

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF INDIANA  
INDIANAPOLIS DIVISION

ROBERT BAILEY,	)	
SHANNON BAILEY,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	No. 1:17-cv-02314-JMS-DML
	)	
MEDTRONIC, INC.,	)	
	)	
Defendant.	)	

**ORDER**

Robert Bailey alleges that he awoke during the night of June 14, 2015 because his heart defibrillator was shocking him. Two years later, Mr. Bailey and his wife Shannon brought suit against the company that manufactured the defibrillator, Medtronic, Inc. (“Medtronic”), in Marion County Superior Court. [Filing No. 101.] The Baileys allege that Medtronic is liable based on five grounds: negligence, product liability, failure to warn, breach of warranty, and loss of consortium. [Filing No. 1-1 at 5-10.] On July 7, 2017, Medtronic removed the Baileys’ suit to this Court on the basis of diversity jurisdiction. [Filing No. 1.] One month later, Medtronic filed a Motion to Dismiss, which is now ripe for the Court’s review. [Filing No. 10.]

**I.  
LEGAL STANDARD**

Under Rule 12(b)(6), a party may move to dismiss a claim that does not state a right to relief. The Federal Rules of Civil Procedure require that a complaint provide the defendant with “fair notice of what the . . . claim is and the grounds upon which it rests.” *Erickson v. Pardus*, 551 U.S. 89, 93 (2007) (quoting *Bell Atlantic v. Twombly*, 550 U.S. 544, 555 (2007)). In reviewing the sufficiency of a complaint, the Court must accept all well-pled facts as true and draw all permissible inferences in favor of the plaintiff. See *Active Disposal Inc. v. City of Darien*, 635

F.3d 883, 886 (7th Cir. 2011). A Rule 12(b)(6) motion to dismiss asks whether the complaint “contain[s] sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). The Court will not accept legal conclusions or conclusory allegations as sufficient to state a claim for relief. See *McCauley v. City of Chicago*, 671 F.3d 611, 617 (7th Cir. 2011). Factual allegations must plausibly state an entitlement to relief “to a degree that rises above the speculative level.” *Munson v. Gaetz*, 673 F.3d 630, 633 (7th Cir. 2012). This plausibility determination is “a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.” *Id.*

## **II. BACKGROUND**

The following are the factual allegations in the Complaint, which the Court must accept as true at this time:

On January 30, 2008, Robert Bailey had surgery, during which a Virtuoso DR Defibrillator, Model # D154AWG (the “Defibrillator”) was implanted. [[Filing No. 1-1 at 4.](#)] The Defibrillator was an implantable cardiac defibrillator sold by Medtronic. [[Filing No. 1-1 at 4.](#)]

On June 14, 2015, Mr. Bailey was awakened at his home because he was being shocked. [[Filing No. 1-1 at 4.](#)] His wife, Shannon Bailey, called an ambulance and Mr. Bailey was taken to the hospital. [[Filing No. 1-1 at 4.](#)] Once at the hospital, the Defibrillator was surgically removed from Mr. Bailey because the leads in the Defibrillator were broken, causing Mr. Bailey to be shocked. [[Filing No. 1-1 at 5.](#)]

On June 12, 2017, the Baileys filed a suit for damages in Marion County Superior Court on the basis of negligence (Count I), product liability (Count II), failure to warn (Count III), breach of warranty (Count IV), and loss of consortium (Count V). [[Filing No. 1-1.](#)] On July 7, 2017,

Medtronic removed the suit to this Court on the basis of diversity jurisdiction, [[Filing No. 1](#)], and on August 11, 2017, Medtronic filed a Motion to Dismiss, [[Filing No. 10](#)], which is now fully briefed.

### **III. DISCUSSION**

Medtronic makes three arguments in support of its Motion to Dismiss, each of which, it contends, renders the Baileys' Complaint defective. [[Filing No. 11 at 7-8.](#)] First, Medtronic argues that the Baileys failed to cite the Indiana Product Liability Act ("IPLA"), which governs "all actions for physical harm brought by a consumer against a manufacturer or seller of a product, regardless of the substantive legal theory." [[Filing No. 11 at 10.](#)] Second, Medtronic argues that the Baileys failed to state a claim under the IPLA or any other statute. [[Filing No. 11 at 5.](#)] Finally, Medtronic argues that the Baileys' claims fail because they are preempted by federal law. [[Filing No. 11 at 13.](#)]

#### **A. Failure to Mention IPLA in the Complaint**

Medtronic's first argument in support of its Motion to Dismiss is unavailing. Medtronic alleges that the Baileys "have not properly pled any cause of action under the IPLA" because the Complaint "is devoid of any mention of the governing statute" and instead contains "a variety of common law claims and theories." [[Filing No. 11 at 10.](#)] As such, Medtronic argues that "the Court should dismiss any claims not brought pursuant to the IPLA." [[Filing No. 11 at 10.](#)]

The Baileys do not dispute that their complaint does not mention the IPLA, but contend that their complaint "employs the language" of the IPLA, [[Filing No. 28 at 4](#)], and that "[t]here is no requirement that the complaint plead the law in order to make it relevant to the operative facts," [[Filing No. 28 at 6](#)].

The Court agrees with the Baileys that there is no requirement for them to specifically cite the IPLA in their complaint. The Seventh Circuit has stated that “[i]nstead of asking whether the complaint points to the appropriate statute, a court should ask whether relief is possible under any set of facts that could be established consistent with the allegations.” *McDonald v. Household Int’l, Inc.*, 425 F.3d 424, 428 (7th Cir. 2005) (quoting *Bartholet v. Reishauer A.G. (Zurich)*, 953 F.2d 1073, 1079 (7th Cir. 1992)). Moreover, Medtronic does not identify any authority supporting the proposition that the failure to cite or mention a statute in a complaint is, by itself, sufficient grounds for dismissal. Medtronic points to an opinion in which the Northern District of Indiana dismissed a complaint, after observing that it “does not so much as mention the IPLA.” See *Cavender v. Medtronic, Inc.*, 2016 WL 6599744, at \*3 (N.D. Ind. Nov. 8, 2016). However, the court in *Cavender* identified numerous issues with the complaint beyond the mere failure to mention the IPLA, most notably the plaintiff’s failure to include facts to define her legal claims. *Id.* at \*7. Medtronic also cites a case in which the Southern District of Indiana observed that, “[a]lthough it is common practice for a plaintiff to cite to statutes and legal rules in its complaint, nothing in the Federal Rules of Civil Procedure requires a plaintiff to do so.” *Am. Int’l Ins. Co. v. Gastite*, 2009 WL 1383277, at \*2 (S.D. Ind. May 14, 2009) (citing *Bartholet*, 953 F.2d at 1079). In *Gastite*, rather than dismissing the complaint on the grounds that it did not explicitly cite the IPLA, the court found it “necessary to clarify the law governing Plaintiff’s action before addressing Defendant’s motion.” *Gastite*, 2009 WL 1383277, at \*2. The same methodology is appropriate in this case where, as in *Gastite*, the IPLA governs the Baileys’ claims.

Originally enacted in 1978 and expanded in 1995, the IPLA “codified the entire field of products liability” law in Indiana. *Weigle v. SPX Corp.*, 729 F.3d 724, 737 (7th Cir. 2013). The IPLA “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](#).

In this case, the Baileys brought five claims, each of which, aside from their loss of consortium claim, consists of an effort on the part of the Baileys, as consumers, to recover from Medtronic, as a manufacturer, for physical harm caused by a product, namely a defibrillator. Accordingly, Counts 1, 2, 3, and 4 of the Baileys’ complaint fall within the gamut of the IPLA. Rather than dismiss the Complaint for failing to point to the appropriate statute, the Court will analyze each claim to determine whether relief under the IPLA is possible under any set of facts that could be established consistent with the allegations.

## **B. Failure to State a Claim**

Medtronic’s contention that the Baileys’ Complaint fails to state a claim can be separated into two arguments that track the Seventh Circuit’s analysis in considering a complaint for a defective product under Illinois law in [Bausch v. Stryker Corp.](#), 630 F.3d 546 (7th Cir. 2010). In *Bausch*, the court analyzed whether the complaint served each of the purposes of Rule 8 of the Federal Rules of Civil Procedure: “giving the defendants fair notice of the nature of the claim against them,” and “stating a claim for relief that was ‘plausible on its face’ as required by *Iqbal* and *Twombly*.” 630 F.3d at 559. In this case, Medtronic contends that the Baileys’ Complaint does neither. On one hand, Medtronic argues that the Complaint provides insufficient facts to provide notice of the nature of the claim. On the other, Medtronic argues that the various Counts of the Complaint request relief that is not plausible under the IPLA.

### *1. Insufficient Facts*

Turning first to the factual allegations in the Complaint, Medtronic contends that the Baileys’ claims should be dismissed for failing to plead sufficient facts to state each claim. [\[Filing](#)

[No. 11 at 11.](#)] Medtronic states that the Baileys’ “only factual allegations” are that Mr. Bailey was implanted with Medtronic’s device, the leads in the device later broke, and that Mr. Bailey suffered from physical injuries as a result. [\[Filing No. 11 at 11-12.\]](#) Such “bare allegations,” Medtronic argues, are insufficient to survive a motion to dismiss. [\[Filing No. 11 at 12.\]](#) Specifically, Medtronic argues that the Baileys’ complaint is deficient because it:

- “fail[s] to allege what, precisely, they consider to be unreasonably dangerous or defective about the Defibrillator,” [\[Filing No. 11 at 14\];](#)
- “says nothing about the manufacturing or design of the Defibrillator; any specific deficiencies for either; how the Defibrillator’s design or manufacture deviated from the applicable standard of care; nor alleges an alternative design,” [\[Filing No. 11 at 14-15\];](#)
- “states no facts—circumstantial or otherwise—indicating that the design or manufacturing of the Defibrillator had anything to do with the alleged injuries,” [\[Filing No. 11 at 15\];](#) and
- does “not allege what, if any, warnings either Mr. Bailey or his physician received; how the warnings were inadequate; whether they knew of the risk of danger that allegedly caused his injury; or what warnings should have been provided that would have prevented Mr. Bailey’s physician from using the device,” [\[Filing No. 11 at 16\].](#)

The Baileys respond that “there are no special pleading requirements for product liability claims in general, or for Class III medical device claims in particular, and the complaint need only meet the ‘plausibility’ standard.” [\[Filing No. 28 at 7.\]](#) They further allege that their complaint contains essentially the same allegations as an amended complaint that the U.S. District Court for the Northern District of Indiana deemed sufficient to survive a motion to dismiss earlier this year. [\[Filing No. 28 at 7-9](#) (citing *Cavender v. Medtronic, Inc.*, 2017 WL 1365354, at \*1 (N.D. Ind. Apr. 14, 2017).]

In its reply brief, Medtronic distinguishes the Baileys’ Complaint from that found in *Cavender*, 2017 WL 1365354, at \*1, where the plaintiff’s amended complaint contained “over a hundred factual allegations.” [\[Filing No. 32 at 3.\]](#) Medtronic also distinguishes the Complaint from the facts set forth in *Bausch*, 630 F.3d 546, arguing that “[t]here is a clear difference in the

inclusion of factual assertions in the Complaint, and those in *Bausch*, which included *some* facts to support a theory of liability or at least rendered the claims plausible.” [\[Filing No. 32 at 3](#) (emphasis in original).]

Numerous cases, including several involving Medtronic as a defendant, have analyzed whether a plaintiff pled sufficient facts under the IPLA. In *Cavender v. Medtronic, Inc.*, for example, the Northern District of Indiana considered two successive motions to dismiss a plaintiff’s IPLA claims. First, the court granted defendant’s motion to dismiss plaintiff’s three page complaint, which alleged that a heart defibrillator malfunctioned in an unspecified way on an unspecified date. *See Cavender 2016 WL 6599744 (“Cavender I”)*. After plaintiffs filed an amended complaint, defendants brought another motion to dismiss, which the court denied, finding that the plaintiff’s amended complaint contained detailed history of the development of the product, alleged the date the product failed, and, “most importantly,” pled detailed facts regarding product recalls, failure to implement proper manufacturing processes, and the failure to follow reporting procedures related to defects. *Cavender, 2017 WL 1365354 (“Cavender II”)*.

Courts have also found that plaintiffs satisfied the general pleading standards where a complaint was significantly less detailed than in *Cavender II*. In *Lyons*, for example, the court held that, even though the complaint neither indicated where plaintiff was injured nor what he was doing when he was injured, plaintiff had nonetheless stated a plausible claim for relief – “namely, that he suffered physical harm due to the Defendant’s defective product.” *Lyons v. Leatt Corp., 2015 WL 7016469, at \*2 (N.D. Ind. Nov. 10, 2015)*.

The Baileys’ Complaint alleges the model of the defective product, how and when Mr. Bailey acquired the defective product, the date and location where Mr. Bailey’s injury occurred, how the product was defective, the manner in which he was harmed, and the actions that were

taken thereafter. The original complaint therefore served the purpose of Rule 8, which is to give defendants fair notice of the nature of the claim against them. See *Bausch*, 630 F.3d at 559.

As to Medtronic’s arguments that the Baileys should have alleged “what, precisely, they consider to be unreasonably dangerous or defective about the Defibrillator,” [Filing No. 11 at 14], the Seventh Circuit’s reasoning in *Bausch* is instructive:

[T]he 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. It is common, for example, for injured plaintiffs to plead both defective manufacture and defective design and to pursue discovery on both theories. . . [in addition,] in the context of Class III medical devices, much of the critical information is kept confidential as a matter of federal law.

*Bausch*, 630 F.3d at 560. In this case, the Baileys alleged that the Defibrillator was removed “because the leads . . . were broken.” [Filing No. 1-1 at 5.] The absence of more specific details does not support a dismissal under Rule 12(b)(6).

## 2. *Whether Relief is Plausible under the IPLA*

Medtronic next contends that the relief the Baileys seek is not plausible under the IPLA. With respect to Counts I and IV, Medtronic argues that the Court must dismiss the Baileys’ negligence and breach of warranty claims because they are not recognized under the IPLA. [Filing No. 11 at 17.] In addition, Medtronic argues that the Baileys failed to state what type of breach of warranty they are attempting to assert. [Filing No. 11 at 17.] With respect to Counts II and III, Medtronic initially argues that the Baileys’ product liability and failure to warn claims must be merged under the IPLA, [Filing No. 11 at 10-11], but then in its reply brief, Medtronic instead states that these claims “must be re-pled under the IPLA,” [Filing No. 32 at 1]. Further, Medtronic argues that Count III must be dismissed under the “learned intermediary doctrine.” [Filing No. 11

[at 16.](#)] Finally, with respect to Count V, Medtronic argues that the Baileys' loss of consortium claim fails because the claims of which it is derivative are insufficiently pled. [\[Filing No. 11 at 19.\]](#)

The Baileys did not respond to Medtronic's argument that their negligence and breach of warranty claims are not recognized by the IPLA, but contend that their complaint "states the multiple theories on which a plaintiff can prove that a product was 'defective' under the IPLA." [\[Filing No. 28 at 6.\]](#) If the Court disagrees, however, the Baileys move the Court to allow them to file an amended complaint. [\[Filing No. 28 at 10.\]](#)

Turning first to the issue of merger under the IPLA, as discussed in Part III.A, Counts I, II, III, and IV each involve actions that – regardless of how they are styled in the Complaint – are governed by the IPLA because each count was brought by a user or consumer against a manufacturer or seller for physical harm caused by a product. [\[Filing No. 1-1 at 5-9.\]](#) Under the IPLA "[a] product can be defective because of a manufacturing defect, a design defect, or a lack of adequate instructions and warnings." *Weigle*, 729 F.3d at 731 (citing *Ind. Code §§ 34-20-2-1 et seq.*; *Hoffman v. E.W. Bliss Co.*, 448 N.E.2d 277, 281 (Ind. 1983)). Varying standards apply to different claims under the IPLA, as follows: "a strict liability standard applies to manufacturing defect claims, whereas a negligence standard applies to design defect and failure to warn claims." *Gardner v. Tristar Sporting Arms, Ltd.*, 2010 WL 3724190, at \*2 (S.D. Ind. Sept. 15, 2010) (citations omitted).

The concept of merger arose in 2003, as district courts in Indiana began grappling with complaints containing products liability allegations that did not fit neatly within the structure of the IPLA. Merger was first used to combine separate claims for negligent failure-to-warn and for strict liability failure-to-warn after the court found that the IPLA recognized "no doctrinal

distinction” between the two claims. See *Hunt v. Unknown Chem. Mfr. No. One*, 2003 WL 23101798, at \*7 (S.D. Ind. Nov. 5, 2003). In the years that followed, courts used merger rather than dismissal to deal with claims for common law negligence, *Tungate v. Bridgestone Corp.*, 2004 WL 771191, at \*6 (S.D. Ind. Mar. 26, 2004), and breach of implied warranty, *Henderson v. Freightliner, LLC*, 2005 WL 775929, at \*3 (S.D. Ind. Mar. 24, 2005).

By 2009, courts began using merger to combine separate counts for product liability torts into one statutory claim under the IPLA. *Gastite*, 2009 WL 1383277 at \*4; see also *Lyons*, 2015 WL 7016469, at \*3 (merging 4 counts of the complaint and denying a motion to dismiss the same); *Lautzenhiser v. Coloplast A/S*, 2012 WL 4530804, at \*5 (S.D. Ind. Sept. 29, 2012) (denying a motion to dismiss and holding that all “claims sounding in tort shall be treated as a merged IPLA claim going forward”). Recently, however, *Fisk v. Medtronic, Inc.*, held that merger was “unnecessary” at the pleading stage because “[w]hether the theories are designated as Counts 1 through 6, or Count 1(a) through 1(f), both parties understand that [the plaintiff] is pursuing a single cause of action under the IPLA” and “if anything, breaking the different theories into separate counts made the complaint easier to understand.” 2017 WL 4247983, at \*4 (N.D. Ind. Sept. 25, 2017).

This Court agrees with the Northern District’s reasoning in *Fisk*: whether each of the Baileys’ product liability counts are merged into one count or maintained in separate counts of the Complaint is largely a distinction without a difference. Indiana law provides multiple theories of recovery for products liability under the IPLA, and the Indiana Pattern Jury Instructions (Civil) contain separate pattern instructions for each theory. See Indiana Pattern Jury Instructions (Civil) Chapter 2100 (providing pattern instructions for manufacturing defects); Indiana Pattern Jury Instructions (Civil) Chapter 2300 (providing pattern instructions for design defects and the failure

to warn). The Baileys can pursue each of the various theories of recovery under the IPLA – claims for manufacturing defects, design defects, and the failure to warn – and there is no sense in “merging” them.

But what of the negligence and breach of warranty claims, which Medtronic argues are not recognized under the IPLA? Here, merger is a useful tool useful for helping courts determine that claims like negligence and breach of warranty are subsumed by the IPLA. *See, e.g., Estabrook, 2017 WL 2166691*, at \*3; *Cavender, 2017 WL 1365354*, at \*4. Therefore, to the extent that the Baileys’ negligence and breach of warranty claims survive the motion to dismiss, such claims are merged with or subsumed by the IPLA, with the Baileys’ negligence claim surviving inasmuch as negligence remains the standard for design defects and failure to warn claims.<sup>1</sup>

However, this still leaves two additional arguments from Medtronic to consider. First, Medtronic argues that Count III – the Baileys’ failure to warn claim – must be dismissed under the “learned intermediary doctrine” because Medtronic owed no duty to warn consumers. [[Filing No. 11 at 16.](#)] However, the Complaint in this case extends beyond warning consumers, because the Baileys explicitly allege that Medtronic failed to provide adequate knowledge of risks to consumers “and/or their physicians.” [[Filing No. 1-1 at 7.](#)] Therefore, the learned intermediary doctrine does not provide grounds to dismiss Count III.

Medtronic also argues that the Baileys failed to state what type of breach of warranty they are attempting to assert. [[Filing No. 11 at 17.](#)] The Complaint merely states that there arose from the sale of the Defibrillator “certain express and implied warranties” and that Medtronic “failed to

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<sup>1</sup> Medtronic is correct in pointing out that one form of warranty claim consists of contractual claims brought pursuant to the Uniform Commercial Code. *See Fisk, 2017 WL 4247983*, at \*7 (citations omitted). However, the Baileys do not allege in their Complaint or in their Response that their warranty claim is a contractual claim. Therefore, the totality of the Baileys’ breach of warranty claim is subsumed by the IPLA.

conform to said warranties.” [\[Filing No. 1-1 at 8.\]](#) The problem with the Baileys’ breach of warranty claim is not a lack of specificity as to the type of claim they are bringing but, rather, the failure to plead sufficient facts to support a claim for breach of warranty under various types of warranty claims. For example, claims for breach of express warranty and breach of implied warranty of fitness for a particular purpose both require vertical privity. See *Atkinson v. P & G-Clairol, Inc.*, 813 F. Supp. 2d 1021, 1026 (N.D. Ind. 2011). Here, the Baileys failed to state from whom the product was purchased, to allege that they entered into any type of bargain or purchase agreement with Medtronic, or to plead any facts that allege vertical privity. As such, the Complaint fails to state a claim for breach of express warranty or breach of implied warranty of fitness for a particular purpose. This leaves only an implied warranty of merchantability and, here too, the Baileys have failed to allege sufficient facts to support their claim. See *Gastite*, 2009 WL 1383277, at \*3 (holding that a plaintiff failed to state a claim for breach of implied warranty of merchantability by merely alleging that a product is not fit for its “intended use and purpose”). For the foregoing reasons, the Baileys’ breach of warranty claim – Count IV of their Complaint – is dismissed with prejudice.<sup>2</sup> All other Counts survive Medtronic’s second argument, including Count V – the Baileys’ loss of consortium claim – which stands as a derivative of Counts I, II, and III.

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<sup>2</sup> Pursuant to [Federal Rule of Civil Procedure 15\(a\)\(1\)\(B\)](#), a plaintiff may amend his complaint as a matter of course in response to a motion to dismiss. *Brown v. Bowman*, 2011 WL 1296274, \*16 (N.D. Ind. 2011). The 2009 notes to that rule emphasize that this amendment “will force the pleader to consider carefully and promptly the wisdom of amending to meet the arguments in the motion.” Here, the Baileys chose not to revise their allegations relating to Count IV despite being aware of Defendant’s arguments in support of dismissal and chose instead to brief the current Motion to Dismiss and adjudicate the issues. The Court is not required to give the Baileys another chance to plead their breach of warranty claim and in its discretion, the Court dismisses Count IV of the Complaint with prejudice.

### C. Federal Preemption

Medtronic's final argument in support of its Motion to Dismiss is that the Baileys' claims are preempted under the Medical Device Amendments Act of 1976 (the "MDA") to the Food, Drug, and Cosmetics Act. [[Filing No. 11 at 19.](#)] As a preliminary matter, the Court notes that preemption is an affirmative defense and, as such, it is properly raised through a Rule 12(c) motion for judgment on the pleadings rather than a Rule 12(b)(6) motion to dismiss. *Fisk*, 2017 WL 4247983, at \*5. Moreover, "pleadings need not anticipate or attempt to circumvent affirmative defenses." *Id.* at \*5 (quoting *Bausch*, 630 F.3d at 561).

Twice in the past year, the U.S. District Court for the Northern District of Indiana discussed federal preemption and the IPLA, first in *Cavender*, 2017 WL 1365354 (Lee, J.) and then in *Fisk*, 2017 WL 4247983 (DeGuilio, J.). In both cases, the Court held that, pursuant to the Seventh Circuit's decision in *Bausch*, 630 F.3d at 552-53, plaintiffs could pursue tort claims under state law for injuries caused by Class III devices under the MDA, but must rely only on violations of federal requirements to support those claims. *Fisk*, 2017 WL 4247983, at \*5; *Cavender*, 2017 WL 1365354, at \*10.

Here, just as in *Fisk*, Medtronic does not appear to dispute that a claim based on a manufacturing defect that results from a failure to comply with federal requirements can avoid preemption. Medtronic instead alleges that the Baileys failed to plead that Mr. Bailey's injuries resulted from a violation of a federal requirement. [[Filing No. 11 at 21.](#)] On this issue, the Court need not belabor the point and adopts the holding in *Fisk* that:

[t]his argument asks more of [the plaintiff] than what is required at the pleading stage, though. In order to ultimately prevail on this claim, [the plaintiff] will have to prove that Medtronic violated a federal requirement in manufacturing the device and that she suffered an injury as a result of a defect caused by that violation. But preemption is an affirmative defense, and complaints need not address or plead around affirmative defenses . . . If a complaint need not plead such a violation in

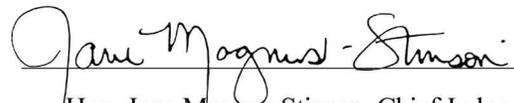
the first place, it follows that a complaint need not trace the injury to such a violation in particular.

*Fisk*, 2017 WL 4247983, at \*5 (citations omitted). Preemption, therefore, does not provide grounds for the Court to dismiss the Baileys' claims at this stage of the proceedings.

**IV.  
CONCLUSION**

For the foregoing reasons, Medtronic's Motion to Dismiss, [[Filing No. 10](#)], is granted in part and denied in part, as follows: the Motion is **GRANTED** as to Count IV of the Complaint, which is **DISMISSED** with prejudice; the Motion is **DENIED** as to Counts I, II, III, and V of the Complaint. Any future statements of claims filed by the Baileys shall be in accordance with the Court's findings herein.

Date: 12/6/2017

  
Hon. Jane Magnus-Stinson, Chief Judge  
United States District Court  
Southern District of Indiana

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