IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

BRENDA S. YOSOWITZ and EDWARD E. YOSOWITZ, M.D.,	§	
Plaintiffs,	§	
v.	§	CIVIL ACTION NO. H-15-2902
COVIDIEN LP,	§	
Defendant.	§	

MEMORANDUM OPINION AND ORDER

Plaintiffs Brenda S. Yosowitz and Edward E. Yosowitz, M.D. (together, "Plaintiffs") sued Covidien LP ("Defendant" or "Covidien") in the 215th Judicial District Court of Harris County, Texas.[1] Defendant removed the case to this court.[2] Pending before the court is Defendant Covidien LP's Motion to Dismiss Plaintiffs' First Amended Complaint (Docket Entry No. 21). For the reasons stated below, the motion to dismiss will be granted, and this action will be dismissed with prejudice.

I. Factual Allegations and Procedural Background

One of the Plaintiffs underwent a procedure to repair two intracranial aneurysms on February 18, 2015.[3] Covidien

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[1]See Plaintiffs' Original Petition, Exhibit B to Defendant Covidien LP's Notice of Removal ("Notice of Removal"), Docket Entry No. 1-2, pp. 9-15.

[2]See Notice of Removal, Docket Entry No. 1.

[3]See Plaintiffs' First Amended Complaint ("Amended Complaint"), Docket Entry No. 17, p. 2 ¶ 7.

manufactures the Pipeline Embolization Device (the "Pipeline") used in the procedure, which is coated with polytetrafluorothylene.[4] Plaintiffs allege the coating delaminated and detached from the delivery wire during surgery, allowing coating particulate to cause a blockage to a blood vessel in the Plaintiff's brain and resulting in mini-strokes from which the Plaintiff has suffered serious injuries.[5]

Plaintiffs filed suit, asserting causes of action for negligence, strict products liability (§ 402-A), breach of express warranty, breach of implied warranty, failure to comply with 21 C.F.R. § 820.30 Design Controls and Federal Food, Drug, and Cosmetic Act § 521(a), 21 U.S.C.A. § 360k(a), and gross negligence.[6] Plaintiffs filed an Amended Complaint after Covidien removed the action to federal court alleging the same causes of action.[7] Covidien had previously filed Defendant Covidien LP's Motion to Dismiss Plaintiffs' Petition and Brief in Support ("Motion to Dismiss") (Docket Entry No. 14) and adopted the arguments in that motion by reference in its present motion.[8] This

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[4]Id. at 2.

[5]Id.

[6]See Plaintiffs' Original Petition, Exhibit B to Notice of Removal, Docket Entry No. 1-2, pp. 11-13.

[7]See Amended Complaint, Docket Entry No. 17, pp. 3-5. The Amended Complaint is nearly identical to the state-court Plaintiffs' Original Petition, but removes defects in design, testing, and packaging from the strict products liability section.

[8]See Docket Entry No. 21, p. 3 (incorporating and adopting by reference the arguments, authority, and exhibits set forth in Docket Entry No. 14).

opinion references the original Motion to Dismiss unless noted otherwise. Covidien moved to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) on federal preemption grounds and because the claims otherwise fail to meet the Federal Rules of Civil Procedure pleading requirements.[9] Plaintiffs respond that not all of their claims are subject to federal preemption and that Covidien's motion is premature.[10]

II. Standard of Review

Under Rule 8 of the Federal Rules of Civil Procedure, a pleading must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). A Rule 12(b)(6) motion tests the formal sufficiency of the pleadings and is "appropriate when a defendant attacks the complaint because it fails to state a legally cognizable claim." Ramming v. United States, 281 F.3d 158, 161 (5th Cir. 2001), cert. denied sub nom. Cloud v. United States, 122 S. Ct. 2665 (2002). The court must accept the factual allegations of the complaint as true, view them in a light most favorable to the plaintiff, and draw all reasonable inferences in the plaintiff's favor. Id.

To defeat a motion to dismiss pursuant to Rule 12(b)(6), a plaintiff must plead "enough facts to state a claim to relief that

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[9]See Motion to Dismiss, Docket Entry No. 14, pp. 8-9. Covidien also argues that Plaintiffs' warranty claims fail for lack of privity between the parties. Id. at 9.

[10]See Plaintiffs' Response in Opposition to Defendant's Motion to Dismiss Plaintiffs' First Amended Complaint ("Plaintiffs' Response"), Docket Entry No. 25.

is plausible on its face." Bell Atlantic Corp. v. Twombly, 127 S. Ct. 1955, 1974 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009) (citing Twombly, 127 S. Ct. at 1965). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." Id. (quoting Twombly, 127 S. Ct. at 1965). "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, 127 S. Ct. at 1966). When considering a motion to dismiss, district courts are "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). "Federal courts are required to dismiss . . . claims based on invalid legal theories, even though they may be otherwise well-pleaded." Flynn v. State Farm Fire & Casualty Insurance Co. (Texas), 605 F. Supp. 2d 811, 820 (W.D. Tex. 2009) (citing Neitzke v. Williams, 109 S. Ct. 1827, 1832 (1989)).

III. Analysis

A. Judicial Notice

Covidien requests that the court take judicial notice of certain publicly available Food and Drug Administration ("FDA") records that Covidien attached to the Motion to Dismiss.[11] These records relate to the FDA premarket approval application ("PMA") process that certain medical devices must undergo, and are all screenshots of the FDA website or PDF-format documents available through the FDA website.[12] A district court reviewing a motion to dismiss must consider the entire complaint "'as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take

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[11]Motion to Dismiss, Docket Entry No. 14, p. 12. See PMA summary page for Pipeline Embolization Device, PMA No. P100018, Exhibit C to Motion to Dismiss, Docket Entry No. 14-4; Pipeline Embolization Device - P100018, Device Approvals, Denials and Clearances, Exhibit D to Motion to Dismiss, Docket Entry No. 14-5; April 6, 2011, Letter to Dr. Cher from Christy Foreman ("PMA Approval Letter"), Exhibit E to Motion to Dismiss, Docket Entry No. 14-6; Summary of Safety and Effectiveness Data (SSED), Exhibit F to Motion to Dismiss, Docket Entry No. 14-7; Instructions for Use for Pipeline Embolization Device, Exhibit G to Motion to Dismiss, Docket Entry No. 14-8; Recently-Approved Devices Summary for Pipeline Embolization Device - P100018, Exhibit H to Motion to Dismiss, Docket Entry No. 14-9.

[12]All are available at http://www.fda.gov and at links from that website. See Exhibit B to Motion to Dismiss, Docket Entry No. 14-3.

judicial notice.'"[13] Funk v. Stryker Corp., 631 F.3d 777, 783 (5th Cir. 2011) (quoting Tellabs, Inc. v. Makor Issues & Rights, Ltd., 127 S. Ct. 2499, 2509 (2007)).

Under Federal Rule of Evidence 201(b)(2), "[t]he court may judicially notice a fact that is not subject to reasonable dispute because it . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Courts in this jurisdiction have recognized that "judicial notice of publicly-available documents and transcripts produced by the FDA, which were matters of public record directly relevant to the issue at hand" is appropriate. Funk, 631 F.3d at 783 ("[W]e hold that it was appropriate for the court to take judicial notice, under Rule 12(b)(6), of the PMA the FDA granted to Stryker for marketing its Trident System."), id.; see also U.S. ex rel. Bennett v. Medtronic, Inc., 747 F. Supp. 2d 745, 756 n.9 (S.D. Tex. 2010) (taking judicial notice of FDA 510k premarket notification cited by the parties in a motion to dismiss and available on the FDA website). Plaintiffs do not dispute the fact that the Pipeline received the FDA's PMA approval and do not argue that the court

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[13]Generally, "[w]hen 'matters outside the pleadings' are submitted in support of or in opposition to a Rule 12(b)(6) motion to dismiss, Rule 12(b) grants courts discretion to accept and consider those materials, but does not require them to do so." Ace American Ins. Co. v. Huntsman Corp., 255 F.R.D. 179, 188 (S.D. Tex. 2008) (citations omitted). If the court chooses to do so, it must treat the Rule 12(b)(6) motion as a motion for summary judgment under Rule 56. Id. (citing Fed. R. Civ. P. 12(d)).

should not take judicial notice of these records. The court concludes that Covidien's exhibits satisfy the requirements of Fed. R. Evid. 201(b) and will take judicial notice of them.[14]

B. Plaintiffs' Claims Are Subject to Dismissal

1. The Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act

To properly address Covidien's preemption arguments, it is necessary to examine the Medical Device Amendments ("MDA"), 21 U.S.C. §§ 360c et seq., to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq. The MDA was enacted "to provide for the safety and effectiveness of medical devices intended for human use." Medtronic, Inc. v. Lohr, 116 S. Ct. 2240, 2245 (1996) (quoting the MDA's preamble). The MDA granted the FDA authority to

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[14]Plaintiffs also attached documents to their Response, but did not request that the court take judicial notice of them. They include: (1) a letter from Plaintiffs' counsel to Defendant's counsel regarding inspection of the subject pipeline embolization devices, Exhibit A to Plaintiffs' Response, Docket Entry No. 25-1; (2) an email from Plaintiffs' counsel to Defendant's counsel asking when the guide wire would be made available for inspection by Plaintiffs' expert, Exhibit B to Plaintiffs' Response, Docket Entry No. 25-2; (3) a recall notice for Covidien Pipeline Embolization Device dated April 1, 2014, Exhibit C to Plaintiffs' Response, Docket Entry No. 25-3; and (4) the affidavit of a Houston Methodist Hospital employee who was present during the procedure performed on Plaintiff, Exhibit D to Plaintiffs' Response, Docket Entry No. 25-4. The court may take judicial notice on its own, but declines to do so for any of these documents except for the recall notice, which is available on the FDA website. The other documents are not relevant to preemption, the basis of this court's decision, and therefore considering them and converting this motion into one for summary judgment is not "likely to facilitate disposing of the action." Ace American Ins., 255 F.R.D. at 188.

regulate medical devices and "swept back some state obligations and imposed a regime of detailed federal oversight." Riegel v. Medtronic, Inc., 128 S. Ct. 999, 1003 (2008).

The MDA defines three classes of "devices intended for human use." See 21 U.S.C. § 360c. Plaintiffs do not dispute that the Pipeline is a "Class III" device. Class III devices are subject to the most federal oversight and must undergo the FDA's rigorous PMA process before the manufacturer may bring them to market.[15] See id. § 360e; Riegel, 128 S. Ct. at 1003; Lohr, 116 S. Ct. at 2246-47. The PMA process requires the FDA to weigh any probable benefit to health from the use of the device against any probable risks of injury or illness from such use. See 21 U.S.C. § 360c(a)(2)(C). The FDA only approves a device if it finds there is a reasonable assurance of the device's safety and effectiveness. See id. § 360e(d). The FDA spends an average of 1,200 hours reviewing each application. See Riegel, 128 S. Ct. 1004; Lohr, 116 S. Ct. at 2247. The FDA reviews the Class III device's proposed labeling and can condition approval on adherence to performance standards, restrictions upon sale or distribution, or compliance with other

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[15]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.'" Riegel, 128 S. Ct. at 1003 (quoting 21 U.S.C. § 360c(a)(1)(C)(ii)).

requirements. Riegel, 128 S. Ct. at 1004. If the manufacturer wants to change design specifications, manufacturing processes, labeling, or "any other attribute[] that would affect safety or effectiveness" after approval, the manufacturer must submit a PMA supplement and obtain FDA approval for the change. Id. at 1005 (citing 21 U.S.C. § 360e(d)(6); 21 C.F.R. § 814.39(c)). Even after approval, Class III devices are subject to reporting requirements. Id. (citing 21 U.S.C. § 360i). The FDA issued a PMA letter for the Pipeline in April of 2011.[16]

2. Express and Implied Preemption Under the MDA

In enacting the MDA "Congress had to balance competing goods when it enacted the Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetics Act (FDCA)." Caplinger v. Medtronic, Inc., 784 F.3d 1335, 1336 (10th Cir. 2015).

> Perhaps most notably, it had to weigh the good of ensuring that proposed medical devices are carefully scrutinized for safety against the good of preserving the freedom of patients and doctors to use potentially life-saving technology as they see fit and without undue delay. One arena in which these objectives clashed during the legislative process involved this question: to what extent (if any) should states be able to layer additional rules on top of Congress's? Allowing more regulation of medical devices could yield benefits for patient safety. But it could also mean forcing manufacturers to abide not one but fifty-one sets of requirements, a prospect that could deter or delay access to innovative devices and wind up hurting more patients than it helps.

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[16]See PMA Approval Letter, Exhibit E to Motion to Dismiss, Docket Entry No. 14-6.

Id. Congress thus included 21 U.S.C. § 360k(a) in the MDA, an express preemption provision that prohibits states from establishing any "requirement" for a medical device

> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
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> (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.

In Riegel, 128 S. Ct. at 1002, the United States Supreme Court considered "whether the pre-emption clause enacted in the [MDA] bars common-law claims challenging the safety and effectiveness of a medical device given premarket approval by the [FDA]." The Court held that the plaintiff's claims under New York common law for strict liability; breach of implied warranty; and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of a balloon catheter were preempted. Id. at 1006-07, 1011.

Riegel established a two-step analysis for determining whether state law claims are preempted under the MDA. First, "[s]ince the MDA expressly pre-empts only state requirements 'different from, or in addition to, any requirement applicable . . . to the device' under federal law, § 360k(a)(1), we must determine whether the Federal Government has established requirements applicable to [the Pipeline]." Id. at 1006. Second, we must determine whether Plaintiffs' "common-law claims are based upon [state] requirements with respect to the device that are 'different from, or in addition to,' the federal ones, and that relate to safety and effectiveness"

or "any other matter included in a requirement applicable to the device." Id. at 1006, 1007. If so, the plaintiff's claim is preempted. See id. To escape preemption by § 360k(a), a state-law claim must be premised on the breach of a state-law duty that is the same as a duty imposed under the FDCA (or one of its implementing regulations). Id. at 1011.

The MDA also contains an implied preemption provision. In Buckman Co. v. Plaintiffs' Legal Committee, 121 S. Ct. 1012, 1017 (2001), the Court held that "the plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law." Id. This holding was based on 21 U.S.C. § 337(a), which states:

> Except as provided in subsection (b) of this section, all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. . . .[17]

The Court stated, "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions: '[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.'" Buckman, 121 S. Ct. at 1018 n.4 (quoting § 337(a)). Thus, although "some parallel state claims survive preemption by the MDA," individuals may not bring "a freestanding

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[17]Subsection (b) allows a State to bring enforcement proceedings in certain situations.

federal cause of action based on violation of the FDA's regulations." See Hughes v. Boston Scientific Corp., 631 F.3d 762, 775 (5th Cir. 2011) (discussing Buckman, 121 S. Ct. 1012).

To avoid implied preemption under Buckman a claim must assert violation of a state tort duty that also violates some FDA requirement. See id. As described by the district court in Riley v. Cordis Corp., 625 F. Supp. 2d 769, 777 (D. Minn. 2009):

> In other words, the conduct on which the claim is premised must be the type of conduct that would traditionally give rise to liability under state law—and that would give rise to liability under state law even if the FDCA had never been enacted. If the defendant's conduct is not of this type, then the plaintiff is effectively suing for a violation of the FDCA (no matter how the plaintiff labels the claim), and the plaintiff's claim is thus impliedly preempted under Buckman.

Together, "Riegel and Buckman create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption." In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation, 623 F.3d 1200, 1204 (8th Cir. 2010) ("In re Medtronic II"); see also Hughes, 631 F.3d at 767 ("Riegel, like the Court's earlier decision in [Lohr, 116 S. Ct. 2240], makes clear that a medical device manufacturer is protected from liability under state-law tort claims related to a defective or dangerous device to the extent that the manufacturer has complied with federal statutes and regulations. However, Riegel and Lohr also make clear that a manufacturer is not protected from state tort liability when the claim is based on the manufacturer's violation of applicable federal requirements."). A

properly pleaded state-law claim must "parallel" FDA requirements and cannot impose additional or different requirements on the manufacturer. See Bass v. Stryker Corp., 669 F.3d 501, 509, 514 (5th Cir. 2012).

3. Plaintiffs' Claims are All Preempted or Fail to Properly Allege a Claim

Covidien argues that Plaintiffs' claims are all either expressly or impliedly preempted by the MDA.[18] Plaintiffs respond that the PMA process does not preempt all state claims and that their claims are not expressly or impliedly preempted.[19]

a. Plaintiffs Have Not Pleaded Any Parallel Claims

In reviewing a motion to dismiss, the court must accept the factual allegations of the complaint as true, view them in a light most favorable to the plaintiff, and draw all reasonable inferences in the plaintiff's favor. Ramming, 281 F.3d at 161. Although Plaintiffs' claims are addressed individually below, a review of the factual allegations and scattered allegations of federal law violations together confirm that Plaintiffs have not adequately pleaded any parallel claims and have therefore failed to state a claim for which relief can be granted.

"Parallel claims must be specifically stated in the initial pleadings. A plaintiff must allege that the defendant violated a

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[18]See Motion to Dismiss, Docket Entry No. 14, pp. 13-27.

[19]See Plaintiffs' Response, Docket Entry No. 25, p. 3.

particular federal specification referring to the device at issue. To properly allege parallel claims, the complaint must set forth facts pointing to specific PMA requirements that have been violated." Wolicki-Gables v. Arrow International, Inc., 634 F.3d 1296, 1301 (11th Cir. 2011) (citations and quotations omitted). Plaintiffs allege that Covidien manufactures the Pipeline placed during the surgery; the Pipeline has a coating to reduce friction, some of which detached during the surgery; the detached coating caused Plaintiff's severe injuries; and Covidien knew prior to the incident that the coating had a tendency to flake off and cause a stroke in patients. After its brief factual statement, the Amended Complaint lists the causes of action detailed below. The Amended Complaint does not set forth facts pointing to specific PMA requirements that have been violated.

The Fifth Circuit addressed the necessity for plaintiffs to properly plead their claims to avoid preemption in Rodriguez v. American Medical Systems, Inc., 597 F. App'x 226, 229 (5th Cir. 2014). The court compared two of its earlier opinions. First, the court discussed Bass, 669 F.3d at 512, where "we held that 'if a plaintiff pleads that a manufacturer of a Class III medical device failed to comply with either the specific processes and procedures that were approved by the FDA or the [FDA's Current Good Manufacturing Practices] and that this failure caused the injury, the plaintiff will have pleaded a parallel claim.'" Id. (citing Wolicki-Gables, 634 F.3d at 1301-02, and In re Medtronic II, 623 F.3d at 1207).

> Bass addressed a claim that an FDA-approved Class III hip implant malfunctioned because of impurities in the manufacturing process. We 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.

Id. at 230 (discussing Bass, 669 F.3d at 510) (citations omitted). The court contrasted Funk, 631 F.3d at 782, where "we addressed a similar claim regarding the same hip implant but held that the plaintiff's pleadings were too conclusory to state a parallel claim."

> Specifically, we 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. Based on this case law, the court held that

> Rodriguez's complaint does not plead a violation of any federal requirement relating to design or manufacturing of the implant, either those specific to the AMS 700 MS or those generally applicable to the manufacturing of medical devices, and he cites no facts supporting a finding of any such violation. He fails to allege a specific defect in the manufacturing process or design, any deviation from the FDA-approved design or manufacturing processes, or any causal connection between a violation of federal requirements and his injuries. Thus, he has failed to plead a parallel claim.

Id.; see also Wolicki-Gables, 634 F.3d at 1301-02 ("These allegations do not 'set forth any specific problem, or failure to comply with any FDA regulation that can be linked to the injury alleged.' Because [plaintiffs] have failed to allege facts in their complaint demonstrating the presence of the elements of a

parallel claim, we are persuaded that the District Court did not err in concluding that their state common law claims were preempted." (citation omitted)). In sum, plaintiffs cannot "simply incant the magic words [that Defendant] violated FDA regulations." Id. at 1301. With this background the court will address the specific claims in Plaintiffs' Amended Complaint.

b. State-law Claims

The Pipeline is a Class III medical device that received premarket approval from the FDA. The PMA process establishes federal "requirements" under the MDA, satisfying the first prong of Riegel. See Riegel, 128 S. Ct. at 1007 (discussing Lohr, 116 S. Ct. 2240); Hughes, 631 F.3d at 768. "Moving to the second prong of the [Riegel] test, we must ask whether the state law at issue creates a requirement that is related to the device's safety or effectiveness and is 'different from or in addition to' a federal requirement." Hughes, 631 F.3d at 768. The Amended Complaint contains state-law claims for negligence, strict products liability, breach of express warranty, and breach of implied warranty. The Supreme Court recognized that state common-law duties – such as those underlying negligence, strict-liability, and implied-warranty claims – impose state "requirements" with respect to medical devices. Riegel, 128 S. Ct. at 1009-10; see also In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation, 592 F. Supp. 2d 1147, 1152 (D. Minn. 2009) ("In re Medtronic I"), aff'd, 623 F.3d 1200 (8th Cir. 2010) ("In the ten months following

Riegel, courts across the country have applied Section 360k(a) broadly, preempting all manner of claims from strict products liability and negligence, to breach of warranty, to failure to warn and manufacturing-and-design-defect, to negligence per se." (citations omitted)).[20] The court concludes that each of Plaintiffs' state-law claims likewise imposes "requirements" with respect to the Pipeline and will address the claims individually to determine whether they impose requirements that are different from or additional to applicable federal requirements and are thus preempted.[21]

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[20]Courts in this jurisdiction and others have concluded that these types of state-law claims impose "requirements." In Timberlake v. Synthes Spine, Inc., Civ. Action No. V-08-4, 2011 WL 711075, at *6 (S.D. Tex. Feb. 18, 2011), for example, the federal district court granted summary judgment for the defendant on the plaintiff's Texas state-law negligence and strict products liability claims because they "impose[d] additional safety requirements such that they would be preempted under Riegel by the federal requirements inherent in the PMA process." (citing Lewkut v. Stryker Corp., 724 F. Supp. 2d 648, 658 (S.D. Tex. 2010)). The court also granted summary judgment for the defendant on the plaintiff's express warranty claim. Id. at *7 (citing Gomez v. St. Jude Medical Daig Division Inc., 442 F.3d 919, 932 (5th Cir. 2006)). In Schouest v. Medtronic, Inc., 13 F. Supp. 3d 692, 706-07 (S.D. Tex. 2014), the court held that strict liability design and manufacturing defect claims, implied warranty, and failure-to-warn claims were preempted. See also DeLeon v. Johnson & Johnson, Civ. Action No. C-11-177, 2011 WL 2618957, at *3 (S.D. Tex. July 1, 2011) (dismissing products liability, negligence, gross negligence, and DTPA claims and collecting cases).

[21]See also Wolicki-Gables, 634 F.3d at 1301-02 (strict liability for manufacturing and design defect, failure to warn, and negligent design, manufacture, and assembly claims preempted); Walker v. Medtronic, Inc., 670 F.3d 569, 576-81 (4th Cir. 2012) (negligence, strict liability, and breach of warranty claims preempted); Caplinger v. Medtronic, Inc., 921 F. Supp. 2d 1206 (W.D. Okla. 2013), aff'd 784 F.3d 1335 (10th Cir. 2015) (dismissing constructive fraud, strict products liability (failure to warn and design defect), breach of express and implied warranty, and negligent failure-to-warn and marketing as preempted).

i. Negligence

Plaintiffs allege that Covidien was negligent "in one or more of the following acts and/or omissions:"

a. Failing to manufacture, market and label a product that would be safe for patients;

b. Failing to manufacture, market and label a product that was consistent with the original design; and

c. Failing to manufacture, market and label a product consistent with FDA regulations and guidelines.

"Each of these acts and/or omissions, singularly and/or in combination, proximately caused the injuries to the Plaintiffs."[22] The fact that the Pipeline received PMA approval indicates that the FDA approved the manufacturing, design, and labeling proposed by Covidien. A state law that requires Covidien to do something other than what was approved by the FDA imposes a different or additional requirement. See Riegel, 552 U.S. at 317 (quoting 21 U.S.C. § 360e(d)); see also Kemp v. Medtronic, Inc., 231 F.3d 216, 230 (6th Cir. 2000) ("To permit a jury to find Medtronic negligent" for failing to manufacture a PMA-approved device in a manner other than as prescribed in the PMA "would be to impose a requirement

[22]Amended Complaint, Docket Entry No. 17, p. 3 ¶¶ 16-17. Plaintiffs also allege that "[t]he negligence of the Defendants was of such a character to make the Defendants guilty of gross negligence . . . ." Id. at 5 ¶¶ 34-35. The Amended Complaint does not provide any information about Covidien's allegedly grossly negligent conduct. Because the negligence claim will be dismissed, the gross negligence claim will also be dismissed.

different from and in addition to those established by the FDA.").[23] Plaintiffs' negligence claim is thus preempted.

Plaintiffs argue that the "strict liability claims of manufacturing defect claims premised on manfacture[r]'s alleged violations of the FDA regulations and requirements should survive"[24] and "the negligent manufacturing claim should survive . . . [because] [t]he negligent claims have been pled as parallel claims that do not impose different or additional requirements than the FDA regulations because Plaintiff has pleaded that Covidien failed to abide by the FDA regulations in the manufacture of the pipeline embolization device."[25]

Plaintiffs cite Bass, 669 F.3d 501, where the court allowed a manufacturing defect claim to proceed because "to the extent they

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[23]See also Millman v. Medtronic, Civ. Action No. 14-CV-1465, 2015 WL 778779, at *5 (D.N.J. Feb. 24, 2015) ("Plaintiffs' claims based on a manufacturing defect, design defect, failure to warn, negligence and a breach of contract/warranty theory are preempted because they impose requirements that are different from the federal requirements set forth in the PMA process."); Zaccarello v. Medtronic, Inc., 38 F. Supp. 3d 1061, 1067-70 (W.D. Mo. 2014) (dismissing manufacturing and design defect negligence and strict liability claims as expressly preempted); Blankenship v. Medtronic, Inc., 6 F. Supp. 3d 979, 988 (E.D. Mo. 2014) (dismissing manufacturing defect, design defect, and failure to warn claims as expressly preempted and strict liability and negligence claims as impliedly preempted). Prior to Riegel courts found preemption under § 360k for these types of claims. See, e.g., Horn, 376 F.3d at 179 (negligence and defective design and manufacture claims preempted by § 360k); Martin v. Medtronic, 254 F.3d 573, 584-85 (5th Cir. 2001) (design, manufacturing process, and failure to warn claims preempted).

[24]Plaintiffs' Response, Docket Entry No. 25, p. 6.

[25]See id.

are premised on violations of FDA regulations, they are parallel claims that are not preempted." Bass, 669 F.3d at 515. Plaintiffs' claims, however, are more similar to those dismissed in Funk, 631 F.3d at 782, where the Fifth Circuit examined this manufacturing defect claim:

> [3.] The hip prostheses 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 design approved by the FDA.
>
> [4.] The hip prostheses deviated, in its construction or quality, from the specifications or planned output. As more particularly set forth below, Plaintiff invokes the doctrine of *res ipsa loquitur* as to the manufacturing defect contained in the hip prosthesis.

The court held the complaint "impermissibly conclusory and vague; it does not specify the manufacturing defect; nor does it specify a causal connection between the failure of the specific manufacturing process and the specific defect in the process that caused the personal injury. Nor does the complaint tell us how the manufacturing process failed, or how it deviated from the FDA approved manufacturing process." Id. (citing Iqbal, 129 S. Ct. at 1949).[26]

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[26]Plaintiffs' final argument is that the motion is premature without any discovery being conducted. See id. at 7. They cite a "voluntary recall" that Covidien issued in April of 2014 to address delamination. See Docket Entry No. 25-3. Plaintiffs do not provide argument or support that this recall notice changes the fact that the FDA issued a PMA for the Pipeline. Plaintiffs did not address this in their Amended Complaint, and as discussed at length, the Amended Complaint fails to allege any proper claims. (continued...)

Plaintiffs plead that Covidien failed to "manufacture, market and label a product that was consistent with the original design" . . . and "a product consistent with FDA regulations and guidelines."[27] These statements provide no information as to how Covidien deviated from the "original design." They do not indicate how the Pipeline is inconsistent with FDA regulations or guidelines, or what regulations or guidelines it is inconsistent with. Such vague and conclusory statements are not sufficient to survive a Rule 12(b)(6) motion to dismiss. See Rodriguez, 597 F. App'x at 229; Zaccarello, 38 F. Supp. 3d at 1069 ("The Court dismisses this claim for failure to include sufficient facts. Plaintiff does not allege facts regarding a particular violation of federal law and, therefore, fails to state a plausible claim. In addition, without more information, the Court is unable to determine whether the federal regulations are parallel to the MDA and whether the claim can exist independent from the MDA."). Thus, Plaintiffs' negligence claims will be dismissed.

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[26](...continued)
The voluntary recall notice does not change that conclusion. See Blanco v. Baxter Healthcare Corp., 158 Cal. App. 4th 1039, 1056, 70 Cal. Rptr. 3d 566, 579-80 (2008) (citations omitted) ("The fact the FDA implemented a Class I recall of the Valve does not alter our conclusion. When the Valve was implanted in Claudia, it had been approved by the FDA through the PMA process. And, we have found no evidence in the record to support the conclusion the FDA revoked the Valve's PMA. . . . The fact the FDA has implemented a Class I recall does not necessarily mean the FDA has completely removed the device from the marketplace."); see generally Bush v. Thoratec Corp., 837 F. Supp. 2d 603 (E.D. La. 2011).

[27]Amended Complaint, Docket Entry No. 17, p. 3 ¶ 16b and c.

ii. Strict Products Liability

Plaintiffs' second cause of action is for "Strict Products Liability (§ 402-A):"

> 19. Plaintiffs will show that the occurrence giving rise to this lawsuit was caused by Defendant Covidien, LP, placing into the stream of commerce an unreasonably dangerous and defective product.
>
> 20. Defendants manufactured, marketed, labeled, assembled, tested (or failed to test), inspected (or failed to inspect), packaged, fabricated, constructed, distributed, and sold the product.
>
> 21. The product was unsafe by reason of the defects in the manufacturing, marketing and labeling.[28]

Covidien's processes for manufacturing, marketing, and labeling the Pipeline were FDA approved in the intensive PMA review. See Riegel, 552 U.S. at 329-30. Plaintiffs' strict products liability claims necessarily impose requirements that are different from or in addition to federal requirements because Plaintiffs do not allege here that Covidien failed to satisfy federal requirements imposed by the PMA process. See, e.g., In re Medtronic I, 592 F. Supp. 2d at 1159 (plaintiffs could not "escape that under their theory of liability, Medtronic would have been required to provide warnings above and beyond those on the Sprint Fidelis leads' product label – a label that was specifically approved by the FDA as part of the PMA process," which would "impose requirements 'different from, or in addition to' those approved by the FDA."); Millman, 2015 WL 778779, at *6 n.5 ("Plaintiffs do not allege the

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[28] Id. at 3-4 ¶¶ 19-21.

design or manufacture of the Activa System devices deviated in any way from the design, manufacture or warning approved by the FDA through the PMA process. Thus, to prevail on their state-law design, manufacturing and failure to warn claims, Plaintiffs necessarily would have to prove that the Activa System devices should have employed a design, manufacture or label different from that approved by the FDA. Riegel squarely forecloses any such claim."). See also Bass, 669 F.3d at 515; Schouest, 13 F. Supp. 3d at 704; Lewkut, 724 F. Supp. 2d at 660; Mills v. Warner-Lambert Co., 581 F. Supp. 2d 772 (E.D. Tex. 2008). Therefore, the strict products liability claims will be dismissed.

iii. Breach of Express Warranty

Plaintiffs allege a breach of express warranty cause of action:

> 23. Plaintiff will show that the injuries and damages were caused by the breach of expressed warranties made by the Defendant.
>
> 24. Defendant placed a product into the stream of commerce that was a violation of its own expressed warranties.
>
> 25. Defendant, in placing the product into the stream of commerce, utilized advertising media and professional publications to urge the purchase and use of the product and expressly warranted to members of the general public, including Plaintiff that it was effective and proper.
>
> 26. Plaintiffs relied upon the representations made by the Defendant, in the purchase of the product.[29]

[29] Id. at 4 ¶¶ 23-26.

The express and implied warranty claims suffer from similar infirmities. "[A] jury would still have to find that the [Pipeline] was unsafe and ineffective in order to find that [Covidien] breached these warranties." See Timberlake, 2011 WL 711075, at *2. The FDA determined otherwise through the PMA process, so the state claim is based on different or additional requirements and is expressly preempted by the MDA. See Miller v. DePuy Spine, Inc., 638 F. Supp. 2d 1226, 1230 (D. Nev. 2009) ("Where . . . an essential element of a plaintiff's claim of breach of express or implied warranty will be proof that a device granted a PMA is not safe or effective, such a contention necessarily conflicts with the FDA's contrary finding and its requirement that the device be made as approved.").[30]

The express warranty claim does not allege that Covidien failed to comply with FDA requirements.[31] The Amended Complaint does not identify actual representations or promises that Covidien made regarding the safety and effectiveness of the Pipeline. In analyzing a similarly cursory complaint, another district court

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[30]See also Caplinger, 784 F.3d at 1340-47 (dismissing express and implied warranty claims as preempted); Gavin v. Medtronic, Inc., No. 12-0851, 2013 WL 3791612, at *15 (E.D. La. 2013) (express and implied warranty claims were preempted); Parker v. Stryker Corp., 584 F. Supp. 2d 1298, 1303 (D. Colo. 2008) ("Plaintiff's express warranty claim would contradict the FDA's determination that the representations made on the label were adequate and appropriate and, thus, impose requirements different from or in addition to the federal requirements.").

[31]See Amended Complaint, Docket Entry No. 17, p. 4.

held "Plaintiff does not allege any facts showing when and how he received notice of such warranties, nor does he allege facts showing that the pacemaker did not comport with such warranties. . . . Stated simply, Plaintiff has alleged nothing to suggest that any warranties made by Defendant were actually breached. Plaintiff has therefore not stated a breach of warranty claim upon which relief can be granted, and that claim will be dismissed." Steen v. Medtronic, Inc., Civ. Action No. 3:10-CV-936-L, 2010 WL 2573455, at *3 (N.D. Tex. June 25, 2010); see also Schouest, 13 F. Supp. 3d at 707 ("While conceptually an express warranty claim could avoid express preemption, what is missing from Schouest's complaint, in its current form, is a description of what specific warranties Medtronic made to Schouest or her physicians.").[32] The same issues arise here; there are no facts alleged that show when and how Plaintiffs received notice of the alleged warranties. See Twombly, 127 S. Ct. at 1965. Moreover, representations such as those made on the label, in warnings, and instructions for use were FDA approved, and any additional or different state law requirement would be preempted. See Gomez, 442 F.3d at 932.

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[32]In Schouest, 13 F. Supp. 3d at 707, the court gave the plaintiff an opportunity to replead on her request after the Rule 12 motion. Here, the court has already granted a post-Rule 12(b)(6) motion for leave to amend. See Order Granting Leave to File Amended Complaint, Docket Entry No. 20.

iv. Breach of Implied Warranty

Plaintiffs next allege breach of implied warranty:

> 28. Plaintiffs will show that the injuries were caused by the breach of implied warranty of merchantability by the Defendant.
>
> 29. Defendants implied to members of the general public, including Plaintiff, that the product was of merchantable quality and safe for the use for which it was intended.
>
> 30. The characteristics referenced above resulted in a condition that rendered the product unfit for the ordinary purpose for which it was to be used because of the lack of something necessary for adequacy.
>
> 31. Plaintiff believes that Defendant violated federal requirements that were a producing cause of their injuries.[33]

"[A]n implied warranty claim is not preempted if the plaintiff alleges that the defendant violated federal requirements *and* can ultimately show a causal link between the violation and the breach of the implied warranty." Bass, 669 F.3d at 517. Plaintiffs do not identify what federal requirements they "believe" Covidien violated. Plaintiffs' vague and conclusory allegation that "Plaintiff believes that Defendant violated federal requirements that were a producing cause of their injuries" cannot support a claim. See Rodriguez, 597 F. App'x at 229; Funk, 631 F.3d at 782. As discussed at length, Plaintiffs cannot "simply incant the magic words [that Defendant] violated FDA regulations." Wolicki-Gables, 634 F.3d at 1301; see also Timberlake, 2011 WL 71105, at *9

[33]Amended Complaint, Docket Entry No. 17, pp. 4-5 ¶¶ 28-31.

(quotations omitted). For these reasons, the implied warranty claim will also be dismissed.

c. Claims for Failure to Comply with the FDCA and Its Implementing Regulations

In addition to the state-law claims, the Amended Complaint contains a claim for "Failure to Comply with 21 C.F.R. § 820.30 Design Controls and Federal Food, Drug, and Cosmetic Act § 521(a), 21 U.S.C.A. § 360k(a):"

> 32. Defendant failed to meet design control requirements of 21 C.F.R. § 820.30 which was a producing cause and/or a proximate cause of Plaintiff's injuries and damages to Plaintiff.
>
> 33. The manufacture of the Pipeline Embolization Device by the Defendant failed to comply with either specific processes or procedures that were approved by the [FDA] or Current Good Manufacturing Practices (CGMPs) themselves and that failure caused injury to Plaintiffs.[34]

21 U.S.C. § 337(a) does not permit "freestanding federal causes of action based on violation of the FDA's regulations," and there is no private cause of action for duties independently created by FDA regulations. See Hughes, 631 F.3d at 775; Buckman, 121 S. Ct. 1018 at n.4; Lewkut, 724 F. Supp. 2d at 659-60. "Defendant failed to meet design control requirements of 21 C.F.R. § 820.30" merely alleges noncompliance with FDA regulations. This claim thus is preempted by § 337(a) and will be dismissed.

The claim that "manufacture of the Pipeline [] by the Defendant failed to comply with either specific processes or

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[34]Amended Complaint, Docket Entry No. 17, p. 5 ¶¶ 32-33.

procedures that were approved by the [FDA] or Current Good Manufacturing Practices (CGMPs) themselves" fails for the same reason.[35] To the extent it is an attempt to assert a claim for violation of the FDCA or its implementing regulations, it is impliedly preempted by § 337(a).

Although this language mirrors the language the Fifth Circuit used in Bass, 669 F.3d at 512, to describe a parallel claim, that is all it does. Even when read in conjunction with the state-law claims discussed above, the Amended Complaint does not allege facts in support of this bare conclusory statement, such as what specific processes or procedures approved by the FDA Covidien failed to comply with, or how Covidien failed to meet any CGMP requirements in manufacturing the Pipeline. See Funk, 631 F.3d at 782; Wolicki-Gables, 634 F.3d at 1301-02. Plaintiffs have not identified 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." Rodriguez, 597 F. App'x at 230 (discussing Funk, 631 F.3d at 782); see Kitchen v. Biomet, Inc., Civ. Action No. 13-18-HRW, 2014 WL 694226, at *5 (E.D. Ky. Feb. 21,

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[35] "CGMPs" are set forth in 21 C.F.R. § 820, the Quality System Regulations applicable to all medical devices. See In re Medtronic II, 623 F.3d at 1206; 21 C.F.R. § 820.1(a)(1) ("The requirements in this part govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The requirements in this part are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the [FDCA].").

2014) (dismissing claims where plaintiff referred to a broad category of federal regulations and failed to allege how the device violated those regulations or how that deviation caused her injuries). Therefore, the court concludes that this claim is subject to dismissal.

IV. Conclusions and Order

For the reasons discussed above, Plaintiffs have not stated any claims upon which relief can be granted in their Amended Complaint. Defendant Covidien LP's Motion to Dismiss Plaintiffs' First Amended Complaint (Docket Entry No. 21) is therefore **GRANTED**, and this action will be dismissed with prejudice.

SIGNED at Houston, Texas, on this 25th day of April, 2016.

SIM LAKE
UNITED STATES DISTRICT JUDGE