

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
AT LOUISVILLE

DONALD SHUMATE

PLAINTIFF

v.

NO. 3:13-CV-01089-CRS

MEDTRONIC, INC. et al.

DEFENDANTS

MEMORANDUM OPINION

This matter is before the court on a motion to remand filed by the plaintiff, Donald Shumate (“Plaintiff”), against the defendants, Medtronic, Inc., Medtronic USA, Inc., Medtronic Sofamor Danek USA, Inc.,¹ John Doe #1, John Doe #2, Norton Hospitals, Inc., Norton Hospital Leatherman Spine Center, Norton Healthcare, Inc., and Norton Enterprises, Inc.² (DN 14).

I.

In June 2006, Plaintiff underwent a lumbar spinal fusion surgery that was performed at Norton Hospital. During the surgery, Plaintiff’s surgeons used a bio-engineered liquid bone graft product known as Infuse Bone Graft. Infuse was allegedly designed, developed, manufactured, promoted, and sold by the Medtronic Defendants. Plaintiff alleges that Infuse is approved by the Federal Drug Administration (“FDA”) for use in a specific type of spinal fusion surgery, and that the Medtronic Defendants have illegally promoted “off-label” use³ of Infuse. Plaintiff claims that his surgeons used Infuse in such an off-label manner during his surgery, and he allegedly suffered injuries as a result.

¹ Defendants Medtronic, Inc., Medtronic USA, Inc., and Medtronic Sofamor Danek USA, Inc. will be collectively referred to as the “Medtronic Defendants.”

² Defendants John Doe #1, John Doe #2, Norton Hospitals, Inc., Norton Hospital Leatherman Spine Center, Norton Healthcare, Inc., and Norton Enterprises, Inc. will be collectively referred to as the “Non-Medtronic Defendants.”

³ “Off-label” usage is defined as “use of a device for some other purpose than that for which it has been approved by the FDA.” *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 350 (2001).

Plaintiff, a citizen of Indiana, filed this action in Jefferson County Circuit Court on November 5, 2013. (Compl., DN 1-1). In the complaint, Plaintiff asserts twelve state law causes of action against the defendants, including, *inter alia*, fraud, fraudulent misrepresentation, fraudulent omission, concealment and nondisclosure, strict products liability, negligence, breach of warranty, and violation of the Kentucky Consumer Protection Act. In sum, Plaintiff alleges that the Medtronic Defendants actively promoted the use of Infuse in manners not approved by the FDA, concealed the side effects associated with off-label use, and provided misleading information regarding Infuse to consumers and the medical community. Plaintiff seeks punitive and compensatory damages for the damages he allegedly suffered as a result of the off-label use of Infuse during his spinal fusion surgery.

The Medtronic Defendants removed the case to this court on November 5, 2013, invoking our diversity of citizenship jurisdiction, as well as our federal-question jurisdiction to hear cases “arising under” federal law. (Notice of Removal, DN 1). Plaintiff has moved to remand. (Mot. to Remand, DN 14).

II.

Pursuant to 28 U.S.C. § 1441(a), a civil action filed in state court is removable only if it could have originally been brought in federal court. 28 U.S.C. § 1441(a). Thus, “a district court must remand a removed case if it appears that the district court lacks subject matter jurisdiction.” *Chase Manhattan Mortg. Corp. v. Smith*, 507 F.3d 910, 913 (6th Cir. 2007). One source of original jurisdiction is diversity of citizenship jurisdiction, which is present only in cases “where the matter in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs, and is between . . . citizens of different States.” 28 U.S.C. § 1332(a).

A second source of original jurisdiction is federal question jurisdiction, which is present only in cases “arising under the Constitution, laws, or treaties of the United States.” 28 U.S.C. § 1331. Such jurisdiction exists where “a well-pleaded complaint establishes either that federal law creates the cause of action or that the plaintiff’s right to relief necessarily depends on resolution of a substantial question of federal law” so that “federal law is a necessary element of one of the well-pleaded . . . claims.” *Franchise Tax Bd. of Cal. v. Construction Laborers Vacation Trust*, 463 U.S. 1, 13, 27–28 (1983). However, “the plaintiff is the master of the claim,” *Caterpillar Inc. v. Williams*, 482 U.S. 386, 392 (1987), and “the fact that the wrong asserted could be addressed under either state or federal law does not . . . diminish the plaintiff’s right to choose a state law cause of action.” *Alexander v. Electronic Data Sys. Corp.*, 13 F.3d 940, 943 (6th Cir. 1994) (citations omitted).

“A defendant seeking to remove a case to federal court has the burden of proving that the district court possesses jurisdiction.” *Williamson v. Aetna Life Ins. Co.*, 481 F.3d 369, 375 (6th Cir. 2007) (citation omitted). “All doubts as to the propriety of removal are resolved in favor of remand.” *Coyne v. American Tobacco Co.*, 183 F.3d 488, 493 (6th Cir. 1999) (citation omitted).

III.

The Medtronic Defendants assert two grounds on which they claim that this court has jurisdiction. First, they argue that the court has diversity jurisdiction because the parties are diverse and the amount in controversy exceeds the jurisdictional threshold of \$75,000. Second, they contend that the court has federal question jurisdiction because Plaintiff’s complaint necessarily raises a substantial question of federal law. The court will address each of these contentions in turn.

A.

The Medtronic Defendants argue that diversity of citizenship jurisdiction exists pursuant to 28 U.S.C. § 1332. Although Plaintiff acknowledges that the parties are diverse, he argues that remand is appropriate because several of the Non-Medtronic Defendants are Kentucky residents and, pursuant to the forum defendant rule, “[a] civil action otherwise removable solely on the basis of the jurisdiction under section 1332(a) of this title may not be removed if any of the parties in interest properly joined and served as defendants is a citizen of the State in which such action is brought.” 28 U.S.C. § 1441(b)(2).⁴

Plaintiff filed his complaint with the Jefferson County Circuit Court on November 5, 2013. That same day, the Medtronic Defendants filed a notice of removal with this court. The Medtronic Defendants contend that the forum defendant rule is inapplicable in the instant action because this notice of removal was filed before any of the Non-Medtronic Defendants were served, thus precluding the application of § 1441(b)(2). Plaintiff acknowledges that the Medtronic Defendants filed the notice of removal on the day that the lawsuit was filed, and that service was not accomplished on either the Non-Medtronic Defendants or the Medtronic Defendants until November 6, 2013.⁵ However, Plaintiff argues that the Medtronic Defendants’

⁴ The removal statute, § 1441(b), was amended in 2011. *See* Federal Courts Jurisdiction and Venue Clarification Act of 2011, Pub. L. No. 112–63, 125 Stat. 758 (2011). Prior to the amendment, the removal statute provided that cases in which federal jurisdiction is based on complete diversity “shall be removable only if none of the parties in interest properly joined and served as defendants is a citizen of the State in which the action is brought.” As amended, the removal statute states, “[a] civil action otherwise removable solely on the basis of the jurisdiction under section 1332(a) of this title may not be removed if any of the parties in interest properly joined and served as defendants is a citizen of the State in which such action is brought.” 28 U.S.C. § 1441(b)(2) (2011). The amended version of the statute applies to actions commenced on or after January 5, 2012. The Medtronic Defendants argue that case law applying the pre-amendment language is inapplicable in the instant action. However, both parties cite to pre-amendment cases to support their arguments. The court finds that “the amendments did not materially change the relevant language of the statute,” and we will accept citations to authority that applies either the pre- or post-amendment version of § 1441(b). *Gentile v. Biogen Idec, Inc.*, 934 F. Supp. 2d 313, 316 n.2 (D. Mass. 2013).

⁵ This is only one of fourteen cases pending before this court involving claims that Medtronic promoted off-label use of Infuse. In each of the other actions, the Medtronic Defendants filed notices of removal on the same day as, or within two business days following, the filing of the complaint. (DN 13-3).

tactics in seeking quick removal before service on any defendant violates the language and intent of the forum defendant rule.

“The proper interpretation of the ‘properly joined and served’ language of the forum defendant rule has not been resolved by the federal appellate courts.” *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, 2012 WL 2919219, *2 (E.D. Ky. July 17, 2012). The Sixth Circuit has recognized that “the inclusion of an *unserved* resident defendant in the action does not defeat removal under 28 U.S.C. § 1441(b),” but it has not indicated when, or if, removal would be warranted when a defendant attempts to “game” the system by watching the state court docket and removes the action before a forum defendant can be joined and served. *McCall v. Scott*, 239 F.3d 808, 813 n.2 (6th Cir. 2001) (citations omitted) (emphasis in original).

One purpose of the forum defendant rule is to prevent an out-of-state plaintiff from gaming the prohibition against removal by joining an in-forum party against whom no legitimate claim is made. *See United Steel Supply, LLC v. Buller*, 2013 WL 3790913, *1 (W.D. Ky. July 19, 2013); *see also Stan Winston Creatures, Inc. v. Toys “R” Us, Inc.*, 314 F. Supp. 2d 177, 180–81 (S.D.N.Y. 2003). The forum defendant rule permits removal if the in-forum party is not properly joined in the lawsuit. The same consideration against gamesmanship would seem to apply when defendants attempt to use the forum defendant rule to their advantage by monitoring the state court docket and quickly removing an otherwise non-removable action before service can be accomplished. *See Ethington v. General Elec. Co.*, 575 F. Supp. 2d 855 (N.D. Ohio 2008); *Allen v. GlaxoSmithKline PLC*, 2008 WL 2247067 (E.D. Pa. May 30, 2008).

The Medtronic Defendants, however, urge the court to apply the plain language of § 1441(b) and ignore the implications that could arise from a literal application of the rule.⁶ They

⁶ This case highlights the problems and inconsistencies that could arise from applying the plain language of the removal statute. In two of the fourteen cases pending before this court, a Kentucky defendant was served on the

contend that the majority of courts in the Sixth Circuit have applied the plain meaning of the statute and denied remand when an action was removed prior to service of a forum defendant. *See, e.g., Linder v. Medtronic, Inc.*, 2013 WL 5486770 (W.D. Tenn. Sept. 30, 2013); *Darsie v. Cone*, 2010 WL 2923285 (E.D. Ky. July 22, 2010). Indeed, a court in this district held:

The plain language of § 1441(b)(2), however, requires proper service for application of the forum defendant rule. The Court is not inclined to disregard this language, or read it out of the statute, especially because Congress amended the forum defendant rule in 2011 without altering the “properly joined and served” language despite the recognized disagreement among courts as to its application.

United Steel Supply, LLC v. Buller, 2013 WL 3790913, *4 (W.D. Ky. July 19, 2013). Although the court narrowly construed the removal statute in that instance, it noted that it would “make[] no judgment as to whether this same holding would apply to cases where the plaintiff actually presents evidence that the defendant engaged in a sort of gamesmanship to obtain federal jurisdiction prior to the time when plaintiff can properly serve him.” *Id.* at *4 n.1.

This case presents the kind of gamesmanship that the court referenced in *United Steel Supply*. Plaintiff has shown that in each of the fourteen cases pending before this court alleging off-label promotion of Infuse by Medtronic, the Medtronic Defendants filed notices of removal within two business days following the filing of the complaint and before service of process was, as a practical matter, possible. (DN 13-3). Indeed, in the instant action, the Medtronic Defendants immediately filed the notice of removal on the day the complaint was filed in state court. This case can be distinguished from *United Steel Supply*, as the single defendant in that action removed the case thirty days after the complaint had been filed. 2013 WL 3790913. The facts of the present case bear more similarity to those in *Ethington*, where the court noted:

same day as the Medtronic Defendants filed the notice of removal. If the court were to strictly apply the language of the statute, as the Medtronic Defendants request, it would lead to absurd results: the court would have to deny remand in twelve of the cases and grant remand in the two cases in which the forum defendant was served coincident with removal.

The tactics employed by defendants such as in the instant case turn Congressional intent on its head by allowing *defendants* to employ gamesmanship, specifically by rushing to remove a newly filed state court case before the plaintiff can perfect service on anyone. Given that Congress intended the “properly joined and served” language to *prevent* litigant gamesmanship, “it would be especially absurd to interpret the same ‘joined and served’ requirement to actually condone a similar kind of gamesmanship from defendants” in instances such as the case at bar.

...

[A] literal application of § 1441(b) would allow defendants to always avoid the imposition of the forum defendant rule as long as they are monitoring state dockets and avoiding service.

Ethington, 575 F. Supp. 2d at 862 (citations and quotations omitted) (emphasis in original).

The behavior in quickly removing before service of process can be made is clearly an attempt to go around the forum defendant rule. Normally, a defendant is probably not aware that a lawsuit has been filed against it until it is served. In this case, it is clear that the Medtronic Defendants were monitoring the filing of suits on the state court docket in order to accomplish removal prior to receiving notice through service that they had been sued. Although the Medtronic Defendants do not admit to gamesmanship in monitoring the state court docket, their pattern of behavior in jack rabbit removal is obvious. Thus, the court finds that the Medtronic Defendants have not met their burden of proving that removal based on diversity of citizenship was not in violation of the intent and purpose of the forum defendant rule.

B.

The Medtronic Defendants alternatively argue that the court has federal question jurisdiction pursuant to 28 U.S.C. § 1331 because Plaintiff’s claims arise under federal law. *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.”). An action “arises under” federal law if (1) “federal law creates the cause of action,” or (2) “the vindication of a right under state

law necessarily turned on some construction of federal law.” *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 808–09 (1986) (quoting *Franchise Tax Bd.*, 463 U.S. at 9). In the instant action, federal law does not create a private right of action. *See id.* at 806–07 (“[T]he FDCA does not create or imply a private right of action for individuals injured as a result of violations of the Act[.]”) (quotation and internal marks omitted). Thus, removal is only proper if Plaintiff’s state law claims “necessarily turn[] on some construction of federal law.” *Id.* at 808–09.

The Medtronic Defendants argue that Plaintiff’s claims “arise under” federal law because Plaintiff must prove a violation of federal law to avoid preemption of his claims under the Medical Device Amendments (“MDA”) to the Federal Food, Drug and Cosmetic Act (“FDCA”).⁷ Section 360k(a) of the MDA preempts any state requirement “which is different from, or in addition to, any requirement” imposed by the MDA. 21 U.S.C. § 360k(a)(1). However, a state is not prevented “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 v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)).

Plaintiff does not seek relief under the MDA. However, Plaintiff’s complaint references the MDA because the MDA establishes the FDA’s process for approving medical devices, such as Infuse, and it is relevant to Plaintiff’s allegations that the Medtronic Defendants promoted Infuse for off-label uses.

⁷ The parties agree that Infuse is a Class III device that is regulated by the MDA. Class III devices are subject to the “rigorous” premarket approval process, which requires the manufacturer to submit a multivolume application that is reviewed by the FDA. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317–18 (2008) (citations omitted). The FDA evaluates, among other things, the “safety and effectiveness” of the device’s proposed label and, after approving the device, thereafter “forbids the manufacturer to make, without FDA permission, changes in . . . labeling . . . that would affect safety or effectiveness.” *Id.* at 318–19 (citing 21 U.S.C. §§ 360c(a)(2)(B), 360e(d)(6)(A)(i)).

The well-pleaded complaint rule “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) (citing *Gully v. First Nat’l Bank*, 229 U.S. 109, 112–13 (1936)). Thus, it is well-settled “that a case may not be removed to federal court on the basis of a federal defense, including the defense of pre-emption, even if the defense is anticipated in the plaintiff’s complaint, and even if both parties concede that the federal defense is the only question truly at issue.” *Id.* at 393 (citing *Franchise Tax Bd.*, 463 U.S. at 12). The Sixth Circuit recognizes three exceptions to the well-pleaded complaint rule: (1) the artful pleading doctrine; (2) the complete preemption doctrine; and (3) the substantial federal question doctrine. *Mikulski v. Centerior Energy Corp.*, 501 F.3d 555, 560 (6th Cir. 2007). Although the Medtronic Defendants raise preemption as a defense to Plaintiff’s state law claims, they acknowledge that the MDA does not completely preempt the field. Accordingly, only the third exception is relevant in the instant action if Plaintiff’s state law claims raise substantial federal questions relating to labeling requirements under the MDA.

Under the substantial federal question doctrine, state law claims can be said to arise under federal law and thus permit the removal of the action to federal court “where the vindication of a right under state law necessarily turn[s] on some construction of federal law.” *Id.* (quoting *Franchise Tax Bd.*, 463 U.S. at 9) (alteration in original). The Supreme Court recognizes that only a narrow category of cases fall within the substantial federal question doctrine, and the Court has provided the lower courts with a framework for determining when state law claims necessarily turn on federal law so as to permit federal jurisdiction.

The Court outlined the contours of the inquiry in *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308 (2005). In *Grable*, the Internal Revenue

Service (“IRS”) seized property belonging to the plaintiff company to satisfy its federal tax delinquency, and the government provided notice to the company by certified mail prior to selling the property to the defendant. *Id.* at 310–11. Although the plaintiff company had, in fact, received notice of the sale, it brought a quiet title action against the defendant in state court five years after the sale, arguing that the IRS had failed to notify it in the manner required by Section 6335(a) of the Internal Revenue Code. *Id.* at 311. The defendant removed the case to the federal district court in Michigan, arguing that the plaintiff’s quiet title action implicated the district court’s “arising under” jurisdiction because it “depended on the interpretation of the notice statute in the federal tax law.” *Id.*

On appeal, the Supreme Court stated the question presented to it as whether “a state-law 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 judicial responsibilities.” *Id.* at 314. The Court ultimately concluded that it had jurisdiction over the plaintiff’s state law causes of action because the issue of whether the plaintiff was given notice within the meaning of the statute was “an essential element of its quiet title claim” *Id.* at 315. Moreover, “[t]he Government’s ‘direct interest in the availability of a federal forum to vindicate its own administrative action’ made the question ‘an important issue of federal law that sensibly belong[ed] in a federal court.’” *Gunn v. Minton*, 133 S. Ct. 1059, 1066 (2013) (quoting *Grable*, 545 U.S. at 315) (alterations in original).

The Court recently revisited this framework in *Gunn v. Minton*, 133 S. Ct. 1059 (2013). In *Gunn*, the plaintiff had previously filed a patent infringement case, which resulted in a judgment that his patent was invalid. *Id.* at 1062. He then sued his lawyer for legal malpractice in state court, arguing that the lawyer had failed to raise an “experimental use” defense in the

patent infringement case. *Id.* at 1063. The state trial court granted the lawyer’s motion for summary judgment. *Id.* The plaintiff then appealed, arguing that the state court lacked subject matter jurisdiction over his malpractice claim because the claim involved a substantial federal issue and thus arose under 28 U.S.C. § 1338(a).⁸ *Id.*

In evaluating the plaintiff’s claim, the Court restated the *Grable* inquiry as follows: “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.” *Id.* at 1065. On balancing these factors, the Court found that the plaintiff’s state law malpractice claim did raise a federal issue relating to the experimental use defense, but the federal issue was not sufficiently substantial so as to compel federal jurisdiction. *Id.* at 1065–68.

This court is not without guidance in applying the framework developed in *Grable*, and further refined by *Gunn*, to a motion to remand involving claims against Medtronic for alleged off-label promotion of Infuse. Several federal district courts have applied this framework to claims that are similar, if not identical, to the ones brought by Plaintiff in the instant action against Medtronic. *See, e.g., H.R. ex rel. Reuter v. Medtronic, Inc.*, — F. Supp. 2d —, 2014 WL 554454 (S.D. Ohio Feb. 13, 2014); *Dillon v. Medtronic, Inc.*, — F. Supp. 2d —, 2014 WL 37759 (E.D. Ky. Jan. 6, 2014); *Anders v. Medtronic, Inc.*, 2014 WL 1652352 (E.D. Mo. Apr. 24, 2014); *Goade v. Medtronic, Inc.*, 2013 WL 6237853 (W.D. Mo. Dec. 3, 2013); *Jenkins v. Medtronic, Inc.*, 984 F. Supp. 2d 873 (W.D. Tenn. 2013).

In proceeding with the *Grable* inquiry, the court first considers whether Plaintiff’s state law claims necessarily raise a federal issue. The Medtronic Defendants contend that Plaintiff must plead a violation of the MDA to ultimately succeed in this action, as Plaintiff must show

⁸ Section 1338(a) gives federal courts exclusive jurisdiction in certain patent matters.

that his claims are not preempted. They argue that this, in turn, will require the court to interpret the MDA. Indeed, to avoid the effect of the MDA's express preemption provision, Plaintiff must allege a violation of state law that parallels a violation of federal law. *Riegel*, 552 U.S. at 330 (citation omitted). Thus, proving a violation of federal law is "necessary" to Plaintiff's case. The court also finds that the federal issue is disputed, as the central issue to be resolved is whether Medtronic promoted off-label uses of Infuse, and whether this promotion was a source of Plaintiff's injuries.

However, the analysis falters with respect to the third element, the substantiality of the federal issue. *Gunn* restricted the application of this element so that it is no longer enough that the federal courts have a greater expertise with federal law. *Gunn*, 133 S. Ct. at 1068 ("But the possibility that a state court will incorrectly resolve a state claim is not, by itself, enough to trigger the federal courts' exclusive patent jurisdiction, even if the potential error finds its root in a misunderstanding of patent law."). *Gunn* clarified the substantiality inquiry to require that the disputed federal issue be "significant to the federal system as a whole." *Id.*

The Court in *Gunn* found that such a requirement was met in *Grable*, because the Court had been "primarily focused not on the interests of the litigants themselves, but rather on the broader significance of the notice question for the Federal Government . . . , emphasiz[ing] the Government's 'strong interest' in being able to recover delinquent taxes through seizure and sale of property, which in turn 'require[d] clear terms of notice'" to buyers. *Id.* at 1066 (quoting *Grable*, 545 U.S. at 310–15). In contrast, the federal issue in *Gunn* did not satisfy the substantiality requirement because "the resolution of a patent issue in the context of a state legal malpractice action can be vitally important to the particular parties," but there needed to be "something more" than a showing of a federal element as part of the cause of action. *Id.* at 1068.

This court similarly concludes that the federal issues in dispute in the instant action fail to meet the “substantiality” requirement in that they are important to the individual litigants, but they are not significant to the federal system as a whole. The United States District Court for the Western District of Missouri came to the same conclusion, applying *Gunn* and remanding the plaintiff’s state law claims. *Goade v. Medtronic, Inc.*, 2013 WL 6237853 (W.D. Mo. Dec. 3, 2013). In *Goade*, the Western District of Missouri held:

There is a need to demonstrate the issue ‘is significant to the federal system as a whole,’ *Gunn*, 133 S.Ct. at 1068—that is, an importance that transcends the parties. As noted, this degree of importance has been found only when the Government’s operations are affected by the federal issue. Only in such cases could it be confidently stated that if Congress had thought about the issue it would have sensibly concluded the dispute should be resolved by a federal court. In contrast, Congress has not created a federal right of action, preempted the entirety of state regulation, or divested state courts of jurisdiction in such matters. This failure is telling and cements the Court’s conclusion that the federal issues raised in the Petition are not substantial within the meaning of *Gunn*.

Id. at *6. Thus, it is not enough that the plaintiff’s state law claims arise under the backdrop of a federal issue. *See, e.g., Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804 (1986) (finding no substantial federal interest arose from the plaintiffs’ reliance on the FDCA to support their state law tort claims relating to adequacy of a drug’s labeling). Instead, the importance of the federal issue must “transcend[] the parties.” *Goade*, 2013 WL 6237853, at *6.

Finally, even if Plaintiff’s complaint presented substantial federal issues, the resolution of this dispute in federal court will “disrupt[] the federal-state balance approved by Congress.” *Gunn*, 133 S. Ct. at 1065. In analyzing this factor, other courts have found it “telling” that Congress chose to neither permit federal jurisdiction, nor completely preclude state jurisdiction, over claims alleging violations of the MDA. Further, the Supreme Court in *Merrell Dow* indicated its unwillingness to open up federal courts to all state law tort claims involving medical

devices. *Merrell Dow*, 478 U.S. at 814–17. Thus, we conclude that the fourth factor weighs against the exercise of jurisdiction in this action.

The court recognizes that two district courts in the Sixth Circuit have denied motions to remand brought by different plaintiffs but involving the same issues and claims against Medtronic. *See H.R. ex rel. Reuter v. Medtronic, Inc.*, — F. Supp. 2d —, 2014 WL 554454 (S.D. Ohio Feb. 13, 2014); *Jenkins v. Medtronic, Inc.*, 984 F. Supp. 2d 873 (W.D. Tenn. 2013). Although the district courts in both instances applied the framework established in *Grable*, they failed to address the Court’s concerns in *Gunn*. It is true that the Court in *Gunn* did not appear to alter the inquiry under *Grable*, but it did emphasize that only a limited subset of cases should fit within the scope of the substantial federal question doctrine. In keeping with these concerns, this court similarly concludes that the instant action does not raise a substantial issue of federal law that is important to the federal system as a whole. *See Gunn*, 133 S. Ct. at 1066–67.

Thus, there is no basis for the court’s jurisdiction, and the action will be remanded to the Jefferson County Circuit Court by separate order and judgment.

August 22, 2014

A handwritten signature in black ink, appearing to read "Charles R. Simpson III", is written over a faint circular seal. The seal contains the text "U.S. DISTRICT COURT" and "JEFFERSON COUNTY, OHIO".

**Charles R. Simpson III, Senior Judge
United States District Court**