UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

DENNIS BRIAN ANDERS, et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	No. 4:14CV00194 ERW
	)	
MEDTRONIC, INC., MEDTRONIC SOFAMOR DANEK USA, INC., and DOES 1 – 100.	)	
	)	
Defendants.	)	

MEMORANDUM AND ORDER

This matter comes before the Court on Plaintiffs Dennis Brian Anders, Lara Anders, Regina Autrey, Diana Banks-Joiner, Catherine Barbee, Mark Barbee, Eula Berry, Linda Betcher, Sheila Bottorf, Margaret Brown, Eddie Brown, Bradley Burdette, Westley Christian, Tracy Christian, Lisa Conroy, Jeffrey Conroy, Linda Coombs, Donald Coombs, Carolyn Davis, Rickey Davis, Joseph Dressler, Jr., Mark Durand, Tracie Durand, Angela Edwards, Michael Heller, John Fairley, Clara Bridget-Fairley, John Fowler, Jennifer Fowler, Leslie Foxworth, Karen Freeman, Mell Furman, Richard Furman, Julia Gabino, Clifton Groves, Horace Harshaw, Ronald Hatchell, Sondra Hatcher, Jason Hatcher, Cynthia Hatcher, Anthony Hawkins, Delores Hawkins, Jerome Hicks, Tammy Jeans, Jason Jeans, Lorenzo Johnson, Marion Johnson, Amanda Keeton, Trisha Keim, Wesley Kercheval, Douglas Kolhoff, Jason Kost, Molly Savage-Kost, Walter Lacroix, Steven Lenhart, Tammy Jones-Lenhart, Mark Lester, Mozell Lynch, Mayme Martin, Sophronia McCord, Gwendolyn Menard, Joseph Fleming, Dennis Mojica, Grismilda Mojica, William Muirhead, Jenny Muirhead, Juvenal Nieves, Caldonia Patrick, Donna Poole, Joey Poole, Lerisce Powell, Erick Powell, Doris Randle, Walter Randle, Jr., Eddie Roberson, Jessica Roberson,

Kendra Williams Russell-El, John Russell-El, Jennifer Shanedling, Sharon Sharp, Scott Shepherd, Tammy Lynn Shepherd, Stephen Sparagno, Margie Sparagno, Wilbur Spaulding, Richard Steinman, Jr., Sandra Steinman, Dellarine Takieddine, Cynthia Taylor, Linda Tinney, James Tinney, Trevor Towne, Reggie Waddle, Barbara Waddle, Sheryl Jacqueline Whitmire, Daniel Williams, Leah Winzer, Christopher Winzer, and Thomas Yellowwolf, Jr.'s Motion to Remand [ECF No. 49].

I. BACKGROUND

On December 26, 2013, Plaintiffs filed a Petition against Defendants Medtronic, Inc., Medtronic Sofamor Danek USA, Inc., and Does 1 through 100[1] in the Circuit Court of the City of St. Louis, Missouri. The Petition alleges injuries related to the Infuse® Bone Graft and LT Cage® Device (Infuse®), a medical device designed, manufactured, and sold by Defendants.

Infuse® is a "Class III" device, that is, a device "that presents a potentially unreasonable risk of injuring patients or that is used to sustain life." *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1203 (8th Cir. 2010) (citing 21 U.S.C. § 360c(a)(1)(C)). Class III devices are approved by the United States Food and Drug Administration (FDA) through a rigorous Premarket Approval (PMA) process, after assurances from the manufacturer that the device is safe and effective. *Id.* The PMA process typically involves a "multivolume application," including, among other things, "full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant," "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device," and "a

[1] Does 1 through 100 represent unknown employees and agents of the other co-defendants.

specimen of the proposed labeling." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 318 (2008) (citing 21 U.S.C. § 360e(c)(1)) (internal quotations omitted).

According to Plaintiffs, the FDA has approved Infuse® for spinal fusion surgeries performed from an anterior approach at specific levels of the spine. The Petition alleges Defendants engaged in a fraudulent marketing and promotional scheme to advertise illegal and dangerous uses of Infuse®. Plaintiffs claim, as a result of Defendants' fraudulent conduct, they underwent surgeries in which Infuse® was used in certain "off label," or unauthorized, ways, causing various injuries. The Petition asserts fifteen state law causes of action: (1) negligence, (2) negligence per se, (3) negligent misrepresentation, (4) strict liability for failure to warn, (5) strict liability for a design defect, (6) strict liability for a manufacturing defect, (7) common law fraud, (8) constructive fraud, (9) fraudulent concealment, (10) breach of express warranty, (11) breach of implied warranty, (12) violation of consumer protection laws, (13) violation of the Missouri Merchandising Practices Act, (14) loss of consortium, and (15) gross negligence, seeking punitive damages. Of the 99 individuals named as Plaintiffs in the Petition, 98 are diverse from Defendants. Defendant Medtronic, Inc. is incorporated under the laws of, and maintains its principal place of business in, Minnesota. One Plaintiff, Jennifer Shanedling, is a citizen of Minnesota and therefore nondiverse from Defendant Medtronic, Inc.[2]

On February 3, 2014, Defendants filed a Notice of Removal with this Court, asserting diversity jurisdiction under 28 U.S.C. § 1332, and federal question jurisdiction under 28 U.S.C. § 1331. The Notice of Removal states the citizenship of the single nondiverse Plaintiff should be

[2] The Court notes the Petition alleges the residence, not state citizenship, of each Plaintiff. "An averment of residence is not the equivalent of an averment of citizenship, for purposes of jurisdiction in the courts of the United States." *Texaco-Cities Serv. Pipe Line v. Aetna Casualty & Surety Co.*, 283 F.2d 144, 145 (8th Cir. 1960). Here, however, the Court ultimately finds remand to be appropriate, even assuming the parties had properly alleged citizenship. Therefore, the Court will disregard this oversight for purposes of the instant Motion.

disregarded under the doctrine of fraudulent misjoinder. In addition, it states this case involves substantial questions of federal law, warranting the Court's exercise of federal question jurisdiction. Plaintiffs now move to remand this case to the Circuit Court of the City of St. Louis.

II. STANDARD

A defendant may remove a case to federal court only if the claim could have been originally brought in federal court. 28 U.S.C. § 1441; *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 808 (1986). Generally, the party seeking removal and opposing remand bears the burden of establishing federal subject matter jurisdiction. *In re Business Men's Assurance Co. of Am.*, 992 F.2d 181, 183 (8th Cir. 1993). The party asserting federal diversity jurisdiction has the burden of proving diversity by a preponderance of the evidence. *In re Prempro Prods. Liab. Litig.*, 591 F.3d 613, 620 (8th Cir. 2010). Additionally, "[t]he presence or absence of federal-question jurisdiction is governed by the 'well-pleaded complaint rule,' which provides that federal jurisdiction exists only when a federal question is presented on the face of the plaintiff's properly pleaded complaint." *Caterpillar Inc. v. Williams*, 482 U.S. 386, 392 (1987). "All doubts about federal jurisdiction should be resolved in favor of remand to state court." *Prempro Prods. Liab. Litig.*, 591 F.3d at 620.

III. DISCUSSION

Defendants contend federal subject matter jurisdiction is proper within this Court for two reasons. First, Defendants argue the Court has diversity jurisdiction, because the single nondiverse Plaintiff was fraudulently misjoined. Second, Defendants maintain the Court has federal question jurisdiction, because this case involves substantial questions of federal law. For reasons stated *infra*, the Court finds it lacks jurisdiction, and the case will be remanded.

A. Diversity Jurisdiction

Defendants contend the Court should ignore the citizenship of Plaintiff Shanedling for purposes of determining diversity jurisdiction, because she was fraudulently misjoined. Defendants state Plaintiff Shanedling was joined in a deliberate attempt to avoid federal jurisdiction. They argue her claims have no real connection with the instant controversy, because the various 99 Plaintiffs have claims arising out of different states, injuries, times, diagnoses, and uses of Infuse®.

Federal courts may exercise diversity jurisdiction over nondiverse parties if there has been fraudulent misjoinder, a doctrine the Eighth Circuit has neither accepted nor rejected. *Tapscott v. MS Dealer Serv. Corp.*, 77 F.3d 1353, 1360 (11th Cir. 1996), *abrogated on other grounds by Cohen v. Office Depot, Inc.*, 204 F.3d 1069 (11th Cir. 2000); *Prempro Prods. Liab. Litig.*, 591 F.3d at 622. Fraudulent misjoinder occurs when a claim involving nondiverse parties has no reasonable procedural basis, because the misjoined claim has "no real connection with the controversy involving the claims that would qualify for diversity jurisdiction." *Prempro Prods. Liab. Litig.*, 591 F.3d at 620 (quoting Ronald A. Parsons, Jr., *Should the Eighth Circuit Recognize Procedural Misjoinder?*, 53 S.D. L. REV. 52, 57 (2008)). Whether a party has been fraudulently misjoined depends on whether there has been an "egregious and grossly improper" joinder "under the broadly-interpreted joinder standards." *Id.* at 624.

As the Honorable Carol Jackson stated in a nearly identical case, "[e]ven assuming that fraudulent misjoinder is a valid basis for jurisdiction, [D]efendants have failed to demonstrate that the joinder of the Minnesota . . . [P]laintiff[] in this action borders on a sham." *Smith v. Medtronic, Inc.*, No. 4:13CV2220 CEJ (E.D. Mo. Apr. 4, 2014) (internal quotations omitted); ECF No. 57-1 at 4. Admittedly, adjudicating the claims of the 99 Plaintiffs will require

resolution of some disparate factual and legal issues. However, each of 99 Plaintiffs involve the same product, Infuse®, and the same alleged illegal marketing scheme. Therefore, Plaintiffs' asserted rights to relief arise out of the same transaction of occurrences, and common questions of law and fact are likely to arise in this action. *See* Fed. R. Civ. P. 20(a). Under these facts, the Court finds Plaintiff Shanedling's joinder far from "egregious." Fraudulent misjoinder does not serve as a basis for federal jurisdiction in this case.[3]

B. Federal Question Jurisdiction

Defendants argue this Court has jurisdiction under 28 U.S.C. § 1331, because adjudicating Plaintiffs' claims would require resolution of substantial, disputed federal questions. Defendants contend, to prevail, Plaintiffs must prove a violation of federal law, because § 360k(a) of the Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 360c, *et seq.*, preempts any state requirement "which is different from, or in addition to," the requirements imposed by the FDCA. Defendants aver Plaintiffs' right to relief depends on the resolution of several substantial federal questions, concerning the scope of FDA approval and the application of § 360k(a).

For purposes of 28 U.S.C. § 1331, a case "arises under" federal law either where (1) "federal law creates the cause of action," or (2) "where the vindication of a right under state law necessarily turn[s] on some construction of federal law." *Merrell Dow Pharm. Inc.*, 478 U.S. at 808-09 (internal quotations omitted). The question whether a claim "arises under" federal law for purposes of federal question jurisdiction must be determined by reference to the "well-

[3] Nor will the Court sever the claims of Plaintiff Shanedling under Federal Rule of Civil Procedure 21, as Defendants suggest. Defendants have failed to establish Plaintiff Shanedling was misjoined. Moreover, they have failed to explain why Plaintiff Shanedling's claims should be severed any more than other Plaintiffs in this case. The Court will not sever her claims merely to usurp diversity jurisdiction where it does not otherwise exist.

pleaded complaint." *Id.* at 808. Where, as here, federal law does not create a private cause of action, "[f]ederal question jurisdiction is available only where (1) the right to relief under state law depends on the resolution of a substantial, disputed federal question, and (2) the exercise of jurisdiction will not disrupt the balance between federal and state jurisdiction adopted by Congress." *Pet Quarters, Inc. v. Depository Trust & Clearing Corp.*, 559 F.3d 772, 779 (8th Cir. 2009) (citing *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 313-14 (2005)). For reasons discussed *infra*, the Court concludes Defendants have failed to satisfy either of these prongs, and the case will be remanded.

1. Resolution of a Substantial, Disputed Federal Question

Defendants argue substantial questions of federal law will necessarily arise, because Plaintiffs must prove FDCA violations to prevail. Defendants state adjudication of this case will require a threshold determination of whether the FDCA prohibits off-label promotion of Infuse®, and other interpretations of federal law. Noting various portions of Plaintiffs' Petition allege violations of federal statutes and regulations, Defendants maintain these federal questions are "substantial," particularly because this case will affect other lawsuits involving allegations that off-label promotion falls outside the preemption clause of § 360k(a).

MDA § 360k(a) provides,

> [N]o 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.

While this provision preempts state laws "different from, or in addition to" federal requirements, "§ 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." *Riegel*, 522 U.S. at 330. "In other words, for a state-law claim to survive express preemption under § 360k(a), [P]laintiffs 'must be suing for conduct that *violates* the FDCA[.]'" *Pinsonneault v. St. Jude Med., Inc.*, 953 F. Supp. 2d 1006, 1013 (D. Minn. 2013) (quoting *In re Medtronic*, 623 F.3d at 1204) (emphasis in original).

Because of § 360k(a), Defendants contend Plaintiffs must prove violations of federal law to prevail, and, as a result, their case necessarily involves substantial questions of federal law. This argument, however, overlooks *Merrell Dow Pharmaceuticals Inc. v. Thompson*, in which the Supreme Court found no substantial question of federal law where plaintiffs alleged a defendant drug manufacturer misbranded a pharmaceutical in violation of the FDCA. 478 U.S. 804, 805-06, 814 (1986). The Court noted the plaintiffs had incorporated the alleged FDCA violations to show a rebuttable presumption of their state law claim of negligence. *Id.* at 805. Notwithstanding this incorporation, the Court held "the presence of the federal issue as an element of a state tort is not the kind of adjudication for which jurisdiction would serve congressional purposes and the federal system." *Id.* at 814. It explained the absence of a private cause of action in the FDCA indicated "a congressional conclusion that the presence of a claimed violation of the statute as an element of the state cause of action is insufficiently 'substantial' to confer federal-question jurisdiction." *Id.*

Defendants take issue with reliance on *Merrell Dow*, because it pre-dates *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308 (2005). *Grable & Sons*, however, did not overrule *Merrell Dow*, which has been favorably cited by various courts in post-*Grable & Sons* cases. *See, e.g., Glanton v. Harrah's Entm't, Inc.*, 297 Fed. Appx. 685, 686-87 (9th Cir. 2008) (relying on *Merrell Dow* to hold federal subject matter jurisdiction did not exist where plaintiff alleged violations of federal regulations in his state constructive discharge

claim); *Mikulski v. Centerior Energy Corp.*, 501 F.3d 555, 566-68 (6th Cir. 2007) (explaining how the Supreme Court "reconcile[d]" *Merrell Dow* with its holding in *Grable & Sons*); *Bennett v. Sw. Airlines Co.*, 484 F.3d 907, 908-10, 912 (7th Cir. 2007) (largely relying on *Merrell Dow* to conclude case did not "arise under" federal law where plaintiffs alleged violations of federal aviation standards in their state tort claims).

Moreover, the holding in *Grable & Sons* was "not . . . contrary" to *Merrell Dow*. *Grable & Sons*, 545 U.S. at 316. In *Grable & Sons*, the Supreme Court held § 1331 jurisdiction existed where the plaintiff filed a state quiet title action, alleging the Internal Revenue Service failed to comply with federal notice requirements when it seized and sold the plaintiff's land. *Id.* at 314-15. The Court explained the meaning of a federal notice statute "appear[ed] to be the only legal or factual issue contested in the case." *Id.* at 315. Distinguishing *Merrell Dow*, the Court stated, "*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." *Id.* at 318 (quoting *Merrell Dow*, 478 U.S. at 810). Helpfully, the Court described the *Merrell Dow* decision as follows:

> The Court saw the missing cause of action not as a missing federal door key, always required, but as a missing welcome mat, required in the circumstances, when exercising federal jurisdiction over a state misbranding action would have attracted a horde of original filings and removal cases raising other state claims with embedded federal issues. For if the federal labeling standard without a federal cause of action could get a state claim into federal court, so could any other federal standard without a federal cause of action. And that would have meant a tremendous number of cases.

Id.

In contrast, the claims in *Grable & Sons* warranted a different outcome. *Id.* at 319. Notwithstanding the absence of a private cause of action, the Court found, "[I]t is the rare state quiet title action that involves contested issues of federal law[.]" *Id.* Ultimately, the Court held,

> Given the absence of threatening structural consequences and the clear interest the Government, its buyers, and its delinquents have in the availability of a federal forum, there is no good reason to shirk from federal jurisdiction over the dispositive and contested federal issue at the heart of the state-law title claim.

Id. at 319-20. In a subsequent case, the Court described *Grable & Sons* as exemplifying a "slim" category of cases; *Grable & Sons* "emphasized that it takes more than a federal element 'to open the 'arising under' door.'" *Empire Healthchoice Assurance, Inc. v. McVeigh*, 547 U.S. 677, 701 (2006) (quoting *Grable & Sons*, 545 U.S. at 313).

In light of this framework, the Court is persuaded *Merrell Dow* remains good law. Aside from the vitality of *Merrell Dow*, however, Defendants contest its applicability here. Noting § 360k(a) applies only to medical devices, not prescription drugs, Defendants argue *Merrell Dow* is inapposite, because § 360k(a) did not compel the plaintiffs in that case to avoid preemption by alleging federal violations. The Court is not persuaded by this line of reasoning. As the Honorable Ortrie Smith stated when confronted with the same argument, "[T]here is no authority suggesting that *Merrell Dow* depends on this distinction – or, for that matter, that the jurisdictional analysis depends on this distinction. The distinction is, in short, meaningless." *Goade v. Medtronic, Inc.*, No. 13-5123-CV-SW-ODS, 2013 WL 6237853, at *5 (W.D. Mo. Dec. 3, 2013). In fact, under Defendants' theory, all state claims "parallel" to the federal requirements would raise substantial federal questions.

In sum, the Court concludes Plaintiffs' Petition fails to raise substantial issues of federal law, precluding § 1331 jurisdiction. This conclusion is amply supported by the cogent reasoning and factual similarities of *Merrell Dow*, the absence of a federal private cause of action, Congress's preservation of parallel state law claims in § 360k(a), and the deluge of state claims that would find their way to federal court if § 1331 jurisdiction existed here. This case does not

fit within the "slim" *Grable & Sons* category, and the Court will therefore grant Plaintiffs' Motion to Remand.

2. Disruption of Balance Between State and Federal Jurisdiction Adopted by Congress

Even if Plaintiffs' Petition presented substantial federal questions, exercising jurisdiction would disrupt the balance between state and federal jurisdiction adopted by Congress. As the Honorable Carol Jackson stated when addressing a nearly identical motion,

> Congress specifically declined to create a federal cause of action under the FDCA. Congress also declined to preempt all state remedies or divest state courts of jurisdiction. The combination of no federal cause of action and no preemption of all state remedies, while not dispositive, is 'an important clue to Congress's conception of the scope of jurisdiction to be exercised under § 1331.' *Grable*, 545 U.S. at 318 (discussing *Merrell Dow*, 478 U.S. 804 (1986)).

Smith v. Medtronic, Inc., No. 4:13CV2220 CEJ (E.D. Mo. Apr. 4, 2014); ECF No. 57-1 at 8. Additionally, the Court is not persuaded by Defendants' argument that "[o]nly a tiny proportion of a small fraction of medical-device cases fall within the narrow category of federal interest present here[,]" because few medical devices are designated Class III devices. ECF No. 53 at 14. Rather, "Defendants' legal analysis would not be confined to Class III medical devices. It would apply, minimally, to all medical devices, and arguably would apply further." *Goade*, 2013 WL 6237853, at *6. Accordingly, the case must be remanded.

C. Fees and Costs

Finally, Plaintiffs request costs pursuant to 28 U.S.C. § 1447(c), which permits the Court to "require payment of just costs and any actual expenses, including attorney fees, incurred as a result of . . . removal." The Court may award fees "only where the removing party lacked an objectively reasonable basis for seeking removal. Conversely, when an objectively reasonable basis exists, fees should be denied." *Martin v. Franklin Capital Corp.*, 546 U.S. 132, 141

(2005). Here, Defendants clearly had objectively reasonable bases for disputing § 1331 jurisdiction; the parties on both sides presented strong arguments on this matter. Plaintiffs' request for costs is denied.

Accordingly,

IT IS HEREBY ORDERED that Plaintiffs' Motion to Remand [ECF No. 49] is **GRANTED**, except to the extent it seeks costs under 28 U.S.C. § 1447(c).

IT IS FURTHER ORDERED that the Clerk of the Court shall remand this action to the Circuit Court of the City of St. Louis, Missouri, from which it was removed.

Dated this 24th Day of April, 2014.

E. RICHARD WEBBER
SENIOR UNITED STATES DISTRICT JUDGE