IN THE UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

MARK FRANCIS MACDUFF SPENCE, SR., et al.,	)	
Plaintiffs,	)	NO. 3:18-cv-0369
v.	)	JUDGE RICHARDSON
DEXCOM, INC., et al.,	)	
Defendants.	)	

MEMORANDUM OPINION

Pending before the Court are Defendant Dexcom's Motion to Sever (Doc. No. 6); Plaintiff's Motion to Remand (Doc. No. 25); Defendants Heritage Medical Associates, Wierum, and Marksbury's[1] Renewed Motion to Dismiss (Doc. No. 34); and Defendant Dexcom's Motion to Dismiss (Doc. No. 36).

BACKGROUND

This action was filed in the Davidson County Circuit Court, seeking damages for the death of Plaintiffs' son, Mark Spence ("Spence"), who died on March 9, 2017, allegedly because of a defective G5 Mobile Continuous Glucose Monitoring System ("the G5") designed, developed, marketed and sold by Defendant Dexcom and prescribed for Spence by Defendant Marksbury, a nurse practitioner employed by Heritage Medical Associates ("Heritage"). Defendant Wierum, a physician employed by Heritage, supervised Spence's treatment with the G5. Doc. No. 1-5.[2]

[1] Defendant Tiffanie Marksbury was known as Tiffanie Wright at the time of the filing of this case but has since married and now goes by Tiffanie Marksbury. Doc. No. 34, n.1.

[2] Defendants Heritage, Marksbury and Wierum will be referred to, collectively, as the "Heritage Defendants."

Plaintiffs contend that the G5 inaccurately measured blood glucose levels and failed to sound when Spence's glucose levels were dangerously high or low. Consequently, Plaintiffs claim, the defective G5 failed to provide an adequate warning to Spence that he was experiencing a severe hypoglycemic event, and he died in his sleep. Doc. No. 30.

Dexcom removed the action to this Court, contending that the Court has original subject matter jurisdiction, pursuant to 28 U.S.C. § 1331, because the case involves the federal Food and Drug Administration ("FDA") and, therefore, arises under the laws of the United States. Dexcom also asserted that Plaintiffs are attempting to enforce provisions of the federal Food, Drug, and Cosmetic Act ("FDCA") and FDA regulations. Dexcom further argued that the Court has diversity jurisdiction, pursuant to 28 U.S.C. § 1332, because there is complete diversity among all properly joined and served parties and the amount in controversy exceeds $75,000.

Soon after removal, Dexcom filed a Motion to Sever the claims against the Heritage Defendants as fraudulently misjoined[3] with the claims against Dexcom and, alternatively, because the Heritage Defendants are not necessary parties. Doc. No. 6. Plaintiffs have responded in opposition to the Motion to Sever (Doc. No. 27), and Dexcom has filed a Reply (Doc. No. 31).

Plaintiffs filed a Motion to Remand the case to state court (Doc. No. 25), to which Dexcom has filed an opposition (Doc. No. 32), and Plaintiffs have filed a Reply. Doc. No. 44.

The Heritage Defendants filed a Renewed Motion to Dismiss Certain Claims (Doc. No. 34), to which Plaintiffs have filed a Response. Doc. No. 39. Dexcom has filed a Motion to Dismiss the First Amended Complaint (Doc. No. 36), to which Plaintiffs have responded (Doc. No. 40), and Dexcom has replied. Doc. No. 45.

[3] Dexcom made clear that its assertion of fraudulent *misjoinder* was in addition to its assertion of fraudulent *joinder*. Doc. No. 6 at n. 1 and Doc. No. 7 at n. 1.

Plaintiff's First Amended Complaint[4] alleges causes of action for product liability/negligent manufacture against Dexcom (Count I); product liability/negligent failure to warn against Dexcom (Count II); product liability/strict liability against Dexcom (Count III); negligence against Heritage Associates (Count IV); negligence against Wierum (Count V); and negligence against Wright/Marksbury (Count VI). Doc. No. 30. Plaintiffs contend that this action must be remanded to state court because there is no diversity of citizenship and no federal question jurisdiction.

REMOVAL AND REMAND

Dexcom removed this action from state court, pursuant to 28 U.S.C. §§ 1441 and 1446 and in reliance upon 28 U.S.C. §§ 1331, 1332 and 1337, alleging federal question jurisdiction and diversity jurisdiction.[5] The party removing the action to federal court bears the burden of showing that the district court has original jurisdiction over the action. *Watson v. Cartee*, 817 F.3d 299, 303 (6th Cir. 2016). Removal petitions are strictly construed, with all doubts resolved against removal. *Gooden v. Unum Life Ins. Co. of America*, 181 F. Supp. 3d 465, 470 (E.D. Tenn. 2016). If at any time before final judgment it appears that the district court lacks subject-matter jurisdiction, the case shall be remanded. 28 U.S.C. § 1447(c).

DIVERSITY JURISDICTION

Dexcom contends that the Court has diversity jurisdiction, pursuant to 28 U.S.C. § 1332, because there is complete diversity among all *properly joined* parties. Because Plaintiffs and the

[4] Although Plaintiff's First Amended Complaint was filed after the Motion to Sever and the Motion to Remand, no party has contended, and the Court does not find, that these motions are somehow less applicable to the First Amended Complaint than to the original Complaint.

[5] The Heritage Defendants consented to removal in accordance with 28 U.S.C. § 1446(b)(2)(A). Doc. No. 1-4.

Heritage Defendants are citizens of the same state, the Court cannot exercise diversity jurisdiction so long as the Heritage Defendants are parties. According to Dexcom, the Heritage Defendants were improperly joined, so their Tennessee citizenship should be disregarded for purposes of assessing diversity of citizenship. Diversity jurisdiction must exist at the time of removal. *Roberts v. Mars Petcare US, Inc.*, 874 F.3d 953, 958 (6th Cir. 2017). The party seeking to bring the case into federal court carries the burden of establishing diversity jurisdiction. S*chmidt v. PennyMac Loan Servs., LLC*, 106 F. Supp. 3d 859, 873 (E.D. Mich. 2015).

SEVERANCE

Dexcom asks the Court to sever the claims of the Heritage Defendants, an action that would "create" diversity jurisdiction by removing all defendants of the same (Tennessee) citizenship as the Plaintiffs. The Federal Rules of Civil Procedure provide that a court may, at any time in the proceeding, on motion or on its own, add or drop a party or sever any claim against a party. Fed. R. Civ. P. 21. Severance is a procedural device to be employed only in exceptional circumstances. *Agnesini v. Doctor's Assocs., Inc.*, 275 F.R.D. 456, 458 (S.D. N.Y. 2011).

In considering a motion to sever under Rule 21, courts consider principles of fundamental fairness and judicial efficiency as well as prejudice to any party or resulting undue delay. *Reynolds v. Merck Sharp & Dohme Corp.*, Case No. 3:15 cv 397, 2016 WL 3090951, at *2 (N.D. Ohio June 2, 2016). The moving party is tasked with establishing that severance is required to avoid prejudice or confusion and to promote the ends of justice. *Id*. (citing *Agnesini*, 275 F.R.D. at 458). Courts have also considered whether settlement of the claims or judicial economy would be facilitated; whether prejudice would be avoided if severance were granted; and whether different witnesses and documentary proof are required for the claims sought to be severed and the claims that would remain. *Reuter v. Medtronic, Inc.*, 996 F. Supp. 2d 671, 682 (S.D. Ohio 2014); *Allstate Ins. Co. v.*

Electrolux Home Products, Inc., No. 1:16cv1946, 2016 WL 6995271, at *3 (N.D. Ohio Nov. 30, 2016). Applying this standard, the court "has virtually unfettered discretion" in determining whether severance is appropriate. *Brown v. Kentucky Utils. Co.*, NO. 3:15-CV-352-GNS, 2015 WL 6476096, at *1 (W.D. Ky. Oct. 26, 2015). Claims may be severed if the court determines, in its discretion, that the interest of justice would be served by doing so. *Does 1-144 v. Chiquita Brands Int'l, Inc.*, 285 F. Supp. 3d 228, 239 (D. D.C. 2018).

FRAUDULENT JOINDER

Dexcom has asserted fraudulent joinder in three different procedural contexts. First, Dexcom asserted it in its Notice of Removal as grounds for the Court's recognition of diversity jurisdiction. (Doc. No. 1 at 10-13). Second, Dexcom has moved to sever the Heritage Defendants on the grounds that they were fraudulently joined. (Doc. No. 7 at 2-4). Third, Dexcom has asserted fraudulent joinder in its opposition to Plaintiffs' motion to remand.[6] (Doc. No. 32 at 14-17). In any of these three contexts, the claim of fraudulent joinder, if valid, would defeat Plaintiff's motion to remand.

[6] Thus, Dexcom has asserted fraudulent joinder in conjunction with removing in the first place, in conjunction with a motion to sever the non-diverse parties that would defeat diversity jurisdiction, and in response to a motion for remand. It appears that each of the three approaches is proper as a procedural matter. The Sixth Circuit has at least tacitly accepted the first of these strategies. *See, e.g., Pollington v. G4S Secure Sols. (USA) Inc*., 712 F. App'x 566 (6th Cir. 2018). The second strategy is permissible. "Under the doctrine of 'fraudulent joinder,' federal courts may sever the non-diverse defendant from the case if the claim against him is so frivolous that its only conceivable purpose is to destroy diversity and prevent removal." *Murriel-Don Coal Co. v. Aspen Ins. UK Ltd*., 790 F. Supp. 2d 590, 592 (E.D. Ky. 2011). It appears that third strategy also is permissible As the Sixth Circuit has explained in a case involving a case of fraudulent joinder but no motion to sever, "When a non-diverse party has been joined as a defendant, then in the absence of a substantial federal question the removing defendant may avoid remand only by demonstrating that the non-diverse party was fraudulently joined. Fraudulent joinder is "a judicially created doctrine that provides an exception to the requirement of complete diversity." *Casias v. Wal-Mart Stores, Inc*., 695 F.3d 428, 432 (6th Cir. 2012) (citations and quotation marks omitted).

To prove fraudulent joinder, a defendant must present sufficient evidence that the plaintiff cannot establish a cause of action against the non-diverse defendants under state law. *Roberts,* 874 F.3d at 958. In other words, the possibility of fraudulent joinder requires proof that the plaintiff has no colorable claim against the non-diverse defendant under state law. *Id*. The district court must resolve all disputed questions of fact and ambiguities in the controlling state law in favor of the non-removing party. *Id*. All doubts as to the propriety of removal are resolved in favor of remand. *Id*. In considering fraudulent joinder allegations, a court applies a test similar to, but more lenient (towards the plaintiff) than, the analysis applicable to a Rule 12(b)(6) motion to dismiss. *Casias v. Wal-Mart Stores, Inc.*, 695 F.3d 428, 433 (6th Cir. 2012). The removing party bears the burden of demonstrating fraudulent joinder. *Id.*

Dexcom has failed to meet its burden. It does not show that Plaintiffs could not establish a cause of action against the Heritage Defendants. The claims against the Heritage Defendants are claims for negligence. To establish a negligence claim under Tennessee law requires Plaintiffs to show: (1) a duty of care owed by the Defendants to the Plaintiff; (2) conduct falling below the applicable standard of care amounting to a breach of that duty; (3) an injury or loss; (4) causation in fact; and (5) proximate, or legal cause. *Kellner v. Budget Car and Truck Rental*, 359 F.3d 399, 403 (6th Cir. 2004).

The element of duty[7] in a negligence action is the legal obligation to conform to a reasonable person standard of care to protect against unreasonable risks of harm. *Eden W. ex rel. Evans v. Tarr*, 517 S.W.3d 691, 695 (Tenn. Ct. App. 2015). Although whether a defendant owed

[7] Dexcom argues that there is no duty in Tennessee for healthcare providers to advise patients of adverse events reported to the FDA. Doc. No. 1 at 12. However, Plaintiffs' claims against the Heritage Defendants go far beyond mere failure to advise Plaintiff of adverse events reported to the FDA.

a plaintiff a duty of care is a question of law for the Court, all persons have a duty to use reasonable care to refrain from conduct that will foreseeably cause injury to others. *Tanner v. Ogden*, No. 3-13-0042, 2014 WL 1413495, at *1 (M.D. Tenn. Apr. 11, 2014). Whether a defendant breached the duty of care and whether cause in fact and proximate cause exist are generally questions of fact for the finder of fact. *Eden W.*, 517 S.W.3d at 695-96.

Dexcom misleadingly argues that the only claims against the Heritage Defendants are failure to advise Spence of an FDA warning letter and a G5 device recall and failure to train Spence on use of the G5. Doc. No. 32 at 15. The First Amended Complaint, however, alleges the following against the Heritage Defendants: (1) negligent failure to exercise the degree of care, skill, and diligence required in recommending that Spence use the G5; (2) negligent failure to conduct appropriate due diligence regarding the G5 before prescribing it for their patients; (3) negligently allowing employees to prescribe the G5 without conducting due diligence; (4) negligent failure to provide warning of the defective nature of the G5; (5) negligent failure to ensure that employees stayed informed about the dangers of the G5; (6) negligently and recklessly prescribing the G5 for Spence; (6) negligent failure to ensure that Spence received appropriate training on the G5; and (7) negligent failure properly to monitor Spence's use of the G5.

Resolving all ambiguities and doubts in favor of Plaintiffs, as the Court is required to do, these allegations sufficiently allege plausible negligence claims against the Heritage Defendants. Dexcom has not shown that Plaintiff has no colorable claim against the non-diverse Heritage Defendants under state law and, therefore, has not shown that they were fraudulently joined. Accordingly, the claim of fraudulent joinder fails and thus neither defeats Plaintiff's motion to remand directly, nor provides a basis to defeat the motion indirectly by severing the Heritage Defendants and thereby destroying diversity jurisdiction. As held by the Sixth Circuit, when a non-

diverse party has been joined as a defendant, then in the absence of a substantial federal question, the removing defendant may avoid remand *only* by demonstrating that the non-diverse party was fraudulently joined. *Casias*, 695 F.3d at 432.

FRAUDULENT MISJOINDER

Dexcom also asserts that the Heritage Defendants were fraudulently *mis*joined in this action. As noted above, the doctrine of fraudulent *joinder* addresses whether a claim is *viable* against the defendant who allegedly was fraudulently joined. By contrast, the doctrine of fraudulent *misjoinder* addresses whether the claims against the defendant who allegedly was fraudulent misjoined—whether or not viable claims standing on their own—were improperly *joined* in the removed action with the claims against the other defendant(s) in order to destroy diversity. *Asher v. Minnesota Mining and Mfg. Co.*, No. Civ.A. 04CV522KKC, 2005 WL 1593941, at *4 (E.D. Ky. June 30, 2005). Fraudulent misjoinder is concerned with the situation where "potentially viable but unrelated claims against resident and non-resident defendants [were] joined in one action to destroy diversity and thereby prevent removal by the non-resident defendants." *Lyons v. Lutheran Hosp. of Ind.*, No. 104CV0728DFHVSS, 2004 WL 2272203, at *4 (S.D. Ind. Sept. 15, 2004).

Whereas the fraudulent *joinder* doctrine has been widely accepted, most courts have declined to adopt the fraudulent *misjoinder* doctrine. *Staubus v. Purdue Pharma., L.P.* No. 2:17-CV-122-TAV-CLC, 2017 WL 4767688, at *4 (E.D. Tenn. Oct. 20, 2017) (collecting cases). Only one decision within the Sixth Circuit, *Asher*,[8] has recognized the fraudulent misjoinder doctrine, and that decision has been questioned in more recent opinions. *Id*.

[8] Even A*sher*, however, noted that the Sixth Circuit has not adopted or addressed the fraudulent misjoinder doctrine. 2005 WL 1593941, at *4.

The Eleventh Circuit, which established the fraudulent misjoinder doctrine in 1996 in *Tapscott v. MS Dealer Serv. Corp.*, 77 F.3d 1353 (11th Cir. 1996), *abrogated on other grounds by Cohen v. Office Depot, Inc.*, 204 F.3d 1069 (11th Cir. 2000). In *Tapscott*,[9] the court held that diversity jurisdiction was proper where diversity was destroyed only through the misjoinder of parties under Fed. R. Civ. P. 20. *Id.* at 1360; *see also Central Bank v. Jerrolds*, No. 14-1163, 2015 WL 1486368, at *3 (W.D. Tenn. March 31, 2015). The doctrine of fraudulent misjoinder emerged in cases in which a plaintiff joined unrelated claims against a non-diverse defendant for the purpose of destroying diversity. *In re Darvocet, Darvon and Propoxyphene Products Liab. Litig.*, 889 F. Supp. 2d 931, 943 (E.D. Ky 2012).

As noted by the court in *Staubus*, several factors weigh against adopting the fraudulent misjoinder doctrine. Even courts that have recognized the doctrine struggle to apply it. *Staubus*, 2017 WL 4767688, at *4; *Central Bank*, 2015 WL 1486368, at *3-4. As noted by the *Central Bank* court, a fraudulent misjoinder analysis requires the Court "to wade into a thorny thicket of unsettled law . . . and the last thing the federal courts need is more procedural complexity." *Central Bank*, 2015 WL 1486368, at *3.

The Court declines to adopt the fraudulent misjoinder doctrine in this case. The Sixth Circuit, as noted earlier, has stated that a removing defendant may avoid remand (unless there is a federal question) *only* by demonstrating that the non-diverse defendant was fraudulently joined, with no mention of fraudulent misjoinder. Casias, 695 F.3d at 432. In addition to the fact that the Sixth Circuit has not adopted this doctrine, the doctrine is ambiguous, and its standards are

[9] At times in its opinion, the court in *Tapscott* used the term "fraudulent joinder" to refer to the concept that since has become known as the doctrine of "fraudulent misjoinder" distinct from the doctrine of fraudulent joinder.

unclear.[10] Because the Court must resolve any ambiguities in favor of remand and the fraudulent misjoinder doctrine disfavors remand, the Court declines to adopt the doctrine in the present action.

In any event, however, Dexcom has failed to demonstrate anything improper, let alone "fraudulent," about the joinder of the Heritage Defendants.[11] As explained below, the claims against the Heritage Defendants are not unrelated to the claims against Dexcom and were in fact properly joined. There is no evidence that Plaintiffs joined unrelated claims against the Heritage Defendants for the purpose of destroying diversity jurisdiction.

NECESSARY PARTIES

Dexcom alternatively urges the Court, if it determines the Heritage Defendants were properly joined, to sever the Heritage Defendants from this action on the grounds that they are not "necessary" parties under Fed. R. Civ. P. 19.[12] To determine whether a defendant is necessary, a court must consider: (1) whether complete relief can be given to existing parties in the defendant's absence; (2) whether disposition in the defendant's absence may impair the defendant's ability to

[10] For example, whether misjoinder must be "egregious" or just something more than "mere misjoinder" is one of many unsettled questions about the fraudulent misjoinder doctrine. *Staubus*, 2017 WL 4767688, at *5.

[11] As suggested in the footnote immediately above, one of the problems with the fraudulent joinder doctrine is that there is no consensus as to whether it requires: (1) an objective inquiry into was joinder was improper; (2) an objective inquiry into whether joinder was egregiously improper or baseless; or (3) an objective inquiry into whether the joinder of claims against a non-diverse defendant was "fraudulent" in the sense that it was in bad faith, as for example if it was motivated by a desire to defeat diversity*, See Rutherford v. Merck & Co*., 428 F. Supp. 2d 842, 854 (S.D. Ill. 2006)

[12] Rule 21 permits a district court to retain diversity jurisdiction over a case by dropping a non-diverse party if that party's presence in the action is not required under Fed. R. Civ. P. 19; that is, the party to be dropped must not be a necessary party (even if it is a *proper* party in that its joinder was proper under the rules of civil procedure). *Priester v. Bent Creek Golf Club, LLC*, No. 3:17-CV-284, 2018 WL 2305703, at *2 (E.D. Tenn. May 21, 2018) (citing *Safeco Ins. Co. of America v. City of White House, TN*, 36 F.3d 540, 545 (6th Cir. 1994)).

protect its interest in the controversy; or (3) whether the defendant's absence would expose existing parties to substantial risk of double or inconsistent obligations. *Id.*; Fed. R. Civ. P. 19(a)(1).

Severing the Heritage Defendants under these circumstances runs the risk of not affording Plaintiffs the opportunity for complete relief, impairing the Heritage Defendants' ability to protect their interest in the controversy, and exposing the parties to inconsistent judgments. In the event of severance, one jury could find that the Heritage Defendants were not negligent because the G5 device was not defective or unreasonably dangerous while, conversely, another jury could find that Dexcom was negligent and is strictly liable because the same G5 device *was* defective and unreasonably dangerous. One jury could find that the G5 device was the proximate cause of Spence's death, and the other jury could find that the G5 device was *not* the proximate cause of Spence's death. Given the assertions of comparative fault, a jury in the Heritage Defendants' case could find that Dexcom, not the Heritage Defendants, is primarily liable for Spence's death, while a jury in Dexcom's case could find that the Heritage Defendants, not Dexcom, are primarily liable for that death. Such a result would deprive Plaintiffs of relief, even though each party was found by a jury to be primarily liable. Furthermore, the two separate juries could render inconsistent decisions on damages.

The Court also notes that the evidence necessary to establish Plaintiffs' claims against the Heritage Defendants significantly overlaps the evidence necessary to establish their claims against Dexcom. The same or similar expert testimony would be required as to both medical negligence and product liability to establish that the G5 was unreasonably dangerous and to establish Plaintiffs' damages. The factual proof as to what happened to Spence—his condition, his treatment, his death, and Plaintiffs' damages—would also be required in both instances.

For these reasons, the Court finds that the Heritage Defendants are "necessary" parties to this action under Fed. R. Civ. P. 19.

PERMISSIVE JOINDER

Alternatively, the Court finds that, even if the Heritage Defendants are not necessary parties, they were permissibly joined in this action pursuant to Fed. R. Civ. P. 20, and, in the Court's discretion, should not be severed.[13] Persons may be joined in one action as defendants if (1) any right to relief is asserted against them jointly, severally, or (in the alternative) with respect to or arising out of the same transaction, occurrence, or series of transactions or occurrences and (2) any question of law or fact common to all defendants will arise in the action. Fed. R. Civ. P. 20(a)(2).[14] Because it does not lend itself to bright-line rules, resolution of this issue generally requires a case-by-case analysis. *Bridgeport Music, Inc. v. 11C Music*, 202 F.R.D. 229, 232 (M.D. Tenn. 2001); *Costello v. Home Depot U.S.A., Inc.*, 888 F. Supp. 2d 258, 263 (D. Conn. 2012). "All logically related claims by or against different parties [properly can] be tried in a single proceeding." *Id*. Under Sixth Circuit precedent, the words "transaction or occurrence" are to be given "broad and liberal interpretation in order to avoid a multiplicity of suits." *Allstate*, 2016 WL 6995271, at *2.

The claims against both Dexcom and the Heritage Defendants arise from the death of Mark Spence and the assertion that his death was caused by a dangerous and defective G5 Mobile Continuous Glucose Monitoring System. Plaintiffs allege that Dexcom manufactured the defective

[13] These Defendants were not permissibly joined simply because they were not fraudulently joined. In other words, even if they were not *fraudulently* joined, the Court must still satisfy itself that they were *properly* joined.

[14] Rule 20(a) is designed to promote judicial economy and trial convenience. *Bridgeport*, 202 F.R.D. at231.

monitor and that the Heritage Defendants prescribed and treated Spence with that defective monitor. Plaintiffs contend that Dexcom was negligent and is strictly liable for defective manufacture and failure to warn. Plaintiff allege that the Heritage Defendants were negligent in selecting and recommending the use of the G5 without determining whether it was a safe and effective device, in failing to warn Spence of the risks of the G5, and in failing to train him regarding use of the G5. Plaintiffs aver that Spence's death was the direct and proximate result of the tortious conductof each and every one of the Defendants. Plaintiffs' right to relief is asserted against all Defendants arising from related activities.

For permissive joinder to be proper, Rule 20 does not require that all questions of law and fact raised by the dispute be common, but neither does it establish any qualitative or quantitative test of commonality. *Lee v. Dell Products, L.P.*, No. 3:06cv0001, 2006 WL 2981301, at *10 (M.D. Tenn. Oct. 16, 2006). The common-question rule requires not that common questions of law or fact predominate, but instead only that the claims involve the same or closely related factual and legal issues. *Allstate*, 2016 WL 6995271, at *3.

The common issues here are whether the G5 device was defective or unreasonably dangerous, whether the G5 device was the cause of Spence's death, and, if so, what amount of damages Plaintiffs are entitled to recover. If the negligence claims against the Heritage Defendants were severed, a jury in that case would have to determine whether the Heritage Defendants breached the standard of care in selecting, prescribing, and treating Spence with the G5 device and whether that breach was the cause of Spence's death. Whether it was prudent to prescribe the G5 device will largely depend upon whether that device was defective and/or unreasonably dangerous. Similarly, in determining whether Dexcom is liable under the product liability causes of action asserted against it, a jury would also have to determine whether the device was defective or

unreasonably dangerous and whether the device was the cause of Spence's death.[15] In both cases, if liability is found, a jury would have to determine the amount of damages to which Plaintiffs are entitled.

For all these reasons, the Court, in its discretion, declines to sever the Heritage Defendants from this action. Dexcom's Motion to Sever will be denied.

FEDERAL QUESTION

Dexcom asserts another basis for this Court's jurisdiction: federal question. The district courts have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States. 28 U.S.C. § 1331. Dexcom claims that Plaintiffs' right to relief depends upon federal law questions and that Plaintiffs are attempting to enforce provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA") and Federal Food and Drug Administration ("FDA") regulations.

The threshold inquiry in determining whether a claim arises under federal law must be determined by reference to the "well-pleaded complaint." *Arrington v. Medtronic, Inc.*, 130 F. Supp. 3d 1150, 1158 (W.D. Tenn. 2014). It is well-settled that neither an actual nor an anticipated federal defense nor the mere presence of a federal issue will establish the necessary jurisdictional elements to remove a state cause of action. *Id*.; *Merrell Dow Pharmaceuticals, Inc. v. Thompson*,[16]

[15] A manufacturer or seller of a product shall not be liable for any injury caused by the product unless the product is determined to be in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller. Tenn. Code Ann. § 29-28-105(a). Besides showing a defective or unreasonably dangerous condition, a product liability plaintiff must always prove that the unreasonably dangerous or defective condition was the proximate cause of his injury. *Jackson v. Ford Motor Co.*, 842 F.3d 902, 907 (6th Cir. 2016).

[16] The Court is aware that *Merrell Dow* did not make a federal cause of action a necessary condition for federal-question jurisdiction; it simply treated the absence of such a cause of action as a factor relevant to, but not dispositive of, the "sensitive judgments about congressional intent" required by 28 U.S.C. § 1331. *Grable & Sons Metal Products, Inc. v. Darue Engineering & Mfg.*, 545 U.S. 308, 309 (2005).

478 U.S. 804, 808 (1986) (defense that raises federal question is inadequate to confer federal jurisdiction).

State laws that implicate a substantial question of federal law can open the door to federal court. *Estate of Cornell v. Bayview Loan Serv., LLC*, 908 F.3d 1008, 1015 (6th Cir. 2018). The question is whether the state-law claim necessarily raises a stated federal issue that is "actually disputed and substantial" and which a federal forum may entertain without disturbing any congressionally-approved balance of federal and state judicial responsibilities. *Id*. This pathway is a "slim category" that is to be read narrowly. *Id*.

The First Amended Complaint alleges state-law causes of action for negligence and violation of the Tennessee Product Liability Act of 1978. Tenn. Code Ann. § 29-28-101, *et seq.* It does not assert a federal cause of action. Doc. No. 30. The First Amended Complaint does reference the FDCA and FDA regulations. *Id*. Plaintiffs reference such federal law to: (1) show notice to Dexcom of multiple complaints concerning the G5; (2) show that the FDA warned Dexcom about its failure to comply with the Medical Device Amendments ("MDA"); (3) state that Dexcom is required to report complaints to the FDA; (4) allege that Dexcom was not in compliance with Pre-Market Approval ("PMA") requirements under the MDA; and (5) argue that Dexcom violated FDA regulations by failing to report certain complaints to the agency.[17]

Notice to Dexcom about complaints, and a warning to Dexcom about failure to comply with the MDA, suggest that Dexcom knew or should have known about a problem—a suggestion that would help establish an element of both strict liability and negligence. Plaintiffs have not, and

[17] Dexcom itself claims that the required reports to the FDA are essentially irrelevant. Doc. No. 1 at 12.

cannot, state a cause of action for Dexcom's alleged failure to report something to the FDA.[18] Plaintiffs allege that Dexcom had a common law duty to report certain things *to the public*. The allegations that Dexcom failed to comply with PMA or FDA requirements do not, and do not purport to, state causes of action; rather, they are *one way* to help show a breach of the standard of care for negligence. Plaintiffs' claims are premised on the dangerous nature of the G5, not on any failure to report or comply with FDA regulations. In other words, the alleged failure to comply with federal regulations is not a separate claim; rather, it is a means of helping to establish the breach of the standard of care required for their state-law claim.

Plaintiffs are also not challenging the federal oversight or original approval of the G5. As shown above, Plaintiffs' action against Dexcom is for creating, manufacturing, marketing, distributing, and failing to warn about an allegedly defective and unreasonably dangerous device in violation of the Tennessee Product Liability Act, *not* for violating federal law. Federal regulations and requirements are part of the context for determining whether Dexcom breached the standard of care. Their alleged violation, however, is not the gravamen of any of Plaintiffs' causes of action, even if it may be part of the proof.

Moreover, the federal issues here are not "substantial." In *Gunn v. Minton*, 568 U.S. 251 (2013), the Supreme Court clarified the substantiality inquiry to require that the disputed federal issue be significant to the federal system as a whole and not just to the particular lawsuit or parties at issue. *Id.* at 260; *Schilmiller v. Medtronic, Inc.*, 44 F. Supp. 3d 721, 730 (W.D. Ky. 2014). In the earlier case of *Grable & Sons Metal Products, Inc. v. Darue Engineering & Mfg*, 545 U.S. 308 (2005), a taxation case, the Court focused on the broader significance of the interests of the federal

[18] Federal law requires that any action to enforce or to restrain violations of the FDCA must be brought by and in the name of the United States. 21 U.S.C. § 337(a). Thus, there is no private right of action.

government in recovering delinquent taxes through the seizure and sale of property. *Schilmiller* at 730. On the other hand, in *Gunn*, the Court held that resolution of a patent issue in the context of a legal malpractice action under state law, although vitally important to the parties, did not include a federal issue that was significant to the federal system as a whole and thus did not support federal-question jurisdiction. *Id*.

Plaintiff's claims against Dexcom are state-law claims. Whether Dexcom complied with federal law is *not* the "necessary" or "central" issue Dexcom characterizes it to be. Again, the common questions of law and fact are whether the G5 was defective and unreasonably dangerous and whether the G5 was the proximate cause of Spence's death. Dexcom's potential defense of compliance with federal law is not sufficient to create federal question jurisdiction. *Merrell Dow*, 478 U.S. at 808; *Arrington*, 130 F. Supp. 3d at 1158. And the Court finds that, as in *Gunn* and *Schilmiller*, the federal issues in dispute in this case fail to meet the substantiality requirement. They are important to these particular litigants, but they are not significant to the federal system as a whole.

Similarly, Dexcom's argument that the MDA pre-empts Plaintiffs' claims against it does not create federal question jurisdiction. The "well-pleaded complaint rule" provides that federal jurisdiction exists only when a federal question is presented on the face of a plaintiff's properly pleaded complaint. *Schilmiller*, 44 F. Supp. 3d at 728. Thus, a case may not be removed to federal court on the basis of a federal defense, even if the defense is anticipated in the plaintiff's complaint. *Id*.; *Merrell Dow*, 478 U.S. at 808 (defense that raises federal question is inadequate to confer federal jurisdiction). Dexcom's defense that the MDA pre-empts Plaintiffs' claims, even if it is a

valid defense, which the Court does not find, is not a basis, under these circumstances, for federal jurisdiction.[19]

The Court finds that it has no federal question jurisdiction in this matter.

CONCLUSION

For all these reasons, Dexcom's Motion to Sever will be denied, Plaintiffs' Motion to Remand will be granted, and this case will be remanded to state court for further proceedings. Defendants' Motions to Dismiss will be denied without prejudice. An appropriate Order will enter.

IT IS SO ORDERED.

Eli Richardson

ELI RICHARDSON
UNITED STATES DISTRICT JUDGE

[19] The Court is aware that the Sixth Circuit recognizes "complete preemption" as an exception to the well-pleaded complaint rule. *Schilmiller*, 44 F. Supp. 3d at 728. In this case, however, even if there were some limited preemption, federal law does not "completely" preempt Plaintiff's product liability and negligence claims.