UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION

TAMI FISK,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 3:17-CV-032 JD
	)	
MEDTRONIC, INC.,	)	
	)	
Defendant.	)	

OPINION AND ORDER

This is a product liability action over a medical device. Plaintiff Tami Fisk had a device known as the SynchroMed II implanted to deliver pain medication directly to her spine, where she experienced chronic pain. The device consisted of a pump implanted in her abdomen, and a catheter that connected to the pump and ran to the spine, where it delivered the medication. After the device stopped working properly, she had the pump removed in 2013, but the catheter remained implanted. She later began experiencing rubbing and poking sensations in her abdomen, and the catheter eventually pierced through her skin. She thus had to undergo a further surgery to remove the catheter, which had developed infections at both ends. Ms. Fisk filed this suit against Medtronic, Inc., which manufactured the device, alleging a variety of theories under state law. Medtronic moved to dismiss, arguing that the claims are barred in part by the statute of limitations, and that the remaining claims either fail to state a valid claim under state law or are preempted by federal law, or both. For the following reasons, the Court grants the motion in part, and denies it in part.

I. FACTUAL BACKGROUND

Plaintiff Tami Fisk suffers from chronic back pain associated with spinal fusions and back surgeries. To treat that pain, she underwent surgery in 2000 to have a SynchroMed II device

implanted in her abdomen to administer pain medication into the intrathecal space of her spine (her spinal canal). The device includes two components: a pump and a catheter. The pump is implanted in the abdomen and connects to a thin catheter that extends back to the spine, where it delivers the medication. The device initially worked well for Ms. Fisk. In 2008, she underwent surgery to replace the pump with a new model, but the original catheter remained in place and was connected to the new pump. The new device began leaking its medication, though, which caused painful granulomas (inflammations). Ms. Fisk was thus weaned off of the medication and stopped using the device by the end of 2012.

In December 2013, Ms. Fisk underwent surgery to remove the device. She alleges that, on the recommendation of Medtronic, which manufactured the device, only the pump was removed, and the catheter was left implanted. About a year later, she began experiencing rubbing and poking sensations in her abdomen, before the catheter finally pierced through her skin and became exposed. Ms. Fisk thus had to undergo another procedure on January 7, 2015, to remove the catheter, which had developed infections on both ends. Ms. Fisk alleges in this action that the catheter was defective and was not safe to have remained implanted.

The SynchroMed II device is a Class III medical device that was approved by the FDA through its Pre-Market Approval process in 1988. As discussed below, Class III medical devices are subject to a rigorous approval process, after which they are subject to continuing requirements that regulate their manufacture and labeling and that require the manufacturer to report incidents or malfunctions in which the device caused or contributed to death or serious injury. Ms. Fisk alleges that Medtronic committed numerous violations of its various obligations over a number of years relative to the SynchroMed II device. She cites a series of warning letters issued to Medtronic by the FDA finding, among other things, that certain of these devices were

"adulterated," in that they were not manufactured in compliance with applicable standards, and that Medtronic failed to implement proper complaint handling procedures and to timely notify the FDA of adverse events. She also alleges that the FDA issued a number of recalls for SynchroMed II devices, and that most recently, the FDA entered a consent decree with Medtronic that barred Medtronic from continuing to manufacture these devices until it meets certain conditions.

Drawing in part on this pattern of conduct, Ms. Fisk alleges that the device that was implanted in her was defective and was not manufactured in compliance with the applicable regulations. She further alleges that Medtronic failed to report adverse events and known problems with the devices to the FDA, and that if the FDA had been properly informed of those issues, she and her doctors would have learned of them in turn and would have removed the catheter when the pump was removed instead of leaving it implanted. Accordingly, she filed a complaint against Medtronic in state court on December 12, 2016, asserting six claims under the Indiana Product Liability Act. Medtronic removed the action to federal court on the basis of diversity of citizenship,[1] and has now moved to dismiss the complaint.

II. STANDARD OF REVIEW

In reviewing a motion to dismiss for failure to state a claim upon which relief can be granted under Federal Rule of Civil Procedure 12(b)(6), the Court construes the complaint in the light most favorable to the plaintiff, accepts the factual allegations as true, and draws all reasonable inferences in the plaintiff's favor. *Reynolds v. CB Sports Bar, Inc.*, 623 F.3d 1143,

[1] Ms. Fisk is a citizen of Michigan; Medtronic is a citizen of Minnesota, as it is a corporation that is incorporated in and has its principal place of business in Minnesota; and the amount in controversy exceeds $75,000. The complaint also named "Doe Defendants 1–10" as defendants, but "defendants sued under fictitious names shall be disregarded" for this purpose. 28 U.S.C. § 1441(b)(1). Those defendants can be disregarded as to the merits as well, as including those sorts of fictitious defendants in the caption of a complaint serves no purpose in federal court.

1146 (7th Cir. 2010). A complaint must contain only a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). That statement must contain sufficient factual matter, accepted as true, to state a claim for relief that is plausible on its face, *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009), and raise a right to relief above the speculative level. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). However, a plaintiff's claim need only be plausible, not probable. *Indep. Trust Corp. v. Stewart Info. Servs. Corp.*, 665 F.3d 930, 935 (7th Cir. 2012). Evaluating whether a plaintiff's claim is sufficiently plausible to survive a motion to dismiss is "'a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.'" *McCauley v. City of Chicago*, 671 F.3d 611, 616 (7th Cir. 2011) (quoting *Iqbal*, 556 U.S. at 678).

III. DISCUSSION

Ms. Fisk asserts six counts against Medtronic, all arising under Indiana law. Though all of the claims are based on the Indiana Product Liability Act, Ms. Fisk set them forth in six counts, which she labeled as follows: (1) manufacturing defect; (2) failure to warn; (3) negligence; (4) breach of express warranty; (5) breach of implied warranty; and (6) negligent misrepresentation. Medtronic moved to dismiss the complaint in its entirety, offering a number of arguments. It first argues that Ms. Fisk's claims are barred by the statute of limitations. It also argues that some of Ms. Fisk's claims do not allege valid theories under state law. Finally, it argues that her claims are preempted by federal law to the extent they would impose requirements beyond those imposed by federal law, and that Ms. Fisk has not adequately pleaded that Medtronic violated its obligations under federal law and that she was injured as a result. After first addressing the statute of limitations, the Court addresses the remaining arguments together, as the pleading and scope of the state law claims and the question of whether those claims are preempted are interrelated.

A. Statute of Limitations

Medtronic argues that Ms. Fisk's claims are barred by the two-year statute of limitations under the Indiana Product Liability Act. Ind. Code § 34-20-3-1(b)(1). Ms. Fisk filed her complaint on December 12, 2016, so any claims that accrued more than two years before that date are barred. Medtronic first notes that Ms. Fisk had her first pump replaced in 2008 (the complaint does not specify why), and that her second pump began leaking before 2010 and was removed in December 2013, all of which occurred more than two years before Ms. Fisk filed the complaint. Thus, Medtronic argues that any claim based on the first pump, the device's failure, or removal of the second pump is barred by the statute of limitations. Ms. Fisk does not take issue with that analysis, but instead argues that her claims are based solely on the catheter that was left implanted after her surgery in 2013, and that later protruded through her skin and had to be removed in January 2015. Accordingly, any claim that may have been asserted other than for the catheter that remained implanted is dismissed.

Medtronic further argues that any claim related to the catheter is barred by the statute of limitations as well. It notes that the complaint alleges that Ms. Fisk first noticed the rubbing and poking sensations in her abdomen in "late 2014." [DE 6 ¶ 16]. Because any claim that accrued before December 12, 2014 is barred, Medtronic asserts that a claim based on the catheter is "likely" barred, and it objects in its reply brief that Ms. Fisk provided "no evidence" of when she first discovered the problem with the catheter. However, the statute of limitations is an affirmative defense, and "'complaints need not anticipate and attempt to plead around defenses.'" *Chicago Bldg. Design, P.C. v. Mongolian House, Inc.*, 770 F.3d 610, 613 (7th Cir. 2014) (quoting *United States v. N. Trust Co.*, 372 F.3d 886, 888 (7th Cir. 2004)). Accordingly, "a motion to dismiss based on failure to comply with the statute of limitations should be granted only where 'the allegations of the complaint itself set forth everything necessary to satisfy the

affirmative defense.'" *Id.* (quoting *United States v. Lewis*, 411 F.3d 838, 842 (7th Cir. 2005)). In other words, dismissal on this ground at the pleading stage is only appropriate when the plaintiff "affirmatively plead[s] [her]self out of court." *Id.*; *see also Vinson v. Vermilion Cty., Ill.*, 776 F.3d 924, 929 (7th Cir. 2015) ("[A] plaintiff may plead herself out of court when she includes in her complaint facts that establish an impenetrable defense to her claims.").

Here, the complaint is ambiguous as to when Ms. Fisk discovered the problem with the catheter—"late 2014" could mean either before or after December 12, 2014. Ms. Fisk thus has not plead herself out of court, as the complaint does not establish that this aspect of her claims is untimely. A plaintiff need not submit evidence at the pleading stage or plead around affirmative defenses, either, so dismissal of this aspect of Ms. Fisk's complaint on statute of limitations grounds is unwarranted. Therefore, Ms. Fisk may proceed on her claims to the extent they are based on the catheter and the problems that led to her injury in late 2014 and the catheter's subsequent removal in 2015.

B. Pleading and Preemption

The rest of Medtronic's arguments address whether Ms. Fisk has properly pleaded her claims and whether those claims are preempted. Medtronic first objects to these claims on state law grounds, arguing that Ms. Fisk improperly divided her theories of liability under the Indiana Product Liability Act into six separate claims, and also that some of her theories either are not cognizable under the IPLA or otherwise fail to state a valid claim under state law. Second, Medtronic argues that Ms. Fisk's state-law claims are preempted by a federal law that prohibits states from imposing on Class III medical devices any requirements that are different from or in addition to those imposed by federal law. 21 U.S.C. § 360k(a). In effect, that provision restricts plaintiffs to only using violations of federal requirements as the bases for any state-law claims. Medtronic argues that Ms. Fisk's claims are preempted either because they would impose

requirements beyond those imposed by federal law, or because Ms. Fisk has failed to adequately plead that she was injured as a result of a particular violation of a federal regulation.[2]

Before addressing each of the claims in turn, the Court will discuss some issues common to the claims. First, Ms. Fisk's claims each arise under the Indiana Product Liability Act, which "governs all actions brought by a user or consumer against a manufacturer for physical harm caused by the product, regardless of the legal theory upon which the action is brought." *Piltch v. Ford Motor Co.*, 778 F.3d 628, 632 (7th Cir. 2015). The IPLA "'imposes liability upon sellers of a product in a defective condition unreasonably dangerous to any user or consumer.'" *Weigle v. SPX Corp.*, 729 F.3d 724, 730 (7th Cir. 2013) (quoting *Ford Motor Co. v. Rushford*, 868 N.E.2d 806, 809 (Ind. 2007)); *see* Ind. Code § 34-20-2-1. There are multiple theories on which a plaintiff can prove that a product was "defective" 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; *see also Nat. Gas Odorizing, Inc. v. Downs*, 685 N.E.2d 155, 161 (Ind. Ct. App. 1997).

Federal courts have often noted that, despite the availability of multiple theories of liability, the IPLA provides for only a single cause of action. Medtronic thus argues at the outset that Ms. Fisk's complaint improperly set forth her various theories of liability in separate counts, instead of combining them into a single count. However, Medtronic has failed to articulate how this argument is anything more than semantics. Courts sometimes state that multiple counts under the IPLA are "merged," but even that is unnecessary at this point. Whether the theories are

[2] Medtronic also raises implied preemption, but only as to the breach of warranty claims, which are being dismissed on other grounds. Ms. Fisk's remaining claims are tort law claims based on manufacturing defects and a failure to warn, not fraud on a federal agency, so those claims are not impliedly preempted. *Bausch*, 630 F.3d at 558; *see also Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013) (en banc).

designated as Counts 1 through 6, or Count 1(a) through 1(f), both parties understand that Ms. Fisk is pursuing a single cause of action under the IPLA. That suffices at the pleading stage, and if anything, breaking the different theories into separate counts made the complaint easier to understand. To the extent this distinction would have any practical effect at a later stage of the case, the parties may revisit the issue then. As to whether Ms. Fisk's various counts assert valid theories of liability under the IPLA, though, that is a separate question, and the Court addresses that issue below.

Some background on preemption is also necessary. Class III medical devices such as the SynchroMed II are devices that are used in supporting or sustaining human life or that present a potential unreasonable risk of illness or injury. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008) (citing 21 U.S.C. § 360c(a)(1)(C)(ii)). Given the critical importance of those sorts of devices, they are subject to the most rigorous approval process and oversight by the FDA. In deciding whether to approve such a device, the FDA must "weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use," and it may grant approval only if it finds there is a "reasonable assurance" of the device's "safety and effectiveness." *Id.* at 318 (citing 21 U.S.C. §§ 360e(d), 360c(a)(2)(C)). Once a device has received premarket approval, federal law forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness. *Id.* at 319. In addition, manufacturers are subject to ongoing reporting requirements, and must inform the FDA of any new studies concerning the device, and of any reported incidents or malfunctions involving the device that could cause or contribute to death or serious injury. *Id.*

To prevent state laws from upsetting the balances struck by this regulatory regime, the statute also includes an express preemption provision. Under § 360k(a), states may not establish "any requirement . . . which is different from, or in addition to, any requirement" imposed under federal law as to those devices. 21 U.S.C. § 360k(a). Thus, to the extent a manufacturer could be held liable under state law despite having complied with the applicable requirements under federal law, state law is preempted. *Riegel*, 552 U.S. at 323–25; *Bausch*, 630 F.3d at 550 ("Medical device manufacturers who subject their Class III devices to the rigorous premarket approval process are protected by federal law from civil liability so long as they *comply* with federal law."); *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005) ("Where a federal requirement permits a course of conduct and the state makes it obligatory, the state's requirement is in addition to the federal requirement and thus is preempted."). This provision does not prevent states from providing causes of action for claims based on violations of federal requirements, though. *Riegel*, 552 U.S. at 330. Accordingly, plaintiffs can still pursue tort claims under state law for injuries caused by Class III devices, but must rely only on violations of federal requirements to support those claims. *Bausch*, 630 F.3d at 552–53.

There is one other important point to note about preemption: it is an affirmative defense. *Id.* at 561. That means, first, that it is properly raised through a Rule 12(c) motion for judgment on the pleadings after the filing of an answer, not through a Rule 12(b)(6) motion to dismiss, though Ms. Fisk does not make anything of that distinction. Second, and more importantly, "pleadings need not anticipate or attempt to circumvent affirmative defenses," *Bausch*, 630 F.3d at 561, so a complaint will only be dismissed on the basis of an affirmative defense only when the plaintiff pleads herself out of court, *Xechem, Inc. v. Bristol-Myers Squibb Co.*, 372 F.3d 899, 901 (7th Cir. 2004) ("Complaints need not contain *any* information about defenses and may not

be dismissed for that omission."). Thus, if a claim plainly relies on a state-law duty that would differ from the federal requirements, it can be dismissed at the pleading stage. *E.g.*, *Bausch*, 630 F.3d at 559 (noting that claims based on violations of "industry" standards that are different from "regulatory" standards could be dismissed); *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1206 (8th Cir. 2010) (holding that a design-defect claim was properly dismissed as preempted because the FDA accepted the design of a Class III medical device in granting pre-market approval of the device). However, a plaintiff does not have a burden at the pleading stage of establishing that a claim *is not* preempted, so a complaint need not allege violations of specific federal requirements in order to avoid dismissal on preemption grounds.[3] *Bausch*, 630 F.3d at 560–62. With those understandings in mind, the Court turns to each of Ms. Fisk's claims.

Count 1: Manufacturing Defect

Ms. Fisk first asserts a claim for a manufacturing defect, arguing that the catheter developed infections and protruded through her skin because it was manufactured out of compliance with its specifications. A manufacturing defect is a cognizable claim under the IPLA, and Medtronic does not argue that this claim fails as a matter of state law. It instead focuses its arguments on preemption. On that topic, Medtronic does not appear to dispute[4] that a claim based on a manufacturing defect that results from a failure to comply with federal requirements can avoid preemption, as federal law imposes strict requirements on the manufacture of these devices. *Bausch*, 630 F.3d at 560 ("[I]f the problem turns out to be a failure to comply with the

[3] Granted, courts have been far from uniform in their approaches towards preemption, and Medtronic has little difficulty citing multiple cases that have accepted its positions (predominantly from district courts outside this circuit). But because this Court is bound by the Seventh Circuit's precedent, it does not address the holdings of those other cases applying different standards.

[4] At least at this stage, though it does contend that *Bausch* was wrongly decided.

FDA's legally enforceable conditions for approval of the device, section 360k will not protect the manufacturer."). It argues, however, that Ms. Fisk has failed to plead that any of her injuries resulted from a particular violation of a federal requirement, so her claim fails for that reason.

This argument asks more of Ms. Fisk than what is required at the pleading stage, though. In order to ultimately prevail on this claim, Ms. Fisk 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. *Bausch*, 630 F.3d at 561. Thus, as the Seventh Circuit noted in *Bausch*, a complaint need not "specify the precise defect or the specific federal regulatory requirements that were allegedly violated" in order to state a claim that avoids preemption at the pleading stage. *Id.* at 560. If a complaint need not plead such a violation in the first place,[5] it follows that a complaint need not trace the injury to such a violation in particular.

Ms. Fisk must still allege that she suffered an injury as a result of a manufacturing defect in order to plead a claim under the IPLA. But that is a matter of state law, and Medtronic does not argue that Ms. Fisk failed to plead a claim under the IPLA—she alleges that she was injured as a result of a manufacturing defect in the catheter that allowed it to become infected and to protrude through her skin. Medtronic's argument goes a step further and asks that Ms. Fisk be required to plead that her injury resulted not just from a manufacturing defect in general (as would suffice under state law), but from a defect caused by a violation of federal requirements in

[5] Ms. Fisk's complaint spends many pages setting forth various warning letters and recalls and other regulatory actions relative to the SynchroMed II device, but as Medtronic notes, she makes little effort to connect those materials to her particular injury. Those sorts of materials might not get her past summary judgment, but at present, the Court construes these allegations as attempting to establish a pattern of violations to support the plausibility of Ms. Fisk's allegations that Medtronic engaged in similar conduct that caused her device to be defective.

particular, in order to state a claim that is not preempted. But since preemption is an affirmative defense, the complaint need not supply those additional allegations to confront that second layer of analysis.

In sum, Ms. Fisk has stated a valid claim under state law that she was injured as a result of a manufacturing defect. Though to ultimately prevail on that claim she will need to prove that the defect resulted from a violation of federal requirements, she has not pleaded herself out of court by relying on requirements that would necessarily be different from or in addition to those imposed by federal law, so the Court cannot conclude at the pleading stage that her claim is preempted. Therefore, the Court denies the motion to dismiss as to Count 1.

Count 2: Failure to Warn

Ms. Fisk next asserts a claim for Medtronic's failure to provide adequate warnings of the risks or defects in its device in light of reports of adverse events that it received and other dangers of which it was aware. Specifically, Ms. Fisk alleges that Medtronic failed to report various information about the device to the FDA, including known problems with the device and adverse events and complaints about the device's performance. She further alleges that if Medtronic had properly provided that information to the FDA, she and her doctors would have learned of the dangers of the device and would have decided to remove the catheter completely during the 2013 surgery, rather than leaving it implanted at that time.

Medtronic offers several arguments in support of dismissal. First, it argues that the claim fails as a matter of state law because, under the "learned intermediary" doctrine, it had no duty to warn Ms. Fisk directly, but only to adequately warn her doctors. *See Phelps v. Sherwood Med. Indus.*, 836 F.2d 296, 303 (7th Cir. 1987). However, this argument misconstrues Ms. Fisk's claim. She does not argue that Medtronic should have disclosed this information to herself—such a claim would have obvious preemption problems, as federal regulations do not require device

manufacturers to disclose adverse events directly to patients. *McMullen*, 421 F.3d at 488–90; *Stengel*, 704 F.3d at 1234 (Watford, J., concurring). Instead, she alleges that Medtronic failed to properly disclose the information *to the FDA*. Thus, Medtronic's argument that it does not have a duty to disclose the information *to Ms. Fisk* is not responsive to this claim.

Medtronic next argues that this claim fails because state law does not impose a duty to convey this information to a third party like the FDA. However, Medtronic does not develop this argument at all, and does not even cite any authority applying Indiana law. Indiana law does impose a duty to warn, and as just noted, that duty will sometimes require the manufacture to provide the information to third parties rather than the end users themselves. *See Nat. Gas Odorizing, Inc. v. Downs*, 685 N.E.2d 155, 163 (Ind. Ct. App. 1997) (holding that a manufacturer can satisfy its duty to warn by relying on a "sophisticated intermediary," depending on factors like whether the manufacturer can reasonably rely on the intermediary to warn the ultimate consumer, and noting that the application of this doctrine is almost always a question for the trier of fact); *see also Phelps*, 836 F.2d at 303 (discussing the similar "learned intermediary" doctrine). In considering similar duties in other states, courts have found that the states' laws would impose a duty to warn the FDA, as required by federal regulations. *E.g.*, *Stengel*, 704 F.3d at 1233;[6] *Laverty v. Smith & Nephew, Inc.*, 197 F. Supp. 3d 1026, 1035 (N.D. Ill. 2016) ("It is true that Illinois does not impose on medical device manufacturers a 'duty to report to the FDA' in so many words. But Illinois does recognize a claim for failure to warn predicated on a product manufacturer's failure to disclose known defects."). In addition, at least one court applying

[6] *Stengel* concluded that Arizona law imposed a duty to report information to the FDA. Notably, the Indiana Court of Appeals relied heavily on the same principles of Arizona law in its discussion of the sophisticated intermediary doctrine in *Downs*, 685 N.E.2d at 163–64, which further suggests that Indiana would recognize such a duty.

Indiana law has accepted at least for purposes of the pleading stage that Indiana law would impose such a requirement. *McAfee v. Medtronic, Inc.*, No. 1:12-cv-417, 2015 WL 3617755, at *5 (N.D. Ind. June 4, 2015) ("Mr. McAfee has stated plausible claims for relief under state law based on an alleged failure to warn the FDA . . . ."), *reconsidered on other grounds*, 2016 WL 2588807 (N.D. Ind. May 5, 2016). This Court does likewise, and declines to dismiss this claim on that basis.

Medtronic next argues that the failure-to-warn claim is preempted. It argues that the state-law duty to warn is not "identical" to the federal requirement to disclose information to the FDA, as state law sometimes contemplates warnings to the user or consumer of a device, so the state requirements are different from or in addition to the federal ones. As just discussed, however, that is not the theory on which Ms. Fisk bases her claim; she relies only on allegations that Medtronic failed to provide information to the FDA, which is a requirement that federal law does impose. If Medtronic complied with the federal requirements, then this claim will ultimately fail, but it will not be preempted if Ms. Fisk can prove that she was harmed by its violation of those federal requirements. *Bausch*, 630 F.3d at 550; *Stengel*, 704 F.3d at 1233; *Laverty*, 197 F. Supp. 3d at 1033 ("Section 360k does not expressly preempt state law claims alleging harm caused by conduct that violates a federally imposed requirement. That is precisely what the [plaintiffs] have alleged: that [the defendant] failed to disclose information relevant to the safety and effectiveness of its device in violation of the rules the FDA set forth as a condition of premarket approval."). Accordingly, the Court cannot conclude at this stage that the claim is preempted on that basis.

Finally, Medtronic argues that Ms. Fisk failed to adequately plead a causal connection between a violation of a federal requirement and her injury. As with the previous claim, though,

this argument asks more than what is required at the pleading stage. Ms. Fisk alleges that Medtronic knew that the device that was implanted in her was defective and dangerous, and that, had Medtronic timely notified the FDA of the known problems and defects, she and her doctors would have learned of those dangers and would have removed the catheter at the same time they removed the pump, instead of leaving the catheter implanted. As discussed by the concurrence in *Stengel*, proving that indirect chain of causation may be a tall order, but that does not mean that these allegations of causation are inadequate. 704 F.3d at 1234 (Watford, J., concurring). In addition, these are the very allegations that were lacking in *McAfee*, on which Medtronic relies. There, the court dismissed the failure-to-warn claim based on a lack of causation because the plaintiff did not allege that if the proper information had been provided to the FDA, his doctor would have learned of the information and pursued a different course of treatment. *McAfee*, 2016 WL 2588807, at *2. Ms. Fisk has alleged that exact causal chain, so her claim does not fail for lack of causation. Accordingly, the Court denies the motion to dismiss this count.

Count 3: Negligence

In Count 3, Ms. Fisk asserts a claim for "negligence." She alleges first that Medtronic failed to manufacture the device in conformity with its specifications, and second that Medtronic failed to report adverse events to the FDA. The first theory appears to duplicate the manufacturing-defect claim in Count 1, and the second theory appears to duplicate the failure-to-warn theory in Count 2. Ms. Fisk does not attempt to explain what theory this count presents that is not already encompassed in the previous counts, and her brief does not even address this count directly. Thus, because this count is merely duplicative of the previous counts, and because the IPLA provides for only a single cause of action anyway, the Court dismisses this count as redundant.

Counts 4 and 5: Beach of Express and Implied Warranties

Ms. Fisk next asserts claims for breaches of express and implied warranties. Medtronic moves to dismiss these claims on both state-law and preemption grounds. As to state law, Medtronic argues that these claims fail because the IPLA subsumes any claims for breaches of warranties. *Cavender v. Medtronic, Inc.*, No. 3:16-cv-232, 2017 WL 1365354, at *6–7 (N.D. Ind. Apr. 14, 2017). Ms. Fisk concedes that point and does not object to the dismissal of these claims, so the Court grants the motion to dismiss as to these counts.

Ms. Fisk states, though, that she wishes to file an amended complaint pleading breach of warranty claims under the Uniform Commercial Code instead of the IPLA. Medtronic argues that those claims would fail under state law as well, as regardless of the label, they would still be product liability claims that would be subsumed by the IPLA. *Piltch v. Ford Motor Co.*, 11 F. Supp. 3d 884, 888 (N.D. Ind. 2014) ("[A] contractual breach of warranty claim would not be governed by the IPLA, but . . . when the claim, as here, is for tortious personal injury, the breach of warranty claim is subsumed by the IPLA."), *aff'd*, 778 F.3d 628 (7th Cir. 2015); *Cavender*, 2017 WL 1365354, at *6–7. That is a possibility, but breach of warranty claims under the UCC are not mutually exclusive with product liability claims under the IPLA. *Roper v. Advanced Neuromodulation Sys., Inc.*, No. 3:16-cv-79, 2017 WL 1367194, at *3 (N.D. Ind. Mar. 31, 2017) ("As long as a breach of warranty claim is not in actuality a mislabeled strict liability claim, Indiana courts direct that it be treated as a contractual claim."); *Collins v. Pfizer, Inc.*, No. 1:08-CV-888, 2009 WL 126913, at *2 (S.D. Ind. Jan. 20, 2009) ("The IPLA does not preempt all claims for breach of warranty under the Uniform Commercial Code."). Because Ms. Fisk has yet to provide a proposed amended complaint, the Court cannot determine at this time which category her claims would fall into. If Ms. Fisk wishes to pursue these claims, she may file a motion for leave to amend her complaint, and the parties can pursue this issue in that context.

For the same reason, the Court declines to address at this time whether those claims would be preempted, as Medtronic argues. True, it is difficult to see what theory Ms. Fisk could present through these claims that would not already be encompassed in her previous claims and that would not ultimately be preempted. However, that question is better addressed once Ms. Fisk has submitted a proposed amended complaint, should she decide to pursue these claims.

Count 6: Negligent Misrepresentation

Last, Ms. Fisk asserts a claim for a negligent misrepresentation, arguing that Medtronic told her doctors that the catheter was safe to remain implanted when in fact it was not. However, this claim fails for multiple reasons as a matter of state law. First, though this count begins by citing to the IPLA, Ms. Fisk does not attempt to ground it in any cognizable theory of liability under that Act; she instead attempts to plead the elements of a stand-alone tort claim. That is problematic since, as previously discussed, the IPLA governs all actions by a user or consumer against a manufacturer for physical harm caused by a product, regardless of the legal theory upon which the action is brought. *Piltch*, 778 F.3d at 632; *see also Lautzenhiser v. Coloplast A/S*, No. 4:11-cv-86, 2012 WL 4530804, at *2 (S.D. Ind. Sept. 29, 2012) ("[T]he IPLA precludes any common law claims on products liability issues."). It might be possible to frame such a claim within the contours of the IPLA, such as by alleging a failure to give proper instructions on the product's use, but Ms. Fisk does not make that argument, and instead focuses only on pleading a stand-alone tort claim.

Second, to the extent such a claim would be available apart from the IPLA, Ms. Fisk has not shown that it would apply to these circumstances. Indiana law has recognized a claim for negligent misrepresentations only in limited contexts, and this claim requires a plaintiff to establish, among other elements, that the defendant "supplie[d] false information for the guidance of others *in their business transactions*." *McCalment v. Eli Lilly & Co.*, 860 N.E.2d

884, 896 (Ind. Ct. App. 2007) (quoting *Eby v. York-Div., Borg-Warner*, 455 N.E.2d 623, 628–29 (Ind. Ct. App. 1983)) (emphasis added); *Lautzenhiser*, 2012 WL 4530804, at *6 (noting that this claim "has not been extended outside the business transaction context in Indiana"). Not only was Ms. Fisk not entering a business transaction in connection with this alleged misrepresentation—she was undergoing a surgery—she was not even acquiring a product at the time—she was having the device *removed*. Thus, she has not pleaded a negligent misrepresentation claim under state law. *Lautzenhiser*, 2012 WL 4530804, at *6 (dismissing such a claim because "[a]ny misrepresentations by [the defendant] were in regard to the safety or efficacy of a potential medical procedure, not a business transaction"). Therefore, the Court grants the motion to dismiss as to this count.

IV. CONCLUSION

For those reasons, the motion to dismiss [DE 8] is GRANTED in part and DENIED in part. The Court denies the motion as to Counts 1 and 2, but grants the motion as to Counts 3 through 6.

SO ORDERED.

ENTERED: September 25, 2017

/s/ JON E. DEGUILIO
Judge
United States District Court