IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

CLAYTON WARMOTH, Plaintiff, v. MEDTRONIC, INC., and MEDTRONIC MINIMED, INC. Defendants.	))))))))))	Case No. CIV-21-712-SLP

O R D E R

Before the Court is Defendants' Motion to Dismiss Plaintiff's Complaint [Doc. No. 10]. Plaintiff has responded [Doc. No. 16] and Defendants have replied [Doc. No. 19].[1] The matter is fully briefed and ready for determination.

I. Introduction

This diversity jurisdiction action involves claims for strict product liability, negligence, breach of express warranty, and breach of implied warranty associated with two medical devices manufactured by Defendants and used together to treat diabetes: the Medtronic MiniMed 670G Insulin Pump ("Insulin Pump") and the MiniMed Infusion Set ("Infusion Set"). Compl. [Doc. No. 1] ¶¶ 7, 12. Defendants move to dismiss all of Plaintiff's claims as to both devices, arguing the claims related to the Insulin Pump are preempted by federal law, and the claims related to the Infusion Set are insufficiently pleaded. Mot. [Doc. No. 10] at 7-8. Plaintiff responds that the claims related to the Insulin

[1] Citations to the parties' submissions reference the Court's ECF pagination.

Pump are not preempted, and that he has stated plausible claims related to the Infusion Set. Resp. [Doc. No. 16] at 2-3.

II. Governing Standard

A pleading must include "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). "To survive a motion to dismiss [under Rule 12(b)(6)], a complaint must contain 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 *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)); *see also Robbins v. Oklahoma*, 519 F.3d 1242, 1247 (10th Cir. 2008). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. But "mere 'labels and conclusions,' and 'a formulaic recitation of the elements of a cause of action' will not suffice; a plaintiff must offer specific factual allegations to support each claim." *Kan. Penn Gaming, LLC v. Collins*, 656 F.3d 1210, 1214 (10th Cir. 2011) (quoting *Twombly*, 550 U.S. at 555).

"Generally, the sufficiency of a complaint must rest on its contents alone." *Gee v. Pacheco*, 627 F.3d 1178, 1186 (10th Cir. 2010). Thus, "[w]hen a party presents matters outside of the pleadings for consideration ... 'the court must either exclude the material or treat the motion as one for summary judgment.'" *Brokers' Choice of Am., Inc. v. NBC Universal, Inc.*, 861 F.3d 1081, 1103 (10th Cir. 2017) (quoting *Alexander v. Oklahoma*, 382 F.3d 1206, 1214 (10th Cir. 2004)). Certain exceptions exist, and the court may consider: (1) documents attached to the complaint as exhibits; (2) documents referenced in

the Complaint that are central to the Plaintiff's claims if the parties do not dispute the documents' authenticity; and (3) matters of which the court may take judicial notice. *Gee*, 627 F.3d at 1186.

Additionally, "[f]air notice of the basis of Plaintiff's claims may be particularly important in the case of a medical device to which the Medical Device Amendments to the Food, Drug, and Cosmetic Act apply because federal law preempts state law requirements that are 'different from, or in addition to' federal requirements." *See Shells v. X-Spine Sys., Inc*., No. CIV-14-1223-D, 2015 WL 736981, at *2 (W.D. Okla. Feb. 20, 2015) (quoting *Riegel v. Medtronic, Inc*., 552 U.S. 312, 324–25 (2008)).

III. Factual Allegations of the Complaint[2]

The Insulin Pump and Infusion Set are medical devices designed and manufactured by Defendants which are used together to deliver insulin to the body and help regulate blood sugar levels for individuals with diabetes. Compl. [Doc. No. 1] ¶¶ 7, 12, 14. Plaintiff began using the Insulin Pump in 2018 to manage his Type 1 diabetes. *Id.* ¶ 8. On July 15, 2019, Plaintiff suffered a hyperglycemic episode due to insufficient insulin, which resulted in decreased motor functions and slurred speech. *Id.* ¶¶ 8-9, 32. Plaintiff alleges a malfunction in the Insulin Pump or the Infusion Set caused his injuries. *Id.* ¶¶ 32-34.

The Insulin Pump was manufactured with a retainer ring designed to lock the individual's insulin cartridge into place in the pump's reservoir compartment. *Id.* ¶ 12. The Infusion Set consisted of a membrane and disposable plastic tubes which transport

[2] The Court views the factual allegations of the Complaint in the light most favorable to Plaintiff as the non-moving party. *Straub v. BNSF Ry. Co*., 909 F.3d 1280, 1287 (10th Cir. 2018).

insulin from the pump to the individual's body. *Id*. Plaintiff alleges a defect in the retainer ring on the Insulin Pump prevented the insulin reservoir from locking into the pump when it was loaded, reducing the amount of insulin the pump supplied. *Id.* ¶¶ 33-34. Plaintiff alleges this specific defect was the basis for a November 2019 recall of the same kind of Insulin Pump he was using. *Id.* ¶ 33. Plaintiff does not specifically allege what defect existed or occurred in the Infusion Set he was using.[3]

IV. Discussion

The parties' briefing considers the Insulin Pump and Infusion Set separately: Defendants argue the claims related to the Insulin Pump are preempted by federal law, but assert the claims related to the Infusion Set are insufficient under Federal Rules of Civil Procedure 8(a) and 12(b)(6). *See* Motion [Doc. No. 10] at 14, n.4. The Court will analyze preemption as to claims involving the Insulin Pump first, and then analyze the claims to the extent they relate to the Infusion Set.[4]

[3] The Court will address other relevant factual allegations as necessary below.

[4] Though not raised by the parties and not part of the Court's decision, it is likely the preemption analysis for the Insulin Pump would apply the same to the Infusion Set because most courts dealing with various components of medical devices in the context of FDCA preemption have considered the devices together, even where one component may not be a Class III device subject to the same level of regulation. *See, e.g., Bentzley v. Medtronic*, 827 F.Supp.2d 443, 452 (E.D. Pa. 2011) ("Plaintiff's contention that, in considering a preemption issue, the Court must break a medical device into its component parts, is without legal support. In fact, courts that have dealt with this issue have done just the opposite."); *see also Duggan, v. Medtronic, Inc*., 840 F.Supp.2d 466, 471 (D. Mass. 2012) ("[O]nce premarket approval is granted, all claims relating to all components of the device are preempted."); *Riley v. Cordis Corp*., 625 F.Supp.2d 769, 780 (D. Minn. 2009) ("It makes no sense—indeed, it would probably be impossible—to pick apart the components of a medical device and apply different preemption analyses to different components."); *Lewkut v. Stryker Corp*., 724 F.Supp.2d 648, 650 (S.D. Tex. 2010) ("[A]ttempting to separate the component parts of a medical device for purposes of preemption is not appropriate."); *Aaron v. Medtronic,*

A. Preemption and the Insulin Pump

Defendants contend all of Plaintiff's claims regarding the Insulin Pump are expressly and impliedly preempted by the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA") at 21 U.S.C. § 360(k) (the express preemption provision) and 21 U.S.C. § 337 (the implied preemption provision). First, Section 360k provides for express preemption of certain state laws:

> (a) Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k; *Brooks v. Mentor Worldwide LLC*, 985 F.3d 1272, 1278 (10th Cir.), *cert. denied*, 142 S. Ct. 477 (2021). The Supreme Court has established a two-part test to evaluate a claim for express preemption: (1) "whether the Federal Government has established requirements applicable to" the medical device; and (2) whether the state law claims impose a requirement that relates to the safety or effectiveness of the device which is "different from, or in addition to" the federal requirements. *Riegel v. Medtronic, Inc*., 552 U.S. 312, 321–22 (2008). Regarding the second part, "[f]ederal law preempts a tort claim 'unless the federal requirements impose duties that are at least as broad as those'

Inc., 209 F.Supp.3d 994, 1003 (S.D. Ohio 2016) ("Premarket approval extends to all components of an approved device, even when a physician uses the components separately.").

imposed by the state law." *Brooks*, 985 F.3d at 1279 (quoting *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1340 (10th Cir. 2015)).[5]

As to implied preemption, 21 U.S.C. § 337(a) provides "all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." Applying this language, the Supreme Court concluded "Congress intended that the MDA be enforced exclusively by the Federal Government." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001). This means the FDCA preempts "any state tort claim that exists 'solely by virtue' of an FDCA violation." *Caplinger*, 784 F.3d at 1339 (citing *Buckman*, 531 U.S. at 353).

The Tenth Circuit has explained the express preemption cases applying § 360k and implied preemption cases applying § 337 leave "only a narrow gap of possible state tort claims":

> Any such claim must be *predicated on* conduct that violates the FDCA but may not be brought *solely because* that conduct violates the FDCA—the conduct must also violate a parallel state-law requirement.
>
> Put differently, to survive preemption, a plaintiff must plead conduct that (1) violates the FDCA (because state law may not impose additional or different duties) and (2) would be actionable under state law independently of the FDCA (because a plaintiff may not seek to enforce the FDCA). And when the pleader misses the gap—that is, when federal law preempts a claim—the court should dismiss that claim.

Brooks, 985 F.3d at 1279 (emphasis in original) (internal citations omitted). If a claim is preempted by federal law, it is subject to dismissal at the motion to dismiss stage, even

[5] There is no dispute the first part of the test is met as to the Insulin Pump because the parties agree the device is regulated by the FDA and subject to the premarket approval process. *See* Compl. [Doc. No. 1] ¶¶ 17-25; Mot. [Doc. No. 10] at 8-10, 12; Resp. [Doc. No. 16] at 4, 10.

though preemption is an affirmative defense. *See, e.g., Caplinger*, 784 F.3d at 1341 ("A district court may grant judgment as a matter of law under Federal Rule of Civil Procedure 12(b)(6) on the basis of an affirmative defense like preemption when the law compels that result.").

There is no dispute the Insulin Pump is a Class III medical device, which is subject to the highest level of FDA oversight and a highly regulated premarket approval ("PMA") process. *See Riegel*, 552 U.S. at 317.[6] The PMA process for a Class III device begins with a rigorous multivolume application involving extensive research and testing. *Id*. at 317-18. On average, the FDA review consumes over 1,200 hours of agency time. *Id.* at 318. Part of the review involves the approval of warnings and labeling, and the FDA must determine they are not false or misleading. *Brooks*, 985. F.3d at 1277. Approval may be conditioned on adherence to performance standards, restrictions on sale or distribution, or further research. *Id.*

The PMA process requires that the FDA find "reasonable assurance" of a Class III device's "safety and effectiveness," § 360e(d), but allows the FDA to "approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives." *Riegel*, 552 U.S. at 318. Once a device has received premarket approval, the MDA forbids the manufacturer from making changes in design specifications,

[6] Nothing in the record explains whether the Infusion Set is a Class III medical device, and Defendants' Motion to Dismiss states the Infusion Set claims "may also be subject to express and/or implied preemption," but they are not asserting preemption as to the Infusion Set in their Motion. [Doc. No. 10] at 14 n.4. The Court declines to analyze preemption as to the Infusion Set because it has not been raised by the parties, though the result may be the same as to the Infusion Set. *See* n.4, *supra*.

manufacturing processes, labeling, or any other attribute that would affect safety or effectiveness without FDA permission. *Id.* at 319 (citing § 360e(d)(5)(A)(i)). Class III devices are also subject to reporting requirements after PMA, and the FDA has the power to withdraw approval based on new data. *Riegel*, 552 U.S. at 319-320; § 360e(e)(1).

i. Strict Product Liability

The Court notes at the outset some confusion about the nature of Plaintiff's claims, primarily whether he intended to assert a strict liability claim for design defect, manufacturing defect, or both. In the Complaint, Plaintiff alleges strict product liability and states he "hereby asserts a design defect claim pursuant to applicable Oklahoma law." Compl. [Doc. No. 1] ¶ 36. However, in Plaintiff's Response, he argues he is also asserting a manufacturing defect claim. Resp. [Doc. No. 16] at 8. Plaintiff does not clearly assert a manufacturing defect claim in the Complaint, although the final paragraph of the strict liability claim alleges Plaintiff sustained injuries "[a]s a direct and proximate result of the design, manufacture and marketing defects. . ." Compl. [Doc. No. 1] ¶ 44.

The Court finds the Complaint did not assert a claim for manufacturing defect. First, "[t]o state a manufacturing defect claim in Oklahoma, a plaintiff must allege that the defective product somehow deviated from its intended design," which the Complaint does not do. *See Wells v. Johnson & Johnson*, 554 F. Supp. 3d 1207, 1211 (W.D. Okla. 2021) (citing *Wheeler v. HO Sports Inc.*, 232 F.3d 754, 756 (10th Cir. 2000)). Additionally, Plaintiff's strict liability allegations relate to the design of the product rather than an error in manufacturing. Compl. [Doc. No. 1] ¶¶ 41-43. *See Wells*, 554 F. Supp. 3d at 1211 ("Here, Plaintiffs' allegations are more akin to a design defect, and thus, fail to state a claim

for a manufacturing defect."). Aside from a generic reference to a manufacturing defect, Plaintiff made no effort to assert that claim until his Response, and the Court will not consider a new claim which was not alleged in the Complaint.

Plaintiff's Response also contains new factual allegations which differ from (and in some instances conflict with) the allegations in the Complaint. For example, the Complaint alleges there was a defect in the locking retainer ring on the Insulin Pump which prevented the insulin reservoir from properly attaching, but Plaintiffs' Response asserts for the first time there was "a missing retainer ring" or a "failure to include . . . the retainer ring." *Compare* Compl. [Doc. No. 1] ¶¶ 33-34; *with* Resp. [Doc No. 16] at 8-9. The Complaint never mentions a missing retainer ring or failure to include the retainer ring. The Court declines to consider these new facts raised in Plaintiff's Response. *See Gee*, 627 F.3d at 1186 ("Generally, the sufficiency of a complaint must rest on its contents alone."); *Hayes v. Whitman*, 264 F.3d 1017, 1025 (10th Cir. 2001) ("[A] court may not consider allegations or theories that are inconsistent with those pleaded in the complaint."); *Clinton v. Sec. Benefit Life Ins. Co*., 63 F.4th 1264, 1275 (10th Cir. 2023) (recognizing "a court considers only the contents of the complaint when ruling on a 12(b)(6) motion," then listing exceptions which do not apply here).

Turning to design defect, the Court finds Plaintiff's claim is subject to dismissal because neither his Complaint nor his Response identify any parallel federal statute or regulation he contends Defendants failed to comply with in relation to the Insulin Pump. *See Caplinger*, 784 F.3d at 1340–41 (affirming dismissal of design defect and breach of warranty claims involving a Class III medical device because the Plaintiff "has not

attempted, in either the district court or this one, to identify a single parallel federal statute or regulation."); *Brooks*, 985 F.3d at 1280 (affirming dismissal of a products liability claim for a Class III medical device in part because "Plaintiffs fail to identify a federal requirement" consistent with the duty alleged in their state law claims); *Nevolas v. Bos. Sci. Corp.*, No. CV-15-894-M, 2016 WL 347721, at *3 (W.D. Okla. Jan. 28, 2016) ("To properly allege parallel claims, the complaint must set forth facts pointing to specific PMA requirements that have been violated." (quoting *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1300 (8th Cir. 2011))).[7]

In his Response, Plaintiff argues the three prior recalls he describes in the Complaint are sufficient to allege a violation of federal law. However, the Complaint does not mention any federal statute or regulation Plaintiff contends was violated in relation to the recalls, nor does Plaintiff do so in his Response. *See* Compl. [Doc. No. 1] ¶¶ 22-33. Moreover, reference to a recall without more is not the same thing as alleging a violation of federal law or failure to comply with federal law. *See, e.g., In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig.*, 592 F. Supp. 2d 1147, 1155-56 (D. Minn. 2009) (dismissing all claims as preempted despite the devices at issue being subject to FDA

[7] Plaintiff's Response cites 21 C.F.R. § 820.70(h), which he asserts "requires manufacturers to establish procedures for removing or limiting manufacturing materials from devices to the extent that the material adversely affects the device's quality." Resp. [Doc. No. 16] at 9 n.1. This regulation is not mentioned in the Complaint, and Plaintiff's Response does not explain how § 820.70(h) connects to his factual allegations or is parallel to his state law claims (which is doubtful given the narrow scope of the regulation). More importantly, however, Plaintiff includes this citation within a discussion regarding a manufacturing defect claim he did not assert in the Complaint and in relation to the Infusion Set which is not part of the present preemption analysis. *Id*. As such, this isolated reference to a federal regulation does not change the Court's conclusion as to the Insulin Pump.

recall.); *see also Erickson v. Bos. Sci. Corp*., 846 F. Supp. 2d 1085, 1093 (C.D. Cal. 2011) ("Many courts have recognized that product recalls do not create a presumption that FDA requirements have been violated.").

Next, Plaintiff's Response asserts for the first time that the defect with the retainer ring in the Insulin Pump "differed [or deviated] from the FDA approved device." Resp. [Doc No. 16] at 9. This is another example of a manufacturing defect allegation which does not appear in the Complaint, and the Court will not consider new facts raised in Plaintiff's Response. Similarly, Plaintiff's Response refers to the general MDA prohibition on changes in design specifications or manufacturing processes absent FDA approval, but the Complaint does not allege the design or the manufacturing process of the Insulin Pump changed after premarket approval, nor does it discuss premarket approval more generally.[8]

Finally, Plaintiff's design defect claim would be preempted by federal law even if he had identified a federal statute or regulation he contends was violated. Plaintiff alleges the Insulin Pump was defective in design and unreasonably dangerous when was placed into the stream of commerce. However, "[o]nce a device survives premarket approval it's

[8] The result would be the same even if these allegations were in the Complaint because a generic reference to deviation from the FDA approved device is insufficient. *See Brooks*, 985 F.3d at 1282 (dismissing a manufacturing defect claim even though "[i]n the Complaint, Plaintiffs conclude that the implants 'differed from the specifications agreed to by the FDA' and 'used materials and components which differed from those approved by the FDA,'" because the Plaintiffs did not offer "any supporting facts."); *see also Swisher v. Stryker Corp*., No. CIV-14-0028-HE, 2014 WL 1153716, at *2 (W.D. Okla. Mar. 14, 2014) ("more is required to make out a parallel claim than conclusory statements that a defendant violated multiple regulations."); *Nevolas*, 2016 WL 347721, at *3 ("The Court finds plaintiff's allegations that defendant was required to follow non-specific federal regulations and current good manufacturing practice requirements, which are applicable to all manufacturers of all medical devices, are insufficient to state a plausible parallel claim upon which relief can be granted.").

immune from state tort suits that seek to impose different or additional safety-related duties like those alleged here." *Caplinger*, 784 F.3d at 1345; *see also Carrelo v. Advanced Neuromodulation Sys., Inc*., 777 F. Supp. 2d 303, 314 (D.P.R. 2011) ("Any allegation by Plaintiffs that challenges the FDA approved design would be expressly preempted because it would impose requirements that are different from, or in addition to, the existing federal regulations."). For all of these reasons, as to the Insulin Pump, the Complaint fails to state a claim for strict products liability sufficient to survive preemption.

ii. Negligence and Failure to Warn

The analysis set forth above applies similarly to Plaintiff's negligence claim regarding the Insulin Pump—Plaintiff does not specify what provisions of federal law were violated or indicate how those violations give rise to recovery under state law. Plaintiff contends his "Complaint contains allegations that Defendant[s] violated various federal safety standards, which resulted in [their] breach of duty to avoid foreseeable dangers with respect to the device." Resp. [Doc. No. 16] at 10. As support for this argument, Plaintiff cites to paragraph 47 of the Complaint, which does not identify any particular federal standards. Accordingly, dismissal of any claim for negligent design or negligent failure to warn is appropriate because Plaintiff does not allege a parallel violation of federal law. *See Caplinger*, 784 F.3d at 1340–41; *Brooks*, 985 F.3d at 1280.

Plaintiff's Response argues his negligent failure to warn claim is "premised on Defendants' . . . failure to provide adverse event reports to the FDA." Resp. [Doc No. 16] at 10. This assertion is not found in the Complaint, and Plaintiff still does not identify the federal statute or regulation he contends was violated in connection with the alleged

reporting failures. Like in *Brooks*, Plaintiff's claim is subject to dismissal because he "ha[s] not offered—and [the Court] will not seek out—a federal requirement to warn patients, [and] any state-law duty to do so adds to the federal scheme as it is before us." 985 F.3d at 1280. Moreover, to the extent Plaintiff argues his failure to warn claim is solely premised on failure to report to the FDA, such a claim would be impliedly preempted. *Id*. at 1280-81 ("*Buckman* made clear that only the federal government may enforce reporting requirements . . . Federal law thus impliedly preempts Plaintiffs' claims based on alleged failures to properly conduct post-approval . . . reporting as attempts to enforce the MDA.") (citing *Buckman*, 531 U.S. at 348–49); *see also Littlebear v. Advanced Bionics, LLC*, 896 F. Supp. 2d 1085, 1092 (N.D. Okla. 2012) ("All claims predicated on the failure to comply with adverse event reporting requirements are impliedly pre-empted" because they "are not substantive safety requirements under state law, but rather administrative requirements."). Accordingly, the Complaint fails to state a claim for negligence as to the Insulin Pump.

iii. Breach of Express Warranty

Plaintiff's breach of express warranty claim alleges "Defendants represented and warranted to the Plaintiff that [their products] were safe for use in accordance with the Defendants' protocols. Said representations were in the form of marketing materials, device information and product materials provided to [Plaintiff]." Compl. [Doc. No. 1] ¶ 56. Plaintiff alleges the Insulin Pump and Infusion Set did not conform to these alleged representations and warranties, meaning they were not safe for use. *See id*. at ¶¶ 57-58. As with the above claims, Plaintiff must identify a parallel federal statute or regulation, and he has failed to do so. *Caplinger*, 784 F.3d at 1340–41 (affirming dismissal of breach

of warranty claims because the plaintiff "has not attempted, in either the district court or this one, to identify a single parallel federal statute or regulation").

Furthermore, Plaintiff's warranty claim depends on an allegation that the Insulin Pump was "not safe for use," and this claim is preempted because the FDA has already approved the product's safety and effectiveness, therefore liability would exceed what federal law requires. *See Caplinger v. Medtronic, Inc*., 921 F. Supp. 2d 1206, 1222 (W.D. Okla. 2013), *aff'd*, 784 F.3d 1335 (10th Cir. 2015) (dismissing an express warranty claim because "[t]o succeed on the express and implied warranty claim, as alleged by plaintiff in her Amended Complaint, plaintiff must persuade a jury that the [device] was not safe and effective, a finding that would be contrary to the FDA's approval"); *Williams v. Cyberonics, Inc*., 388 F. App'x 169, 171 (3d Cir. 2010) ("Success on appellants' breach of warranty claims would require them to show that the [device] was unsafe or ineffective despite the PMA process, thereby interfering with the requirements already established by the MDA, which has preempted safety and effectiveness determinations for a device."); *White v. Medtronic, Inc*., No. 18-11590, 2019 WL 1339613, at *6 (E.D. Mich. Feb. 20, 2019), *report and recommendation adopted*, No. 18-11590, 2019 WL 1330923 (E.D. Mich. Mar. 25, 2019), *aff'd*, 808 F. App'x 290 (6th Cir. 2020) (finding a very similar express warranty claim preempted for the same reasons where the plaintiff alleged "Medtronic represented that Infuse was safe and effective"). As such, the Complaint is insufficient to state a claim for breach of express warranty as to the Insulin Pump.

iv. Breach of Implied Warranty

An implied warranty claim is governed by Oklahoma's Uniform Commercial Code. *Mears v. Astora Women's Health, LLC*, No. CIV-18-1091, 2019 WL 1590592, *4 (W.D. Okla. Apr. 12, 2019) (quoting *Kirkland v. General Motors Corp.*, 521 P.2d 1353, 1365 (Okla. 1974)). Recovery requires proof that a merchant sold goods that were not "merchantable" at the time of sale. *Collins Radio Co. of Dallas, Tex. v. Bell*, 623 P.2d 1039, 1053 (Okla. Civ. App. 1980). Under Oklahoma law, goods are "merchantable" if they are fit for their ordinary purpose. *Schrock v. Wyeth, Inc*., 727 F.3d 1273, 1288 (10th Cir. 2013) (citing *Perry v. Lawson Ford Tractor Co*., 613 P.2d 458, 463 (Okla. 1980)). Plaintiff alleges the products at issue were not fit for their ordinary purpose because they were "unreasonably dangerous," and they were "not safe, adequately packaged and labeled, and did not conform to the representations Defendant made." Compl. [Doc. No. 1] ¶¶ 63-64.

Again, Plaintiff does not identify any parallel federal requirement he contends was violated, which likewise subjects this claim to dismissal. *Caplinger*, 784 F.3d at 1340–41. Moreover, Plaintiff's implied warranty claim rests on allegations that the products were unsafe or inadequately labeled, either of which, if found, would be contrary to the FDA's approval and therefore preempted. *See Caplinger*, 921 F. Supp. 2d at 1222; *see also Williams*, 388 F. App'x at 171; *Gomez v. St. Jude Med. Daig Div. Inc*., 442 F.3d 919, 931 (5th Cir. 2006) ("To permit a jury to decide [the plaintiff's] claims that the information, warnings, and training material the FDA required and approved through the PMA process were inadequate under state law would displace the FDA's exclusive role and expertise in this area and risk imposing inconsistent obligations on [the defendant]."); *Marion v. Smith*

& Nephew, Inc., No. 115CV00096JNPBCW, 2016 WL 4098608, at *6 (D. Utah July 28, 2016) ("The FDA granted the [device] PMA deeming it fit for the particular purposes for which it had been approved. To the extent the [plaintiffs] seek to argue that despite FDA approval the device was not in fact fit for the particular purpose approved by the FDA, that claim is preempted because it would impose different and additional standards than imposed under federal law."). Accordingly, Plaintiff's implied warranty claim related to the Insulin Pump is subject to dismissal.

B. The Infusion Set

Defendants argue Plaintiff failed to plead sufficient facts as to the Infusion Set to state a claim for strict product liability, negligence, or breach of express or implied warranty. Mot. [Doc. No. 10] at 8. Specifically, Defendants assert Plaintiff has not plausibly alleged what was wrong with his Infusion Set or what warning should have existed. *Id*. at 24. In his Response, Plaintiff relies on the allegations of previous recalls to assert a defect caused his injury. Resp. [Doc No. 16] at 7, 9, 13. However, unlike the Insulin Pump, the Complaint does not specifically allege Plaintiff's Infusion Set had the same defect as any of those which were recalled, and the factual allegations appear to negate any implied overlap between the recalls and Plaintiff's device.

First, Plaintiff's claims generally consist of legal conclusions not tied to the facts he alleges. Compl. [Doc. No. 1] ¶¶ 35-65. Plaintiff's primary factual allegation regarding the Infusion Set states: "[a]s a result of the defective MiniMed Infusion Sets, Clayton Warmoth did not receive enough insulin, which resulted in severe hyperglycemia and physical as well as mental/emotional injury." *Id*. ¶ 32. While sufficient to allege an injury, this

allegation does not explain how Plaintiff's Infusion Set was defective, or how that defect caused his injury.

The Complaint includes numerous factual allegations regarding other infusion sets manufactured by Defendants, including prior recalls in 2009, 2013, and 2017, each of which pre-dates Plaintiff's use of the product beginning in 2018. *Id.* ¶¶ 8, 17-31. Plaintiff specifically alleges he was using the same Insulin Pump which was recalled in 2019, but he does not allege he used any Infusion Set which was recalled. As such, the connection between those previously recalled devices and the alleged defect with Plaintiff's Infusion Set is unclear.

More specifically, the Complaint describes an Infusion Set recalled in June 2013 due to an issue with fluid blocking the vents and causing delivery of too much or too little insulin, but Plaintiff does not allege this same defect from 2013 existed or occurred in his Infusion Set in 2019. *Id.* ¶¶ 23-24. More recently, a similar defect was identified in an Infusion Set recalled in 2017 which resulted in an "over-delivery of insulin." *Id.* ¶¶ 25, 30. The Complaint alleges the "MiniMed Infusion Sets" were recalled in 2017, and that Plaintiff was injured in 2019 "[a]s a result of the defective MiniMed Infusion Sets," but it does not state the alleged defect in 2019 was the same as the defect which prompted the recall in 2017. *Id.* ¶¶ 28, 32.

Other allegations in the Complaint appear to negate any relationship between the Infusion Sets recalled in 2017 and the Infusion Set Plaintiff started using in 2018. First, Plaintiff alleges the 2017 recall included notice of an updated design with "new and enhanced membrane material that significantly reduces the risk." *Id.* ¶ 31. Next, Plaintiff

alleges the 2017 recall occurred due to fluid blocking the infusion set membrane which would result in an "over-delivery of insulin," "fast delivery of multiple days' worth of insulin," and "hypoglycemia"—but Plaintiff repeatedly alleges he "did not receive enough insulin," which resulted in hyperglycemia. *Id.* ¶¶ 8-9, 32. Plaintiff does not expressly allege his Infusion Set suffered from the same specific defect as any of those subject to a prior recall, and the facts pleaded appear to negate any implied connection between Plaintiff's injuries and the defect which prompted the 2017 recall of Infusion Sets. This leaves the Court without a plausible explanation of what defect existed in Plaintiff's Infusion Set, or how the Infusion Set caused Plaintiff's injuries.

i. Strict Products Liability

For strict product liability, Plaintiff must allege: (1) Defendants were in the business of selling a product; (2) the product was defective when it left Defendants' control; (3) the defect renders the product unreasonably dangerous to the consumer; and (4) the defect directly caused Plaintiff's injury. *Kirkland*, 521 P.2d at 1363. The defect alleged "may be the result of a problem in the product's design or manufacture, or it may be the result of inadequate warnings regarding use of the product." *Wheeler*, 232 F.3d at 757 (internal quotation marks omitted). For a design defect, the product is defective if something about its design "renders it less safe than expected by the ordinary consumer." *Rodgers v. Beechcraft Corp.*, 759 F. App'x 646, 676 (10th Cir. 2018) (quoting *Lamke v. Futorian Corp.*, 709 P.2d 684, 686 (Okla. 1985)). However, "[t]he mere fact that a plaintiff was injured by a product does not raise any presumption of defectiveness. . ." *Reed v. Smith & Nephew, Inc.*, 527 F. Supp. 2d 1336, 1354 (W.D. Okla. 2007) (citing *Kirkland*,

521 P.2d at 1363).

The Complaint alleges the Infusion Set Plaintiff used was "defective," but it does not explain what was wrong with Plaintiff's Infusion Set specifically, or how that defect caused his injury. As explained above, unlike his allegation regarding the Insulin Pump (which states the Insulin Pump he was using had the same defect as those subject to the 2019 recall), Plaintiff does not clearly allege his Infusion Set suffered from the same defect as those subject to the 2017 recall or any other recall. To the extent Plaintiff intended to allege the defect in his Infusion Set was the same as those devices subject to the 2017 recall, that defect is inconsistent with his injuries: Plaintiff alleges the infusion sets recalled in 2017 caused an over-delivery of insulin and hypoglycemia, but Plaintiff suffered hyperglycemia due to insufficient insulin.

Moreover, Plaintiff has not stated a claim for design defect because he has not pleaded any facts related to the design of the product, any flaw with the design, or how that design defect caused his injury. *See Brooks*, 985 F.3d at 1281-82 (dismissing strict product liability claims under *Iqbal* where the complaint involved "largely historical facts" and "d[id] not touch on any specific flaw . . . relevant to Plaintiffs' own device"); *Hammonds v. Bos. Sci., Inc*., No. CIV-11-0663-HE, 2011 WL 4978369, at *2 (W.D. Okla. Oct. 19, 2011) (dismissing strict liability and negligence claims involving generic factual allegations regarding various issues with the medical device because "absent from the amended complaint is any statement of how this specific . . . device failed or otherwise caused injury to the plaintiff").

ii. Negligence

The parties do not dispute that the elements of a negligence claim under Oklahoma law are duty, breach, causation, and injury. *Martinez v. Angel Expl., LLC*, 798 F.3d 968, 974 (10th Cir. 2015) (citing *Scott v. Archon Grp., L.P.*, 191 P.3d 1207 (Okla. 2008)). Plaintiff asserts Defendants breached the standard of care because the products they sold were defective, unreasonably dangerous, and Defendants failed to include adequate warnings and instructions. Compl. [Doc. No. 1] ¶¶ 46-47. However, as explained above, Plaintiff has not pleaded facts regarding a defect with his Infusion Set, nor has he alleged a plausible connection between the recalled Infusion Sets and the one he was using. Plaintiff's conclusory allegation that the Infusion Set was defective fails to support a claim for negligence. *See Polando v. Sears, Roebuck & Co.*, No. CIV-13-0038-HE, 2013 WL 791232, at *1 (W.D. Okla. Mar. 4, 2013) (dismissing a negligent product liability claim regarding an electric stove because the plaintiff "has not 'nudged [her negligence/products liability and breach of warranty] claims across the line from conceivable to plausible," even though she alleged the stove failed to sustain the arc of electricity allowing the arc to jump to the Plaintiff causing her burns. (quoting *Twombly*, 550 U.S. at 555)).

Plaintiff's failure to warn claim is similarly deficient. The Complaint does not contain any factual allegations regarding warnings, how Defendants' warnings were deficient, or a specific danger Defendants failed to warn about. The only failure to warn allegations are conclusory statements regarding "inadequate post-marketing warning," "inadequate reporting," "a continuing duty to give an adequate warning of known or reasonably foreseeable dangers," and "marketing defects." ¶¶ 38, 40(c), 44. These generic

allegations without supporting facts are insufficient to state a claim. *Cf. White v. Mylan, Inc.*, No. CIV-12-402-D, 2012 WL 6951323, at *3 (W.D. Okla. Dec. 28, 2012) (dismissing strict liability and negligent failure to warn claims because the plaintiff did not allege how the product was defective and did not connect the side effects the defendants allegedly failed to warn about to his injuries).

Plaintiff's Response asserts the failure to warn claim is premised on failure to report adverse events to the FDA. Resp. [Doc. No. 16] at 10. However, the Complaint does not contain any allegations regarding a failure to report an adverse event related to the Infusion Set. The only specific reporting allegation refers to a 2009 letter from the FDA citing reporting failures, but Plaintiff alleges this letter was issued regarding "the firm where MiniMed pumps are manufactured"—it does not mention the Infusion Set. Compl. [Doc. No. 1] ¶ 17. The Complaint goes on to allege a failure to report "an incident involving a MiniMed insulin pump," but this allegation does not mention (or otherwise appear to relate to) the Infusion Set. *Id*. ¶ 18. Without any factual allegations related to warnings or reporting associated with the Infusion Set, Plaintiff's failure to warn claim is subject to dismissal regardless of whether it sounds in strict liability or negligence.[9]

iii. Express Warranty

Plaintiff's express warranty claim sounds in contract and is governed by Oklahoma's Uniform Commercial Code. *See Kirkland*, 521 P.2d at 1357. Under Oklahoma law, an

[9] The Complaint contains generic failure to warn allegations within the causes of action for strict liability and negligence, although Plaintiff's Response suggests the failure to warn claim was intended to be negligent failure to warn. *Compare* Compl. [Doc. No. 1] ¶¶ 38, 40(c), 44, 47(a), (e)-(h); *with* Resp. [Doc No. 16] at 10-12.

express warranty includes "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain." 12A O.S. § 2–313. As a result of the affirmation or promise the seller warrants "that the goods shall conform to the affirmation or promise." *Id.* Here, Plaintiff generically alleges Defendants "represented and warranted" their products were "safe" in their "marketing materials, device information and product materials." Compl. [Doc. No. 1] ¶ 56. However, Plaintiff does not identify any particular affirmations, statements, or warranties as to any product, including the Infusion Set, and this claim is therefore subject to dismissal. *See Recker v. C.R. Bard, Inc.*, 491 F. Supp. 3d 1029, 1035-36 (W.D. Okla. 2020) (dismissing an express warranty claim because the plaintiff did not "identify the specific statements on which he base[d] this claim" and "there is no great complexity to identifying affirmative statements.").

iv. Implied Warranty

As explained above, an implied warranty claim is also governed by Oklahoma's Uniform Commercial Code, and it requires Plaintiff to allege the product was not merchantable (*i.e.*, unfit for its ordinary purpose) at the time of sale. *See Schrock*, 727 F.3d at 1288. Here, Plaintiff alleges he used the Infusion Set from 2018 until his injury in 2019, but the product was "defective in design," unsafe, and lacked adequate warnings. Compl. [Doc. No. 1] ¶¶ 8, 63-64. As with each of the above claims, Plaintiff does not explain how the Infusion Set he used was defective, unsafe, or inadequately labeled, nor does he plead any plausible connection between the issues with prior recalled Infusion Sets. Moreover,

Plaintiff does not allege the product was not merchantable at the time of sale. Plaintiff fails to state an implied warranty claim as to the Infusion Set.

C. Leave to Amend

At the end of Plaintiff's Response, he includes one sentence requesting leave to amend his Complaint. Resp. [Doc No. 16] at 14. Plaintiff does not explain what he believes he would clarify or add to an amended complaint with regard to his factual allegations or his legal claims. Plaintiff states only that he "believes that any perceived deficiency in the current state of his pleading can be supplemented with additional facts, if necessary, and clarified." *Id*. Plaintiffs' failure to supply any particularity defeats his request to amend. *See Brooks*, 985 F.3d at 1283 ("[A]ny request for a court order, such as a request for leave to amend, must state with particularity the grounds for the order.").

Moreover, Plaintiff has not filed a formal motion requesting leave to amend, and as the Tenth Circuit has held: "bare requests for leave to amend do not rise to the status of a motion and do not put the issue before the district court." *Brooks*, 985 F.3d at 1283. Nor has Plaintiff complied with this Court's local rule governing amendment pursuant to Rule 15(a)(2) of the Federal Rules of Civil Procedure. *See* LCvR 15.1.[10]

Under these circumstances, Plaintiff has failed to provide sufficient notice of the basis for amendment. *See Calderon v. Kan. Dep't of Soc. & Rehab. Servs*., 181 F.3d 1180, 1186–87 (10th Cir. 1999) (explaining "a request for leave to amend must give adequate notice to the district court and to the opposing party of the basis of the proposed amendment

[10] Any amendment is governed by Rule 15(a)(2), as Plaintiff did not timely amend as a matter of course under Rule 15(a)(1).

before the court is required to recognize that a motion for leave to amend is before it" and noting the Circuit has held an informal request to amend made in a response to a motion to dismiss was insufficient); *see also Albers v. Bd. of Cty. Comm'rs of Jefferson Cty., Colo.*, 771 F.3d 697, 706 (10th Cir. 2014) ("[A] bare request to amend in response to a motion to dismiss is insufficient to place the court and opposing parties on notice of the plaintiff's request to amend and the particular grounds upon which such a request would be based."); *Barrett v. Univ. of N.M.*, 562 F. App'x 692, 694–95 (10th Cir. 2014) (mere suggestion in opposition to motion to dismiss that plaintiff should be allowed leave to amend was insufficient; a "formal motion to amend, accompanied by a purported amended complaint, gives the [trial] judge an opportunity to consider whether the new complaint can pass muster" and "[a] less disciplined approach wastes time and effort"). The Court, therefore, denies Plaintiff's request for leave to amend.

V. Conclusion

IT IS THEREFORE ORDERED that Defendants' Motion to Dismiss [Doc. No. 10] is GRANTED. Plaintiff's claims for strict product liability, negligence, breach of express warranty, and breach of implied warranty as to the Insulin Pump are DISMISSED WITH PREJUDICE on preemption grounds. All other claims are DISMISSED WITHOUT PREJUDICE.

A separate judgment of dismissal shall be entered contemporaneously with this Order.

IT IS SO ORDERED this 9th day of June, 2023.

SCOTT L. PALK
UNITED STATES DISTRICT JUDGE