UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
SOUTHERN DIVISION -- LONDON

TRACEY PATTERSON and BRANDY RECORD, **Plaintiffs,** **V.** **BAYER CORPORATION LLC, et al.,** **Defendants.**	**CIVIL ACTION NO. 6:17-CV-48-KKC** **OPINION & ORDER**

This matter is before the Court on a Motion to Remand to Perry County Circuit Court filed by plaintiffs (DE 6). The plaintiffs have also requested a hearing with this Court in connection with their Motion to Remand (DE 11). For the following reasons, plaintiffs' motion to remand (DE 6) is **GRANTED** and plaintiffs' motion for hearing (DE 11) is **DENIED**.

I. BACKGROUND

The plaintiffs originally filed this civil suit in Perry Circuit Court on January 31, 2017 (DE 1-1, Complaint). In their Complaint, Plaintiffs named five defendants: Bayer Corporation, Bayer Healthcare LLC, Bayer Essure, Inc., (f/k/a Conceptus, Inc.), and Bayer Healthcare Pharmaceuticals, Inc. (collectively herein called the "Bayer defendants"), Appalachian Regional Healthcare, Inc. (d/b/a Hazard ARH Regional Medical Center) ("ARH"), and James Delmar Dawson Jr., M.D. Defendants timely removed the action to this Court on grounds of both federal question and diversity jurisdiction. (DE 1, at 2-3). Plaintiffs claim this Court has no jurisdiction and have asked that the matter be remanded back to state court. (DE 6). The issues have been sufficiently briefed by both parties and a hearing is not necessary.

This case involves the plaintiffs' use of a permanent birth control device called "Essure." Plaintiffs Patterson and Record both underwent surgery at ARH to have the Essure device implanted, Patterson in 2016 and Record in 2013. Defendant Dawson performed the implant procedure on plaintiff Patterson, and a non-party, Misty Thompson, performed the implant procedure on plaintiff Record. Both plaintiffs allege that they suffered injuries because ARH failed to properly inform them of the risks associated with the device, and failed to use reasonable care in implanting the device (DE 1-1).

The plaintiffs contend that the device was originally created by Conceptus, Inc., a company bought by Bayer in 2013 (DE 1-1, at 18-20). In 2002, Essure was granted pre-market approval as a Class III medical device by the Food and Drug Administration, pursuant to the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act *See* (DE 1-1 at 35). The plaintiffs do not attack the pre-market approval process. Instead, the plaintiffs' complaint alleges the Bayer defendants failed to conform to FDA requirements regarding post-market monitoring of the device. As a specific example of this conduct, plaintiffs allege that Conceptus failed to report to the FDA adverse effects that were discovered once Essure became widely used in the market, despite having an affirmative duty to do so (DE 1-1, at 2, 75). Plaintiffs allege that these actions constitute a violation of various state tort laws and that, but for the violations, the plaintiffs would never have used the device (DE 1-1).

II. ANALYSIS

Although several motions are pending in this matter, the Court must first determine whether removal from Perry County Circuit Court was proper. On a motion to remand, the burden rests with the defendant to prove that this Court has original jurisdiction. *Eastman v. Marine Mech. Corp.*, 438 F.3d 544, 549 (6th Cir. 2006).

Original jurisdiction exists through either diversity of citizenship, *see* 28 U.S.C. §§ 1332(a) and 1441(b), or federal question jurisdiction, *see* 28 U.S.C. §§ 1331 and 1441(a). When doubts as to the propriety of removal exist, "the removal statute should be strictly construed and all doubts resolved in favor of remand." *Eastman*, 438 F.3d at 550. The Court considers the parties' arguments on jurisdiction below.

A. Federal Question Jurisdiction

Courts have consistently applied the "well-pleaded complaint" rule when reviewing federal question jurisdiction on a motion to remand. "To determine whether the claim arises under federal law, we examine the 'well pleaded' allegations of the complaint and ignore potential defenses…." *Mikulski v. Centerior Energy Corp*., 501 F.3d 555, 560 (2007) (quoting *Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 6 (2003)). As a result of the rule, "federal questions presented by defenses—or even by the plaintiff's anticipatory rebuttal of an expected defense—cannot support jurisdiction." *Dillon v. Medtronic, Inc.*, 992 F.Supp.2d 751, 755 (2014) (citing *Franchise Tax Bd. v. Constr. Laborers Vacation Trust*, 463 U.S. 1, 10 (1983)). "So, with only rare exception, a dispute over whether federal law trumps the plaintiff's state cause of action does not satisfy § 1331, since preemption is usually raised as a defense." Id. (citing *Caterpillar Inc. v. Williams*, 482 U.S. 386, 393 (1987). "'[R]emoval and preemption are two distinct concepts,' and the fact that plaintiffs' claim might ultimately prove to be preempted does not establish that it is removable to federal court." *Strong v. Telectronics Pacing Systems, Inc*., 78 F.3d 256, 261 (6th Cir. 1996) (quoting *Warner v. Ford Motor Co.*, 46 F.3d 531 (6th Cir. 1995).

In their Complaint, Plaintiffs assert various state-law tort claims against the defendants. *See* (DE 1-1, Pl. Complaint); *see also* (DE 6-2, Pl. Mem. in Support of Mtn.

to Remand, at 3). As such, the claims within the well-pleaded complaint do not directly arise under federal law or jurisdiction. However, the United States Court of Appeals for the Sixth Circuit recognizes three exceptions to the well-pleaded complaint rule, by which defendants can still show that federal jurisdiction is proper. *See Mikulski*, 501 F.3d at 560. The first two exceptions, artful-pleading and complete preemption, are inapplicable in this case. The artful pleading doctrine requires there first to be a federal cause of action that the plaintiff is trying to artfully plead around, which Congress has not provided under the FDCA. *See Mikulski,* 501 F.3d at 560; 21 U.S.C. § 337(a). Further, the Sixth Circuit has specifically declined to extend the doctrine of complete preemption to the Medical Device Amendments of the FDCA. *See Strong,* 78 F.3d at 259. Thus, only the third exception, the substantial federal question doctrine, is at issue.

1) The substantial federal question doctrine

Plaintiffs' Complaint does not directly raise a federal question. The United States Supreme Court has held, however, that federal courts have federal question jurisdiction over state law claims that raise a substantial federal issue, but only when the exercise of such jurisdiction will not upset the balance of state and federal judicial responsibilities. *See Grable & Sons Metal Products, Inc., v. Darue Engineering & Manufacturing,* 545 U.S. 308, 125 S.Ct. 2363 (2005).

The Sixth Circuit, relying on *Grable*, has developed a three-part test to determine whether state law claims implicate federal question jurisdiction:

> (1) The state-law claim must necessarily raise a disputed federal issue; (2) the federal interest in the issue must be substantial; and (3) the exercise of jurisdiction must not disturb any congressionally approved balance of federal and state judicial responsibilities.
>
> *Mikulski*, 501 F.3d at 568.

a. Whether the state law claim raises a disputed federal issue

In Plaintiffs' Complaint, the claims for relief arise exclusively under state law. The Supreme Court has specifically stated that the MDA only preempts state requirements that are "different from, or in addition to" requirements imposed by federal law, leaving room for independent state causes of action. *Riegel v. Medtronic, Inc.,* 552 U.S. 312, 330 (2008). "Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* In this case, it is unclear that litigation regarding the defendants' state duties—duties that merely parallel federal law—will necessarily raise a disputed federal issue. But even if the Court were to assume a disputed federal issue, the claims fail the remaining two elements of the test as discussed below.

b. Whether the federal issues are substantial

The Sixth Circuit has set forth four factors for determining whether state law claims implicate substantial federal issues. They are:

> 1) Whether the case includes a federal agency, and particularly, whether that agency's compliance with the federal statute is in dispute; (2) whether the federal question is important (i.e., not trivial); (3) whether a decision on the federal question will resolve the case (i.e. the federal question is not merely incidental to the outcome); and (4) whether a decision as to the federal question will control numerous other cases.

Mikulski, 501 F.3d at 570.

The claims in this case do not implicate a federal agency or call upon this Court to review an agency's compliance with the federal statute in dispute. *Mikulski*, 501 F.3d at 568-570. Here, it is the conduct of private companies, the Bayer defendants, which allegedly violated state tort laws.

Second, the federal questions that may be raised in this litigation do not appear to be important to the federal judicial system as a whole, as required by the Supreme Court in *Gunn*. *See Gunn v. Minton*, 568 U.S. 251, 263 (2013). Here, the defendants state that the "federal issues are hotly contested," but cite the conduct of the parties and the sufficiency of plaintiffs' allegations as contested, rather than any meaningful interpretation of the MDA or federal law. *See e.g.,* (DE 10 at 7-8) (pointing the Court to plaintiffs' failure to rely on statements made by the defendants, and plaintiffs' failure to show that defects in manufacturing and training caused their injuries). Defendants offer little or no evidence that applying the federal requirements in issue, particularly reporting requirements, to the parties' conduct will implicate broader or more substantial federal issues, or control numerous other cases going forward. *See Mikulski,* 501 F.3d at 570-571. Further, it appears that at least some of the reporting obligations may be fairly unique to these defendants. In a premarket approval letter, some of the reporting obligations were described as "[i]n addition to the post approval requirements," and "agreed to" by the Bayer defendants and an agency of the FDA. (DE 1-2, Premarket Approval Letter). Regardless, it is unclear that applying routine provisions of the MDA to defendants' conduct, without more, places this case in the "special and small category of cases" that raise issues important to the federal system as a whole. *Gunn,* 568 U.S. at 258-260.

While federal preemption will be raised in this case, that alone does not raise a substantial issue of federal law. "[State] courts are capable of deciding whether the plaintiffs' claims against [the defendant] are preempted," and it is not a basis for conferring federal jurisdiction. *In Re Darvocet, Darvon and Propoxyphene Products*

Liability Litigation, 889 F.Supp.2d 931, 938 (E.D. Ky 2012); *see also Strong,* 78 F.3d at 261 (quoting *Warner v. Ford Motor Co.,* 46 F.3d 531 (6th Cir. 1995).

Finally, since plaintiffs have brought various state-law tort claims, each with various elements and none of which are compliance with the MDA, it is unclear that the federal issues in this case will be dispositive. Ultimately, it appears that any violation of federal law will only be used as evidence to prove a broader violation of Kentucky state law. That federal issues may be raised among state law claims is not enough to confer jurisdiction, since state courts are presumptively competent to apply federal law. *See Mikulski,* 501 F.3d at 560.

c. Whether the exercise of jurisdiction will disturb any congressionally approved balance of federal and state judicial responsibility

In considering the balance of state and federal judicial responsibilities, this Court should consider whether Congress created a private right of action under the Statute in dispute, and whether Congress would have meant to welcome the particular state law tort case into federal court. *See Grable,* 545 U.S. at 318-319 (citing *Merrell Dow Pharmaceuticals Inc., v. Thompson,* 478 U.S. 804, 106 S.Ct. 3229 (1986)). In this case, Congress has neither provided a private right of action, "nor completely precluded state jurisdiction over claims alleging violations of the MDA." *Schilmiller,* 44 F.Supp.3d at 731. Further, the Supreme Court has made it clear that states have the power to provide damage actions premised on violations of the FDCA, and that such actions merely parallel federal law. *Riegel,* 552 U.S. at 330. Given such, this Court once again joins the many district courts finding that the types of claims raised here do not pass the *Grable* test, and do not confer federal question jurisdiction. *See Johnson v. Bayer Corp.,* No. 4:16-CV-729 (CEJ), 2016 WL 3015187 (E.D. Mo. 2016); *Dorman v. Bayer*

Corp., No. 4:16-CV-601 (HEA), 2016 WL 7033765 (E.D. Mo. 2016); *Dillon v. Medtronic, Inc.*, 992 F.Supp.2d 751 (E.D. Ky. 2014); *Schilmiller v. Medtronic, Inc.,* 44 F.Supp.3d 721 (W.D. Ky. 2014); *McCann v. West Chester Hospital, LLC,* 233 F.Supp.3d 607 (S.D. Ohio 2017); *Lee v. Kirkpatrick,* No. 1:16-CV-123 (GNS), 2016 WL 7197478 (W.D. Ky. 2016).

B. Diversity Jurisdiction Over Plaintiff Record's Claims

Defendants allege that this Court has diversity jurisdiction over plaintiff Record's claims, and that ARH has been fraudulently joined. (DE 10 at 12-20). Specifically, defendants allege that all claims against ARH by plaintiff Record are foreclosed by Kentucky's statute of limitations, and that ARH's joinder is an attempt to improperly destroy diversity jurisdiction. Additionally, the defendants argue that plaintiff Record's claims have been fraudulently misjoined to those of plaintiff Patterson. (DE 10 at 16). As an alternative form of relief in the event the Court does not exercise federal question jurisdiction over the entire case, Defendants ask the Court to sever plaintiff Patterson's claims from plaintiff Record's as fraudulently misjoined, and retain diversity jurisdiction over the claims of plaintiff Record. (DE 10 at 19).

While some circuits have allowed defendants to establish fraudulent joinder by raising the affirmative defense of an expired statute of limitations, the Sixth Circuit has yet to rule on the issue. *See Williams v. Altman,* 2013 U.S. Dist. LEXIS 281 (E.D. Ky. 2013). However, since the defendants have not carried their burden of establishing the affirmative defense, this Court need not resolve the issue of whether it is even proper to consider an affirmative defense when reviewing a motion to remand based upon fraudulent joinder. *See e.g., Williams,* 2013 U.S. Dist. LEXIS 281, at *13 n.2.

1) Fraudulent Joinder

Fraudulent joinder of a local party "will not defeat removal on diversity grounds." *Saginaw Housing Com'n v. Bannum, Inc.,* 576 F.3d 620, 624 (6th Cir. 2009) (quoting *Coyne v. Am. Tobacco Co.,* 183 F.3d 488, 493 (6th Cir. 1999)). Joinder of a party is fraudulent "when the non-removing party joins a party against whom there is no colorable cause of action." *Id.* The burden of proof rests with the removing party, and requires showing that the non-removing party could not have established a cause of action under state law against the non-diverse party that was joined. *Coyne,* 183 F.3d at 493. In reviewing such a claim, this Court must resolve "all disputed questions of fact and ambiguities in the controlling state law in favor of the non-removing party [and] [a]ll doubts as to the propriety of removal are resolved in favor of remand." *Id.* (quoting *Alexander v. Electronic Data Sys. Corp.,* 13 F.3d 940, 949 (6th Cir. 1994)). A district court is generally limited to piercing the pleadings in search of *undisputed* facts that negate the underlying claim and, even within this context of limited piercing, must draw any contested issues of fact in the plaintiff's favor. *See Casias v. Wal-mart Stores, Inc.,* 695 F.3d at 428, 433 (6th Cir. 2012); *see also Walker v. Philip Morris USA, Inc.,* 443 Fed. Appx. 946, 954-956 (6th Cir. 2011).

While the Court is confined to the above mentioned review of defendants' fraudulent joinder claim, the statute of limitations is an affirmative defense that the defendants must prove. *See* Ky. R. Civ. P. 8.03; *Lynn Mining Co. v. Kelly,* 394 S.W.2d 755, 759 (Ky. 1965). Kentucky has a one-year statute of limitations for medical malpractice claims. Ky. Rev. Stat. Ann. § 413.140(1)(e), (2). The claim begins to accrue at the time the injury is first discovered, or when it should have been discovered in the exercise of reasonable care. *Id.* To discover an injury, a plaintiff must know two things: (1) that

she has been wronged; and (2) the identity of the person who wronged her. *Wiseman v. Alliant Hosps., Inc.,* 37 S.W.3d 709, 712 (Ky. 2000). The Sixth Circuit has guided our analysis on the knowledge necessary to trigger the Kentucky statute of limitations:

> In constructing knowledge, [] a court must give special consideration to the patient's perspective because '[o]ne who possesses no medical knowledge should not be held responsible for discovering an injury based on the wrongful act of a physician'…In Kentucky, when there is a disputed issue of fact as to when a plaintiff 'discovered or should have discovered' his cause of action, that factual issue should be resolved by the jury in cases in which the plaintiff has asked for a jury….Federal law does not present a conflict with Kentucky law.

Elam v. Menzies, 594 F.3d 463, 466-467 (6th Cir. 2010) (quoting *Wiseman,* 37 S.W.3d at 712-713). Since the plaintiffs filed this case on January 31, 2017, the defendants must prove that, prior to January 31, 2016, plaintiff Record knew, or should have known, that she was injured by ARH.

In *Williams v. Altman,* 2013 U.S. Dist. LEXIS 281 (E.D. Ky. 2013), this Court ruled on arguments very similar to the ones brought by the defendants in this case. In *Williams*, the Court reiterated that inferences arising from factual disputes about when a plaintiff knew or should have known of an injury under the Kentucky statute of limitations must be drawn in favor of the plaintiff at this stage. *See id.* at *15-17. In reviewing the defendants' arguments that the plaintiff should have known of her medical injury years before she filed her complaint, this Court held that, "[defendants] may ultimately be correct, but that is not for this Court to say at this juncture." *Id.* Instead, the Court reasoned:

> [W]hen [plaintiff's] pain and suffering began is not dispositive. What matters is when she should have realized that she had been wronged. Under Kentucky law that is a question of fact for the jury. And the defendants offer no evidence that would prevent a reasonable jury from accepting [plaintiff's] claim that she had no reason to suspect medical malpractice until her appointment on October 4, 2011…The defendants point to the fact that she experienced pelvic pain before her October 2011 appointment, and that the FDA issued Public Health Notifications. But those facts do not definitively establish that [plaintiff] should have known she was the victim of malpractice. She has no medical expertise.

> So a jury could find it reasonable for [plaintiff] not to realize that the symptoms she experienced were the result of medical malpractice…Judging this evidence and drawing factual inferences based on the weighing of that evidence is for a jury, not a judge.

Id. at 15-17 (citations omitted). Similarly in this case, the defendants have only pointed to inferences arising from facts that are disputed by the plaintiffs. As such, the defendants have not carried their burden of proving that the Kentucky statute of limitations prevents the plaintiff from having a colorable basis of recovery under Kentucky law.

Here, the defendants cite to several pieces of evidence purportedly showing that plaintiff Record should have known about her claims against ARH. At this procedural stage, the Court disagrees. Defendants point to evidence of Record's symptoms prior to January 31, 2016, as proof that she should have known her claims had accrued. Specifically, defendants cite the Complaint, in which plaintiff Record admits to having presented to Primary Care Centers of Eastern Kentucky with complaints of fatigue and hair loss, and admits to experiencing irregular uterine bleeding following her Essure implant. (DE 1-1 at 82). Further, defendants point to medical records from January 2014 in which it is noted that Record's last menstrual period was July 29, 2013, and that bleeding has been "nonstop since [E]ssure." (DE 6-3, Ex. L at 69). Finally, in January 2016, Record once again visited Primary Care Centers of Eastern Kentucky and complained of "back and [abdominal] pain from esure [sic] tubal." (DE 6-3, Ex. P at 80). The "History of Present Illness" section of the medical record from the visit states that, "Essure a couple of years ago causing the abdominal pain." *Id.*

Plaintiffs counter these arguments with other facts in the record. Plaintiffs point to Record's own declaration, in which she states that when presenting to an APRN at the Primary Care Centers of Eastern Kentucky on October 18, 2013, the APRN "did not

suggest or seriously consider that [hair loss and fatigue] were related to Essure." (DE 6-3 at 4-5). Medical records from the visit show that labs were ordered that appear to concern blood cell counts, thyroid hormones, a comprehensive metabolic panel, and Vitamin B-12 and Magnesium. (DE 6-3 at 47-49). After a visit to the same medical facility on November 11, 2013, Record contends that, "[a]gain, no one suggested the possibility that [lower back pain] was related to Essure," and that on November 12, 2013, doctors conducted an x-ray of her spine. (DE 6-3 at 5).

As to irregular uterine bleeding, Record alleges that it is true that she presented to Doctor Thompson on January 24, 2014 and reported that her menstrual period was practically nonstop since Essure. (DE 6-2 at 17). But Record claims that "Dr. Thompson did not suggest at any time that Essure caused any of this, but suggested that vitamin deficiencies may play a role." (DE 6-3 at 5). After suffering from pain for over two and a half years, Record alleges that she suggested to Dr. Crystal M. Fletcher-Jones that the pain may be related to Essure, and Dr. Jones completely rejected that suggestion, and certainly did not prescribe any treatment related to Essure. (DE 6-3 at 6). Specifically as to the visit in January 2016 in which Record presented to Dr. Jones with "back and [abdominal] pain from esure [sic] tubal," plaintiffs point out that Dr. Jones ordered an x-ray of Record's spine, a mammogram screening, and Clotrimazole cream presumably for her complaints of dry skin, rather than recommending any treatment regarding the Essure device. (DE 6-3 at 80-81).

Record contends that it was not until August 10, 2016, after being referred to a GYN specialist, that she first received medical confirmation that Essure may be causing her symptoms. (DE 6-3 at 7). And other than a few passing references to symptoms that began after her Essure procedure, the defendants have shown no evidence that Record did or should have drawn the inference sooner, despite repeatedly presenting for

medical treatment and repeatedly being treated for something other than Essure. *See e.g., Elam,* 594 F.3d at 466 ("[A] court must give special consideration to the patient's perspective because one who possesses no medical knowledge should not be held responsible for discovering an injury based on the wrongful act of a physician") (internal quotations omitted).

Finally, defendants claim that Record had sufficient knowledge that she had been wronged, given that she had been told Essure would be "essentially pain free," and then suffered irregular bleeding and significant pain. (DE 10 at 15). While this inference may ultimately be correct, it is disputed. In the face of multiple medical professionals reciting causes other than the Essure product, this Court cannot conclude that such an inference establishes fraudulent joinder. *See Williams,* 2013 U.S. Dist. LEXIS 281, 15-17 ("Judging this evidence and drawing factual inferences based on the weighing of that evidence is for a jury, not a judge").

A question of fact exists as to when Record knew or should have known of ARH's alleged role in her injury—their alleged malpractice in placing the device—before January 31, 2016. At best, the defense asks this Court to infer such knowledge from other facts within the record, facts that are disputed by Record. While the defendants may ultimately be correct as to knowledge, such disputes are best resolved by juries, not a court reviewing fraudulent joinder. *See Williams,* 2013 U.S. Dist. LEXIS 281, 15-17; *see also Elam,* 594 F.3d at 466-467.

2) Fraudulent Misjoinder

Finally, the defendants argue that plaintiff Record's claims have been fraudulently misjoined to those of plaintiff Patterson. (DE 10 at 16) To the extent the Court does not exercise federal question jurisdiction over the entire case, the defendants ask the Court to sever plaintiff Patterson's claims from plaintiff Record's as fraudulently misjoined,

and retain diversity jurisdiction over the claims of plaintiff Record. (DE 10 at 19). That argument, however, is now moot because the Court has found that Record has colorable claims against the defendants. Thus, applying fraudulent misjoinder to retain only the claims brought by Record would have no effect because complete diversity would still be lacking, and remand would still be necessary.

III. CONCLUSION

The defendants have not carried their burden of showing that this Court has original jurisdiction. Original jurisdiction exists through either diversity of citizenship, *see* 28 U.S.C. §§ 1332(a) and 1441(b), or federal question jurisdiction, *see* 28 U.S.C. §§ 1331 and 1441(a). Finding neither, this Court must remand.

Accordingly, it is hereby **ORDERED** as follows:

(1) This matter is **REMANDED** to the docket of the Perry County Circuit Court;

(2) All remaining motions are **DENIED AS MOOT**; and

(3) This case is **STRICKEN** from the Court's active docket.

Dated April 23, 2018.

Karen K. Caldwell

KAREN K. CALDWELL, CHIEF JUDGE
UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY