UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

SAM CELINO SR., ET AL.	**CIVIL ACTION**
VERSUS	**No. 20-2298**
BIOTRONIK, INC.	**SECTION I**

ORDER & REASONS

Barbara Celino ("Barbara") passed away in 2019 following years of heart-related medical issues.[1] Barbara's surviving spouse, Sam Celino, Sr., and the couple's three sons[2] (collectively, the "Celinos"), brought this action individually and on behalf of Barbara against Biotronik, Inc. ("Biotronik"), a medical device manufacturer. The Celinos assert a claim under the Louisiana Products Liability Act ("LPLA") and four other claims under Louisiana law.[3] Biotronik moves to dismiss these claims pursuant to Federal Rule of Civil Procedure 12(b)(6).[4] For the following reasons, the motion is granted except as to the Celinos' LPLA 'design defect' claim. As explained *infra*, the Court will dismiss the motion without prejudice as to that claim only, allowing the Celinos one final opportunity to amend their complaint.

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[1] R. Doc. No. 31, at 7 ¶ 10 (First Amended Complaint).
[2] The three sons named in the amended complaint are Sam Celino, Jr., Christian Celino and Colin Celino. *Id.* at 1 ¶ 1.
[3] *Id.* at 3 ¶ 6. The Celinos have confirmed that they are pursuing only these claims. R. Doc. No. 39, at 1–2 (the Celinos' opposition to the instant motion).
[4] R. Doc. No. 32-1, at 1 (Biotronik's Motion to Dismiss).

I. BACKGROUND

According to the amended complaint,[5] Barbara suffered from a medical condition that affected her heart's ability to properly pump blood.[6] Barbara's physician, who is not identified in the amended complaint, told her that her condition would necessitate an implantable electronic defibrillator to regulate her heartbeat.[7] Barbara's doctor recommended a defibrillator manufactured by Biotronik.[8] That

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[5] The amended complaint summarized *infra* represents the Celinos' second bite at the apple. The Court previously dismissed a motion to dismiss, ordering the Celinos to file an amended complaint that addressed the complaint's deficiencies. R. Doc. No. 23; *see Chiasson v. Medtronic Inc.*, No. 16-789, 2016 WL 4191837, at *4 (E.D. La. Aug. 9, 2016) (Fallon, J.) (noting the technical complexity of preemption cases, gathering cases where courts granted leave to amend difficult-to-decipher complaints that failed to adequately allege a parallel claim, and doing the same). This is not the first time a Section of this Court has had to allow the Celinos' counsel to amend a complaint that contained "unnecessarily repetitive legally conclusive assertions." *Robertson v. AstraZeneca Pharms., LP*, No. 15-438, 2015 WL 5823326, at *1 (E.D. La. Oct. 6, 2015) (Barbier, J.).

The Court has made every effort to glean the relevant allegations from the amended complaint—and to address the Celinos' arguments made in opposition to the motion. But the Court's efforts to do so have been hampered by the fact that both documents are internally inconsistent and lack any meaningful structure. Consequently, despite the fact that the Celinos are represented by counsel, the Court has been forced to structure this opinion (and its analysis of the motion) by doing its best to understand the arguments the Celinos were *trying* to raise, rather than responding to each individual point made in their opposition.

The Court will not, however, construe the Celinos' pleadings liberally, as it would for a *pro se* party. They have retained counsel. It is counsel's responsibility to advocate for her clients.

[6] R. Doc. No. 31, at 7 ¶ 10. For purposes of the instant motion, the Court accepts the Celinos' factual allegations as true, except as noted). *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

[7] *Id.* at 7 ¶¶ 10–11.

[8] *Id.* The device was a "Lumax 340 HF-T." *Id.* at 7 ¶ 10.

device was a component in a system that included monitoring software and wires ("leads").[9] Barbara underwent surgery to implant the device in 2008.[10]

At some point, "the battery depleted," and the defibrillator began producing "unnecessary shocks" that Barbara felt throughout her body.[11] This necessitated a second surgery in which Barbara received a replacement Biotronik defibrillator; that surgery occurred on October 21, 2013.[12]

This second defibrillator, however, also experienced problems.[13] One of "the wires or lead[14] [sic] had become disconnected and the other lead broke/fractured."[15] This "upon information and belief shortened the ICD device life," necessitating

[9] *Id.* at 5–7 ¶¶ 9–10.
[10] *Id.* at 7 ¶ 10.
[11] *Id.* at 9 ¶ 15.
[12] *Id.* at 7 ¶ 10. This device was a "Lumax 740 HF-T." *Id.*
[13] *Id.* at 9 ¶ 15.
[14] The Celinos identify these leads as the "Serox S53," "Linox SD 65/16," and "Corox OTW-75-UP." *Id.* at 7 ¶ 10.
[15] *Id.* As explained *infra*, the Celinos make numerous allegations about 'the lead' that are impossible to connect to any specific item.

further surgery.[16] Barbara also "received bad service from Biotronik," which the Celinos allege compounded her suffering and constituted a breach of contract.[17]

Barbara had the second defibrillator replaced with another Lumax 740 HF-T in April 2019.[18] Sadly, Barbara passed away two months later.[19] The Celinos allege that "injuries from the defects and malfunctioning of the Biotronik ICD implanted in her heart and chest . . . took a toll on [Barbara's] body," leading to her death "from complications due to her complex surgery of having to have [the devices] replaced too often."[20]

The Celinos sued, asserting claims under the LPLA and the Louisiana Unfair Trade Practices and Consumer Protection Act ("LUTPA"). They also assert independent claims of "wrongful death," "survival," and breach of a service contract.[21]

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[16] *Id.* at 9 ¶ 15. While the relevant allegation's structure makes it hard to follow, the Celinos also appear to allege that one or both of these leads somehow "damaged [Barbara's] heart because the medical device was supposed to pump blood back into her her heart Instead [sic] the blood was seeping from her heart; and blood was accumulating[.]" *Id.* This statement appears disconnected from the rest of the allegation (and, indeed, the rest of the amended complaint) which claims that Barbara died because the second device had to be replaced early due to the disconnected and fractured leads' decreasing its life. *Id.*

The Celinos also allege that "the home monitoring system" associated with this second device "did not work properly" in that it "never called into Biotronik like it was supposed to" do when Barbara received "unnecessary shocks." *Id.* This allegation is also confusing, as the Celinos allege that the "first Biotronik ICD," not the second, unnecessarily shocked Barbara. *Id.*

[17] *Id.* The Celinos do not describe the poor customer service, or how it deviated from any contract.

[18] *Id.* at 7 ¶ 10.

[19] *Id.*

[20] *Id.*

[21] *See* R. Doc. No. 39, at 4–5.

Biotronik argues that the Celinos' claims under the LPLA should be dismissed because they (1) are preempted by federal law and (2) fail to comply with the minimum pleading standards established by the Federal Rules of Civil Procedure.[22] Biotronik also argues that the LPLA's exclusivity provision subsumes the remaining state-law claims.[23]

The Celinos contend that their claims are not preempted because the relevant devices did not undergo the appropriate FDA approval process and, alternatively, because the LPLA claims parallel federal law, nullifying preemption. They also argue that, at a minimum, the service contract claim is not subsumed by the LPLA's exclusivity provision.

The Court notes that, while the Celinos have dropped their allegation that "[t]he exact cause of the failure" of the devices "is not yet known or determined,"[24] the amended complaint still offers the Court no real sense of what the Celinos think happened to Barbara. However, the Court reads the allegation that Barbara "died from complications due to her complex surgery of having to have her Biotronik ICD implants replaced too often which took a toll on her body for all these surgeries"[25] to imply that anything that went wrong with one of the devices necessitated one of the surgeries, and that, without those surgeries, Barbara would not have died. But that

[22] R. Doc. No. 32-1, at 11–21.
[23] *Id.* at 21.
[24] R. Doc. No. 1-1, at 3 ¶ 13.
[25] R. Doc. No. 31, at 7 ¶ 10.

is an implication, not an allegation. And it is difficult to review a complaint that offers no clear theory of what happened.

II. RULE 12(b)(6) STANDARD

Pursuant to Rule 12(b)(6), a district court may dismiss a complaint or part of a complaint when a plaintiff fails to set forth well-pleaded factual allegations that "raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555; *see Cuvillier v. Taylor*, 503 F.3d 397, 401 (5th Cir. 2007). The 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).[26] 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.* (citing *Twombly*, 550 U.S. at 570). If the well-pleaded factual allegations "do not permit the court to infer more than the mere possibility of misconduct," then "the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Id.* at 679 (quoting Fed. R. Civ. Proc. 8(a)(2)) (alteration in original).

In assessing the complaint, a court must accept all well-pleaded facts as true and construe all factual allegations in the light most favorable to the plaintiff. *Spivey*

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[26] In their opposition, the Celinos argue that *Iqbal* "is not applicable and has nothing to do with products liability nor medical devices, nor the FDA nor service contracts and should not be considered" because it "is about a Pakistani detainee and is a criminal case." R. Doc. No. 39, at 23. *Iqbal* was, in fact, a civil case. *See generally* 556 U.S. 662 (addressing a *Bivens* action). And, according to Westlaw, it has been cited favorably more than 239,850 times. If the Court is wrongly applying *Iqbal*, it does so in good company.

v. Robertson, 197 F.3d 772, 774 (5th Cir. 1999); *Gentilello v. Rege*, 627 F.3d 540, 544 (5th Cir. 2010). However, courts "do not accept as true conclusory allegations, unwarranted factual inferences, or legal conclusions." *Plotkin v. IP Axess Inc.*, 407 F.3d 690, 696 (5th Cir. 2005) (citing *Southland Sec. Corp. v. INSpire Ins. Solutions, Inc.*, 365 F.3d 353, 361 (5th Cir. 2004)). Furthermore, "the Court must typically limit itself to the contents of the pleadings, including attachments thereto." *Admins. of the Tulane Educ. Fund v. Biomeasure, Inc.*, No. 08-5096, 2011 WL 4352299, at *3 (E.D. La. Sept. 16, 2011) (Vance, J.) (citing *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498 (5th Cir. 2000)). "Dismissal is appropriate when the complaint 'on its face show[s] a bar to relief.'" *Cutrer v. McMillan*, 308 F. App'x 819, 820 (5th Cir. 2009) (quoting *Clark v. Amoco Prod. Co.*, 794 F.2d 967, 970 (5th Cir. 1986) (alteration in original)).

III. LAW AND ANALYSIS

A. Louisiana Products Liability Act

Because the Court is sitting in diversity, it is bound by the substantive law of Louisiana, the forum state. *See Learmonth v. Sears, Roebuck & Co.*, 710 F.3d 249, 258 (5th Cir. 2013). The LPLA "establishes the exclusive theories of liability" under Louisiana law against manufacturers "for damage caused by their products." La. Stat. § 9:2800.52. A product manufacturer is "liable to a claimant for damage proximately caused by a characteristic of the product that renders the product unreasonably dangerous when such damage arose from a reasonably anticipated use of the product by the claimant or another person or entity." *Id.* § 9:2800.54(A).

A product is unreasonably dangerous under the LPLA "if and only if" the product is unreasonably dangerous (1) "in construction or composition," (2) "in design," (3) because of an inadequate warning, or (4) because of nonconformity to an express warranty. *Id.* § 2800.54(B). Consequently, the LPLA provides four recovery theories: construction or composition defect (also known as manufacturing defect), design defect, inadequate warning, and breach of express warranty. *See id.*

The Celinos pursue all four of these liability theories.

B. Preemption

The Supreme Court has set forth in detail the standard for federal preemption of products liability claims based on medical devices covered by the Medical Devices Amendments of 1976 ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"), concluding that, in many cases, such claims are expressly preempted. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008); *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

Federal preemption is based in the Supremacy Clause of the United States Constitution. It states: "This Constitution, and the Laws of the United States, which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land." U.S. Const. art. VI, § 2. Therefore, when a state law conflicts with a federal law, the federal law preempts the state law and negates its effect. *See Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 106–07 (1992). Federal preemption can be "either express or implied." *Id.* at 98. Express preemption occurs when a federal statute directly conflicts with state law. *See id.* Implied preemption, however, arises where "federal law so thoroughly occupies a legislative field 'as to make reasonable the

inference that Congress left no room for the States to supplement it,'" *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (quoting *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982)), "where 'compliance with both federal and state regulations is a physical impossibility,'" *Gade*, 505 U.S. at 98 (quoting *Fl. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963)), "or where state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Id.* (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

Before 1976, states supervised the introduction of new medical devices as they came to market. *See Riegel*, 552 U.S. at 315–16. But Congress eventually determined that state supervision was insufficient to manage the risks posed by these devices, so it enacted the MDA. *See id.* The MDA centralized the regulation of medical devices by the U.S. Food and Drug Administration ("FDA") and further "swept back some state obligations." *Id*.

Devices covered by the MDA are assigned one of three categories based on the degree of potential risk associated with a given device. 21 U.S.C. § 360c. Class I devices—those deemed the least 'risky'—are subject to the least stringent regulations. *Riegel*, 552 U.S. at 316 (citing 21 U.S.C. § 360c(a)(1)(A)). Class II devices are subject to the same requirements as those assigned for Class I, as well as further "'special controls' such as performance standards and postmarket surveillance measures." *Id.* at 316–17 (citing 21 U.S.C. § 360c(a)(1)(B)). Generally, "a device is assigned to Class III if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness, and the device is

'purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health,' or 'presents a potential unreasonable risk of illness or injury.'" *Id.* at 317 (quoting 21 U.S.C. § 360c(a)(1)(C)). Class III devices are highly regulated and must undergo a rigorous premarket approval process ("PMA process") prior to release. *See id.* at 317–18; *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 343–45 (2001). However, this process is not required if the application is submitted under § 510(k). *See Bass v. Stryker Corp.*, 669 F.3d 501, 506–07 (5th Cir. 2012).[27]

PMA requires that manufacturers provide the FDA with "reasonable assurance" their devices are both safe and effective. *See* 21 U.S.C. § 360e(c)(1)(A). The FDA expends around 1,200 hours reviewing a typical application. *See Riegel*, 552 U.S. at 318 (citing *Lohr*, 518 U.S. at 477). Once a Class III device receives PMA, its manufacturer is forbidden from making any changes to the design specifications, manufacturing process, labeling, or any other attribute that would affect the product's safety or effectiveness, absent supplemental FDA approval. *See id.* at 319. Supplemental review is evaluated under largely the same criteria as the initial application—distinguishing it from the § 310(k) process discussed *supra*. *See Bass*, 669 F.3d at 508.

i. Express Preemption

[27] When considering a § 510(k) application, the FDA asks whether a product is "substantially equivalent" to one that has already been approved. *Id.* (citing *Riegel*, 552 U.S. at 317).

To help the FDA maintain regulatory authority over medical devices, Congress explicitly preempted state oversight by enacting 21 U.S.C. § 360k(a).[28] This MDA provision expressly preempts state-law tort claims for injury caused by a medical device if "(1) 'the Federal Government has established requirements applicable to [the device]'; and (2) the claims are based on state-law requirements that are 'different from, or in addition to, the federal ones, and that relate to safety and effectiveness.'" *Bass*, 669 F.3d at 507 (quoting *Riegel*, 552 U.S. at 321–22) (alteration in original, internal quotation omitted). The Supreme Court has concluded that Class III devices that undergo the PMA process satisfy the first prong of this analysis because the FDA requires them "to be made with almost no deviations from the specifications in [the relevant] approval application," because it has "determined that the approved form provides a reasonable assurance of safety and effectiveness." *Riegel*, 552 U.S. at 323. This distinguishes them from Class III products that undergo the § 510(k) process; those do not get the benefit of preemption because that process "does not impose federal requirements on a device." *Bass*, 669 F.3d at 507 (citing *Lohr*, 518 U.S. at 493–94).

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[28] The statute provides, excluding a reference to an exception not relevant here, that:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement–
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

Under certain circumstances, though, problems with devices that satisfy the first prong of the inquiry may still form the basis of a products liability claim. When a manufacturer of such a device violates FDA regulations, a plaintiff may recover under state law tort theories provided that those theories "parallel" the federal violation. *Riegel*, 552 U.S. at 330. For a claim to be parallel, the state-law duty must not create any requirements that are different from or greater than the FDA requirements. *See id.* "Essentially, in a parallel claim, relief is sought under state law alleging that certain conduct of the defendant resulted in a breach of a state duty, that this conduct also resulted in a breach of an FDA-imposed federal regulation, and that certain damages resulted from this breach." *Chiasson*, 2016 WL 4191837, at *4. "If the Plaintiff fails to properly plead her parallel claim, that is, she pleads a violation of a state law that imposes different or additional regulations . . . her claim will be preempted." *Id.*

This parallel claim exception to express MDA preemption is narrow, and it is only one part of the inquiry. *See id.*; *see also Bush v. Thoratec Corp.*, 837 F. Supp. 2d 603, 608 (E.D. La. 2011) (Fallon, J.) (describing the act of pleading a viable parallel claim as "threading the needle"). Even if a claim is not expressly preempted by the MDA, it may still be impliedly preempted under *Buckman*. 531 U.S. at 352–53.

ii. Implied Preemption

As mentioned, state-law claims not expressly preempted by the MDA are still impliedly preempted if they "exist solely by virtue" of FDA regulations. *Buckman*, 531 U.S. at 352–53; *see, e.g.*, *In re Taxotere (Docetaxel) Products Liability Litigation*,

No. 162740, 2021 WL 1295087, at *2 (E.D. La. Apr. 7, 2021) (Milazzo, J.) (concluding that a Michigan statute allowing for manufacturer liability in situations where defendants "[i]ntentionally withhold[] . . . or misrepresent[]" information from the FDA was preempted under *Buckman*). Congress granted the FDA the sole authority to enforce violations of the MDA. *See Buckman*, 531 U.S. at 347–51. Because the federal government retains this exclusive authority, private litigants do not have the ability to sue for noncompliance based solely on FDA regulations. *Id.* at 353. Put another way, state law cannot give a plaintiff a right of action to enforce the MDA. *See id.* Such claims "exist[] solely by virtue" of the FDA's requirements, and private litigants cannot step into a regulatory role explicitly given to the federal government. *Id.* at 348–51. Because the FDA has the lone authority to police, deter, and punish fraud, a private litigant's enforcement of fraudulent conduct would impede the FDA's ability to police such fraud. *See id.* at 350–51.

But *Buckman* does not preempt claims of a violation of an independent state-law duty, nor does it prevent plaintiffs from supporting such claims with evidence "that [a defendant manufacturer] violated the FDA's . . . regulations [for medical devices]." *Hughes v. Bos. Sci. Corp.*, 631 F.3d 762, 775 (5th Cir. 2011) (comparing *Buckman* with *Lohr* and other cases where courts had not applied preemption); *see also Bass*, 669 F.3d at 514 (discussing *Hughes*). For example, a state-law failure to warn claim based on a manufacturer's failure to comply with FDA reporting regulations is not inherently preempted. *See Hughes*, 631 F.3d at 775.

But such claims are still, of course, vulnerable to express preemption under the MDA, as articulated in *Riegel*. *See, e.g.*, *id.* at 769 (acknowledging that "such a claim is preempted . . . to the extent that it purports to impose liability despite [a manufacturer's] compliance with FDA regulations"). This means that, functionally, claims asserted regarding relevant devices must "fit through [a] narrow gap available between both express and implied preemption." *Gavin v. Medtronic, Inc.*, No. 12-851, 2013 WL 3791612, at *5 (E.D. La. July 19, 2013) (Brown, J.). To do so, the claim "must allege that a well-recognized duty owed under state law was breached by a manufacturer's conduct that violates" FDA regulations. *Id.* In other words, the plaintiff must identify a federal requirement and show that the manufacturer did not comply with that federal requirement. *See, e.g.*, *Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011). But they must *also* show that the violative conduct "would give rise to a recovery under state law *even in the absence of* [the relevant FDA regulations]." *Gavin*, 2013 WL 3791612, at *5 (quoting *Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206, 1215 (W.D. Okla. 2013)) (emphasis added).

The Fifth Circuit has also concluded that a plaintiff must do this in a manner that "meet[s] the *Twombly* plausibility standard." *Bass*, 669 F.3d at 509. And, of course, the state-law claims themselves must satisfy that same standard. *See Funk*, 631 F.3d at 782 (applying *Iqbal* and rejecting a manufacturing defect claim for failure to "specify a causal connection between the failure of the specific manufacturing process and the specific defect in the process that caused the personal injury [and to describe] . . . how the manufacturing process failed [and] how it deviated from the

FDA approved manufacturing process"). Put another way, both the state law claim itself and the reasons it survives preemption must satisfy *Twombly* and *Iqbal*. *See id.* As explained below, the Celinos' LPLA claims do not do so.

C. *The relevant products[29] underwent the PMA process, satisfying the first prong of* Riegel.

[29] The Celinos' opposition purports to "narrow down" the scope of the lawsuit "before discovery," explaining that "the two (2) Biotronik leads are the problem." R. Doc. No. 39, at 2. It adds that "[t]he other defective product was the home monitoring system which is not a Class III device thus, all of defendant's preemption arguments are moot with respect to the home monitoring system that did not work or function properly." *Id.* The Court takes this as an indication that the Celinos are only pursuing their claims with regards to those three products.

Confusingly, though, the statement regarding the monitoring system directly contradicts the amended complaint, which describes the "Biotronik Patient Home Monitoring and software" as a "Biotronik FDA Class 3 Medical Device[] in violation of FDA laws," R. Doc. No. 31, at 14 ¶ 20, because "[u]pon information and belief the product failed due to problems and glitches in the software, technical failures in the software, technical failures by Biotronik with wireless connectivity, including but not limited to the internet being down or out." *Id.* at 16 ¶ 22. The amended complaint alleges that this violated "21 U.S.C.A § 360c(a)(1)(A)." *Id.* at 14 ¶ 20. As an aside, the Court notes that that provision generally defines Class I devices. That seems irrelevant here—and even if it were not, the provision offers little for Biotronik to "violate."

Regardless, the Court will not allow the Celinos to make allegations that directly contradict their amended complaint—and for the first time in an opposition memorandum, no less. *See Pellegrin v. C.R. Bard*, No. 17-12473, 2018 WL 3046570, at *1 (E.D. La. June 20, 2018) (Vance, J.) (confronting a similar issue in a medical device case and noting "that it is 'inappropriate to raise new facts and assert new claims in an opposition to a motion to dismiss'" (quoting *Goodwin v. Hous. Auth. of New Orleans*, No. 11-1397, 2013 WL 3874907, at *9 n.37 (E.D. La. July 23, 2013) (Morgan, J.)). And, even if it was inclined to do so, leave to amend on this point would be futile, as the FDA records of which the Court has taken judicial notice indicate that the home monitoring system software *was* treated as a Class III device and *did* receive both an initial and a supplemental approval from the FDA. *See* R. Doc. No. 41-6, at 1.

In reviewing the instant motion, then, the Court will assume that the Celinos' allegations are limited to the leads.

The Celinos contend that their LPLA claims are not subject to express preemption because the leads did not undergo the PMA process or, in the alternative, because it is unclear whether the devices in fact underwent that process.

For its part, Biotronik has introduced FDA records indicating that each device at issue—including the leads—has received premarket approval and/or supplemental premarket approval—not § 510(k) approval.[30] It asks that the Court take judicial notice of the records.[31] Notably, the Celinos have not challenged the legitimacy of these documents.

Although a court's review of a Rule 12(b)(6) motion to dismiss is typically limited to the complaint, a court may also take judicial notice of certain matters, including "publicly-available documents . . . produced by the FDA." *Funk*, 631 F.3d at 783. And the Fifth Circuit has held that "the determination of whether [a given Class III device] was subject to the PMA process is a question of law" and that allegations regarding whether a device underwent the PMA process or did not are "legal conclusion[s] that [a] district court [is] not required to accept as true." *Bass*, 669 F.3d at 507–08.

The Celinos' argument regarding the devices and their approval process is inconsistent and conflates the PMA/supplemental approval process with the § 510(k) process. At bottom, though, the Celinos appear to be arguing they are unsure of whether the devices underwent PMA approval—and that the Court should deny the

[30] *See* R. Doc. No. 41, at 3; R. Doc. Nos. 41-1, 41-2, 41-3, 41-4, 41-5, 41-6 (each indicating that the relevant device was *not* granted expedited review).
[31] R. Doc. No. 41, at 3 n.1.

motion to dismiss and allow discovery on the issue.[32] The Court does not see why it should do so, when the FDA records—unchallenged evidence of which the Court can take judicial notice—make it clear that the devices were approved under the PMA/supplemental approval regime, not § 510(k).

For that reason, the Court takes judicial notice of the fact that the leads (and other devices, for that matter) underwent the PMA/supplemental approval process. Consequently, the first requirement in the *Riegel* express preemption analysis is satisfied. 552 U.S. at 323.

D. Each of the Celinos' LPLA claims is either preempted or insufficiently alleged to state a claim.

The Court must determine (1) whether a finding of liability on any of the Celinos' LPLA theories would impose requirements that are different from or add to those established by the MDA, satisfying the second prong of *Riegel* and rendering them preempted and (2) if not, whether the allegations are sufficient to state a claim under LPLA. *See id.* The Court notes that, "[b]ecause of the potential for preemption, courts [in the Fifth Circuit] have required . . . specificity in pleading parallel claims." *Chiasson*, 2016 WL 4191837, at *4 (citing *Funk*, 631 F.3d at 782). With that in mind, the Court will address each of the claims in turn.

i. Defective Construction or Composition

The Celinos first allege that the Biotronik defibrillator system and leads were unreasonably dangerous in construction or composition (*i.e.*, that Barbara's death

[32] R. Doc. No. 39, at 23–24.

was the result of manufacturing defects).[33] The Court concludes that the Celinos' failure to adequately allege a causal link between violations of FDA manufacturing regulations that support a LPLA manufacturing defect claim and Barbara's death prevents a finding that the claim is parallel. The Court also concludes that, even if the claim *was* parallel, it does not meet the minimum pleading requirements under the LPLA. For either reason, the claim fails.

Under the LPLA, a plaintiff can prove a manufacturing defect if, "at the time the product left [the] manufacturer's control, the product deviated in a material way from the manufacturer's specifications or performance standards for the product or from otherwise identical products manufactured by the same manufacturer." La. Stat. § 9:2800.55. "This is a narrow and demanding test" because the plaintiff must show "that the *particular* product used by the [relevant individual] deviated from its intended design." *Guidry v. Janssen Pharms.*, 206 F. Supp. 3d 1187, 1197–98 (E.D. La. 2016) (Feldman, J.) (emphasis in original). In other words, the plaintiff must show "what a manufacturer's specifications or performance standards are for a particular product" *and* "how the product in question materially deviated from those standards so as to render it unreasonably dangerous." *Lyles v. Medtronic Sofamor Danek, USA, Inc.*, 871 F.3d 305, 311 (5th Cir. 2017) (quoting *Morris v. United Servs. Auto. Ass'n*, 756 So. 2d 549, 558 (La. App. 2 Cir. 2000)). Plaintiffs "must also show that the alleged defect was the cause-in-fact of [the] injury, as well as the 'most probable cause.'" *Rhodes v. Covidien LP*, No. 18-10667, 2019 WL 2162845, at *3

[33] R. Doc. No. 31, at 18 ¶ 30.

(Vance, J.) (quoting *Wheat v. Pfizer, Inc.*, 31 F.3d 340, 342 (5th Cir. 1994)). Allegations that "merely recite[] the elements" of a claim are inadequate. *Aucoin v. Amneal Pharms., LLC*, No. 11-1275, 2012 WL 2990697, at *10 (E.D. La. July 20, 2012) (Brown, J.).

A successful parallel claim under a manufacturing defect theory requires a plaintiff to allege a violation of a state-law duty that is parallel to a federal requirement regarding the manufacturing process. *See Rodriguez v. Am. Med. Sys., Inc.*, 597 F. App'x 226, 229–30 (5th Cir. 2014). The plaintiff must explain "how the manufacturing process failed, or how it deviated from the FDA approved manufacturing process," *and* explain the "causal connection between the failure of the specific manufacturing process and the specific defect in the process that caused the personal injury." *Funk*, 631 F.3d at 782. *Bass v. Stryker Corp*, 669 F.3d 501, a Fifth Circuit case finding an adequately alleged parallel claim, is instructive.

> *Bass* addressed a claim that an FDA-approved Class III hip implant malfunctioned because of impurities in the manufacturing process. [The Fifth Circuit] held that the plaintiff did state parallel claims where the complaint specified which FDA regulations were violated in the manufacturing process, alleged that the manufacturer had received a warning letter from the FDA regarding the manufacturing defect, and eventually recalled the implant due to the defect.

Rodriguez, 597 F. App'x at 230 (discussing *Bass*, 669 F.3d at 510) (citations omitted). In *Funk v. Stryker Corp.*, however, the Fifth Circuit "addressed a similar claim regarding the same hip implant but held that the plaintiff's pleadings were too conclusory to state a parallel claim." *Id.* (discussing *Funk*, 631 F.3d at 782). It noted "that Funk's complaint did not specify the manufacturing defect, did not specify a

causal connection between a failure of the manufacturing process and a specific defect in the process that caused the personal injury, and did not specify how the process deviated from the FDA approved manufacturing process." *Id.* (discussing *Funk*, 631 F.3d at 782).

The Celinos offer a laundry list of regulations that Biotronik allegedly violated.[34] But, as Biotronik notes, the majority of these allegations are little more than "passing reference[s]" and, crucially, do not explain "how any alleged violations . . . are parallel to the state-law claims at issue here."[35] As explained *supra*, a viable parallel manufacturing defect claim would explain what violation occurred, what state-law claim is parallel to that violation, and how the violation caused the injury. *See Bass*, 669 F.3d at 510; *Rodriguez*, 597 F. App'x at 230; *Funk*, 631 F.3d at 782. The vast majority of the Celinos' claims do little more than identify a regulation and allege that Biotronik violated it. While this may be a "skeletal requirement[] for a cognizable parallel claim under the LPLA," it is not "sufficient[ly] specific[] for this Court to accurately determine whether a successful[] parallel claim may exist." *Chiasson*, 2016 WL 4191837, at *4; *see Funk*, 631 F.3d at 782 (describing as "impermissibly conclusory and vague" an allegation that a "hip [prosthesis] contained a manufacturing defect in that it was manufactured in such a manner that impurities, residues and bacteria remained on the prosthesis in violation of the FDA standards and requirements and in violation of the manufacturing processes and

[34] *See, e.g.*, R. Doc. No. 31, at 10–12 ¶ 17.
[35] R. Doc. No. 32, at 2.

design approved by the FDA"). This amended complaint falls far short of the level of detail (and clarity) offered in *Bass*.

The closest the Celinos come is an allegation that "[u]pon information and belief, Biotronik did not manufacture [Barbara's] purchased ICD and lead in accordance with FDA standards where the lead is not to produce more than 1KV/50A peak output . . . . Plaintiffs believe the Biotronik ICD and lead exceed this output causing the device to break, fall apart, malfunction, oversensing, over shocking and depleting the battery and damaging the lead."[36]

While the Celinos fail to identify the violated regulations, this is still a fairly specific allegation; the Court can reasonably conclude the Celinos are arguing that the lead produced too much power,[37] in violation of an FDA regulation. This argument—that the leads caused the battery to fail—seems irrelevant in light of the Celinos' statement in their opposition that their claim extends only to the leads. Still, the Court might see the argument that this "damage[ed] the lead" as tied to the Celinos' allegation that "[t]he lead implanted in Barbara . . . malfunctioned and failed and 'fractured' and the other became disconnected."[38] *But see Scianneaux v. St. Jude Medical S.C., Inc.*, 961 F. Supp. 2d 808, 813 (E.D. La. 2013) (Vance, J.) (rejecting an

[36] R. Doc. No. 31, at 11 ¶ 17. There are other references to FDA regulations regarding leads, but they are far too vague to be helpful. *See, e.g.*, *id.* at 12 ¶ 17 (arguing that Biotronik violated an FDA regulation requiring leads to be compliant with a particular industry standard but offering no description of the relevant standard or how it was violated).

[37] While the Court is unsure as to how this allegation is consistent with the Celinos' description of the leads as "steroid releasing," *id.* at 6 ¶ 9, it accepts the allegation as true in reviewing this motion.

[38] *Id.* at 6 ¶ 9.

allegation that "the leads failed" as conclusory). And, while 'the leads failed' is arguably inadequate, it is more substantive than anything else the Celinos offer that is tied to a violation of an FDA regulation.

But Barbara had three devices installed, each with different leads.[39] The Celinos allege that only *one* was manufactured in violation of the unnamed FDA regulation. Which was it? The Celinos do not say.[40]

And, even if the Court were to ignore that issue, it would still need to identify a *Twiqbal*-compliant allegation that this violation is *also* a violation of LPLA. *See, e.g.*, *id.* ("[I]n addition to pleading a violation of FDA regulations, a plaintiff must plead facts in support of each element of a claim under the LPLA."). As explained, in order to state a manufacturing defect claim under the LPLA, the Celinos would need to identify "[Biotronik's] specifications or performance standards" for the lead *and* explain how the lead "materially deviated from those standards so as to render it unreasonably dangerous." *Lyles*, 871 F.3d at 311 (quotation omitted). On that front, the Celinos allege (1) "upon information and believes [sic] . . . the . . . leads . . . had a non-conforming materials [sic] or the parts were either defective in design, process, constructed improperly and composition,"[41] (2) "[u]pon information and belief, Biotronik has a history of violating FDA laws in manufacturing by using

[39] *Id.* (identifying leads named Setrox, Linox SD, and Corox OTW 75-Up Steroid).
[40] The Court suspects they are describing a lead associated with the second installed device, as an earlier allegation regarding that device mentions that "one of the wires or lead, had become disconnected and the other lead broke/fractured." *Id.* at 9 ¶ 15. How that relates to power output, the Celinos do not say.
[41] *Id.* at 14 ¶ 20.

Nonconforming material in its Lumax ICDs,"[42] (3) "[a]t the time, the products left Biotronik's control, the product [sic] deviated in a material way from FDA standards, specifications, laws and regulations,"[43] (4) "[u]pon information and belief, an example of the Biotronik Lumax ICD system, lead . . . defect can be found in a sampling of the numerous FDA supplements,"[44] (5) "[u]pon information and belief, the Biotronik products are unreasonably dangerous in construction or composition because their manufacturing standards are substandard and do not comply with manufacturing standards of medical devices and component parts as required by the FDA; upon information and belief the Biotronik products are adulterated,"[45] and (6) "[t]he product was unreasonably dangerous when it left the control of the manufacturer and did not conform to FDA standard [sic] nor standards of safety under Louisiana law nor the standard for manufacturing standard and specifications."[46]

The amended complaint is, to say the least, "light on factual allegations and heavy on conclusory statements;" these allegations are far too conclusory to be of any help. *Scianneaux*, 961 F. Supp. 2d at 813. Certainly, none can be said to do more than state the elements of the claim, which is insufficient. *Aucoin*, 2012 WL 2990697, at *10. But the Court does not think the allegations go even that far, because they lack *any* reference to the Biotronik standard that whichever lead the Celinos are referencing failed to meet. That is a key component of a manufacturing defect (as

[42] *Id.* at 15 ¶ 21 (emphasis omitted).
[43] *Id.* at 17 ¶ 24.
[44] *Id.* at 17 ¶ 26.
[45] *Id.* at 18 ¶ 30.
[46] *Id.* at 22 ¶ 43.

opposed to design defect, addressed *infra*) claim. Without it, parallel or not, the Celinos' manufacturing defect claim fails. And so it does.

The Celinos' opposition also offers only conclusory argument suggesting that the elements of a manufacturing defect claim are adequately alleged.[47] Indeed, the opposition comes close to acknowledging the claim's deficiency, explaining the Celinos are "making claims under all theories of recovery under the [LPLA] since discovery has not commenced."[48] The Celinos emphasize that "[t]he case is at the pleading stage, not the actual trial."[49]

The opposition does purport to identify the particular leads that failed, explaining that "Barbara['s] Sprint Quattro leads broke."[50] But this statement makes little sense, as the Celinos do not allege that Sprint Quattro leads were ever implanted in Barbara—and FDA records confirm that the Sprint Quattro is *not a Biotronik product*.[51] And, even if it were the right product, the Celinos have not alleged that it deviated from Biotronik's specifications and standards.

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[47] *See, e.g.*, R. Doc. No. 39, at 5–6 ("The facts stated in Celino's [sic] petition are not speculative . . . there is no speculation here; its facts. Proof of the facts is there.").
[48] *Id.* at 13.
[49] *Id.* at 7.
[50] *Id.* at 14.
[51] *See* U.S. Food & Drug Admin., *Premarket Approval (PMA)* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&sortcolumn=do_desc&PAGENUM=500&pmanumber=P920015 (last visited April 28, 2021).

The Court suspects that counsel may have incorrectly altered opposition from one of the lawsuits she has recently filed against the manufacturer of that device, a different medical device company. *See, e.g.*, *Reddick v. Medtronic, Inc.*, No. 18-8568, 2021 WL 798294, at *1 (E.D. La. Mar. 2, 2021) (Morgan, J.) (raising allegations about the "Sprint Quattro Secure Lead"). This "undermine[s] the credibility of . . . counsel, who

Ultimately, the Celinos' manufacturing defect claim is preempted and fails to state a claim under the LPLA because it fails to allege a way in which the leads (or any other Biotronik product) both violated FDA regulations *and* deviated from Biotronik's specifications and standards in a manner that was the proximate cause of Barbara's death. The Celinos have already been given leave to amend once. Therefore, the claim will be dismissed with prejudice.

ii. Defective Design

The Celinos also allege the leads were unreasonably dangerous in design.[52] They argue that this claim is not preempted despite the FDA's approval of the devices because, "upon information and belief," Biotronik committed fraud during the PMA process, meaning that the FDA never approved the actual design of the products.[53]

It is true that *Buckman* does not prevent plaintiffs from using a 'fraud against the FDA' theory to support an independent state-law claim—only from using it as independent grounds for a claim. *See, e.g.*, *Hughes*, 631 F.3d at 775–76. But, pursuant to Federal Rule of Civil Procedure 9(b), allegations of fraud must be made with particularity, even when they are made in support of a claim. The parties have not addressed whether that standard should apply to arguments that a stand-alone claim is not preempted 'because' of a fraud, which appears to be the Celinos' argument as to their design defect claim. *See Naquin v. Medtronic*, No. 20-2401, 2020 WL

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is obligated under Rule 11 not to file a pleading containing factual assertions that do not have evidentiary support or will not have such support after discovery." *Pellegrin*, 2018 WL 3046570, at *1.

[52] R. Doc. No. 31, at 18 ¶ 31.

[53] *Id.* at 10 ¶ 17.

7060150, at *6 (E.D. La. Dec. 2, 2020) (Ashe, J.) (rejecting as conclusory an allegation that a similar claim was not preempted because the manufacturer had "not been truthful about the products that are the subject of this litigations [sic]").

But the Court need not decide that issue today because, assuming the Celinos' design defect claim is not preempted, it still falls short of even the relaxed standard courts sometimes employ to review the sufficiency of LPLA design defect claims.

To prove a design defect claim under the LPLA, the Celinos must show that: "(1) [t]here existed an alternative design for the product that was capable of preventing [Barbara's] damage; and (2) [t]he likelihood that the product's design would cause [Barbara's] damage and the gravity of that damage outweighed the burden on [Biotronik] of adopting [the] alternative design and the adverse effect, if any, of such alternative design on the utility of the product." *Johnson v. Teva Pharms. USA, Inc.*, 758 F.3d 605, 612 (5th Cir. 2014) (quoting La. Stat. § 9:2800.56). "The occurrence of an injury does not give rise to the presumption that the design was unreasonably dangerous." *Fuller v. Eisai, Inc.*, No. 20-1675, ___ F. Supp. 3d ___, 2021 WL 149122, at *4 (E.D. La. Jan. 15, 2021) (Africk, J.) (quoting *Rivers v. Remington Arms Co.*, No. 17-17124, 2018 WL 746392, at *4 (E.D. La. Feb. 7, 2018) (Africk, J.)). Similarly, "[a] conclusory allegation that an alternate design exists will not suffice." *Rivers*, 2018 WL 746392, at *4 (quoting *Robertson*, 2015 WL 5823326, at *4).

"However, at least in the context of pharmaceutical [design defect] claims, courts do not require that plaintiffs 'plead extremely "detailed factual allegations"' to

survive a motion to dismiss." *Fuller*, 2021 WL 149122, at *5 (quoting *Flagg v. Stryker Corp.*, 647 F. App'x 314, 317 (5th Cir. 2016) (quoting *Iqbal*, 556 U.S. at 678)). All that is needed to satisfy *Twombly*'s plausibility standard are allegations sufficient "'to raise a reasonable expectation that discovery will reveal evidence of' the necessary claims or elements." *Flagg*, 617 F. App'x at 317 (quoting *In re S. Scrap Material Co., LLC*, 541 F.3d 584, 587 (5th Cir. 2008)).

Nonetheless, *some* allegation is required, even after *Flagg*. *See, e.g.*, *Lewis v. Baxter Int'l Inc.*, No. 16-16391, 2017 WL 661324, at *4 (E.D. La. Feb. 17, 2017) (Fallon, J.) (concluding that, even in light of the difficulties posed by pre-discovery dispositive motions in products liability cases, "conclusory allegations" of a design defect were insufficient); *Pellegrin*, 2018 WL 3046570, at *5 (similar); *see generally Flagg*, 617 F. App'x at 318 (explaining that this relaxed application of *Twombly* and *Iqbal* does not allow "fishing expedition[s]" to proceed to "lengthy and expensive discovery"). *Flagg* does not require courts to accept wholly conclusory allegations. *See, e.g.*, *Dubroc v. Bristol-Meyers Squibb*, No. 18-833, 2019 WL 3756469, at *4 (M.D. La. Aug. 8, 2019) (rejecting the notion that *Flagg* renders conclusory allegations sufficient). For example, allegations that "there existed an alternative design for the product that was capable of preventing Plaintiff's damages with use of other materials that did not 'bleed,'" have been found insufficient. *Id.*

The Celinos repeatedly allege that various Biotronik devices were "defective," including at least one lead.[54] They explain that "the leads were defective [sic]

[54] *See, e.g.*, R. Doc. No. 31, at 4 ¶ 8.

Biotronik did not manufacture the lead in accordance with [sic] FDA's manufacturing standards and due to upon [sic] information and belief, Biotronik used defective materials, defective design, defective construction, and defective software."[55] They also "alleges [sic] the [sic] upon information and believes [sic] the . . . leads . . . were . . . defective in design."[56] Finally, they add that "[t]he Biotronik products are unreasonably dangerous in design because for [sic] the same reasons previously stated in the previous paragraph and the petition.[57] The defective designs include, defective process designs, defective medical device design . . . and defective software design, all in violation and in non-conforming [sic] of FDA laws."[58]

Those are all conclusory statements, to say the least. But even if they were not, the Celinos would *still* fail to state a design defect claim. The only allegation contained in the amended complaint that even touches upon the elements of a LPLA design defect claim states, without identifying any particular Biotronik product, that "[a]lternatives in construction, design, composition, and products existed at he [sic] time that could have prevented the damage," and that "[t]he likelihood that Biotronik's design and the construction and composition would cause damage and the gravity of the damage outweighs the burden on the manufacturer to use a different design, constructor, [sic] or material in composition."[59] At best, this merely recites

[55] *Id.* at 6 ¶ 9.
[56] *Id.* at 14 ¶ 20. *See also id.* at 17 ¶ 25 ("Upon information and belief, Biotronik's . . . lead . . . [was] defective in design[.]").
[57] The Court does not know what those reasons are.
[58] *Id.* at 18 ¶ 31.
[59] *Id.* at 22 ¶ 43.

some of the elements of a LPLA design defect claim—and fails to point to an alternative design. "Even under the seemingly less rigorous approach to products liability cases . . . set forth in *Flagg*, [the Celinos have] still failed to state a claim." *Dubroc*, 2019 WL 3756469, at *4.

The Court has already provided the Celinos one chance to amend their complaint. And the Celinos are represented by counsel. Under most circumstances, the Court would be inclined to dismiss this claim with prejudice.

However, in light of *Flagg*, and out of an abundance of caution, the Court will allow the Celinos one more opportunity to amend this claim. If they fail to do so adequately, the claim will be dismissed with prejudice.

iii. Inadequate Warning

The Celinos further contend the Biotronik devices are unreasonably dangerous because "an adequate warning about the products has not been provided concerning the numerous problems, and malfunctions of these products and their component parts in violation of the FDA laws."[60] The Court need not evaluate whether the claim is preempted because it falls woefully short of the requirements to state such a claim under the LPLA.

"To successfully maintain a failure-to-warn claim under the LPLA, a plaintiff must demonstrate that the product in question has a potentially damage-causing characteristic and that the manufacturer failed to use reasonable care to provide an adequate warning about this characteristic." *Stahl v. Novartis Pharms. Corp.*, 283

[60] *Id.* at 19 ¶ 32.

F.3d 254, 264 (5th Cir. 2002) (citing *Grenier v. Med. Eng'g Corp.*, 243 F.3d 200, 205 (5th Cir. 2001)).

Louisiana applies the learned intermediary doctrine to medical devices. *Willett v. Baxter Int'l, Inc.,* 929 F.2d 1094, 1098–99 (5th Cir. 1991). Under that doctrine, a manufacturer's obligation to consumers is "fulfilled when the . . . treating physician is informed of any potential side effects or risks from the [device's] use so that they may intelligently decide on its use and advise the patient." *Stahl*, 283 F.3d at 267 (quoting *McCarthy v. Danek Med., Inc.*, 65 F. Supp. 2d 410, 413 (E.D. La. 1999) (Lemelle, J.)). "The premise underlying a failure-to-warn claim in the learned intermediary context is that the patient is claiming that the manufacturer failed to adequately warn the *treating physician*." *Id.* at 268 (emphasis retained).

In such circumstances, a medical device may be unreasonably dangerous because of an inadequate warning if: (1) the defendant failed to warn the plaintiff's doctor of a risk associated with the product that was otherwise unknown to the doctor; and (2) the failure to warn the doctor was both a cause in fact and the proximate cause of the plaintiff's injury. *Willett*, 929 F.2d at 1098. To prove causation, the plaintiff must show that "a proper warning would have changed the decision of the treating physician, *i.e.* that but for the inadequate warning, the treating physician would not have used . . . the product." *Id.* at 1099.

The Celinos allege Biotronik failed to warn Barbara's doctors "regarding the unreasonably dangerous and defective products that were implanted and used in the care and treatment of Barbara Celino, pertaining to the products listed above, subject

to the litigation."[61] They also claim "[t]he labels Biotronik presented to FDA [sic] for approval by FDA [sic] were not truthful and were misleading."[62]

Biotronik argues that this claim must be dismissed because, among other reasons, the Celinos fail to "allege that, but for the allegedly inadequate warning, [Barbara's] doctor would not have used the" Biotronik products—an allegation required by the learned intermidiary doctrine.[63] The Celinos offer the following response, which the Court reproduces in full:

> Defendant's cite of *Stahl*, 283 F.3d at 265 pertaining to the Learned intermediary doctrine does not apply because Biotronik has documentation and brochures and warranties that state Biotroniks [sic] products are free of manufacturing defects and Biotronik has stated the products [sic] life are for [sic] much longer than they actually are. Biotronik's medical devices break and malfunction on an ongoing basis. Biotronik has also provided Biotronik information and advertisements and brochures that their products have a zero malfunction rate.[64]

That, as far as the Court can tell, does not address Biotronik's argument. And the Celinos' failure to allege that Barbara's doctors would not have used the relevant Biotronik devices had they been properly warned is, in fact, fatal to their claim—as even *Flagg* acknowledged. 647 F. App'x at 316, 316 n.3 (citing *Stahl*, 283 F.3d at 268, and concluding that the district court "properly dismissed" plaintiff's failure-to-warn claim where he "failed to include any allegations about . . . whether [the treating physician] would have used the [relevant products] if given . . . [an adequate]

[61] *Id.* at 19–20 ¶ 36.
[62] *Id.* at 19 ¶ 32.
[63] R. Doc. No. 32-1, at 19.
[64] R. Doc. No. 39, at 24–25.

warning, as required under Louisiana law"). The failure-to-warn claim will therefore be dismissed with prejudice.

iv. Breach of Express Warranty

The Celinos also bring a LPLA claim for breach of an express warranty against Biotronik.[65] To succeed using this theory, a plaintiff must show "(1) the manufacturer made an express warranty regarding the product, (2) the [decedent] was induced to use the product because of that warranty, (3) the product failed to conform to that express warranty, and (4) the [decedent's] damage was proximately caused because the express warranty was untrue." *Caboni v. Gen. Motors Corp.*, 278 F.3d 448, 452 (5th Cir. 2002) (citing La. Stat. § 9:2800.58).

The Celinos argue that the Biotronik devices did not conform to an express warranty that they "have product life with proven performance."[66] They also point to a statement by Biotronik that the products were "99% and 100% safe," with a malfunction rate of "0% to less than 1% and/or estimated for any part of the component system."[67]

Biotronik argues that express warranty claims under the LPLA are preempted,[68] and that, to the extent this is no longer a categorical rule,[69] the Celinos' claim is inadequate to avoid preemption because it "fails to allege how the alleged

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[65] R. Doc. No. 31, at 19 ¶ 33.
[66] *Id.* at 8 ¶ 12.
[67] *Id.*
[68] R. Doc. No. 41, at 6 (citing *Gomez*, 442 F.3d at 932).
[69] Biotronik acknowledges that *Wildman v. Medtronic, Inc.*, 874 F.3d 862 (5th Cir. 2017), suggests a possible limit to *Gomez*. *Id.* at 6 n.3.

breach of warranty also constituted a violation of federal law—the touchstone of a parallel claim."[70]

Biotronik also argues that, even if the claim were not preempted, the Celinos' "claim fails because they have not sufficiently identified the express warranty they rely on."[71] Biotronik also notes that "absent from the Amended Complaint are any allegations that either [Barbara] or her doctor relied upon any alleged express warranty or that [Barbara's] alleged damages were caused by any allegedly false express warranty.[72]

In response, the Celinos cite *Wildman* (discussed *infra*) and argue that it controls here because "Biotronik had an express warranty Celino was deceived into believing there was a safe and effective product."[73] The Celinos also argue (again for the first time in opposition) that "MDT was present in the operating room when the ICD was implanted and MDT, through their representatives assigns [sic] known as technicians, followed [Barbara] an [sic]."[74] Finally, the Celinos add in opposition that "[t]he nurses and physicians relied completely on Biotronik, Biotronik is paid for their services."[75]

The Fifth Circuit has previously held that, because the LPLA "requires proof that 'the express warranty was untrue,'" it imposes duties that "relate to, and are

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[70] *Id.* at 6.
[71] *Id.* at 6 n.3.
[72] R. Doc. No. 32-1, at 20.
[73] R. Doc. No. 39, at 14–15.
[74] *Id.* at 22.
[75] *Id.*

potentially inconsistent with, the federal regulatory scheme" and is, therefore, "preempted." *Gomez*, 442 F.3d at 932. Indeed, any warranty claim "challeng[ing] a representation the FDA blessed in the approval process . . . is preempted." *Wildman*, 874 F.3d at 868 (citing *Gomez*, 442 F.3d at 931–32).

The warranty at issue in *Gomez* was approved during the PMA process. 442 F.3d at 932. In *Wildman*, though, the relevant warranty went "beyond what the FDA evaluated in its approval process." 874 F.3d at 870. Because of this, "[a] verdict finding that [the manufacturer] misled customers . . . in making this representation . . . would not undermine any FDA finding concerning the safety of the device." *Id.* Therefore, to the extent the relevant "warranty goes beyond what the FDA considered," the claim is not preempted. *Id.* at 869.

Even following *Wildman*, though, such claims must still be adequately alleged. *See id.* at 870–71. *Wildman* itself acknowledged that these claims "often fail for other reasons," including "a failure to allege the claim with [adequate] particularity." *Id.* at 870. Indeed, despite reversing and remanding the decision below, *Wildman* explicitly instructed the district court to review the claim's sufficiency closely, including whether the plaintiff "allege[d] reliance on the warranty." *Id.* at 871.

As Biotronik notes, the amended complaint (and, for that matter, the Celinos' opposition to the instant motion), does not identify whether the alleged warranty goes beyond what the FDA approved. That deficiency alone is fatal, as it means the Celinos have failed to adequately allege a parallel claim.

But even if it were a parallel claim, the Celinos have still failed to allege what the LPLA requires—that the warranty induced Barbara or her doctor to use the relevant products. The amended complaint itself offers little on the point. The opposition includes three statements that are conceivably relevant. First, the Celinos claim that "Biotronik had an express warranty Celino was deceived into believing there was a safe and effective product."[76] But, even if the Court were to read "Celino" as 'Barbara and her doctors,' this statement tells the Court nothing about what Barbara or her doctor would have done if no warranty was offered.

Second, the Celinos claim "MDT was present in the operating room when the ICD was implanted and MDT, through their representatives assigns [sic] known as technicians, followed [Barbara] an [sic]."[77] The Court believes 'MDT' is a reference to Medtronic, an unrelated manufacturer of similar devices against whom the Celinos' counsel has brought numerous lawsuits. But even if the Court reads "MDT" to mean "Biotronik," this allegation also fails to suggest any inducement. It is therefore inadequate.

Finally, the Celinos add in opposition that "[t]he nurses and physicians relied completely on Biotronik, Biotronik is paid for their services."[78] While this statement includes the word "relied," it is far too vague to be of any use.

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[76] R. Doc. No. 39, at 14–15.
[77] *Id.* at 22.
[78] *Id.*

Because the Celinos have not adequately established a parallel claim and because they did not allege reliance on any warranty, their claim fails. It will be dismissed with prejudice.

E. Remaining State-Law Claims

i. LUTPA, "wrongful death," and "survival action"

The Celinos next contend Biotronik violated the Louisiana Unfair Trade Practice and Consumer Protection Law ("LUTPA") because it engaged in deceptive behavior.[79] Specifically, they contend that Biotronik intentionally manufactured, sold, distributed, and marketed products with knowledge that consumers would be exposed to serious danger.[80] Biotronik responds that these claims are subsumed by the LPLA.[81] In opposition, the Celinos "acknowledge that the [LPLA] is the exclusive remedy for the products," and offer no response to Biotronik's argument except as to their breach of contract claim, discussed *infra*.[82]

The LUTPA prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." La. Stat. § 51:1405(A). But the passage of the LPLA altered a claimant's ability to recover under the LUTPA. La. Stat. § 9:2800.52. The LPLA "establishes the exclusive theories of liability for manufacturers for damage caused by their products." *Id.* Courts consistently hold that the LPLA bars plaintiffs from making a claim against a manufacturer for

[79] R. Doc. No. 31, at 25 ¶ 51.
[80] *Id.* at 26 ¶ 52.
[81] R. Doc. No. 32-1, at 21.
[82] R. Doc. No. 39, at 1.

damage caused by a product under LUTPA. *See Johnson*, 758 F.3d at 615–616; *see also, e.g.*, *Reddick*, 2020 WL 2759077, at *4 (holding that the LPLA bars LUTPA claims).

There is no dispute that Biotronik is a manufacturer, nor that the Celinos are alleging damage caused by Biotronik products. Consequently, the Celinos' LUTPA claim is subsumed by the LPLA.[83]

iii. Breach of Contract

The Celinos finally argue Biotronik breached a service contract it entered into with Barbara, though they "[do] not have possession of the contract."[84] "This service contract [was] at least a three-party contract that included the now shuttered and closed doctor's clinic and the doctor that was located in St. Tammany Parish."[85] The Celinos allege that "[u]pon information and belief this service contract states that it will provide 24 hour/7days [sic] a week monitoring services and patients [sic] services and home health services to . . . [Barbara]."[86] This was to include "patient services for any of patients [sic] needs, concerns, complaints, or need for medical attention that may arise during the monitoring of her heart and heart condition."[87] The Celinos

[83] Similarly, because the LPLA established the exclusive theories of liability against manufacturers for damage caused by their products, the Celinos' survival action and wrongful death action—to the extent that these are independent claims—are also dismissed. *See Jefferson v. Lead Indus. Ass'n*, 106 F.3d 1245, 1250–51 (5th Cir. 1997) (holding that a plaintiff cannot recover from a manufacturer for damage caused by a product on the basis of any theory of liability not set forth in the LPLA).
[84] R. Doc. No. 31, at 23 ¶ 46.
[85] *Id.* at 23 ¶ 46.
[86] *Id.*
[87] *Id.*

allege that Biotronik provided "bad service" that constantly disrupted Barbara's life.[88] However, they offer no detail, except that Barbara "failed to get the proper services as per the contract and as per the price she was paying for the services"[89] and that "Biotronik failed to perform its service obligations and continuously breached the contracts and their obligations to [Barbara] and/or her third-party doctors."[90]

Biotronik argues that the Celinos do not identify "any action or inaction by Biotronik that constituted a breach of contract."[91] It describes the allegations as conclusory, distinguishing the instant claim from a similar one alleged in *Reddick*, where the court held a plaintiff sufficiently pleaded a breach of contract claim.[92]

Under Louisiana law, an obligation "is a legal relationship whereby a person . . . is bound to render a performance in favor of another." La. Civ. Code art. 1756. When an obligor fails to perform a conventional obligation, she is liable for the damages caused by that failure. *Id.* art. 1994. To recover, a plaintiff must prove: "(1) the obligor's undertaking [of] an obligation to perform, (2) the obligor failed to perform the obligation (the breach), and (3) the failure to perform resulted in damages to the obligee." *Favrot v. Favrot*, 68 So. 3d 1099, 1108–09 (La. App. 4 Cir. 2011).

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[88] *Id.* at 24 ¶ 46.
[89] *Id.* at 24 ¶ 47.
[90] *Id.* at 25 ¶ 49.
[91] R. Doc. No. 41, at 7.
[92] *Id.* (citing 2020 WL 2759077, at *7).

Because this breach of contract claim is not based on damage caused by Biotronik's product but by Biotronik's allegedly inadequate service, the Court will assume *arguendo* that it is not barred by the LPLA. *See* La. Stat. § 9:2800.52.

However, Biotronik is correct that the allegations here are inadequate to support a claim. In *Reddick*, the plaintiffs offered examples of actions that breached the alleged agreement. *Id.* at *10 (denying motion to dismiss where the plaintiff alleged failure to provide "24 hour and seven day a week . . . technical support relating to the [relevant device]"). Here, the Celinos do not identify *how* Biotronik failed to perform the obligations listed in the alleged service agreement—or what those obligations were. *See* La. Civ. Code art. 1994. While the Celinos claim Barbara received "bad" service, they offer nothing more—not even an allegation that the service was not, in fact, around-the-clock. Their bare assertions "amount to nothing more than a formulaic recitation of the elements" of a breach of contract claim. *Iqbal*, 556 U.S. at 681 (quotation omitted). The claim will therefore be dismissed with prejudice.

IV. CONCLUSION

The Celinos have failed to state a non-preempted claim upon which relief can be granted. While leave to amend shall be freely given "when justice so requires," Fed. R. Civ. Proc. 15(a)(2), it is "by no means automatic." *Hutcheson v. Dallas Cty.*, ___ F.3d ___, 2021 WL 1344002, at *5 (5th Cir. Apr. 12, 2021) (quoting *Ashe v. Corley*, 992 F.2d 540, 542 (5th Cir. 1992)). The Celinos were "already provided . . . an opportunity to amend . . . and the amended complaint is still deficient." *Id.* However,

given the nature of design defect claims, and out of an abundance of caution, the Celinos will be given one more opportunity to adequately state *that* claim only. Therefore,

IT IS ORDERED that Biotronik's motion to dismiss is **GRANTED IN PART** and **DISMISSED WITHOUT PREJUDICE IN PART**; all claims addressed above except for the claim of a LPLA violation premised on a design defect are **DISMISSED WITH PREJUDICE**.

IT IS FURTHER ORDERED that the Celinos may file an amended complaint as to the design defect theory only. That amended complaint shall be filed no later than **MAY 14, 2021**. The Court will not consider other claims.

New Orleans, Louisiana, April 28, 2021.

LANCE M. AFRICK
UNITED STATES DISTRICT JUDGE