UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WILLIAM A. WARD,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Case No. 20-cv-00027 (APM)**
	)	
ZOLL LIFEVEST HOLDINGS LLC et al.,	)	
	)	
Defendants.	)	
	)	

MEMORANDUM OPINION AND ORDER

I. INTRODUCTION

The LifeVest WCD 4000 ("LifeVest") is a wearable defibrillator that is approved by the FDA and considered a Class III medical device. The LifeVest is designed to administer an electrical shock to a person experiencing a heart arrythmia; an alarm incorporated into the LifeVest is supposed to sound as a warning before the shock is administered. Upon hearing the alarm, the LifeVest wearer can prevent the shock by pressing buttons on the device.

Plaintiff William Ward filed this action against the makers of the LifeVest, ZOLL LifeVest Holdings, LLC and ZOLL Services, LLC (collectively, "Defendants" or "ZOLL"). He seeks damages for injuries he allegedly sustained after the LifeVest he was wearing failed to issue an alarm before delivering an unnecessary shock. Defendants move to dismiss Plaintiff's Second Amended Complaint ("Complaint"), asserting that Plaintiff's claims are preempted by federal law, inadequately pleaded, or both. For the reasons that follow, the court grants in part and denies in part Defendants' motion.

II. BACKGROUND

In 2016, after suffering a heart attack, Plaintiff William Ward was outfitted with a LifeVest manufactured and marketed by Defendants. Pl.'s Second Am. Compl., ECF No. 29 [hereinafter Compl.], ¶ 1. The LifeVest is a wearable defibrillator that is regulated as a Class III medical device by the U.S. Food and Drug Administration ("FDA"), which means that it is "closely scrutinized and [must go] through a rigorous [premarket approval] process." Defs.' Mot. to Dismiss Pl.'s Second Am. Compl., ECF No. 31 [hereinafter Defs.' Mot.], at 7 (internal quotation marks omitted); *see also id.* at 7–9; Compl. ¶¶ 1, 45. The LifeVest monitors the patient's heart when worn, and if it detects a malignant arrythmia, it delivers a "defibrillating pulse to the heart through therapy electrodes in an attempt to restore an effective rhythm." FDA, Summary of Safety and Effectiveness Data at 4 [hereinafter SSED], https://www.accessdata.fda.gov/cdrh_docs/pdf/p010030B.pdf. When the LifeVest detects an arrythmia, it is designed to issue an alarm and "instructs the patient to stop the impending shock by pressing the response buttons to avoid receiving a shock." *Id.*

Plaintiff alleges that one day in December 2016 his LifeVest did not perform as promised. His LifeVest erroneously detected an arrythmia and shocked him without issuing any alarm, giving him no opportunity to prevent the shock by pressing the device's response buttons. Compl. ¶¶ 24, 30–31. He alleges that the force of the shock "knocked" him to the ground, and that he sustained bruising, swelling, and burns as well as emotional distress as a result. *Id.* ¶¶ 31, 39, 40–41.

He filed suit against Defendants in the Superior Court of the District of Columbia, seeking relief for his injuries on state common law grounds. *See* Notice of Removal, ECF No. 1. Defendants removed to federal court, *id.*, and eventually moved to dismiss Plaintiff's Complaint.

Defs.' Mot.; Defs.' Mot., Mem. of P. & A. in Supp. of Defs.' Mot., ECF No. 31-1 [hereinafter Defs.' Br.], at 1–2. That motion is now ripe for review.

III. LEGAL STANDARD

"To survive a motion to dismiss, 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 Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (1955)). 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." *Id.* The factual allegations in the complaint need not be "detailed"; however, the Federal Rules demand more than "an unadorned, the-defendant-unlawfully-harmed-me accusation." *Id.*

The court must accept a plaintiff's factual allegations as true and "construe the complaint 'in favor of the plaintiff, who must be granted the benefit of all inferences that can be derived from the facts alleged.'" *Hettinga v. United States*, 677 F.3d 471, 476 (D.C. Cir. 2012) (quoting *Schuler v. United States*, 617 F.2d 605, 608 (D.C. Cir. 1979)). The court need not accept as true either "a legal conclusion couched as a factual allegation," *Papasan v. Allain*, 478 U.S. 265, 286 (1986), or "inferences . . . unsupported by the facts set out in the complaint," *Kowal v. MCI Commc'ns Corp.*, 16 F.3d 1271, 1276 (D.C. Cir. 1994). If the facts as alleged fail to establish that a plaintiff has stated a claim upon which relief can be granted, then a court must grant the defendant's Rule 12(b)(6) motion. *See Am. Chemistry Council, Inc. v. U.S. Dep't of Health & Human Servs.*, 922 F. Supp. 2d 56, 61 (D.D.C. 2013).

IV. DISCUSSION

A. Design-Defect Claim (Count II)

The court begins its discussion with Count II because it provides helpful background for the remaining claims. Plaintiff asserts a design-defect claim under District of Columbia law. Specifically, he alleges that "defendants' LifeVests, including Mr. Ward's LifeVest," are "defectively designed" because "false detections and inappropriate shocks could be eliminated through feasible corrections to the LifeVest's detection and alarm systems." Compl. ¶¶ 93–94. Defendants argue this count is straightforwardly preempted by the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act. Defs.' Mot. at 16–20; 21 U.S.C. § 360k(a). The court agrees.

The MDA contains an express preemption provision. Section 360k(a) provides that "no State . . . may establish or continue in effect with respect to a device intended for human use any requirement" relating to "the safety or effectiveness of the device" that "is different from, or in addition to, any requirement applicable under [the statute] to the device." 21 U.S.C. § 360k(a). The Supreme Court has set forth a two-step inquiry for evaluating whether state-law claims regarding medical devices, such as the LifeVest, are expressly preempted under this provision. First, courts must consider "whether the Federal Government has established requirements applicable to" the device. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321–22 (2008). If so, they must consider "whether the [plaintiff's] common-law claims are based upon [state] requirements with respect to the device that are 'different from, or in addition to,' the federal ones." *Id.* (quoting 21 U.S.C. §360k(a)). The FDA's affirmative grant of premarket approval ("PMA") to a medical device, which Defendants received for the LifeVest, Compl. ¶ 45, satisfies the first prong. *Id.*

As for the second prong, state common law tort claims "do impose 'requirements,'" *id.* at 323 (cleaned up), and so are preempted by the MDA, unless the plaintiff can "establish that the state law claims it seeks to maintain are truly parallel to the federal requirements at issue." *Kubicki v. Medtronic, Inc.* (*Kubicki II*), 293 F. Supp. 3d 129, 172 (D.D.C. 2018). This means that a plaintiff must "(1) point to *specific* federal requirements that the manufacturer violated; (2) *specifically* identify a state law claim that is parallel to the federal requirements, and (3) causally connect the simultaneous violations of federal and state law . . . to the alleged injury." *Id.* at 171–72.

As noted, Count II of the Complaint asserts a design-defect claim under District of Columbia law. A product is "defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design . . . , and the omission of the alternative design renders the product not reasonably safe." Restatement (Third) of Torts: Prods. Liab. § 2(b) (Am. L. Inst. 1998); *see also Hull v. Eaton Corp.*, 825 F.2d 448, 454 (D.C. Cir. 1987) (recognizing a strict-liability design-defect claim under District of Columbia law). Courts have consistently held that such design-defect claims regarding Class III medical devices are expressly preempted by the MDA. *See, e.g.*, *In re Medtronic, Inc.*, 623 F.3d 1200, 1206 (8th Cir. 2010); Defs.' Br. at 17 n.7 (citing cases). "Once a device has received premarket approval, the MDA 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." *Riegel*, 552 U.S. at 319. Changes to the device's design must be made through "an application for supplemental premarket approval" filed with the FDA. *Id.* A state-law requirement that would require a device manufacturer to have adopted a different

design would conflict directly with the design approved by the FDA and, for that reason, is expressly preempted.

Plaintiff acknowledges this law but attempts to avoid it by insisting that his is not a traditional design-defect claim. His claim is "that *the LifeVest fails to conform to its FDA-approved design.*" Pl.'s Mem. of P. & A. in Opp'n to Defs.' Mot. to Dismiss, ECF No. 34 [hereinafter Pl.'s Opp'n], at 11. Thus understood, he says, he alleges not that ZOLL should have designed the LifeVest differently but that "the actual design of the LifeVest—the design according to which it actually operates—is not the FDA-approved design." *Id.* at 12. But his Complaint does not actually advance this theory. It alleges something more conventional: "[T]he LifeVest was and is defectively designed because its software for detecting arrhythmias routinely cause 'false detections' of arrhythmias" due to various factors. Compl. ¶ 89. And, "[t]he false detections and inappropriate shocks could be eliminated through feasible corrections to the LifeVest's detective and alarm systems." *Id.* ¶ 94. These allegations make out precisely the type of design-defect claim that courts have held are expressly preempted by the MDA. *See In re Medtronic*, 623 F.3d at 1206 (holding that allegations that "are attacks on the risk/benefit analysis that led the FDA to approve an inherently dangerous Class III device . . . are expressly preempted"). And Plaintiff cannot escape preemption by recasting his claim through his opposition brief. *See Kingman Park Civic Ass'n v. Gray*, 27 F. Supp. 3d 142, 168 (D.D.C. 2014).

The court therefore grants Defendants' motion to dismiss Count II of Plaintiff's Complaint.

B. Manufacturing-Defect Claim (Count I)

Defendants argue that "Plaintiff's manufacturing defect claim fails because it is merely a design defect claim disguised in a manufacturing claim's clothing" and therefore is expressly

preempted. Defs.' Br. at 25. Alternatively, Defendants contend that Plaintiff "has not sufficiently pleaded a manufacturing defect claim."[1] *Id.* at 28. The court disagrees with both arguments.

Manufacturing-defect claims are capable of threading the "narrow gap" between express and implied preemption "in which plaintiffs can proceed to vindicate established state law duties that exist entirely independent of federal law . . . to the extent that such common law tort claims are truly parallel to the requirements of federal law." *Kubicki II*, 293 F. Supp. 3d at 173 (internal quotation marks omitted); *see id.* at 173 & n.20 (allowing manufacturing-defect claim to proceed where design-defect claim was preempted). As Defendants note, "the only possible manufacturing defect claim" that can "survive[] preemption is one where such a defect was caused by a problem in the manufacturing process that deviated from the PMA-manufacture specifications, not the [FDA-approved] design of the device." Defs.' Br. at 28. Accepting the facts as true and construing the Complaint in the light most favorable to Plaintiff, he has alleged such a defect.

Plaintiff has identified at least two potential shortcomings of the LifeVest that he was wearing: First, he points to the failure of the alarm to go off before it delivered a shock. Compl. ¶¶ 77, 82. According to the FDA's Summary of Safety and Effectiveness Data ("SSED") for the LifeVest, "[t]he device communicates with the patient through voice and display messages, tones or alarms and vibration of a stimulator against the skin. When the device detects an arrhythmia, it

[1] Defendants also argue that Plaintiff's manufacturing-defect claim is impliedly preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), "because it seeks to enforce the FDCA and suggests ZOLL may have committed fraud on the FDA." Defs.' Br. at 34–35. The court disagrees with this characterization of Plaintiff's claim. As discussed in greater detail below, Plaintiff has alleged facts "suggesting that a[] manufacturing defect caused the alarms on Plaintiff's LifeVest not to go off." *Id.* at 34. And to the extent that "Plaintiff implies that ZOLL . . . failed to adjust the detection software to reduce the rate of inappropriate shocks from what was set forth in the SSED and fail[ed] to report adverse effects to the FDA," *id.* at 35, he does so to support his theories of design-, manufacturing-, and warning-defect liability, not to level an accusation that Defendants "made fraudulent representations to the FDA." *Kubicki II*, 293 F. Supp. 3d at 186. Of course, if Plaintiff's claim does indeed hinge on Defendants' misrepresentations to the FDA, the court agrees that this claim is preempted.

also instructs the patient to stop the impending shock by pressing the response buttons to avoid receiving a shock while conscious because of the pain associated with the shock." SSED at 4. It further describes the device's "Alarm Module" as "designed to alert the patient to certain conditions through lights and voice messages." *Id.* at 5. It is therefore plausible that the pre-shock warning alarm is part of the product design that the FDA approved and thus a federal requirement for the LifeVest.[2]

Second, Plaintiff alleges that the software or algorithm in the LifeVest as manufactured—as opposed to what was approved by the FDA—results in too many unnecessary shocks. Compl. ¶¶ 78, 84. As both parties acknowledged in oral argument on this motion, if Plaintiff alleges a deviation from the FDA-approved, intended design of the LifeVests, even if that deviation occurs on a widespread, systemic basis across entire lots of LifeVests, that allegation can be properly understood as supporting a manufacturing defect, not a design defect. *See* Hr'g Tr. (draft), Sept. 13, 2021, at 13–14 (Defendants' counsel confirming that there could be a "manufacturing defect theory that could involve every product in a lot, for example, having the same flaw," including if "every single item was not manufactured consistent with the design"); *id.* at 29:25–30:7 (Plaintiff's counsel agreeing that "I would not have a problem characterizing that as a manufacturing defect claim").

In addition to these deviations from the FDA-approved design, Plaintiff also alleges that Defendants failed to follow the FDA's Current Good Manufacturing Practice ("CGMP") regulations. Compl. ¶¶ 79–80 (citing CGMPs requiring documentation of "procedures for

[2] The parties vigorously disagree whether the SSED "establishe[s] requirements applicable to" the LifeVest. *Riegel*, 552 U.S. at 321. The court need not resolve this dispute at the present stage. The SSED contains "a detailed summary of information . . . submitted to the [FDA] . . . [that] was the basis for" PMA approval. 21 U.S.C. § 360j(h)(1). Thus, at this stage, it is at least plausible that the SSED reflects the PMA requirements.

implementing corrective and preventive action," 21 C.F.R. § 820.100; maintenance of "complaint files," § 820.198(a); review of "quality system[s]," § 820.20(c); reports to the FDA of "death or serious injury" caused by a device, § 803.50(a)(1); and development, maintenance, and implementation of written reporting procedures, § 803.17). Defendants argue that CGMPs cannot, in general, form the basis of federal requirements for the preemption analysis, Defs.' Br. at 30–34, but this is not necessarily so. *See Kubicki II*, 292 F. Supp. 3d at 180 (noting that courts "must evaluate whether *particular* CGMPs prescribe duties specifically enough to permit evaluation of the parallel character of a state law claim" (emphasis added)). "[R]eliance on CGMPs may be appropriate where . . . a specific defective Class III device injured a consumer, and the plaintiff did not have access to the specific federal requirements in the PMA prior to commencing the lawsuit." *Bass v. Stryker Corp.*, 669 F.3d 501, 512 (5th Cir. 2012) (internal quotation marks omitted) (quoting *In re Medtronic*, 623 F.3d at 1206). Plaintiff here has not yet been given access to the PMA in full. *See* Compl. ¶¶ 51, 54; *see also In re Medtronic*, 623 F. 3d at 1206 ("[T]he FDA's specific federal manufacturing requirements are set forth in the agency's PMA approval files that are accessible, without discovery, only to [Defendants] and to the FDA."). In any event, contrary to Defendants' contention, *see* Defs.' Br. at 30–32, Plaintiff does not rely solely on violations of the CGMPs as the basis of his claim. He also pleads, as discussed above, specific deviations from the approved design requirements. *See supra* at 7–8. These combined allegations are sufficient to plead a parallel claim. *See Bass*, 669 F.3d at 512 (holding that "if a plaintiff pleads that a manufacturer of a Class III medical device failed to comply with either the specific processes and procedures that were approved by the FDA or the CGMPs themselves *and* that this failure caused the injury, the plaintiff will have pleaded a parallel claim").

Still, Defendants insist that Plaintiff's manufacturing-defect claim is inadequately pleaded because Plaintiff "does not identify any way in which his LifeVest deviated from the FDA-approved manufacturing specifications." Defs.' Br. at 24–25. But Defendants demand too much at the pleadings stage. A plaintiff "need not state in his complaint the precise defect that caused [his] LifeVest to malfunction." *Godelia v. Doe 1*, 881 F.3d 1309, 1318 (11th Cir. 2018); *see also Kubicki v. Medtronic* (*Kubicki I*), No. 12-cv-00734 (CKK), 2013 WL 1739580, at *4 (D.D.C. Mar. 21, 2013) ("[T]here are no special pleading requirements for product liability claims in general, or for Class III medical device claims in particular." (internal quotation marks omitted)); *Kubicki II*, 293 F. Supp. 3d at 173 n.20 (allowing a manufacturing-defect claim to proceed past summary judgment where "Plaintiffs concede that they do not have evidence at this point that there were any specific deviations from any . . . manufacturing specifications that the FDA approved" (alteration in original)). As noted, Plaintiff has pleaded at least two defects in the product—the failure of the alarm to sound and a software- or algorithm-related defect that results in too many false positive shocks. *See* Compl. ¶¶ 77–78, 82, 84. Plaintiff need not specify at this stage *why* those alleged manufacturing defects occurred. The court therefore denies Defendants' motion with respect to Plaintiff's manufacturing-defect claims.

C. Express-Warranty Claim (Count III)

Plaintiff asserts that "Defendants breached the warranties [they] made when [they] contracted with Mr. Ward and outfitted him with the LifeVest, which did not perform as warranted." Compl. ¶ 106. This, he argues, forms the basis of a nonpreempted common law breach-of-express-warranty claim. Pl.'s Opp'n at 25–26. Defendant counters that this claim is

both expressly preempted and inadequately pleaded. Defs.' Mot. at 36. The court agrees with Defendants in part.

A common law express-warranty claim requires the plaintiff to show that "the defendant breached an express promise made about the product sold." *Witherspoon v. Philip Morris, Inc.*, 964 F. Supp. 455, 464 (D.D.C. 1997). "[P]reemption may be avoided where the representations at issue exceed the scope of the FDA approved statements, thereby establishing a contractual obligation voluntarily entered into by the manufacturer." *Kubicki I*, 2013 WL 1739580 at *9 (internal quotation marks omitted); *see also Godelia*, 881 F.3d at 1322 ("If ZOLL's various statements held its product out as meeting a higher standard than that required by the FDA, this was ZOLL's independent undertaking."). Thus, "to the extent [a plaintiff] seeks to impose liability on [a defendant] for voluntarily making warranties, [a plaintiff] is not imposing any different or additional requirements on [a defendant]." *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 788 (D. Minn. 2009). The court understands Plaintiff to base his claim on three distinct alleged promises by a ZOLL representative, and it will take each of those representations in turn.

The court begins with Plaintiff's assertion that Defendants' representative assured him that any shock the LifeVest delivered would be only a "mild jolt." Compl. ¶ 101. The SSED, by contrast, suggests that LifeVest shocks are so painful that they should generally occur only when a patient is unconscious. SSED at 4 ("When the device detects an arrhythmia, it also instructs the patient to stop the impending shock by pressing the response buttons to avoid receiving a shock while conscious because of the pain associated with the shock."). As Plaintiff pleads it, the ZOLL representative affirmatively told him that the LifeVest's shocks would be less painful than Defendants and the FDA understand them to be, and he relied on this representation in entering a

contract with Defendants. Compl. ¶¶ 18–20. Accepting these facts as true and construing the Complaint in the light most favorable to Plaintiff, his express-warranty claim based on the "mild jolt" representation passes muster.

The court concludes otherwise as to the next alleged representation. Plaintiff asserts that Defendants "assured Mr. Ward at the time he was being outfitted with the LifeVest that it would accurately monitor his heart and 'save his life.'" Compl. ¶ 101. This statement cannot form the basis of a parallel claim for breach of express warranty. It is not a "statement[] [holding Defendants'] product out as meeting a higher standard than that required by the FDA." *Godelia*, 881 F.3d at 1322. Rather, this representation is one where "an essential element" of the claim "will be proof that a device granted a PMA is not safe or effective," which "necessarily conflicts with the FDA's contrary finding." *Miller v. DePuy Spine, Inc.*, 638 F. Supp. 2d 1226, 1229–30 (D. Nev. 2009). "Such a warranty claim is directly preempted by *Riegel*." *Id.* at 1230.

The third alleged representation is more complicated. Plaintiff asserts that a ZOLL "representative explained that Mr. Ward could prevent the mild jolt by pressing a button on the LifeVest," and that this statement forms the basis of a nonpreempted express-warranty claim. Compl. ¶ 18. As Plaintiff pleads it, the ZOLL representative offered a description of the device's intended function. *See* SSED at 4. If it is indeed a federal requirement that the LifeVest's alarm go off before every shock, and the FDA has approved ZOLL making statements describing that intended function, this claim is preempted under *Riegel*. *See Miller*, 638 F. Supp. 2d at 1229–30; *Riley*, 625 F. Supp. 2d at 787–88. If, however, the PMA does not require that the alarm go off every time the LifeVest detects a malignant arrhythmia before delivering a shock, then this representation by ZOLL's representatives to Plaintiff may constitute a voluntary warranty that the

device conforms to a higher standard than that required by the FDA, *see Godelia*, 881 F.3d at 1322, in which case Plaintiff's express-warranty claim is not expressly preempted. The court notes this theory of liability is perhaps inconsistent with Plaintiff's manufacturing-defect claim, which depends upon the existence of precisely this requirement under the PMA. Nonetheless, the court will allow this third theory of breach of express warranty to go forward in the alternative if it turns out that the PMA does not require the alarm sound before any shock is delivered.

D. Failure-to-Warn Claim (Count IV)

Plaintiff's failure-to-warn claim involves two separate theories. One is straightforwardly foreclosed by *Riegel*; the other is, at present, inadequately pleaded. The court will therefore grant Defendants' motion to dismiss Plaintiff's failure-to-warn claim.

Plaintiff's first failure-to-warn theory is anchored in the patient agreement and verbal warnings Plaintiff received from the ZOLL representative who outfitted him with the LifeVest. Compl. ¶ 116. He alleges that, in effect, he was not provided a complete set of warnings. *Id.* A failure-to-warn claim premised on a manufacturer's failure to deliver precisely the warnings mandated by the FDA can form the basis of parallel claims. *Cf. Kubicki II*, 293 F. Supp. 3d at 184–85; *In re Medtronic*, 592 F. Supp. 2d 1147, 1159 (D. Minn. 2000). But Plaintiff has not pleaded such a claim. Indeed, it is not clear what the requisite FDA-approved warning requirements for the LifeVest are. *See* Compl. ¶ 113. It is possible (although unlikely) that *no* warning was required under the PMA, which would render any warning Plaintiff argues he should have been given an "additional warning requirement[] beyond what the FDA has approved," Defs.' Br. at 21, and so would render his claim preempted. *See Kubicki II*, 293 F. Supp. 3d at 187–88.

Because there is no indication in the Complaint that Defendants deviated in their warnings from what the FDA required, Plaintiff's first failure-to-warn theory is foreclosed.[3]

Plaintiff's second failure-to-warn theory, based on Defendants' federal reporting obligations, is preempted. Compl. ¶ 117. Plaintiff contends that "[h]ad Defendants made" reports of alarm failures and inappropriate shocks "to the FDA's MAUDE database," "as they were required to do under 21 C.F.R. §§ 803.50 and 803.52, patients such as Mr. Ward would have been made aware of, and thus been warned of, these incidents." *Id.* The problem for Plaintiff is that a state-law duty to warn consumers is a different requirement from the federal duty to report to the FDA. It is "undisputed fact that there is no D.C. common law claim that imposes liability for a manufacturer's failure to report to the FDA adverse incidents concerning an approved medical device." *Kubicki II*, 293 F. Supp. 3d at 183. The *Kubicki II* court exhaustively dispelled the theory underlying Plaintiff's argument, and the court will not rehash that analysis in full now. But suffice it to say that unless both the state-law claim and the applicable federal law contain a requirement that Defendants report adverse incidents to the FDA, there is no parallel claim. Plaintiff alleges only the possibility, under state law, that manufacturers *may* discharge their duty to warn by reporting to a third party. Pl.'s Opp'n at 16–18 (first citing Restatement (Second) of Torts § 388 cmt. n (Am. L. Inst. 1965); and then citing *Russell v. G.A.F. Corp.*, 422 A.2d 989, 992 (D.C. 1980)). That is not enough to make a state-law claim parallel. The motion as to Plaintiff's failure-to-warn claim is therefore granted.

[3] If Plaintiff learns of specific FDA warning requirements for the LifeVest during discovery—and learns that those warnings were not given—he may move for leave to amend his Complaint.

E. Negligence (Count V)

Plaintiff asserts a claim of negligence based on Defendants' alleged breach of their duty to act with reasonable care in designing and manufacturing the LifeVest, including their failure to adequately warn him about how the LifeVest would function. Compl. ¶¶ 122–129. Because negligence claims, like strict liability and other state common law claims, "impose state requirements that differ[] from, or add[] to," federal requirements, *Riegel*, 552 U.S. at 321; Defs.' Br. at 37–38; Pl.'s Opp'n at 26–27, the court grants Defendants' motion with respect to the negligence count to the same extent it dismisses Plaintiff's other claims.

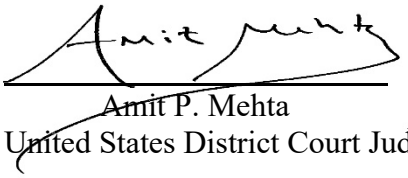
V. CONCLUSION

For the foregoing reasons, the court denies Defendants' motion as to Count I (manufacturing defect) and grants Defendants' motion as to Count II (design defect).

As to Count III (breach of express warranty), the court grants the motion with respect to the portions of the claim premised on Defendants' representation that the LifeVest was accurate and would save Plaintiff's life, but denies the motion with respect to the portions of the claim premised on Defendants' representations as to the degree of the shock. Additionally, Defendants' representations about Plaintiff's ability to prevent shocks are actionable as an alternative theory of liability.

The court grants the motion as to Count IV (failure to warn) and dismisses that claim without prejudice.

The court grants the motion as to Count V (negligence) to the extent it is premised on Plaintiff's dismissed claims.



Dated: September 20, 2021

Amit P. Mehta
United States District Court Judge