IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF VIRGINIA

Alexandria Division

SCOTT T. CARMINE,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 1:15-cv-1207
	)	
GLEN JEFFREY POFFENBARGER, MD, ET AL.,	)	
	)	
	)	
Defendants.	)	

M E M O R A N D U M O P I N I O N

Before the Court is Plaintiff Scott T. Carmine's ("Carmine") Motion to Remand this product liability and medical malpractice case to Virginia state court. (Mem. in Supp. [Dkt. 2].) One of the product manufacturer defendants, Medtronic Sofamor Danek USA, Inc. ("MSD"), filed a memorandum in opposition to remand. (Mem. in Opp'n [Dkt. 5].) For the following reasons, the Court will remand the entire case.

I. Background

Carmine brought this suit in the Circuit Court for Prince William County, Virginia alleging various state-law theories of product liability and medical malpractice.[1] (Compl.

[1] Specifically, Carmine raised the following claims against the Product Defendants: (1) Manufacturing Defect; (2) Failure to Warn; (3) Design Defect; (4) Negligence; (5)

[Dkt. 1-4].) The case arises from injuries Carmine allegedly sustained during and after his spinal fusion surgery on February 29, 2012. Spinal fusion is a procedure comparable to welding, whereby "one or more of the vertebrae of the spine are united together, or 'fused,' so that motion no longer occurs between them." (*Id.* ¶ 29.) The "fusion" is achieved by surgically inserting a bone graph between the vertebrae. The Product Defendants[2] in this case manufacture and promote an FDA-approved medical device called Infuse®, which is used in spinal fusion surgeries to facilitate bone growth.

Infuse® includes two components. (*Id.* ¶ 40.) The first component is a collagen sponge that absorbs a protein engineered to promote fusion when applied to a bone graph. (*Id.*) The second component is a thimble-sized hollow metal cylinder or "cage" that holds two vertebrae in place and houses the collagen sponge. (*Id.*) The two components are sold separately, but the initial FDA-approved label allegedly indicated that they must be used together. (*Id.*) Furthermore, Carmine contends that Infuse® is approved for only surgeries conducted through an incision in

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Negligence Per Se; (6) Fraud; (7) Breach of Implied Warranties; and (8) Breach of Express Warranties. (Compl. ¶¶ 120-85.) Additionally, he raised state-law claims of medical malpractice and negligence against the surgeon and hospitals that performed the surgery. (*Id.* ¶¶ 186-96.)

[2] The Product Defendants are MSD; Medtronic, Inc.; Wyeth, Inc.; Wyeth Pharmaceuticals Inc.; and Pfizer Inc.

the abdomen and involving the fusion of one tier of vertebrae. (*Id.* ¶ 42.) Defendant Glen Jeffrey Poffenbarger, MD ("Poffenbarger") allegedly did not follow these approved uses when he performed Carmine's surgery.

Carmine's surgery involved several alleged "off-label" uses of Infuse®. For example, Poffenbarger inserted the Infuse® collagen sponge and protein into a cage produced by a different manufacturer. (*Id.* ¶ 106.) Poffenbarger also allegedly performed the surgery through an incision in Carmine's back, rather than in his abdomen. (*Id.* ¶¶ 101, 109.) Additionally, the surgery involved the fusion of multiple tiers of vertebrae, instead of just a single tier. Carmine alleges that the Product Defendants promoted such "off-label" uses, which are known to create a "significantly enhanced risk" of post-surgery complications and violate the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360c *et seq.* (*Id.* ¶¶ 110-12.)

The MDA imposes degrees of oversight for medical devices that vary depending on the risks associated with the device. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). Infuse® is a Class III device, the most heavily regulated. (Compl. ¶ 23.) To replace unmanageable and

conflicting state regulation of such devices, Congress included the following express preemption provision within the MDA:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement: (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). This preemption clause, however, "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case are 'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330. Additionally, Congress explicitly chose not to provide a private cause of action to consumers harmed by violations of the FDCA. 21 U.S.C. § 337(a) ("Except as provided in subsection (b) of this section, all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."). Thus, federal law impliedly preempts private claims based "solely" on a violation of FDCA requirements. *See Sanchez v. Boston Scientific Corp.*, 38 F. Supp. 3d 727, 744 (S.D.W. Va. 2014) ("The FDCA impliedly preempts private claims that seek to

enforce FDCA provisions against a manufacturer." (citing *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001))).

Thirty-five days after Carmine filed his state-court Complaint, and before any defendant was served, MSD removed the case to this Court under a theory of federal question jurisdiction. (*See* Notice [Dkt. 1] ¶¶ 9, 24-25.) Carmine timely filed a motion to remand, which MSD opposed. In its memorandum in opposition, MSD asks the Court to deny remand or to alternatively sever the nondiverse medical malpractice defendants ("Medical Defendants")[3] and retain diversity jurisdiction over the product liability counts. The Court will address these issues in turn.

II. Standard of Review

A state court case is removable under 28 U.S.C. § 1441(a) only when "the district courts of the United States have original jurisdiction." 28 U.S.C. § 1441(a). Because removal raises "significant federalism concerns," courts must construe removal jurisdiction strictly. *Mulcahey v. Columbia Organic Chems. Co.*, 29 F.3d 148, 151 (4th Cir. 1994). Accordingly, "[i]f federal jurisdiction is doubtful, a remand is

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[3] The Medical Defendants are Dr. Poffenbarger, Mary Washington Healthcare Physicians, and Mary Washington Healthcare. (Compl. ¶¶ 6-10.)

necessary." *Id.* The party seeking removal bears the burden of demonstrating jurisdiction. *Id.*

Federal district courts have original jurisdiction over "all civil actions arising under the Constitution, laws, or treaties of the United States." 28 U.S.C. § 1331. When considering whether an action arises under federal law, "'the well-pleaded complaint rule' demands that we confine our inquiry to the 'plaintiff's statement of his own claim . . . unaided by anything alleged in anticipation or avoidance of defenses which it is thought the defendant may interpose.'" *Flying Pigs, LLC v. RRAJ Franchising, LLC*, 757 F.3d 177, 181 (4th Cir. 2014) (quoting *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 809 (1988)). "Most of the cases brought under § 1331 federal question jurisdiction 'are those in which federal law creates the cause of action.'" *Mulcahey*, 29 F.3d at 151 (quoting *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 809 (1986)). There is, however, a slim category of cases that arise under state law but implicate a significant federal issue. *See Grable & Sons Metal Prod., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 312 (2005). Such cases create a narrow basis for jurisdiction called "substantial federal question jurisdiction." *Gunn v. Minton*, 133 S. Ct. 1059, 1065 (2013); *Flying Pigs*, 757 F.3d at 182.

To fall within this narrow basis for jurisdiction, the state-law cause of action must implicate a federal issue that is necessarily raised, actually disputed, substantial, and capable of resolution in a federal court without disrupting the federal-state balance of power. *Flying Pigs*, 757 F.3d at 183 n.8 (quoting *Gunn*, 133 S. Ct. at 1065). "Where all four of these requirements are met . . . jurisdiction is proper because there is a serious federal interest in claiming the advantages thought to be inherent in a federal forum, which can be vindicated without disrupting Congress's intended division of labor between state and federal courts." *Gunn*, 133 S. Ct. at 1065 (internal quotations omitted). The application of these factors is a "litigation-provoking problem." *Merrell Dow*, 478 U.S. at 810. That problem is readily apparent in cases alleging violations of FDCA requirements. Because of the large number of cases addressing this issue, the Court had the benefit of many well-reasoned opinions to guide its analysis.

III. Analysis

A. Motion to Remand

As described above, the Supreme Court has articulated a four-factor test for determining whether substantial federal question jurisdiction exists. Under that test, "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." *Gunn*, 133 S. Ct. at 1065. The Court will address those factors in turn.

(1) Necessarily Raised and Actually Disputed

"[A] plaintiff's right to relief for a given claim necessarily depends on a question of federal law only when *every* legal theory supporting the claim requires the resolution of a federal issue." *Flying Pigs*, 757 F.3d at 182 (quoting *Dixon v. Coburg Dairy, Inc.*, 369 F.3d 811, 816 (4th Cir. 2004)). Under this standard, the Court finds that only Carmine's count of negligence *per se* necessarily raises an issue of federal law. In all the remaining counts, "the most one can say is that a question of federal law is lurking in the background." *Pinney v. Nokia, Inc.*, 402 F.3d 430, 446 (4th Cir. 2005) (quoting *Gully v. First Nat'l Bank*, 299 U.S. 109, 117 (1936)). The Court will now address each of MSD's many arguments for why a federal issue is necessarily raised.

First, MSD argues that the Court must resolve issues of federal law to determine whether the Product Defendants' promotion of Infuse® included "off-label" uses. For example, MSD contends the Court must decide whether the FDCA prohibits off-

label promotion at all (Mem. in Opp'n at 9), whether premarket approval extends to a product generally or only to specified uses of the product (*id.* at 10.), whether premarket approval applies to product components or only to the complete product (*id.*), and other similar issues. Under the well-pleaded complaint rule, however, these issues are not necessarily raised. Each of these federal issues is only relevant to whether Carmine's state-law claims are preempted under § 360k(a). As such, they are not part of the well-pleaded complaint, even if the complaint mentioned those issues in anticipation of the preemption defense and even if preemption is the only real issue in dispute in this litigation. *See Pinney*, 402 F.3d at 446 ("'[A] case may not be removed to federal court on the basis of a federal defense, including the defense of preemption,' even if the complaint begs the assertion of the defense, and even if 'the defense is the only question truly at issue in the case.'" (quoting *Franchise Tax Bd.*, 463 U.S. at 14)). Therefore, Carmine's allegations regarding off-label uses do not necessarily implicate a substantial federal question. *Cf. Goade v. Medtronic, Inc.*, No. 13-5123, 2013 WL 6237853, *4 (W.D. Mo. Dec. 3, 2013) (finding in a very similar Infuse® case that "[e]ven if Defendants are correct and Congress has provided

a preemption defense, this defense cannot support federal jurisdiction").

MSD's argument that substantial federal question jurisdiction creates "an exception" to the well-pleaded complaint rule is not convincing.[4] Notwithstanding MSD's cited-cases, courts in the Fourth Circuit continue to apply the well-pleaded complaint rule in their substantial federal question jurisdictional analysis. As an initial matter, there is good reason to conclude that MSD's cited cases do not recognize a true exception to the well-pleaded complaint rule. *See Dillon v. Medtronic, Inc.*, 992 F. Supp. 2d 751 (E.D. Ky. 2014) (describing thoroughly and convincingly why no such exception exists). Regardless of the rule in those circuits, however, the Fourth Circuit made clear in *Pinney v. Nokia, Inc.* that it is error for a district court to apply substantial federal question jurisdiction without "recognizing that its inquiry [is] limited by the well-pleaded complaint rule." 402 F.3d 430, 446 (4th Cir. 2005). In that case, the district court found a

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[4] MSD cites the following cases in support of its argument that the well-pleaded complaint does not apply when courts evaluate substantial federal question jurisdiction: *Mikulski v. Centerior Energy Corp.*, 501 F.3d 555, 560 (6th Cir. 2007); *Devon Energy Prod. Co. v. Mosaic Potash Carlsbad, Inc.*, 693 F.3d 1195, 1203 (10th Cir. 2012); *N.Y. v. Shinnecock Indian Nation*, 686 F.3d 133, 141 (2d Cir. 2012); *In re Air Crash at Lexington, Ky.*, 486 F. Supp. 2d 640, 645 (E.D. Ky. 2007).

substantial federal question by "in effect anticipat[ing]" that the defendants would raise a federal preemption defense that the plaintiff would be called upon to rebut. *Id.* at 445-46. Thus, the district court found a federal question necessarily raised because it could proceed "only by resolving whether the claims are preempted by the FCA and the federal [radio frequency] radiation standards." *Id.* at 446. The Fourth Circuit reversed and emphasized the familiar rule that "a case may not be removed to federal court on the basis of a federal defense, including the defense of preemption, even if the complaint begs the assertion of the defense, and even if the defense is the only question truly at issue in the case." *Id.* at 446 (internal quotations omitted). Thus, the federal question triggering jurisdiction must appear in the elements of Carmine's causes of action.

MSD's second argument for the presence of a federal issue is, similarly, that federal law is inherent in Carmine's claims because he must prove a "parallel" violation of federal law as an element of his state law claims. (Mem. in Supp. at 7-9.) The Supreme Court has explicitly held, however, that a state tort claim incorporating allegations of an FDCA violation does not arise under federal law for purposes of § 1331. *See Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 813-17

(1986). And other district courts have found in similar FDCA cases involving the Infuse® product that "*Merrell Dow* not only remains good law generally, but it is specifically sufficient to establish that these state claims do not arise under federal law." *Goade*, 2013 WL 6237853, at *4.

MSD argues that *Merrell Dow* is not dispositive because that case involved a drug—not a device—and drugs are not governed by the express preemption clause of § 360k(a). (Mem. in Opp'n at 22.) MSD contends that *Merrell Dow* primarily relied on the fact that the FDCA regulation of drugs provided "no federal cause of action and no preemption of state remedies." *Grable*, 545 U.S. at 318. Thus, according to MSD, the MDA's express preemption of state law remedies differentiates this case from *Merrell Dow*. Like many other courts to consider this argument, "[t]he Court is not persuaded by this line of reasoning." *Anders v. Medtronic, Inc.*, No. 4:14cv194, 2014 WL 1652352, at *6 (E.D. Mo. Apr. 24, 2014) (quoting *Goade*, 2013 WL 6237853, at *5). "There is no authority suggesting that *Merrell Dow* depends on this distinction—or, for that matter, that the jurisdictional analysis depends on this distinction. The distinction is, in short, meaningless." *Id.* (quoting *Goade*, 2013 WL 6237853, at *5).

MSD's third argument for the presence of a necessary federal question is that Carmine's manufacturing defect claim alleges a violation of the FDA's Current Good Manufacturing Practices. (Mem. in Opp'n at 11.) Similarly, Carmine's negligence claim also alleges a violation of the FDCA and premarket approval requirements. (Compl. ¶ 144(j).) These allegations of federal law violations, however, are not "necessary" to Carmine's claims of manufacturing defect or common law negligence. In both claims, the alleged violation of federal law is only one of several arguments made to show a breach of the appropriate standard of care. In *Pinney*, the Fourth Circuit concluded that federal law is not necessarily raised when it serves as "only one factor" in assessing a defendant's liability. *Pinney*, 402 F.3d at 446. In other words, when "a plaintiff can establish, without the resolution of an issue of federal law, all of the essential elements of his state law claim, then the claim does not necessarily depend on a question of federal law." *Id.* at 442 (citing *Franchise Tax Bd.*, 463 U.S. at 13)). In this case, a violation of federal law would serve as only one, non-dispositive factor in both the manufacturing defect and negligence claims. Therefore, federal law is not necessarily raised.

MSD's fourth argument is that the Complaint's background section alleges the FDA misclassified Infuse® as a device rather than a drug. (Mem. in Opp'n at 12.) In that section, the Complaint states that "[b]y approving the Infuse components as a device, the FDA abused its discretion, thus requiring reclassification." (Compl. ¶ 99.) Even MSD acknowledges, however, that this argument is merely an attempt to "avoid the preemption of [Carmine's] claims under 21 U.S.C. § 360k(a)—which applies only to devices, not drugs." (Mem. in Opp'n at 12.) The misclassification of the device is not even mentioned in the sections of the Complaint actually asserting the theories of relief. Thus, the misclassification argument is, again, an argument in anticipation of the defense of preemption and not part of the well-pleaded complaint. Furthermore, Carmine need not prove misclassification to establish an element of any of his ten counts. Therefore, the question of whether the FDA misclassified Infuse® is not a federal issue necessarily raised in this case.

Although MSD does not make the argument, there is one count that necessarily raises an actually disputed issue of federal law. Count five alleges negligence *per se*, which requires proof that "the defendant violated a statute that was enacted for public safety," "that [plaintiff] belongs to the

class of persons for whose benefit the statute was enacted, and that the harm that occurred was of the type against which the statute was designed to protect," and "that the statutory violation was a proximate cause of his injury." *Halterman v. Radisson Hotel Corp.*, 523 S.E.2d 823, 825 (Va. 2000.) Thus, a negligence *per se* claim necessarily requires a violation of some statute. And in this case, Carmine alleges a violation of a federal statute, the FDCA. (*See* Compl. ¶ 147 ("Product Defendants had a duty to comply with the applicable FDCA and PMA requirements referenced above."). Negligence *per se* alleging a violation of federal law as the source of duty and negligence is "[t]he paradigmatic example of a state claim with an embedded (though not necessarily significant) federal issue." *Dillon*, 992 F. Supp. 2d. at 756. Furthermore, MSD vigorously asserts that it did not violate the FDCA. Therefore, Count five raises a necessary and actually disputed issue of federal law, but it is the only count to do so.

(2) *Substantial*

It requires more than the presence of a necessary and disputed federal issue to create substantial federal question jurisdiction; the federal issue must also be substantial. In the recent case of *Gunn v. Minton*, the Supreme Court clarified that substantiality does not mean "significant to the particular

parties in the immediate suit; that will *always* be true when the state claim 'necessarily raise[s]' a disputed federal issue." 133 S. Ct. 1059, 1066 (2013). Substantiality requires something more. "The substantiality inquiry under *Grable* looks instead to the importance of the issue to the federal system as a whole." *Id.* "[T]his degree of importance has been found only when the Government's operations are affected by the federal issue." *Goade*, 2013 WL 6237853, at *6 (discussing *Grable*, 545 U.S. at 315 and *Smith v. Kansas City Title & Trust Co.*, 255 U.S. 180 (1921)).

It is telling that MSD's discussion of substantiality never cites *Gunn*. (*See* Mem. in Opp'n at 13-18.) Instead, MSD contends that the Court should judge substantiality under a four-factor test that predates *Gunn* and appears to be applied only in the Sixth Circuit. *See Mikulski v. Centerior Energy Corp.*, 501 F.3d 555, 570 (6th Cir. 2007).[5] Although *Mikulski*

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[5] The *Mikulski* factors include the following:

> (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

derived these factors from its interpretation of the Supreme Court case of *Empire Healthcare Assurance Inc. v. McVeigh*, 547 U.S. 671, 700 (2006), that case is not the Supreme Court's most recent discussion of the substantiality factor. Furthermore, it is not apparent that *Empire*'s discussion was limited to the "substantiality" analysis, as several of the factors are duplicative of other elements in the *Grable* test. Perhaps for these reasons, the Court could not locate any district court in the Fourth Circuit adopting the *Mikulski* or *Empire* factors as its substantiality standard. Accordingly, the Court will look to *Gunn* for guidance on what "substantial" means, not *Mikulski*.

The parties have cited many district court cases discussing whether the legal issues raised in state-law claims against Infuse® for off-label promotion are "substantial." All the post-*Gunn* cases finding substantiality that MSD cites, however, come from district courts in the Sixth Circuit applying *Mikulski* and three of those cases were authored by the same district court judge. *Arrington v. Medtronic, Inc.*, No. 2:14-cv-02473, 2014 WL 10384579, at *10-11 (W.D. Tenn. Sept. 2, 2014); *H.R. ex rel. Reuter*, 996 F. Supp. 2d 671, 679-80 (S.D.

> numerous other cases (i.e., the issue is not anomalous or isolated).

Mikulski, 501 F.3d at 570.

Ohio 2014); *Jenkins v. Medtronic, Inc.*, 984 F. Supp. 2d 873, 880-81 (W.D. Tenn. 2013); *see also Hafer v. Medtronic, Inc.*, 99 F. Supp. 3d 844, 850 (W.D. Tenn. 2015) (noting prior denial of remand motion).

When looking outside the Sixth Circuit, district courts in the Eighth and Eleventh Circuits have interpreted *Gunn* to mean that substantiality did not exist in Infuse® product liability cases like this one. *See 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). Additionally, at least one district court in the Sixth Circuit concluded that substantiality did not exist in a similar Infuse® case and distinguished several of its sister courts as failing to acknowledge *Gunn* in their analysis. *See Schilmiller v. Medtronic, Inc.*, 44 F. Supp. 3d 721, 731 (W.D. Ky. 2014) (noting that *H.R. ex rel. Reuter* and *Jenkins* "failed to address the Court's concerns in *Gunn*"). The Court finds the conclusions reached in *Schilmiller*, *Hilyard*, *Anders*, *Mooney*, and *Goade* more closely align with the standards articulated in *Gunn* and joins

those courts in concluding that any federal issues necessarily raised in this case are not substantial.

The federal issues in dispute here, while important to the individual litigants, are not significant to the federal system as a whole. None of the issues in this case would affect the Government's operation. The disputes relate to whether medical manufacturers designed, manufactured, and promoted an unreasonably dangerous product. These questions are clearly important to the Product Defendants, but do not affect the operation of the federal system in the way that was evident in *Smith v. Kansas City Title & Trust Co.* or in *Grable*. Therefore, any federal issues raised here are not substantial.

(3) *Balance of Federal-State Powers*

Although the absence of substantiality is dispositive, the Court will also address the balance between federal and state judicial responsibilities. As other courts considering this factor in Infuse® cases have noted, it is "telling that Congress chose to neither permit federal jurisdiction, nor completely preclude state jurisdiction, over claims alleging violations of the MDA." *Schilmiller*, 44 F. Supp. 3d at 731. "The combination of no federal cause of action and no preemption of all state remedies, while not dispositive, is an important clue to Congress's conception of the scope of jurisdiction to be

exercised under § 1331." *Anders*, 2014 WL 1652352, at *7 (quotation omitted). Furthermore, the Supreme Court has expressed unwillingness to open the federal courthouse doors to all state-law tort claims involving FDCA labeling violations. *See Merrell Dow*, 478 U.S. at 814-17.

MSD's argument that only a "small percentage" of a "tiny faction" of medical devices is as heavily regulated as Infuse® is not convincing. As a general matter, the raw number of products receiving premarket approval each year is not as important as the breadth of the product's use in the marketplace. For example, Infuse® alone has already provoked 800 lawsuits against Medtronic and the company estimates over 4,500 claimants have not yet filed. *See Medtronic, Inc. Annual Report* (Form 10-K), at 119 (June 23, 2015). Additionally, as other courts have found, MSD's "legal analysis would not be confined to Class III medical devices. It would apply, minimally, to all medical devices, and arguably would apply further." *Anders*, 2014 WL 1652352, at *7 (quoting *Goade*, 2013 WL 627853, at *6). Thus, accepting MSD's argument poses a real risk of upsetting the balance of state and federal judicial responsibilities that Congress contemplated.

In sum, only one of Carmine's ten counts necessarily raises an actually disputed federal issue. That federal issue,

however, is not substantial under the *Gunn* standard and therefore does not create substantial federal question jurisdiction in this case. Additionally, accepting federal jurisdiction over this case would upset the balance between state and federal judicial responsibilities. Accordingly, the case must be remanded.

B. Motion to Sever

As an alternative position, MSD contends that the Court should sever the nondiverse Medical Defendants in an attempt to bring this case within the Court's § 1332 diversity jurisdiction. MSD argues that severance would be proper under Federal Rule of Civil Procedure 21 because the "claims against the Medical Defendants are distinct from [Carmine's] claims against the Product Defendants, are predicated on different standards of care, and alleged different conduct." (Mem. in Opp'n at 27.) Thus, MSD contends the Medical Defendants are dispensable and severance would not prejudice Carmine. MSD also cites several recent cases in which a district court severed nondiverse medical defendants in cases alleging similar claims of medical product liability. *See Sullivan v. Calvert Mem. Hosp.*, No. PJM 15-1188, 2015 WL 4614467 (D. Md. July 30, 2015); *H.R. ex rel. Reuter v. Medtronic, Inc.*, 996 F. Supp. 2d 671, 682-83 (S.D. Ohio 2014).

Carmine rebuts that severance is not proper because the claims against all Defendants are "inextricably bound to the same core set of facts and issues." (Mem. in Supp. at 5.) Additionally, Carmine asserts that the Medical Defendants are likely to blame the Product Defendants for Carmine's injuries, and vice versa. Thus, severance would "severely prejudice Plaintiff's ability to prosecute his claims." (*Id.* at 6.)

"[I]t is well settled that Rule 21 invests district courts with authority to allow a dispensable nondiverse party to be dropped at any time." *Newman-Green, Inc. v. Alfonzo-Larrain*, 490 U.S. 826, 833 (1989). Whether to grant such severance, however, "is committed to the discretion of the trial court, and it does not follow as a matter (of) right that a party can be dropped at the mere desire" of another party. *Caperton v. Beatrice Pocahontas Coal Co.*, 585 F.2d 683, 692 (4th Cir. 1978) (internal quotation omitted). In addition to determining whether a party is indispensable,[6] district courts considering severance look to "fundamental fairness, judicial economy,

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[6] A party is indispensable if, "in the party's absence, the court cannot accord complete relief among existing parties; or that person claims an interest relating to the subject of the action and is so situated that disposing of the action in the person's absence may: (i) as a practical matter impair or impede the person's ability to protect the interest; or (ii) leave an existing party subject to a substantial risk of incurring double, multiple, or otherwise inconsistent obligations because of the interest." Fed. R. Civ. P. 19(a)(1).

prejudice, undue delay, as well as the dual threat of duplicitous litigation and inconsistent verdicts." *Tinsley v. Streich*, No. 3:15cv00043, 2015 WL 7009488, at *9 (W.D. Va. Nov. 12, 2015) (quoting *John S. Clark Co., Inc. v. Travelers Indem. Co. of Ill.*, 359 F. Supp. 2d 429, 441 (M.D.N.C. 2004)); *see also Newman-Green*, 490 U.S. at 838 ("That discretion is guided by consideration of whether dismissal of the nondiverse party or parties will prejudice any of the parties remaining in the case, and whether the presence of the nondiverse party provides a tactical advantage for one party."). Furthermore, the Supreme Court has noted that the Federal Rules of Civil Procedure encourage "entertaining the broadest possible scope of action consistent with fairness to the parties." *United Mine Workers of Am. v. Gibbs*, 383 U.S. 715, 724 (1966). Accordingly, "Rule 21 discretion should be exercised sparingly." *Tinsley*, 2015 WL 7009488, at *9.

At the outset, it is important to note that MSD is not arguing for severance under two other distinct legal doctrines that permit the court to disregard the citizenship of nondiverse parties and retain jurisdiction. First, MSD does not argue that the Medical Defendants were fraudulently joined, which would permit severance where there is "no possibility of success against those defendants." *Stephens v. Kaiser Found. Health*

Plan of the Mid-Atl. States, Inc., 807 F. Supp. 2d 375, 379 (D. Md. 2011). Second, MSD does not argue that the Medical Defendants were fraudulently misjoined, which some courts have found permits severance where "claims against certain defendants, while provable, have no real connection to the claims against other defendants in the same action and were only included in order to defeat diversity jurisdiction and removal."[7] *Wyatt v. Charleston Area Med. Ctr., Inc.*, 651 F. Supp. 2d 492, 496 (S.D.W. Va. 2009). Instead of arguing those theories, MSD relies exclusively on the Court's purely discretionary Rule 21 authority. The Court declines to exercise that authority here.

A recent case from the Western District of Virginia presenting similar facts provides compelling reasons for declining to sever nondiverse defendants in a case simultaneously alleging medical malpractice and product liability.[8] In *Tinsley v. Streich*, the plaintiff brought medical malpractice claims against doctors and hospitals for their

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[7] The Fourth Circuit has not yet expressly adopted fraudulent misjoinder as a basis for severance. *See Tinsley*, 2015 WL 7009488, *5 ("The Fourth Circuit has not yet expressly adopted the fraudulent misjoinder doctrine and district courts within the circuit have disagreed as to whether to adopt it."). As no party raises fraudulent misjoinder in this case, this opinion does not opine on whether its adoption is appropriate.

[8] Carmine filed a notice of supplemental authority identifying *Tinsley v. Steich*, No. 3:15-cv-00043, 2015 WL 7009488 (W.D. Va. Nov. 12, 2015) on November 14, 2015.

failure to diagnose his child with an adverse reaction to acetaminophen. No. 3:15cv00043, 2015 WL 7009488, at *7 (W.D. Va. Nov. 12, 2015). The plaintiff also raised product liability claims against the drug manufacturers for unreasonable design, testing, manufacturing, marketing, and labeling of acetaminophen. After finding the defendants properly joined, the court declined to exercise its Rule 21 discretion because "the overarching allegation in this case is a global failure to warn of the connection between acetaminophen and SJS/TEN [a serious skin condition]." *Id.* at *10. In light of the overarching factual and legal similarities among the claims against both sets of defendants, the court found that "the considerations of fairness to parties, trial convenience, and efficient administration of justice all weigh in favor of it declining to sever the claims against both sets of defendants." *Id.* Specifically, the court noted that severance would increase the risk of inconsistent judgments and potentially enable both sets of defendants to blame the other defendants for the injuries alleged. *Id.* This Court finds those same concerns compelling in this factually similar case and declines to sever the Medical Defendants.

Even assuming the Medical Defendants are dispensable parties, something Carmine does not appear to dispute, severance

is not appropriate. Broadly stated, Carmine's Complaint alleges a failure to warn him of the foreseeable and known dangers of the off-label use of Infuse® and the injuries he sustained when the Medical Defendants used Infuse® in that way. Although the specific elements of each theory of relief are distinct, his entitlement to damages on all theories arises from the surgery in which the Medical Defendants implanted the Product Defendants' device into his body. Thus, as in *Tinsley*, there is a real concern that each group of defendants could attribute Carmine's injuries to the other group's conduct. The Product Defendants could argue that Infuse®, if properly used, does not have an increased risk of injuries even if the use is off-label. Similarly, the Medical Defendants could argue that the surgery was properly performed, but the product was defectively designed. The potential risk of this "empty chair" defense cautions against severing the defendants in this case.

Furthermore, separate trials would increase the risk of inconsistent verdicts. As the court noted in *Tinsley*, "if the court were to sever the claims in this case, a jury in the state court action may find that the [medical defendants] were not negligent in treating Kaylee because the [product defendants] failed to warn them of the risks of developing SJS/TEN." *Tinsley*, 2015 WL 7009488, at *10. In a later federal

trial on product liability, "a jury may find that the [product defendants] properly warned of the connection between SJS/TEN and acetaminophen usage." *Id.* The same concern would be unnecessarily injected into this case if the Court severed the defendants.

MSD's citation to *Sullivan v. Calvert Memorial Hospital* does not persuade the Court to sever. In *Sullivan*, the plaintiff raised medical malpractice and product liability claims related to the surgical implant of a defective transvaginal sling into her pelvic region and the failure to properly remove a catheter used during that surgery. No. PJM 15-1188, 2015 WL 4614467, at *1-2 (D. Md. July 30, 2015). The product liability defendants removed the case, arguing that the nondiverse medical defendants should be severed under Rule 21. The court first found that the medical defendants were not necessary parties under Rule 19 because the medical malpractice and product liability claims involved different legal and factual inquiries and resolution of one set of claims would not necessarily resolve the remaining claims. That analysis, however, only determined that the medical defendants were not necessary. As a final point in favor of severance, the *Sullivan* court noted "a critical policy reason why the Court exercises its discretion and severs the two defendant groups." *Id.* at *5.

Severance was "particularly appropriate" because it permitted the product liability case to be transferred to a current multi-district litigation. *Id.* Therefore, any prejudice to the plaintiff from a multi-forum litigation was offset by the convenience to the defendants of taking advantage of the consolidation of cases in the multi-district litigation.

Unlike in *Sullivan*, there is no competing efficiency policy promoted by dividing Carmine's case between two separate jurisdictions. Severance would instead require duplicative presentation of at least some common factual and legal issues in separate judicial forums. Furthermore, the Court declines to find that the mere fact that a party is not necessary under Rule 19 justifies a discretionary remedy that should "be exercised sparingly." As such, the Court declines to sever the medical defendants in this case.

IV. Conclusion

For the foregoing reasons, the Court will grant Plaintiff's motion to remand and deny Defendant MSD's motion to sever the nondiverse defendants.

An appropriate order will follow.

/s/

December 29, 2015
Alexandria, Virginia

James C. Cacheris
UNITED STATES DISTRICT COURT JUDGE