

H.R. v. Medtronic, Inc.

United States District Court for the Southern District of Ohio, Western Division
February 13, 2014, Decided; February 13, 2014, Filed
Case No. 1:13-cv-859

Reporter: 2014 U.S. Dist. LEXIS 18419; 2014 WL 554454

H.R., A MINOR, BY AND THROUGH HER PARENTS AND NATURAL GUARDIANS, STEVE AND TRICIA REUTER, Plaintiffs, vs. MEDTRONIC, INC, et al., Defendants.

Core Terms

federal question, federal law, federal court, doctrine, federal issue, cause of action, medical device, premarket, federal jurisdiction, preempt, state requirement, well-pleaded, state law, off-label, indispensable, manufacturer, oversight, substantial-federal-question, cosmetic, food, defendant's absence, federal interest, federal statute, federal forum, state-law, diversity

Case Summary

Overview

HOLDINGS: [1]-The substantial federal question doctrine applied to the present case; [2]-The Jenkins decision from the United States District Court for the Western District of Tennessee was directly on point and persuasive; [3]-Since the Medical Device Amendments to the Food, Drug, and Cosmetic Act applied, plaintiffs' claims clearly implicated federal law; [5]-There was a substantial federal interest in the issues raised in the complaint; [6]-The doctors and the hospital were neither necessary nor indispensable as there were no product liability claims against them, and severing them would not be unduly prejudicial; [7]-The claims against the promoter involve allegations of violations of federal law, but no such allegations are made against the doctors and hospital.

Outcome

Motion to remand was granted in part and denied in part.

LexisNexis® Headnotes

Civil Procedure > ... > Jurisdiction > Subject Matter Jurisdiction > General Overview
Civil Procedure > ... > Removal > Postremoval Remands > Jurisdictional Defects
Civil Procedure > ... > Removal > Postremoval Remands > Motions for Remand

HN1 On a motion for remand, the question is whether a district court lacks subject matter jurisdiction. 28 U.S.C.S. § 1447(c).

Civil Procedure > ... > Removal > Procedural Matters > General Overview
Evidence > Burdens of Proof > Allocation

HN2 A defendant bears the burden of establishing that removal was proper.

Civil Procedure > ... > Subject Matter Jurisdiction > Federal Questions > Well Pleased Complaint Rule
Civil Procedure > Preliminary Considerations > Removal > General Overview
Civil Procedure > ... > Removal > Postremoval Remands > General Overview
Civil Procedure > Preliminary Considerations > Federal & State Interrelationships > General Overview

HN3 Removal raises significant federalism concerns and, for that reason, federal courts must strictly construe such jurisdiction. Accordingly, a federal court must resolve any doubt of its removal jurisdiction in favor of state court jurisdiction. In other words, the issue is whether the case was properly removed in the first instance. Specifically, 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.

Civil Procedure > ... > Subject Matter Jurisdiction > Federal Questions > General Overview
Civil Procedure > ... > Subject Matter Jurisdiction > Jurisdiction Over Actions > General Overview
Civil Procedure > ... > Removal > Specific Cases Removed > Federal Questions
Civil Procedure > ... > Removal > Procedural Matters > General Overview

HN4 Removal of an action to federal court based on original jurisdiction is provided for in 28 U.S.C.S. §§ 1441(a) and 1331 as to all civil actions arising under the Constitution, laws, or treaties of the United States .

Civil Procedure > ... > Subject Matter Jurisdiction > Federal Questions > Substantial Questions
Civil Procedure > ... > Subject Matter Jurisdiction > Federal Questions > Well Pleased Complaint Rule
Civil Procedure > ... > Subject Matter Jurisdiction > Jurisdiction Over Actions > General Overview
Civil Procedure > ... > Removal > Specific Cases Removed > Federal Questions

HN5 The arising under gateway into federal court has two distinct portals. A federal court has original jurisdiction if

a plaintiff's well-pleaded complaint establishes that either federal law creates the cause of action, or that a plaintiff's right to relief involves the resolution or interpretation of a substantial question of federal law.

Civil Procedure > ... > Subject Matter Jurisdiction > Federal Questions > Well Pleased Complaint Rule

Civil Procedure > ... > Removal > Specific Cases Removed > Federal Questions

HN6 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. Because a 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.

Civil Procedure > ... > Subject Matter Jurisdiction > Federal Questions > Well Pleased Complaint Rule

Civil Procedure > ... > Removal > Specific Cases Removed > Federal Questions

HN7 Although the majority of cases removed to federal court set forth causes of action that plainly raise federal issues, there are three exceptions to the well-pleaded complaint that confer federal question jurisdiction when a federal cause of action is not evidenced on the face of the complaint: (1) the artful-pleading doctrine, (2) the complete preemption doctrine, and (3) the substantial-federal-question doctrine.

Civil Procedure > ... > Subject Matter Jurisdiction > Federal Questions > General Overview

Civil Procedure > ... > Removal > Specific Cases Removed > Federal Questions

HN8 Under the artful pleading doctrine, federal question jurisdiction exists when a plaintiff shrouds its complaint with state law claims in order to avoid federal jurisdiction when its claims are truly federal causes of action. However, rarely will a federal court seek to determine whether the real nature of the claims is federal, regardless of plaintiff's characterization, instead most removal courts correctly confine that practice to areas of the law pre-empted by federal substantive law.

Civil Procedure > ... > Subject Matter Jurisdiction > Federal Questions > General Overview

Civil Procedure > ... > Removal > Specific Cases Removed > Federal Questions

Civil Procedure > ... > Federal & State Interrelationships > Federal Common Law > Preemption

HN9 Under the complete-preemption doctrine, federal question jurisdiction exists when Congress has intended the preemptive force of a federal statute to be so extraordinary that any claim purportedly based on that

preempted state law is considered, from its inception, a federal claim, and therefore arises under federal law. The United States Supreme Court has only applied the complete-preemption doctrine in three areas: (1) Section 301 of the Labor Management Relations Act of 1947, 29 U.S.C.S. § 185; (2) the Employee Retirement Income Security Act of 1975, 29 U.S.C.S. §§ 1001-1461; and (3) the National Bank Act, 12 U.S.C.S. § 39.

Civil Procedure > ... > Subject Matter Jurisdiction > Federal Questions > Substantial Questions

Civil Procedure > ... > Removal > Specific Cases Removed > Federal Questions

HN10 Under the substantial-federal-question doctrine, federal question jurisdiction exists when the state-law claim necessarily states a federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing a congressionally approved balance of federal and state judicial responsibilities. More plainly stated, a state law cause of action may arise under federal law where the vindication of a right under state law depends on the validity, construction, or effect of federal law.

Civil Procedure > ... > Subject Matter Jurisdiction > Federal Questions > Substantial Questions

Civil Procedure > ... > Subject Matter Jurisdiction > Federal Questions > Well Pleased Complaint Rule

Civil Procedure > ... > Removal > Specific Cases Removed > Federal Questions

Civil Procedure > Preliminary Considerations > Federal & State Interrelationships > General Overview

HN11 Where a well-pleaded complaint does not seek relief under federal law, a court may find removal proper if the plaintiff's complaint raises a substantial federal question. Under the precedent of the United States Court of Appeals for the Sixth Circuit and the United States Supreme Court, the substantial-federal-question doctrine has three parts: (1) the state-law claim must necessarily raise a disputed federal issue, (2) the federal interest in the issue must be substantial, and (3) the exercise of jurisdiction must not disturb any congressionally approved balance of federal and state judicial responsibilities.

Civil Procedure > ... > Subject Matter Jurisdiction > Federal Questions > Substantial Questions

Civil Procedure > ... > Subject Matter Jurisdiction > Federal Questions > Well Pleased Complaint Rule

Civil Procedure > ... > Removal > Specific Cases Removed > Federal Questions

HN12 If a complaint satisfies the well-pleaded-complaint rule, that is if federal law is invoked on the face of the complaint without regard to anything alleged in anticipation of avoidance of defenses which it is thought a defendant may interpose, then jurisdiction exists under 28

U.S.C.S. § 1331 regardless of whether the federal issues raised are significant or not.

Governments > Courts > Judicial Precedent

HN13 The opinions of other federal district courts are persuasive but not binding authority on a federal district court.

Civil Procedure > ... > Federal & State Interrelationships > Federal Common Law > Preemption

Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

Healthcare Law > Medical Treatment > Medical Devices > General Overview

HN14 The Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act expressly preempts any state requirement on devices intended for human issue that is different from, or in addition to, any requirement applicable under the MDA or that relates to the safety or effectiveness of the device. 21 U.S.C.S. § 360k(a). The only way a state requirement can be exempted from that express preemption is if the state requirement is more stringent than a requirement under the MDA which would be applicable to the device if an exemption were not in effect; or if the state requirement is required by compelling local conditions; and if compliance with the requirement would not cause the device to be in violation of any applicable requirement under the MDA. 21 U.S.C.S. § 360k(b).

Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

Healthcare Law > Medical Treatment > Medical Devices > Classification & Regulation

Healthcare Law > Medical Treatment > Medical Devices > Premarket Approval

HN15 The Medical Device Amendments to the Food, Drug, and Cosmetic Act classifies medical devices in three distinct categories: (1) Class I devices, which are subject to the lowest oversight, 21 U.S.C.S. § 360c(a)(1)(A); (2) Class II devices, which are subject to special controls, 21 U.S.C.S. § 360c(a)(1)(B); and (3) Class III devices, which are subject to premarket approval and the highest federal oversight, 21 U.S.C.S. § 360c(a)(1)(C). The premarket approval process for Class III devices requires multivolume applications to be submitted by the manufacturer and approximately 1,200 hours of review for each application by the Food and Drug Administration.

Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

Healthcare Law > Medical Treatment > Medical Devices > Premarket Approval

HN16 A device will be granted premarket approval only if there is a reasonable assurance of safety and effectiveness,

and if the proposed labeling is neither false nor misleading. 21 U.S.C.S. § 360e(d)(1)(A). The Food and Drug Administration determines the safety and effectiveness of the device: (1) with respect to the persons for whose use the device is represented or intended; (2) with respect to the conditions of the use prescribed, recommended, or suggested in the labeling of the device; and (3) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use. 21 U.S.C.S. § 360c(a)(2).

Civil Procedure > ... > Federal & State Interrelationships > Federal Common Law > Preemption

Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

Healthcare Law > Medical Treatment > Medical Devices > Premarket Approval

HN17 Once a device receives premarket approval, the Food and Drug Administration (FDA) requires a device to be made with almost no deviations from the specifications in its approval application. The only manner for which a device can be modified is for the manufacturer to submit a supplemental application that details the effects the modifications would have on the safety or effectiveness of the device. 21 U.S.C.S. § 360e(d)(6)(A)(i). After premarket approval, manufactures are required to submit detailed reports for the FDA's continuous oversight of the device. 21 U.S.C.S. § 360i. The Medical Device Amendments to the Food, Drug, and Cosmetic Act preempts any state-law claim that imposes a requirement that is different from or in addition to those imposed by the FDA.

Civil Procedure > ... > Federal & State Interrelationships > Federal Common Law > Preemption

Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

Healthcare Law > Medical Treatment > Medical Devices > Premarket Approval

HN18 Whether premarket approval imposes preemptive federal requirements only with respect to specific uses, or instead imposes preemptive federal requirements with respect to the device generally is a substantial disputed question of federal law. There is no state-law equivalent of off label, the concept is entirely federal so claims necessarily raise substantial federal questions by requiring a court to interpret the meaning of the Food, Drug, and Cosmetics Act and its implementing regulations.

Civil Procedure > ... > Removal > Specific Cases Removed > Federal Questions

Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

Healthcare Law > Medical Treatment > Medical Devices > General Overview

HN19 Under the Medical Device Amendments to the Food, Drug, and Cosmetic Act, a plaintiff must allege an

injury that plausibly arises from the violation of an identifiable federal standard. Therefore, a plaintiff cannot prevail unless they allege and ultimately prove a violation of federal law.

Civil Procedure > ... > Subject Matter Jurisdiction > Federal Questions > General Overview

Civil Procedure > ... > Removal > Specific Cases Removed > Federal Questions

HN20 A federal court may assert federal question jurisdiction over a matter that contains significant federal issues. Only a complaint, not a motion to dismiss or answer and notice of removal, can establish federal question jurisdiction, and thus such jurisdiction cannot be predicated on an actual or anticipated defense. The United States Supreme Court has identified four aspects of a case or an issue that affect the substantiality of the federal interest in that case or issue: (1) whether the case includes a federal agency, and particularly, whether that agency's compliance with the federal statute is in dispute; (2) whether the federal question is important, i.e., not trivial; (3) whether a decision on the federal question will resolve the case, i.e., the federal question is not merely incidental to the outcome; and (4) whether a decision as to the federal question will control numerous other cases, i.e., the issue is not anomalous or isolated.

Civil Procedure > ... > Subject Matter Jurisdiction > Federal Questions > Substantial Questions

Civil Procedure > ... > Removal > Specific Cases Removed > Federal Questions

HN21 A substantial federal question exists where, although the elements of the claims asserted by a plaintiffs are governed by state law, the threshold issues that will determine liability require the interpretation of federal statutes and regulations.

Civil Procedure > ... > Federal & State Interrelationships > Federal Common Law > Preemption

Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

Healthcare Law > Medical Treatment > Medical Devices > Premarket Approval

Torts > Procedural Matters > Preemption > Express Preemption

Torts > Procedural Matters > Preemption > Implied Preemption

HN22 Off-label promotion allegations do not alter the fact that claims arising from the alleged off-label use of a medical device are expressly preempted under [21 U.S.C.S. § 360k\(a\)](#) and impliedly preempted under [21 U.S.C.S. § 337\(a\)](#).

Civil Procedure > ... > Subject Matter Jurisdiction > Federal Questions > Substantial Questions

Civil Procedure > ... > Removal > Specific Cases Removed > Federal Questions

Civil Procedure > Preliminary Considerations > Federal & State Interrelationships > General Overview

HN23 Even when a state action discloses a contested and substantial federal question, the exercise of federal jurisdiction is subject to a possible veto. For the federal issue will ultimately qualify for a federal forum only if federal jurisdiction is consistent with congressional judgment about the sound division of labor between state and federal courts governing the application of [28 U.S.C.S. § 1331](#). There is no bright-line rule in determining the presence of a federal issue because determinations about federal jurisdiction require sensitive judgments about congressional intent, judicial power, and the federal system. The relevant inquiry is whether there is reason to think Congress would prefer that the federal questions presented be resolved by state courts.

Civil Procedure > ... > Removal > Specific Cases Removed > Federal Questions

Civil Procedure > Preliminary Considerations > Federal & State Interrelationships > General Overview

Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

Healthcare Law > Medical Treatment > Medical Devices > Classification & Regulation

Healthcare Law > Medical Treatment > Medical Devices > Premarket Approval

HN24 Congress expressly prescribed the regulation of Class III devices to federal law through the Medical Device Amendments to the Food, Drug, and Cosmetic Act, which states that any state requirement that seeks to impose a requirement different from, or in addition to, and federal requirement applicable to the device will be preempted. [21 U.S.C.S. § 360k\(a\)\(1\)](#). Congress expressly enacted [§ 360k](#) as a general prohibition on non-Federal regulation. H.R. Rep. No. 94-853 at 45. As the Jenkins decision held, conferring federal question jurisdiction in cases arising from the alleged off-label promotion of Class III device with premarket approval which necessarily involve an issue closely bound by federal law, would have a microscopic effect on the state-federal jurisdictional balance. Moreover, since Congress imposed a regime of detailed federal oversight, it would be nonsensical to prevent such claims to be removed to a federal forum.

Civil Procedure > Parties > Joinder of Parties > Misjoinder

HN25 [Fed. R. Civ. P. 21](#) grants a court discretion to retain jurisdiction by severing claims against nondiverse dispensable defendants. Factors for the court to consider include whether: (1) claims arise out of the same transaction or occurrence, (2) claims present some common question of law or fact, (3) settlement of claims of judicial economy would be facilitated, (4) prejudice would be avoided if severance were granted, and (5)

different witnesses and documentary proof are required for separate claims.

Civil Procedure > ... > Joinder of Parties > Compulsory Joinder > Necessary Parties

HN26 A court has authority to allow a dispensable non-diverse party to be dismissed from a case under certain limited circumstances. Pursuant to [Fed. R. Civ. P. 19\(a\)](#), to determine whether or not a party is indispensable a court must perform a two-step analysis. First, the court should consider whether: (1) complete relief cannot be given to existing parties in the defendant's absence, (2) disposition in the defendant's absence may impair his ability to protect his interest in the controversy, or (3) the defendant's absence would expose existing parties to substantial risk of double or inconsistent obligations.

Civil Procedure > ... > Jurisdiction > Diversity Jurisdiction > General Overview

Civil Procedure > Parties > Joinder of Parties > Misjoinder

Civil Procedure > ... > Joinder of Parties > Compulsory Joinder > Necessary Parties

HN27 [Fed. R. Civ. P. 21](#) permits a district court to retain diversity jurisdiction over a case by dropping a nondiverse party, if that party's presence in the action is not required under [Fed. R. Civ. P. 19](#).

Civil Procedure > ... > Joinder of Parties > Compulsory Joinder > Indispensable Parties

Civil Procedure > ... > Joinder of Parties > Compulsory Joinder > Necessary Parties

HN28 If a party is necessary under the first prong of the [Fed. R. Civ. P. 19\(a\)](#) analysis, a court must then determine whether or not the party is indispensable by considering whether: (1) a judgment rendered in the party's absence would prejudice the available party, (2) such prejudice could be lessened or avoided, (3) a judgment rendered in the party's absence would be adequate, and (4) the plaintiff has an adequate remedy if the action is dismissed for non-joinder.

Civil Procedure > ... > Joinder of Parties > Compulsory Joinder > Indispensable Parties

Civil Procedure > ... > Joinder of Parties > Compulsory Joinder > Necessary Parties

Torts > Procedural Matters > Multiple Defendants > General Overview

HN29 Multiple proceedings and inconsistent results in state and federal court can occur whenever joint tortfeasors are not parties to the same lawsuit. That form of prejudice, however, does not require a finding that joint tortfeasors are necessary or indispensable parties.

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For Childrens Hospital Medical Center, doing business as Cincinnati Children's Hospital Medical Center, Christopher Gordon, M.D., Todd Maugans, M.D., Defendants: Jon David Brittingham, LEAD ATTORNEY, Dinsmore & Shohl - 1, Cincinnati, OH; Allison Davis, Dinsmore and Shohl, Cincinnati, OH.

Judges: Timothy S. Black, United States District Judge.

Opinion by: Timothy S. Black

Opinion

ORDER GRANTING IN PART AND DENYING IN PART PLAINTIFFS' MOTION TO REMAND (Doc. 20)

This civil action is before the Court on Plaintiffs' motion to remand (Doc. 20) and the parties' responsive memoranda (Docs. 24, 28¹).²

I. FACTUAL BACKGROUND AND PROCEDURAL POSTURE

Plaintiffs allege state law causes of action for: (1) negligence; (2) informed consent; (3) battery; (4) fraudulent concealment and inducement; (5) intentional infliction of emotional distress; (6) loss of consortium; (7)

¹ Defendants [*2] include Medtronic, Inc. and Medtronic Sofamor Danek USA, Inc. ("MSD") (collectively the "Medtronic Defendants"), and Children's Hospital Medical Center ("CHMC"), Dr. Christopher Gordon, and Dr. Todd Maugans (collectively the "Medical Defendants"). The Medical Defendants did not oppose the motion to remand.

² Also pending before this Court is the Medtronic Defendants' motion to dismiss. (Doc. 19). The motion to remand must be resolved before the motion to dismiss, because if remand is appropriate, then the state court should decide the motion to dismiss. [Cadle Co. v. Reiner, Reiner & Bendett](#), No. 4:06cv1873, 2006 U.S. Dist. LEXIS 78161, at *1 (N.D. Ohio Oct. 26, 2006).

strict product liability; (8) strict liability (inadequate warning or instruction); (9) defective design, formulation and/or manufacture or construction; (10) breach of express and implied warranties; and (11) fraud. (Doc. 7). These causes of action are based [*3] upon Plaintiffs' allegations that the Medtronic Defendants improperly and illegally promoted and sold a bone graft device, the Infuse® Bone Grate, for unapproved and unreasonably dangerous surgical applications. (*Id.*) Plaintiffs contend that because the Infuse® was used in a manner inconsistent with the Food and Drug Administration ("FDA") approval, Defendants should be found liable for negligent use and promotion of the Infuse® through an off-label manner. (*Id.* at ¶ 24). Additionally, Plaintiffs allege that as a result of an unapproved surgery performed by the Medical Defendants with the Infuse®, Plaintiff, an infant child, suffered severe and permanent injuries, including seizures, intracranial pressure, and neurological damage. (*Id.* at ¶ 91).

Defendants removed the case from Hamilton County Court of Common Pleas to the Southern District of Ohio. (Doc. 1). Subsequently, Plaintiffs filed the motion to remand, arguing that this case was improperly removed from state court because no federal cause of action exists. (Doc. 20). Conversely, Defendants assert that because the Infuse® is classified as a Class III, FDA premarket approved device under the Medical Device Amendments of 1976 ("MDA") [*4] to the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"), 21 U.S.C. § 360k(a), the case properly belongs under federal jurisdiction.

II. STANDARD OF REVIEW

HN1 On a motion for remand, the question is whether the district court lacks subject matter jurisdiction. 28 U.S.C. § 1447(c). **HN2** 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). **HN3** 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, 106 S. Ct. 3229, 92 L. Ed. 2d 650 (1986).³ 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, 61 S. Ct. 868, 85 L. Ed. 1214 (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, 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 Servs., Inc., No. C-3-06-51, 2006 U.S. Dist. LEXIS 25845, at *1 (S.D. Ohio May 2, 2006).

HN4 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." Defendants maintain that Plaintiffs' complaint contains a claim "arising under" federal law. **HN5** "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.*

HN6 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, 107 S. Ct. 2425, 96 L. Ed. 2d 318 (1987)). Because the plaintiff is the master of his complaint, the [*6] 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.

HN7 Although the majority of cases removed to federal court set forth causes of action that plainly raise federal issues, there are three exceptions to the "well-pleaded complaint" that confer federal question jurisdiction when a federal cause of action is not evidenced on the face of the complaint: (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).

HN8 Under the artful pleading doctrine, federal question jurisdiction exists when a plaintiff shrouds its complaint with state law claims in order to avoid federal jurisdiction when its claims are truly federal causes of action. See Her Majesty the Queen in Right of the Province of Ontario v. City of Detroit, 874 F.2d 332, 339 (6th Cir. 1989). However, rarely will the federal court "seek to determine whether the real nature of the claims is federal, regardless of plaintiff's characterization, [instead] most [removal courts] correctly confine this practice to areas [*7] of the law pre-empted by federal substantive law." Mikulski, 501 F.3d at 561.

HN9 Under the complete-preemption doctrine, federal question jurisdiction exists when Congress has "intend[ed] the preemptive force of a federal statute to be so extraordinary that 'any claim purportedly based on that

³ See [*5] also Long, 201 F.3d at 757 ("[B]ecause they implicate federalism concerns, removal statutes are to be narrowly construed.").

pre-empted state law is considered, from its inception, a federal claim, and therefore arises under federal law.” *Mikulski*, 501 F.3d at 563. The Supreme Court has only applied the complete-preemption doctrine in three areas: (1) *Section 301* of the Labor Management Relations Act of 1947, 29 U.S.C. § 185; (2) the Employee Retirement Income Security Act of 1975, 29 U.S.C. §§ 1001-1461; and (3) the National Bank Act, 12 U.S.C. § 39.

Finally, *HN10* under the substantial-federal-question doctrine, federal question jurisdiction exists when “the state-law claim necessarily state[s] a federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing a congressionally approved balance of federal and state judicial responsibilities.” *Grable & Sons Metal Products, Inc. v. Darue Eng’g & Mfg.*, 545 U.S. 308, 314, 125 S. Ct. 2363, 162 L. Ed. 2d 257 (2005). More plainly stated, a state law cause of action may arise [*8] under federal law where “the vindication of a right under state law depends on the validity, construction, or effect of federal law.” *Mikulski*, 501 F.3d at 565.

III. ANALYSIS

This Court finds that the substantial federal question doctrine applies to the instant case.

HN11 “Where a well-pleaded complaint does not seek relief under federal law, a court may find removal proper if the plaintiff’s complaint raises a ‘substantial’ federal question.” *Landers v. Morgan Asset Mgmt, Inc.*, No. 08-2260, 2009 U.S. Dist. LEXIS 30891, at *17 (W.D. Tenn. Mar. 31, 2009). Under Sixth Circuit and Supreme Court precedent, “the substantial-federal-question doctrine [has] three parts: (1) the state-law claim must necessarily raise a disputed federal issue; (2) the federal interest in the issue must be substantial; and (3) the exercise of jurisdiction must not disturb any congressionally approved balance of federal and state judicial responsibilities.” *Nayyar v. Mt.*

Carmel Health Sys., No. 2:12cv189, 2012 U.S. Dist. LEXIS 128050, at *5 (S.D. Ohio Sept. 10, 2012) (citing *Mikulski v. Centerior Energy Corp.*, 501 F.3d 555, 568 (6th Cir. 2007) (*en banc*), in turn citing *Grable*, 545 U.S. at 313-14).

Notably, a district [*9] court in Tennessee recently denied remand in a materially similar case also arising from the alleged off-label promotion of the Infuse® device, holding that it “ha[d] jurisdiction” over claims such as those asserted here “under the substantial-federal-question doctrine.” *Jenkins v. Medtronic, Inc.*, No. 2:13cv2004, 2013 U.S. Dist. LEXIS 165787, at *3, 8 (W.D. Tenn. Nov. 21, 2013).⁴ The Court finds *Jenkins* to be directly on point and persuasive.⁵

A. Disputed Federal Issue

The first step in the *Grable* analysis is to determine whether Plaintiffs’ claims “necessarily raise a disputed federal issue.” *Mikulski*, 501 F.3d at 568. Since the Infuse® is a Class III, premarket approved device under the Medical Device Amendments (“MDA”) to the Food, [*11] Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. Sections 360(c) *et seq.*, the Court looks to the MDA to examine this first element.

HN14 The MDA expressly preempts any state requirement on devices intended for human issue that is “different from, or in addition to, any requirement applicable under [the MDA]” or that “relates to the safety or effectiveness of the devise.” 21 U.S.C. § 360k(a). The only way a state requirement can be exempted from this express preemption is if “the [state] requirement is more stringent than a requirement under [the MDA] which would be applicable to the device if an exemption were not in effect;” or if the state requirement is “required by compelling local conditions;” and if “compliance with the requirement would not cause the device to be in violation of any applicable requirement [under the MDA].” 21 U.S.C. § 360k(b).

⁴ Conversely, a district court in Kentucky recently remanded a materially similar case. *Dillion v. Medtronic, Inc.*, No. 13-105, 2014 U.S. Dist. LEXIS 747 (E.D. Ky. Jan. 6, 2014). Remand was based on a finding that “the substantial-federal-question doctrine is not a true exception to the well-pleaded-complaint rule” and “a state-based claim will support jurisdiction under [28 U.S.C.] Section 1331 only if it satisfied both the well-pleaded complaint rule and raises significant federal issues.” *Id.* at 4, n.1. This Court finds, however, that *HN12* if a complaint satisfies the well-pleaded-complaint rule, that is if federal law is invoked on the face of the complaint without regard to “anything alleged in anticipation of avoidance of defenses which it is thought [*10] the defendant may interpose” (*Franchise Tax Bd. v. Constr. Laborers Vacation Trust*, 463 U.S. 1, 10, 103 S. Ct. 2841, 77 L. Ed. 2d 420 (1983)), then jurisdiction exists under *Section 1331* regardless of whether the federal issues raised are significant or not. Accordingly, this Court is not persuaded by the holding in *Dillon*. Moreover, the court in *Dillon* did not cite *Jenkins*, and hence did not refute or distinguish its analysis.

⁵ *HN13* “[T]he Opinions of other district courts are persuasive but not binding authority on this Court.” *Kuhns v. City of Allentown*, 636 F. Supp. 2d 418, 437 (E.D. Pa. 2009). See also *Manley v. Horsham Clinic*, No. 00-4904, 2001 U.S. Dist. LEXIS 11516, at *4 (E.D. Pa. Aug. 9, 2001) (“In matters concerning federal law a District Court is bound only by the decisions of the Court of Appeals for the Circuit in which it sits and by the decisions of the United States Supreme Court...not...fellow district court judges.”).

HN15 The MDA classifies medical devices in three distinct categories: (1) Class I devices, which are subject to the lowest oversight (*See* [21 U.S.C. § 360c\(a\)\(1\)\(A\)](#)); (2) Class II devices, which are subject to special controls, (*See* [21 U.S.C. § 360c\(a\)\(1\)\(B\)](#)); and (3) Class III devices, which are subject to premarket approval and the highest federal oversight, [*12] (*See* [21 U.S.C. § 360c\(a\)\(1\)\(C\)](#)). The premarket approval process for Class III devices requires multivolume applications to be submitted by the manufacturer and approximately 1,200 hours of review for each application by the FDA. *Riegel v. Medtronic, Inc.*, [552 U.S. 312, 318, 128 S. Ct. 999, 169 L. Ed. 2d 892 \(2008\)](#). **HN16** A device will be granted premarket approval only if "there is a reasonable assurance of safety and effectiveness," and if "the proposed labeling is neither false nor misleading." [21 U.S.C. § 360e\(d\)\(1\)\(A\)](#). The FDA determines the safety and effectiveness of the device:

(A) with respect to the persons for whose use the device is represented or intended,

(B) with respect to the conditions of the use prescribed, recommended, or suggested in the labeling of the device, and

(C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

[21 U.S.C. § 360c\(a\)\(2\)](#).

HN17 Once a device receives premarket approval, the FDA requires the device "to be made with almost no deviations from the specifications in its approval application." *Riegel*, [552 U.S. at 323](#). The only manner for which a device can be modified is for the manufacturer to submit a supplemental application [*13] that details the effects the modifications would have on the safety or effectiveness of the device. *See* [21 U.S.C. § 360e\(d\)\(6\)\(A\)\(i\)](#). After premarket approval, manufacturers are required to submit detailed reports for the FDA's continuous oversight of the device. *See* [21 U.S.C. § 360i](#). The MDA preempts any state-law claim that imposes a requirement that is "different from or in addition to" those imposed by the FDA. *Riegel*, [552 U.S. at 321-28](#).⁶

HN19 Plaintiffs must allege an injury that "plausibly arises from the violation of an identifiable federal standard." *White v. Stryker Corp.*, 818 F. Supp.2d 1032, 1039-40 (W.D. Ky. 2011). Therefore, plaintiffs cannot prevail unless they allege and ultimately prove a violation of federal law. Accordingly, Plaintiffs' claims clearly implicate federal law.

B. Substantial Federal Interest

Next, **HN20** a federal court may assert federal question jurisdiction over a matter that contains significant federal issues. *Grable*, [545 U.S. at 312](#). Only a complaint (and not a motion to dismiss or answer and notice of removal) can establish federal question jurisdiction, and thus such jurisdiction "cannot be predicated on an actual or anticipated defense." *Vaden v. Discover Bank*, [556 U.S. 49, 50, 129 S. Ct. 1262, 173 L. Ed. 2d 206 \(2009\)](#).

The Supreme Court has identified four aspects of a case or an issue that affect the substantiality of the federal interest [*15] in that case or issue:

(1) whether the case includes a federal agency, and particularly, whether that agency's compliance with the federal statute is in dispute;

(2) whether the federal question is important (*i.e.*, not trivial);

(3) whether a decision on the federal question will resolve the case (*i.e.*, the federal question is not merely incidental to the outcome); and

(4) whether a decision as to the federal question will control numerous other cases (*i.e.*, the issue is not anomalous or isolated).

Mikulski, [501 F.3d at 570](#). The Court will address each factor in turn.

1. Federal questions are important

While this case does not involve an agency's compliance with federal statute, it does present important federal

⁶ Plaintiff alleges that when the FDA granted premarket approval to the Infuse® device, the FDA's approval was limited to certain uses of the device (Doc. 7 at ¶¶ 29-32), and that as a consequence, "there were no FDA-imposed requirements specific to the non-approved uses of Infuse® and therefore no FDA-approved labeling for such off-label uses" (*Id.* at ¶ 34). However, **HN18** whether premarket approval imposes preemptive federal requirements only with respect to specific uses, or instead imposes preemptive federal requirements with respect to the device generally is a substantial disputed question of federal law. *See, e.g., Riley v. Cordis Corp.*, [625 F. Supp.2d 769, 779 \(D. Minn. 2009\)](#). "[T]here is no state-law equivalent of 'off label'...[t]he concept [*14] 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." *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).

questions about federal regulation of Class-III medical devices. Plaintiffs concede that "the federal government has a substantial interest in regulating medical devices." (Doc. 20 at 6). However, Plaintiffs attempt to distinguish that interest from the federal government's interest in regulating tort claims arising from such devices. While Plaintiffs argue that "common-law causes of action for negligence and strict liability do impose 'requirements'" on medical devices, "excluding [*16] common-law duties from the scope of pre-emption would make little sense." *Riegel*, 552 U.S. at 323, 325. Like in *Grable*, this Court will be required to decide as a threshold question whether defendants violated federal law and therefore this case presents a substantial federal question. See, e.g., *Hartland Lakeside Joint No. 3 Sch. Dist. v. WEA Ins. Corp.*, No. 12-C-154, 2012 U.S. Dist. LEXIS 57085, at *15 (E.D. Wis. 2012) (*HN21* substantial federal question existed where, "[a]lthough the elements of the claims asserted by the plaintiffs are governed by state law, the threshold issues that will determine liability require the interpretation of federal statutes and regulations").

2. Resolution of the federal issue is dispositive

There is no question that resolution of the federal issues in the Medtronic Defendants' favor would end the case. See, e.g., *Jenkins*, 2013 U.S. Dist. LEXIS 165787 at 18 (resolution of federal questions presented will "dispose of the case when decided upon").

3. Resolution of these issues will control other cases

Another case implicating very similar issues is currently pending before this Court. See *Aaron v. Medtronic, Inc.*, No. 1:13cv202 (S.D. Ohio Mar. 22, 2013). While [*17] the number of cases like this one is likely to be small, because very few medical devices are subject to *Section 360k(a)*, and only a portion of those cases involve allegations of off-label promotion, it is clear that the federal issue presented by this case "is not anomalous or isolated," but likely to be present in other cases involving medical devices that have received premarket approval from the FDA. See, e.g., *Jenkins*, 2013 U.S. Dist. LEXIS 165787 at 18 (resolution of federal questions presented by claims arising from alleged off-label promotion of the Infuse® device will "control numerous other cases"); *Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206, 1215 (W.D. Okla. 2013) (holding that *HN22* "off-label promotion allegations do not" alter the fact that claims arising from the alleged off-label use of the Infuse® device are expressly preempted under *Section 360k(a)* and impliedly preempted under *Section 337(a)*).

Accordingly, the Court finds that there is a substantial federal interest in the issues raised in Plaintiffs' complaint.

C. Balance of Federal and State Judicial Responsibilities

Finally, the Court must examine whether a conferral of federal question jurisdiction over Plaintiffs' [*18] claims would upset the state-federal jurisdictional balance.

HN23 [E]ven when the state action discloses a contested and substantial federal question, the exercise of federal jurisdiction is subject to a possible veto. For the federal issue will ultimately qualify for a federal forum only if federal jurisdiction is consistent with congressional judgment about the sound division of labor between state and federal courts governing the application of *Section 1331*.

Grable, 545 U.S. at 313-314. There is no bright-line rule in determining the presence of a federal issue because "determinations about federal jurisdiction require sensitive judgments about congressional intent, judicial power, and the federal system." *Merrell Dow*, 478 U.S. at 810. The relevant inquiry is whether there is "reason to think Congress would prefer "that the federal questions presented here "be resolved by state courts." *State of Michigan v. Bay Mills Indian Cmty.*, 695 F.3d 406, 413 (6th Cir. 2012).

The instant action invokes the MDA because of the categorization of the Infuse® as a Class III device. See *Jenkins*, 2013 U.S. Dist. LEXIS 165787 at 20. *HN24* Congress expressly prescribed the regulation of Class III devices to federal [*19] law through the MDA which states that any state requirement that seeks to impose a requirement "different from, or in addition to, and [federal] requirement applicable to the device" will be preempted. 21 U.S.C. § 360k(a)(1). Congress expressly enacted *Section 360(k)* as a "general prohibition on non-Federal regulation" (H.R. Rep. No. 94-853 at 45). As *Jenkins* held, "conferring federal question jurisdiction" in cases arising from the alleged off-label promotion of Class III device with premarket approval which necessarily involve "an issue...closely bound by federal law [,] would have a 'microscop[ic] effect' on the state-federal jurisdictional balance." *Id.*, 2013 U.S. Dist. LEXIS 165787 at *20 (quoting *Grable*, 545 U.S. at 315). Moreover, since Congress "imposed a regime of detailed federal oversight" (*Riegel*, 552 U.S. at 316), it would be nonsensical to prevent such claims to be removed to a federal forum.

II. Diversity Jurisdiction

Defendants maintain that this case was properly removable based on diversity jurisdiction, despite the presence of non-diverse Medical Defendants.

Plaintiffs "reside in Fairfield Township, Butler County, Ohio." (Doc. 7 at ¶ 1). Thus, Plaintiffs are citizens

[*20] of Ohio. Defendant Medtronic is a "Minnesota corporation, with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432." (*Id.* at ¶ 38). Thus, Medtronic is a citizen of Minnesota.⁷ Defendant MSD "is a Tennessee corporation with its principal place of business at 1800 Pyramid Place, Memphis, Tennessee 38132." (*Id.* at ¶ 6). Thus, MSD is a citizen of Tennessee. Defendant CHMC is "located in Cincinnati, Hamilton County, Ohio." (*Id.* at ¶ 2). Thus, CHMC is a citizen of Ohio. Christopher Cordon, M.D. is located in Cincinnati, Ohio and Todd Maugans, M.D., is located in Orlando, Florida. Therefore, Drs. Gordon and Maugans are citizens of Ohio and Florida, respectively.⁸

HN25 *Federal Rule of Civil Procedure 21* [*21] grants the Court discretion to "retain jurisdiction...by severing claims against nondiverse dispensable defendants." *DeGidio v. Centocor, Inc., No. 3:09cv721, 2009 U.S. Dist. LEXIS 126887, at *2 (N.D. Ohio June 29, 2009)* (citing *Newman-Green, Inc. v. Alfonso-Larrain, 490 U.S. 826, 832, 109 S. Ct. 2218, 104 L. Ed. 2d 893 (1989)*). Factors for the court to consider include: (1) whether claims arise out of the same transaction or occurrence; (2) whether claims present some common question of law or fact; (3) whether settlement of claims of judicial economy would be facilitated; (4) whether prejudice would be avoided if severance were granted; and (5) whether different witnesses and documentary proof are required for separate claims. *Disparte v. Corporate Exec. Bd., 223 F.R.D. 7 (D.D.C. 2004)*.

Medtronic Defendants maintain that discretion is properly exercised in cases like this, involving product-liability claims against a medical-products manufacturer and separate medical malpractice claims against health-care providers. (Doc. 1 at ¶¶ 13, 48). Conversely, Plaintiffs maintain that they would be prejudiced by having to pursue separate actions in two different forums because they would expend time, money, and energy, risking

[*22] inconsistent judgments and factual and legal findings, and the opportunity for each defendant to point the finger at the missing chair at trial.

HN26 This Court has authority to allow a dispensable non-diverse party to be dismissed from a case under

certain limited circumstances. Pursuant to *Rule 19(a)*, to determine whether or not a party is indispensable a court must perform a two-step analysis. First, the court should consider whether: (1) complete relief cannot be given to existing parties in the defendant's absence; (2) disposition in the defendant's absence may impair his ability to protect his interest in the controversy; or (3) the defendant's absence would expose existing parties to substantial risk of double or inconsistent obligations. *Safeco Ins. Co. v. City of White House, 36 F.3d 540, 546 (6th Cir. 1994)* (**HN27** "*Rule 21 of the Federal Rules of Civil Procedure* permits a district court to retain diversity jurisdiction over a case by dropping a nondiverse party, if that party's presence in the action is not required under *Federal Rule of Civil Procedure 19.*"). Therefore, while the parties to this action are not completely diverse because Plaintiffs are citizens of the same state as Defendants [*23] CHMC and Christopher Cordon, M.D, under *Rule 21*, "[o]n motion or on its own, the court may at any time, on just terms, add or drop a party." *Fed. R. Civ. P. 21*.

HN28 If the party is necessary under the first prong of the analysis, the court must then determine whether or not the party is indispensable by considering whether: (1) a judgment rendered in the party's absence would prejudice the available party; (2) such prejudice could be lessened or avoided; (3) a judgment rendered in the party's absence would be adequate; and (4) the plaintiff has an adequate remedy if the action is dismissed for non-joinder. *Soberay Mach. & Equip. Co. v. MRF Ltd., 181 F.3d 759, 764 (6th Cir. 1999)*.

In the instant case, the Medical Defendants are neither necessary nor indispensable because resolution of the tort claims against them would not resolve the products liability claims against the Medtronic Defendants, and vice versa. *Kelly v. Aultman Physician Ctr., No. 5:13cv994, 2013 U.S. Dist. LEXIS 75429, at *9 (N.D. Ohio May 29, 2013)*. Moreover, the claims "involve different legal standards and difference factual allegations." *DeGidio v. Centocor, Inc., No. 3:09cv721, 2009 U.S. Dist. LEXIS 61412, at *3 (N.D. Ohio July 8, 2009)*.⁹ [*24] "[T]here are no product liability claims against the Medical Defendants

⁷ See also *Branson v. Medtronic, Inc., No. 5:06cv332, 2007 U.S. Dist. LEXIS 3586, at *1-2 (M.D. Fla. Jan. 18, 2007)* (denying plaintiff's motion to remand following removal by Medtronic on the ground that Medtronic's principal place of business is in Minnesota).

⁸ The complaint also names Defendants John Does 1-30. For purposes of removal, "the citizenship of defendants sued under fictitious names shall be disregarded." *28 U.S.C. § 1441(a)*. See also *Soliman v. Phillip Morris Inc., 311 F.3d 966, 971 (9th Cir. 2002)*.

⁹ See also *Todd v. Merrill Dow Pharms., Inc., 942 F.2d 1173, 1176 (7th Cir. 1991)* (finding the physician who ordered the injection of a drug "not indispensable" in a products liability case against a drug manufacturer); *Phillips v. Knoll Pharm. Co., No. 5:03cv8044, 2003 U.S. Dist. LEXIS 28620, at *13 (N.D. Ohio Sept. 4, 2003)* (dropping physician defendants under *Rule 21* to perfect diversity jurisdiction after finding them to be dispensable parties); *Williams v. Knoll Pharm. Co., No. 5:03cv8030,*

and there are nothing but product liability claims against” the Medtronic Defendants. [Kelly, 2013 U.S. Dist. LEXIS 75429 at 5-6](#). Furthermore, the claims against the Medtronic Defendants involve allegations of violations of federal law, but no such allegations are made against the Medical Defendants.

The mere fact that Plaintiff will be maintaining two lawsuits is not unduly or unfairly prejudicial, and does not require a finding that the Medical Defendants [*25] are necessary or indispensable parties. [DeGidio, 2009 U.S. Dist. LEXIS 61412, at 4](#) (citing [PaineWebber, Inc. v. Cohen, 276 F.3d 197, 204 \(6th Cir. 2001\)](#) (HN29 “multiple proceedings and inconsistent results in state and federal court...can occur whenever joint tortfeasors are not parties to the same lawsuit. This form of prejudice, however, does not require a finding that joint tortfeasors are necessary or indispensable parties.”)). Accordingly, this Court finds that severing the Medical Defendants will not be “unduly prejudicial.”¹⁰

IV. CONCLUSION

For the reasons discussed above, the Court *sua sponte* severs the Medical Defendants and Counts pertaining thereto (See Doc. 7 at ¶¶ 85-116), which are entirely between Ohio residents and entirely dependent upon state law, and **REMANDS** those claims to the Hamilton County Court of Common Pleas. To that extent, Plaintiffs’ motion to remand (Doc. 20) is **GRANTED**.

Further, the Court retains jurisdiction over the Medtronic Defendants and Counts pertaining [*26] thereto (See Doc. 7 at ¶¶ 117-169), as claims between diverse citizens. To that extent, Plaintiffs’ motion to remand (Doc. 20) is **DENIED**.

IT IS SO ORDERED.

Date: 2/13/14

/s/ Timothy S. Black

Timothy S. Black

United States District Judge

[2003 U.S. Dist. LEXIS 28618, at *8-12 \(N.D. Ohio July 11, 2003\)](#) (dismissing non-diverse healthcare defendants to retain diversity of citizenship over pharmaceutical defendant).

¹⁰ The Court finds that upon severance, the amount in controversy between Plaintiffs and the Medtronic Defendants will exceed \$75,000 as required by 29 U.S.C. Section 1332(a). (See, e.g., Doc. 1 at ¶¶ 53-54).