

biologic medical device called Infuse in surgical procedures performed on patients at its facilities. The Complaint further alleges that Defendant used Infuse in manners not specifically approved by the Food and Drug Administration (FDA), otherwise known as “off-label” use. Defendant is also alleged to have fraudulently concealed the fact that Infuse was used in many surgeries, and also that Infuse was being used in an off-label manner. Based on these allegations, the Complaint raises claims of: (1) fraud; (2) negligence; (3) violating the Ohio Consumer Sales Protection Act; and (4) negligent credentialing, supervision, and retention. (*Id.* at 37–43).

Plaintiff’s Complaint was styled as a Class Action Complaint, with the alleged class being “any [Infuse] patient at Children’s Hospital Dr. Durrani implanted [Infuse] who is not already a Deters Law Office or other law office client who has brought a claim for [infuse].” (*Id.* at 2). The Complaint claims that the Deters Law Firm, which represents Plaintiff in this action, has brought similar claims against Defendant on behalf of 185 known individuals, and that this action is on behalf of all those who have not yet acquired representation but have been affected. (*Id.* at 35).

Defendant removed this action to federal court on June 30, 2015. (Doc. 1). Defendant’s notice of removal claimed two bases for the Court’s jurisdiction. First, the notice alleged that the Court has federal question jurisdiction under 28 U.S.C. § 1331. Second, the notice alleged that the Court had jurisdiction under the Class Action Fairness Act of 2005 (“CAFA”), 28 U.S.C. §§ 1332(d) and 1453. Plaintiff filed a motion for remand on August 19, 2015, challenging both these bases for jurisdiction. (Doc. 12).

II. STANDARD OF REVIEW

On a motion for remand, the question is whether the district court lacks subject matter jurisdiction. 28 U.S.C. § 1447(c). Defendant bears the burden of establishing that removal was proper. *Long v. Bando Mfg. of Am., Inc.*, 201 F.3d 754, 757 (6th Cir. 2000). Removal raises significant federalism concerns and, for this reason, federal courts must strictly construe such jurisdiction. *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 808 (1986). Accordingly, a federal court must resolve any doubt of its removal jurisdiction in favor of state court jurisdiction. *Shamrock Oil & Gas Corp. v. Sheets*, 313 U.S. 100, 108-09 (1941). In other words, the issue is whether the case was properly removed in the first instance. *Provident Bank v. Beck*, 952 F. Supp. 539, 540 (S.D. Ohio 1996). Specifically, the issue is whether the plaintiff's well-pleaded complaint asserts a cause of action created by federal law or depends on the resolution of a substantial question of federal law. *Jordan v. Humana Military Healthcare Serv., Inc.*, No. C-3-06-51, 2006 U.S. Dist. LEXIS 25845, at *1 (S.D. Ohio May 2, 2006).

Removal of an action to federal court based on original jurisdiction is provided for in 28 U.S.C. §§ 1441(a), 1331 as to: "all civil actions arising under the Constitution, laws, or treaties of the United States." Defendant maintains that Plaintiff's complaint contains a claim "arising under" federal law.

"The 'arising under' gateway into federal court has two distinct portals." *Eastman v. Marine Mech. Corp.*, 438 F.3d 544, 550 (6th Cir. 2006). This Court has original jurisdiction if Plaintiff's well-pleaded complaint establishes that either federal law creates

the cause of action, or that Plaintiff's right to relief involves the resolution or interpretation of a substantial question of federal law. *Id.*

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." *Loftis v. United Parcel Serv., Inc.*, 342 F.3d 509, 514 (6th Cir. 2003) (quoting *Caterpillar Inc. v. Williams*, 482 U.S. 386 (1987)). Because the plaintiff is the master of his complaint, the fact that a claim could be stated under federal law does not prevent a plaintiff from only stating it under state law. *Eastman*, 438 F.3d at 550.

III. ANALYSIS

A. This Court does not have federal question jurisdiction over this civil action.

In the notice of removal, Defendant claimed that this Court had jurisdiction over this matter under 28 U.S.C. § 1441 because "[Plaintiff's allegations] present substantial questions of federal law, which cannot be adequately addressed in state court." (Doc. 1, at 4).

Federal question jurisdiction would sit with this Court if the Court concludes that the federal issues presented in this case are: (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. (Doc. 12-1 at 12); *Gunn v. Minton*, 133 S. Ct. 1059, 1065 (2013); *see also Grable & Sons Metal Prods. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 314 (2005).

Plaintiff's Motion to Remand concedes the first two elements set forth by *Grable* and *Gunn*. (Doc. 12-1, at 12). Indeed, the first element is clear given that Plaintiff's Complaint spends twelve pages of the Complaint (Doc. 7, at 9–15, 22–26) discussing the substance of various federal laws and federal response to Infuse, including the Federal Food, Drug, and Cosmetic Act ("FDCA") and Medical Device Amendments to the Food, Drug, and Cosmetic Act ("MDA"), and alleging that CCHMC's conduct violated these federal laws. (See Doc. 7, at 6, 9–30). Furthermore, these assertions are disputed between the parties, as CCHMC firmly contends that the off-label use of Infuse does not violate any federal law or any FDA regulations. See *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 34, 350 (2001) (recognizing off-label usage as "an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine."); *Wash. Legal Found. v. Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000) ("A physician may prescribe a legal drug to serve any purpose that he or she deems appropriate, regardless of whether the drug has been approved for that use by the FDA.").

However, Plaintiff argues that the third and fourth factors set forth by *Grable* and *Gunn* are inapplicable. (Doc. 12-1, at 12–15). Specifically, Plaintiff argues that the federal law question is not substantial, and that it is not capable of resolution in federal court without disrupting the federal-state balance approved by Congress. (*Id.*).

The federal issues presented by Plaintiff in this case are not substantial to a degree that would grant this Court subject matter jurisdiction. Plaintiff's claims revolve around accusations that Defendant allowed the use of Infuse in a manner that was "off-label" in

violation of the FDCA. Evaluating the claims in this case will necessarily require the reviewing court to interpret the FDCA and its implementing regulations. In a previous decision, this Court held that the federal issues raised by Plaintiff were substantial under the *Grable* analysis in a very similar recent case. In *H.R. (“Reuter”) v. Medtronic, Inc.*, the Court held that a case presenting issues surrounding the propriety of off-label use raised a substantial federal question. *Reuter*, 996 F. Supp. 2d 671, 679 (S.D. Ohio 2014) (“[T]here is no state-law equivalent of ‘off label’ . . . [t]he concept is entirely federal [so the claims] necessarily raise substantial federal questions by requiring the Court to interpret the meaning of the FDCA and its implementing regulations.”) (quoting *In re Zyprexa Products Liab. Litig.*, No. 04-MD-1596, 2012 U.S. Dist. LEXIS 87228, at *5 (E.D.N.Y. June 22, 2012)).

However, that decision did not take into account the United States Supreme Court’s holding in *Gunn*. While *Gunn* did not alter the four factors from *Grable* used to evaluate whether a federal interest was substantial, that decision emphasized the restricted circumstances in which a federal issue could be held as “substantial.” *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 vast majority of relevant federal court opinions post-*Gunn* have held that a state tort claim revolving around liability for the misuse of Infuse does not raise a substantial federal issue despite the claim’s reliance on FDCA

regulations. *See Schillmiller v. Medtronic, Inc.*, 44 F.Supp.3d 721, 731 (W.D. Ky. 2014); *Hilyard v. Medtronic, Inc.*, 21 F.Supp.3d 1012, 1018–20 (E.D. Mo.2014); *Anders v. Medtronic, Inc.*, No. 4:14cv194, 2014 WL 1652352, at *5–7 (E.D. Mo. Apr. 24, 2014); *Mooney v. Henkin*, No. 8:13-cv-3213, 2014 WL 523034, at *3-4 (M.D. Fla. Feb. 9, 2014); *Goade v. Medtronic, Inc.*, No. 13-5123, 2013 WL 6237853, at *4–6 (W.D. Mo. Dec. 3, 2013). *But see Dooley v. Medtronic, Inc.*, 39 F. Supp. 3d 973 (W.D. Tenn. 2014) (finding in an analogous case that state claims over the use of Infuse raised a substantial federal question due to the importance of federal regulations to the case).

This Court joins with the prevailing consensus in holding that there is no substantial federal issue raised in this civil action. While the interpretation of FDCA regulations will be of supreme importance to the parties in this case, that interpretation will not be “significant to the federal system as a whole” as required by *Gunn*. *Gunn*, 133 S.Ct. at 1068. None of the issues in this case would affect the Government’s operation. Therefore, these issues are not substantial.

Accordingly, this Court does not have federal question jurisdiction over this matter.

B. This Court has jurisdiction over this action under the Class Action Fairness Act of 2005 (CAFA) and will not decline to exercise that jurisdiction.

Defendant’s notice of removal also claimed that this Court had jurisdiction over this matter Under the Class Action Fairness Act of 2005 (“CAFA”), 28 U.S.C. §§ 1332(d) and 1453. CAFA gives federal district courts original jurisdiction over any class action in which the putative class consists of more than 100 members and the

amount in controversy is in excess of \$5,000,000. 28 U.S.C. § 1332(d)(2), (5). Plaintiff concedes that these jurisdictional requirements are met. However, Plaintiff claims that multiple exceptions to jurisdiction contained in CAFA apply.

An important factor for evaluating whether certain exceptions to federal jurisdiction under CAFA apply is what percentage of putative class members reside in the initial forum state. Under CAFA, a district court must decline jurisdiction if greater than two-thirds of the members of all proposed plaintiff classes in the aggregate are citizens of the State in which the action was originally filed and at least one significant defendant is a citizen of the State in which the action was originally filed. 28 U.S.C. § 1332(d)(4)(A). A district court must also decline jurisdiction if greater than two-thirds of the members of all proposed plaintiff classes in the aggregate are citizens of the State in which the action was originally filed and all of the primary defendants are citizens of that state. 28 U.S.C. § 1332(d)(4)(B).

The only defendant in this case, CCHMC, is a citizen of Ohio. Not all putative class members in this case are known at this time; however, the data available to this Court demonstrates that less than two-thirds of the putative class members are citizens of Ohio. In Plaintiff's own provided sampling of potential class members, consisting of 70 known Plaintiffs suing the manufacturer of Infuse, 65.7% of the sample is from Ohio, less than the two thirds needed to require the Court to decline jurisdiction. (Doc. 12-1, at 19). Defendant's analysis of all pending cases against CCHMC relating to Dr. Durrani shows that 60.6% of those plaintiffs are citizens of Ohio. (Doc. 14, at 12-13). Exact counts of class members are not required for the Court to evaluate the applicability of the

CAFA exceptions, and the Court extrapolates from the available data that less than two thirds of potential class members in this case are residents of Ohio.¹ Accordingly, neither of the two CAFA exceptions contained in 28 U.S.C. § 1332(d)(4)(A)–(B) that would require the Court to decline to exercise jurisdiction apply.

Because a sampling of potential class members indicates that less than two thirds of putative class members are citizens of Ohio, the only mechanism available for denying jurisdiction of this class action is 28 U.S.C. § 1332(d)(3), which states:

(3) A district court may, in the interests of justice and looking at the totality of the circumstances, decline to exercise jurisdiction under paragraph (2) over a class action in which greater than one-third but less than two-thirds of the members of all proposed plaintiff classes in the aggregate and the primary defendants are citizens of the State in which the action was originally filed based on consideration of—

(A) whether the claims asserted involve matters of national or interstate interest;

(B) whether the claims asserted will be governed by laws of the State in which the action was originally filed or by the laws of other States;

(C) whether the class action has been pleaded in a manner that seeks to avoid Federal jurisdiction;

(D) whether the action was brought in a forum with a distinct nexus with the class members, the alleged harm, or the defendants;

(E) whether the number of citizens of the State in which the action was originally filed in all proposed plaintiff classes in the aggregate is substantially larger than the number of citizens from any other State, and the citizenship of the other members of the proposed class is dispersed among a substantial number of States; and

¹ Plaintiff requests that the Court allow limited discovery on the issue of class composition to assist in a determination of what percentage of the putative class resides in Ohio, citing previous federal cases where such discovery was allowed. (Doc. 12-1, at 18–19). The Court does not find that necessary. Although the Court could allow such discovery were the Court to determine that the sample size of known potential Plaintiffs was insufficient to make a determination, the sample sizes provided by the parties (70 individuals by Plaintiff’s count, 66 by Defendants’ count) are sufficient to rule without additional discovery.

(F) whether, during the 3-year period preceding the filing of that class action, 1 or more other class actions asserting the same or similar claims on behalf of the same or other persons have been filed.

28 U.S.C. § 1332(d)(3).

On balance, these factors favor this Court's exercising jurisdiction over this case. Most significantly, this is a case of national interest. Several products liability cases related to the use of Infuse have already been heard by this Court. *See, e.g., Aaron v. Medtronic et al.*, 2016 WL 5242957 (S.D. Ohio 2016). Any decision regarding Defendant's liability for using Infuse in surgeries will have an impact on many similar cases across the country yet to be decided. Additionally, despite the Court's holding that the federal issues in this case do not rise to the level required to grant the Court federal question jurisdiction, the need to interpret FDCA regulations in evaluating this case does weigh, at least to some degree, in favor of this Court's exercising jurisdiction under CAFA. Finally, the fact that a substantial minority of potential plaintiffs in this case comes from states other than Ohio (primarily but not exclusively Kentucky) also guides this Court to accept jurisdiction. This case is not a "local controversy" confined to Ohio—it is a multistate class action with a geographically diverse set of Plaintiffs that has broad implications for future litigation across the country. A federal court is the proper venue for adjudicating this case.

Accordingly, the Court will not decline jurisdiction on this case.

C. This Court need not rule on whether Plaintiff’s CAFA exception arguments are time barred.

In a supplemental memorandum in opposition to Plaintiff’s motion to remand, Defendant argues that Plaintiff has forfeited his CAFA exception arguments by moving for remand too late.

All of the CAFA exceptions cited by Plaintiff in his motion to remand refer to a federal district court’s *declining* to exercise jurisdiction, either mandatorily or voluntarily. Therefore, these exceptions presume that the Court does in fact have jurisdiction over the action. Accordingly, these exceptions can be waived by a Plaintiff’s failure to timely invoke them. *Clark v. Lender Processing Servs.*, 562 F. App’x 460, 465 (6th Cir. 2014); *see also Graphic Comm’ns Local 1B Health & Welfare Fund A v. CVS Caremark Corp.*, 636 F.3d 971, 973 (8th Cir. 2011); *Visendi v. Bank of Am., N.A.*, 733 F.3d 863, 869–70 (9th Cir. 2013).

However, although the Sixth Circuit has ruled that the CAFA exceptions are waivable, it has not ruled on exactly *when* these exceptions are waived, and other circuit courts have issued divergent rulings. The Fifth Circuit has ruled that CAFA objections are waived if not filed within 30 days of removal, citing 28 U.S.C. § 1447, which states that “a motion to remand the case on the basis of any defect other than lack of subject matter jurisdiction must be made within 30 days after the filing of the notice of removal[.]” *In re Shell Oil Co.*, 932 F.2d 1518, 1521 (5th Cir.), *cert. denied*, 502 U.S. 1049 (1991) (“section 1447(c) “requires remand *on any ground other than lack of subject matter jurisdiction* to be sought within 30 days of the filing of a notice of removal”)

(quoting 14A Charles A. Wright, et al., *Federal Practice and Procedure* § 3739, at 95 (2d ed. Supp.1990)) (emphasis the court’s); *Williams v. A C Spark Plugs Div. of Gen'l Motors Corp.*, 985 F.2d 783, 787 (5th Cir. 1993) (“Only in the case of a lack of subject matter jurisdiction . . . may the plaintiff object to removal after the thirty-day limit. Any other objection is procedural and waived after thirty days.”).

However, other circuits have ruled differently regarding when a CAFA exception is waived on the premise that the CAFA exceptions operate as abstention doctrines. *See, e.g., Graphic Communications Local 1B Health & Welfare Fund “A” v. CVS Caremark Corp.*, 636 F.3d 971, 973 (8th Cir. 2011) (local controversy exception); *Gold v. New York Life Ins. Co.*, 730 F.3d 137, 141-142 (2d Cir. 2013) (home state controversy exception). As the United States Supreme Court held in *Quackenbush v. Allstate Ins. Co.*, 517 U.S. 706, 712 (1996), an “abstention-based remand order does not fall into either category of remand order described in § 1447(c), as it is not based on lack of subject matter jurisdiction or defects in removal procedure.” Therefore, the federal appellate courts that have found the CAFA exceptions to be “abstention-based” have held that the 30-day limitation of § 1447(c) does not apply to a motion to remand on the basis of abstention. *See Hinson v. Norwest Fin. S.C., Inc.*, 239 F.3d 611, 614 (4th Cir. 2001) (affirming grant of motion to remand filed more than 30 days after removal, based on discretion to abstain from exercising jurisdiction, and stating that “[s]ection 1447(c) is . . . not applicable”); *Graphic Communications v. CVS Caremark*, 636 F.3d at 974–976 (8th Cir. 2011) (stating that “doctrines such as abstention” are “outside the . . . bounds” of § 1447(c)); *Kamm v. ITEX Corp.*, 568 F.3d 752, 756 (9th Cir. 2009) (stating that “remands based on

abstention . . . are not covered by § 1447(c),” analogizing remand motion based on forum selection clause to abstention-based motion, and holding that the 30-day limit did not apply); *Snapper v. Redan*, 171 F.3d 1249, 1252–1260 (11th Cir. 1999) (reviewing history of § 1447(c), and stating that “a determination that a federal court should abstain in a particular case . . . does not mean the removal was defective” and that “the term ‘defect’” in § 1447(c) only “refers to removal defects”); *Melahn v. Pennock Ins., Inc.*, 965 F.2d 1497, 1503 (8th Cir. 1992) (“We decline . . . to apply the thirty-day rule to bar the plaintiff’s ‘untimely’ motion to remand based upon abstention.”); *Abdale v. North Shore-Long Island Jewish Health System, Inc.*, 2014 WL 2945741 at *7–*8 (E.D.N.Y. 2014) (based on the decisions of *Gold* and *Graphic Communications*, “remand motions based on CAFA need only be raised within a ‘reasonable time,’ not within the thirty-day deadline under 28 U.S.C. § 1447(c)”; *Lippincott V. PNC Bank, N.A.*, 2012 WL 1894275 at *4 (D. Md. 2012).

This Court does not need to determine in the first instance for this circuit whether the CAFA exceptions to jurisdiction need be filed within 30 days, as held by the Fifth Circuit, or within a “reasonable time,” as held by several other circuits, to rule on this motion to remand. This Court has already held that the CAFA exceptions do not apply to the facts of this case (*see supra* Part III.B)—therefore, a ruling on whether the attempt to invoke those exceptions was time barred is moot.

IV. CONCLUSION

Based upon the foregoing, Plaintiff’s motion to remand (Doc. 12) is **DENIED**.

IT IS SO ORDERED.

Date: 2/8/17



Timothy S. Black
United States District Judge