PUBLISH

UNITED STATES COURT OF APPEALS

FOR THE TENTH CIRCUIT

AMBER BROOKS; JAMIE GALE, Plaintiffs - Appellants, v. MENTOR WORLDWIDE LLC, Defendant - Appellee.	No. 19-3240

Appeal from the United States District Court for the District of Kansas (D.C. No. 2:19-CV-02088-KHV-TJJ)

(Filed Jan. 26, 2021)

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Before **HARTZ**, **PHILLIPS**, and **CARSON**, Circuit Judges.

CARSON, Circuit Judge.

As is its prerogative, Congress heavily regulates the production and use of medical devices. In doing so, Congress has introduced federal law to an area state law, alone, once governed. That introduction of federal law has left, by both express and implied preemption, only a narrow gap within which a plaintiff can plead a tort claim arising from the failure of a medical device. Successful pleading requires navigating a legal quagmire that has consumed unwary legal professionals for more than forty years. Today we again wade into that quagmire.

Plaintiffs Amber Brooks and Jamie Gale brought tort claims based on injuries they sustained when their breast implants began deteriorating. The district court found that they failed to state a claim upon which relief could be granted and dismissed their Complaint with prejudice. Plaintiffs ask us to reverse the district court's dismissal. We agree with the district court that federal law preempts some of Plaintiffs' claims and that Plaintiffs insufficiently pleaded the rest. Therefore, exercising jurisdiction under 28 U.S.C. § 1291, we affirm.

I.

In 1976, Congress passed the Medical Device Amendments (MDA) to the Federal Food, Drug, and

Cosmetics Act (FDCA). Riegel v. Medtronic, Inc., 552 U.S. 312, 316 (2008). Through that legislation, Congress standardized and regulated the safety and effectiveness of medical devices. Id. at 315–16. Class III devices—those subject to the strictest controls—must go through a premarket approval (PMA) process, administered by the Food and Drug Administration (FDA). Id. at 317. The PMA process begins with a rigorous application, involving extensive research and testing and usually requiring a multi-volume submission. Id. The approval process may last years, consuming over 1,200 hours of agency review time on average, and often requires that the manufacturer continue to study and report information about the device during and after approval. Id. at 317–18. The FDA may refer the application to a panel of experts or require further data from the manufacturer. Id. Only upon "reasonable assurance" of the device's safety and effectiveness, weighing any probable benefit to health against any probable risk of injury or illness, may the FDA approve a Class III device. Id. at 318. Part of every PMA review involves warnings and labeling. Id. And the FDA may only approve labels and warnings if it determines they are not false or misleading. Id. The FDA may condition premarket approval on adherence to performance standards, restrictions on sale or distribution, or further research. See id. at 319. After approval, a manufacturer may not change "design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." Id. Furthermore, the FDA may subject approved devices to ongoing reporting obligations and can revoke approval

based on new or existing data and must do so when "it determines that a device is unsafe or ineffective." Id. at 319–20.

Because this case comes to us at the motion-to-dismiss phase, we take the facts from the Complaint. In 2003, Defendant Mentor Worldwide LLC submitted its application for premarket approval of the "MemoryGel" silicone breast implant. Almost three years later, the FDA granted approval subject to Defendant conducting a range of post-approval studies. Defendant failed to properly conduct these studies and to report their results in a variety of ways. These failures included low follow-up rates and high drop-out rates for the studies, failure to collect data, failure to report data, reporting inconsistent data, lack of adequate sample sizes in studies, inadequate summarization of findings and results, failure to update labeling in accordance with findings, and omitting information about study methodology. Defendant also failed to fulfill reporting obligations that were not tied to specific post-approval studies and, while the PMA application was pending, whistleblowers alleged that Defendant had been fraudulent in its reporting.

In the years before the PMA process, Defendant manufactured and used MemoryGel implants for clinical testing, under an "investigational device exemption," granted by the FDA. During this period, whistleblower complaints led to a federal investigation of Defendant's Texas manufacturing facility. The investigation resulted in a consent decree under which Defendant agreed to remedy specific deficiencies and

conduct future operations in accordance with federal law and the FDA's "quality system regulation" for manufacturing standards.

After Defendant completed the PMA process, Plaintiffs received MemoryGel implants. Both soon felt negative effects. Gale developed various symptoms and health problems. Brooks experienced even more symptoms and problems. Physicians eventually removed both Plaintiffs' implants. Gale's implants had both leaked. Brooks's implants apparently leaked as well. Upon removal of the implants, some of Plaintiffs' symptoms went away, some diminished in severity, and others remained.

Plaintiffs filed their Complaint in the United States District Court for the District of Kansas. Defendant moved to dismiss the Complaint for failure to state a claim. The district court dismissed the case with prejudice. See Fed. R. Civ. P. 41(b). The district court found that federal law preempted all of Plaintiffs' claims and, in any event, Plaintiffs failed to sufficiently plead their claims. The district court also determined that Missouri law, rather than Kansas law, applied to Brooks's claims and denied Plaintiffs' request for leave to amend their Complaint.

II.

This case presents two discrete issues. First, whether the district court erred in granting Defendant's motion to dismiss for failure to state a claim. We review this decision de novo, Wasatch Equality v. Alta

Ski Lifts Co., 820 F.3d 381, 386 (10th Cir. 2016), including the district court's rulings on preemption, Cerveny v. Aventis, Inc., 855 F.3d 1091, 1096 (10th Cir. 2017). And second, whether the district court erred in declining to grant Plaintiffs leave to amend their Complaint. We review this decision for an abuse of discretion. Warnick v. Cooley, 895 F.3d 746, 754 (10th Cir. 2018).

III.

In their Complaint, Plaintiffs sought to plead claims for failure to warn and manufacturing defect, sounding in ordinary negligence, negligence per se, and strict liability. For the reasons below, we conclude that federal law preempts their negligence per se claims and their failure-to-warn claims that sound in ordinary negligence and strict liability. We further hold Plaintiffs insufficiently pleaded their ordinary negligence and strict liability claims for manufacturing defect.

A.

The FDCA and MDA contain two preemption provisions relevant here.[1] The first provides for express preemption of certain state laws:

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[1] Plaintiffs assert that the district court erred in finding that Missouri law, rather than Kansas law, governs Brooks's tort claims. When a federal court exercises subject-matter jurisdiction based on 28 U.S.C. § 1332, it applies the substantive law of the state in which it sits, including that state's choice-of-law principles. Pepsi-Cola Bottling Co. of Pittsburg, Inc., v. PepsiCo, Inc.,

> (a) Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
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> (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. The Supreme Court established a two-part test to evaluate a claim for express preemption. Riegel v. Medtronic, Inc., 552 U.S. 312, 321–22

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431 F.3d 1241, 1255 (10th Cir. 2005). Thus, the United States District Court for the District of Kansas applies Kansas's choice-of-law principles. Where an act or omission in one state leads to an injury in another state, Kansas applies the law of the state where the injury occurred. Ling v. Jan's Liquors, 703 P.2d 731, 735 (Kan. 1985) (rejecting the "most-significant-relationship" test and holding that Kansas law controlled where an event in Missouri led to injury in Kansas). The district court determined that, although Brooks's operation occurred in Kansas, she alleged that the resulting injuries arose in Missouri. Therefore, the district court said, under Kansas's choice-of-law rules Missouri law applies to Brooks's claims.

Although Plaintiffs urge this as a potential error, we need not decide which state's law applies because either would reach the same result below regardless. We do not couch the discussion in this section of our opinion in terms of either state's law, and our analysis does not depend on which state's law applies. Rather, we look to Plaintiffs' Complaint and conclude that federal law preempts their claims as stated.

(2008). First, we must ask "whether the federal government has established requirements applicable to" the implants. Id. at 321. The parties do not dispute that the MDA applies to the implants.[2] Second, we must determine whether the state-law claims impose a requirement that relates to the safety or effectiveness of the implant and differs from or adds to the federal requirements. Id. at 321–22. Federal law preempts a tort claim "unless the federal requirements impose duties that are at least as broad as those" imposed by the state law. Caplinger v. Medtronic, Inc., 784 F.3d 1335, 1340 (10th Cir. 2015).

> The second preemption statute provides that
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> > Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. . . .

21 U.S.C. § 337. Interpreting and applying this requirement is easier than the first. "Congress intended that the MDA be enforced exclusively by the Federal Government." Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 352 (2001). Thus, the FDCA preempts "any state tort claim that exists 'solely by virtue' of an FDCA violation." Caplinger, 784 F.3d at 1339 (quoting Buckman, 531 U.S. at 353). Along with express preemption, this implied preemption provision

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[2] In any event, these implants have endured the premarket approval process, which subjects them to federal requirements. See Caplinger v. Medtronic, Inc., 784 F.3d 1335, 1340 (10th Cir. 2015).

leaves only a narrow gap of possible state tort claims. Any such claim must be *predicated on* conduct that violates the FDCA but may not be brought *solely because* that conduct violates the FDCA—the conduct must also violate a parallel state-law requirement.

Put differently, to survive preemption, a plaintiff must plead conduct that (1) violates the FDCA (because state law may not impose additional or different duties) and (2) would be actionable under state law independently of the FDCA (because a plaintiff may not seek to enforce the FDCA). See In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig., 623 F.3d 1200, 1204 (8th Cir. 2010) (internal citation omitted). And when the pleader misses the gap—that is, when federal law preempts a claim—the court should dismiss that claim. See Caplinger, 784 F.3d at 1337, 1347.

1.

We first address Plaintiffs' negligence per se theory. Insofar as the Complaint alleged failure-to-warn or manufacturing-defect claims based on negligence per se, federal law preempts those claims. Congress and the courts have clearly defined the narrow gap: a plaintiff may sue under a state-law cause of action *for* conduct that violates the MDA but not *because* that conduct violates the MDA. When we ask whether liability under negligence per se exists independently under state law, regardless of the FDCA or MDA, we must answer "no." See Buckman, 531 U.S. at 353. Plaintiffs' negligence per se theory relies on a federal

requirement to supply the duty of care and looks to a violation of the requirement as the breach of that duty. See id. Any negligence per se action premised on an MDA violation necessarily seeks to enforce the MDA rather than a parallel state-law duty. And only the United States may enforce the MDA. 21 U.S.C. § 337(a); id. at 349 n.4.

Furthermore, negligence per se premised on a violation of the MDA lacks viability under the laws of either Kansas or Missouri. Kansas law limits negligence per se to violations of a statute for which the legislature intended to create a private cause of action. Cullip ex rel. Pitts v. Domann ex rel. Domann, 972 P.2d 776, 782 (Kan. 1999); Rhoten v. Dickson, 223 P.3d 786, 803 (Kan. 2010). Similarly, Missouri law limits negligence per se to violations of a statute where the legislature intended to replace the ordinary negligence standard of care. Lowdermilk v. Vescovo Bldg. & Realty Co., Inc., 91 S.W.3d 617, 629 (Mo. Ct. App. 2002); J.J.'s Bar & Grill, Inc. v. Time Warner Cable Midwest, LLC, 539 S.W.3d 849, 869 (Mo. Ct. App. 2017). The MDA's text tells us that Congress created no private cause of action in the MDA, and Buckman tells us that Congress did not intend the MDA to supplant state-law duties of care. 21 U.S.C. § 337(a); 531 U.S. at 352–53. For these reasons, we conclude that the district court properly dismissed Plaintiffs' negligence per se theory.

2.

This leaves ordinary negligence and strict liability for failure to warn. The district court found, and we agree, that Plaintiffs sought to allege that Defendant breached a duty to warn (1) patients, (2) physicians, and (3) the FDA about the implants' health risks. Like the district court, we conclude that federal law preempts these claims.

First, Plaintiffs identify no federal requirement that a Class III-device manufacturer provide a warning directly to a patient. Plaintiffs' briefing addresses preemption in vague, general, and largely historical terms but never nails down a specific argument about any of their claims. We are under no obligation to "search[ ] out theories and authorities [Plaintiffs] have not presented for [themselves]." Caplinger, 784 F.3d at 1342. And we have expressed particular hesitation to do so in this area of law where "there exists so much risk of going astray." Id. Because Plaintiffs have not offered—and we will not seek out—a federal requirement to warn patients, any state-law duty to do so adds to the federal scheme as it is before us. Id. at 1341. Federal law expressly preempts any such addition. Id.

Next, Plaintiffs alleged that Defendant had a duty to warn physicians directly by updating its warning labels. But just as above, Plaintiffs fail to identify a federal requirement that Defendant do so. In fact, a Class III device manufacturer ordinarily *may not* change or update its warning labels and package inserts without prior FDA approval. 21 U.S.C. § 360e(d); Caplinger, 784

F.3d at 1341. Defendant could have changed its labeling without FDA approval by a permissive mechanism, but that mechanism is not mandatory. 21 C.F.R. § 814.39. It allows, but does not require, a change. McMullen v. Medtronic, Inc., 421 F.3d 482, 489 (7th Cir. 2005). And absent a federal requirement that they do so, federal law expressly preempts any state-law duty requiring a manufacturer to update its labeling. In re Medtronic, 623 F.3d at 1205; Caplinger, 784 F.3d at 1341.

Finally, Plaintiffs alleged that Defendant violated its duty to warn the FDA. They claim that Defendant did not properly conduct post-approval, FDA-mandated testing and report negative results. Plaintiffs also theorize that this reporting would have indirectly warned physicians of the implants' dangers. But Plaintiffs have not identified a state-law duty to comply with FDA-imposed post-approval requirements such as testing and reporting. Buckman made clear that only the federal government may enforce reporting requirements and investigate and respond to suspected fraud. 531 F.3d at 348–49. Similarly, the government retains the exclusive right to enforce post-approval requirements for continued testing, including the right to revoke approval for noncompliance. See id.; 21 C.F.R. § 814.82(c). Federal law thus impliedly preempts Plaintiffs' claims based on alleged failures to properly conduct post-approval testing and reporting as attempts to enforce the MDA. 21 U.S.C. § 337(a); Buckman, 531 U.S. at 348–49; Caplinger, 784 F.3d at 1339.

As a result, the district court properly dismissed Plaintiffs' failure-to-warn claims.

B.

We turn now to the remaining manufacturing-defect claims. We use the Iqbal/Twombly standard to determine whether Plaintiffs have stated a plausible claim. Brown v. Montoya, 662 F.3d 1152, 1162–63 (10th Cir. 2011). In applying this standard, we take Plaintiffs' well-pleaded facts as true, view them in the light most favorable to Plaintiffs, and draw all reasonable inferences from the facts in favor of Plaintiffs. Id. at 1162. A plausible claim includes facts from which we may reasonably infer Defendant's liability. Id. at 1163. Plaintiffs must nudge the claim across the line from conceivable or speculative to plausible. Id. Allegations that are "'merely consistent with' a defendant's liability" stop short of that line. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 557 (2007)). Labels, conclusions, formulaic recitations of elements, and naked assertions will not suffice. Id. An allegation is conclusory where it states an inference without stating underlying facts or is devoid of any factual enhancement. Kellum v. Mares, 657 Fed. App'x 763, 770 (10th Cir. 2016) (unpublished) (citing Black's Law Dictionary (10th ed. 2014)).[3] Conclusory allegations are "not entitled to the assumption of

[3] See also Camasta v. Jos. A. Bank Clothiers, Inc., 761 F.3d 732, 740 (7th Cir. 2014); McCauley v. City of Chicago, 671 F.3d 611, 622–23 (7th Cir. 2011) (Hamilton, J., dissenting in part).

truth." Khalik v. United Air Lines, 671 F.3d 1188, 1193 (10th Cir. 2012). In fact, we disregard conclusory statements and look to the remaining factual allegations to see whether Plaintiffs have stated a plausible claim. Waller v. City & Cnty. of Denver, 932 F.3d 1277, 1282 (10th Cir. 2019). We must draw on our experience and common sense in evaluating the plausibility of a claim. Iqbal, 556 U.S. at 679. The degree of specificity needed to establish plausibility and provide fair notice depends on the context and the type of case. Id.; Robbins v. Oklahoma, 519 F.3d 1242, 1248 (10th Cir. 2008).

Plaintiffs fail to allege facts reflecting any negligence in the manufacturing of the implant or that the implant was, in fact, defective. Although the Complaint spins a wide-reaching story of noncompliance with FDA regulations and requirements, bad conduct, whistle-blower complaints, misrepresented data, and other horrors, it does little to support this highly conclusory story with specific facts. Bald accusations such as "defendant violated the law," "defendant failed to exercise reasonable care," and the like will not support a claim for relief. Iqbal, 556 U.S. at 679 ("While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations."). Plaintiffs do allege largely historical facts that almost entirely deal with indiscretions in conducting studies and reporting results. But these factual allegations do not touch on any specific flaw in the manufacturing process relevant to Plaintiffs' own implants. Nor does Plaintiffs' 38-page, 201-paragraph Complaint describe a particular flaw in the specific implants they received.

In the Complaint, Plaintiffs conclude that the implants "differed from the specifications agreed to by the FDA" and "used materials and components which differed from those approved by the FDA," without alleging any supporting facts. They also conclude that Defendant (1) "fail[ed] to follow good manufacturing practices," (2) had "not complied with applicable federal regulations" and "fail[ed] to adhere to manufacturing protocols approved by the FDA," (3) "carelessly and negligently s[old] and distribut[ed]" the implants "in violation of" federal law, "negligently incorporate[ed] components and/or materials" that were not "commercially reasonable" and "could not stand up to normal usage," and "fail[ed] to exercise reasonable care in inspecting and testing . . . manufacturing, quality control and quality assurance processes." Plaintiffs did not plead factual allegations to support these or any of their other conclusions, and thus they cannot sustain a claim for relief.

Given the lack of factual allegations relevant to their manufacturing-defect claims and the conclusory nature of the Complaint regarding those claims, we agree with the district court that Plaintiffs have not adequately pleaded these claims. The district court, therefore, properly dismissed the manufacturing-defect claims.

IV.

Finally, Plaintiffs argue that the district court erred in denying their request "that the dismissal be

entered without prejudice to provide them with an opportunity to amend." Plaintiffs included this one-sentence request at the end of their response to Defendant's motion to dismiss. But Plaintiffs did not comply with District of Kansas Local Rule 15.1 (requiring that the proposed pleading be attached to a motion for leave to amend) and did not explain how any amendment would relate to the preemption issue. So the district court declined to grant leave to amend and granted Defendant's motion to dismiss with prejudice. To find an abuse of discretion, we must conclude that this decision was "arbitrary, capricious, whimsical, or manifestly unreasonable." Bylin v. Billings, 568 F.3d 1224, 1229 (10th Cir. 2009) (quoting Orr v. City of Albuquerque, 417 F.3d 1144, 1153 (10th Cir. 2005)).

Federal Rule of Civil Procedure 15(a)(1) provides that a plaintiff may amend its complaint as a matter of right within 21 days after a defendant serves a Rule 12(b) motion. By this mechanism, a plaintiff can seek to cure any defect identified in the motion. But Plaintiffs declined to take this course. After expiration of the time to amend as a matter of right, Plaintiffs could have formally moved for leave to amend in compliance with the applicable Federal Rules and Local Rule 15.1. But they did not. They chose, instead, to make a one-sentence request in their response to the motion to dismiss. Plaintiffs argue that such bare requests "serve an important function, in that a party is able to make a general request without being placed in a difficult situation of diluting their primary position." Opening Br. 37. Here, Plaintiffs apparently took the "primary

position" that their original Complaint could survive the motion to dismiss.

We have long held that bare requests for leave to amend do not rise to the status of a motion and do not put the issue before the district court. Glenn v. First Nat. Bank in Grand Junction, 868 F.2d 368, 370–71 (10th Cir. 1989) ("A naked request for leave to amend asked for as alternative relief when a party has the unexercised right to amend is not sufficient."). Such "shot[s] in the dark" do not request "an order contemplated under the rules," do not state any particular grounds for the request, and lack basis. Id. at 370. "A court need not grant leave to amend when a party fails to file a formal motion." Calderon v. Kan. Dep't of Soc. & Rehab. Servs., 181 F.3d 1180, 1186 (10th Cir. 1999) (also recognizing the importance of compliance with local rules). Furthermore, any request for a court order, such as a request for leave to amend, must state with particularity the grounds for the order. Id. (citing Fed. R. Civ. P. 7(b)(1)). Because we do not recognize Plaintiffs' single sentence as a cognizable motion, the district court did not abuse its discretion in denying that request. See Glenn, 868 F.2d at 371; Calderon, 181 F.3d at 1186–87 ("a request for leave to amend must give adequate notice to the district court and to the opposing party of the basis of the proposed amendment before the court is required to recognize that a motion for leave to amend is before it"); see also Warnick, 895 F.3d at 755 (finding no abuse of discretion where a plaintiff merely suggested she should be allowed to amend and violated D. Kan. Local Rule 15.1).

Our precedent also requires that to amend a pleading after the dismissal of a case, a party must first move to reopen the case under Federal Rule of Civil Procedure 59(e) or 60(b) and then move for leave to amend under Rule 15 in accordance with the Rule 7 standard. Calderon, 181 F.3d at 1185. But Plaintiffs did not take this route either. They argue that this "process places [a] significant burden on the plaintiffs" and "creates a due process issue." Opening Br. 37. This underdeveloped argument constitutes a perfunctory invitation to explore a possible constitutional issue embedded in the Federal Rules of Civil Procedure. Because Plaintiffs did not raise it before the district court and did not adequately develop it on appeal, we will not accept that invitation. See Bronson v. Swensen, 500 F.3d 1099, 1104 (10th Cir. 2007). Plaintiffs made a strategic choice to stand by their "primary position" and took none of the available avenues to amend their Complaint. We will not protect them from their own inaction. See Glenn, 868 F.2d at 371. The district court did not abuse its discretion in denying Plaintiffs' request.

AFFIRMED.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

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

MEMORANDUM AND ORDER

(Filed Sep. 23, 2019)

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]

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

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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 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.

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, 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]

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[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" 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

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

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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

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 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

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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.

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.

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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.

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. 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 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

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

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

RELEVANT STATUTORY AND REGULATORY PROVISIONS

21 U.S.C. § 337. Proceedings in name of United States; provision as to subpoenas

(a) Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

(b)(1) A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 341, 343(b), 343(c), 343(d), 343(e), 343(f), 343(g), 343(h), 343(i), 343(k), 343(q), or 343(r) of this title if the food that is the subject of the proceedings is located in the State.

(2) No proceeding may be commenced by a State under paragraph (1) –

> **(A)** before 30 days after the State has given notice to the Secretary that the State intends to bring such proceeding,
>
> **(B)** before 90 days after the State has given notice to the Secretary of such intent if the Secretary has, within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding, or
>
> **(C)** if the Secretary is diligently prosecuting a proceeding in court pertaining to such food, has

settled such proceeding, or has settled the informal or formal enforcement action pertaining to such food.

In any court proceeding described in subparagraph (C), a State may intervene as a matter of right.

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21 U.S.C. § 360h. Notification and other remedies

(a) Notification

If the Secretary determines that –

(1) a device intended for human use which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health, and

(2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this chapter (other than this section) to eliminate such risk,

the Secretary may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all health professionals who prescribe or use the device and to any other person (including manufacturers, importers, distributors, retailers, and device users) who should properly receive such notification in order to eliminate such risk. An order under this subsection shall require that the individuals subject to the risk with respect to

which the order is to be issued be included in the persons to be notified of the risk unless the Secretary determines that notice to such individuals would present a greater danger to the health of such individuals than no such notification. If the Secretary makes such a determination with respect to such individuals, the order shall require that the health professionals who prescribe or use the device provide for the notification of the individuals whom the health professionals treated with the device of the risk presented by the device and of any action which may be taken by or on behalf of such individuals to eliminate or reduce such risk. Before issuing an order under this subsection, the Secretary shall consult with the persons who are to give notice under the order.

(b) Repair, replacement, or refund

(1)(A) If, after affording opportunity for an informal hearing, the Secretary determines that –

> **(i)** a device intended for human use which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health,
>
> **(ii)** there are reasonable grounds to believe that the device was not properly designed or manufactured with reference to the state of the art as it existed at the time of its design or manufacture,
>
> **(iii)** there are reasonable grounds to believe that the unreasonable risk was not caused by failure of a person other than a manufacturer, importer,

distributor, or retailer of the device to exercise due care in the installation, maintenance, repair, or use of the device, and

(iv) the notification authorized by subsection (a) would not by itself be sufficient to eliminate the unreasonable risk and action described in paragraph (2) of this subsection is necessary to eliminate such risk,

the Secretary may order the manufacturer, importer, or any distributor of such device, or any combination of such persons, to submit to him within a reasonable time a plan for taking one or more of the actions described in paragraph (2). An order issued under the preceding sentence which is directed to more than one person shall specify which person may decide which action shall be taken under such plan and the person specified shall be the person who the Secretary determines bears the principal, ultimate financial responsibility for action taken under the plan unless the Secretary cannot determine who bears such responsibility or the Secretary determines that the protection of the public health requires that such decision be made by a person (including a device user or health professional) other than the person he determines bears such responsibility.

(B) The Secretary shall approve a plan submitted pursuant to an order issued under subparagraph (A) unless he determines (after affording opportunity for an informal hearing) that the action or actions to be taken under the plan or the manner in which such action or actions are to be taken under the plan will not

assure that the unreasonable risk with respect to which such order was issued will be eliminated. If the Secretary disapproves a plan, he shall order a revised plan to be submitted to him within a reasonable time. If the Secretary determines (after affording opportunity for an informal hearing) that the revised plan is unsatisfactory or if no revised plan or no initial plan has been submitted to the Secretary within the prescribed time, the Secretary shall (i) prescribe a plan to be carried out by the person or persons to whom the order issued under subparagraph (A) was directed, or (ii) after affording an opportunity for an informal hearing, by order prescribe a plan to be carried out by a person who is a manufacturer, importer, distributor, or retailer of the device with respect to which the order was issued but to whom the order under subparagraph (A) was not directed.

(2) The actions which may be taken under a plan submitted under an order issued under paragraph (1) are as follows:

> **(A)** To repair the device so that it does not present the unreasonable risk of substantial harm with respect to which the order under paragraph (1) was issued.
>
> **(B)** To replace the device with a like or equivalent device which is in conformity with all applicable requirements of this chapter.
>
> **(C)** To refund the purchase price of the device (less a reasonable allowance for use if such device has been in the possession of the device user for one year or more –

(i) at the time of notification ordered under subsection (a), or

(ii) at the time the device user receives actual notice of the unreasonable risk with respect to which the order was issued under paragraph (1),

whichever first occurs).

(3) No charge shall be made to any person (other than a manufacturer, importer, distributor or retailer) for availing himself of any remedy, described in paragraph (2) and provided under an order issued under paragraph (1), and the person subject to the order shall reimburse each person (other than a manufacturer, importer, distributor, or retailer) who is entitled to such a remedy for any reasonable and foreseeable expenses actually incurred by such person in availing himself of such remedy.

(c) Reimbursement

An order issued under subsection (b) with respect to a device may require any person who is a manufacturer, importer, distributor, or retailer of the device to reimburse any other person who is a manufacturer, importer, distributor, or retailer of such device for such other person's expenses actually incurred in connection with carrying out the order if the Secretary determines such reimbursement is required for the protection of the public health. Any such requirement shall not affect any rights or obligations under any contract to which the person receiving reimbursement or the person making such reimbursement is a party.

(d) Effect on other liability

Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

(e) Recall authority

(1) If the Secretary finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the device) –

> **(A)** to immediately cease distribution of such device, and
>
> **(B)** to immediately notify health professionals and device user facilities of the order and to instruct such professionals and facilities to cease use of such device.

The order shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such device. If, after providing an opportunity for such a hearing, the Secretary determines that

inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

(2)(A) If, after providing an opportunity for an informal hearing under paragraph (1), the Secretary determines that the order should be amended to include a recall of the device with respect to which the order was issued, the Secretary shall, except as provided in subparagraphs (B) and (C), amend the order to require a recall. The Secretary shall specify a timetable in which the device recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.

(B) An amended order under subparagraph (A) –

(i) shall –

(I) not include recall of a device from individuals, and

(II) not include recall of a device from device user facilities if the Secretary determines that the risk of recalling such device from the facilities presents a greater health risk than the health risk of not recalling the device from use, and

(ii) shall provide for notice to individuals subject to the risks associated with the use of such device.

In providing the notice required by clause (ii), the Secretary may use the assistance of health professionals who prescribed or used such a device for individuals. If a significant number of such individuals cannot be

identified, the Secretary shall notify such individuals pursuant to section 375(b) of this title.

(3) The remedy provided by this subsection shall be in addition to remedies provided by subsections (a), (b), and (c).

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21 U.S.C. § 360i. Records and reports on devices

(a) General rule

Every person who is a manufacturer or importer of a device intended for human use shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such device is not adulterated or misbranded and to otherwise assure its safety and effectiveness. Regulations prescribed under the preceding sentence –

> **(1)** shall require a device manufacturer or importer to report to the Secretary whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices –
>
> > **(A)** may have caused or contributed to a death or serious injury, or
> >
> > **(B)** has malfunctioned and that such device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, which report under this subparagraph –

(i) shall be submitted in accordance with part 803 of title 21, Code of Federal Regulations (or successor regulations), unless the Secretary grants an exemption or variance from, or an alternative to, a requirement under such regulations pursuant to section 803.19 of such part, if the device involved is –

(I) a class III device;

* * *

(2) shall define the term "serious injury" to mean an injury that –

(A) is life threatening,

(B) results in permanent impairment of a body function or permanent damage to a body structure, or

(C) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure;

(3) shall require reporting of other significant adverse device experiences as determined by the Secretary to be necessary to be reported;

(4) shall not impose requirements unduly burdensome to a device manufacturer or importer taking into account his cost of complying with such requirements and the need for the protection of the public health and the implementation of this chapter;

(5) which prescribe the procedure for making requests for reports or information shall require that each request made under such regulations for submission of a report or information to the Secretary state the reason or purpose for such request and identify to the fullest extent practicable such report or information;

(6) which require submission of a report or information to the Secretary shall state the reason or purpose for the submission of such report or information and identify to the fullest extent practicable such report or information;

* * *

(b) User reports

(1)(A) Whenever a device user facility receives or otherwise becomes aware of information that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility, the facility shall, as soon as practicable but not later than 10 working days after becoming aware of the information, report the information to the Secretary and, if the identity of the manufacturer is known, to the manufacturer of the device. In the case of deaths, the Secretary may by regulation prescribe a shorter period for the reporting of such information.

(B) Whenever a device user facility receives or otherwise becomes aware of –

(i) information that reasonably suggests that a device has or may have caused or contributed to

the serious illness of, or serious injury to, a patient of the facility, or

(ii) other significant adverse device experiences as determined by the Secretary by regulation to be necessary to be reported,

the facility shall, as soon as practicable but not later than 10 working days after becoming aware of the information, report the information to the manufacturer of the device or to the Secretary if the identity of the manufacturer is not known.

(C) Each device user facility shall submit to the Secretary on an annual basis a summary of the reports made under subparagraphs (A) and (B). Such summary shall be submitted on January 1 of each year. The summary shall be in such form and contain such information from such reports as the Secretary may require and shall include –

(i) sufficient information to identify the facility which made the reports for which the summary is submitted,

(ii) in the case of any product which was the subject of a report, the product name, serial number, and model number,

(iii) the name and the address of the manufacturer of such device, and

(iv) a brief description of the event reported to the manufacturer.

(D) For purposes of subparagraphs (A), (B), and (C), a device user facility shall be treated as having

received or otherwise become aware of information with respect to a device of that facility when medical personnel who are employed by or otherwise formally affiliated with the facility receive or otherwise become aware of information with respect to that device in the course of their duties.

* * *

(3) No report made under paragraph (1) by –

(A) a device user facility,

(B) an individual who is employed by or otherwise formally affiliated with such a facility, or

(C) a physician who is not required to make such a report,

shall be admissible into evidence or otherwise used in any civil action involving private parties unless the facility, individual, or physician who made the report had knowledge of the falsity of the information contained in the report.

(4) A report made under paragraph (1) does not affect any obligation of a manufacturer who receives the report to file a report as required under subsection (a).

* * *

(6) For purposes of this subsection:

(A) The term "device user facility" means a hospital, ambulatory surgical facility, nursing home, or outpatient treatment facility which is not a physician's office. The Secretary may by regulation

include an outpatient diagnostic facility which is not a physician's office in such term.

(B) The terms "serious illness" and "serious injury" mean illness or injury, respectively, that –

(i) is life threatening,

(ii) results in permanent impairment of a body function or permanent damage to a body structure, or

(iii) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

* * *

(e) Device tracking

(1) The Secretary may by order require a manufacturer to adopt a method of tracking a class II or class III device –

(A) the failure of which would be reasonably likely to have serious adverse health consequences; or

(B) which is –

(i) intended to be implanted in the human body for more than one year, or

(ii) a life sustaining or life supporting device used outside a device user facility.

(2) Any patient receiving a device subject to tracking under paragraph (1) may refuse to release, or refuse

permission to release, the patient's name, address, social security number, or other identifying information for the purpose of tracking.

* * *

(g) Reports of removals and corrections

(1) Except as provided in paragraph (2), the Secretary shall by regulation require a manufacturer or importer of a device to report promptly to the Secretary any correction or removal of a device undertaken by such manufacturer or importer if the removal or correction was undertaken –

> **(A)** to reduce a risk to health posed by the device, or
>
> **(B)** to remedy a violation of this chapter caused by the device which may present a risk to health.

A manufacturer or importer of a device who undertakes a correction or removal of a device which is not required to be reported under this paragraph shall keep a record of such correction or removal.

(2) No report of the corrective action or removal of a device may be required under paragraph (1) if a report of the corrective action or removal is required and has been submitted under subsection (a).

(3) For purposes of paragraphs (1) and (2), the terms "correction" and "removal" do not include routine servicing.

(h) Inclusion of devices in the postmarket risk identification and analysis system

(1) In general

(A) Application to devices

The Secretary shall amend the procedures established and maintained under clauses (i), (ii), (iii), and (v) of section 355(k)(3)(C) of this title in order to expand the postmarket risk identification and analysis system established under such section to include and apply to devices.

(B) Exception

Subclause (II) of clause (i) of section 355(k)(3)(C) of this title shall not apply to devices.

(C) Clarification

With respect to devices, the private sector health-related electronic data provided under section 355(k)(3)(C)(i)(III)(bb) of this title may include medical device utilization data, health insurance claims data, and procedure and device registries.

(2) Data

In expanding the system as described in paragraph (1)(A), the Secretary shall use relevant data with respect to devices cleared under section 360(k) of this title or approved under section 360e of this title, including claims data, patient survey

data, and any other data deemed appropriate by the Secretary.

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21 U.S.C. § 360k. State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –

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

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if –

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement –

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

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21 C.F.R. § 803.50 If I am a manufacturer, what reporting requirements apply to me?

(a) If you are a manufacturer, you must report to us the information required by § 803.52 in accordance with the requirements of § 803.12(a), no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market:

(1) May have caused or contributed to a death or serious injury or

(2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

(b) What information does FDA consider "reasonably known" to me?

(1) You must submit all information required in this subpart E that is reasonably known to you. We consider the following information to be reasonably known to you:

(i) Any information that you can obtain by contacting a user facility, importer, or other initial reporter;

(ii) Any information in your possession; or

(iii) Any information that you can obtain by analysis, testing, or other evaluation of the device.

(2) You are responsible for obtaining and submitting to us information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters.

(3) You are also responsible for conducting an investigation of each event and evaluating the cause of the event. If you cannot submit complete information on a report, you must provide a statement explaining why this information was incomplete and the steps you took to obtain the information. If you later obtain any required information that was not available at the time you filed your initial report, you must submit this information in a supplemental report under § 803.56 in accordance with the requirements of § 803.12(a).