UNITED STATES DISTRICT COURT EASTERN DISTRICT OF KENTUCKY SOUTHERN DIVISION PIKEVILLE

MARETTA WORRIX,)	
Plaintiff,)	Civil No. 13-111-ART
v.)	
MEDTRONIC INC4 -1)	MEMORANDUM OPINION
MEDTRONIC, INC., et al.,)	AND ORDER
Defendants.)	
)	
	*** *** ***	***

Maretta Worrix asserts several state common-law claims against the defendants stemming from their promotion and use of Infuse, a bone grafting device regulated by federal law. Contending that federal law preempts Worrix's claims, the defendants removed the case to this Court, invoking its federal question jurisdiction under 28 U.S.C. § 1331. The defendants alternatively rely on diversity jurisdiction under § 1332 since they allege that Worrix fraudulently joined the non-diverse defendants. But since preemption is merely a defense, and Worrix has at least one colorable state-law claim against the non-diverse defendants, the Court must remand the case back to state court.

BACKGROUND

On July 7, 2010, Maretta Worrix underwent lumbar fusion surgery at Pikeville Medical Center Hospital. R. 1-1 ¶ 320. Surgeons inserted defendant Medtronic, Inc.'s Infuse between two of her vertebrae. *Id.* ¶ 323. Designed to stimulate bone growth, Infuse is a bioengineered protein regulated as a medical device by the Food and Drug Administration (FDA). In Worrix's case, her surgeons implanted the Infuse using a posterior approach

(through her back), a procedure not contemplated by Infuse's FDA-approved label. *Id.* ¶ 50. After surgery, Worrix developed significant pain in her lower back and follow-ups with her surgeons revealed excessive bone growth. *Id.* ¶¶ 324-25. She attributes those symptoms to the "off-label" use of Infuse. *Id.* ¶ 325.

Seeking damages for her complications, Worrix brought this suit against Medtronic and several codefendants in Pike County Circuit Court. *See* R. 1-1. She pleads various state causes of action, including products liability, fraud-related claims, and medical malpractice. According to Worrix, Medtronic is responsible for her injuries because it illegally promoted the off-label use of Infuse and concealed its risks. *Id.* ¶¶ 70–75. Had her doctors been fully aware of those risks, she claims, they would not have used Infuse in an off-label fashion. *Id.* ¶ 77. Worrix levels similar allegations regarding off-label promotion against local Medtronic sales representative Theresa McGrann. *Id.* ¶ 51-52, 321. Pikeville Medical Center, Inc. (PMC) is also vicariously liable, Worrix contends, since her surgeons' off-label use of Infuse was inconsistent with the medical standard of care. *Id.* ¶ 402–05.

The defendants counter that federal law preempts Worrix's claims and, regardless, that those claims must be handled through arbitration. *See* R. 9 (motion to dismiss); R. 12 (motion to compel arbitration). They accordingly removed the case to this Court, invoking both its federal-question jurisdiction to hear cases "arising under" federal law, and its diversity jurisdiction to hear suits between citizens of different states. *See* R. 1 ¶ 11. Worrix and Medtronic are diverse, but Worrix shares the same citizenship as PMC and McGrann. *Id.* ¶¶ 35–38. Despite this lack of complete diversity, the defendants argue that the Court can ignore PMC and McGrann for the purpose of diversity jurisdiction because Worrix

fraudulently joined them to defeat removal. *Id.* Worrix disagrees and moved to remand. *See* R. 10.

DISCUSSION

Unlike state trial courts, "[f]ederal courts are courts of limited jurisdiction, possessing only that power authorized by Constitution and statute." *Gunn v. Minton*, 133 S.Ct. 1059, 1064 (2013) (quoting *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994)) (internal quotation marks omitted). As the party seeking removal, Medtronic has the burden of demonstrating that the Court has jurisdiction over this matter. *Eastman v. Marine Mech. Corp.*, 438 F.3d 544, 549 (6th Cir. 2006). Kentucky courts are presumptively competent to interpret and faithfully apply federal law. *See Mikulski v. Centerior Energy Corp.*, 501 F.3d 555, 560 (6th Cir. 2007) (en banc).

In a nearly identical case against Medtronic, this Court rejected federal question jurisdiction based on the defendants' assertions of preemption. *See Dillon v. Medtronic*, No. 13-105, R. 31 (E.D. Ky. December 20, 2013). For the reasons described in *Dillon*, the federal issues in this case do not provide a basis for arising-under jurisdiction pursuant to § 1331. That leaves only diversity jurisdiction as a basis for removal. But unless Worrix fraudulently joined both of the non-diverse defendants, the Court must remand this case back to state court.

Defendants seeking to prove fraudulent joinder face an uphill climb. To invoke this judicially created exception to the normal rule requiring complete diversity, the removing defendants must produce "sufficient evidence" that Worrix cannot establish a cause of action under Kentucky law against either Kentucky defendant. *Coyne v. Am. Tobacco Co.*, 183 F.3d 488, 493 (6th Cir. 1999). This is a more substantial burden than the defendants would

face if they had brought a motion to dismiss under Rule 12(b)(6). See Casias v. Wal-Mart Stores, Inc., 695 F.3d 428, 433 (6th Cir. 2012) (describing the test from the plaintiff's perspective as "more lenient than" analysis applied on motion to dismiss). They must show that there is no "colorable basis" to predict that Worrix "may recover" against one of the Kentucky defendants. *Id.* (quoting *Coyne*, 183 F.3d at 493). A claim is colorable if "there is arguably a reasonable basis for predicting that state law might impose liability on the facts involved." Alexander v. Elec. Data Sys. Corp., 13 F.3d 940, 949 (6th Cir. 1994) (quoting Bobby Jones Garden Apartments, Inc. v. Suleski, 391 F.2d 172, 176 (5th Cir. 1968)). In reviewing the defendants' allegation of fraudulent joinder and the motion to remand, the Court may "pierce the pleading" and consider evidence that is normally reserved for summary judgment, such as affidavits. Casias, 695 F.3d at 433 (citing Walker v. Philip Morris USA, Inc., 443 F. App'x 946, 952–54 (6th Cir. 2011)). But the Court may do so only for the limited purpose of identifying "undisputed facts that negate the claim." *Id.* (quoting Walker, 443 F. App'x at 955–56). Disputed questions of fact and ambiguities in state law are resolved in favor of Worrix. See Alexander, 13 F.3d at 949. Her motive for joining the nondiverse defendants is irrelevant. See Jerome-Duncan, Inc. v. Auto-By-Tel, LLC, 176 F.3d 904, 907 (6th Cir. 1999).

The defendants separately attack each of Worrix's claims against PMC and McGrann, but they also offer two overarching theories as to why joinder of the non-diverse defendants is fraudulent: Worrix's claims are internally inconsistent, and those claims must be resolved through arbitration. These arguments do not establish that all of Worrix's claims are "so frivolous that [they have] no hope of success." *Murriel–Don Coal Co., Inc. v. Aspen Ins. UK Ltd.*, 790 F. Supp. 2d 590, 594 (E.D. Ky. 2011) (citing *Saginaw Hous. Comm'n v. Bannum*,

Inc., 576 F.3d 620, 624 (6th Cir. 2009)). All Worrix needs is one colorable claim against either defendant to defeat the accusations of fraudulent joinder. And that she has. Because there is a reasonable basis for predicting that state law might impose liability for the malpractice of Worrix's surgeons on PMC, a non-diverse defendant, the Court lacks jurisdiction over the entire case and must grant Worrix's motion to remand.

I. Malpractice Claims Against PMC

Worrix claims that PMC is liable for her injuries because its surgeons negligently used Medtronic's Infuse in an off-label manner. See R. 1-1 ¶ 402 ("The use by PMC of Infuse® was a deviation of standard medical practice, in light of the information which was known or should have been known by PMC at the time of Plaintiff's surgery."). The defendants respond that this allegation does not state a malpractice claim because Worrix has failed to plead "any specific allegations that might suggest that her physicians failed to perform her procedure with the requisite level of care and skill." R. 19 at 33. But the defendants err in using federal pleading standards to try and say Worrix's claim was fraudulently joined. Fraudulent joinder is not about whether a claim would make it in federal court. On the contrary, the doctrine applies only if the plaintiff lacks a colorable cause of action against the non-diverse defendants "in state court." Spizizen v. Nat'l City Corp., 516 F. App'x 426, 429 (6th Cir. 2013). And while the test for fraudulent joinder does not depend on the plaintiff's subjective motive, assessing colorability through the lens of state procedure makes perfect sense since fraudulent joinder is, after all, about sniffing out when plaintiffs are simply trying to defeat removal. When a plaintiff meets the forum's pleading standard, there is little reason to suspect jurisdictional shenanigans. For the purposes of fraudulent

joinder, the Court will therefore construe Worrix's state complaint as a Kentucky trial court would.

Contrary to the defendants' suggestion, Kentucky courts do not hold complaints to the standard that federal courts do under Federal Rule of Civil Procedure 12(b)(6). To survive a motion to dismiss in federal court, a complaint "must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." See Ashcroft v. Igbal, 556 U.S. 662, 678 (2009) (internal quotation marks omitted). Kentucky, on the other hand, still follows the old notice-pleading regime. See Hoke v. Cullinan, 914 S.W.2d 335, 339 (Ky. 1995) ("[T]he central purpose of pleadings remains notice."). Kentucky courts thus may dismiss plaintiffs' complaints only where they "would not be entitled to relief under any set of facts which could be proved." Fox v. Grayson, 317 S.W.3d 1, 7 (Ky. 2010) (internal quotation marks omitted). Pleading legal conclusions is not fatal as long as the complaint gives the defendant fair notice of the claim. See Pierson Trapp Co. v. Peak, 340 S.W.2d 456, 460 (Ky. 1960). Kentucky courts construe complaints liberally. See Smith v. Isaacs, 777 S.W.2d 912, 915 (Ky. 1989). While Worrix's malpractice claim may be conclusory, it contains adequate substance to provide PMC the fair notice needed to craft a meaningful answer.

As to the merits of that claim, there is a reasonable basis to conclude it may succeed. Medical malpractice has the same elements as any other negligence claim: 1) duty, 2) breach, 3) causation, and 4) injury. *Grubbs ex rel. Grubbs v. Barbourville Family Health Ctr.*, 120 S.W.3d 682, 687 (Ky. 2003) (collectively referring to the last two elements as "consequent injury"). Physicians have a "duty to use the degree of care and skill expected of a competent practitioner of the same class and under similar circumstances." *Id.* While off-

label use is certainly not a *per se* breach of that duty, the FDA labeling "is relevant and useful information regarding the [medical] standard of care." *Hyman & Armstrong, P.S.C. v. Gunderson*, 279 S.W.3d 93, 114 (Ky. 2008). By itself, such deviation from the label may not ultimately be enough to overcome a motion for summary judgment, since proving the standard of care in medical malpractice cases generally requires expert testimony. *See Blankenship v. Collier*, 302 S.W.3d 665, 670 (Ky. 2010). But at this stage, when review of Worrix's complaint is even more forgiving than on a motion to dismiss, the Court cannot reasonably expect Worrix to produce such testimony.

The appropriate medical standard of care is plainly in dispute, and *Gunderson* suggests it might correspond to the FDA-approved label. Worrix's account of the available sources describing the risks of off-label use of Infuse also suggests her surgery may have been inconsistent with the applicable standard of care. *See* R. 1-1 ¶¶ 165–75, 178. Although many of those sources are specific to the use of Infuse during neck surgeries, one article notes complications from other off-label procedures. *See id.* ¶ 174. Together these reports might have suggested to a doctor at the time of Worrix's surgery that any off-label use of Infuse was simply too risky. This supports a plausible malpractice claim because physicians' duty of care requires that they stay abreast of medical developments. *See Stacy v. Williams*, 69 S.W.2d 697, 704 (Ky. 1934). None of this is to say Worrix's claim ultimately will succeed, but that claim is at least colorable since legal doubts about the standard of care are resolved in her favor. *See Alexander*, 13 F.3d at 949.

II. Conflicting Allegations

Worrix claims that Medtronic suppressed information about the dangers of Infuse *and* that her PMC surgeons should have known of those dangers. The defendants claim that this

apparent inconsistency supports a finding of fraudulent joinder. This argument fails for two reasons.

First, even if her allegations are in tension, the Kentucky Civil Rules, like the Federal Rules, allow alternative or inconsistent pleadings. *See* Ky. R. Civ. P. 8.05(2) ("A party may... state as many separate claims... as he has regardless of consistency."); *see also* Fed. R. Civ. P. 8(d)(3) (allowing the same inconsistent pleading approach in federal courts). The defendants' argument therefore cannot be squared with the applicable pleading rules since Worrix is free to bring inconsistent claims. *See Smith v. Smithkline Beecham Corp.*, No. 10-73-ART, 2010 WL 3432594, at *2 (E.D. Ky. Aug. 30, 2010). Inconsistency has no bearing on whether her claims are colorable and thus no implications for whether the non-diverse defendants are fraudulently joined.

Second, liberally construing Worrix's complaint, it is far from clear that her allegations against Medtronic are inconsistent with those against PMC. It is entirely plausible that Medtronic could have engaged in a pattern of concealing information about Infuse's risks and yet that a reasonable surgeon would still have known of those risks from the information already available. As already discussed, Worrix alleges that information about Infuse's off-label dangers was public by the time of her surgery. See R. 1-1 ¶ 165-75, 178. As a result, even if PMC surgeons were misled by Medtronic about the full risks of using Infuse off-label, perhaps they still had enough warning from other sources that their duty of care required a different course. Cf. Smith, 2010 WL 3432594, at *2 (holding that despite claims manufacturer concealed information about drug's risks, claims against physician were still colorable because information about the drug's dangers was "independently available"). Moreover, despite ignoring those red flags, Medtronic's cover-

up might still have made the difference. With fully accurate information, perhaps, as Worrix alleges, her surgeons would have declined to use Infuse in an off-label manner, *see* R. 1-1 ¶ 77, even though without that information they already knew enough to conclude such a procedure was unwise. Worrix's allegations are thus not necessarily inconsistent at all.

III. Arbitration

The defendants lastly argue that Worrix's claims against the non-diverse defendants are subject to arbitration and as such, their joinder is fraudulent. *See* R. 19 at 37–39. Courts have uniformly rejected this argument. *See Cobalt Mining, LLC. v. Bank of Am., N.A.*, No. 3:07-598-S, 2008 WL 695887, at *3 (W.D. Ky. Mar. 12, 2008) (citing cases). One of the reasons for this conclusion is that the validity and scope of the arbitration agreement are often at issue. *Id.* The parties in this case hotly contest both. *Compare* R. 13 at 26–30 *with* R. 19 at 37–39. The defendants even concede that Worrix "has consistently argued that she did not knowingly sign the arbitration agreement." R. 19 at 37. So, even if an otherwise valid and clearly applicable arbitration agreement is enough to make a claim frivolous for purposes of fraudulent joinder, that is not what the Court faces here. Since factual disputes are resolved in favor of Worrix, *see Alexander*, 13 F.3d at 949, the Court must reject the defendants' claims of fraudulent joinder based on arbitration.

CONCLUSION

For the reasons discussed, the Court lacks subject-matter jurisdiction over this case. It is accordingly **ORDERED** that Maretta Worrix's motion to remand, R. 10, is **GRANTED**. This case is **REMANDED** to the Pike Circuit Court. All pending motions are **DENIED AS**MOOT, and this case shall be **STRICKEN** from the Court's active docket.

This the 23rd day of December, 2013.

Signed By:

Amul R. Thapar AT

United States District Judge