

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF LOUISIANA

MATTHEW NAQUIN

CIVIL ACTION

VERSUS

NO. 20-2401

MEDTRONIC, INC.

SECTION M (5)

**ORDER & REASONS**

Before the Court is the motion of defendant Medtronic, Inc. (“Medtronic”) to dismiss.<sup>1</sup> Plaintiff Matthew Naquin opposes the motion.<sup>2</sup> Medtronic replies in further support of its motion.<sup>3</sup> Having considered the parties’ memoranda, the record, and the applicable law, the Court issues this Order & Reasons allowing Naquin the opportunity to seek leave to amend his complaint to plead with specificity his breach-of-contract claim for services, but dismissing all other claims with prejudice.

**I. BACKGROUND**

This case arises from personal injuries resulting from allegedly defective medical devices. Naquin has a history of heart problems including coronary heart disease, congestive heart failure, two heart attacks, and a previous “heart surgery placing stents and angioplasty.”<sup>4</sup> An unidentified cardiologist recommended a Medtronic Evera XT VR Implantable Cardiac Defibrillator (“ICD”) which was surgically implanted into Naquin’s chest on March 30, 2016.<sup>5</sup> The ICD included a wire component, the Sprint Quattro (the “Lead”).<sup>6</sup> The Lead was allegedly

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<sup>1</sup> R. Doc. 9.

<sup>2</sup> R. Doc. 14.

<sup>3</sup> R. Doc. 17.

<sup>4</sup> R. Doc. 2-1 at 3.

<sup>5</sup> *Id.* at 3, 6.

<sup>6</sup> *Id.*

defective which caused the entire device to fail.<sup>7</sup>

On June 23, 2019, the entire device had to be removed and replaced three years and three months after the original implantation.<sup>8</sup> Naquin spent the next three months in the hospital recovering and faced significant medical consequences as a result.<sup>9</sup> He alleges that the ICD was meant to last a lifetime while the Lead was represented to have a product life of ten to eleven years.<sup>10</sup>

Naquin filed suit under two primary theories of liability under Louisiana law: (1) the Louisiana Products Liability Act (“LPLA”) for seven Medtronic devices<sup>11</sup> and (2) breach of contract.<sup>12</sup>

## II. PENDING MOTION

Medtronic argues that all of Naquin’s claims are preempted by federal law and should be

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<sup>7</sup> *Id.* Naquin later alleges numerous potential causes for the failure of the device. *Id.* at 3-4 (“Upon information and belief, the Medtronic ICD Evera and its component parts were defective either due to defective Sprint Quattro lead, defective electrodes, defective insulation, and defective design of the software used in his device and home monitoring system, and defective software for patient monitoring systems.”); at 4 (“Upon information and belief, Naquin Medtronic device was faulty because it oversensed, and it delivered unnecessary and numerous shocks to his heart and damaged his heart even further than it was already damaged.”); at 12 (“Upon information and belief Medtronic violated FDA laws and regulations by fraud, recklessness, gross negligence and negligence regarding the Medtronic FDA Class I, Class II, Class II [*sic*] medical devices that were implanted in Naquin and devices and products that were provided, sold and/or leased to Naquin. Upon information and belief, Medtronic failed to comply with FDA laws and regulations pertaining to Medtronic Class I, Class II and Class III medical devices. ... Plaintiff, Naquin, alleges the [*sic*] upon information and believes [*sic*] the following: the leads in the Sprint Quattro had a non-conforming material or the part in the leads was defective in design, process, constructed improperly and composition. ... Plaintiff, Naquin, alleges upon information and belief that the software had a defective design in the ICD and My Carelink system.”); at 13 (“Upon information and belief, the Evera ICD malfunctioned and did not function properly since Matthew Naquin received unnecessary shocks and was subjected to pain, and it resulted in making him disabled and permanently disabled.”); *see also id.* at 14-17, 19-27.

<sup>8</sup> *Id.* at 3.

<sup>9</sup> *Id.* For a complete list of alleged damages, *see id.* at 26-27, 29.

<sup>10</sup> *Id.*

<sup>11</sup> *Id.* at 2, 6 (the ICD, the Lead, the Medtronic Reveal LINQ, the Medtronic Reveal Insertable Loop Recorder, the Medtronic My Carelink Patient Monitor and Software, the Medtronic and EDevice Inc. Wirex, and the Medtronic Vital Sync Virtual Patient Monitors Platform and software).

<sup>12</sup> *Id.* at 2. In addition, Naquin makes a myriad of tangential assertions that do not rise to the level of claims. *See, e.g., id.* at 2 (“questions of federal law are implied and may be referenced during the proceedings, more specifically, Title 21 U.S.C.A. *et seq.*, the Federal Food, Drug and Cosmetic Act, Federal Trade Commission, and other federal laws”); at 4, 14-15 (the products “were subject to a U.S. Food and Drug Administration recall and/or should have been included in the recalls”); *see also id.* at 22-23.

dismissed.<sup>13</sup> It asserts that the two core medical devices, the ICD and Lead, are Class III medical devices which complied with the federal premarket approval (“PMA”) process,<sup>14</sup> and that state-law claims seeking to impose different or additional requirements on PMA-approved medical devices are preempted by federal law.<sup>15</sup> In addition, Medtronic argues that Naquin cannot plead a parallel state-law claim that falls within the narrow exception to federal preemption.<sup>16</sup> In the alternative, Medtronic argues that all of Naquin’s claims are subsumed under the LPLA and he has not pleaded sufficient facts to allege such a claim.<sup>17</sup>

In opposition, Naquin argues that Medtronic’s motion does not address all seven of the medical devices at issue or all three of the causes of action he alleges in his complaint.<sup>18</sup> To avoid the preemption that accompanies the “rigorous” PMA process, he argues that Medtronic may have used an abbreviated PMA process.<sup>19</sup> Naquin urges that he pleaded a non-preempted parallel claim under the LPLA.<sup>20</sup> His breach-of-contract claim, he contends, should not be subsumed under the LPLA because Medtronic is not just a manufacturer but also a provider of services.<sup>21</sup> He asserts that motions to dismiss are viewed with disfavor and rarely granted and that he has sufficiently pleaded the elements of his claims.<sup>22</sup>

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<sup>13</sup> R. Doc. 9-1 at 15-23.

<sup>14</sup> *Id.* at 15-17.

<sup>15</sup> *Id.* at 17-19; R. Doc. 17 at 6-7.

<sup>16</sup> R. Docs. 9-1 at 20-23; 17 at 2-6.

<sup>17</sup> R. Docs. 9-1 at 23-26; 17 at 8-9.

<sup>18</sup> R. Doc. 14 at 2-3. In addition to the LPLA and breach-of-contract claims, Naquin says in his opposition (but not in his complaint) that he is asserting a claim under Louisiana’s Unfair Trade Practices Act (“LUTPA”), La. R.S. 51:401 *et seq.* R. Doc. 14 at 18-19. Construing Naquin’s opposition as a motion for leave to amend, the amendment is denied as futile because the LUTPA claim is subsumed in his LPLA claim, *see, e.g., Pitre v. Yamaha Motor Co.*, 51 F. Supp. 3d 644, 661-63 (E.D. La. 2014) (dismissing LUTPA claim as barred by the LPLA), which is itself preempted by federal law, as discussed below.

<sup>19</sup> R. Doc. 14 at 5-13.

<sup>20</sup> *Id.* at 13-14.

<sup>21</sup> *Id.* at 16-18.

<sup>22</sup> *Id.* at 9-10, 14-16.

### III. LAW & ANALYSIS

#### A. Rule 12(b)(6) Standard

The Federal Rules of Civil Procedure require a complaint to contain “a short and plain statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a)(2). Rule 8 “does not require ‘detailed factual allegations,’ but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). The statement of the claim must “‘give the defendant fair notice of what the ... claim is and the grounds upon which it rests.’” *Twombly*, 550 U.S. at 555 (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). A pleading does not comply with Rule 8 if it offers “labels and conclusions,” “a formulaic recitation of the elements of a cause of action,” or “‘naked assertions’ devoid of ‘further factual enhancement.’” *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 555, 557) (alteration omitted).

Rule 12(b)(6) of the Federal Rules of Civil Procedure permits a party to move to dismiss for “failure to state a claim upon which relief can be granted.” Fed. R. Civ. P. 12(b)(6). “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.’” *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). A claim is plausible on the face of the complaint “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.* (citing *Twombly*, 550 U.S. at 556). Plausibility does not equate to probability, but rather “it asks for more than a sheer possibility that a defendant has acted unlawfully.” *Id.* (citing *Twombly*, 550 U.S. at 556). “Where a complaint pleads facts that are ‘merely consistent with’ a defendant’s liability, it ‘stops short of the line between possibility and plausibility of ‘entitlement to relief.’”” *Id.* (quoting *Twombly*, 550 U.S. at 557). Thus, if the facts pleaded in the complaint “do not permit the court to infer more than the mere possibility of

misconduct, the complaint has alleged – but it has not ‘shown’ – ‘that the pleader is entitled to relief.’” *Id.* at 679 (quoting Fed. R. Civ. P. 8(a)(2)) (alteration omitted).

In considering a Rule 12(b)(6) motion to dismiss for failure to state a claim, a court employs the two-pronged approach utilized in *Twombly*. The court “can choose to begin by identifying pleadings that, because they are no more than conclusions [unsupported by factual allegations], are not entitled to the assumption of truth.” *Iqbal*, 556 U.S. at 679. However, “[w]hen there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief.” *Id.* “[The] task, then, is to determine whether the plaintiff has stated a legally cognizable claim that is plausible, not to evaluate the plaintiff’s likelihood of success.” *Body by Cook, Inc. v. State Farm Mut. Auto. Ins.*, 869 F.3d 381, 385 (5th Cir. 2017) (quoting *Doe ex rel. Magee v. Covington Cty. Sch. Dist.*, 675 F.3d 849, 854 (5th Cir. 2012)). Motions to dismiss are disfavored and rarely granted. *Turner v. Pleasant*, 663 F.3d 770, 775 (5th Cir. 2011) (citing *Harrington v. State Farm Fire & Cas. Co.*, 563 F.3d 141, 147 (5th Cir. 2009)).

A court’s review of a Rule 12(b)(6) motion to dismiss “is limited to the complaint, any documents attached to the complaint, and any documents attached to the motion to dismiss that are central to the claim and referenced by the complaint.” *Lone Star Fund V (U.S.), L.P. v. Barclays Bank PLC*, 594 F.3d 383, 387 (5th Cir. 2010) (citing *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498-99 (5th Cir. 2000)). A court may also take judicial notice of certain matters, including public records and government websites. *Dorsey v. Portfolio Equities, Inc.*, 540 F.3d 333, 338 (5th Cir. 2008); *see also Kitty Hawk Aircargo, Inc. v. Chao*, 418 F.3d 453, 457 (5th Cir. 2005). Thus, in weighing a Rule 12(b)(6) motion, district courts primarily look to the allegations found in the complaint, but courts may also consider “documents incorporated into the complaint by reference or integral to the claim, items subject to judicial notice, matters

of public record, orders, items appearing in the record of the case, and exhibits attached to the complaint whose authenticity is unquestioned.” *Meyers v. Textron, Inc.*, 540 F. App’x 408, 409 (5th Cir. 2013) (citing *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007)).

## **B. Analysis**

### **1. Naquin’s state-law claims under the Louisiana Products Liability Act are preempted by federal law and must be dismissed.**

The Medical Device Amendments of 1976, 21 U.S.C. §§ 360c *et seq.* (“MDA”) were enacted by Congress to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*, to provide a uniform federal regulatory framework for medical devices. The MDA requirements preempt state-law claims concerning medical devices except in narrow circumstances:

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(a).

To determine whether state-law claims are preempted by the MDA, a court engages in a two-step inquiry. First, a court must determine whether the federal government has established requirements applicable to the medical device in question. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321 (2008). Second, if there are applicable federal requirements, the inquiry shifts to consider whether the state-law claims “rely upon ‘any requirement’ of [state] law applicable to the [device] that is ‘different from, or in addition to,’ federal requirements and that ‘relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device.’” *Id.* at 323 (quoting 21 U.S.C. § 360k(a)). If the answer is yes, the state-law

claims are preempted by federal law and must be dismissed. *Id.* at 326.

The first prong of the inquiry asks whether there are federal requirements for the medical device in question. The PMA process – a “rigorous regime” in which the “FDA spends an average of 1,200 hours reviewing each application and grants premarket approval only if it finds there is a ‘reasonable assurance’ of the device’s ‘safety and effectiveness,’” *id.* at 317-18 (quoting 21 U.S.C. § 360e(d); other citation omitted) – “imposes ‘requirements’ under the MDA.” *Id.* at 322. If a device has been approved through the PMA process, it satisfies the federal requirements prong. “We concluded [in *Riegel*] that premarket approval imposes requirements relating to safety and effectiveness because the FDA requires a device that has received premarket approval to be made with almost no design, manufacturing, or labeling deviations from the specifications in its approved application.” *Altria Grp., Inc. v. Good*, 555 U.S. 70, 86 (2008) (alterations and quotation marks omitted); *see also Bass v. Stryker Corp.*, 669 F.3d 501, 507 (5th Cir. 2012) (“Devices that are approved through PMA procedures automatically satisfy the ‘federal requirements’ prong.”) (citing *Riegel*, 552 U.S. at 322). A court may consider publicly available documents to determine whether a device has achieved premarket approval. *Id.* at 507-08.

Naquin himself alleges that all but one of the seven products allegedly at issue in this litigation have received premarket approval.<sup>23</sup> Therefore, with the exception of the Medtronic Wirex (“Wirex”), the other six products at issue satisfy the first prong automatically because they have completed the PMA process, as Naquin confesses in his complaint.<sup>24</sup>

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<sup>23</sup> R. Doc. 2-1 at 21 (“The Medtronic products listed supra that are the subject of this litigation have received premarket approval from the FDA and have gone through the premarket notification process with the FDA, FDA Premarket Approval (PMA) PMA number. The Wirex product does not have FDA approval. Wirex is a component part of the system, thus can render the whole Medtronic ICD system as unapproved by the FDA.”). Medtronic also provided evidence of PMA for the ICD (R. Doc. 9-2) and Lead (R. Doc. 9-4).

<sup>24</sup> Naquin does not allege at any point in his complaint that he used a Wirex. The strongest indication of the Wirex’s role in this case is when he alleges that “Upon information and belief the [ICD] and [Lead] work together as

Once the federal requirements prong has been satisfied, the inquiry shifts to determine whether the state-law claim “is different from, or in addition to, any requirement applicable under this chapter to the device, and 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). In other words, are the claims “based on state law requirements that are different from, or in addition to the federal ones, and that relate to safety and effectiveness”? *Rodriguez v. Am. Med. Sys., Inc.*, 597 F. App’x 226, 228 (5th Cir. 2014) (quoting *Bass*, 669 F.3d at 507). If the state-law claim imposes an additional requirement that relates to safety, it is preempted and must be dismissed.

Generally, ““common-law causes of action for negligence and strict liability do impose “requirement[s]” and would be pre-empted by federal requirements specific to a medical device.”” *Pardo v. Medtronic Inc.*, 2010 WL 5300847, at \*3 (E.D. La. Dec. 15, 2010) (quoting *Riegel*, 552 U.S. at 323-24). States cannot “indirectly regulate the safety and effectiveness of an FDA approved medical device through the tort system.” *Poole v. Hologic, Inc.*, 2010 WL 3021528, at \*5 (W.D. La. July 29, 2010) (collecting cases).

Under Louisiana law, the LPLA “provides ‘the exclusive theories of liability for manufacturers for damage caused by their products.’” *McQuiston v. Boston Sci. Corp.*, 2009 WL 4016120, at \*6 (W.D. La. Nov. 19, 2009) (quoting La. R.S. 9:2800.52). These theories include: (1) defect in construction or composition; (2) defect in design; (3) inadequate warning; and (4) failure to comply with an express warranty. La. R.S. 9:2800.54(B). “Louisiana courts have ‘held the LPLA subsumes all possible causes of action, with the exception of a claim in

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a system and are combined products and these two products also work in conjunction and together with the above aforementioned Medtronic products.” R. Doc. 2-1 at 9. This claim presumably includes the Wirex. He also alleges that the Wirex is a component part of the device. *See supra* note 23. However, nowhere in the complaint is the Wirex alleged to have been defective or caused harm in any specific way. Without any factual allegation that the Wirex is concretely connected to the injuries in this case, claims related to the device must be dismissed.



redhibition.” *Id.* (quoting *Touro Infirmary v. Sizeler Architects*, 947 So. 2d 740, 744 (La. App. 2006)). In this case, Naquin asserts claims against Medtronic as a manufacturer under the LPLA. Such claims brought under the LPLA are preempted by federal law. *Hinkel v. St. Jude Med., S.C., Inc.*, 869 F. Supp. 2d 739, 746 (E.D. La. 2012) (“[E]ven before the Supreme Court’s decision in *Riegel*, the Fifth Circuit had generally found LPLA claims to be preempted by the MDA.”) (citing *Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919 (5th Cir. 2006)); *Cenac v. Hubbell*, 2010 WL 4174573, at \*7 (E.D. La. Oct. 21, 2010) (“The state law LPLA that forms the basis for the plaintiff’s claim creates state requirements that are “different from or in addition to” the federal requirements.”) (quoting *Bencomo v. Guidant Corp.*, 2009 WL 1951821, at \*5 (E.D. La. June 30, 2009); alterations omitted).

Additionally, Naquin alleges breach-of-warranty claims,<sup>25</sup> but Louisiana warranty claims – whether express (as is specifically provided in the LPLA) or implied – are preempted by federal law. “The Fifth Circuit analyzed the Louisiana express warranty statute and concluded that when the representations at issue are approved by the FDA through the premarket approval process ‘the duties arising under the Louisiana breach of warranty statute relate to, and are potentially inconsistent with, the federal regulatory scheme’ and as a result any such claim is preempted.” *Bencomo*, 2009 WL 1951821, at \*5 (quoting *Gomez*, 442 F.3d at 932); *see also McQuiston*, 2009 WL 4016120, at \*6 (holding a Louisiana breach-of-an-implied-warranty claim would also be preempted under federal law relying on *Riegel*).

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<sup>25</sup> “Naquin’s Sprint Quattro failed to comply with the 10 and 11 year warranty that was provided to Matthew Naquin through his physicians, and medical providers, and by Medtronic, Inc. and its employees, agents and representative, and business affiliates.” R. Doc. 2-1 at 10; *see also id.* at 5 (“Upon information and belief, Medtronic has engaged in fraudulent and deceptive practice by not disclosing to doctors, healthcare providers and patients, the actual rate of defects and risks of their products to healthcare providers and patients.”). Even if Naquin’s claims were not preempted by federal law, such claims must be dismissed when, as here, the warranty in question is not specifically alleged. *Wildman v. Medtronic, Inc.*, 874 F.3d 862, 870-71 (5th Cir. 2017) (collecting cases).

After *Riegel*, parallel state-law claims are the sole survivors of the broad sweep of federal preemption. Such claims are based on an independent state-law claim but allege a violation of federal regulations. *Webb v. Mentor Worldwide LLC*, 453 F. Supp. 3d 550, 557 (N.D.N.Y. 2020) (“In other words, the plaintiff’s state-law claim must parallel a federal-law duty under the MDA but also exist independently of the MDA.”) (quoting *A.F. ex rel. Fogel v. Sorin Grp. USA, Inc.*, 346 F. Supp. 3d 534, 541 (S.D.N.Y. 2018); alterations and quotation marks omitted); *Doe v. Bausch & Lomb, Inc.*, 443 F. Supp. 3d 259, 272 (D. Conn. 2020) (“Plaintiffs must advance a state law claim that parallels federal law ‘but which ... is not wholly derivative of federal law.’”) (quoting *Nagel v. Smith & Nephew, Inc.*, 2016 WL 4098715, at \*4 (D. Conn. July 28, 2016); alteration in original).

The Fifth Circuit has held that to successfully plead a parallel state-law claim, the plaintiff must allege 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 [*i.e.*, the FDA’s Current Good Manufacturing Practices] themselves *and* that this failure caused the injury.” *Bass*, 669 F.3d at 512 (emphasis in original). A complaint will be insufficient when it fails to “specify the manufacturing defect,” “specify a causal connection between the failure of the specific manufacturing process and the specific defect in the process that caused the personal injury,” or “tell us how the manufacturing process failed, or how it deviated from the FDA approved manufacturing process.” *Id.* at 509 (quoting *Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011)). The burden is on the plaintiff to state “‘with particularity what went wrong in the manufacturing process and cite[] the relevant FDA manufacturing standards [the manufacturer] allegedly violated.’” *Id.* at 510 (quoting *Funk*, 631 F.3d at 782).

In conclusory fashion, Naquin alleges that his “state product liability claims do not create requirements that are different from or greater than the FDA requirements.”<sup>26</sup> He fails to identify any defect in the manufacturing process or any violation of federal regulations that caused his injuries. For instance, he states that he “invokes the doctrine of Res Ipsa Loquitor in this petition; and that the defendant is liable under this doctrine.”<sup>27</sup> The Fifth Circuit upheld the dismissal of a complaint relying on *res ipsa loquitor* because it does not “tell us how the manufacturing process failed, or how it deviated from the FDA approved manufacturing process.” *Funk*, 631 F.3d at 782. Similarly, Naquin submits a variety of explanations for the alleged medical device defect,<sup>28</sup> but he admits, “[t]he exact cause of the failure is not yet known or determined.”<sup>29</sup> Such claims do not fall within the narrow exception of parallel state-law claims and must be dismissed when they fail to “specify the manufacturing defect.” *Bass*, 669 F.3d at 509 (quoting *Funk*, 631 F.3d at 782).

Naquin alleges that “Medtronic is in violation of FDA regulations because Medtronic has not been truthful about the products that are the subject of this litigations [*sic*].”<sup>30</sup> “Plaintiffs cannot simply incant the magic words ‘Medtronic violated FDA regulations’ in order to avoid preemption.” *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009) (dismissing manufacturing defect claim as inadequate under *Twombly* standard). Naquin makes no specific allegation that would demonstrate that Medtronic provided false information to the FDA through the PMA process or that it misled doctors and patients. There is not even an alleged incident that would allow the factfinder to assess its

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<sup>26</sup> R. Doc. 2-1 at 12.

<sup>27</sup> *Id.* at 3.

<sup>28</sup> *See supra* note 7.

<sup>29</sup> R. Doc. 2-1 at 10.

<sup>30</sup> *Id.* at 11; *see also id.* at 13 (“Medtronic violated this statute because [it] obtained FDA premarketing approval ... by providing FDA with misinformation, false information, negligent misinformation or insufficient information ... for the FDA to provide ‘reasonable assurance of the safety and effectiveness of the [Lead].’”).

validity. In another example of Naquin’s conclusory pleading, he alleges that, “Medtronic has not been truthful in its advertising, brochures, websites, services, etc.,” and that “Medtronic has made express warranties that go beyond the FDA approval.”<sup>31</sup> Again, such vague and conclusory assertions are insufficient. The Fifth Circuit upheld the dismissal of a Texas deceptive trade practices claim when the plaintiff failed “to allege whether or how [the manufacturer’s] marketing materials deviated from FDA-approved requirements.” *Rodriguez*, 597 F. App’x at 230. Here, there is no opportunity to compare an express representation of Medtronic to what was approved for marketing or labelling by the FDA because neither is alleged by Naquin. Since Naquin has not adequately alleged a parallel state-law claim that Medtronic violated a federal regulation and such violation caused his injuries, he does not have a claim against Medtronic as a manufacturer of medical devices that is not preempted by federal law.

**2. Naquin’s breach of contract claim for services is vague and conclusory, but he may amend his complaint for the limited purpose of adequately pleading such claim.**

Naquin may be able to assert a non-preempted breach-of-contract claim against Medtronic in its capacity as a provider of services, *see, e.g., Reddick v. Medtronic, Inc.*, 2020 WL 2759077, at \*7, 10 (E.D. La. Apr. 14, 2020), but he has not sufficiently pleaded one in his complaint on file. He alleges the existence of a variety of contracts that may be at issue including, for example, “a contract between Matthew Naquin, an obligee, and Medtronic, Inc., an obligor and its related parties and affiliates who are obligors,” “a written and verbal contract

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<sup>31</sup> *Id.* at 11; *see also id.* at 5 (“Medtronic advertises and represents that it has a safe ICD product that will last a lifetime and the lead part, Sprint Quattro that will last at least 10-11 years; and they advertise that they have good services but Medtronic actually sold defective products and provided bad service.”), at 17 (“Medtronic engaged in negligent, reckless, manufacturing, selling, constructing, designing, assembling, labeling, supplying, promoting, and upon information and belief fraudulent selling, warranting, promoting, labeling and manufacturing.”), at 21 (“The Medtronic product [*sic*] are unreasonably dangerous because the products do not conform to an express warranty made by Medtronic manufacturer of the products and do not conform to FDA laws, specifications and standards and are in violation of FDA laws and regulations.”).

between Medtronic, Inc. and Matthew Naquin,” and “either a three way contract or subcontract between Matthew Naquin’s physicians and their staff and the Hospitals and Cardiology Clinics and Medtronic, Inc.”<sup>32</sup> The existence of a contract, its terms, and any purported breach must be asserted with specificity. For example, the Fifth Circuit upheld the dismissal of a Texas breach-of-contract claim for a medical device when the plaintiff did not “allege how the advertising or promotional materials created a valid and enforceable contract, d[id] not describe the terms of any such contract, and d[id] not explain how any statements made by [the doctor] could have given rise to a contract between” the manufacturer and plaintiff. *Rodriguez*, 597 F. A’ppx at 231. Under Louisiana law, “[a]n obligation is a legal relationship whereby a person, called the obligor, is bound to render a performance in favor of another, called the obligee.” La. Civ. Code art. 1756. Such performance can be in the form of “giving, doing, or not doing something.” *Id.* In order to proceed with this claim, Naquin must amend his complaint to state with specificity the basis of the legal relationship, who is the obligor, what performance was promised, how the contract was breached, and what damages have resulted. To be clear, alleged breaches of warranty – or any contract stemming from Medtronic’s role as a manufacturer – are preempted by federal law and have been dismissed. This opportunity to amend is limited only to alleged contracts for services.

#### IV. CONCLUSION

Accordingly, for the foregoing reasons,

IT IS ORDERED that the motion of defendant Medtronic, Inc. to dismiss is GRANTED IN PART AND DENIED IN PART.


Matthew Naquin has fourteen (14) days from the date of this Order & Reasons to seek leave of court to file an amended complaint curing the deficiencies in the complaint addressed

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<sup>32</sup> R. Doc. 2-1 at 27; *see also id.* at 6-7, 28-29.

herein. If Naquin fails to cure the pleading deficiencies in the allotted time, Medtronic, Inc.'s motion to dismiss (R. Doc. 9) will be GRANTED in whole. All other claims are dismissed with prejudice.

New Orleans, Louisiana, this 2nd day of December, 2020.

  
BARRY W. ASHE  
UNITED STATES DISTRICT JUDGE