UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION

MIRIAM CAVENDER,	)	
	)	
Plaintiff,	)	
v.	)	Case No. 3:16-CV-232
	)	
MEDTRONIC, INC.,	)	
	)	
Defendant.	)	

OPINION AND ORDER

This matter is before the Court on the motion to dismiss and memorandum in support filed by Defendant Medtronic, Inc. (docket entries 21 and 22). Plaintiff Miriam Cavender filed a response in opposition (DE 23) and Medtronic filed a reply (DE 26). For the reasons discussed in this order, the motion is DENIED. The Plaintiff's claims for negligence, negligence *per se*, and breach of express and implied warranties are SUBSUMED by the Indiana Product Liability Act claim and merged into a cause of action under that statute for manufacturing defect, design defect and failure to warn; the motion is DENIED as to the issue of federal preemption. This case will proceed on Plaintiff Miriam Cavender's cause of action under the IPLA.

BACKGROUND

Plaintiff Miriam Cavender had health problems that required surgical implant of a cardiac defibrillator. Her doctors implanted a defibrillator that was manufactured by Medtronic. Cavender alleged that the product "malfunctioned causing . . . Cavender to become [severely] injured as a direct and proximate result of the defective product and hazardous condition of said product." Original Complaint (DE 4), p. 2.[1] She filed this lawsuit on March 24, 2016, asserting

[1] Cavender filed her original Complaint in the St. Joseph Circuit Court and Medtronic removed it to this court on April 21, 2016, on the basis of diversity jurisdiction. Notice of

strict product liability, breach of warranty, and negligence claims against Medtronic. *Id.* Medtronic filed a motion to dismiss Cavender's original Complaint in its entirety on May 31, 2016 (DE 9). The Court issued an Opinion and Order (DE 19), *Cavender v. Medtronic, Inc.*, 2016 WL 6599744 (N.D.Ind. Nov. 8, 2016), concluding that "Cavender's complaint is woefully insufficient under the Rule 12(b)(6) pleading standard and dismissal is warranted[.]" (*id*., p. 4) but that Cavender should be afforded the opportunity to file an amended complaint "in which she shall plead her product liability claims pursuant to the IPLA (to include only claims for manufacturing defect, design defect, or failure to warn) and present facts and clearly articulated legal theories to support any additional claims she contends are valid (be they breach of warranty or violation of FDA or other federal regulation)." *Id*., p. 23. The Court then ruled as follows:

> 1) Plaintiff Miriam Cavender's common law negligence claim is DISMISSED WITH PREJUDICE;
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> 2) Plaintiff's product liability claims and UCC breach of warranty claims are DISMISSED WITHOUT PREJUDICE; and
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> 3) Plaintiff is ordered to file an amended complaint within 30 days of the date of this Opinion and Order, in which she shall plead her product liability claims pursuant to the Indiana Product Liability Act ("IPLA") (to include only claims for manufacturing defect, design defect, or failure to warn), and present facts and clearly articulated legal theories to support any additional claims she contends are valid (be they breach of warranty or violation of FDA regulations). Medtronic is directed to file an answer to plaintiff's amended complaint (or a second motion to dismiss should Defendant conclude that one is necessary) within 30 days from the date of the filing of Plaintiff's amended complaint.

Court's Opinion and Order (DE 19); *Cavender*, 2016 WL 6599744. Cavender filed her Amended Complaint on December 7, 2016 (DE 20). The Amended Complaint, according to Cavender,

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Removal (DE 1).

presents her claims properly and corrects the defects in her original Complaint that the Court identified in its previous order. Not so, contends Medtronic, which filed its renewed motion to dismiss the Amended Complaint. Medtronic contends that the arguments it presented in favor of dismissal the first time are still valid and that Cavender's Amended Complaint, like her original one, fails to state a valid claim and must be dismissed pursuant to Fed.R.Civ.P. 12(b)(6). Medtronic states that "[t]his Court's dismissal order gave Plaintiff a clear mandate: present plausible facts and clearly articulated legal theories. The Amended Complaint . . . does neither." Defendant's Memorandum in Support of Motion to Dismiss (DE 22), p. 1.

STANDARD OF REVIEW

Rule 12(b)(6) allows a defendant to move to dismiss a complaint that has fails to "state a claim upon which relief can be granted." Fed.R.Civ.P. 12(b)(6). When deciding a motion to dismiss under Rule 12(b)(6), the court accepts as true all factual allegations in the complaint and draws all inferences in favor of the plaintiff. *Bielanski v. County of Kane*, 550 F.3d 632, 633 (7th Cir. 2008). The complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed.R.Civ.P. 8(a)(2). In *Bell Atlantic Corp. v. Twombly*, the Supreme Court explained that the complaint must allege facts that are "enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. 544, 555 (2007). Stated differently, the complaint must include "enough facts to state a claim to relief that is plausible on its face." *Hecker v. Deere & Co.*, 556 F.3d 575, 580 (7th Cir. 2009) (internal citation and quotation marks omitted). To be facially plausible, the complaint must allow "the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556).

DISCUSSION

Even though the Court determined that it could not resolve the issues raised in Medtronic's first motion to dismiss since Cavender's original Complaint was too vague, the Court proceeded to "address the legal arguments presented in the motion to dismiss, even though most of them cannot be resolved at this point, in order to provide what the Court hopes will be a framework for streamlining the presentation of Cavender's claims, whatever they may be, and Medtronic's defenses." *Cavender*, 2017 WL 6599744 at * 2. In response to that order, Cavender filed a 31-page Amended Complaint (her original Complaint consisted of four pages) in which she asserts four claims against Medtronic. Cavender's first claim, which she titled "First Claim for Relief (Product Liability)," seeks relief under the Indiana Products Liability Act, based on allegations of strict liability, manufacturing defect, design defect, and failure to warn. Amended Complaint, pp. 23-25. Her "Second Claim for Relief (Breach of Implied and Express Warranties)" asserts claims under the Uniform Commercial Code. *Id*., pp. 25-27. Her "Third Claim for Relief (Negligence)" asserts an Indiana common law negligence claim (*id*., pp. 27-28). And her "Fourth Claim for Relief (Negligence per se)" includes a claim for negligence *per se* that she contends is distinct from her traditional negligence claim because it is based on alleged violations of federal regulations (*id*., pp. 28-29).

Medtronic's present motion to dismiss raises exactly the same issues and incorporates the same arguments as its original motion, and Cavender's Amended Complaint and her brief in opposition to the motion do likewise. The only thing that has changed is that Cavender filed a much longer, more detailed complaint the second time around. The Amended Complaint still includes *all* the same claims Cavender attempted to present in her original Complaint, although

they are dressed in much more elaborate apparel (as Medtronic is quick to point out). In its original motion to dismiss, Medtronic characterized Cavender's original Complaint as "a scattershot" of claims–a characterization this Court concluded was accurate. *Cavender*, 2017 WL 6599744 at *3. Cavender's Amended Complaint does not take a similar scattershot approach, seeing as it organizes her claims neatly and provides an abundance of specific factual allegations that were conspicuously (even fatally) absent from her first attempt. That said, the Amended Complaint still takes the proverbial "kitchen sink" or "throw it all against the wall" approach. This is evidenced by the fact that the Amended Complaint still includes claims that this Court already dismissed the first time around, as well as claims with doubtful legal foundation (as in her breach of warranty claims), all of which were discussed at some length in the Court's previous order. On the other hand, Cavender's Amended Complaint sets forth her claims with much more specificity, both in terms of factual assertions and legal theories, which is a huge improvement over her original Complaint, and so the Court can turn to assessing the sufficiency of those claims in light of the motion to dismiss.

Before turning to the dispositive issues the Court must clear away some dust. In its memorandum in support of its motion, Medtronic begins by attacking Cavender's Amended Complaint for two reasons: first, because it "now alleges that a different Medtronic device, the Sprint Fidelis 6949 Lead, injured her[,]" whereas her original Complaint stated that her injuries were caused by a Medtronic "Viva XT CRT-D Defibrillator[,]" (Defendant's Memorandum, pp. 2-3); and second, because it "mirrors the Master Consolidated Complaint relating to the Leads that has already been fully litigated and dismissed–***with prejudice at the pleading stage***." *Id*., p. 4 (citing *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F.Supp.2d 1147

(D.Minn. 2009))[2] (emphasis in original). Medtronic attached to its memorandum a copy of the Master Complaint filed in the multidistrict *Medtronic Leads* litigation (more on that below) and notes that Cavender's Amended Complaint is a "copy and paste" version of it. *See*, *e.g.*, Defendant's Memorandum, pp. 4-5 (comparing language in Master Complaint to language in Cavender's Amended Complaint). Both of Medtronic's contentions are correct but ultimately not relevant. They are included for the purpose of casting aspersions on Cavender's Amended Complaint by drawing attention to what this Court has already referred to as Cavender's elaborate window dressing of her claims. In other words, while the claims contained in her original Complaint were barely discernible, they now jump vividly off the page in full regalia, all because they are clothed in language taken–largely verbatim–from another complaint filed against Medtronic that was summarily dismissed by another district court eight years ago. Cavender responds to these contentions by arguing "so what?" She explains that she now alleges that her injuries were caused by a different Medtronic device simply because she "found that the product alleged in the Original Complaint, the Viva XT CRT-D Defibrillator, was in error because it did not encompass the Leads (the wires that are part of the defibrillator) and Plaintiff's claims relate more specifically to the Leads." Plaintiff's Response, p. 3. Cavender states that she "amended her Complaint to allege the specific product[,]" that "[b]ecause the statute of limitation has not run, the correction does not prejudice Medtronic[,]" and "because Plaintiff was not part of the MDL actions, the Eighth Circuit decisions do not prevent Plaintiff from bringing her claims." *Id*. Cavender admits that her Amended Complaint names a different (or at least more

[2] The district court decision was affirmed by the Eighth Circuit. *Medtronic Leads*, 623 F.3d 1200 (8th Cir. 2010).

specific) Medtronic product and that it mirrors the Master Complaint from the *Medtronic Leads* litigation. It does the latter, Cavender maintains, because "many of the same factual assertions [in] the MDL Complaint . . . apply to Plaintiff's case and claims." *Id*.[3] But these arguments about the language in Cavender's Amended Complaint threaten to distract from the overarching issue here, which is the sufficiency of Cavender's allegations, as presented in her Amended Complaint (even if it is not an entirely original piece of prose), under the prevailing Rule 12(b)(6) standard of review. Medtronic continues to insist that the emperor has no clothes and that all of Cavender's claims, notwithstanding their new attire, should be dismissed for the same reasons presented in the company's original motion. Those reasons, again, are that Cavender's negligence claims are not cognizable, her breach of warranty claims "still sound in tort[]" and "are therefore still subsumed by the IPLA[,]" her claims "are based on nothing more than generic allegations . . . ," and that *all* her claims are preempted by the federal Medical Device Amendments. Defendant's Reply, pp. 1-2.

I. Applicable law.

Resolution of the issues raised by Medtronic's motion to dismiss requires application of state and federal statutes and an understanding of the interplay between them. Those statutes, of course, are the Indiana Product Liability Act, I.C. § 34-20-1-1, *et seq*., and the Medical Device Amendments to the Food, Drug and Cosmetics Act, 21 U.S.C. § 360c *et seq.*

A. IPLA subsumption.

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[3] Medtronic does not argue that the district court or Eighth Circuit opinions in the *Medtronic Leads* litigation have precedential effect–that is, the company does not argue that the holdings in those cases mandate dismissal of this one–but does contend that those opinions are instructive since they address all the same claims and defenses presented in this case.

The IPLA expressly states that "[t]his [Act] governs all actions that are: (1) brought by a user or consumer; (2) against a manufacturer or seller; and (3) for physical harm caused by a product; regardless of the substantive legal theory or theories upon which the action is brought." Ind. Code § 34-20-1-1. This means that the "IPLA subsumes both strict liability and negligence actions[.]" *Lyons v. Leatt Corp*., 2015 WL 7016469, at *2-3 (N.D.Ind. Nov. 10, 2015) (citing *Gardner v. Tristar Sporting Arms, Ltd.*, 2010 WL 3724190, at *2 (S.D.Ind. Sept. 15, 2010)). A plaintiff who alleges that a product was defective due to a manufacturing defect, design defect, or failure to warn, states claims "that are all recognized under IPLA." *Id*. (citing *In re Lawrence W. Inlow Accident Litig.*, 2002 WL 970403, at *12 (S.D.Ind. Apr.16, 2002)) (stating that IPLA governs all actions "for physical harm brought by a consumer against a manufacturer or seller of a product, regardless of the substantive legal theory"). *Id.* "A product may be defective within the meaning of IPLA because of a manufacturing flaw, a design defect, or a failure to warn of the dangers associated with the product's use." *Id*. (citing *Cook v. Ford Motor Co.*, 913 N.E.2d 311, 319 (Ind.Ct.App. 2009)). "Under the IPLA, a strict liability standard applies to manufacturing defect claims . . . whereas a negligence standard applies to design defect and failure to warn claims." *Gardner*, 2010 WL 3724190, at *2 (citing *Myers v. Briggs & Stratton Corp.*, 2010 WL 1579676, at *3 (S.D.Ind. April 16, 2010); *Burt v. Makita USA, Inc.*, 212 F.Supp.2d 893, 897 (N.D.Ind. 2002)).

In *Lyons*, the plaintiff brought a product liability action and included in his complaint claims for negligence, gross negligence, strict liability, and breach of warranty. This Court (Judge Springmann) held as follows:

While the Defendant is correct that IPLA subsumes both strict liability and

> negligence actions, *see Gardner* . . . , 2010 WL 3724190, at *2 . . . , dismissal is improper here. First, when viewing the allegations in a light most favorable to the non-movant, the Plaintiff has satisfied the general pleading standards by stating a plausible claim for relief–namely, that he suffered physical harm due to the Defendant's defective product. Accordingly, the Plaintiff's strict liability and negligence claims are properly treated as merged claims under IPLA.

Lyons, 2015 WL 7016469, at *2-3 (citing *Atkinson v. P & G-Clairol, Inc.*, 813 F.Supp.2d 1021, 1024 (N.D.Ind. 2011); *Cincinnati Ins. Cos. v. Hamilton Beach/Proctor-Silex, Inc.*, 2006 WL 299064, at *3 (N.D.Ind. Feb.7, 2006); *Bourne v. Marty Gilman, Inc.*, 2005 WL 1703201, at *3 n. 2 (S.D.Ind. July 20, 2005)). Medtronic argues that the law is clear and well established, and that Cavender's claims–whether based on a negligence theory, strict liability theory, or breach of warranty theory–are all subsumed by the IPLA, which is her only vehicle for bringing a claim for personal injuries caused by an allegedly defective product. As this Court noted in *Atkinson*, "it is . . . proper for [plaintiff's] claims of strict liability and negligence to be merged into one claim under the IPLA. . . . Therefore, [plaintiff's] claims of negligence and strict liability . . . will be incorporated to form one products liability claim under the IPLA." *Atkinson*, 813 F.Supp.2d at 1024 (citing *Am. Int'l Ins. Co. v. Gastite*, 2009 WL 1383277 at *4 (S.D.Ind. May 14, 2009); *Bourne*, 2005 WL 1703201 *3 at n. 2; *Henderson v. Freightliner, LLC*, 2005 WL 775929, at *3 (S.D.Ind. Mar. 24, 2005); *Tungate v. Bridgestone Corp.*, 2004 WL 771191, at *6 (S.D.Ind. Mar. 26, 2004)).

In the present case, Cavender has unquestionably alleged that she suffered personal injuries proximately caused by Medtronic's allegedly defective product. She was admonished by the Court in its previous order for not presenting these claims as an action under the IPLA. In her Amended Complaint she pleads exactly such an action, but also includes a negligence claim and

attempts to *add* a negligence *per se* claim, apparently as independent creatures separate from her IPLA claim. But the law regarding IPLA subsumption is clear and Cavender's claims for personal injury, whether based on a theory of strict liability, negligence, or negligence *per se*, (or even breach of warranty, as discussed below) are subsumed by the IPLA and merged into an action for damages pursuant to that statute.

1. Common law negligence claim.

Cavender's claims for negligence and negligence *per se* should not have been included in her Amended Complaint. Cavender concedes that her "third claim for relief," i.e., her common law negligence claim, "was mistakenly included in Cavender's Amended Complaint." Plaintiff's Response, p. 4. Cavender admits that "this Court stated in its prior Order [that the] IPLA subsumes negligence claims made under state law and this Court's prior dismissal with prejudice applies to Count III of the Amended Complaint." *Id*. Indeed, the Court dismissed this claim in its previous order. While it is difficult to discern any practical difference between dismissal of this claim and its merger or subsumption into the IPLA, courts in this circuit have held routinely that merging claims into a single IPLA action (whether it is based on theories of manufacturing defect, design defect, failure to warn, or a combination thereof) is preferable and more proper than outright dismissal. "Plaintiffs' common law claims and breach of implied warranty claims are in effect superseded by or merged into their statutory product liability claims, so the case will proceed on only the statutory claims." *Lyons*, 2015 WL 7016469, at *3. "Because Counts I-IV of the Plaintiff's Complaint are properly treated as merged under IPLA, the Defendant's request to dismiss such counts is denied." *Henderson*, 2005 WL 775929, at *1. "[The] motions for summary judgment are denied with the qualification that plaintiff's common law and breach of

implied warranty claims are superseded by their statutory claims. The case will proceed to trial on the statutory product liability claims only." *Id*. at * 18. This Court, then, will follow suit and hold that Cavender's common law negligence claim is subsumed and merged into her cause of action under the IPLA (notwithstanding the fact that a negligence claim, in and of itself, is not cognizable under that statute).

2. Negligence *per se* claim.

While Cavender concedes that she cannot assert a common law negligence claim, she does not offer the same concession as to her claim for negligence *per se*, arguing that it is a valid claim because it "alleges negligence *per se* for violations of the Federal laws and regulations applicable to the [defibrillator]." Plaintiff's Response, p. 3. She further claims that Medtronic's alleged "violations of the Federal requirements remove any immunity granted to Medtronic." *Id*. In other words, Cavender claims that her common law claim for negligence *per se* is somehow transformed into a claim that escapes IPLA subsumption because it is founded on allegations that Medtronic violated *federal* regulations. Medtronic argues that "[t]he fact that Plaintiff asserts her claim here is based on federal law violations does not mean negligence *per se* is not a common law negligence theory. . . . Negligence–*per se* or otherwise–is not a federal tort claim, but rather a common law negligence claim." Defendant's Reply, p.1. Cavender's argument that such a claim is valid because it is based on violations of federal regulations "creates a false distinction[]" between a common law negligence claim and a federal tort claim. *Id*., p. 3 (citing *Moore v. Hamilton Se. Sch. Dist.*, 2013 WL 4607228, at *10 (S.D.Ind. Aug. 29, 2013)) ("Negligence per se under state tort law can be premised on the violation of a federal statute, with the statute providing the standard of conduct and *state common law* furnishing the other elements of the

tort.") (italics added). Stated differently, Medtronic is arguing that Cavender is trying to mask a state law negligence claim as something else–a sort of hybrid state law/federal law claim that is *not* subsumed by the IPLA (which she concedes *does* subsume her other negligence claim). Medtronic says it must be dismissed because Cavender's new negligence *per se* claim is just another way of alleging *any* common law negligence claim, and because this Court, in its prior Opinion and Order, held that "'[o]n this issue Medtronic is correct–the IPLA subsumes Cavender's common law negligence claim. For this reason, ***any*** common law negligence claim Cavender includes in her complaint must be, and is hereby ***dismissed with prejudice***.'" Defendant's Memorandum in Support, p. 6 (quoting this Court's Opinion and Order (DE 19), p. 14) (boldface and italics in memorandum).[4] Just because Cavender claims she is basing her negligence *per se* claim on alleged violations of federal regulations does not magically transform a common law negligence claim into a different claim that then sneaks under the fence of the IPLA, which is expressly intended to subsume all such common law claims. Cavender also argues that because her negligence *per se* claim is based on alleged violations of federal regulations it "remove[s] any immunity granted to Medtronic." But this argument is convoluted. While it is true that certain claims based on alleged violations of federal regulations *might* escape the preemptive clutches of § 360k (as discussed below), that is a separate issue entirely from whether Cavender's claim is subsumed by the IPLA. The Court addressed this issue in its previous order, explaining as follows:

[4] Again, notwithstanding the Court's dismissal of all of Cavender's claims in her original Complaint, which was based solely on that Complaint's failure to meet the Rule 12(b)(6) pleading standard, the claims included in her Amended Complaint, which *do* meet that standard, are now more properly merged into her IPLA claim rather than dismissed.

> In pleading the negligence and strict liability counts, the [plaintiffs] allege the same basic facts regarding the design and manufacture of the [product] and describe the same resulting physical harm from its alleged malfunction. Each count aligns with the requirements of [the IPLA] with an identical set of facts. Each claim is asserted by the same consumer against the same manufacturer for the same physical harm caused by the same product. Though the [plaintiffs] have alleged underlying theories that include design defects, manufacturing defects, and negligence, the [IPLA] explicitly states that it governs "regardless of the substantive legal theory upon which the action is brought." Consequently, the [plaintiffs'] negligence claim . . . duplicates the strict liability claim. . . .

Cavender, 2016 WL 6599744 at *7 (quoting *Hamilton Beach/Proctor-Silex*, 2006 WL 299064 at *2). Cavender's arguments boil down to this. She concedes that her regular, run-of-the-mill state law negligence claim is subsumed by the IPLA and should not have been included in her Amended Complaint. But then she contends that her new claim for negligence *per se* survives on its own, is not subsumed by the IPLA because its factual foundation consists of allegations of violations of federal regulations, and that it escapes § 360k preemption to boot. Such a bulletproof claim would be a boon to plaintiffs like Cavender, but no such claim is cognizable under Indiana law or the facts of this case. Cavender did not include a negligence *per se* claim in her original Complaint and her attempt to add it now cannot stand. Anyway, based on the facts of this case, this claim is nothing more than another way of stating a product liability claim for personal injury. Just like her negligence claim, it is not a cognizable independent claim and is subsumed by the IPLA.

3. UCC breach of warranty claims.

Cavender's Amended Complaint, like her original one, includes claims for breach of warranty under the Uniform Commercial Code. Medtronic seeks dismissal of these claims for the same reasons set forth in its original motion; that is, the claims are subsumed by the IPLA and/or

preempted by federal law and/or fail to state a claim for several other reasons (including lack of notice and lack of privity). Defendant's Memorandum, pp. 7-9.

The issue of IPLA subsumption gets a bit stickier when a plaintiff asserts breach of warranty claims against the manufacturer of a product. As Judge Springmann explained in *Lyons*:

> As the Indiana Supreme Court has noted, "several federal district courts and other panels of the [Indiana] Court of Appeals have held that tort-based breach of warranty claims have been subsumed into the [IPLA]." *Kovach v.* [*Caligor*] *Midwest*, 913 N.E.2d 193, 197 (Ind. 2009); *see, e.g.*, *Atkinson*, 813 F.Supp.2d at 1024; *Gardner*, 2010 WL 3724190, at *2-3; *Henderson v. Freightliner, LLC*, . . . 2005 WL 775929, at *3 (S.D.Ind. Mar. 24, 2005). Conversely, breach of warranty claims alleged under Indiana's Uniform Commercial Code (UCC) are deemed independent from IPLA. *Atkinson*, 813 F.Supp.2d at 1024 (noting that the Indiana Supreme Court has established that different damages are available for a defective product under tort and contract law).
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> Here, despite the Plaintiff's use of language that may suggest a contract-based claim (i.e., "reasonably fit for the general uses and purposes intended"), the Amended Complaint contains no additional facts to support a breach of warranty claim based in contract. Notably, in his brief, the Plaintiff failed to respond to the Defendant's argument that the breach of warranty claim sounds in tort. As such, the Court will construe Count II as "an incorrectly labeled strict product liability claim," *see B & B Paint Corp. v. Shrock Mfg., Inc.*, 568 N.E.2d 1017, 1019 (Ind.Ct.App. 1991), and therefore, will treat Count II as merged . . . under IPLA.

Lyons, 2015 WL 7016469, at *2-3.

So, *some* breach of warranty claims are subsumed by the IPLA and *some* are not. "To be clear, a contractual breach of warranty claim would not be governed by the IPLA, but as this court has explained, when the claim, as here, is for tortious personal injury, the breach of warranty claim is subsumed by the IPLA." *Piltch v. Ford Motor Co.*, 11 F.Supp.3d 884, 888 (N.D.Ind. 2014), aff'd, 778 F.3d 628 (7th Cir. 2015) (citing *Hathaway v. Cintas Corporate Services, Inc.*, 903 F.Supp.2d 669, 673 (N.D.Ind. 2012)). This Court also addressed breach of warranty claims in *Atkinson*, explaining as follows:

> As the Supreme Court of Indiana observed, district courts within the bounds of the Seventh Circuit Court of Appeals have found that the IPLA supplants breach of implied warranty claims. *See e.g., Henderson*, 2005 WL 775929, at *3; *Gardner v. Tristar Sporting Arms*, 2010 WL 3724190, at *2-3 (S.D.Ind. Sept. 15, 2010). District courts and Indiana appellate courts have clarified that while breach of implied warranty claims that sound in tort are redundant with strict liability claims under the IPLA, "claims under the IPLA are independent from breach of warranty claims alleged under Indiana's adoption of the [UCC]." *Cincinnati Ins. Cos. v. Hamilton Beach/Proctor-Silex, Inc.*, 2006 WL 299064, at *3 (N.D.Ind. Feb. 7, 2006); *Gastite*, 2009 WL 1383277, at *3 n. 1 (stating that "[a]lthough the IPLA provides a single cause of action for a user seeking to recover in tort" for harm caused by a defective product, "a plaintiff may maintain a separate cause of action under a breach of warranty theory" because "[t]he adoption of the IPLA did not invalidate the provisions of the UCC."); *Hitachi Constr. Mach. Co. v. AMAX Coal Co.*, 737 N.E.2d 460, 465 (Ind.Ct.App. 2000) (quoting *B & B Paint Corp. v. Shrock Mfg., Inc.*, 568 N.E.2d 1017, 1020 (Ind.Ct.App.1991)) ("The UCC and the [IPLA] provide alternative remedies. The adoption of the [IPLA] did not vitiate the provisions of the UCC."). An Indiana appellate court has explained that "a breach of warranty claim should be treated as a contractual claim when it is not merely an incorrectly labeled strict product liability claim." *B & B Paint Corp.*, 568 N.E.2d at 1019.

Atkinson, 813 F.Supp.2d at 1023-25.

Cavender's breach of warranty claims are no different from those presented in many of the cases discussed or cited above–product liability claims for personal injuries disguised as warranty claims by a plaintiff attempting to avoid subsumption of those claims by the IPLA or preemption of them by the MDA. But if it walks like a duck and quacks like a duck, it's a tort–not a breach of warranty claim–and it is subsumed by the IPLA. It is very telling that Cavender, like the plaintiff in *Lyons*, "failed to respond to the Defendant's argument that the breach of warranty claim sounds in tort." Cavender works hard to convince the Court that her breach of warranty claims are distinct from her tort claim for various reasons (*see* Plaintiff's Response, pp. 7-11), but she shies away from even attempting to refute the obvious–her

allegations not only sound in tort, they scream in tort. They are "merely . . . incorrectly labeled strict product liability claim[s]." For these reasons, Cavender's claims for breach of implied and express warranties are subsumed by the IPLA.

II. Medical Device Amendments preemption.

Having concluded that Cavender has sufficiently pleaded a cause of action under the IPLA, the Court now must determine whether that cause of action is preempted altogether.[5] The good news is that there is plenty of case law discussing the issue of preemption under the MDA. The bad news is that this abundance of case law reveals that the issue is about as clear as mud. To make it a bit less opaque, the Court begins with a review of the MDA.

The Medical Device Amendments to the FDCA give the Food and Drug Administration the authority to regulate medical devices like the Medtronic Leads at issue in this case. 21 U.S.C. § 360c *et seq.* The MDA established different levels of scrutiny to be applied to various medical devices before they are approved for marketing. 21 U.S.C. § 360c(a)(1). The highest level of

[5] There is a tangential issue in this case regarding preemption. Cavender points out that "[p]reemption is an affirmative defense, which pleadings need not anticipate or attempt to circumvent, and does not justify a dismissal under Rule 12(b)(6)." Plaintiff's Response, p. 4. She contends that she should not have to "defend" against an affirmative defense at this stage, thus the Court should not consider the defense as a basis for dismissal. She is correct, of course, and Medtronic does not take issue with that statement of law, but argues that since Cavender "admittedly copied and pasted the very detailed, dismissed MDL complaint relating to this Lead[,]" she has, "[u]nder Seventh Circuit law . . . pled enough facts for the Court to consider the affirmative defense of preemption." Defendant's Reply, p. 2. That is, since the matter of preemption was discussed and analyzed in the *Medtronic Leads* MDL case–the very case from which Cavender scavenged her Amended Complaint–the general rule that a plaintiff's complaint does not have to anticipate or refute affirmative defenses is not applicable here and Cavender cannot use it as a "defense to the defense," as it were. After all, this issue of the affirmative defense afforded under § 360k continues to be widely litigated; it is part and parcel of any case involving a Class III medical device. However, given that the Court finds that Cavender's IPLA claims are not preempted, at least for purposes of the motion to dismiss, this issue is rendered irrelevant.

scrutiny is applied to devices that are "purported or represented to be for a use in supporting human life or for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury. . . ." 21 U.S.C. § 360c(a)(1)(c)(ii). Such devices are deemed to be "Class III" medical devices. (It is undisputed that the Leads at issue here–and in fact the entire defibrillator–is a Class III medical device.) Class III medical devices are subject to a premarket approval process set forth in the MDA. "That process is designed to 'provide reasonable assurance' of the device's safety and efficacy." *Ilarraza v. Medtronic, Inc*., 677 F.Supp.2d 582, 585 (E.D.N.Y. 2009) (quoting 21 U.S.C. § 360(a)(C)(ii)(II)). The court in *Ilarraza* included an excellent discussion of the history of MDA preemption, explaining as follows:

> The MDA premarket approval of Class III medical devices is a "rigorous" process that typically requires submission of a multivolume application that includes reports of safety and efficacy studies, an explanation of the devices' components as well as details regarding its manufacturing, packaging and installation. *See generally* 21 U.S.C. § 360e; *Riegel* [*v. Medtronic, Inc*., 552 U.S. 312, 317] 128 S.Ct. [999] at 1004 [(2008)]. It is only after premarket approval that the manufacturer may begin to manufacture and market the device. After premarket approval, there can be no change in the design, manufacturing or labeling of a medical device that would affect safety or effectiveness of the device, absent further review and approval by the FDA. *Riegel*, 128 S.Ct. at 1005.
> . . .
>
> The MDA was passed in response to the introduction of sophisticated medical devices, the risks of which were not properly managed by state law tort systems. *See Riegel*, 128 S.Ct. at 1003. The statute's comprehensive review process ensures the safety and efficacy of medical devices that were previously subject to a patchwork of state tort law. *See Riegel*, 128 S.Ct. at 1003. To ensure uniformity in the safety and efficacy standards to which medical devices would be held, Congress included an express preemption provision in the statute. That section of the MDA provides, in relevant part, that:
>
> > [N]o State or political subdivision of a State may establish or continue in effect with respect to [medical devices covered by the MDA] any

> requirement–
>
> (1) which is different from or in addition to, any requirement applicable under [the MDA] to the device, and
>
> (2) which relates to the safety or effectiveness of the device or any other matter included in a requirement applicable to the device[.]
>
> 21 U.S.C. § 360k(a).
>
> The Supreme Court has considered the question of whether the MDA preemption provision bars a state law tort action based upon common law principles of negligence, breach of warranty and strict liability. In *Riegel*, the Court held clearly that such claims were barred by the preemption clause of the MDA. The Court focused on the fact that the MDA preemption clause bars the imposition only of requirements that "are different from, or in addition to" requirements imposed by Federal law. *Riegel*, 128 S.Ct. at 1011. The imposition of the tort standards of fifty different states would clearly run afoul of the statutory preemption.
>
> The Court went on to hold that the MDA preemption provision does not bar a state from imposing a damages remedy for a claim premised on the violation of federal law. In such a lawsuit, the plaintiff would seek damages for the violation of federal, and not state law–duties that the Court referred to as "parallel" to FDA requirements. *Riegel*, 128 S.Ct. at 1011. Thus, the court left open a narrow class of state court actions that could seek damages for injuries alleged to have been caused by federally regulated medical devices. Such lawsuits can be referred to as "parallel" actions. *See In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation*, 592 F.Supp.2d 1147, 1152 (D.Minn. 2009) (referring to narrow "back door" left open by *Riegel*).

Ilarraza, 677 F.Supp.2d at 585-86. In *Ilarraza*, the plaintiff brought suit against Medtronic for personal injuries allegedly sustained when a Class III medical device, in that case a surgically implanted medication pump, failed to function properly as a result of Medtronic's alleged failure to comply with several FDA regulations. In his amended complaint, Mr. Ilarraza asserted only one claim, which he titled "'Negligence Per Se (A 'Parallel Action')." *Id*. at 585 (quoting plaintiff's amended complaint). The district court concluded that the claim was preempted under § 360k because the plaintiff "fails to state a parallel claim. This is because no regulation relied

upon refers specifically to the medical device at issue here." *Id*. at 588. The court then held that since the plaintiff's complaint failed to allege that any of the federal regulations he claimed were violated applied directly to the implanted medication pump about which he complained, he thereby did "nothing more than engage [in] a 'formulaic recitation of the elements of a cause of action.' . . . Where, as here, the plaintiff has done nothing more than recite unsupported violations of general regulations, and fails to tie such allegations to the injuries alleged, the complaint is properly dismissed." *Id*. (quoting *Twombly*, 550 U.S. at 555).

In arriving at that conclusion, the court in *Ilarraza* cited approvingly the district court's decision dismissing the complaint in *Bausch v. Stryker Corp*., 2009 WL 2827954 (N.D.Ill. Aug 31, 2009). However, that decision was subsequently overturned by the Seventh Circuit, which in turn cited *Ilarraza* and expressly rejected its reasoning. *See Bausch*, 630 F.3d 546, 554 (7th Cir. 2010), cert. denied, 565 U.S. 976 (2011) ("[W]e essentially agree with Judge Melloy's dissent in *Medtronic Leads.* Judge Melloy argued that the plaintiffs could not be expected to plead their claims with greater specificity without discovery to obtain access to confidential government and company documents."). In other words, the Seventh Circuit took a decidedly different approach to the issue of MDA preemption as it applies to state law claims than did the court in *Ilarraza* or the Eighth Circuit in the *Medtronic Leads* litigation, and Cavender's argument in opposition to preemption turns on that difference.

The *Medtronic Leads* case involved multiple suits by plaintiffs who claimed they suffered personal injuries after implantation of the Sprint Fidelis 6949 Lead, the same product at issue in this case. The plaintiffs asserted claims for negligence, negligence *per se*, failure to warn, defective design, manufacturing defect, and breach of warranty, just as Cavender does in this

case. The district court dismissed all of the plaintiffs' claims, holding that they were preempted by the MDA, and the Eighth Circuit affirmed. *Medtronic Leads*, 623 F.3d 1200 (8th Cir. 2010). The appellate court concluded that § 360k preemption applied across the board and precluded all of the plaintiffs' claims.

Cavender states that the *Medtronic Leads* case has no precedential authority and so does not preclude her from bringing her claims in a court in the Seventh Circuit, and she insists that the *Bausch* decision provides her a path forward. Cavender is correct on both counts. Cavender's claims would likely not survive a motion to dismiss if this case was pending in a court in the Eighth Circuit (or perhaps the Eastern District of New York). In the Seventh Circuit, however, the issue of MDA preemption is not as black and white.

In *Bausch*, the plaintiff brought suit against Stryker Corporation, the manufacturer of a hip replacement device that was implanted in Ms. Bausch, asserting common law negligence claims (under Illinois state law) and product liability claims. Stryker moved to dismiss Bausch's complaint under Rule 12(b)(6), arguing that her common law claims were preempted by federal law (i.e., the MDA) and that her complaint failed to meet the Rule 12(b)(6) pleading threshold. The district court granted Stryker's motion to dismiss but the Seventh Circuit reversed, concluding that while Bausch's complaint was admittedly thin on factual allegations, the facts pled were sufficient to meet the pleading standard under Rule 12(b)(6). The facts contained in the complaint included the following:

1) Stryker Corporation manufactured the hip replacement product that was implanted in Bausch;

2) the device was "a Class III medical device subject to the authority of the FDA[]";

3) prior to Bausch's surgery, Stryker had received reports that its hip replacement product failed

after implantation and the company had recalled a portion of the products;

4) prior to Bausch's surgery, the FDA conducted an investigation and issued a letter to Stryker in which the Agency warned that the company's hip replacement device was "adulterated" as a result of improper manufacturing processes;

5) the Stryker hip replacement device implanted in Bausch failed to function properly; and

6) the Stryker device implanted in Bausch was later subject to a recall.

Bausch, 630 F.3d at 559. The district court agreed with Stryker's argument that these factual allegations were insufficient to state a claim since they failed to "specify the precise defect or the specific federal regulatory requirements that were allegedly violated." *Id*. at 560. The Seventh Circuit rejected that conclusion and wrote that "[w]e do not see a fatal defect in the original complaint that would have justified its dismissal, let alone entry of a final judgment dismissing the action with prejudice." *Id*. at 559. The court explained its holding as follows:

> The original complaint served the purposes of Rule 8 of giving the defendants fair notice of the nature of the claim against them and of stating a claim for relief that was "plausible on its face" as required by *Iqbal* and *Twombly.* In deciding whether a complaint can survive a motion to dismiss, we have consistently said: "As a general rule . . . notice pleading remains the standard." *Windy City Metal Fabricators & Supply, Inc. v. CIT Tech. Financing Services*, 536 F.3d 663, 667 (7th Cir. 2008). Pursuant to Rule 8, pleading is meant to "'focus litigation on the merits of a claim' rather than on technicalities that might keep plaintiffs out of court." *Brooks v. Ross*, 578 F.3d 574, 580 (7th Cir. 2009), quoting *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 514, 122 S.Ct. 992, 152 L.Ed.2d 1 (2002). We give the plaintiff "the benefit of imagination, so long as the hypotheses are consistent with the complaint." *Bissessur v. Indiana Univ. Bd. of Trs.*, 581 F.3d 599, 603 (7th Cir. 2009), quoting *Sanjuan v. American Bd. of Psychiatry and Neurology, Inc.*, 40 F.3d 247, 251 (7th Cir. 1994). "Together, these rules ensure that claims are determined on their merits rather than on pleading technicalities." *Christensen v. County of Boone*, 483 F.3d 454, 458 (7th Cir. 2007).
> . . .
>
> Defendants object that the original complaint does not specify the precise defect

> or the specific federal regulatory requirements that were allegedly violated. Although the complaint would be stronger with such detail, we do not believe the absence of those details shows a failure to comply with Rule 8 of the Federal Rules of Civil Procedure or can support a dismissal under Rule 12(b)(6). First, Rule 9(b) does not impose any special requirement that such a claim be pled with particularity, as it does for fraud claims, for example.
>
> Second, the victim of a genuinely defective product–for example, an air bag that fails to inflate in a serious automobile collision, or an implantable cardiac defibrillator that delivers powerful electric shocks to a heart that is functioning normally–may not be able to determine without discovery and further investigation whether the problem is a design problem or a manufacturing problem. . . .
>
> Third, in the context of Class III medical devices, much of the critical information is kept confidential as a matter of federal law. The specifications of the FDA's premarket approval documents, for example, are confidential, and there is no public access to complete versions of these documents. An injured patient cannot gain access to that information without discovery. See 21 C.F.R. § 814.9; [*In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*], 623 F.3d [1200,] 1211 n. 7 (Melloy, J., dissenting). If the problem turns out to be a design feature that the FDA approved, section 360k will protect the manufacturer. *Riegel,* 552 U.S. at 330, 128 S.Ct. 999. But if the problem turns out to be a failure to comply with the FDA's legally enforceable conditions for approval of the device, section 360k will not protect the manufacturer.

Bausch, 630 F.3d at 559-60. Based on that reasoning, the Seventh Circuit concluded that Bausch's complaint survived Stryker's motion to dismiss. *See*, *Laverty v. Smith & Nephew, Inc*., 197 F.Supp.3d 1026, 1032 (N.D.Ill. 2016) ("The Seventh Circuit disagreed with the notion that section 360k leaves no room for common law products liability claims and found that the plaintiff's claims were not expressly preempted under the MDA."); *see also*, *Waltenburg v. St. Jude Med., Inc*., 33 F.Supp.3d 818, 828 (W.D.Ky. 2014) (recognizing that the Seventh Circuit, as a result of *Bausch*, "require[s] the least specificity to plead a claim that will survive a motion to dismiss[,]" based on preemption, while "the other end of the spectrum is the Eleventh Circuit's decision in *Wolicki–Gables v. Arrow International, Inc.*, a decision which set forth a standard

requiring the highest degree of pleading specificity." *Waltenburg*, (citing *Wolicki-Gables*, 634 F.3d 1296 (11th Cir. 2011)).

Medtronic argues that *Bausch* is inapplicable since that decision was based largely on the fact that the plaintiffs had pleaded sufficiently "commensurate with the amount of information they can access prior to discovery," which Medtronic contends is not as much of a hindrance to Cavender as it was to the plaintiff in *Bausch*. Medtronic argues that "*Bausch* is distinguishable from this case because of the unique, fully-developed litigation landscape. The *Bausch* court was concerned that plaintiffs would be barred from stating claims through no fault of their own because they do not have access to key records or documents. Here, there is no uncertainty about the claims Plaintiff is trying to assert. She is trying to assert the same, detailed and developed facts from the MDL Complaint." Defendant's Memorandum, p. 15. In other words, Cavender does not face the same challenge as the plaintiff in *Bausch* because even if she proceeded to the discovery phase she would be unable to uncover any evidence that would allow her to state a claim that would survive preemption, and so this Court should adopt the approach taken by the Eighth Circuit in *Medtronic Leads* and find that her claims are preempted. Cavender responds by noting that the Seventh Circuit in *Bausch* discussed the Eighth Circuit's decision in the *Medtronic Leads* litigation, expressly disagreed with it, and even went so far as to cite Judge Melloy's dissent as the basis for its holding. Plaintiff's Response, p. 6 ("*Bausch* squarely addressed *Medtronic Leads* and agreed with Judge Melloy's dissent."). So, concludes Cavender, "Medtronic is therefore wrong to claim that *Bausch* does not compel a result different from that in *Medtronic Leads*." *Id*. The Court agrees that *Bausch* precludes dismissal of Cavender's IPLA claim at this point and the motion to dismiss must be denied as to the issue of federal preemption

of that claim.

The Court concludes that Cavender has pleaded sufficient facts to satisfy the federal pleading standard and survive the Rule 12(b)(6) motion. Cavender's Amended Complaint clearly states a product liability claim for personal injuries under the IPLA, which also survives preemption. Her Amended Complaint does not lack specificity as did her original Complaint. In fact, the Amended Complaint (like the Master Complaint after which it is modeled) begins with a detailed history of the development of the Medtronic defibrillator leads, alleges that one of the leads in Cavender's implanted device broke or failed in 2015 (it was originally implanted in 2004), and, most importantly, pleads detailed facts supporting her allegations that Medtronic intentionally withheld crucial information about the Leads from the FDA, failed to implement proper manufacturing processes, that the FDA issued a recall of all Sprint Fidelis leads in October 2007, and that Medtronic violated several FDA regulations by not following prescribed reporting procedures related to problems or defects. Amended Complaint, pp. 4-23. The following are just a few of the factual allegations Cavender includes in her Amended Complaint:

> Medtronic was aware that the Sprint Fidelis leads were a significant departure from the Transvene and Quattro lead technology and the Sprint Fidelis leads manifested veracious issues that would affect their effectiveness and longevity, Medtronic in violation of FDA regulations withheld this information from the FDA during the PMA supplement process. Accordingly, the issues that arose with the Sprint Fidelis Leads became known to the medical community only after the FDA's approval of the Sprint Fidelis PMA Supplements. Such issues were only known to Medtronic and not the FDA at the time of the approval and the FDA could not and did not approve the safety and efficacy of the Sprint Fidelis leads with knowledge of such information. *Id*., p. 6;
>
> . . .
>
> During the time Medtronic manufactured the Sprint Fidelis leads at its Puerto Rican facilities, inadequate manufacturing processes were implemented that

> virtually ensured that all cables were damaged. P *Id*., p. 8;
> . . .
>
> Medtronic failed to manufacture and inspect the Sprint Fidelis leads in a manner consistent with and as prescribed by the FDA-approved specification for manufacture and inspection of the Sprint Fidelis leads. *Id*., p. 22.

That small sampling of assertions in Cavender's Amended Complaint serves to illustrate that her complaint is sufficiently detailed so as to "provide the grounds for her entitlement to relief." Cavender's allegations, looked at as a whole and taken as true for purposes of the motion to dismiss, clearly and specifically state a cause of action under the IPLA for personal injuries allegedly caused by Medtronic's product. Notwithstanding her attempts to assert additional claims and theories of recovery, the true foundation for Cavender's lawsuit can be found in just a few of the 150 paragraphs included therein, including the following:

> 1) On or about the January 25, 2006, the Sprint Fidelis 6949 leads were implanted in the Plaintiff, Miriam Cavender, for medical purposes;
>
> 2) On or about August 27, 2015, Cavender suffered repetitive shocking by her ICD defibrillator;
>
> 3) On admission to the emergency room, it was determined that the right ventricle Sprint Fidelis 6949 lead fractured, which caused the repeated shocks;
>
> 4) The lead fracture resulted in Cavender undergoing implantation of a new ICD lead and capping of the old lead due to its malfunction;
>
> 5) The lead fracture also resulted in Cavender sustaining personal injuries the effects of which may be permanent and lasting; incurring hospital, doctor and medical expenses that she may continue to incur in the future; and incurring pain and suffering that she may continue to incur in the future, all of which damages are in an amount yet uncertain.

Amended Complaint, p. 4, ¶¶ 22-26. Cavender summarizes her cause of action by alleging, in the 147th and final paragraph of her 31-page Amended Complaint, that "[a]s a direct and proximate

result of the wrongful conduct of Medtronic, Miriam Cavender sustained personal injuries the effects of which may be permanent and lasting[.]" *Id*., p. 29. Notwithstanding the many ways Cavender dresses her claims, they all boil down to a claim for personal injuries allegedly caused by a Medtronic medical device, meaning that Cavender has sufficiently pled a cause of action under the IPLA, which subsumes her other "claims" and affords the only avenue for her to pursue this case against Medtronic. Furthermore, her assertions and allegations are sufficient to provide notice to Medtronic of the claim against it, the grounds for that claim, and the basis for Plaintiff's request for damages. That is sufficient to survive the motion to dismiss, especially given, as even the court in *Ilarraza* noted, "heightened factual pleading is not the new order of the day" even in light of *Twombly*. *Ilarraza*, 677 F.Supp.2d at 584; *see Twombly*, 550 U.S. at 569 ("[W]e do not require heightened fact pleading of specifics, but only enough facts to state a claim to relief that is plausible on its face."). Cavender has pleaded sufficient facts to avoid dismissal under Rule 12(b)(6) as to her claim under the IPLA, and the *Bausch* decision mandates that she be permitted, at this juncture, to proceed with that claim notwithstanding the preemption clause in the MDA.

CONCLUSION

For the reasons discussed above, the motion to dismiss filed by Defendant Medtronic, Inc., (DE 21) is DENIED. The Plaintiff's claims for negligence, negligence *per se*, and breach of express and implied warranties are SUBSUMED by the Indiana Product Liability Act claim and merged into a single cause of action under that statute for manufacturing defect, design defect and failure to warn; the motion is DENIED as to the issue of federal preemption. This case will proceed on Plaintiff Miriam Cavender's cause of action pursuant to the IPLA.

Date: April 14 , 2017.

/s/ William C. Lee
William C. Lee, Judge
United States District Court
Northern District of Indiana