IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

AMBER BROOKS and JAMIE GALE	)	
	)	
Plaintiffs,	)	**CIVIL ACTION**
	)	
v.	)	**No. 19-2088-KHV**
	)	
MENTOR WORLDWIDE, LLC,	)	
	)	
Defendant.	)	
	)	

MEMORANDUM AND ORDER

On February 14, 2019, Amber Brooks and Jamie Gale filed suit against Mentor Worldwide, LLC. Complaint (Doc. #1). Plaintiffs allege that Mentor manufactured and sold defective silicone breast implants which injured plaintiffs. Plaintiffs sue Mentor under several theories: negligence and negligence per se based on manufacturing defects and a failure to warn (Count 1), strict products liability based on failure to warn (Count 2) and strict products liability based on manufacturing defects (Count 3). This matter is before the Court on Mentor's Rule 12(b)(6) Motion To Dismiss Plaintiffs' Complaint (Doc. #10) filed April 15, 2019.[1] For reasons stated below, the Court sustains Mentor's motion.[2]

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[1] Citing Fed. R. Civ. P. 12(g)(2), plaintiff Brooks asserts that the Court should not consider this motion because three minutes before Mentor filed its motion to dismiss, it filed a motion to sever and a motion to transfer or dismiss Brooks' claims for improper venue. The Court acknowledges this argument but finds that for the purposes of judicial efficiency, these matters are properly raised and should be decided at this stage. AK Steel Corp. v. PAC Operating Ltd. P'ship, No. 15-9260-CM, 2018 WL 4184928, at *3 (D. Kan. Aug. 31, 2018) (considering motion to dismiss even though defendant did not raise arguments in prior motion to dismiss); see Albers v. Bd. of Cty. Comm'rs of Jefferson Cty., Colo., 771 F.3d 697, 704 (10th Cir. 2014) (even if successive motion did not satisfy Rule 12(g)(2) requirements, error harmless because movant could present argument in motion for judgment on pleadings).

[2] In response to Mentor's motion to dismiss, plaintiffs request that if the Court dismisses their claims, dismissal should be without prejudice to provide them an opportunity to

Factual Background

Highly summarized, plaintiffs' complaint alleges the following:

In 1976, Congress passed the Medical Device Amendments ("MDA") to the federal Food Drug and Cosmetic Act ("FDCA"). Under the MDA, certain medical devices are subject to regulation depending on their classification. The FDA eventually classified silicone gel-filled breast implants as Class III devices. Among other requirements, the FDCA required manufacturers of these implants to submit pre-market approval applications ("PMAs") with data showing a reasonable assurance of safety and effectiveness. Although it initially denied pre-market approval, the FDA approved Mentor's PMA on November 17, 2006. The FDA conditioned its approval on Mentor conducting six post-approval studies to further assure the safety of the devices. For a variety of reasons, Mentor did not properly conduct these studies, or report negative test results to the FDA.

On September 11, 2009, Jamie Gale received Mentor silicone gel breast implants. After receiving them, she began to experience health problems, including skin rashes, inflammation, fatigue, brain fog, aching, weight gain, hair loss, gastrointestinal issues, rising blood pressure, food allergies, severe hearing loss and dry eyes. On May 24, 2017, an MRI showed extracapsular silicone around both implants. On July 25, 2017, Gale had the implants surgically removed. After that, some of her symptoms and conditions improved or disappeared, while others remained.

Amber Brooks received Mentor silicone gel breast implants on March 4, 2016. After the surgery, Brooks also began to experience health issues, including muscle and joint pain, fatigue,

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amend. Opposition To Defendant Mentor Worldwide LLC's Rule 12(b)(6) Motion To Dismiss (Doc. #16) at 15. Local Rule 15.1 sets forth specific requirements for amending complaints. Because plaintiffs did not comply with these requirements and do not explain how any purported amendments would relate to the issue of preemption, the Court does not grant plaintiffs leave to amend at this time.

vaginal infections, dry eyes and blurry vision, weight loss, enlarged tonsils, rashes, fevers and chills, insomnia, chest pain, constipation and dizziness. Approximately six months later, she was hospitalized for sepsis and a life-threatening staph infection. On February 17, 2017, Brooks had her implants surgically removed. After that, some of her symptoms and conditions improved or disappeared, while others remained.

Plaintiffs allege that Mentor's breast implants caused their injuries. Plaintiffs sue Mentor under several theories: negligence and negligence per se based on manufacturing defects and failure to warn (Count 1), strict products liability based on failure to warn (Count 2) and strict products liability based on manufacturing defects (Count 3).

Legal Standards

In ruling on a motion to dismiss under Rule 12(b)(6), Fed. R. Civ. P., the Court assumes as true all well-pleaded factual allegations and determines whether they plausibly give rise to an entitlement of relief. Ashcroft v. Iqbal, 556 U.S. 662, 679 (2009). To survive a motion to dismiss, a complaint must contain sufficient factual matter to state a claim which is plausible – and not merely conceivable – on its face. Id. at 679-80; Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007). To determine whether a complaint states a plausible claim for relief, the Court draws on its judicial experience and common sense. Iqbal, 556 U.S. at 679. Plaintiffs make a facially plausible claim when they plead factual content from which the Court can reasonably infer that defendant is liable for the misconduct alleged. Id. at 678. However, plaintiffs must show more than a sheer possibility that defendant has acted unlawfully – it is not enough to plead facts that are "merely consistent with" defendant's liability. Id. (quoting Twombly, 550 U.S. at 557). Where the well-pleaded facts do not permit the Court to infer more than the mere possibility of misconduct, the complaint has alleged – but has not "shown" – that the pleader is entitled to relief.

Id. at 679. The degree of specificity necessary to establish plausibility and fair notice depends on context; what constitutes fair notice under Fed. R. Civ. P. 8(a)(2) depends on the type of case. Robbins v. Okla., 519 F.3d 1242, 1248 (10th Cir. 2008).

The Court need not accept as true those allegations which state only legal conclusions. See Iqbal, 556 U.S. at 678; Hall v. Bellmon, 935 F.2d 1106, 1110 (10th Cir. 1991). Rather, plaintiffs bear the burden of framing their complaint with enough factual matter to suggest that they are entitled to relief; it is not enough to make threadbare recitals of a cause of action accompanied by conclusory statements. Twombly, 550 U.S. at 556. A pleading that offers labels and conclusions, a formulaic recitation of the elements of a cause of action or naked assertions devoid of further factual enhancement will not stand. Iqbal, 556 U.S. at 678.

Analysis

I. Applicable Law

Because this is a diversity case, the Court will apply federal procedural law and the substantive law that the forum state would apply. See Sylvia v. Wisler, No. 13-02534-EFM, 2019 WL 1384296, at *2 (D. Kan. Mar. 27, 2019) (citing Evans v. Orion Ethanol, Inc., No. 09-1245-MLB, 2011 WL 2516929, at *1 (D. Kan. June 23, 2011)); see also Burnham v. Humphrey Hosp. Reit Trust, Inc., 403 F.3d 709, 712 (10th Cir. 2005)). For the purposes of diversity jurisdiction, choice-of-law rules are substantive. Sylvia, 2019 WL 1384296, at *2. Accordingly, the Court will apply Kansas choice-of-law rules for torts. Under these rules, the *lex loci delicti* doctrine requires the Court to apply the law of the state where the wrong occurred. Id. (citing Ling v. Jan's Liquors, 237 Kan. 629, 634 (1985)). Where the wrong occurred is where plaintiff suffered injury. Id. (citing Ling, 237 Kan. at 634).

Mentor asserts that Kansas law should apply to Gale, and that Missouri law should apply to Brooks. Mentor argues that unlike Gale, who resided in Kansas before, during and after the alleged injury, Brooks has been a Missouri resident at all material times. Specifically, although Brooks allegedly received her implants in Kansas, all of her alleged injuries occurred in Missouri. Mentor points to plaintiffs' complaint, which specifies that "soon after" surgery – that is, after she returned home to Missouri - Brooks began experiencing symptoms, and that six months after the surgery - while still living in Missouri - she was hospitalized with sepsis and a staph infection. Complaint (Doc. #1) ¶ 12. According to Mentor, Brooks "is not suing her plastic surgeon and makes no allegation that any injury occurred in Kansas during her implantation surgery." Defendant Mentor Worldwide LLC's Memorandum In Support Of Rule 12(b)(6) Motion to Dismiss Plaintiffs' Complaint (Doc. #11) at 8. Rather, she is suing the manufacturer of the allegedly defective implants, which caused injuries when she returned to Missouri. In response to Mentor's motion to dismiss for failure to state claim, plaintiffs do not argue where Brooks' alleged injury occurred, nor do they mention what state law applies to her claims.

For the purposes of this analysis, and absent argument to the contrary, the Court assumes that Brooks suffered her injuries in Missouri. All of her injuries which the complaint lists, including the physical ailments and infections, occurred after Brooks had returned to Missouri. See Ling, 237 Kan. at 634 (applying Kansas law because injuries occurred in car accident in Kansas even though liquor was sold in Missouri). Accordingly, pursuant to Kansas choice-of-law rules, Missouri law applies to Brooks' claims, and Kansas law applies to Gale's claims.[3]

[3] Because Kansas law applies to Gale's claims, Mentor asserts that the Court should consolidate all of her claims into a single products liability action under the Kansas Product Liability Act ("KPLA"), K.S.A. § 60–3301. Neither Mentor nor plaintiffs explain the significance of "consolidation" for purposes of this motion to dismiss. Specifically, it does not appear that "consolidating" Gale's claims affects the preemption issue. Even if the KPLA "consolidates"

II. Federal Preemption

A. Express Preemption

Mentor asserts that the MDA expressly and impliedly preempts plaintiffs' state tort claims. The MDA contains an express preemption provision, which states in relevant part as follows:

> [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).

In Riegal v. Medtronic, Inc., 552 U.S. 312 (2008), the Supreme Court established a two-part test for analyzing the express preemption provision under the MDA. First, the Court decides whether the FDA has established "requirements" specific to the device at issue.[4] Riegal, 522 U.S. at 321-22. Second, the Court determines whether the state-law claim would impose any requirement that "relates to the safety or effectiveness of the device" and is "different from, or in addition to," the federal requirement. Id. at 323. If it does so, the MDA expressly preempts it. Id.

However, the MDA "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations." Id. at 330. This means that while a state law cannot

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Gale's claims, the Court may assess her individual theories of recovery under the KPLA. See Mattos v. Eli Lilly & Co., No. 12-1014-JWL, 2012 WL 1893551, at *3 (D. Kan. May 23, 2012) (Court individually considered two bases for liability under KPLA: failure to warn and design defect); see also Messer v. Amway Corp., 210 F. Supp. 2d 1217, 1236 (D. Kan. 2002), aff'd, 106 F. App'x 678 (10th Cir. 2004) (Court individually assessed design defect and warning claims that plaintiffs brought under negligence and strict product liability theories). Therefore it is unnecessary to "consolidate" Gale's claims in order to determine whether the MDA preempts them.

[4] The parties do not dispute that the MDA applies to Mentor's breast implants. See Complaint (Doc. #1) ¶¶ 27-29. The MDA classifies breast implants as Class III medical devices and imposes regulations on such devices. 21 U.S.C. § 515e; 21 C.F.R. § 878.3530.

impose different or additional requirements than those under federal law, it can impose "parallel" requirements. Id. To determine whether a state claim is parallel, the Court asks whether defendant's conduct allegedly violated state law without violating federal law. See McMullen v. Medtronic, Inc., 421 F.3d 482, 489 (7th Cir. 2005) (citing Bates v. Dow Agrosciences LLC, 544 U.S. 431, 454 (2005)); see also Wolicki-Gables v. Arrow Int'l, Inc., 634 F.3d 1296, 1300 (11th Cir. 2011); In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig., 623 F.3d 1200, 1205 (8th Cir. 2010); Caplinger v. Medtronic, Inc., 921 F. Supp. 2d 1206, 1213 (W.D. Okla. 2013), aff'd, 784 F.3d 1335 (10th Cir. 2015). If defendant's conduct violates state law but not federal law, the state law claim is not parallel: it imposes more requirements than federal law. See Caplinger v. Medtronic, Inc., 784 F.3d 1335, 1341 (10th Cir. 2015) (MDA expressly preempts state law design defect and breach of warranty claims because no parallel federal requirement); see also McMullen, 421 F.3d at 489; see also Wolicki-Gables, 634 F.3d at 1300 (MDA expressly preempts state claim because defendant could be liable despite complying with FDA regulations).

B. Implied Preemption

Mentor also argues that the MDA impliedly preempts plaintiffs' state law claims. Under the MDA, all actions to enforce FDA requirements concerning medical devices "shall be by and in the name of the United States." 21 U.S.C. § 337(a). In Buckman Co. v. Plaintiffs' Leg. Comm., 531 U.S. 341 (2001), the Supreme Court held that this provision bars private litigants from seeking to enforce requirements under the FDCA, including the MDA. 531 U.S. at 349 n.4. That is, the MDA impliedly preempts a cause of action that does not arise under a parallel state law, but under the federal requirements themselves. To determine whether plaintiff is attempting to enforce federal requirements, the Court determines whether liability would exist independently under state law, regardless of the FDCA or MDA. See id. at 353; see also Pontious v. Medtronic, Inc., No.

11-4069-CM, 2011 WL 6091749, at *2 (D. Kan. Dec. 7, 2011) (MDA impliedly preempts claim under Kansas Consumer Protection Act ("KCPA") because it is based on failure to report to FDA information required by federal regulations).

C. Preemption Applied To Plaintiffs' Claims

While their specific allegations are somewhat difficult to follow, plaintiffs assert two overarching theories of recovery. First, they bring failure to warn claims under theories of negligence, negligence per se[5] and strict products liability. Second, plaintiffs assert manufacturing defect claims under theories of negligence, negligence per se[6] and strict products liability. The Court finds that the MDA either expressly or impliedly preempts all of these claims.

(i) Failure to Warn Theories

Plaintiffs argue that Mentor's duty to warn extended to three different parties: (1) patients, (2) the FDA and (3) physicians.

Plaintiffs first argue that Mentor had a duty to warn patients of health risks associated with its implants. The Court can easily dispose of this claim. Neither plaintiff can sue for failure to warn patients because Kansas and Missouri have adopted the learned intermediary doctrine, which holds that a manufacturer's duty to warn extends only to prescribing physicians, and not to patients.

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[5] Plaintiffs cannot recover under the theory of negligence per se based on violations of the FDCA. In Kansas, negligence per se "is limited to violations of a statute where the legislature intended to create an individual right of action for injury arising out of a statutory violation." Vanderwerf v. SmithKlineBeecham Corp., 414 F. Supp. 2d 1023, 1028 (D. Kan. 2006). The same is true in Missouri. Weinbach v. Starwood Hotels & Resorts Worldwide, Inc., No. 4:16CV783JCH, 2017 WL 3621459, at *5 (E.D. Mo. Aug. 23, 2017). Here, "Congress did not intend a private federal remedy for violations of the FDCA." Vanderwerf, 414 F. Supp. 2d. at 1027. Therefore, a claim for negligence per se under Kansas law cannot be based on an FDCA violation. Accordingly, the Court dismisses plaintiffs' theories of negligence per se that are based on FDCA violations.

[6] For reasons stated in footnote 5, plaintiffs cannot recover under the theory of negligence per se based on FDCA violations.

See Samarah, 70 F. Supp. 2d at 1204 (citing Humes v. Clinton, 246 Kan. 590 (1999)); see also Mitchell v. Covidien Plc, No. 14-0636-CV-W-FJG, 2015 WL 12804270, at *5 (W.D. Mo. Sept. 28, 2015). Even if state law permitted plaintiffs to bring a claim for failure to warn patients, the MDA would expressly preempt that claim because plaintiffs have not identified any such requirement under federal law. Accordingly, a state law mandating this warning would be adding to the federal requirements, which the MDA expressly preempts. See Caplinger, 784 F.3d at 1341 (MDA expressly preempts state law design defect and breach of warranty claims because no parallel federal requirement).

Plaintiffs next argue that Mentor had a duty to warn the FDA. Under plaintiffs' complaint, this allegation breaks down into two separate theories: (1) Mentor had a duty to properly conduct the FDA-mandated testing and (2) Mentor had a duty to report negative test results to the FDA in accordance with federal regulations. Plaintiffs advance various theories about how Mentor's studies were flawed. The MDA impliedly preempts these claims. Plaintiffs have not identified a state law that required Mentor to conduct follow-up studies in accordance with FDA regulations, nor have plaintiffs identified a state law that required Mentor to report findings to the FDA. Therefore, plaintiffs are not enforcing state law, but attempting to enforce FDA regulations. The MDA impliedly preempts this type of action. See Pontious, 2011 WL 6091749, at *2 (MDA impliedly preempts KCPA claim based on failure to report to FDA information required by federal regulations).

Finally, plaintiffs argue that Mentor had a duty to warn physicians about health risks associated with its implants, both *directly* (by updating its labels) and *indirectly* (by reporting to the FDA). First, plaintiffs argue that after receiving pre-market approval, Mentor had a duty to update its warning labels to include defects which it discovered during post-approval studies. Even

if state law imposed such a requirement, plaintiffs can only avoid express preemption by identifying a parallel federal law that imposed the same requirement. See Caplinger, 784 F.3d at 1341 (MDA expressly preempts state law design defect and breach of warranty claims because no parallel federal requirement). Plaintiffs cannot do so, because it does not exist. In fact, as the Tenth Circuit has explained, "once the FDA approves a device's label as part of the premarket approval process . . ., the manufacturer usually may not alter the label's warnings without prior agency approval." Id. (citing 21 U.S.C. § 360e(d)). Therefore, any state law claim that would have required Mentor to make label updates would necessarily impose a requirement beyond those imposed by federal law. Accordingly, the MDA expressly preempts this theory of recovery. See id. (MDA expressly preempts state tort duty that requires defendant to "revise label that federal regulation precludes it from revising").

Similarly, the MDA prohibits plaintiffs from asserting that Mentor had a duty to directly warn physicians by revising its product labeling through the Changes Being Effected ("CBE") procedure. Plaintiffs argue that after receiving pre-market approval, Mentor could file a CBE that would allow it to update the labeling without FDA approval. Complaint (Doc. #1) ¶ 110. Plaintiffs' use of the word "could" is worth noting. The CBE procedure is permissive, not mandatory. 21 C.F.R § 814.39; McMullen, 421 F.3d at 489 (21 C.F.R § 814.39 permits but does not require manufacturer to revise labeling); In re Medtronic, Inc., 623 F.3d at 1205 (same). Because federal law did not require Mentor to update its labeling, the MDA expressly preempts any state law that would effectively require it to do so. McMullen, 421 F.3d at 489; In re Medtronic, Inc., 623 F.3d at 1205 ("[e]ven if federal law allowed [defendant] to provide additional warnings, . . . any state law imposing an additional requirement is preempted" under MDA).

Second, plaintiffs suggest that Mentor had a duty to indirectly warn physicians by reporting negative study results to the FDA. Specifically, plaintiffs argue that had Mentor reported adverse events to the FDA pursuant to 21 C.F.R. § 803.50, that information would have been available to the public, "including physicians," and that those physicians "may" have used the federal database to obtain safety information on these specific implants. Complaint (Doc. #1) ¶ 102. Plaintiffs conclude that "it would have effectively warned physicians of those adverse events both directly and through discussion of those events that would have followed in the literature and at meetings." Complaint (Doc. #1) ¶ 113.

These allegations require the Court to first assume that the FDA would have included the results in a publicly-accessible adverse-event database, which it is not required to do. 21 C.F.R. § 803.9(a); see Connelly v. St. Jude Med., Inc., No. 17-2006-EJD, 2018 WL 732734, at *1 n.1 (N.D. Cal. Feb. 6, 2018) (FDA "may disclose" adverse-event reports in database, but is not required to do so (quoting 21 C.F.R. § 803.9(a))); Pinsonneault v. St. Jude Med., Inc., 953 F. Supp. 2d 1006, 1016 (D. Minn. 2013) (adverse-event reports not automatically made public and decision is within FDA discretion). The allegations would also require the Court to assume that plaintiffs' physicians would have accessed that information and relied on it to alter their treatment decisions with plaintiffs. These allegations are far too speculative to meet the "plausibility" standard of Twombly and Iqbal. See Iqbal, 556 U.S. at 679-80; see also Twombly, 550 U.S. at 555 (to survive motion to dismiss, complaint must contain sufficient factual matter to state claim which is plausible – and not merely conceivable – on its face).

Even if these allegations were not speculative, the MDA would impliedly preempt this theory of recovery. Plaintiffs have not identified any state law that required Mentor to report adverse events to the FDA. Accordingly, like their other claims relating to FDA reporting,

plaintiffs are not seeking to enforce state law, but are attempting to enforce federal requirements. See Pontious, 2011 WL 6091749, at *2 (MDA impliedly preempts KCPA claim based on failure to report information to FDA as required by federal regulations, not under state law). The MDA impliedly preempts this theory of recovery. Therefore, the Court dismisses plaintiffs' claims of failure to warn.

(ii) Manufacturing Defect Theories

Plaintiffs assert manufacturing defect claims under the theories of negligence, negligence per se and strict products liability. Under the negligence theory, the complaint lists plaintiffs' allegations as follows: (1) Mentor's implants did not comply with FDA specifications, (2) Mentor used materials that the FDA did not approve, (3) Mentor failed to follow good manufacturing practices, (4) Mentor failed to "properly meet the applicable standard of care by not complying with applicable federal regulations and failing to adhere" to FDA manufacturing protocols, (5) Mentor carelessly and negligently sold and distributed implants in violation of applicable federal law, (6) Mentor's implants negligently included materials that "could not stand up to normal usage and/or . . . differed from those which were commercially reasonable," (7) Mentor failed to exercise reasonable care in inspecting and testing the implants and (8) Mentor failed to exercise reasonable care "in its manufacturing, quality control and quality assurance processes." Complaint (Doc. #1) ¶ 120.

The MDA impliedly preempts each allegation that relies on violations of federal law. To survive implied preemption, a claim must be independently based on state law. Buckman, 531 U.S. at 353. Any claim that purports to enforce federal law must necessarily fail. Id. Here, this includes allegations 1, 2, 4 and 5: implants not complying with FDA specifications, using material that the FDA did not approve, failing to meet the standard of care by not complying with FDA

protocols and distributing implants in violation of applicable federal law. Complaint (Doc. #1) ¶ 120. Each of these claims is based not on state law, but exclusively on violations of federal law. The claims would not exist without the FDCA, including the MDA. See id. Accordingly, the MDA impliedly preempts these claims. See Pontious, 2011 WL 6091749, at *2 (MDA impliedly preempts KCPA claim based on failure to report to FDA information required by federal regulations).

Plaintiffs apparently argue that these claims are based on state law, and that federal regulations merely provide the appropriate standard of care. In other words, to conjure up a parallel state claim that survives implied preemption, plaintiffs argue that Mentor violated state law *because* it violated federal law. This is a roundabout way of asserting a negligence per se claim based on a violation of the FDCA. As explained, plaintiffs cannot bring such a claim under Kansas law.[7]

This analysis leaves the following allegations as potential candidates for plaintiffs' independent state-law claim: Mentor failed to follow good manufacturing practices during the manufacture of its implants (claim 3), Mentor's implants negligently included materials that "could not stand up to normal usage and/or which differed from those which were commercially reasonable" (claim 6), Mentor failed to exercise reasonable care in inspecting and testing of the product (claim 7) and Mentor failed to exercise reasonable care "in its manufacturing, quality control and quality assurance processes" (claim 8). Complaint (Doc. #1) ¶ 120. These conclusory statements are insufficient to satisfy Twombly and Iqbal. See Iqbal, 556 U.S. at 678; see also Twombly, 550 U.S. at 556 (pleading that offers labels and conclusions, formulaic recitation of

[7] For reasons stated in footnote 5, plaintiffs cannot recover under the theory of negligence per se based on FDCA violations.

elements of cause of action or naked assertions devoid of further factual enhancement will not stand).

Plaintiffs' manufacturing defect claims under the strict products liability theory fail for the same reasons. Under this theory, plaintiffs continue to allege that Mentor violated state law *because* it violated federal law. Plaintiffs allege that Mentor's manufacturing process "did not comply with the FDA's Quality System Regulations and design control requirements." Complaint (Doc. #1) ¶ 192. Specifically, plaintiffs assert that various defects, including silicone leakage due to a porous implant shell, do not comply with FDA specifications, and "therefore" constitute manufacturing defects. Id. Here, plaintiffs are again attempting to enforce federal law. The MDA impliedly preempts these theories of recovery. See Pontious, 2011 WL 6091749, at *2. Plaintiffs' remaining claims do not sufficiently establish independent state-law claims because they do not satisfy Twombly and Iqbal. Plaintiffs simply allege that Mentor violated state law "by placing [the implants] into the stream of commerce in a defective and unreasonable dangerous condition." Complaint (Doc. #1) ¶ 193. These are conclusory allegations and are insufficient to establish a claim under state law. Therefore, the Court dismisses plaintiffs' manufacturing defect claims.

IT IS THEREFORE ORDERED that defendant's Rule 12(b)(6) Motion To Dismiss Plaintiffs' Complaint (Doc. #10) filed April 15, 2019 is **SUSTAINED**.

IT IS FURTHER ORDERED that defendant's Motion To Sever Claims And Motion To Dismiss Or Transfer Plaintiff Brooks' Claims For Improper Venue (Doc. #8) filed April 15, 2019 is **DISMISSED** as moot.

Dated this 23rd day of September, 2019 at Kansas City, Kansas.

s/ Kathryn H. Vratil
KATHRYN H. VRATIL
United States District Judge