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 9 and 10). Plaintiff Miriam Cavender filed a response in opposition (DE 15) and Medtronic filed a reply (DE 18). For the reasons discussed in this order, the court holds as follows:

1) Plaintiff Miriam Cavender's common law negligence claim is DISMISSED WITH PREJUDICE;

2) Plaintiff's product liability claims and UCC breach of warranty claims are DISMISSED WITHOUT PREJUDICE; and

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 regulation). 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.

BACKGROUND

Miriam Cavender had health problems that required surgical implant of a cardiac defibrillator. On March 16, 2015, doctors implanted a Viva XT CRT-D Defibrillator, which was manufactured by Medtronics. Cavender alleges 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." Complaint (DE 4), p. 2. She filed this lawsuit on March 24, 2016, apparently asserting product liability, breach of warranty, and negligence claims against Medtronic. *Id.*[1] In Count I of her Complaint, Cavender alleges that Medtronic "is strictly liable to . . . Cavender[] for designing, manufacturing and placing into the stream of commerce the said implant-able [sic] defibrillator which was unreasonably dangerous for its reasonably foreseeable uses." *Id*. She contends that "[a]s a direct and proximate result of the strict liability, breach of duties . . . [of] strict liability and breach of warranty . . . [Cavender] sustained personal injuries . . . ." *Id*., p. 3. Also in Count I, Cavender contends that Medtronic is liable "with respect to its failure to warn or adequately warn or instruct in the safe use of said implant-able [sic] defibrillator." *Id*. In Count II of her Complaint, Cavender asserts a state law negligence claim against Medtronic. *Id*., pp. 3-4.

Medtronic contends that Cavender's claims must be dismissed under Fed.R.Civ.P. 12(b)(6) for failure to state a claim. Motion to Dismiss, p. 1. More specifically, Medtronic states that Cavender's claims should be dismissed "in whole or in part, under the Indiana Product

[1] Cavender filed her 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 Removal (DE 1).

Liability Act ('IPLA')[,]" that her complaint fails to state any valid breach of warranty claim, and that her "tort claims are preempted under the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act . . . 21 U.S.C. § 360k(a)." Defendant's Memorandum, pp.7-8.[2]

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, 127 S.Ct. 1955, 167 L.Ed.2d 929 (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, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009) (citing *Twombly*, 550 U.S. at 556).

[2] The court cites to pages of Medtronic's briefs using the page numbers assigned to each page by the court's electronic docketing system (and which appear at the top right corner of each page). These page numbers may not coincide with the numbers appearing on the original document.

DISCUSSION

There are two things about the pending motion to dismiss that are obvious from the outset. First, Cavender's complaint is woefully insufficient under the Rule 12(b)(6) pleading standard and dismissal is warranted. That said, Medtronic's motion jumps the gun a bit given that it raises substantive legal defensives (some possibly dispositive) to claims that may not even exist in Cavender's complaint. Some of the issues raised by Medtronic are better suited for presentation in a motion for summary judgment, but that can't happen until Cavender cleans up her complaint enough that the precise causes of action she is asserting–and the facts on which those claims are based–are clear. The court cannot resolve many of the substantive defenses raised by Medtronic at this point since Cavender's complaint, as it stands now, fails to state a valid claim in the first place. The path forward for this case is for Cavender's claims to be dismissed, for her to file an amended complaint, and for Medtronic to be in a position to file an answer to the complaint. All of that said, the court will 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.

Medtronic's arguments for dismissal are summarized in a few paragraphs in its memorandum. Medtronic begins by attacking the factual sufficiency of Cavender's complaint:

> Plaintiff's complaint is only three pages and consists of two counts. Within the two counts, the complaint asserts a scattershot of common law causes of action, including strict liability based on a manufacturing defect, a design defect, and a failure to warn; breach of express and implied warranties; and negligence based on a manufacturing defect, a design defect, and a failure to warn. Despite these many causes of action, the complaint contains few if any factual allegations. There are, indeed, only three facts alleged in the entire complaint: (1) Medtronic

> designed, manufactured, and put the Defibrillator into the stream of commerce; (2) the Defibrillator supposedly "malfunctioned" in an unspecified way; [and] (3) . . . the Defibrillator "[severely] injured Plaintiff in some unspecified way.

Id., p. 7. Medtronic then argues that Cavender's claims "should be dismissed with prejudice . . . for three reasons. First, Indiana law (which governs this case) does not provide for any common law causes of action in personal injury product liability cases. Rather, Plaintiff's only right to relief would be under the [IPLA], which Plaintiff has failed to cite or use as the basis for her Complaint. . . . Second, Plaintiff has failed to plead facts to support any theories of liability whether under common law or under the IPLA. . . . Third, all of Plaintiff's tort claims are preempted under the [MDA]." *Id*., pp. 7-8.

Cavender's argument in opposition to the motion is stated even more succinctly. She argues that this court should "deny the motion to dismiss on all bases under the guidance of the recent Seventh Circuit case *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010), which addresses all the arguments posed by Medtronic." Plaintiff's Response, p. 1. That sentence is very intriguing, given that it implies that one case will inform the resolution of the present motion; and it turns out that the *Bausch* case is indeed applicable and helpful in many respects, although resolution of the issues presented in Medtronic's motion is not as simple as applying the holding of *Bausch*, which Medtronic claims Cavender misapplies anyway.

I. Indiana Product Liability Act preemption.

Medtronic argues that "the Court should dismiss the entire complaint because it is not brought pursuant to the IPLA, or alternatively, dismiss all claims not predicated on a manufacturing defect, design defect, or failure to warn." Defendant's Memorandum, p. 10. 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. That language is pretty darn clear and would seem to be the end of the inquiry here since, as Medtronic points out, Cavender's complaint does not so much as mention the IPLA. Medtronic's characterization of Cavender's complaint as "a scattershot of . . . causes of action" is accurate. Cavender includes in almost every paragraph of her complaint phrases like "stream of commerce," "defective product," "use and purpose intended," "inherently and unreasonably dangerous," "express and implied warranties," "reasonably foreseeable uses," "failure to warn," "strict liability," and "negligence." Complaint, pp. 1-4. These terms, most of which are commonly associated with product liability actions, pop up like weeds throughout Cavender's complaint but lack any factual context. Put another way, Cavender uses language in her complaint that implies (or from which the court and Medtronic infer) she is asserting several different product liability claims (defective design, failure to warn, and so forth), some type of breach of warranty claim, and a common law negligence claim, but her complaint states her causes of action in a very vague and cursory manner. In fact, near the end of her complaint Cavender summarizes her claims by stating that "[a]s a direct and proximate result of the negligence and breach of duties of [Medtronic], including but not limited to negligence, . . . Cavender[] sustained personal injuries . . . ." (Complaint, p. 4), an awkward and open-ended sentence that adds to the confusing presentation of her claims. It's not that Cavender's complaint is insufficient just because it lacks express reference to the IPLA or the MDA or some common law liability theory. Rather, as Medtronic insists, it is insufficient because it lacks context from which the Defendant and the court can ascertain the precise nature–or more specifically the

precise legal and factual bases–of Cavender's claims. Medtronic emphasizes that "there are no common law product liability claims for personal injuries under Indiana law[,]" since "'the IPLA provides for a single cause of action, regardless of the plaintiff's substantive legal theories[.]'" Defendant's Memorandum, p. 11 (citations omitted). Therefore, argues Medtronic, Cavender's "complaint is thus without a valid legal basis and . . . should be dismissed." *Id*. (citation omitted). Medtronic then sharpens its point a bit by stating that "[i]f the Court excuses [Cavender's] failure to offer the proper statutory basis [for her claims], the Court must still dismiss all of the personal injury claims not based on a manufacturing defect, design defect, or failure to warn. The IPLA recognizes only those three possible theories of recovery." *Id*. (citations omitted).

As stated, Cavender claims in her response brief that the *Bausch* case precludes dismissal of her complaint and that it "addresses all the arguments posed by Medtronic." Cavender insists that her complaint "adequately recites the theories of recovery *under the Indiana Product Liability Act*." Plaintiff's Response, p. 2 (italics added). She also argues that her complaint "*employs the language* of Chapter 2 of the IPLA[.]" *Id*., p. 3 (italics added). Cavender concludes this argument by proclaiming that "*[s]ubstantively*, the Complaint properly allege[s] facts to bring a product liability claim *under the IPLA*." *Id*., p. 4 (citing *Bausch*, 630 F.3d at 562) (italics added). So, Cavender's argument in opposition to the motion to dismiss is this: her complaint states valid product liability claims under the IPLA even though it doesn't cite the IPLA as the legal basis for those claims, and the *Bausch* case supports her position. (She presents a second argument–related to her breach of warranty claims, which she says have an independent legal basis in the UCC–that the court will address below.)

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 (or the *Iqbal*/*Twombly* threshold, if one prefers) since she failed to allege sufficient facts to support any claim against Stryker. The district court granted Stryker's motion to dismiss (and also denied Bausch's request for leave to amend her complaint, but more on that point later) 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]

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

[3] It is undisputed that the defibrillator that is the subject of this lawsuit is designated as a Class III medical device. As Medtronic explains it: "Different types of devices receive different levels of FDA scrutiny. . . . Devices that support or sustain human life, or present a potential unreasonable risk of injury, are designated 'Class III' devices." Defendant's Memorandum, p. 8 (citing 21 U.S.C. § 360c(a)(1)(C)(ii)). This fact is significant because, as Medtronic points out, Class III devices are subject to a strict FDA "premarket approval" process, which in turn "imposes federal requirements that preempt state tort claims." *Id*., p. 17 (citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008)). This premarket approval process, according to Medtronic, invokes the provisions of the MDA, in particular the preemption provision in § 360k. Since Cavender's claims in this case are unclear, the court is unable to determine if the provisions of the MDA apply.

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 itself subject to a later recall.

Bausch, 630 F.3d at 559. The district court agreed with Stryker 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 Seventh Circuit's opinion is instructive in many ways, and therefore warrants careful consideration. 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. . . .
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> 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. Another district court had occasion to apply the *Bausch* holding in the case of *Tillman v. Smith & Nephew, Inc*., 2013 WL 3776973 (N.D. Ill. July 18, 2013). In *Tillman*, the plaintiff alleged claims of negligence and product liability against the defendant, which manufactured or distributed a Class III hip implant device that the plaintiff claimed caused him injury. The defendant moved to dismiss Tillman's complaint on grounds of preemption and for failure to meet the pleading standard of Rule 12(b)(6). As to the latter issue, the district court, relying in large part on *Bausch*, held as follows:

> Smith & Nephew argues that Tillman's amended complaint is "nothing more than an 'unadorned, the-defendant-unlawfully-harmed-me accusation'" that, unlike the complaint examined in *Bausch*, does not provide a sufficient factual basis for

> liability. . . . In *Bausch*, the plaintiff had alleged that a batch of hip replacement systems had been recalled and that the FDA had informed and in fact issued a letter to the manufacturer warning of quality control violations. 630 F.3d at 558–59. Here, no such facts relating to the [product] are alleged, although Tillman does complain that Smith & Nephew did not properly respond to adverse incident reports, . . . allowing the inference that such reports were made. Although to a lesser extent than the plaintiffs in *Elmore* [*v. Smith & Nephew, Inc.*, 2013 WL 1707956, (N.D.Ill. April 19, 2013)],[4] Tillman does allege facts as to the medical complications that occurred after the implantation. These complications plausibly suggest a link between his injuries and the alleged [product] defects. Additional allegations would strengthen Tillman's claims, but Tillman's pleading "is commensurate with the amount of information [he] can access prior to discovery." *Elmore*, 2013 WL 1707956, at *6. Thus, Tillman's claims will be allowed to proceed as pleaded.

Tillman, 2013 WL 3776973, at *5.

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[4] In *Elmore*, the plaintiff brought claims of negligence and strict product liability against Smith & Nephew for injuries she allegedly suffered due to problems with the same hip product at issue in *Tillman*, and the defendant moved to dismiss the complaint on the same grounds–that is, that Elmore's claims were preempted and also failed to meet the Rule 12(b)(6) pleading standard. The district court denied the motion, again relying on *Bausch*, and held as follows:

> As pled, plaintiffs' complaint is plausible on its face. Two revision surgeries, coupled with increased chromium and cobalt levels in [plaintiff's] blood, provide sufficient factual grounding on which to base negligence and strict liability claims. The complaint does more than assert bare legal conclusions. It makes a reasonable inference of liability, at the very least, plausible on the face of the complaint. While recalls and warning letters, such as those presented *Bausch,* would strengthen plaintiffs' complaint, they are not necessary to survive a motion to dismiss. As the Seventh Circuit has noted, plaintiffs alleging defective manufacture are at a disadvantage in terms of discovery. *Bausch*, 640 F.3d 546. By including the report prepared after the second revision surgery, plaintiffs have at least attempted to include device-specific information, in addition to facts related to [plaintiff's] injuries. Plaintiffs' pleading burden is commensurate with the amount of information they can access prior to discovery. *Id.* at 561. Here, plaintiffs have assembled the minimal factual grounding necessary to meet the plausibility standard required under *Twombly* and *Iqbal.* Consequently, the complaint complies with Fed.R.Civ.P. 8.

Elmore, 2013 WL 1707956, at *6.

The difference between Cavender's complaint and the complaints in *Bausch*, *Tillman* and *Elmore* is that the plaintiffs in those cases included much more in the way of factual assertions to support their claims. In the present case, as Medtronic repeatedly points out in its briefs, Cavender's complaint contains only a few factual assertions. She states that Medtronic "designed, manufactured and marketed the product in question," that the defibrillator was implanted on March 16, 2015, that it "malfunctioned," and that she suffered serious physical injuries as a result of that malfunction. Complaint, pp. 1-2. Medtronic argues that since Cavender's complaint contains only skeletal factual assertions (if that), it cannot be compared to the complaints at issue in *Bausch*, *Tillman*, or *Elmore*–each of which included at least *some* facts that supported a theory of liability (or at least rendered the claims plausible). In this case, however, Cavender offers almost nothing. There are no factual assertions about how or when the defibrillator malfunctioned, what made it "unreasonably dangerous," how the alleged malfunctioned injured her, what design or manufacturing defect it allegedly had, what federal regulation Medtronic allegedly violated, or anything else that would help define Cavender's claims. As Medtronic puts it, Cavender "can plead more facts than the three barebones [sic] facts in the complaint, and she offers no explanation for why she has not offered any facts regarding: the warnings received (or not received or what she alleges should have been received); exactly what express and implied warranties Medtronic extended and how they were breached (and whether and how they were relied upon); what was supposedly defective with the defibrillator that was implanted in her; and how the defibrillator's defect caused her unspecified injuries." Defendant's Reply, p. 9. Cavender's complaint, as it stands, is nothing more than the sort of "unadorned, the-defendant-unlawfully-harmed-me accusation" referred to in *Tillman*. It is chock-

full of keywords that imply, and from which the court believes it is reasonable to infer, that Cavender is attempting to assert various product liability claims. And, in fact, Cavender now says that is exactly what her complaint does, arguing that it "employs the language" of the IPLA.

Cavender's argument is unconvincing. Sure, it is obvious from the words she uses in her complaint that she is basing her claims on various product liability theories, but her precise claims, and the legal bases for them, are difficult to discern given that she fails to include facts to define them. It is not sufficient simply to pay lip service to a cause of action–a plaintiff must allege facts that render that claim *plausible*. In *Bausch*, *Tillman*, and *Elmore* the plaintiffs survived motions to dismiss because their complaints "assembled the minimal factual grounding necessary to meet the plausibility standard[.]" *Elmore*, 2013 WL 1707956, at *6. Cavender's complaint, in contrast, is still in the "assembly required" stage, and the question now becomes what to do about that. As the Seventh Circuit explained in *Bausch*:

> When a complaint asserts claims that are legally valid and those that are not, the correct judicial response is not to dismiss the complaint, let alone with prejudice. It's not even necessary to require a plaintiff to file a "cleaner" amended complaint. The case may proceed under the original complaint, with the understanding, provided by the court if necessary, as to the proper scope of claims that can survive the legal challenge.

Bausch, 630 F.3d at 559–60. Cavender's complaint needs work, which she tacitly acknowledges in her brief when she asks for permission to do that work in lieu of outright dismissal of her case. *See* Plaintiff's Response, p. 10 ("Plaintiff respectfully requests that [the court] dismiss the case without prejudice to allow reasonable opportunity for the Plaintiff to amend her complaint to make specific allegations.") (citing *Bausch*, 630 F.3d at 562) ("Generally, if a district court dismisses for failure to state a claim, the court should give the party one opportunity to try to cure

the problem."). Cavender's request is reasonable, especially given the nature of this suit, and the court will grant that request with regard to all of her claims (with the exception of her state law negligence claim).

II. Common law negligence claim.

While Cavender will have an opportunity to clarify her claims in her amended complaint, one of them obviously cannot survive and must be dismissed. It is apparently undisputed that Cavender cannot maintain a common law negligence claim in this case. (She does not mention anything about a negligence claim in her brief, although she does not concede it either.) This same issue was before this court in a case in which Magistrate Judge Rodovich wrote as follows:

> 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 I.C. § 34–20–2–1 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 Act 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. . . .

Cincinnati Ins. Companies v. Hamilton Beach/Proctor-Silex, Inc., 2006 WL 299064 at *2 (N.D.Ind. Feb. 7, 2006) at *2. On 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.

III. Medical Device Amendments preemption.

Medtronic also argues that Cavender's complaint is fatally defective because "all of [her] tort claims are preempted under the Medical Device Amendments to the Federal Food, Drug, and

Cosmetic Act[.]" Defendant's Memorandum, p. 8 (citing 21 U.S.C. § 360k(a)). "This federal statute[,]" contends Medtronic, "preempts Plaintiff's state law claims because the Defibrillator is a Class III, life-saving medical device, and its specifications, intended uses, and warnings were rigorously reviewed and vetted by the FDA prior to its approval." *Id*. Medtronic argues that "Plaintiff's claims seek to impose state-law requirements on the manufacturing, design, and labeling requirements for the Defibrillator that are different from or in addition to those imposed by the FDA." *Id*.

Section 360k(a) states, in pertinent part, that ". . . no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement–(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a). Medtronic says this statute preempts Cavender's causes of action. Defendant's Memorandum, pp. 16-17 (citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008)). Medtronic is correct that § 360k can preempt certain claims against manufacturers of Class III medical devices, as the *Riegel* case explains (and as Medtronic summarizes in its memorandum at pages 17-20). This might well be a solid argument, but since Cavender's claims are so difficult to discern it is unclear whether this preemption defense applies.[5]

[5] Neither the issue of § 360k preemption in cases involving Class III devices nor the application of the holding in *Riegel* to such cases have been discussed much, especially in the circuit courts, and so the matter of federal preemption remains an open one–or at least a more nuanced one than Medtronic's memorandum would suggest. *See Bausch*, 630 F.3d at 552-54 (discussing *Riegel* and § 360 preemption).

Cavender, however, argues that her claims are not preempted and again relies on *Bausch* to support her position. In *Bausch*, the defendant presented the same federal preemption argument that Medtronic presses here. Indeed, the Seventh Circuit addressed the issue of federal preemption in *Bausch* and reversed the district court's dismissal of Bausch's claims. The court held as follows:

> Section 360k provides immunity for manufacturers of new Class III medical devices to the extent that they comply with federal law, but it does not protect them if they have violated federal law. Just as a plaintiff in an auto accident may use the other driver's speeding violation as evidence of negligence, plaintiff Bausch claims that she was injured by Stryker's violations of federal law in manufacturing the device implanted in her hip. It remains to be seen whether she can prove those allegations, including causation and damages. But if she can prove those allegations of harm caused by violations of federal law, her claims under state law would not impose on defendants any requirement "different from, or in addition to, any requirement" imposed by federal law. Her claims are not preempted.

Bausch, 630 F.3d at 553. Cavender then argues that "if Plaintiff can prove violations of federal law by Medtronic in the design, manufacture, and marketing of the Defibrillator, then her claims under state law would not impose requirements different from or in addition to federal law requirements." Plaintiff's Response, p. 9. This is so, says Cavender, because "'Section 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements.'" *Id*. (quoting *Bausch*, 630 F.3d at 552) (in turn quoting *Riegel*, 552 U.S. at 330). Cavender concludes by arguing that her complaint should survive the motion to dismiss because this case is in the early stages and she "would need the benefit of discovery to gain access to information to allow proof of such a violation." *Id*. (citing *Bausch*, 630 F.3d at 560) ("[T]he victim of a genuinely defective product–for example . . . 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.").

Cavender's argument is that her complaint should be deemed sufficient under *Bausch* because she has included all the facts she can absent formal discovery. Put another way, she is arguing that her complaint contains the "minimal factual grounding necessary" to support a claim based on an alleged violation of federal regulations by Medtronic which, in turn, would render § 360k preemption inapplicable. Once again, however, Cavender's statements of the law are correct but her application of it to her complaint is too much of a stretch. In *Bausch*, for example, the plaintiff expressly alleged that the defendant "violated federal law in manufacturing the [device]. The device was implanted in her body six days after the [FDA] informed the defendants that a component of the . . . hip system was 'adulterated' and that the . . . manufacturing processes failed to comply with federal standards." *Bausch*, 630 F.3d at 549. In the present case, Cavender's complaint is completely devoid of any facts whatsoever that would even *imply* that she is alleging a violation of federal law. She makes no reference to FDA regulations, the MDA, the FDCA, or any other statute; she doesn't even use the words "federal law," or other language from which the court could infer that such a claim is present in her complaint. The plaintiff in *Bausch* offered a factual basis for her claim of violation of federal law that was sufficient to render her claim "plausible" even in light of the preemption provision of § 360k. Cavender, on the other hand, hasn't even pled a violation of federal law, let alone presented any facts to support such a claim. On this issue, Cavender can't even resort to the sort of "substantial compliance" argument she uses to try to save her (now purported) IPLA claims. Whether she can

plead such a claim (or whether she even intends to) remains to be seen; but for present purposes, Cavender's complaint does not state a claim based on an allegation that Medtronic violated some federal law or regulation. And, assuming she does intend to pursue such a claim, she still faces the difficulties inherent in maintaining such a claim when it involves a Class III device and the provisions of the MDA. Cavender's amended complaint will clarify this issue also.

IV. Breach of warranty claims.

Cavender includes in her complaint language that implies she is asserting claims of breach of express and implied warranties. Complaint, p. 2. She states in her complaint that "Medtronic, Inc., expressly and impliedly warranted that [the Defibrillator] . . . was safe, not inherently dangerous, and fit for the proper uses and purposes intended for it, and thus the Defendant, breached those express and implied warranties, including a warranty for fitness of use[.]" *Id*.

Medtronic contends that Cavender cannot maintain breach of warranty claims for several reasons. First, Medtronic once again argues that "the IPLA preempts these tort-based warranty claims." Defendant's Memorandum, p. 15. Medtronic then also argues that "even if Plaintiff's warranty claims were not supplemented [sic] by the IPLA, they are insufficiently pled." *Id*. This second basis for dismissal comprises of three distinct arguments. First, Medtronic contends that "all of the warranty claims should be dismissed for want of notice. Plaintiff was required to, and has not, pled that she gave pre-suit notice of this litigation to Medtronic." *Id*. (citing I.C. § 26-1-2-607(3)(a)) (requiring pre-suit notice for warranty claims); *Lemon v. Anonymous Physician*, 2005 WL 2218359, at * 2 (S.D.Ind. Sept. 12, 2005) ("Any claim the [plaintiffs] may have for contractual breach of implied warranties is barred because the [plaintiffs] failed to allege that

they had given [defendant] notice of the breach prior to filing suit."); *McClure Oil Corp. v. Murray Equip., Inc.*, 515 N.E.2d 546, 554 (Ind.Ct.App. 1987) ("Timely notice of a breach of warranty is a substantive condition precedent to recovery[.]"). Second, Medtronic argues that Cavender's complaint fails to include any allegations about the Defibrillator being unfit for its particular and intended purpose, thus barring any claim for breach of implied warranty of merchantability (*Id*., citations omitted). And third, Medtronic argues that Cavender has not pled a breach of express warranty claim since "[t]here is no allegation that [Cavender] bought the device directly from Medtronic . . ." and such "[p]rivity . . . is required to state an express warranty claim." *Id*., pp. 15-16 (citing *Atkinson v. P & G-Clairol, Inc.*, 813 F.Supp.2d 1021, 1027 (N.D.Ind. 2011)). Because of these alleged defects, Medtronic states that Cavender's "warranty claims are too indefinite to meet pleading standards [and] must be dismissed." *Id*., p. 16.

As to Medtronic's argument that her warranty claims are subsumed by the IPLA, Cavender argues that the claims, which she now says are brought pursuant to the UCC, are distinct from her other claims and so are not subsumed by the IPLA. In support of this position, Cavender cites the case of *Hitachi Const. Mach. Co. v. AMAX Coal Co.*, 737 N.E.2d 460 (Ind.Ct.App. 2000), which she claims stands for the proposition that "[a]ctions brought under the IPLA and the [UCC] represent two different causes of action. The IPLA governs product liability actions in which the theory of liability is negligence or strict liability in tort, while the UCC governs *contract* cases which are based on breach of warranty." Plaintiff's Response, p. 4 (italics added). Cavender's statement of the holding in *Hitachi* is correct, but it doesn't apply to her

claims because she ignores the word "contract" that she includes in her own sentence.[6] It is true that the court in *Hitachi* held that strict liability claims under the IPLA are distinct from breach of warranty claims under the UCC. The Indiana Court of Appeals reversed the trial court's conclusion that the plaintiff's breach of warranty claims were subsumed by the IPLA. However, the appellate court did so because it concluded that the plaintiff's breach of warranty claim "clearly sounded in contract, and may not be considered an allegation of negligence or strict liability in tort to be 'subsumed' by the [IPLA]. . . . Accordingly, we remand . . . to the trial court for further proceedings, noting that [the plaintiff's] implied warranty theory, which sounds in contract, *may* form the basis for recovery." *Hitachi*, 737 N.E.2d at 465–66 (italics in original). This is a crucial distinction since on its face, Cavender's entire complaint clearly "sounds in tort." Cavender does not include any facts or statements or even magic words from which a contract-based warranty claim can be inferred. So, the fact that IPLA claims are distinct from UCC claims is all well and good, but might also be inapplicable here, since it is not clear from Cavender's complaint what type of warranty claim or claims she is asserting.[7]

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[6] Actually, it's not Cavender's sentence; it is a verbatim quotation from *Hitachi* even though it is not designated as such, which in turn quotes from *B & B Paint Corp. v. Shrock Mfg., Inc.*, 568 N.E.2d 1017, 1020 (Ind.Ct.App. 1991). *See* 737 N.E.2d at 465.

[7] Cavender's complaint is clear about one thing–she is suing to recover damages for personal injury she claims she suffered as the result of an allegedly defective product. What's not clear is whether she is attempting to assert a UCC breach of warranty claim for damages to the device itself or some other form of damages she allegedly incurred. This is important because, as this court has noted, "Indiana law under the Products Liability Act and under general negligence law is that damage from a defective product or service may be recoverable under a tort theory if the defect causes personal injury or damage to other property, but contract law governs damage to the product or service itself and purely economic loss arising from the failure of the product or service to perform as expected." *Hathaway v. Cintas Corp. Servs., Inc.*, 903 F.Supp.2d 669, 673 (N.D. Ind. 2012). In *Hathaway*, this court concluded that the plaintiffs' breach of warranty claims against the manufacturer of a product were subsumed by the IPLA since they clearly sounded in

As to Medtronic's argument regarding privity, Cavender responds by noting that "'lack of privity . . . no longer precludes a buyer from asserting a claim for damages based on . . . breach of warranty under Indiana's [UCC].'" *Id*. (quoting *Cincinnati Ins.*, 2006 WL 299064 at * 3). But while lack of privity might not preclude her warranty claim, it might not save it either, since the complaint fails to state specifically what type of breach of warranty claim Cavender is attempting to assert. As this court has noted, "[v]ertical privity is not required for a claim of breach of the implied warranty of merchantability even if that claim sounds in contract. . . . Still, vertical privity is required for claims of breach of express warranty and breach of implied warranty of fitness for a particular purpose." *Atkinson v. P & G–Clairol, Inc.*, 813 F.Supp.2d at 1026.

Even assuming for the sake of argument that Cavender could plead and support a breach of warranty claim, Medtronic says she still loses because she was required under the UCC to provide notice of the alleged breach to Medtronic, and the failure to do so precludes recovery. The *Cincinnati Insurance* case is clear on this point also: "The buyer must provide notice to the seller within a reasonable time after discovery of the breach or be precluded from pursuing

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tort. "'The IPLA effectively supplants both the common law negligence claims and the breach of implied warranty claims.'" *Id*. (quoting *Henderson v. Freightliner, LLC*, 2005 WL 775929, at *3 (S.D.Ind. Mar. 24, 2005)). Based on the reasoning in *Hathaway*, any breach of warranty claim Cavender is asserting or intends to assert might very likely be subsumed by the IPLA, just as Medtronic argues. If Cavender intends to assert a breach of warranty claim under the UCC then her amended complaint will say so and the issue of subsumption of those claims might have to be revisited, just as the court might have to revisit all of Medtronic's arguments. Once again, however, these substantive arguments are largely hypothetical at this point, which is why Cavender needs to craft an amended complaint that presents her claims clearly (and that does not include words or phrases that imply a cause of action she is *not* asserting). Cavender argues in her brief that she has a valid UCC claim or claims, distinct from her IPLA claims, so she will be given a chance to shed light on her theory in her amended complaint.

damages. I.C. § 26–1–2–607(3)(a). This section creates a condition precedent to recovery for warranties created under Uniform Commercial Code." *Cincinnati Ins.*, 2006 WL 299064, at *3 (citing *McClure Oil Corp. v. Murray Equipment, Inc.*, 515 N.E.2d 546, 554 (Ind.App. 1987)). Cavender does not allege in her complaint that she provided the requisite notice nor does she address the issue in her brief. This same pleading defect was also addressed in *Cincinnati Insurance* and the court noted as follows:

> Regarding the requirement to plead notice under Rule 9(c), the Complaint is devoid of even a general allegation that the [plaintiffs] gave notice to [the defendant] of the warranty claims prior to filing suit. In briefing, the [plaintiffs] claim that [the defendant] was provided notice . . . However, a belated assertion that the substantive requirement has been met does not cure the Complaint's failure to meet the pleading requirements of Rule 9(c). Consequently, Count II of the [plaintiffs'] Complaint is dismissed without prejudice. *See Redfield* [*v. Continental Cas. Co.*], 818 F.2d 596, 610 (7th Cir. 1987) ("The appropriate remedy for a plaintiff's failure to allege compliance with conditions precedent is dismissal without prejudice.").

Cincinnati Ins. Companies, 2006 WL 299064, at *4. The issue of whether any breach of warranty claim can be asserted along with IPLA claims, and the issue of whether and to what extent privity is required for such a claim, are a bit nuanced, as discussed in *Cincinnati Insurance*. *See* 2006 WL 299064, at *3 (discussing *Hitachi*, *Thiele v. Faygo Beverage, Inc.*, 489 N.E.2d 562, 584 (Ind.App. 1986), and *Hyundai Motor Am., Inc. v. Goodin*, 822 N.E.2d 947, 956-59 (Ind. 2005)). But once again, the court cannot address these issues, even if they might be dispositive, since it is unclear from Cavender's complaint exactly what warranty claims she is alleging in the first place. She uses phrases like "Medtronic, Inc., expressly and impliedly warranted," "[Medtronic] breached those express and implied warranties," and "fitness of use," but that's as far as she goes. Those phrases imply several different breach of warranty theories, but Cavender fails to

include any facts to elucidate those causes of action. Instead, she resorts to arguing–just as she did regarding her claims under the IPLA–that because she made reference to breach of warranty claims and because such claims can be brought separately from IPLA claims, her complaint is sufficient to survive a Rule 12(b)(6) motion. She is incorrect. Again, the court is optimistic that Cavender will clarify these claims in an amended complaint, assuming she intends to pursue them as UCC claims. Like all her claims, Cavender's breach of warranty claim or claims face obstacles. Whether she can overcome those obstacles depends on what she pleads in her amended complaint. For the reasons discussed above, Cavender's breach of warranty claims are dismissed without prejudice.

CONCLUSION

For the reasons discussed in this order, the court holds as follows:

1) Plaintiff Miriam Cavender's common law negligence claim is DISMISSED WITH PREJUDICE;

2) Plaintiff's product liability claims and UCC breach of warranty claims are DISMISSED WITHOUT PREJUDICE; and

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 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). Medtronic is directed to file an answer to plaintiff's amended complaint (or a second motion to dismiss should Defendant

conclude that one is warranted) within 30 days from the date of the filing of Plaintiff's amended complaint.

Date: November 8, 2016.

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