL 914274, *7-10 (Conn. Super. Ct. Dec. 15, 1998) (holding that medical monitoring damages could not be recovered when plaintiffs demonstrated no physical manifestation of an asbestos-related disease).
- *Mergenthaler v. Asbestos Corp. of America*, 480 A.2d 647, 651 (Del. 1984) (explicitly holding that a claim for monitoring is not maintainable in the absence of a present, physical disease).
- *Wood v. Wyeth-Ayerst Labs.*, 82 S.W.3d 849 (Ky. 2002) ("With no injury there can be no cause of action, and with no cause of action there can be no recovery. It is not the remedy that supports the cause of action, but rather the cause of action that supports a remedy.").
- La. Civ. Code Ann. Art 2315 (West 1999) (legislatively overruling *Bourgeois v. A.P. Green Indus. Inc.,* 716 So. 2d 355 (La. 1998), as to causes of action accruing after July 9, 1999, and stating that "damage" does not "include costs for future medical treatment, services, surveillance, or procedures of any kind

[6] Although *Badillo* did not resolve whether medical monitoring damages might be available to a Plaintiff asserting another cause of action, it emphasized that any such remedy requires a viable underlying cause of action. *Id.* at 440. Moreover, the plaintiffs in *Badillo* never explained when such a remedy might be appropriate absent a present physical injury. *Id. See Badillo v. Am. Tobacco Co.*, 202 F.R.D. 261, 264 (D. Nev. 2001) (noting that Plaintiffs "failed to demonstrate a viable cause of action to which medical monitoring could properly be tied as a remedy").

unless such treatment, services, surveillance, or procedures are directly related to a manifest physical or mental injury or disease").

- *Henry v. Dow Chem. Co.*, 701 N.W.2d 684, 690-91 (Mich. 2005) (in action for medical monitoring for possible negative health effects from dioxin discharges from chemical plant, stating that the court was "not aware of any Michigan cases in which a plaintiff has recovered on a negligence theory without demonstrating some present physical injury" and explaining that "[t]he present physical injury requirement establishes a clear standard by which judges can determine which plaintiffs have stated a valid claim, and which plaintiffs have not").
- *Elam v. Alcolac, Inc.*, 765 S.W.2d 42 (Mo. Ct. App. 1988) (deciding an evidentiary issue by allowing testimony concerning future risk of cancer but also determining that medical surveillance may be recovered as an item of damages in a case involving plaintiffs with physical and biological manifestations of injury including autoimmune dysfunction); *see also Thomas v. FAG Bearings Corp. Inc.*, 846 F. Supp. 1400, 1410 (W.D. Mo. 1994) (holding in a diversity case, without any reference to Missouri law, that medical monitoring requires plaintiff to prove actual, present injury).
- *Badillo v. American Brands, Inc.*, 16 P.3d 435, 440-41 (Nev. 2001) (denying a common law cause of action for medical monitoring and refusing to allow monitoring as a remedy under the facts of the case).
- *Lowe v. Philip Morris Incorporated, et al.*, No. 0111-11895 (Circuit Court of Multnomah County, OR, Nov. 4, 2003) (dismissing plaintiff's negligence claim seeking medical monitoring damages because lack of present injury resulted in failure to state a claim); *see also Mead v. Aventis Pasteur, Inc.*, et al., No. 0107-07137 (Circuit Court of Multnomah County, OR, October 8, 2003) (dismissing plaintiffs' strict liability claim seeking medical monitoring damages and independent medical monitoring claim for the same reasons).
- *Garcia v. Aventis Pasteur Inc., et al.*, No. 01-2-27335-3-SEA (Superior Court of King County, WA, April 7, 2003) (refusing to recognize medical monitoring as a cause of action because Washington law requires present, physical injury to state a negligence claim); *see also Duncan v. Northwest Airlines, Inc.*, 203 F.R.D. 601 (W.D. Wash. 2001) (anticipating that Washington courts would not recognize a cause of action for medical monitoring because Washington law requires existing injury in order to pursue a negligence claim).

Likewise, numerous federal courts have recognized that their forum states do not recognize medical monitoring:

- *Trimble v. Asarco, Inc.*, 232 F.3d 946, 962-63 (8th Cir. 2000) (holding Nebraska law has not recognized a cause of action for damages for medical monitoring and predicting that Nebraska courts would not judicially adopt such a right or remedy), abrogated on other grounds by *Exxon Mobil Corp. v. Allapattah Servs.*, 125 S. Ct. 2611 (2005).
- *Parker v. Brush Wellman, Inc.*, 377 F. Supp. 2d 1290, 1296 (N.D. Ga. 2005) (holding plaintiffs who endured only "sub-clinical, cellular, and sub-cellular damage" from alleged exposure to beryllium in manufacturer's products did not sustain an actionable injury and rejecting the creation of a medical monitoring fund for plaintiffs who have not endured a cognizable tort injury because no Georgia court has ever indicated an inclination to recognize such a remedy).
- *Johnson v. Abbott Laboratories*, 2004 WL 3245947 (Ind. Cir. Dec. 31, 2004) (citing *Hunt v. Am. Wood Preserves Inst.,* No. IP-02-0389-C-M/S (S.D. Ind. July 30, 2002) (noting that a claim for medical monitoring is not cognizable under Indiana law)).
- *Paz v. Brush Engineered Materials, Inc.*, 351 F. Supp. 2d 580, 586 (S.D. Miss. 2005) *rev'd* on other grounds 445 F.3d 809 (5th Cir. 2006) (holding that Mississippi Supreme Court has not recognized a claim for medical monitoring: "In Mississippi, recognizing a medical monitoring claim would conflict with precedent establishing that a plaintiff allegedly exposed to a toxic or hazardous material does not have a compensable injury until a disease caused by such an exposure results").
- *Carroll v. Litton Sys., Inc.*, No. B-C-88-253, 1990 WL 312969 at *87 (W.D.N.C. October 29, 1990) (refusing to allow a medical-monitoring claim in absence of clear direction of the North Carolina legislature, and noting that even if North Carolina courts recognized medical monitoring, they would require a present physical injury).
- *Rosmer v. Pfizer*, No. CIV. A. 9:99-228018 RB, 2001 WL 34010613 at *5 (D.S.C. March 30, 2001) ("A fundamental flaw with Plaintiff proceeding to represent a medical monitoring class is the fact that South Carolina has not recognized a cause of action for medical monitoring.").
- *Witherspoon v. Philip Morris Inc.*, 964 F. Supp. 455, 467 (D.D.C. 1997) (where plaintiff asked court to order defendant tobacco company to create medical monitoring fund for plaintiff and general public, determining, with no reference to D.C. law, that medical monitoring requires that the plaintiff suffer a present injury).
- *Ball v. Joy Technologies Inc.*, 958 F.2d 36 (4th Cir. 1992) (dismissing plaintiff's claim for medical-monitoring damages because Virginia law requires a present, physical injury prior to recovery for negligence).

Still other states have not addressed medical monitoring in any context whatsoever. These states include Alaska, Arkansas, Hawaii, Idaho, Iowa, Maine, Maryland, Massachusetts, Minnesota, New Hampshire, New Mexico, North Dakota, Oklahoma, Rhode Island, South Dakota, Tennessee, Texas, Vermont, Wisconsin and Wyoming. As such, there is no indication these jurisdictions would recognize claims for medical monitoring.

The few states to recognize medical monitoring have done so only in the narrow context of toxic-exposure cases capable of causing latent diseases and for policy reasons inapplicable to medical devices:

- *Burns v. Jaquays*, 752 P.2d 28, 33 (Ariz. Ct. App. 1988) (where plaintiffs in asbestos-exposure case claimed damages for medical monitoring for the development of cancer or other asbestos-related diseases, holding medical monitoring is available in the absence of present, physical injury but limiting the ruling to the specific facts of the case).
- *Potter v. Firestone Tire & Rubber Co*., 863 P.2d 795, 824 (Cal. 1993) (holding medical monitoring is available to groundwater-contamination plaintiffs in the absence of present, physical injury and noting that "there is an important public health interest in fostering access to medical testing for individuals whose exposure to toxic chemicals creates an enhanced risk of disease, particularly in light of the value of early diagnosis and treatment for many cancer patients") (citation omitted).
- *Petito v. A.H. Robins Co. Inc.*, 750 So. 2d 103, 106 (Fla. Dist. Ct. App. 1999) (in case where Fen-Phen plaintiffs sought injunction requiring defendants to fund court-supervised medical monitoring, holding medical monitoring is available in the absence of present, physical injury and requiring plaintiffs prove, among other elements, "exposure greater than normal background levels to a proven hazardous substance . . .") (citation omitted).
- *Lewis v. Lead Industries Association, Inc*., 793 N.E.2d 869, 873 (Ill. App. Ct. 2003) (in lead-exposure case, finding that "the 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").

- *Lamping, et al. v. American Home Products Inc., et al*., No. DV-97-85786/93, at *14 (Mont. 4th Dist. Feb. 2, 2000) (recognizing a medical-monitoring claim under the specific facts of the case "because of the statistically high risk of serious heart valve disease from the use of fen/phen drugs, and the . . . benefits of mitigating against those serious injuries through early detection and treatment" and also certifying a medical-monitoring class consisting of all Montana residents who had consumed certain appetite-suppression drugs).
- *Ayers v. Township of Jackson*, 525 A.2d 287, 312 (N.J. 1987) (holding medical monitoring is available in groundwater-contamination case in the absence of present, physical injury where plaintiffs demonstrate that "such surveillance to monitor the effect of exposure to toxic chemicals is reasonable and necessary"). *But see Theer v. Philip Carey Co.*, 628 A.2d 724, 733 (N.J. 1993) (in case involving a plaintiff indirectly exposed to asbestos, limiting *Ayers* to cases where a plaintiff can show a direct correlation between the exposure to a hazardous substance and "the unique harm entailed in an increased risk of future injury . . . [,]" and mentioning that *Ayers* was special because the defendant in that case was a public entity that was required to pay medical-monitoring costs); *Vitanza v. Wyeth, Inc.*, No. ATL-2093-04-MT, 2006 WL 462470, at *8-9 (N.J. Super. Ct. Law Div. Jan. 24, 2006) (in case involving plaintiffs who used hormone replacement drug, explaining that *Ayers* was "derived specifically for environmental tort actions, not for a [product] liability consumer fraud case" and refusing to extend *Ayers* to drug recipient plaintiffs who cannot allege a manifest injury); *Sinclair v. Merck & Co., Inc.*, No. ATL-L-2093-04-MT, 2005 WL 1278364, at *7 (N.J. Super. May 19, 2005) (in case where plaintiffs alleged a significantly increased risk of myocardial infarctions and other latent or unrecognized injuries as a result of consuming the drug Vioxx, stating that New Jersey law allowed medical monitoring as a form of relief in only limited situations, such as environmental-tort actions or asbestos-exposure cases).
- *Abusio v. Consolidated Edison Co. of N.Y., Inc.*, 656 N.Y.S.2d 371, 372 (N.Y. App. Div. 1997) (requiring plaintiffs in action to recover medical-monitoring costs from exposure to polychlorinated biphenyls [PCBs] to show a "clinically demonstrable presence of PCBs in the plaintiff's body, or some indication of PCB-induced disease" in order to receive medical monitoring); *Bano v. Union Carbide Corp.*, No. 03-7417, 2004 WL 516238, at *15 (2d Cir. Mar. 17, 2004) (in case where plaintiffs alleged injuries from contaminated groundwater and sought reimbursement for the costs of medical monitoring, holding that proof of medical-monitoring claims under New York law required individualized inquiries, as a plaintiff had to prove some physical presence or indication of disease).
- *Redland Soccer Club, Inc. v. Department of the Army*, 696 A.2d 137, 146 (Pa. 1997) (in case where plaintiffs alleged exposure to hazardous waste,

recognizing a cause of action for medical monitoring in the absence of a present, physical injury and requiring a plaintiff to prove, among other elements, "exposure greater than normal background levels to a proven hazardous substance . . .").

- *Hansen v. Mountain Fuel Supply Co.*, 858 P.2d 970, 976-77 (Utah 1993) (in case where plaintiffs sought compensation for periodic medical tests to facilitate early diagnosis and treatment of asbestos-related illnesses, recognizing a claim for medical monitoring in the absence of present, physical injury and noting the "important public health interest in fostering access to medical testing for individuals whose exposure to toxic chemicals creates an enhanced risk of disease") (citation omitted).
- *Bower v. Westinghouse Electric Corp.*, 522 S.E.2d 424, 430-31 (W.Va. 1999) (recognizing a cause of action for medical monitoring in the absence of present, physical injury in case where plaintiffs alleged exposure to toxic substances from debris from the manufacture of light bulbs).
- *Cook v. Rockwell Int'l Corp*., 778 F. Supp. 512 (D. Colo. 1991) (in case where plaintiffs alleged exposure to hazardous waste and sought population-based health surveys, speculating that Colorado would recognize a claim for medical monitoring).
- *Day v. NLO*, 851 F. Supp. 869, 879-81 (S.D. Ohio 1994) (where plaintiffs brought a class action against manufacturer of nuclear weapons for exposure to radiation, holding medical monitoring is available in the absence of present, physical injury).

All in all, a super-majority of states have either rejected or do not recognize no-injury medical monitoring. The minority of states that have recognized no-injury medical monitoring have limited such recognition to toxic-tort or drug cases for policy reasons inapplicable here. In these cases, unlike here, plaintiffs allege exposure to a disease-causing agent and that their risk of developing a future latent disease could be reduced by medical monitoring and early detection and treatment. As explained next, medical monitoring in the toxic-tort and drug context is not analogous to "device monitoring," as plaintiffs suggest.

E. No court has ever recognized the type of "device monitoring" that plaintiffs are requesting under the guise of medical monitoring.

As explained above, no jurisdiction in the United States has recognized a cause of action for medical monitoring of plaintiffs with potentially defective medical devices. Defendants respectfully submit that the reason no jurisdiction has ever countenanced this type of medical monitoring is because it is plainly not medical monitoring at all. What plaintiffs are proposing here has nothing to do with detection of latent diseases that may result from plaintiffs' exposure to toxic substances. Instead, plaintiffs here are proposing a theory even more novel than "medical monitoring." What plaintiffs are proposing is "device monitoring."

Such "device monitoring" presumably would periodically test an individual's device to see whether there is any sign that the device is prone to failure. There is nothing else to monitor; defendants' conduct did not cause the various progressive heart conditions from which plaintiffs suffer, and there is no legal basis for requiring defendants to pay for monitoring those pre-existing diseases. Unlike medical monitoring, which is novel and limited to cases involving exposure to a latent-disease-causing agent, there would be no limits on such "device monitoring"; any presently functioning device capable of failing and causing future physical injury to a presently uninjured individual would give rise to a claim for device monitoring. Thus, numerous courts to consider such device monitoring have rejected it. *See*, *e.g.*, *In re Orthopedic Bone Screw Products Liability Litigation,* MDL No. 1014, No. Civ. A. 93-7074, 1995 WL 273597, at *9 (E.D. Pa. Feb. 22, 1995) (concluding that medical monitoring is not appropriate "in products

liability cases, where diseases caused by exposure to toxic substances are not the type of injury at issue"); *cf. Martin v. Am. Med. Sys*., 1995 WL 680630, *6 (S.D. Ind. Oct. 25, 1995) (recognizing that medical monitoring was not appropriate where recipients of penile implants "are necessarily already under the supervision of a doctor for treatment of the underlying impotence problem and follow-up care for the surgically implanted device").

For example, if plaintiffs' allegations here were sufficient to state a claim for device monitoring, then so would allegations that plaintiffs' airbags *might fail*. Car owners who allege that their airbags carry a remote risk that they will fail to deploy during an accident could state a claim for device monitoring of their airbags, entitling plaintiffs to monthly inspections by auto mechanics to detect signs of failure.

Allegations of an efficacious monitoring method are essential to any claim for medical monitoring. Here, plaintiffs through their Master Complaint concede that they are unaware whether a medical-monitoring regime exists that is appropriate for their devices:

> "[I]t is not yet clear how often individuals will have to be examined to determine whether their ICD has short circuited and it remains unclear, from what has been made to the public, as to whether there is an alternative method of identifying a defective device that would minimize the need for ongoing constant examination and medical surveillance."

(Master Complaint, ¶ 91). Nor can plaintiffs plead that any test in existence is capable of determining "if and when devised will fail in the future." (Master Complaint ¶152).

If medical-monitoring claims were extended to allow "device monitoring," as plaintiffs propose, actions for medical monitoring could be pursued against every medical-device manufacturer based on the possibility -- however remote -- that an individual's properly functioning medical device carries a remote risk that it will fail at some point in the future. Defendants respectfully urge the Court to reject plaintiffs' invitation to create a new cause of action for "device monitoring" and to instead dismiss all medical-monitoring claims.

Moreover, the underlying rationale that motivated the few courts that have recognized claims for medical monitoring are utterly inapplicable to plaintiffs' claims for device monitoring. The "sound policy reasons for allowing the recovery of medical monitoring costs" discussed in asbestos and toxic-exposure cases such as *Day v. NLO*, 851 F. Supp. 869, 881 (S.D. Ohio 1994), *Hansen v. Mountain Fuel Supply***,** 858 P.2d 970, 976-77 (Utah 1993), *Potter v. Firestone Tire and Rubber Co.*, 863 P.2d 795, 824 (Cal. Ct. App. 1993), and *Ayers v. Township of Jackson*, 525 A.2d 287, 313 (N.J. 1987) have no logical application to a medical-device case:

- *The public-health interest in providing medical testing for individuals whose exposure to toxic substances creates significantly increased risk of disease*: While medical monitoring has been found to be appropriate when an exposure can give rise to a truly enhanced risk of disease, such as asbestosis, plaintiffs plead no possibility of early detection of device failure, and explicitly concede there is no way to determine in advance (much less early) if a given device will fail or not. There is no developing disease to identify early and treat. There is simply no analogous public-health interest in device monitoring.
- *The availability of monitoring before plaintiffs' disease manifests may prevent or mitigate future illness and thus reduce the overall costs of the litigation*: No such advantage applies in the medical device context. There is no subsequent manifestation of any condition (other than the pre-existing cardiac conditions

from which plaintiffs already suffer) that will worsen and result in further overall costs to Defendants. Even if there were, there is no way device monitoring could identify and avoid manifestation of that condition. There is no basis for supposing that allowing the premature prosecution of potential claims will avoid significant litigation costs at some later date.

- *Societal notions of fairness and elementary justice*: To the extent such an individual experiences anxiety, such notions of fairness are already vindicated by allowing such individuals to pursue an emotional distress claim to the extent his or her jurisdiction allows such recovery. What is unfair and impracticable is to hold a manufacturer of a medical device liable for pointless device monitoring expenses of individuals whose devices have been and continue to function perfectly.
- *The difficulty of proving causation where the disease manifests years after exposure*: As opposed to latent, often-multifactorial creeping diseases caused by toxic exposures, there can be little difficulty in determining whether a given device malfunctioned. An analysis of a given plaintiff's device will indicate whether the device functioned as intended or malfunctioned. While the issue of whether an alleged device malfunction was the proximate cause of a given plaintiff's death or medical complication may require additional individualized medical analysis and testimony, these are discrete identifiable events capable of determination on each case's individual facts that do not require the invention of a new form of recovery.

None of the proffered justifications for allowing the recovery of medical monitoring costs in the absence of a presently physical injury apply to this litigation. Accordingly, there is no justification or basis for allowing device monitoring claims to proceed even in the minority jurisdictions that have recognized medical monitoring in the narrow context of toxic-exposure cases, much less the decisive majority of jurisdictions that either do not recognize or have flatly rejected medical monitoring under any paradigm.

* * *

The majority of courts have either rejected medical-monitoring claims in the absence of a present physical injury or have remained silent on the issue. The minority that have recognized medical-monitoring claims in the absence of a present physical

injury do so only in very narrow circumstances involving toxic-tort exposure and for policy reasons utterly inapplicable to the context of medical devices. Given the novel and limited support for medical monitoring -- and the complete vacuum of authority in support of "device monitoring" of medical devices -- it would be inappropriate for this Court to expand the applicable states' laws to recognize plaintiffs' novel medical-monitoring claims, particularly given the underlying requirement that plaintiffs allege a present injury. Accordingly, Defendants respectfully request that the Court dismiss Plaintiffs' Medical Monitoring claim (Count XVI) as to all Plaintiffs.

V. NO-INJURY PLAINTIFFS' CONSUMER-PROTECTION CLAIMS MUST BE DISMISSED UNDER THE LAW OF ALMOST EVERY STATE. (COUNT VIII)

Plaintiffs assert their claims under the consumer-protection laws of all 50 states in Count VIII: "Defendants' actions . . . constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statues, as listed below . . . ." *See* Master Complaint, Count VIII at ¶ 320. Plaintiffs then summarily list one or more consumer-protection statutes for each state and request that this Court interpret and apply these statutes. *See id*.

Each of the 50 states' consumer-protection laws is different.[7] Yet under nearly all of the consumer-protection statutes pleaded in Count VIII, plaintiffs whose only injury is

[7] *See, e.g.*, *Clement v. American Honda Finance Corp*. 176 F.R.D. 15, 23 (D.Conn. 1997) (noting that "many states' unfair trade practices statutes allow for private causes of action and provide for minimum statutory damages ranging between $25 and $2000, other states' statutes either do not provide for private causes of action, or specify that actual damages can be recovered in a private action, but do not provide

"no-injury" cannot allege a cognizable injury -- whether denominated as "pecuniary loss," "actual loss," or "property or monetary loss" -- because their devices continue to function and have provided plaintiffs exactly what they bargained for. *See* Appendix A.

The no-injury plaintiffs have working devices. They have not suffered any physical injury tied to device malfunction. They have likewise suffered no pecuniary loss. Despite these realities, Plaintiffs in Count VIII attempt to state consumer-protection claims in the absence of cognizable injury on behalf of all plaintiffs. Plaintiffs invite the Court to recognize consumer-protection claims based on fear of device failure, even though most courts have not. *See* Appendix A.

This Court should not accept Plaintiffs' invitation. For the foregoing reasons, Defendants request that the Court dismiss the consumer-protection claims of those plaintiffs who have failed to allege present injury caused by device malfunction or whose only injury is fear of device failure.[8]

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for minimum damage awards"); *In re General Motors Corp. Anti-Lock Brake Products Liability Litigation*, 966 F. Supp. 1525, 1536 (E.D. Mo. 1997) ("Each state statute is unique and plaintiffs are required to plead the essential elements of each one.").

[8] As discussed in detail in Appendix A, no-injury plaintiffs cannot state claims under the following states' consumer protection statutes: Ala. Code §§ 8-19-1 *et seq.*; Alaska Stat. §§ 45.50.471 *et seq.*; Ariz. Rev. Stat. Ann. §§ 44-1522 *et seq.*; Ark. Code Ann. §§ 4-88-101 *et seq.*; Cal. Civ. Code §§ 1770 *et seq.*; Cal. Bus. & Prof. Code §§ 17200 *et seq.*; Conn. Gen. Stat. §§ 42-110a *et seq.*; Del. Code Ann. Tit. 6, §§ 2511 *et seq.* and §§ 2531 *et seq.*; D.C. Code §§ 28-3901 *et seq.*; Fla. Stat. §§ 501.201 *et seq.*; 815 Ill. Comp. Stat. 505/1 *et seq.*; Ind. Code Ann. §§ 24-5-0.5-1 *et seq.*; Iowa Code §§ 714.16 *et seq.*; Kan. Stat. Ann. §§ 50-623 *et seq.*; Ky. Rev. Stat. Ann. §§ 367.170 *et seq.*; La. Rev. Stat. Ann. §§ 51:1401 *et seq.*; Me. Rev. Stat. Ann. tit. 5, §§ 205A *et seq.*; Md. Code Ann., Com. Law §§ 13-101 *et seq.*; Minn. Stat. §§ 325D.43 *et seq.* and §§ 325F.67 *et seq.*; Miss. Code Ann. §§ 75-24-1 *et seq.*; Mo. Ann. Stat. §§

PART TWO: DEVICE RECIPIENT PLAINTIFFS GENERALLY

In Part Two, Defendants show that many plaintiffs -- no matter what their injury -- cannot state claims for implied warranty, unjust-enrichment, or statutory consumer-protection, and that none of Plaintiffs' fraud-based claims are stated with the required particularity.

VI. PLAINTIFFS' CLAIMS FAIL UNDER MANY OF THE 50 STATES' CONSUMER PROTECTION LAWS. (COUNT VIII)

Although Plaintiffs provide a laundry list of citations for each jurisdiction's consumer protection statutes in Count VIII of their Master Complaint, as noted above, they fail to properly plead the elements of any state's consumer protection statutes. Thus, Plaintiffs simply never address the threshold requirements contained in many of these state statutes. Many of the statutes pleaded by Plaintiffs contain requirements that Plaintiffs cannot meet. In addition to their failure based on lack of cognizable injury, Plaintiffs' claims, on their face, fail in the following states for the following reasons.[9]

407.010 *et seq.*; Mont. Code Ann. §§ 30-14-101 *et seq.*; Neb. Rev. Stat. §§ 59-1601 *et seq.*; N.J. Rev. Stat. §§ 56:8-1 *et seq.*; N.M. Stat. §§ 57-12-1 *et seq.*; N.Y. Gen. Bus. Law §§ 349 *et seq.* and §§ 350-e *et seq.*; N.C. Gen. Stat. §§ 75-1.1 *et seq.*; N.D. Cent. Code §§ 51-12-01 *et seq.* and §§ 51-15-01 *et seq*; Okla. Stat. Tit. 15 §§ 751 *et seq.*; Or. Rev. Stat. §§ 646.605 *et seq.*; 73 Pa. Stat. §§ 201-1 *et seq.*; R.I. Gen. Laws. §§ 6-13.1-1 *et seq.*; S.C. Code Ann. §§ 39-5-10 *et seq.*; Tenn. Code Ann. §§ 47-18-101 *et seq.;* Tex. Bus. & Com. Code Ann. §§17.41 *et seq.*; Va. Code Ann. §§ 59.1-196 *et seq.*; Wash. Rev. Code. §§ 19.86.010 *et seq.*; W. Va. Code §§ 46A-6-101 *et seq.*; Wis. Stat. §§ 100.20 *et seq.*

[9] Defendants believe that Plaintiffs' Count VIII claims fail in every jurisdiction. Defendants' arguments here, however, are limited to those jurisdictions where Plaintiffs' pleadings fail on threshold issues, and are not exhaustive. Defendants reserve additional arguments under the various jurisdictions as appropriate for consideration in future dispositive motions.

A. Under many states' consumer-protection statutes, Plaintiffs may not assert the claims in the Master Complaint.

Under many states' consumer-protection statutes, plaintiffs do not have standing to bring a claim either as an individual or in a representative capacity, or cannot bring a claim on behalf of a class. Iowa's law does not permit private claims. *See* Iowa Code. §714.16(7). And various states do not permit class actions, or any representative actions.[10] Plaintiffs' claims under these states' laws should be dismissed.

Sixteen states have provisions limiting the availability of private rights of action to those who buy goods "primarily for personal, family, or household purposes."[11] 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. *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

[10] S.C. Code §39-5-140(a)); Miss. Code Ann. § 75-24-15(4); Ala. Code §8-19-10(f); O.C.G.A. § 10-1-399(a); La. Rev. Stat. Ann. 51:1409(A); Mont. Stat. § 30-14-133(1)); Miss. Code § 75-24-15(4); and Tenn. Code Ann. § 47-18-109(a)(1).

[11] *See* Ala. Code § 8-19-3; Cal. Civ. Code § 1761(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); Mich. Comp. Laws § 445.904; 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.

medical device, even though that device is 'used' on them for 'personal purposes'"). Plaintiffs did not purchase their devices from Defendants as a consumer good and therefore do not meet the definition of consumer. Accordingly, plaintiffs' consumer-protection claims under the laws of these sixteen states should be dismissed.

B. Plaintiffs' claims improperly use consumer-protection statutes as vehicles for personal-injury claims that do not benefit the public.

Multiple state statutes provide, and courts in additional jurisdictions have held, that where "the essence of plaintiff's lawsuit is personal injury," involving allegations of negligence and product liability, it serves no public benefit. *Berczyk v. Emerson Tool Co.*, 291 F. Supp. 2d 1004, 1018-1120 (D. Minn. 2003) (confirming that private plaintiffs under Minnesota's consumer-protection statutes must "demonstrate that their proposed cause of action benefits the public"). *Hall v. Walter*, 969 P.2d 224 (Colo. 1998); *Bauer v. Mellon Mortgage Co.*, 680 N.Y.S.2d 397, 400 (N.Y. Sup. Ct. 1998). The essence of Plaintiffs' claims, and the emotional distress and medical-expenses damages that they seek, are predominantly for personal injury. Plaintiffs' claims are personal, not public, in nature and therefore do not meet the public benefit requirement found in the state statutes of Colorado, Georgia,[12] Minnesota, Nebraska,[13] New York, South Carolina,[14] Washington,[15] and West Virginia.[16]

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[12] *Zeeman v. Black*, 273 S.E.2d 910, 915 (Ga. Ct. App. 1980) (holding that although a plaintiff may be a "consumer" with regard to the transaction, if the deceptive or unfair act had or has no potential for harm to the general consuming public, the allegedly wrongful act was not made in the context of the consumer marketplace).

For this same reason, Plaintiffs' claims are explicitly prohibited by Hawaii and Utah law, which provides that consumer-protection statutes are not to be used as a vehicle for personal-injury lawsuits. *See* H.R.S. § 480-2. *Beerman v. Toro Mfg. Corp.*, 615 P.2d 749, 754 (1980); Utah Code Ann. § 13-11-22(1)(c) ("this act does not apply to . . . a claim for personal injury or death"). And, under Louisiana law, the Louisiana Products Liability Act ("LPLA") applies to all product-liability actions and "establishes the exclusive theories of liability against manufacturers for damage caused by their products." LSA-R.S. §9:2800.52. Thus, Plaintiffs may not pursue statutory consumer-protection claims or other claims of fraud or misrepresentation against product manufacturers under Louisiana law.

C. Plaintiffs' Count VIII claim fails for additional state-specific reasons.

Plaintiffs' claims under Alabama law fail because their election to pursue common law claims forecloses asserting statutory consumer protection claims.[17] The Plaintiffs'

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[13] Nebraska consumer-protection law is inapplicable to private wrongs where the public interest is unaffected. *Arthur v. Microsoft Corp.*, 267 Neb. 586, 676 N.W.2d 29 (2004); *Nelson v. Lusterstone Surfacing Co.*, 258 Neb. 678, 605 N.W.2d 136 (2000).

[14] Unfair or deceptive acts or practices have impact upon the public interest, and thus are actionable if acts or practices have potential for repetition. *Crary v. Djebelli*, 496 S.E.2d 21 (S.C. 1998).

[15] *See Lightfoot v. McDonald*, 544 P.2d 88 (Wash. 1976).

[16] W.Va. Code § 46A-6-101(2) ("this article shall not be construed to prohibit acts or practices . . . which are not injurious to the public interest").

[17] Ala. Code §8-19-15(b) ("An election to pursue any civil remedies available at common law, by statute or otherwise, for fraud, misrepresentation, deceit, suppression of material facts or fraudulent concealment arising out of any act, occurrence or transaction actionable under this chapter shall exclude and be a surrender of all rights and remedies available under this chapter.").

claim under Wis. Stat. § 100.20(5), should be dismissed because the complaint does not allege violation of a department order, or DATCP administrative rule, which is necessary to bring a claim under § 100.20(5). Courts in Pennsylvania have held that Consumer fraud claims against prescription drug manufacturers are barred by the learned intermediary doctrine,[18] and in Texas they are preempted under the Federal Medical Care Device Amendments.[19]

VII. ALL PLAINTIFFS' CLAIMS FOR BREACH OF IMPLIED WARRANTIES MUST BE DISMISSED. (COUNT V)

In Count V plaintiffs contend that Defendants "impliedly warranted that their Devices . . . were merchantable and fit and safe for ordinary use" and that their devices "were fit for their particular purposes." (Master Complaint, ¶ 299). Plaintiffs then allege that Defendants breached the implied warranties because their devices were unmerchantable and unfit for ordinary use when sold, in that they allegedly "are defective and have short circuited or otherwise failed to function, or are subject to an enhanced risk that they will not function, as represented and intended." (*Id.* ¶ 300).

While the laws of all states regarding breaches of implied warranties differ in many material aspects -- so many, in fact, that it would be impossible to adjudicate these claims together -- there are some baseline elements common to the laws of many states.

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[18] *See Heindel v. Pfizer Inc.*, 381 F. Supp. 2d 364, 384-385 (D.N.J. 2004) (applying PA law).

[19] Under Texas law, the Texas Deceptive Trade Practices Act has been held expressly preempted by the Federal Medical Device Amendments. *See Worthy v. Collagen*, 967 S.W.2d 360, 363 (Tex.), *cert. denied*, 524 U.S. 954 (1998); *Baker v. St. Jude Med., S.D., Inc.*, 178 S.W.3d 127, 137 (Tex. App.- Houston [1st Dist.] 2005, pet. filed).

Because Plaintiffs have not pleaded and cannot plead some of these key requirements of implied warranty claims, they have failed to adequately allege a claim for breach of any implied warranty under the laws of a number of states.

A. Plaintiffs cannot state a claim for breach of the warranty of fitness for a particular purpose.

First, Plaintiffs seem to be attempting to plead a breach of both (1) the implied warranty of merchantability and (2) the implied warranty of fitness for a particular purpose. However, the warranty of fitness for a particular purpose only applies (as its name suggests) if there is some *particular use* -- *other than a product's usual use* -- for which the buyer intends to use the product. 1 James J. White and Robert S. Summers, Uniform Commercial Code §§ 9-10 (4th ed. 1995) (emphasis added).[20] Indeed, a prerequisite to asserting such a claim is that the seller must have reason to know of that buyer's particular purpose in choosing to purchase the seller's product. *Willmar Cookie Co. v. Pippin Pecan Co.*, 357 N.W.2d 111, 115 (Minn. Ct. App. 1984).

[20] *See also, e.g.*, *Rutledge v. Arrow Aluminum Indus., Inc.*, 733 So. 2d 412, 415 (Ala. Civ. App. 1998) (the implied warranty of fitness arises "where the seller has reason to know of a particular purpose for which a good is required"); *Doug Connor, Inc. v. Proto-Grind, Inc.*, 761 So. 2d 426, 427-28 (Fla. Dist. Ct. App. 2000) (implied warranty of fitness arises where "the seller at the time of contracting has reason to know any particular purpose for which the goods are required"); *Frank v. Edward Hines Lumber Co.*, 761 N.E.2d 1257, 1267 (Ill. App. Ct. 2001) (implied warranty of fitness for a particular purpose is inferred where "the seller has reason to know the buyer needs the goods for a particular purpose and knows the buyer is relying on the seller's skill in selecting the goods"); *Leavitt v. Monaco Coach Corp.*, 616 N.W.2d 175, 179 (Mich. Ct.. App. 2000) ("to establish a valid warranty of fitness for a particular purpose, 'the seller must know, at the time of sale, the particular purpose for which the goods are required and also that the buyer is relying on the seller to

Plaintiffs have seemingly attempted to plead the requirement that Defendants had reason to know of a particular use (*see* Master Complaint ¶ 299), but have not pleaded any special or particular purpose for which plaintiffs used their devices. In short, Plaintiffs have not alleged that their devicess were used for anything but their normal, intended use. (*See id.* ¶ 48 ("[t]he purpose of the ICD is to correct abnormal heart rhythm"); ¶ 53 ("Pacemakers are used to manage disorders that disrupt the heart's normal electrical conduction system.")). For this reason alone, Plaintiffs' claims for breach of the warranty of fitness for a particular purpose must be dismissed.

B. Many of the implied warranty of merchantability claims are barred because the plaintiffs lack vertical privity with Defendants.

Vertical privity refers to the links in the chain of distribution between manufacturer, distributor, and ultimately, consumer. In order to recover on a breach of warranty theory against a manufacturer, some states require a consumer to be in privity -- to have a direct contractual nexus -- with that manufacturer. Clark & Smith, The Law Of Product Warranties, ¶ 10.01[1], at 10-3 (1984). Privity requirements vary from state to state. Indeed, in *Osborne v. Subaru of America, Inc.*, 198 Cal. App. 3d 646 (1988), the court found that these state-by-state variations related to privity precluded a class action based upon an implied warranty theory. There is no variation, however, on the effect of the privity requirement if applicable -- it acts as a bar to an implied warranty claim where a buyer did not purchase the product directly from the defendant. Because plaintiffs have

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select or finish suitable goods'") (quoting *Ambassador Steel Co., v. Ewald Steel Co.*, 190 N.W.2d 275 (Mich. Ct. App. 1971)).

not alleged that they purchased their devices directly from Defendants, application of the requirement means that plaintiffs' claims in those states requiring privity must be dismissed for this reason as well. *See* Appendix B.

Because plaintiffs have failed to allege that they purchased their devices directly from Defendants, they are unable to demonstrate the vertical privity required in some states for breach of implied warranty of merchantability claims. Plaintiffs' failure to demonstrate this essential element should result in the dismissal of those claims that will be decided under the laws of Alabama, Arizona, California, Florida, Georgia, Illinois, Kansas, Kentucky, New York, Oregon, Tennessee, and Wisconsin. (See Appendix B).

Here, Plaintiffs' claims for breach of the warranty of fitness for a particular purpose lack any allegations that the devices were used for anything but their normal, intended use. Similarly, as previously explained, no-injury plaintiffs' claims for breach of the warranty of merchantability lack allegations that Plaintiffs did not receive the benefit of their bargain. Further, the claims under the laws of those states requiring notice or vertical privity fail to allege the required notice or vertical privity.

For the foregoing reasons, Defendants respectfully request that the Court dismiss Count V for:

- Breach of warranty of fitness for a particular purpose for all Plaintiffs
- Breach of warranty of merchantability for no-injury plaintiffs

VIII. PLAINTIFFS' UNJUST ENRICHMENT CLAIMS MUST BE DISMISSED. (COUNT XVII)

In addition to their claims for consumer fraud and breach of implied warranty, plaintiffs seek equitable relief in the form of unjust enrichment. (Master Complaint ¶

371-74). That claim fails as well because plaintiffs cannot allege that Defendants were unjustly enriched absent an injury to plaintiffs from paying for and receiving the devices, and because plaintiffs have not alleged that they have no adequate remedy at law.

First, because they have not alleged an injury, the no-injury plaintiffs cannot demonstrate that any enrichment is "unjust." As explained above, for many plaintiffs in this MDL, there is no allegation that the devices caused any harm. Plaintiffs received exactly what they thought they were purchasing -- a fully-functioning Device. Any enrichment of Defendants from the sale of the devices therefore cannot be "unjust." To the contrary, as one court found, "to succeed on . . . the unjust enrichment . . . claims, Plaintiffs would have to demonstrate that they were either injured by [a prescription drug], or that [it] did not provide them any health benefits." *In re Baycol Prods. Liab. Litig.*, 218 F.R.D. 197, 213-14 (D. Minn. 2003). *See also Lewis v. Bayer AG*, 66 Pa. D. & C.4th 470, 504 (Pa. Ct. Com. Pl. 2004) ("If an individual consumed an effective cholesterol-reducing medication which was "unsafe" because of inadequate warnings or because of increased exposure to serious injury and as a chance and fate provided in fact suffers no injury, no equitable claim for unjust enrichment can lie."); *Albertson v. Wyeth, Inc.,* 63 Pa. D. & C.4th 514, 536 (Pa. Ct. Com. Pl. 2003) (dismissing unjust enrichment claim because "plaintiffs did receive the product they sought, a hormone replacement therapy. Plaintiffs merely allege that Prempro was not safe, and that Wyeth knew it was unsafe but promoted the drug anyway. These allegations are insufficient to state a claim for unjust enrichment.").

Here, the no-injury plaintiffs' allegations do not support a claim that an injustice would result if Defendants retained whatever unspecified benefits one might speculate they conferred on Defendants. These plaintiffs do not allege that the devices failed to work effectively for them. Nor do they allege that they suffered any injuries from the devices. There can be no injustice in Defendants' retaining any payments these plaintiffs indirectly made to them for the devices, absent any allegations that these plaintiffs received a product that was ineffective or that caused them some injury. Even if one assumes, arguendo, that the no-injury plaintiffs had been misled by Defendants, they do not plead any facts establishing that they would have paid any less to Defendants. This is particularly true for those plaintiffs who were insured and merely paid a specific co-payment. *See Eli Lilly & Co., v. Roussel Corp.*, 23 F. Supp. 2d 460, 496 (D.N.J. 1998).[21]

Second, many plaintiffs have failed to allege that they lack an adequate legal remedy, which is a prerequisite to their unjust enrichment claims in a number of states. *See* Appendix C. "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. 2003) (dismissing claims because lack of adequate remedy not specifically pleaded) (internal quotations omitted). Because unjust enrichment is an equitable remedy, those states' laws require plaintiffs to

[21] It is also unlikely that Defendants were enriched at the expense of explant patients who would otherwise undergo explantation as part of the normal course of treatment. This argument will be addressed on summary judgment.

specifically plead that they have no remedy at law.[22] Here, not only do plaintiffs fail to plead this element, they also demonstrate precisely the opposite by pleading numerous legal remedies. Accordingly, plaintiffs from those states requiring a lack of adequate legal remedy have failed to state a claim for unjust enrichment on this ground as well.

Plaintiffs have not alleged the requirement found in a number of states that a plaintiff specifically plead lack of adequate legal remedy. *See* Appendix C. Additionally, because no-injury Plaintiffs' claims for unjust enrichment lack any allegations of injury, they are unable to demonstrate the requirement that any enrichment is "unjust." For the foregoing reasons, Defendants respectfully request that the Court dismiss Count XVII for: unjust enrichment claims as to all Plaintiffs.

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[22] A plaintiff's inability to state a claim under the existing law does not demonstrate an inadequate remedy at law. If that were the case, any plaintiff who failed to meet the elements of a legal remedy could always fall back on a claim for unjust enrichment or other equitable remedies. Courts consistently reject such attempts to expand their equitable authority to areas in which a plaintiff is unable to state a claim. The Supreme Court of Michigan, for example, recently held that where a claim for medical monitoring was not cognizable under current Michigan law, awarding a medical monitoring program as an equitable remedy would be an impermissible expansion of the common law. *Henry v. The Dow Chem. Co.*, 701 N.W.2d 684, 701-02 (Mich. 2005). The Henry court concluded that the "[p]laintiff's reliance on the nature of the relief they seek essentially puts the cart before the horse. Regardless of what sort of remedy a plaintiff requests, we must nevertheless determine whether that remedy is supported by a valid claim." Id. at 702. The court also emphasized that a court "cannot 'create substantive rights under the guise of doing equity,' or 'confer rights' where none exists." *Id*. (citations omitted); *see also Wood v. Wyeth Ayerst Labs.*, 82 S.W.3d 849, 855 (Ky. 2002) ("It is not the remedy that supports the cause of action, but rather the cause of action that supports a remedy."); *J.C. Penney Co. v. United States Treasury Dep't*, 439 F.2d 63, 68 (2d Cir. 1971) ("[T]he mere fact that more desirable remedies are unavailable does not mean that existing remedies are inadequate.").

IX. ALL PLAINTIFFS' FRAUD-BASED CLAIMS ARE SUBJECT TO DISMISSAL UNDER RULE 9(B). (COUNTS VI – VIII, IX, XVIII, XIX - XXI, XXIII)

Fed R. Civ. P 9(b) mandates that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." Rule 9(b) is designed to prevent litigants from filing baseless claims and "then attempting to discover unknown wrongs." *See Shushany v. Allwaste, Inc.*, 992 F.2d 517, 521 (5th Cir. 1993). Because one of the main purposes of the rule is to facilitate a defendant's ability to respond and to prepare a defense to charges of fraud, *Greenwood v. Dittmer,* 776 F.2d 785, 789 (8th Cir.1985), conclusory allegations that a defendant's conduct was fraudulent and deceptive are not sufficient to satisfy the rule. *In re Flight Transp. Corp. Sec. Litig.,* 593 F. Supp. 612, 620 (D. Minn. 1984).

To determine "whether the 'circumstances' constituting fraud are stated with particularity under Rule 9(b)," the test in the Eighth Circuit requires that every such allegation contain:

- The time, place, and contents of the alleged fraud;
- The identity of the person allegedly committing fraud; and
- What was given up or obtained by the alleged fraud.

See Roberts v. Francis, 128 F.3d 647, 651 (8th Cir. 1997). In other words, plaintiffs must plead the "who, what, when, where, and how" of a fraud or fraud-based claim. *See Tuttle v. Lorillard Tobacco Co*., 118 F. Supp. 2d 954, 963 (D. Minn. 2000) (quoting *Parnes v. Gateway 2000, Inc.*, 122 F.3d 539, 549-50 (8th Cir. 1997)). An allegation of reliance "fails the particularity requirement of Rule 9(b)" if it "only states a conclusion that actual

reliance existed" and is absent any allegation that anyone actually read any of the misleading statements or knew of their existence. *See Morse v. Abbott Labs.,* 756 F. Supp. 1108, 1112 (N.D. Ill. 1991). These particularity requirements apply to "all of [plaintiffs'] averments, as opposed to 'several' or 'many'" of them. *See Wright v. Brooke Group Ltd*., 114 F. Supp. 2d 797, 834 (N.D. Iowa 2000). Accordingly, mere conclusory allegations that a defendant's conduct was fraudulent or deceptive will not satisfy Rule 9(b). *See Tuttle*, 118 F. Supp. 2d at 963.

Rule 9(b) is not limited to claims expressly identified by plaintiffs as fraud. Instead, "where fraud lies at the core of the action, Rule 9(b) applies." *See Hayduk v. Lanna*, 775 F.2d 441, 443 (5th Cir. 1995). Plaintiffs' claims purporting to be predicated on consumer-protection statutes (*i.e.*, statutory consumer fraud, unlawful trade practices, deceptive trade practices, and false advertising) are also subject to Rule 9(b)'s heightened pleading requirements. *See Marvin Lumber & Cedar Co. v. PPG Indus., Inc.*, No. 4-95-739, 1998 WL 1056973, *12 (D. Minn. Aug. 6, 1998) (referring to district court's dismissal of consumer fraud, unlawful trade practices, deceptive trade practices, and false advertising claims for failure to plead with particularity pursuant to Rule 9(b)). Thus, the pleading requirements of Rule 9(b) apply to Plaintiffs' consumer-protection claims.[23] By

[23] *See*, *e.g.*, *State v. GAF Corp.*, 760 P.2d 310, 313 (Utah 1988) (Utah Consumer Sales Protection Act requires "intent to deceive" before deceptive trade practice can be found); *Burton v. R.J. Reynolds Tobacco Co.*, 884 F. Supp. 1515, 1524 (D. Kan. 1995) (applying Rule 9(b) to claims under Kansas Consumer Protection Act); *Duran v. Clover Club Foods Co.*, 616 F. Supp. 790, 793 (D. Colo. 1985) (applying Rule 9(b) to claims under Colorado Consumer Protection Act); *see also NCC Sunday Inserts, Inc. v. World Color Press, Inc.,* 692 F. Supp. 327, 330 (S.D.N.Y.1988) (holding

the same token, Rule 9(b) applies to Plaintiffs' unjust enrichment claim. *Brege v. Lakes Shipping Co., Inc*. 225 F.R.D. 546, *549 (E.D. Mich. 2004) (requiring unjust enrichment claim to be pleaded under Rule 9(b) and noting "whether as part of a fraud claim or an element of a non-fraud claim, the 'averment of fraud' must be stated with the requisite particularity") (citing *Vess v. Ciba-Geigy Corp. USA,* 317 F.3d 1097 (9th Cir. 2003)). Indeed, the following claims are all subject to Rule 9(b) because fraud lies at the core of these claims:

- Fraud (Count VI);
- Constructive Fraud (Count VII);
- Unfair and Deceptive Trade Practices Under State Law (Count VIII);
- Violation of the Senior Citizen and Handicapped Person Consumer Fraud Act Minnesota Statute § 325F.71 And/Or Similar Statutes in Effect in Other Jurisdictions (Count IX);
- Violation of the Minnesota Deceptive Trade Practice Act (Count XVIII);
- Violation of the Minnesota Prevention of Consumer Fraud Act (Count XIX);
- Violation of Minnesota False Statements in Advertising Statute (Count XX);
- Unfair and Deceptive Trade Practices Under State Law (Count XXI); and
- Unjust Enrichment (Count XXIII).

Plaintiffs have not met their burden of pleading these fraud-based claims with particularity.

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requirements of Rule 9(b) apply to state-based deceptive-trade-practices claims because Rule 9(b) is a procedural rule).

A. Plaintiffs' conclusory fraud-based allegations fail to satisfy Rule 9(b).

The fraud-based claims in Plaintiffs' Master Complaint do not meet Rule 9(b). The Master Complaint purports to state eight fraud-based claims on behalf of fourteen named Device Recipient plaintiffs, and numerous other putative class members. But nowhere is there a specific allegation that provides particulars concerning any element of any alleged fraudulent acts by any of the Defendants.

Plaintiffs' fraud-based allegations are of the most general sort. These are a representative sample of Plaintiffs' allegations:

- "Guidant's CRM Division had known for more than three years that there were defects in the Ventak Prizm 2 DR 1861" and other devices, yet Guidant "failed to communicate information about the defects to the medical community, individuals who had been implanted with the Devices, or the public." ¶¶ 79, 81.

- "Dear Doctor" letters sent by Guidant have been "inconsistent, unclear and incomplete" ¶ 80. As a result, "recipients and their medical advisories remain confused and unclear as to the risks of the Devices and the appropriate course of action to take." *Id*.

- "Guidant's flawed disclosures did not comply with FDA regulations" because "information was incomplete and misleading and did not adequately disclose the Device defects." ¶ 82.

- In a June 24, 2005 patient letter, "Guidant continued to falsely reassure the public that '[t]he safety and well being of patients is foremost in our minds' and that Guidant maintains a 'steadfast dedication to patients.' Letter from Allan Gorsett, Vice President, Reliability and Quality Assurance, Guidant Corp., to Patients with Contak Renewal 1 & 2 Devices at 1 (June 24, 2005)." ¶ 193.

- Based on marketing brochures touting the "long life" of Guidant's ICDs, "Plaintiffs and many other individuals have had to have their devices prematurely explanted long before the expected life of the products had run." ¶ 197.

- "Guidant sales representatives consistently visit with individuals and physicians, attempting to persuade them that, notwithstanding the various FDA Class I recalls, explantation of the Devices is unnecessary." ¶ 200.

- "Plaintiffs relied upon the statements when purchasing the devices and having them implanted in their bodies." ¶ 313.

- Plaintiffs allege that "individuals and physicians remain uninformed and confused about whether the Devices should be explanted, or whether all of the defects have been disclosed." ¶ 199.

None of Plaintiffs' fraud allegations provide particulars concerning any element of any alleged fraudulent acts by any of the Defendants. Plaintiffs do not identify any specific statements made by Defendants; nor do they allege whether any Plaintiff saw and/or heard any alleged statements made by Defendants; nor do they allege when the alleged false statements were made; nor that they justifiably relied on any specific alleged false statements made by Defendants.

Defendants cannot adequately prepare a defense without particularized fraud allegations. There is no indication whether Plaintiffs are alleging that Defendants' sales representatives made statements to doctors, and whether those doctors, in turn, communicated those statements to plaintiffs. Nor is there any indication whether Plaintiffs are alleging direct communications between Defendants' sales representatives and plaintiffs. Nor is there any allegation that Plaintiffs saw or relied upon statements in pamphlets or other device-related literature. Nor have Plaintiffs alleged whether the various types of Defendants' statements were consistent or conflicting. Plaintiffs allege that Defendants' statements caused "confusion," but this allegation may or may not be meant as an allegation of fraud. See, e.g., ¶ 80.

In short, Plaintiffs completely fail to provide the necessary "who, what, when, where and how" required by Rule 9(b).[24] Courts consistently dismiss claims based only on general allegations, which do little more than recite the basic elements of fraud.[25] Indeed, it is well established that when "pleading fraud, a plaintiff cannot make conclusory allegations."[26] Plaintiffs fail to provide even so much as a hint as to the time, place or specific contents of any allegedly false statement or how any alleged fraudulent statement was conveyed to plaintiff. In addition, Plaintiffs fail to adequately plead justifiable reliance--an essential element of fraud.[27] Failure to plead this information violates the requirements of Rule 9(b).[28]

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[24] *See Tuttle*, 118 F. Supp. 2d at 963.

[25] *See Carlon v. Thaman* (*In re Nationsmart Corp.* Sec. Litig.), 130 F.3d 309, 320 (8th Cir. 1997) (upholding dismissal of claims under Rule 9(b) because plaintiff filed claims with necessary specificity); *see also Hayduk v. Lanna*, 775 F.2d 441, 444-45 (1st Cir. 1985).

[26] *See Roberts*, 128 F.3d at 651; *see also Guidry v. Bank of LaPlace*, 740 F. Supp. 1208, 1216 (E.D. La. 1990), aff'd, 954 F.2d 278 (5th Cir. 1992).

[27] *See Clark v. Olson*, 726 S.W.2d 718, 719 (Mo. 1987)(describing elements of fraud claim as including "the hearer's reliance on the truth of the representation ... [and] the hearer's right to rely thereon").

[28] *See Keith v. Stoelting*, 915 F.2d 996, 1000 (5th Cir. 1990); *Wayne Inv., Inc. v. Gulf Oil Corp.*, 739 F.2d 11, 14 (1st Cir. 1984). Failure to properly plead an essential element of a claim subjects the claim to dismissal under Rule 12(b)(6). *See Blackburn v. Marshall*, 42 F.3d 925, 931 (5th Cir. 1995) (dismissal is proper if complaint fails to allege an essential element of the claim); *see also Fleming v. Lind-Waldock & Co.*, 922 F.2d 20, 24 (1st Cir. 1990) (essential element is lacking when plaintiff relies on subjective characterizations or unsubstantiated conclusions).

B. Plaintiffs' failure to plead the elements of any consumer-protection statute violates Rule 9(b).

Plaintiffs assert their claims under the consumer-protection laws of all 50 states in Count VIII: "Defendants' actions . . . constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statues, as listed below . . . ." *See* Master Complaint at ¶ 320. Plaintiffs then summarily list one or more consumer-protection statutes for each state and request that this Court interpret and apply these statutes. *See id*.

Violating Rule 9(b), plaintiffs fail to allege the proper *elements* of each and every statute. This provides the basis for dismissal of Plaintiffs' consumer-fraud claims. As one MDL court noted when it dismissed a similarly poorly pled consumer-fraud claim, "Each state's [consumer-protection] statute is unique and plaintiffs are *required to plead the essential elements of each one*. Plaintiffs have completely failed to do so." *In re Gen. Motors Corp. Anti-Lock Brake Prods. Liab. Litig.*, 966 F. Supp. 1525, 1536 (E.D. Mo. 1997). Thus, because Plaintiffs have failed to plead the "essential elements" of *each* of their consumer-fraud claims, these claims must be dismissed.

Courts require plaintiffs to specifically plead the elements of consumer-protection claims because the elements of consumer-protection laws vary greatly. *Compare* Cal. Bus. & Prof. Code § 17500 (defining "unfair competition" as "dissemination of any statement . . . which is known . . . or *should be known* to be untrue or misleading") *with* Nev. Rev. Stat. Ann. § 598.0903 (2003) (requiring that defendant "knowingly made a false representation in a transaction"). Thus, while some states require a defendant knew

a statement was misleading, others only require that a defendant *should* have known. Still others have *no* scienter element. Some statutes go further and require intent, with regard to "concealments," but no intent to deceive, with regard to "misrepresentations." N.J. Stat. Ann. § 56:8:1.[29]

Here, Plaintiffs' fraud allegations in the Master Complaint lack sufficient particularity under Rule 9(b), leaving Defendants in no position to reasonably and meaningfully respond to and prepare a defense to Plaintiffs' bare-bones allegations of fraud. Because Plaintiffs have not alleged the elements necessary to maintain statutory fraud claims under *each* of the 50 states, Count VIII must be dismissed.

* * *

For the foregoing reasons, Defendants respectfully request that the Court dismiss the following fraud-based claims:

[29] Various states' consumer-protection laws diverge wildly on numerous fronts besides the "scienter" or "level of intent" element. For example, with regard to standing requirements, some statutes limit standing to competitors. *See* Del. Code Ann. Tit. 6 § 2533 (unless action brought by Attorney General on behalf of consumers); Okla. Stat. Ann. Tit. 78, § 53. Others can only be enforced by the Attorney General. *See* Iowa Code § 714.16 (4)-(7); North Dakota Stat. § 51-15-02. Some states do not permit individual plaintiffs to bring class actions. *See* Ala. Code § 8-19-10(f); Ga. Code § 10-1-399(a); Miss. Code Ann. § 75-24-15(4); Mont. Code Ann. § 30-14-133; Ohio Rev. Code Ann. § 1345.09(B). Some states permit a private cause of action only where an administrative order has been violated. *See* Wis. Stat. § 100.20(5). Other states prohibit private actions for damages. *See* Ga. Code Ann. § 10-1-373; Haw. Rev. Stat. Ann. § 481A-4; Me. Rev. Stat. Ann. 10, § 1213 (injunction only remedy under Act). Several states require a plaintiff to provide written notice of their claims before filing a lawsuit. *See* Cal. Civ. Code § 1782; Tex. Bus. & Com. Code Ann. § 17.505. Several other states prohibit a private cause of action unless the alleged unfair or deceptive act impacts the public interest. *See Ly v. Nystrom*, 615

- Fraud (Count VI);
- Constructive Fraud (Count VII);
- Unfair and Deceptive Trade Practices Under State Law (Count VIII);
- Violation of the Senior Citizen and Handicapped Person Consumer Fraud Act Minnesota Statute § 325F.71 And/Or Similar Statutes in Effect in Other Jurisdictions (Count IX);
- Violation of the Minnesota Deceptive Trade Practice Act (Count XVIII);
- Violation of the Minnesota Prevention of Consumer Fraud Act (Count XIX);
- Violation of Minnesota False Statements in Advertising Statute (Count XX);
- Unfair and Deceptive Trade Practices Under State Law (Count XXI); and
- Unjust Enrichment (Count XXIII).

X. CONCLUSION

For the foregoing reasons, Defendants respectfully request that this Court enter the accompanying Proposed Order dismissing Plaintiffs' claims with prejudice, and provide such further relief as the Court deems just and proper.

N.W.2d 302, 314 (Minn. 2000); *Hall v. Walter*, 969 P.2d 224 (Colo. 1998); *Bauer v. Mellon Mortgage Co.*, 680 N.Y.S.2d 397, 400 (N.Y. Sup. Ct. 1998).

Respectfully submitted,
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