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United States Court of Appeals
Tenth Circuit

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Christopher M. Wolpert
Clerk of Court

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)

Anthony A.B. Dogali (Barbara U. Uberoi with him on the briefs), Dogali Law Group, P.A., Tampa, Florida, for Plaintiffs-Appellants.

Dustin B. Rawlin (Jeffrey C. Sindelar, Jr. with him on the brief), Tucker Ellis LLP, Cleveland, Ohio, for Defendant-Appellee.

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:

> (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—
>
> (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 (2008). First, we must ask "whether the federal government has established requirements

[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., 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.

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

> 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 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.

[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).

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 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

[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).

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, (4) "negligently incorporate[ed] components and/or materials" that were not "commercially reasonable" and "could not stand up to normal usage," and (5) "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.