UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NORTH CAROLINA
ASHEVILLE DIVISION
DOCKET NO. 1:17-cv-00031-MOC-DCK

KRISTIANA TWEED BURRELL,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**ORDER**
	)	
BAYER CORPORATION	)	
BAYER HEALTHCARE LLC	)	
BILTMORE OB-GYN, P.A.	)	
BAYER HEALTHCARE	)	
PHARMACEUTICALS, INC.	)	
BAYER ESSURE, INC.	)	
CHRISTOPHER FORD WILLIAMS	)	
STACY D TRAVIS,	)	
	)	
Defendants.	)	

THIS MATTER is before the court on the plaintiff's Motion to Remand (#16). A parallel Order will be entered in the related case of Burrell v. Bayer et al., Case No. 1:17-cv-32. Having considered the Motion and reviewed the pleadings, the court enters the following Order.

FINDINGS AND CONCLUSIONS

I. Background

The instant case, and its analogous related case (No. 1:17-cv-32) were filed in December 2016 in North Carolina state court. Each of these cases relate to Ms. Kristiana Tweed Burrell's use of Essure, a FDA-approved Class III medical device, which was marketed collectively by the Bayer defendants ("Bayer" or "Bayer defendants"). Essure

is a form of permanent birth control. Plaintiff's allegations, *inter alia*, accuse the Bayer defendants of violations of both federal law and state laws in the manufacturing, marketing, sale, and distribution of the Essure birth control device. (#16) at 3.

The Bayer defendants, with the consent of the other defendants in this case, filed a Notice of Removal (#1) on January 26, 2017. On February 10, 2017, plaintiff Kristiana Burrell filed a Motion to Remand to State Court (#16) and accompanying Memorandum of Law (#17). The matter has been fully briefed, and is ripe for review.[1]

II. Legal Standard

Subject matter jurisdiction is a threshold issue for justiciability in federal court. Absent a proper basis for subject matter jurisdiction, a removed case must be remanded to state court. Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 96 (1998). The party asserting federal jurisdiction has the burden of proving that subject matter jurisdiction exists. Richmond, Fredericksburg & Potomac R. Co. v. United States, 945 F.2d 765, 768 (4th Cir.1991).

Federal courts are courts of limited jurisdiction, and removal of cases is generally proper only when it may have otherwise been brought in federal court originally. Darcangelo v. Verizon Communications, Inc., 292 F.3d 181, 186 (4th Cir. 2002). Here, there is not diversity of citizenship among the parties.[2] Accordingly, subject matter

[1] The court notes that a number of Motions are pending in this matter and its related case, including the Motion to Consolidate (#28) and Motion to Dismiss (#11). As the court would lack jurisdiction to rule on such matters if the case were to be remanded, it will analyze the Motion to Remand (#16) first.

[2] As removal here is not related to diversity of citizenship, the court acknowledges the plaintiff's objection to removal based on the Forum Defendant Rule, 28 U.S.C. § 1441(b)(2) but need not address it as it is inapplicable to

jurisdiction must relate to federal question jurisdiction. See 28 U.S.C. § 1331 ("The district courts shall have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States.").

In interpreting the court's statutory authority under federal question jurisdiction, the Supreme Court has distinguished between cases where federal law creates the cause of action asserted, such as 42 U.S.C. § 1983, and where a claim "necessarily raise[s] a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state power." Merrill Lynch, Pierce, Fenner & Smith Inc. v. Manning, 136 S. Ct. 1562, 1570, 194 L. Ed. 2d 671 (2016) (quoting Grable & Sons Metal Products, Inc. v. Darue Engineering & Mfg., 545 U.S. 308, 314 (2005)). In doing so, the Court, in a unanimous decision, articulated a four-part test, writing:

> That is, federal jurisdiction over a state law claim will lie if a federal issue is: (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress. Where all four of these requirements are met, we held, jurisdiction is proper because there is a "serious federal interest in claiming the advantages thought to be inherent in a federal forum," which can be vindicated without disrupting Congress's intended division of labor between state and federal courts.

Gunn v. Minton, 133 S. Ct. 1059, 1065 (2013) (citations omitted).

Within this Circuit, the appellate court has noted that federal law can either create the cause of action or federal jurisdiction may rest on plaintiff's right to relief depending

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the instant case. As plaintiff noted, removal was not based on diversity jurisdiction. Pl. Memorandum (#17) at 8.

on resolution of a substantial question of federal law. See Battle v. Seibels Bruce Ins. Co., 288 F.3d 596, 606–07 (4th Cir. 2002). Removal from state court is available if the face of the complaint raises a federal question that could have been the basis for an original action in district court. Lontz v. Tharp, 413 F.3d 435, 439–40 (4th Cir. 2005); see also Moehring v. Mortg. Elec. Registration Sys., Inc., No. 3:13-CV-00567-MOC, 2014 WL 1091071, at *8 (W.D.N.C. Mar. 17, 2014).

III. Discussion

The court will examine the claims made by plaintiff under the Supreme Court's four-part test as to examine whether the face of the complaint raises a federal question that would be the basis for original action in federal court.

A. Necessarily Raised and Actually Disputed

The plaintiff's Complaint (#1-1, #1-2) necessarily raises federal law. The plaintiff concedes that he has alleged that the defendants violated the federal requirements of the Federal Food, Drug and Cosmetic Act (FDCA). (#17) at 3. It is undisputed that Essure was a Class III medical device. Such devices are subject to pre-market approval by the FDA. As such, they are subject to the Medical Device Amendments of 1976 ("MDA") to the FDCA. See 21 U.S.C. § 360k(a).

The Complaint is replete with references to the FDA. Federal oversight of the Bayer defendants is a necessary part of this case, and plaintiff raises the question of the Bayer defendants' duties under the FDCA, as amended by the MDA, and whether they complied with such responsibilities. Accordingly, the plaintiff's Complaint necessarily

raises federal issues, particularly agency action and the MDA, and the actions of the Bayer defendants and health providers under such federal oversight are the subject of this and the related suit.

In objecting to the application of federal jurisdiction, the plaintiff relies, in large part, upon cases that do not bind this court. See Johnson v. Bayer Corp., No. 4:16-CV-729 (CEJ), 2016 WL 3015187, at *1 (E.D. Mo. May 26, 2016), appeal dismissed (Aug. 29, 2016); Rios v. Bayer Corp., No. 16-CV-1010-SMY-RJD, 2016 WL 5929246, at *2 (S.D. Ill. Oct. 12, 2016).

In one case, currently on appeal to the Seventh Circuit, a court applied that Circuit's federal question jurisdictional test to find that the allegation that defendants' conduct "violates the FDCA and consideration of federal regulations may indeed be involved in the disposition of this action, those facts alone are insufficient to create federal question jurisdiction." Rios, 2016 WL 5929246, at *2. The court respectfully disagrees. The Rios court focused on the fact that the FDCA did not create a cause of action. Id. Subsequent to the Supreme Court ruling cited in Rios, and as explained above, there are two pathways that cases can be brought under federal question jurisdiction. In Rios, like here, there is no cause of action under the FDCA. However, there is a second way, the plaintiff's right to relief could necessarily arise out of federal law. See Merrill Lynch, supra. Accordingly, the analysis should not begin and end with the question of whether the federal law creates a cause of action; instead, under the Supreme Court's

more recent guidance, courts must look to whether federal law is necessarily implicated. The answer here is yes.

The MDA, as noted in 21 U.S.C. § 360k, provides the federal government with exclusive authority over the safety and effectiveness of medical devices, subject to the exemptions noted in that law. The federal law reads:

> **(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

21 U.S.C. § 360(k)(a).[3] The law is implicated here clearly. In order to succeed, the plaintiff must demonstrate that the device or defendants' conduct deviated from prevailing law. In the case of the device's marketing and manufacture, those relevant laws are federal in nature. Accordingly, they are implicated here and in dispute.

B. Substantial and Able to be Decided Without Disrupting the Federal-State Balance

[3] The court notes plaintiff's contention that Johnson covers the "exact same arguments" and "same exact theories" as in this case. (#17) at 4. The Johnson court found that the plaintiffs' claim in that case "must be for conduct that violates the FDCA" and that the "federal issues in the complaint were necessarily raised and are actually disputed." Johnson, 2016 WL 3015187, at *3.

Plaintiff cites to a case from the Eastern District of Missouri for the proposition that the issues in this case are not "substantial" and would upset the federal-state balance. In that case, Johnson v. Bayer Corp., the court's colleague elsewhere on the federal bench noted that the issues involved with that suit related to Essure were related to the MDA and FDCA and actually in dispute. 2016 WL 3015187, at *3. The court reasoned that it was not "substantial" as "Congress specifically declined to create a federal private cause of action under the FDCA." Johnson, 2016 WL 3015187, at *3. Moreover, the Johnson court reasoned that Congress "declined to preempt all state remedies or divest state courts of jurisdiction in the FDCA" and as such the adjudication of state law claims would "disrupt the federal-state balance approved by Congress." Id.

The court is guided by later Supreme Court precedent, which explicitly rejected the dispositive reading of earlier case law. See Grable at 318 ("Accordingly, *Merrell Dow* should be read in its entirety as treating the absence of a federal private right of action as evidence relevant to, but not dispositive of, the "sensitive judgments about congressional intent" that § 1331 requires."). If the Supreme Court *actually* intended there to be two pathways to federal question jurisdiction (federally-created or "arising from" federal law), it simply cannot be that the lack of a federal cause of action would foreclose the second pathway. The lack of a private, federally-created cause of action may be a "clue" to Congressional intent behind § 1331, but it is far from dispositive if the second pathway ("arising from" federal law) is to be of any real-world application. See Grable at 318.

With regard to the federal-state balance, Congress in this case passed the MDA, explicitly pre-empting state law as a general rule. It would be farcical to override that explicit Congressional act with the implicit notion that § 1331 was written with FDA-approved medical devices like Essure in mind. In setting up the MDA, Congress acted with the intent that medical devices would be regulated exclusively by the FDA and state law would be generally preempted. See 21 U.S.C. § 360k. Accordingly, it would not upset the federal-state balance to have such claims be brought in federal court, as FDA-approved Class III devices require pre-market approval under the MDA as to their safety and effectiveness.

The crux of the plaintiff's Complaint here, as it is in her husband's related case, was that the medical device was *not safe*, they were not warned of the attendant risks, it was manufactured inappropriately, and it was marketed using unfair trade practices. As one of many examples from the Complaint, it is argued that "[u]nder federal law and regulations, the Bayer defendants were under a continuing duty to comply with the requirements listed…and with the FDCA in the manufacture, development, promotion, marketing, labeling, and sale of Essure." Complaint (#1-2) at ¶ 197. Federal law governs those duties, under the MDA, and the FDA has authority to regulate products like Essure, as it did when it inspected the Bayer's manufacturing facilities and issued a Black Box Warning. See Complaint (#1-1) at ¶ ¶89-105, 132. Indeed, plaintiff's Complaint (#1-1) itself notes that the "FDCA requires medical device manufacturers like the Bayer

defendants to maintain and submit information as required by FDA regulation…including submitting Adverse Reaction Reports…and establishing internal procedures for reviewing complaints and event reports, 21 C.F.R. § 820.198(a)." Id. at ¶ 55. Moreover, the plaintiff's Complaint (#1-1) alleges that the Bayer defendants had a duty to reasonably warn the users of the product about the risks involved and that the failure to meet relevant federal obligations violated state law. Id. at ¶ 57.

The labeling of FDA-approved medical devices is governed by the FDA under the MDA, and state law is generally pre-empted under 21 U.S.C. § 360k. It does not upset the federal-state balance to allow federally-approved medical devices to be sued for alleged safety risks and labeling defects in federal court. Further, the dispute is indeed substantial as it challenges the federal oversight of Class III medical device products and the fact that there is no private right of action under the FDCA is not dispositive.

IV. Conclusion

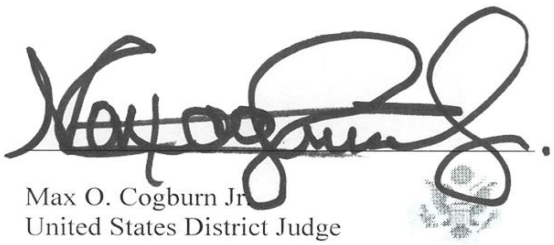
Upon review of the Supreme Court's four-part test, as articulated in Gunn, the case presently before the court meets the standard to be adjudicated in federal court under federal question jurisdiction. It is properly a case that "arises from" federal law, as the MDA was passed by Congress to govern the safety and effectiveness of Class III medical devices, like Essure. See 21 U.S.C. § 360k. Accordingly, remand would be inappropriate. Both this and the coordinate case, 1:17-cv-32, could be properly brought in federal court as the face of the complaint "arises from" federal law—the FDCA as amended by the

MDA—and raises a substantial federal question under § 1331. See Battle 288 F.3d at 606-07.

ORDER

IT IS, THEREFORE, ORDERED that plaintiff's Motion to Remand (#16) is **DENIED.**

Signed: March 17, 2017



Max O. Cogburn Jr
United States District Judge