UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
HAMMOND DIVISION

KIRK J. BLEDSOE,

Plaintiff,

v.

MEDTRONIC, INC.,

Defendant.

CAUSE NO.: 2:18-CV-133-TLS

OPINION AND ORDER

This matter is before the Court on Defendant Medtronic, Inc.'s Motion to Dismiss [ECF No. 8], filed on April 12, 2018. For the reasons set forth below, the Court GRANTS in part and DENIES in part Defendant Medtronic, Inc.'s Motion to Dismiss.

FACTUAL BACKGROUND

The following facts are alleged in the Plaintiff's Complaint [ECF No. 4]. On June 14, 2011, Plaintiff Kirk J. Bledsoe was implanted with a SynchroMed II Programmable Implantable Drug Infusion System ("SynchroMed Infusion System")[1] to treat an unspecified medical condition. Compl. ¶ 16, ECF No. 5. The SynchroMed Infusion System is a medical device that is used to treat certain medical conditions by delivering medication via an implanted pump and catheter. *Id.* ¶ 2. Defendant Medtronic, Inc., a Minnesota corporation, designs, manufactures, and sells the SynchroMed Infusion System, including the system implanted in the Plaintiff. *Id.* ¶¶ 3,

[1] The Plaintiff's Complaint refers to the device as a "Medtronic SynchroMed II Programmable Pump, model 8637-40." Compl. ¶ 14. To ensure accuracy, the Court has opted to refer to the device as a "SynchroMed II Programmable Implantable Drug Infusion System," the name used by the Defendant (the creator of the device). Def.'s Mem. Supp. Mot. Dismiss 1, ECF No. 9.

6, 16, 31. Between March 2008 and March 2017, the Defendant issued ten recalls on the SynchroMed Infusion System. *Id.* ¶¶ 13–15, 17–23.

In January 2015, the Plaintiff underwent a series of evaluations regarding his device at Methodist Hospital in Merrillville, Indiana. *Id.* ¶ 25. During each of the evaluations, a Medtronic representative was present. *Id.* At no point during the January 2015 evaluations was the Plaintiff informed of the recalls, and, based on the series of evaluations, the Plaintiff was led to believe that his device was in perfect working condition. *Id.* In November 2015, the Plaintiff underwent another series of implant evaluations at Methodist Hospital. *Id.* ¶ 26. At no point during the second series of evaluations was the Plaintiff informed of the recalls to his device, and he was, once more, led to believe his device was working properly. *Id.*

On December 7, 2015, the Plaintiff's device malfunctioned. *Id.* ¶ 27. This malfunction resulted in the Plaintiff requiring an emergency trip to the hospital for immediate evaluation. *Id.* Again, a Medtronic representative was present during the December 7, 2015 evaluation. *Id.* For a third time, the Plaintiff was not informed of the recalls to his device and was led to believe his device was working properly. *Id.*

On December 29, 2015, the Plaintiff's device once again malfunctioned. *Id.* ¶ 28. Due to the two malfunctions, the Plaintiff was hospitalized from December 20, 2015, through January 4, 2016. *Id.* During the Plaintiff's hospitalization, it was determined that the motor on his device had stalled. *Id.* Again the Plaintiff was evaluated by a Medtronic representative, who advised him that the device had restarted and that no further evaluation was needed. *Id.* The Plaintiff requested an additional evaluation from the Medtronic representative, but his request was denied. *Id.* At no point during his hospitalization was the Plaintiff informed of the recalls of his device. *Id.*

Over the next several months, the Plaintiff's device continued to malfunction. *Id.* ¶ 29. Ultimately, the device's motor stalled completely, resulting in a failure of the Plaintiff's device. *Id.* On October 27, 2016, the Plaintiff's device was explanted. *Id.* ¶ 30. The Plaintiff claims that as a result of the malfunction and removal of the device he has suffered and continues to suffer substantial medical expenses, loss of quality of life, severe and permanent pain and suffering, a depreciated and impaired marital relationship, severe and permanent physical impairment, and other damages. *Id.* ¶ 33.

PROCEDURAL HISTORY

On November 3, 2017, the Plaintiff filed his Complaint [ECF No. 5] in Porter County, Indiana, Superior Court, bringing claims under the Indiana Products Liability Act and seeking relief for unspecified injuries he sustained as a result of a defective SynchroMed Infusion System. *Id*. ¶ 1. On April 5, 2018, the Defendant removed this case to federal court on the basis of diversity of citizenship.[2] *See* Notice of Removal, ECF No. 1. On April 12, 2018, the Defendant filed the instant Motion to Dismiss [ECF No. 8] requesting that the Court dismiss the Complaint pursuant to Federal Rule of Civil Produce 12(b)(6) because it fails to state a claim upon which relief can be granted. The Plaintiff filed his Response in Opposition to Defendant's Motion to Dismiss [ECF No. 13] on April 26, 2018, and the Defendant filed its Reply Memorandum in Support of its Motion to Dismiss on May 3, 2018 [ECF No. 14]. On July 9, 2019, Defendant filed a supplement titled Additional Authorities Supporting Defendant Medtronic Inc.'s Motion to Dismiss [ECF No. 23].

[2] Federal jurisdiction is proper because the amount of damages in controversy exceeds $75,000 and the parties are citizens of different states—the Plaintiff is a citizen of Indiana and the Defendant is a citizen of Minnesota, as it is a Minnesota corporation with its primary place of business in Minnesota. *See* 28 U.S.C. § 1332(a)(1), (c)(1).

LEGAL STANDARD

A motion to dismiss brought under Rule 12(b)(6) "challenges the viability of a complaint by arguing that it fails to state a claim upon which relief may be granted." *Camasta v. Jos. A. Bank Clothiers, Inc.*, 761 F.3d 732, 736 (7th Cir. 2014) (citing Fed.R.Civ.P. 12(b)(6); *Gen. Elec. Capital Corp. v. Lease Resolution Corp.*, 128 F.3d 1074, 1080 (7th Cir.1997)). The Court presumes that all well-pleaded allegations are true, views these well-pleaded allegations in the light most favorable to the Plaintiff, and accepts as true all reasonable inferences that may be drawn from the allegations. *Reynolds v. CB Sports Bar, Inc.*, 623 F.3d 1143, 1146 (7th Cir. 2010). Surviving a Rule 12(b)(6) motion "requires more than labels and conclusions . . . [f]actual allegations must be enough to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556).

ANALYSIS

The Plaintiff asserts three counts against the Defendant, all of which arise under Indiana law. Although not specified in each count, the counts are necessarily brought pursuant to the Indiana Products Liability Act ("IPLA"). *See Dague v. Piper Aircraft Corp.*, 418 N.E.2d 207, 212 (Ind. 1981) ("[I]t seems clear the legislature intended that the [IPLA] govern all product liability actions, whether the theory of liability is negligence or strict liability in tort."). Count 1 and Count 2 are both titled "Negligence"; however, the counts are more aptly described as a failure to warn claim (Count 1) and a design and manufacturing defect claim (Count 2). Count 3 is a strict liability claim.

The Defendant, in the instant Motion, sets forth several reasons why the Complaint should be dismissed: (A) the form of the Complaint is improper under the IPLA; (B) the Complaint fails to meet the Federal Rule of Civil Procedure 8(a) pleading requirements; and (C) the Plaintiff's claims are preempted by the Medical Device Amendments to the Food, Drug and Cosmetic Act. The Court will address each argument in turn.

A. Consolidation of Claims under the IPLA

The Defendant contends that the Plaintiff's Complaint is inconsistent with Indiana law because it details three distinct counts, while the IPLA, regardless of the legal theory, provides for a single cause of action. 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." Ind. Code § 34-20-1-1. It is well established that the IPLA "govern[s] all product liability actions, whether the theory of liability is negligence or strict liability in tort." *Dague*, 418 N.E.2d at 212. Therefore, an IPLA claim is properly brought under a single count in one cause of action. *Atkinson v. P&G-Clairol, Inc.*, 813 F. Supp. 2d 1021, 1023–24 (N.D. Ind. 2011) (citing cases).

The Plaintiff agrees with the Defendant but contends that it is sufficient that the Court "treat the claims as a single, merged cause of action under [the] IPLA for [purposes] of Defendant's motion to dismiss." Pl.'s Mem. in Supp. of Resp. in Opp'n to Def.'s Mot. to Dismiss 6. The Plaintiff is correct. In cases where a plaintiff has brought multiple claims under the IPLA—such as the instant case—courts generally allow for the claims to be merged into a single count. *See, e.g.*, *Atkinson*, 813 F. Supp. 2d at 1024; *Am. Int'l Ins. Co. v. Gastite*, No. 1:08-CV-1360, 2009 WL 1383277, at *4 (S.D. Ind. May 14, 2009). Considering that merging the claims is more efficient than dismissing the Complaint and waiting for the Plaintiff to file an

amended pleading, the Court will consider the Complaint to contain one count alleging a cause of action under the IPLA.

B. Federal Rule of Civil Procedure 8(a) Pleading Standard

The Defendant next argues that the Complaint does not satisfy the pleading requirements mandated by Federal Rule of Civil Procedure 8(a)(2). Rule 8(a)(2) requires that a complaint contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2).

Although Plaintiff does not detail the facts of how his system malfunctioned, the Complaint nevertheless alleges the following: the Plaintiff was implanted with the SynchroMed Infusion System; the Defendant designed, manufactured, and sold the SynchroMed Infusion System; the Plaintiff's SynchroMed Infusion System repeatedly malfunctioned; the Plaintiff's SynchroMed Infusion System malfunctioned because the Defendant negligently failed to comply with applicable laws and regulations; the Plaintiff's SynchroMed Infusion System was eventually removed due to repeated malfunctions; the Plaintiff suffered injuries due to the malfunction and removal of his SynchroMed Infusion System; and the Plaintiff's injuries are the direct and proximate cause of the Defendant's negligent conduct. These allegations certainly comprise a short and plain statement of a products liability action that put the Defendant on notice of the Plaintiff's claim

The Court recognizes that the Complaint is not perfect; however, perfection is hardly the standard for surviving a 12(b)(6) motion. Federal preemption aside, when presuming all well-pleaded allegations to be true, viewing the well-pleaded allegations in the light most favorable to the Plaintiff, and accepting as true all reasonable inferences to

be drawn from the allegations, the Court can reasonably infer that the Defendant is liable to the Plaintiff for the alleged misconduct.

C. Preemption by the Medical Device Amendments to the Food, Drug and Cosmetic Act

The Defendant's primary argument is that the Plaintiff's claim under the IPLA should be dismissed because it is preempted by the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act ("FDCA"). The Plaintiff argues that the Defendant's objection is premature, as preemption is an affirmative defense and cannot be the basis of a motion to dismiss pursuant to Federal Rule of Civil Procedure12(b)(6). The Plaintiff also contends that his claims are not preempted by the MDA.

The IPLA provides that

> a person who sells . . . any product in a defective condition unreasonably dangerous to any user or consumer . . . is subject to liability for physical harm caused by that product to the user or consumer or to the user's or consumer's property if:
>
> > (1) that user or consumer is in the class of persons that the seller should reasonably foresee as being subject to the harm caused by the defective condition;
> >
> > (2) the seller is engaged in the business of selling the product; and
> >
> > (3) the product is expected to and does reach the user or consumer without substantial alteration in the condition in which the product is sold by the person sought to be held liable under this article.

Ind. Code § 34-20-2-1. The MDA preemption provision states:

> [N]o 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).

To determine whether the Plaintiff's IPLA claims are preempted by the MDA, background on the FDCA and MDA is necessary.

1. FDCA and MDA Background

Congress enacted the MDA in response to consumer and regulatory concerns surrounding the design, manufacture, and distribution of medical devices. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996). The MDA classifies medical devices into three classes, with each being subject to a different level of regulation. *Id.* at 476–77. Class III devices are devices that either "'presen[t] a potential unreasonable risk of illness or injury,' or which are 'purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health'" and are subject to the highest level of regulation. *Id*. at 477 (quoting 21 U.S.C. § 360c(a)(1)(C)). The SynchroMed Infusion System is a Class III device. *See Fisk v. Medtronic, Inc.*, No. 3:17-CV-32, 2017 WL 4247983, at *1 (Sept. 25, 2017).

One way a Class III device can be introduced into the market is through the FDA's rigorous premarket approval process. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317–18 (2008). During this process, the FDA spends, on average, over 1,000 hours reviewing all information regarding the safety and efficacy of the device to ultimately decide whether to approve the device. *Id.* During its review, "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 may grant

approval only if it is reasonably assured of the device's "'safety and effectiveness.'" *Fisk v. Medtronic, Inc.*, No. 3:17-CV-32, 2017 WL 4247983, at *4 (Sept. 25, 2017) (quoting *Riegel*, 522 U.S. at 318). After receiving 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. 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. (quoting *Riegel*, 522 U.S. at 319) (internal citations omitted). The SynchroMed Infusion System received premarket approval on September 12, 2003. Def.'s Mem. Supp. Mot. Dismiss 1.[3]

2. MDA Preemption Standard

In *Riegel v. Medtronic, Inc.*, the Supreme Court addressed the scope of the MDA preemption, as applied to Class III medical devices that have obtained premarket approval. Specifically, the Supreme Court outlined a two-part test to determine whether state claims are preempted as to a particular medical device. *See Reigel*, 552 U.S. at 320–21. The MDA preempts state requirements that are different or in addition to federal requirements; therefore, a court must first determine whether any federal requirements are applicable to the medical device. *Id.* at 321–22 (citing 21 U.S.C. § 360k(a)). To satisfy this part of the preemption test, the federal requirement must be specific to the device in question and not simply reflect "'generic concerns about device regulation generally.'" *Id.* at 322 (quoting *Lohr*, 518 U.S. at 501).

If federal requirements exist, the court must then determine whether a plaintiff's claims rely upon a state law that is "'different from, or in addition to'" the applicable federal

[3] The Court can take judicial notice of this fact pursuant to Federal Rule of Evidence 201(b) because the fact can be accurately and readily determined by using the resources available on the FDA's webpage, which is an accurate source that the Court cannot reasonably question. *See* Fed. R. Evid. 201(b).

requirements and whether the state law "'relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device.'" *Riegel*, 552 U.S. at 323 (quoting 21 U.S.C. § 360k(a)). This generally protects "[m]edical device manufacturers who subject their Class III devices to the rigorous premarket approve process" from state law claims "so long as they comply with federal law." *Bausch v. Stryker Corp*., 630 F.3d 546, 550 (7th Cir. 2010). However, "'§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations.'" *Id.* at 552 (quoting *Riegel*, 552 U.S. at 330). Therefore, courts should allow a state law claim to proceed if it is based on an alleged violation of federal law. *Id.* at 552.

3. Motion to Dismiss Pursuant to Rule 12(b)(6) for Preempted Claims

Before assessing the Defendant's preemption arguments, the Court must determine whether the Defendant can raise issues of preemption at this point in the proceedings. Preemption is an affirmative defense; therefore, the Defendant should have "[filed] an answer to plead preemption as an affirmative defense and [subsequently moved] for judgement on the pleadings under Rule 12(c)." *Bausch*, 630 F.3d at 561. Complaints cannot be dismissed for failing to anticipate an affirmative defense; therefore, the Defendant's Motion to Dismiss will be granted only if the Plaintiff has pled himself out of court. *See Xechem, Inc. v. Bristol-Myers Squibb Co.*, 372 F.3d 899, 901 (7th Cir. 2004) ("Only when the plaintiff pleads itself out of court—that is, admits all the ingredients of an impenetrable defense—may a complaint that otherwise states a claim be dismissed under Rule 12(b)(6)." (citing *Walker v. Thompson*, 288 F.3d 1005 (7th Cir. 2002))). In summation, the Court will only dismiss the Plaintiff's claims if they "plainly [rely] on a state-law duty that would differ from the federal requirements." *Fisk*, 2017 WL 4247983, at *5 (citing *Bausch*, 630 F.3d at 559).

4. ***Applicable Federal Requirements***

In *Riegel*, the Court held that the premarket approval process imposes requirements that satisfy the first part of the MDA preemption test. 552 U.S. at 322–323. As previously explained, the SynchroMed Infusion System underwent the premarket approval process and received premarket approval on September 12, 2003; therefore, there are federal requirements applicable to the SynchroMed Infusion System.

5. State Requirements Different from or in Addition to the Applicable Federal Requirements

Since the first part of the MDA preemption test has been satisfied, the analysis must continue to the second part of the test. As previously explained, during this stage of the proceedings, the Court will only dismiss a claim as preempted if the claim clearly relies on a requirement that is in addition to or different from the applicable federal requirements.

Even though the Complaint contains three separate counts, they are necessarily one claim under the IPLA. Fortunately, the Plaintiff's claims are easily discernible because they arise from the IPLA, which only supports three types of actions: (a) failure to warn, (b) design defect, and (c) manufacturing defect. *Aregood v. Givaudan Flavors Corp.*, 904 F.3d 475, 482 (7th Cir. 2018) ("'The [IPLA] provides that a plaintiff can satisfy the second element—that the product was defective—by showing one of the following: a design defect, a manufacturing defect, or a failure to warn.'" (quoting *Ritchie v. Glidden Co.*, 242 F.3d 713, 720 (7th Cir. 2001))). The analysis for each type of claim is different and will be conducted in turn.

a. Failure to Warn

The Plaintiff alleges that the Defendant is liable for "failing to advise healthcare providers and users, specifically [Plaintiff], of the numerous recalls and known defects associated with the product implanted in [Plaintiff] and the unreasonable dangers and harms

accounted therewith." Compl. ¶ 41. This claim is based on well-established principles of tort law, as

> "A product . . . is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe."

Restatement (Third) of Torts: Prod. Liab. § 2 (Am. Law Inst. 1998). This type of claim would, in most instances, be a valid claim over which this Court would preside. However, there are conflicting federal requirements that are directly applicable to the SynchroMed Infusion System, namely that a medical device manufacturer is only required to report adverse findings to the FDA. *See McAfee v. Medtronic, Inc.*, No. 1:12-CV-417, 2015 WL 3617755, at *5 (N.D. Ind. June 4, 2016) (citing 21 U.S.C. § 360k(a); *Riegel*, 552 U.S. at 321–22; *McMullen v. Medtronic*, 421 F.3d 482, 488; *Mitchell v. Collogen Corp.*, 126 F.3d 902, 913–14 (7th Cir. 1997)). Indeed, the duty on which the Plaintiff's failure to warn claim is based exists only at the state and not the federal level. *See id.* This necessarily means that the state requirement is in addition to the federal requirement and, therefore, is preempted by the MDA.

b. Design Defect

The Complaint also includes a design defect claim. For a plaintiff to succeed on a design defect claim under the IPLA, he or she must show that "'the manufacturer or seller failed to exercise reasonable care under the circumstances in designing the product.'" *TRW Vehicle Safety Sys., Inc. v. Moore*, 936 N.E.2d 201, 209 (Ind. 2010) (quoting Ind. Code § 34-20-2-2). In other words, demonstrating a design defect under Indiana law requires the plaintiff to "'compare the costs and benefits of alternative designs' and 'show that another design not only could have

prevented the injury but also was cost-effective under general negligence principles." *Piltch v. Ford Motor Co.*, 778 F.3d 628, 632 (7th Cir. 2015) (quoting *Pries v. Honda Motor Co.*, 31 F.3d 543, 545–46 (7th Cir. 1994)).

This requirement is problematic because, as a part of the premarket approval process, the design of a Class III device has already been determined to meet federal requirements. If a design defect claim that concerns a medical device and is based on Indiana law were to succeed, it would necessarily mean that the FDA's risk/benefit analysis was incorrect and that the medical device should have been safer even if it, overall, resulted in a less effective device. *See In re Medtronic, Inc.*, 623 F.3d 1200, 1206 (8th Cir. 2010). Such a challenge to the FDA's approval process is what the MDA prevents because such a challenge imposes requirements different from those at the federal level and, overall, causes disruption to the federal system. *Id.* (citing *Riegel*, 552 U.S. at 325). Accordingly, the Plaintiff's design defect claims are preempted by the MDA.

c. Manufacturing Defect

Finally, the Plaintiff raises a manufacturing defect claim. To assert this claim, the Complaint alleges that "Defendant Medtronic had a duty to exercise reasonable care, and to comply with the existing standards of care, in its . . . manufacture . . . of [the SynchroMed Infusion System]," that "Defendant Medtronic was negligent in failing to exercise reasonable care and in failing to reasonably and adequately comply with applicable codes, standards, regulations . . . and/or specifications established, adopted, promulgated, or approved by the United States . . . or by any agency of the United State [sic] . . . including the FDA," and that, "[a]s a direct and proximate result of Defendant Medtronic's negligence in the . . . manufacture . . . of its [SynchroMed Infusion System], [Plaintiff] suffered injuries and damages . . . ." Compl. ¶¶ 44, 47, 49.

To succeed on a manufacturing defect claim under the IPLA, a plaintiff must show that the product deviates from its intended design. *Piltch*, 778 F.3d at 632–33. Unlike a design defect or failure to warn claim, a manufacturing defect claim does not immediately appear to be preempted. In fact, the Seventh Circuit—as well as numerous other circuits and district courts—has held that a manufacturing defect claim based on a violation of federal law is not expressly preempted by Section 360k of the MDA. *See Bausch*, 630 F.3d at 553 (citing cases). Although the Defendant has cited numerous cases where manufacturing defect claims were dismissed as preempted at the district court level, the Court is inclined (and obligated) to follow the Seventh Circuit's precedent and conclude that manufacturing defect claims premised on a violation of federal law are not preempted by the MDA.

The Defendant supplements its preemption argument by alleging that the Plaintiff's claim is insufficient because it fails to cite to a specific federal regulation that was violated and fails to establish a causal link between the Defendant's violation of a federal requirement and his injury. Neither argument is persuasive.

Although the Defendant repeatedly contends that the Plaintiff needs to cite to a particular federal requirement in his pleadings, this pleading requirement simply does not exist. The Seventh Circuit has established that "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 [360k] preemption at the pleading stage." *Fisk*, 2017 WL 4247983, at *5 (quoting *Bausch*, 630 F.3d at 560). Furthermore, the complaint certainly alleges that his injuries were the direct and proximate result of the Defendant's negligence and that the Defendant's negligence included, among other things, failing to comply with the federal requirements.

To prevail on his claim, the Plaintiff will ultimately have to specify a violation of a particular federal requirement and will have to prove that his injury was the direct and proximate cause of that violation. However, such a requirement is not imposed at this point in the proceedings. Therefore, to the extent the Plaintiff's Complaint alleges that his injuries were caused by a manufacturing defect in the production of his medical device *and* that the defect was caused by a violation of the federal requirements, his claim is properly pled and not preempted.[4]

CONCLUSION

For the reasons stated above, the Defendant's Motion to Dismiss [ECF No. 8] is GRANTED in part and DENIED in part. The Plaintiff's claims, except for any manufacturing defect claim based on violation of federal law, are DISMISSED.

SO ORDERED on January 3, 2020.

s/ Theresa L. Springmann
CHIEF JUDGE THERESA L. SPRINGMANN
UNITED STATES DISTRICT COURT

[4] In its Motion to Dismiss, the Defendant also argues that any claims alleging a violation of the FDCA would be impliedly preempted under the Supreme Court's decision in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 (2001). The Defendant cites *In re Medtronic, Inc.* to support its argument. In that case, the Eighth Circuit interpreted *Riegel* and *Buckman* as "'creat[ing] a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption.'" *In re Medtronic, Inc.*, 623 F.3d 1200, 1204 (8th Cir. 2010) (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009)). However, in *Bausch* the Seventh Circuit declined to interpret *Buckman* in the manner described by the Defendant and instead determined that *Buckman* applies only to fraud on the agency claims. *Bausch*, 630 F.3d at 557. The Plaintiff's Complaint contains no allegations of fraud; therefore, the Defendant's argument of implied preemption is irrelevant.