

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

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GLORIA JOHNSON, et al.)	
)	
Plaintiffs,)	Case No. _____
)	
v.)	Judge _____
)	
BAYER, CORP., BAYER HEALTHCARE)	
LLC., BAYER ESSURE, INC., (F/K/A)	JURY TRIAL DEMANDED
CONCEPTUS, INC.), BAYER)	
HEALTHCARE PHARMACEUTICALS,)	
INC., BAYER A.G,)	
)	
Defendants.)	
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NOTICE OF REMOVAL

Defendants Bayer Corporation, Bayer Essure Inc., Bayer HealthCare LLC, and Bayer HealthCare Pharmaceuticals Inc. (together, “Bayer”) by and through their undersigned counsel, hereby provide notice pursuant to 28 U.S.C. §§ 1331, 1332, 1441, and 1446 of the removal of the above-captioned case from the Circuit Court of the City of St. Louis (the “Circuit Court”), to the United States District Court for the Eastern District of Missouri, Eastern Division. The grounds for removal are as follows:

1. On or about April 13, 2016, 92 Plaintiffs from 30 different states and the District of Columbia filed a Petition for Damages (“Petition”) in the Circuit Court for the City of St. Louis in this civil action styled *Johnson, et al. v. Bayer Corp., et al.* The Petition alleges that Plaintiffs suffered various injuries as a result of their individual experiences using Essure, an

FDA-approved Class III medical device that serves as a form of permanent female birth control. *See* Ex. A (Petition for Damages).¹

2. Essure was approved by FDA through the rigorous premarket approval (“PMA”) process in 2002. Ex. B (Premarket Approval Order). Since then, FDA has granted numerous supplemental approvals, including as recently as June 2015, *see* Ex. C (FDA website noting PMA Supplements), repeatedly reviewing and approving Essure’s design, construction, manufacturing, testing, training requirements, warnings, instructions for use, patient information, and all other labeling.

3. After a public hearing in September and months of investigation, FDA recently reaffirmed that “FDA believes Essure remains an appropriate option for the majority of women seeking a permanent form of birth control.” Ex. D (FDA News Release (Feb. 29, 2016), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm488313.htm>).

4. In addition to this Notice of Removal, Bayer will file a Motion to Dismiss and Motion to Sever. The Motion to Dismiss will demonstrate that this Court should dismiss the claims of the non-Missouri Plaintiffs for lack of personal jurisdiction and under the doctrine of forum non conveniens, and that the Court should dismiss all of Plaintiffs’ claims as preempted and inadequately pled. The Motion to Sever will show that Plaintiffs’ claims should be severed because they are misjoined.

5. As set forth more fully below, this case is properly removed because this Court has both diversity jurisdiction and federal question jurisdiction. First, this Court has diversity jurisdiction because the amount in controversy with respect to each Plaintiff exceeds \$75,000

¹ On April 28, 2016, Bayer removed a similar 32-plaintiff case to this Court from the City of St. Louis. *See* Notice of Removal, *Dorman v. Bayer Corp.*, 4:16-cv-00601, ECF Doc. 1.

and complete diversity of citizenship exists between the proper Plaintiffs and Defendants.

Although 11 of the 92 Plaintiffs—Sophia Yates, Natalie Palka, Marlen Vega, Jerri Leers, Carrie Allegratti, Yesenia Del Valle, Lisa DeLorenzo, Kristinia Gonzalez, Ashley B. Thomas, Jennifer Kerrigan, and Robin Wronski—allege that they are citizens of states in which a Defendant is incorporated or has its principal place of business, their joinder does not defeat complete diversity. To the contrary, this Court should exercise its discretion to consider and grant Bayer’s forthcoming Motion to Dismiss the claims of these non-Missouri Plaintiffs for lack of personal jurisdiction or under the forum non conveniens doctrine before determining whether complete diversity exists. Once this Court dismisses the claims of the non-diverse Plaintiffs, there is complete diversity between the remaining Plaintiffs and Defendants.

6. Alternatively, if this Court considers subject matter jurisdiction before considering Bayer’s Motion to Dismiss—which it need not and should not do, *see, e.g., Ruhrgas AG v. Marathon Oil Co.*, 526 U.S. 574, 588 (1999)—this Court should ignore the citizenship of the 11 non-diverse Plaintiffs because they are fraudulently joined and misjoined.

7. Second, this Court also has federal question jurisdiction. This case involves a medical device that was approved by FDA after receiving the highest level of scrutiny available in the federal regulatory system. Only 1% of medical devices receive this rigorous federal approval. In addition, Essure has been subject to ongoing, intense review by the FDA, which included public hearings addressing the same federal regulatory issues that form the premise of this lawsuit. Plaintiffs plead violations of federal law on the face of their Petition. And, although they also assert state-law claims, Plaintiffs’ right to relief turns on resolution of the federal-law questions, and the exercise of federal question jurisdiction here will not disrupt the balance between state and federal jurisdiction, in light of the extraordinary federal involvement

in the very issues that are at the heart of this case. *See, e.g., Pet Quarters, Inc. v. Depository Trust & Clearing Corp.*, 559 F.3d 772, 779 (8th Cir. 2009).

I. THE PROCEDURAL REQUIREMENTS OF REMOVAL ARE MET.

8. Pursuant to 28 U.S.C. § 1446(a) and E.D. Mo. L.R. 2.03, true and correct copies of all process, pleadings, orders and other documents filed in the state court action are attached as Exhibit A.

9. Plaintiffs' Petition was served on Bayer HealthCare LLC and Bayer Healthcare Pharmaceuticals Inc., on April 20, 2016, and on Bayer Corporation and Bayer Essure Inc., on April 25, 2016. Accordingly, this Notice of Removal is timely under 28 U.S.C. § 1446(b)(1), which requires a notice of removal to be filed within 30 days of the service of a complaint upon the defendants. *See Murphy Bros., Inc. v. Michetti Pipe Stringing, Inc.*, 526 U.S. 344, 354 (1999) (30-day time limit for removal runs from date of formal service of the initial complaint).

10. Defendant Bayer AG has not yet been served in this matter. Nevertheless, all Defendants—each of which is represented by the undersigned—join in or consent to this Notice of Removal. *See* 28 U.S.C. § 1446(b)(2).²

11. The United States District Court for the Eastern District of Missouri, Eastern Division, presides in the locality in which the state court action is now pending. It is therefore a proper forum for removal. *See* 28 U.S.C. §§ 105(a)(1), 1441(a).

² Bayer AG which has not been served and which is represented by the undersigned, consents in this removal, but respectfully reserves all other rights. *See City of Clarksdale v. BellSouth Telecomm'ns., Inc.*, 428 F.3d 206, 214 n.15 (5th Cir. 2005) (“A defendant’s removal to federal court does not waive its right to object to service of process.”); *Rogers v. Amalgamated Transit Union Local 689*, 98 F. Supp. 3d 1, 5 (D.D.C. 2015) (unserved defendant who consented to removal did not waive objection to service of process); 14C Wright & Miller, et al., *Federal Practice and Procedure* § 3738 (4th ed. 2009) (“[D]efendants do not waive any defense by removing a case to federal court.”).

12. No Defendant is a citizen of the State of Missouri, the state where this action was brought. *See id.* § 1441(b)(2).

13. A copy of this Notice of Removal is being served on Plaintiffs, and a copy is being filed with the Circuit Court for the City of St. Louis, Missouri. *See id.* § 1446(d).

14. If any questions arise about this removal, Bayer respectfully requests the opportunity to present briefing and oral argument in support of removal.

II. REMOVAL IS PROPER BECAUSE THIS COURT HAS SUBJECT MATTER JURISDICTION PURSUANT TO 28 U.S.C. §§ 1332 AND 1441.

15. A defendant may remove an action from state court to federal court if the action could have been brought originally in federal court. *See* 28 U.S.C. § 1441. Here, federal jurisdiction exists based upon diversity of citizenship pursuant to 28 U.S.C. § 1332, because this is a civil action between citizens of different states, and it is facially apparent that the amount in controversy with respect to each plaintiff exceeds the sum of \$75,000, exclusive of interest and costs. *See id.* § 1332(a); *see also OnePoint Solutions, LLC v. Borchert*, 486 F.3d 342, 346 (8th Cir. 2007).

A. The Amount-In-Controversy Exceeds \$75,000.

16. Although Plaintiffs do not specifically allege the amount of damages in their complaint, it is “facially apparent” that the damages sought, including any punitive damages, with respect to each of the Plaintiffs exceed \$75,000. *See* 28 U.S.C. § 1446(c)(2); *e.g., Kina v. Mindland Funding, LLC*, 2015 WL 5487357, at *2 (E.D. Mo. Sept. 16, 2015) (quoting *Allen v. R & H Oil & Gas Co.*, 63 F. 3d 1326, 1336 (5th Cir. 1995)); *Hollenbeck v. Outboard Marine Corp.*, 201 F. Supp. 2d 990, 994 (E.D. Mo. 2001); *see also Allison v. Sec. Benefit Life Ins. Co.*, 980 F.2d 1213, 1215 (8th Cir. 1992) (“Punitive damages are included in determining the amount in controversy.”).

17. Plaintiffs allege that they have experienced a wide variety of injuries, including device migration, hysterectomy, abdominal pain, pelvic pain, back pain, perforated organs, and autoimmune issues such as Hashimoto's disease. Petition ¶ 141.

18. Further, in support of their request for punitive damages, Plaintiffs allege that Bayer knew Essure was dangerous and ineffective, withheld information from Plaintiffs, their physicians, the medical community, and the public at large. *See id.* ¶¶ 211-14. Courts have found the amount in controversy satisfied in similar cases, in which plaintiffs have asserted similar injuries, alleged similar degrees of pain, and requested punitive damages. *See, e.g., In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, 2007 WL 2572048, at *5 (D. Minn. Aug. 30, 2007) (amount-in-controversy requirement satisfied where plaintiff alleged serious injuries from medical device and sought punitive damages and other plaintiffs alleging injuries from same device plead damages in excess of \$75,000).³

19. Moreover—although Bayer denies that any relief is warranted—Missouri juries routinely award compensatory damages in excess of \$75,000 in product liability cases where liability is found, further supporting the conclusion that the jurisdictional minimum requirement is satisfied. *See, e.g., Foster v. Catalina Indus., Inc.*, 55 S.W.3d 385, 389 (Mo. Ct. App. 2001); *Cole v. Goodyear Tire & Rubber Co.*, 967 S.W.2d 176, 179, 182 (Mo. Ct. App. 1998).

³ *See, e.g., In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prod. Liab. Litig.*, 692 F. Supp. 2d 1025, 1040 (S.D. Ill. 2010) (“Given the severe and ongoing nature of the injuries alleged, the court finds that it is plausible and supported by the preponderance of the evidence that the amount in controversy has been established.”), *aff’d sub nom.* 643 F.3d 994 (7th Cir. 2011); *In re Rezulin Prods. Liab. Litig.*, 133 F. Supp. 2d 272, 296 (S.D.N.Y. 2001) (complaint alleging various injuries from prescription drug “obviously” met amount-in-controversy requirement).

20. Thus, given the nature of Plaintiffs' alleged injuries, the scope of damages sought, and the lack of any express limitation on the amount of damages sought, each Plaintiff's claim plainly satisfies the jurisdictional amount requirement.

B. Complete Diversity Of Citizenship Exists.

21. There is complete diversity of citizenship between the proper parties.

22. Defendant Bayer Corporation is an Indiana corporation with its principal place of business in Pennsylvania. Petition ¶ 94. Thus, for diversity purposes, it is a citizen of Indiana and Pennsylvania. *See* 28 U.S.C. § 1332(c).

23. Plaintiffs allege that Defendant Bayer HealthCare LLC is incorporated in Delaware, that its principal place of business is in Pennsylvania, that its sole member is Bayer Corp., and that it has manufacturing operations in California. Petition ¶ 95. Bayer HealthCare LLC is actually a limited liability company formed under the laws of Delaware. Its citizenship is determined by the citizenship of its nine members. *GMAC Commercial Credit LLC v. Dillard Dep't Stores, Inc.*, 357 F.3d 827, 829 (8th Cir. 2004). Those members are:

- a. Bayer Medical Care Inc., a Delaware corporation with its principal place of business in Pennsylvania;
- b. NippoNex Inc., a Delaware corporation with its principal place of business in New Jersey;
- c. Bayer West Coast Corporation, a Delaware corporation with its principal place of business in California at the time the Petition was filed; on April 21, 2016, Bayer West Coast Corporation's principal place of business moved to New Jersey;
- d. Bayer Essure Inc., a Delaware corporation with its principal place of business in California at the time the Petition was filed; on April 21, 2016, Bayer Essure Inc.'s principal place of place moved to New Jersey;
- e. Bayer Consumer Care Holdings LLC, a limited liability company, the sole common member of which is Bayer East Coast LLC and the sole preferred member of which is Bayer HealthCare US Funding LLC. Bayer East Coast LLC's sole member is Bayer US Holding LP, and Bayer HealthCare

US Funding LLC's members are Bayer AG, Bayer Pharmaceuticals AG, and Bayer World Investments B.V. Bayer US Holding LP is a limited partnership in which Bayer World Investments B.V. is the sole General Partner and Bayer Solution B.V. is the sole Limited Partner. Both Bayer World Investments B.V. and Bayer Solution B.V. are incorporated in and have their principal places of business in the Netherlands. Bayer AG and Bayer Pharmaceuticals AG are German corporations with their principal places of business in Germany;

- f. Dr. Scholl's LLC, a limited liability company, the sole member of which is Bayer HealthCare US Funding LLC;
- g. Coppertone LLC, a limited liability company, the sole member of which is Bayer HealthCare US Funding LLC;
- h. MiraLAX LLC, a limited liability company, the sole member of which is Bayer HealthCare US Funding LLC; and
- i. Bayer HealthCare US Funding LLC, a limited liability company, whose members are Bayer AG, Bayer Pharmaceuticals AG, and Bayer World Investments B.V. Bayer AG is a German corporation with its principal place of business in Germany; Bayer Pharmaceuticals AG is a German corporation with its principal place of business in Germany; and Bayer World Investments B.V. is incorporated in and has its principal place of business in the Netherlands.

Accordingly, Bayer HealthCare LLC was a citizen of Delaware, California, Pennsylvania, Germany, and the Netherlands for purposes of diversity jurisdiction at the time the Petition was filed. Since April 21, 2016, it has been a citizen of Delaware, New Jersey, Pennsylvania, Germany, and the Netherlands.

24. Defendant Bayer Essure Inc., is a Delaware corporation with its principal place of business at the time the Petition was filed in California. Petition ¶ 96. Thus, for diversity purposes, it was a citizen of Delaware and California at the time the Petition was filed. *See* 28 U.S.C. § 1332(c). Because Bayer Essure Inc.'s principal place of business has been in New Jersey since April 21, 2016, it is now a citizen of Delaware and New Jersey for diversity purposes. *Id.*

25. Bayer HealthCare Pharmaceuticals Inc. is a Delaware corporation with its principal place of business in New Jersey. Petition ¶ 97. Thus, for diversity purposes, it is a citizen of Delaware and New Jersey. *See* 28 U.S.C. § 1332(c).

26. Bayer A.G. is a German corporation. Petition ¶ 98. Thus, for diversity purposes, it is a citizen of Germany. *See* 28 U.S.C. § 1332(c).

27. The 92 unrelated Plaintiffs allege that they are citizens of the District of Columbia and 30 different States: Arizona, Arkansas, California, Colorado, Florida, Georgia, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Mississippi, Missouri, New Jersey, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, South Dakota, Tennessee, Texas, Virginia, Washington, West Virginia, and Wisconsin. Petition ¶¶ 2-93.

Specifically:

- a. Plaintiff Shelley Wicklund is a citizen of Arizona, *id.* ¶ 77;
- b. Plaintiff Terria Kittrell is a citizen of Arkansas, *id.* ¶ 39;
- c. Plaintiff Sophia Yates is a citizen of California, *id.* ¶ 3;
- d. Plaintiff Natalie Palka is a citizen of California, *id.* ¶ 22;
- e. Plaintiff Marlen Vega is a citizen of California, *id.* ¶ 26;
- f. Plaintiff Jerri Leers is a citizen of California, *id.* ¶ 30;
- g. Plaintiff Carrie Allegreti is a citizen of California, *id.* ¶ 51;
- h. Plaintiff Monika Morales is a citizen of Colorado, *id.* ¶ 32;
- i. Plaintiff Teresa Thompson is a citizen of Colorado, *id.* ¶ 40;
- j. Plaintiff Laurie Anderson is a citizen of Colorado, *id.* ¶ 66;
- k. Plaintiff Michelle L. Lenhart is a citizen of Colorado, *id.* ¶ 85;
- l. Plaintiff Tanya Bonapare is a citizen of the District of Columbia, *id.* ¶ 67;
- m. Plaintiff Cynthia Gaffney is a citizen of Florida, *id.* ¶ 56;

- n. Plaintiff Bibi Ahamad is a citizen of Florida, *id.* ¶ 61;
- o. Plaintiff Dawn R. Whitfield is a citizen of Florida, *id.* ¶ 84;
- p. Plaintiff Annessa J. Furr is a citizen of Florida, *id.* ¶ 86;
- q. Plaintiff Selena M. Minges is a citizen of Florida, *id.* ¶ 88;
- r. Plaintiff Tara A. Bach is a citizen of Florida, *id.* ¶ 89;
- s. Plaintiff Tara L. Vargas is a citizen of Florida, *id.* ¶ 90;
- t. Plaintiff Crytalblue Kintyhtt is a citizen of Florida, *id.* ¶ 91;
- u. Plaintiff Jody Camarda is a citizen of Florida, *id.* ¶ 92;
- v. Plaintiff Regina Taylor is a citizen of Georgia, *id.* ¶ 19;
- w. Plaintiff Jonnie Lopez is a citizen of Georgia, *id.* ¶ 46;
- x. Plaintiff Brittany Hood is a citizen of Georgia, *id.* ¶ 47;
- y. Plaintiff Tonya Wiggins is a citizen of Georgia, *id.* ¶ 49;
- z. Plaintiff Andri Pilgram is a citizen of Georgia, *id.* ¶ 75;
- aa. Plaintiff Francesca Fischetti is a citizen of Illinois, *id.* ¶ 31;
- bb. Plaintiff Carrie Long is a citizen of Illinois, *id.* ¶ 42
- cc. Plaintiff Rachel L. Omerod is a citizen of Illinois, *id.* ¶ 73;
- dd. Plaintiff Kristinia Gonzalez is a citizen of Indiana, *id.* ¶ 6;
- ee. Plaintiff Ashley B. Thomas is a citizen of Indiana, *id.* ¶ 82;
- ff. Plaintiff Taishna Novak is a citizen of Iowa, *id.* ¶ 33;
- gg. Plaintiff Patten J. Hansen is a citizen of Iowa, *id.* ¶ 69;
- hh. Plaintiff Tamara Sparks is a citizen of Kentucky, *id.* ¶ 25;
- ii. Plaintiff Kara Green is a citizen of Kentucky, *id.* ¶ 29;
- jj. Plaintiff Qu'mara L. Cox is a citizen of Kentucky, *id.* ¶ 78;
- kk. Plaintiff Amberly L. Collins is a citizen of Kentucky, *id.* ¶ 79;
- ll. Plaintiff Stacia Williams is a citizen of Louisiana, *id.* ¶ 28;

- mm. Plaintiff Kathleen G. Tilbrook is a citizen of Maryland, *id.* ¶ 74;
- nn. Plaintiff Marci Marry is a citizen of Michigan, *id.* ¶ 17;
- oo. Plaintiff Amber Burgtorf is a citizen of Michigan, *id.* ¶ 55;
- pp. Plaintiff Kathryn Lynn Stanley is a citizen of Michigan, *id.* ¶ 57;
- qq. Plaintiff Delina Coleman is a citizen of Michigan, *id.* ¶ 58;
- rr. Plaintiff Tiffanie Shouse is a citizen of Michigan, *id.* ¶ 59;
- ss. Plaintiff Kristen Gorlewski is a citizen of Michigan, *id.* ¶ 62;
- tt. Plaintiff Teresa Conroe is a citizen of Michigan, *id.* ¶ 63;
- uu. Plaintiff Kathleen Butler is a citizen of Michigan, *id.* ¶ 64;
- vv. Plaintiff Sarah Jorgensen is a citizen of Minnesota, *id.* ¶ 45;
- ww. Plaintiff Margaret L. Mooney is a citizen of Minnesota, *id.* ¶ 70;
- xx. Plaintiff Mirand F. Bennett is a citizen of Minnesota, *id.* ¶ 87;
- yy. Plaintiff Leslie Cain is a citizen of Mississippi, *id.* ¶ 60;
- zz. Plaintiff Gloria Johnson is a citizen of Missouri, *id.* ¶ 2;
- aaa. Plaintiff Marissa Boylan is a citizen of Missouri, *id.* ¶ 7;
- bbb. Plaintiff Keri Rohne-Jumper is a citizen of Missouri, *id.* ¶ 8;
- ccc. Plaintiff Rose Ganira is a citizen of Missouri, *id.* ¶ 9;
- ddd. Plaintiff Tara Schaper is a citizen of Missouri, *id.* ¶ 10
- eee. Plaintiff Debra K. Shultz is a citizen of Missouri, *id.* ¶ 68;
- fff. Plaintiff Lynn Schenk is a citizen of Missouri, *id.* ¶ 93;
- ggg. Plaintiff Yesenia Del Valle is a citizen of New Jersey, *id.* ¶ 4;
- hhh. Plaintiff Robin Wronski is a citizen of New Jersey, *id.* ¶ 81;
- iii. Plaintiff Elena Mendez is a citizen of New York, *id.* ¶ 41;
- jjj. Plaintiff Lisa Saenz is a citizen of New York, *id.* ¶ 44;
- kkk. Plaintiff Amanda Myers is a citizen of North Carolina, *id.* ¶ 23;

- lll. Plaintiff Sherry Watson is a citizen of North Carolina, *id.* ¶ 52;
- mmm. Plaintiff Sherry C. Yong is a citizen of North Carolina, *id.* ¶ 83;
- nnn. Plaintiff Misty Adkins is a citizen of Ohio, *id.* ¶ 20;
- ooo. Plaintiff Jaime Bartschi is a citizen of Oklahoma, *id.* ¶ 21;
- ppp. Plaintiff Rachel Priest is a citizen of Oregon, *id.* ¶ 26;
- qqq. Plaintiff Lisa DeLorenzo is a citizen of Pennsylvania, *id.* ¶ 5;
- rrr. Plaintiff Jennifer Kerrigan is a citizen of Pennsylvania, *id.* ¶ 72;
- sss. Plaintiff Darbi Klebsch is a citizen of South Dakota, *id.* ¶ 34;
- ttt. Plaintiff Tequila Wright is a citizen of Tennessee, *id.* ¶ 71;
- uuu. Plaintiff Patricia D. Salido is a citizen of Tennessee, *id.* ¶ 76;
- vvv. Plaintiff Alana Spears is a citizen of Texas, *id.* ¶ 11;
- www. Plaintiff Mekisha Baker is a citizen of Texas, *id.* ¶ 14;
- xxx. Plaintiff Leighcourtney Smith is a citizen of Texas, *id.* ¶ 15;
- yyy. Plaintiff Tara Berliski is a citizen of Texas, *id.* ¶ 16;
- zzz. Plaintiff Lauren Miller is a citizen of Texas, *id.* ¶ 18;
- aaaa. Plaintiff Kelly Reynolds is a citizen of Texas, *id.* ¶ 24;
- bbbb. Plaintiff Kasey Kummell is a citizen of Texas, *id.* ¶ 36;
- cccc. Plaintiff Kellee Peebles is a citizen of Texas, *id.* ¶ 37;
- dddd. Plaintiff Tamara Floyd is a citizen of Texas, *id.* ¶ 48;
- eeee. Plaintiff Megan Serrato is a citizen of Texas, *id.* ¶ 50;
- ffff. Plaintiff Amy Gosnell is a citizen of Texas, *id.* ¶ 53;
- gggg. Plaintiff Lakesha Waters is a citizen of Texas, *id.* ¶ 54;
- hhhh. Plaintiff Christine A. Cervantes is a citizen of Texas, *id.* ¶ 80;
- iiii. Plaintiff Carrie Pons is a citizen of Virginia, *id.* ¶ 13;
- jjjj. Plaintiff Dana Henderson is a citizen of Virginia, *id.* ¶ 35;

kkkk. Plaintiff Azah Brihm is a citizen of Virginia, *id.* ¶ 43;

llll. Plaintiff Tiffany Nokes is a citizen of Washington, *id.* ¶ 65;

mmmm. Plaintiff Cathy Hunter is a citizen of West Virginia, *id.* ¶ 38;

nnnn. Plaintiff April Ward is a citizen of Wisconsin, *id.* ¶ 12.

28. Only seven of the 92 Plaintiffs—Gloria Johnson, Marissa Boylan, Keri Rhone-Jumper, Rose Ganira, Tara Schaper, Debra K. Shultz, and Lynn Schenk—allege that they are citizens of Missouri. The remaining 85 Plaintiffs allege no connection whatsoever to Missouri. Indeed, more Plaintiffs are citizens of each of Florida, Michigan, and Texas, than of Missouri.

29. Plaintiffs alleges that complete diversity is destroyed by the presence of three Plaintiffs—Sophia Yates, Lisa DeLorenzo, and Yesenia Del Valle—who are citizens of California, Pennsylvania, and New Jersey, respectively. But those Plaintiffs allege no connection with the Missouri Plaintiffs, do not base their claims on any conduct or injuries that occurred in Missouri, and do not otherwise allege any kind of connection to Missouri. The same is true for the additional California, Pennsylvania, and New Jersey Plaintiffs—Jennifer Kerrigan, Natalie Palka, Marlen Vega, Jerri Leers, Carrie Allegretti, and Robin Wronski—and the two Indiana Plaintiffs—Kristinia Gonzalez and Ashley B. Thomas.⁴

30. These non-diverse Plaintiffs are joined in this single action in a forum with which they have no connection for the sole purpose of attempting to destroy complete diversity. But the presence of seven Plaintiffs residing in California, New Jersey, Pennsylvania, and Indiana does not destroy diversity jurisdiction for two distinct reasons:

First, this Court should exercise its discretion to consider personal jurisdiction and forum non conveniens at the threshold, and grant Bayer's Motion to Dismiss the claims of the non-

⁴ Plaintiffs do not allege that these eight Plaintiffs destroy diversity jurisdiction.

Missouri Plaintiffs—including the non-diverse Plaintiffs—under these doctrines. Once the non-Missouri Plaintiffs claims are dismissed, complete diversity exists between the remaining Missouri Plaintiffs and Defendants. Moreover, as will be shown in the Motion to Dismiss, those remaining claims also fail as a matter of law because they are preempted and inadequately pled.

Second, in the alternative, the citizenship of the non-Missouri Plaintiffs—including the non-diverse Plaintiffs—poses no impediment to diversity under the doctrine of fraudulent misjoinder and fraudulent joinder, even if this court considers jurisdiction before a Motion to Dismiss. Thus, this Court may grant Bayer’s forthcoming Motion to Sever the various Plaintiffs’ claims and remand only the claims of any non-diverse Plaintiffs that this Court does not otherwise dismiss.

1. There is complete diversity between the proper parties because this Court lacks personal jurisdiction over the non-diverse Plaintiffs’ claims.

31. The United States Supreme Court has made clear that courts have discretion to consider a motion to dismiss for lack of personal jurisdiction before considering a motion to remand for lack of subject matter jurisdiction, especially if the personal jurisdiction question is “straightforward” and the subject matter jurisdiction question is “difficult and novel.” *Ruhrgas*, 526 U.S. at 588; *accord Crawford v. F. Hoffman-La Roche Ltd.*, 267 F.3d 760, 764 (8th Cir. 2001). Thus, where it is clear that the court lacks personal jurisdiction over non-diverse plaintiffs’ claims, there is no need to consider the doctrine of fraudulent misjoinder or fraudulent joinder: the court should *first* dismiss the non-diverse plaintiffs’ claims for lack of personal jurisdiction and *then*—in light of the diversity between the remaining plaintiffs and defendants—deny the motion to remand. *See, e.g., Cantor Fitzgerald, L.P. v. Peaslee*, 88 F.3d 152, 153 (2d Cir. 1996); *Villar v. Crowley Maritime Corp.*, 990 F.2d 1489, 1494-95 (5th Cir. 1993), *cert. denied* 510 U.S. 1044 (1994); *Kraft v. Johnson & Johnson*, 97 F. Supp. 3d 846, 854-55 (S.D.

W.Va. 2015); *Wolstenholme v. Bartels*, 2011 WL 4359989, at *1 n.1 (E.D. Pa. Sept. 19, 2011), *aff'd*, 511 F. App'x 215 (3d Cir. 2013); *Foslip Pharm., Inc. v. Metabolife Int'l, Inc.*, 92 F. Supp. 2d 891, 899 (N.D. Iowa 2000); *Martino v. Viacao Aerea Riograndense, S.A.*, 1991 WL 13886, at *4 (E.D. La. Jan. 25, 1991); *Nolan v. Boeing Co.*, 736 F. Supp. 120, 127 (E.D. La. 1990).

32. This Court should follow this approach here. The personal jurisdiction issue is “simple when compared with,” *Crawford*, 267 F.3d at 764, the more “novel” and complex jurisdictional questions presented in multi-plaintiff complaints, *In re Prempro Prods. Liab. Litig.*, 591 F.3d 613, 620-22 (8th Cir. 2010); *see also Kraft*, 97 F. Supp. 3d at 850-51 (describing fraudulent misjoinder as “relatively recent and untested”). This Court should therefore consider the personal jurisdiction issue first.

33. The personal jurisdiction question is “straightforward,” *Ruhrgas*, 526 U.S. at 588, since this Court plainly lacks either general or specific personal jurisdiction over Bayer with respect to non-diverse Plaintiffs’ claims.

34. Personal jurisdiction may be general or specific. General jurisdiction covers claims “unrelated to the defendant’s contacts with the forum state,” and exists when the defendant’s contacts unrelated to the claims at issue are so “continuous and systematic” as to render the defendant “essentially at home” in the forum state. *See Daimler AG v. Bauman*, 134 S. Ct. 746, 760-61 & n.19 (2014); *Viasystems, Inc. v. EBM-Papbst St. Georgen GmbH & Co., KG*, 646 F.3d 589, 595 (8th Cir. 2011); *see also Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 919-20 (2011); *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 415-16 (1984).

35. Here, there is no general personal jurisdiction because no Defendant is incorporated in Missouri, has its principal place of business in Missouri, or has such continuous

and systematic ties to Missouri as to render it “at home” in Missouri. *Daimler*, 134 S. Ct. at 760-61 & n.19; *see also Keeley v. Pfizer Inc.*, 2015 WL 3999488, at *2 (E.D. Mo. July 1, 2015).

Although Plaintiffs suggest that general jurisdiction exists based on Bayer’s Essure sales and marketing in Missouri, Petition ¶ 1, it is plain that “[s]imply marketing and selling a product in a state does not make a defendant’s affiliation with the state so ‘continuous and systematic as to render them essentially at home in the forum state.’” 2015 WL 3999488, at *2 (quoting *Goodyear*, 564 U.S. at 919). Nor does the fact that Bayer Corporation, Bayer HealthCare LLC, and Bayer HealthCare Pharmaceuticals Inc., are registered to do business in Missouri,⁵ *see* Petition ¶ 1, make Bayer subject to general personal jurisdiction in the state or constitute consent to personal jurisdiction, *see Keeley*, 2015 WL 3999488, at *4 & n.2. *But see Mitchell v. Eli Lilly & Co.*, 2016 WL 362441, at *8 (E.D. Mo. Jan. 29, 2016).

36. Similarly, specific personal jurisdiction exists only if a defendant “has sufficient ‘minimum contacts with [the forum state] such that the maintenance of the suit does not offend ‘traditional notions of fair play and substantial justice.’”” *Viasystems*, 646 F.3d at 594 (quoting *Int’l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)). Unlike general jurisdiction, specific jurisdiction “focuses on ‘the relationship among the defendant, the forum, and the litigation.’” *Keeley*, 2015 WL 3999488, at *3 (quoting *Walden v. Fiore*, 134 S. Ct. 1115, 1121 (2014)).

37. Bayer is not subject to specific personal jurisdiction with respect to the claims of the non-Missouri Plaintiffs (including all non-diverse Plaintiffs). None of these Plaintiffs’ injuries arise out of or relate to any conduct or transaction that occurred in Missouri. *Keeley*, 2015 WL 3999488, at *3; *see also Barthomome v. Pfizer, Inc.*, 2016 WL 366795, at *2 (E.D.

⁵ Defendant Bayer Essure Inc. is not registered to do business in Missouri. *See* Missouri Secretary of State, Missouri Online Business Filing, <https://bsd.sos.mo.gov/BusinessEntity/BESearch.aspx?SearchType=0> (last visited May 20, 2016).

Mo. Jan. 29, 2016); *Clarke v. Pfizer, Inc.*, 2015 WL 5243876, at *2 (E.D. Mo. Sept. 8, 2015). Because personal jurisdiction is claim-specific, *see Sun World Lines, Ltd. v. March Shipping Corp.*, 585 F. Supp. 580, 584-85 (E.D. Mo. 1984), *aff'd*, 801 F.2d 1066 (8th Cir. 1986), non-Missouri Plaintiffs cannot “piggyback” off the specific personal jurisdiction that exists for the handful of Missouri Plaintiffs. *See Level 3 Commc’ns, LLC v. Ill. Bell Tel. Co.*, 2014 WL 50856, at *2 (E.D. Mo. Jan. 7, 2014), *vacated in part on other grounds on reconsideration*, 2014 WL 1347531 (E.D. Mo. Apr. 4, 2014); *accord In re Testosterone Replacement Therapy Prods. Liab. Litig. Coordinated Pretrial Proceedings*, 2016 WL 640520, at *5-6 (N.D. Ill. Feb. 18, 2016); *Turi v. Main Street Adoption Servs., LLP*, 2009 WL 2923248, at *13 (E.D. Mich. Sept. 9, 2009), *aff’d in part, rev’d in part, and remanded on other grounds*, 633 F.3d 496 (6th Cir. 2011).

38. Because Bayer is not subject to personal jurisdiction in Missouri with respect to non-Missouri Plaintiffs’ claims, those claims (and those Plaintiffs) should be dismissed. The remaining Plaintiffs all reside in Missouri, a State in which no Defendant is a citizen. *See* 28 U.S.C. § 1332(c). Accordingly, this Court has diversity jurisdiction over the proper parties’ claims.

2. There is complete diversity between the proper parties because the non-Missouri Plaintiffs’ claims should be dismissed under the doctrine of forum non conveniens.

39. Alternatively, this Court also may exercise its discretion to dismiss the non-Missouri Plaintiffs’ claims under the doctrine of forum non conveniens before considering whether complete diversity exists. *See, e.g., Iwag v. Geisel Compania Maritima, S.A.*, 882 F. Supp. 597, 602 (S.D. Tex. 1995) (recognizing that “a district court sitting in diversity jurisdiction [may] decide a motion to dismiss for forum non conveniens before a motion to remand”). Forum non conveniens applies where, as here, “(1) . . . an adequate alternative forum is available, and

(2) . . . the balance of private and public interest factors favors dismissal.” *DeSirey v. Unique Vacations, Inc.*, 2014 WL 272369, at *1 (E.D. Mo. Jan. 24, 2014). Both of these factors are met.

40. Each non-Missouri Plaintiff has an adequate alternative forum in her home state.

41. The balance of private and public interest factors demonstrates that dismissal is appropriate here. The private factors include: ease of access to and cost of obtaining witnesses, as well as other practical problems. The public factors include avoiding court congestion, the local interest in having localized controversies decided locally, the interest in having trial in a forum that is at home with the applicable law, the interest in avoiding conflict of laws questions, and the unfairness of burdening Missouri citizens with jury duty to decide claims unrelated to Missouri. *See de Melo v. Lederle Labs., Div. of Am. Cyanamid Corp.*, 801 F.2d 1058, 1062-63 (8th Cir. 1986); *see also Piper Aircraft Co. v. Reyno*, 454 U.S. 235, 241 n.6 (1981).

42. The non-Missouri Plaintiffs’ claims should be dismissed because (1) those claims are likely to require the presence of physician witnesses who are not located in Missouri, (2) there is no reason to burden Missouri courts and jurors with 85 sets of claims involving non-Missouri Plaintiffs who allegedly suffered injuries outside of Missouri, and (3) dismissing claims of non-Missouri Plaintiffs will avoid the need to resolve numerous conflict of laws issues.

43. Accordingly, this Court should dismiss the non-Missouri Plaintiffs’ claims under the doctrine of forum non conveniens, and find complete diversity between the remaining Plaintiffs and Defendants.

3. There is complete diversity because the non-Missouri Plaintiffs are fraudulently misjoined.

44. Even if this Court considers the forthcoming Motion to Sever first, the presence of the non-diverse Plaintiffs does not destroy diversity jurisdiction because they are fraudulently misjoined. Accordingly, the Court should grant Bayer’s Motion to Sever.

45. “Fraudulent misjoinder occurs when a plaintiff sues a diverse defendant in state court and joins a viable claim involving a nondiverse party, . . . even though the plaintiff has no reasonable procedural basis to join them in one action because the claims bear no relation to each other.” *In re Prempro*, 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)). The Eighth Circuit has suggested that it would recognize fraudulent misjoinder if a misjoinder is “egregious.” *Id.* at 622. Misjoinder occurs when joined claims do not both (1) “aris[e] out of the same transaction, occurrence, or series of transactions or occurrences,” and (2) involve “any question of law or fact common to all plaintiffs.” Fed. R. Civ. P. 20(a); *In re Rezulin Prods. Liab. Litig.*, 168 F. Supp. 2d 136, 144 (S.D.N.Y. 2001) (“Misjoinder of parties occurs when a party fails to satisfy the conditions for permissive joinder under Rule 20(a).”); *see also* Mo. Sup. Ct. R. 52.05; *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, 2012 WL 1118780, at *3 (D.N.J. Apr. 3, 2012) (“Missouri’s permissive joinder rule is substantively identical to” Federal Rule 20(a).”), *aff’d*, 751 F.3d 150 (3d Cir. 2014).

46. Here, as shown above, the non-Missouri Plaintiffs are fraudulently misjoined because of the clear and indisputable lack of personal jurisdiction. As this Court has recognized, the absence of personal jurisdiction is a basis to find fraudulent misjoinder where, as here, the arguments supporting personal jurisdiction are especially weak or “improbable.” *See Littlejohn v. Janssen Research & Dev., LLC*, 2015 WL 1647901, at *1 (E.D. Mo. Apr. 13, 2015). In light of *Daimler, Keeley, Level 3*, and the other cases cited above, the lack of personal jurisdiction with respect to the non-Missouri Plaintiffs’ claims is palpable and this Court may therefore conclude their inclusion in this Complaint amounts to fraudulent misjoinder.

47. The misjoinder here is particularly clear for the additional reason that the various Plaintiffs' claims do not "aris[e] out of the same transaction, occurrence, or series of transactions or occurrences." *See* Fed. R. Civ. P. 20. To the contrary, Essure is a highly regulated medical device that is available only through a patient's prescribing physician. The far-flung Plaintiffs joined together in this litigation had their devices placed at various different times, in different states, and in different circumstances; and they allegedly suffered separate and distinct injuries.

48. The only possible connection in the Plaintiffs' various experiences is that they all involve the same prescription medical device. But, as this Court has recognized, plaintiffs are misjoined where "[e]ach [p]laintiff was injured at different times in different states allegedly from their use of [the product] that was presumably prescribed by different healthcare providers." *Alday v. Organon USA, Inc.*, 2009 WL 3531802, at *1 (E.D. Mo. Oct. 27, 2009) *Boschert v. Pfizer, Inc.*, 2009 WL 1383183, at *3 (E.D. Mo. May 14, 2009) (similar).

49. Similarly, "[a] multitude of cases around the country have held that plaintiffs were not properly joined when the only common link among them was a defective drug or medical device." *Stinnette v. Medtronic Inc.*, 2010 WL 767558, at *2 (S.D. Tex. Mar. 3, 2010) (citing *In re Rezulin*, 168 F. Supp. 2d at 145-46; *Graziose v. Am. Home Prods. Corp.*, 202 F.R.D. 638, 640 (D. Nev. 2001)); *see, e.g., In re Propecia (Finasteride) Prod. Liab. Litig.*, 2013 WL 3729570, at *3 (E.D.N.Y. May 17, 2013) (allowing removal from Missouri state court; case transferred to MDL); *In re Fosamax*, 2012 WL 1118780, at *4 (rejecting joinder of claims against the manufacturers and seller of the same drug); *In re Seroquel Prods. Liab. Litig.*, 2006 WL 3929707, at *4 (M.D. Fla. Dec. 22, 2006) ("Because these multiple plaintiff cases do not appear to seek relief arising from the same transaction or occurrence, severance of the individual plaintiffs is proper."), *adopted*, 2007 WL 219989 (M.D. Fla. Jan. 26, 2007); *In re Baycol Prods.*

Liab. Litig., 2002 WL 32155269, at *2 (D. Minn. July 5, 2002) (finding joinder improper based on the “many differences between the unique histories of each plaintiff”); *In re Diet Drugs*, 1999 WL 554584, at *3 (E.D. Pa. July 16, 1999) (holding multiple plaintiffs alleging damages in a single case arising from ingestion of diet drugs were “clearly misjoined” under Fed. R. Civ. P. 20(a)); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 1995 WL 428683, at *6 (E.D. Pa. July 17, 1995) (“[J]oinder based on the belief that the same occurrence or transaction is satisfied by the fact that claimants have the same or similar device of a defendant manufacturer implanted in or about their spine is . . . not a proper joinder . . .”).

50. Severance is particularly appropriate here in light of the disparate factual and legal issues that pertain to each Plaintiff. Each Plaintiff’s claim will be dominated by distinctive factual issues, such as the specific details of each Plaintiff’s Essure procedure, each Plaintiff’s medical history prior to that procedure, the type and nature of the injuries each Plaintiff allegedly suffered, causation of those injuries, the training and performance of each Plaintiff’s physician, each Plaintiff’s and her physician’s reliance on alleged misrepresentations, and each Plaintiff’s and her physician’s consideration of Essure’s labeling and warnings that existed at the times of each Plaintiff’s alleged injuries. Similarly, each Plaintiff’s claim will involve disparate legal questions unique to the law of 31 separate jurisdictions, such as elements of common law actions, the learned intermediary doctrine, the availability of punitive damages, and the length of applicable statutes of limitations.⁶

⁶ Unlike *Anders v. Medtronic, Inc.*, 2014 WL 1652352 (E.D. Mo. Apr. 24, 2014), this case does not involve an alleged scheme to promote a medical device off-label. *Anders* held that such a “scheme” constituted the same transaction, occurrence, or series of transactions or occurrences for purposes of Rule 20. *Id.* at *3. Here, by contrast, Plaintiffs’ claims will necessarily turn on an individualized inquiry into whether and how any alleged misrepresentation or failure to warn impacted each individual patient and her doctor’s decision to use Essure. *See, e.g., Simmons v.*

4. There is complete diversity because the non-Missouri Plaintiffs are fraudulently joined.

51. In the alternative, the Court also should disregard the citizenship of the non-diverse Plaintiffs because they are fraudulently joined. “The doctrine of fraudulent joinder allows a district court to assume jurisdiction over a facially nondiverse case temporarily and, if there is no reasonable basis for the imposition of liability under state law, dismiss the nondiverse party from the case and retain subject matter jurisdiction over the remaining claims.” *Murphy v. Aurora Loan Servs., LLC*, 699 F.3d 1027, 1031 (8th Cir. 2012); *see also Anderson v. Home Ins. Co.*, 724 F.2d 82, 84 (8th Cir. 1983) (per curiam) (“Joinder designed solely to deprive federal courts of jurisdiction is fraudulent and will not prevent removal.”); *Peterson v. Concentra, Inc.*, 2007 WL 1459826, at *1 (E.D. Mo. May 16, 2007 (“[I]t is well-settled that the district court will not allow removal jurisdiction to be defeated by the plaintiff’s destruction of complete diversity of citizenship by the . . . improper joinder of parties”) (alteration in original). Plaintiffs, as well as defendants, can be fraudulently joined. *See, e.g., Allen v. Bayer Healthcare Pharm., Inc.*, 2014 WL 655585, at *2-4 (E.D. Mo. Feb. 20, 2014); *Witherspoon v. Bayer HealthCare Pharm. Inc.*, 2013 WL 6069009, at *4 (E.D. Mo. Nov. 18, 2013).

52. As set forth above, there is no reasonable basis under which the non-Missouri Plaintiffs may subject Bayer to general or specific personal jurisdiction in Missouri. Because the only plausible basis for including these non-Missouri Plaintiffs in this action is to destroy diversity jurisdiction, this Court should apply the doctrine of fraudulent joinder and find complete diversity of citizenship.

Wyeth Labs., Inc., 1996 WL 617492, at *3-4 (E.D. Pa. Oct. 24, 1996) (misrepresentations or failure to warn by the defendants did not satisfy the “same transaction, occurrence, or series of transactions or occurrences” requirement).

III. REMOVAL IS PROPER BECAUSE THIS COURT HAS SUBJECT MATTER JURISDICTION PURSUANT TO 28 U.S.C. §§ 1331 AND 1441.

53. This Court also has federal question jurisdiction pursuant to 28 U.S.C. §§ 1331, 1441.

54. Federal question jurisdiction exists where a plaintiff pleads federal violations on the face of the complaint and “the vindication of a right under state law necessarily turn[s] on some construction of federal law.” *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 808 (1986) (quoting *Franchise Tax Bd. v. Construction Laborers Vacation Trust*, 463 U.S. 1, 9 (1983)). This “captures the commonsense notion that a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues.” *Grable & Sons Metal Prods., Inc. v. Darue Eng’g & Mfg.*, 545 U.S. 308, 312 (2005). “[T]he question is, does a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities.” *Id.* at 314.

55. Thus, federal question jurisdiction exists 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*, 559 F.3d at 779. This Court should find that both those factors are met, and that federal question jurisdiction exists here—just as other courts have done in cases involving heavily regulated PMA medical devices. *See Jenkins v. Medtronic, Inc.*, 984 F. Supp. 2d 873, 878 (W.D. Tenn. 2013) (finding federal question jurisdiction because state-law product liability claims regarding PMA medical device required the court “to examine federal law, and, even more specifically, examine federal requirements imposed by the FDA through the

premarket approval process”); *H.R. ex rel. Reuter v. Medtronic, Inc.*, 996 F. Supp. 2d 671, 677-78 (S.D. Ohio 2014) (similar); *cf. Bowdrie v. Sun Pharm. Indus. Ltd.*, 909 F. Supp. 2d 179, 184-85 (E.D.N.Y. 2012) (finding federal question jurisdiction in product liability drug case where “boundaries of Plaintiffs’ claims . . . are established by the FDCA”).

56. Here, Plaintiffs’ claims turn on whether Defendants violated federal regulatory requirements. *See* § III.A, *infra*. Moreover, FDA’s recent investigation into and response to the very issues that are the subject of this case renders the federal interest particularly substantial and warrant the exercise of federal jurisdiction to resolve the overwhelmingly federal issues of law at issue in this case. *See* Petition ¶¶ 135-40.

A. Plaintiffs’ Right To Relief Depends On The Resolution Of Substantial Federal Questions.

57. Substantial federal questions arise “on the face” of the Petition “as demonstrated by the words [Plaintiffs] themselves selected.” *Country Club Estates, L.L.C. v. Town of Loma Linda*, 213 F.3d 1001, 1004 (8th Cir. 2000). Indeed, Plaintiffs predicate their state-law claims on numerous alleged violations of federal requirements that they plead directly in their Petition. For example, Plaintiffs allege that Bayer:

- a. “violated [its] duty of care with regard to specifications and protocols set forth in federal regulations, PMA, Supplements, and/or the [PMA] Conditions of Approval ” Petition ¶ 144;
- b. “violated federal law in the manufacture of Essure,” *id.* ¶ 147;
- c. “failed to . . . fil[e] PMA supplements, update[e] [Essure’s] label pursuant to 21 C.F.R. § 820.39(d), or submit[] MDRs,” *id.* ¶ 170;
- d. “manufactur[ed] actual Essure® devices that differ from the specifications set forth in the PMA, its Supplements, the Conditions of Approval and/or other federal regulations,” *id.* ¶ 182;
- e. “failed to manufacture the Essure® devices consistent with federal requirements,” *id.* ¶ 183;

- f. “violated federal law and/or were cited by the FDA for [federal violations],” *id.* ¶ 187;
- g. disseminated false information in violation of the PMA, 21 U.S.C. § 352(q), and 21 C.F.R. § 814.80, *id.* ¶ 196.

58. These allegations of federal violations are not tangential: Plaintiffs’ right to relief “depends on” their resolution. *Pet Quarters*, 559 F.3d at 779. As part of the Medical Device Amendments, Congress adopted a “general prohibition on non-Federal regulation” of medical devices, H.R. Rep. No. 94-853, at 45 (1976), by expressly preempting “any requirement” imposed by state law relating to the safety or effectiveness of a medical device that “is different from, or in addition to, any requirement applicable . . . to the device” under federal law. 21 U.S.C. § 360k(a). As the Supreme Court held in *Riegel v. Medtronic, Inc.*, premarket approval of a Class III medical device establishes federal requirements applicable to that device, and state-law tort claims targeting the safety and effectiveness of the device impose state-law requirements. 552 U.S. 312, 321-25 (2008). Thus, to the extent state-law claims rest on duties “different from, or in addition to” federal requirements, they are expressly preempted. *Id.* at 330; *see also In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010) (“The plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § 360k(a)”) (emphasis omitted). For this reason, Plaintiffs cannot succeed on their state-law claims unless they show that Bayer violated a federal requirement.

59. It is no answer to say that the federal-law questions arise only in the context of a preemption defense. In rejecting a similar attempt to defeat federal question jurisdiction, another court explained that “Plaintiffs have set the landscape and scope of the issues that would be addressed in this case, and Defendants have properly asserted an applicable preemption defense to Plaintiffs’ claims.” *Jenkins*, 984 F. Supp. 2d at 880. Here as well, Plaintiffs “set the landscape” when they pleaded violations of federal law on the face of their own Petition. Having

done so, Plaintiffs may not now deny that their Petition raises federal questions. *Country Club Estate*, 213 F.3d at 1004.

60. *Anders v. Medtronic, Inc.*, 2014 WL 1652352 (E.D. Mo. Apr. 24, 2014), does not require finding an absence of a substantial federal question. First, *Anders* is not binding and is not persuasive in the circumstances presented here. *Anders* mistakenly held that a case involving a Class III medical device was controlled by *Merrell Dow*, which rejected federal question jurisdiction in a case involving prescription drugs. *Anders*, 2014 WL 1652352, at *6. The court in *Anders* acknowledged that the express preemption provision of § 360k applies to PMA medical devices and not prescription drugs, but the court rejected this distinction as a valid basis for finding federal question jurisdiction. *See id.* Significantly, in *Merrell Dow*, it was of “primary importance” that the FDCA provided “no federal cause of action and no preemption of state remedies for misbranding.” *Grable*, 545 U.S. at 318. In enacting § 360k, Congress expressed the importance of federal law in resolving product liability claims with respect to that small category of medical devices that receives the most rigorous federal oversight, preempting any state law claim that is “different from, or in addition to” a federal requirement with respect to such a device. *Riegel*, 552 U.S. at 316, 326.

61. Second, *Anders* is distinguishable: while that court declined federal subject matter jurisdiction in that case, it noted the Supreme Court’s holding that “there is no good reason to shirk from federal jurisdiction over [a] dispositive and contested federal issue at the heart of” a case when there are no “threatening structural consequences” to federal jurisdiction and the parties have a “clear interest . . . in the availability of a federal forum.” *Grable*, 545 U.S. at 319-20; *see Anders*, 2014 WL 1652352, at *6. Here, both conditions are met. Plaintiffs’ failure to adequately plead the alleged violations of federal requirements is fatal to their claims.

62. Moreover, there is a strong interest in resolving these issues in a federal forum. FDA's involvement in this matter is extraordinary: it has not only conducted the usual stringent PMA review and evaluated numerous PMA supplements, but FDA also has specifically investigated *the very matters* that are the subject of Plaintiffs' claims and made a determination just two months ago that Essure remains "an appropriate option for the majority of women seeking a permanent form of birth control." FDA News Release (Feb. 29, 2016) (Ex. D). Plaintiffs are simply asking this Court to second-guess this determination by a federal agency pursuant to federal law. Preventing adjudication of the claims here in a federal forum therefore does not "threaten[] structural consequences"; rather, it properly recognizes and protects the significant federal interest in this case by allowing the adjudication of the important federal issues at stake here in a federal forum.

B. Federal Jurisdiction Will Not Disrupt the Federal-State Balance.

63. For similar reasons, the exercise of federal jurisdiction will not disrupt the balance between federal and state law that Congress has erected. Federal jurisdiction here would be confined to a "small fraction of medical-device cases"—namely, those in which FDA has taken specific steps to address the alleged issues that are the subject of Plaintiffs' complaint. *See generally Anders*, 2014 WL 1652352, at *7. At the same time, jurisdiction will permit a federal court to decide important questions of federal law. *See Reuter*, 996 F. Supp. 2d at 680.

64. Accordingly, this Court should exercise federal question jurisdiction here.

CONCLUSION

WHEREFORE, Notice is given that this action is removed from the Circuit Court of the City of St. Louis, Missouri, to the United States District Court for the Eastern District of Missouri, Eastern Division.

Dated: MAY 20, 2016

Respectfully submitted,

HEPLERBROOM LLC

By: /s/ Gerard T. Noce

Gerard T. Noce, #27636

gtn@heplerbroom.com

W. Jason Rankin, #62672

wjr@heplerbroom.com

211 North Broadway, Suite 2700

St. Louis, MO 63102

314-241-6160

Fax: 314-241-6116

*Attorneys for Defendants Bayer Corporation,
Bayer HealthCare LLC, Bayer Essure Inc., and
Bayer HealthCare Pharmaceuticals Inc.*

CERTIFICATE OF SERVICE

I hereby certify that on this 20th day of May, 2016, a true and correct copy of the foregoing document was served upon the following via the Court's electronic notification system, electronic mail, and/or U.S. Mail, postage prepaid:

James P. Holloran
Thomas E. Schwartz
Mark J. Gaertner
Justin D. Guerra
HOLLORAN SCHWARTZ & GAERTNER
2000 South Eighth St.
St. Louis, MO 63104
Tel: 314-772-8989
Fax: 314-772-8990
jholloran@holloranlaw.com
tschwartz@holloranlaw.com
mgaertner@holloranlaw.com
jguerra@holloranlaw.com

Holly Kelly Ennis, Esq
ENNIS & ENNIS, P.A.
1101 Pennsylvania Ave., NW, 6th Floor
Washington, DC 20004
Tel: 800-856-6405
hckennis@ennislaw.com

G. Sean Jez, Esq.
Jessica Kasischke, Esq.
David Hobbs, Esq.
FLEMING | NOLEN | JEZ, LLP
2800 Post Oak Blvd., Ste. 4000
Houston, Texas 77056
Tel: 713-621-7944
Sean_jez@flaming-law.com
Jessica_kasischke@flaming-law.com
David_hobbs@flaming-law.com

Attorneys for Plaintiffs

/s/ Gerard T. Noce
*Attorney for Bayer Corporation, Bayer
HealthCare LLC, Bayer Essure Inc., and Bayer
HealthCare Pharmaceuticals Inc.*