IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

KATHLEEN HAFER, et al.,	)	
Plaintiffs,	)	
v.	)	Case Nos. 2:13-cv-02340-JTF-dkv
	)	2:13-cv-02341-JTF-dkv
MEDTRONIC, INC., and MEDTRONIC SOFAMOR DANEK USA, INC.,	)	2:13-cv-02342-JTF-cgc
	)	2:13-cv-02343-JTF-dkv
	)	2:13-cv-02344-JTF-tmp
Defendants	)	2:13-cv-02345-JTF-dkv
	)	2:13-cv-02346-JTF-cgc
	)	2:13-cv-02347-JTF-tmp
	)	2:13-cv-02348-JTF-dkv
	)	2:13-cv-02349-JTF-tmp
	)	2:13-cv-02350-JTF-dkv
	)	2:13-cv-02351-JTF-tmp
	)	2:13-cv-02433-JTF-dkv
	)	2:13-cv-02488-JTF-dkv
	)	2:13-cv-02644-JTF-dkv
	)	2:13-cv-02645-JTF-cgc
	)	2:13-cv-02699-JTF-tmp
	)	2:13-cv-02706-JTF-dkv
	)	2:13-cv-02709-JTF-dkv
	)	2:13-cv-02783-JTF-tmp
	)	2:13-cv-02861-JTF-cgc
	)	2:13-cv-02862-JTF-cgc
	)	2:13-cv-02864-JTF-cgc
	)	2:13-cv-02865-JTF-cgc
	)	2:13-cv-02866-JTF-cgc
	)	2:13-cv-02868-JTF-cgc
	)	2:13-cv-02869-JTF-cgc
	)	2:13-cv-02870-JTF-cgc
	)	2:13-cv-02871-JTF-cgc
	)	2:13-cv-02872-JTF-cgc
	)	2:13-cv-02873-JTF-cgc
	)	2:13-cv-02883-JTF-cgc
	)	2:13-cv-02985-JTF-cgc
	)	2:14-cv-02196-JTF-cgc
	)	2:14-cv-02212-JTF-cgc
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ORDER GRANTING DEFENDANTS' MOTION TO DISMISS

Before the Court comes Defendants' Motion to Dismiss the Master Complaint filed on May 30, 2014. (ECF No. 56).[1] On June 30, 2014, Plaintiffs Kathleen Hafer, et al., filed their Response in Opposition to Defendants' Motion to Dismiss. (ECF No. 57). Defendants filed a Reply in Support of their Motion to Dismiss on July 21, 2014. (ECF No. 59). To this date, Plaintiffs have filed several supplemental authorities in opposition to Defendants' Motion to Dismiss. (ECF Nos. 61; 80-81). Additionally, Defendants have filed several supplemental authorities in support of their Motion to Dismiss. (ECF Nos. 62; 66-67; 72-77; 83).

On August 13, 2014, oral arguments were held before this Court on Defendants' Motion to Dismiss. (ECF. No. 68). The Court allowed the parties to file additional briefs in support of their positions by August 20, 2014. On August 20, 2014, both parties filed their Post-Hearing Supplemental Memoranda in support of their positions. (Pls.' Post-Hearing Suppl. Memo., ECF No. 70; Defs.' Post-Hearing Brief, ECF No. 71). After reviewing the Motion, Responses, oral

[1] Because of the volume of the cases, this Court will look to the first filed case, *Hafer v. Medtronic, Inc.*, 2:13-cv-02340-JTF-dkv, for guidance as to docket entry numbers, dates, and filings for the purposes of this Order. As such, all reference to the ECF No.'s will refer to *Hafer v. Medtronic, Inc.*, 2:13-cv-02340-JTF-dkv, unless otherwise indicated. The Court notes that some of the filing dates are different for each case. However, the differences in the filing dates have no bearing on the substantive issues of this case.

arguments by the parties, and supplemental briefings, the Court GRANTS Defendants' Motion to Dismiss with leave given to Plaintiffs to amend certain deficiencies.

I. PROCEDURAL AND FACTUAL BACKGROUND

A. Procedural History of Medtronic Cases

Between May 24, 2013 and January 21, 2015, the Defendants have removed several cases from the Circuit Court of Tennessee for the Thirtieth Judicial District at Memphis, Shelby County ("Circuit Court") to the United States District Court for the Western District of Tennessee.[2] Subsequently, Plaintiffs have filed individual Motions to Remand, arguing that their claims would be more appropriately adjudicated in state court rather than federal court. To this date, the Court has denied Plaintiffs' Motions to Remand.

On April 2, 2014, the Court held a Scheduling Conference to coordinate the pending Medtronic cases. (ECF No. 45). Plaintiffs were directed to file a Master Complaint and Defendants were directed to file a Response to the Master Complaint. On April 28, 2014, a Master Complaint, encompassing all current and future Medtronic cases, was filed before this Court. (Master Compl., *Mobley v. Medtronic, Inc.*, 2:13-cv-02985-JTF-cgc, ECF No. 37). On May 1, 2014, Plaintiffs filed an Amended Master Complaint, which states that "[a]llegations pled herein are deemed pled in any previously-filed case pending in this Court, and in all future related cases adopting this Master Complaint,[3] and Plaintiff-specific allegations in individual Complaints already filed of record are incorporated herein by reference." (ECF No. 52-1 at 2). Plaintiffs' claims are based upon their allegations that Defendants improperly and illegally

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[2] At the time of the filing of this Order, this Court has a total of 141 pending Medtronic cases with plaintiffs from more than thirty states.

[3] As shown by the caption of Plaintiff's Notice of Supplemental Authority of January 15, 2015, (ECF No. 80), Plaintiffs have all adopted the Master Complaint.

promoted and sold the Infuse® Bone Graft/LT-Cage® Lumbar Tampered Fusion Device ("Infuse®") in an off-label manner, which caused numerous harmful and painful effects on Plaintiffs. In order to lay a proper foundation for the analysis of Plaintiffs' claims, the Court finds it necessary to give a history of the Infuse® device and expound upon Plaintiffs' claims.

B. Background on Medical Device Classification and the PMA Process

Prior to the enactment of the Medical Device Amendments of 1976 ("MDA") to the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"), states individually were left to regulate medical devices. *Perez v. Nidek Co.*, 711 F.3d 1109, 1117 (9th Cir. 2013). Now, Congress has "swept back some state obligations and imposed a regime of detailed federal oversight." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). A medical device must go through a "'rigorous process'", in which the "manufacturer must submit detailed studies and investigations of the device's safety and effectiveness, and a full description of the device's components and how it may be used." *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1173 (C.D. Cal. 2013) (citing *Riegel*, 552 U.S. at 316-18).

The MDA imposes this oversight and regulates state obligations on medical devices by classifying devices into three categories. *See* 21 U.S.C. § 360c. Class I devices are subject to the lowest oversight under 21 U.S.C. § 360c(1)(A); Class II devices are subject to special controls under 21 U.S.C. § 360c(1)(B), such as the § 510(k) process of 21 U.S.C. § 360(k); and Class III devices are subject to the premarket approval and the highest federal oversight under 21 U.S.C. § 360c(1)(C). Class III medical devices are classified as such because,

> (i) [I]t (I) cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and (II) cannot be classified as a class II device because insufficient information exists to determine that the special controls described

> in [21 U.S.C. § 360c(1)(B)] would provide reasonable assurance of its safety and effectiveness, and
>
> (ii) (I) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial important in preventing impairment of human health, or (II) presents a potential unreasonable risk of illness or injury, is to be subject, in accordance with section 515 [21 U.S.C. § 360e], to premarket approval to provide reasonable assurance of its safety and effectiveness.

21 U.S.C. § 360c(1)(C).

Class III medical devices that are "substantially equivalent" to Class III devices previously introduced into the market may not undergo the PMA review. Instead, these "substantially equivalent" Class III devices and all new Class I and Class II devices are subject to the less rigorous § 510(k) process, pursuant to 21 U.S.C. § 360(k). *See Medtronic, Inc. v. Lohr,* 518 U.S. 470, 478-79 (1996). The § 510(k) process is how the majority of new devices, specifically Class III devices, enter the market.[4] *See Riegel*, 552 U.S. at 317. Unlike the PMA process, which requires nearly 1,200 hours for review of an application, "the § 510(k) review is completed in an average of only 20 hours" and is "by no means comparable to the PMA process." *Lohr*, 518 U.S. at 478-79. Under the PMA process, a Class III medical device will only enter the market once the FDA has reviewed the design, labeling, and manufacturing specifications of the device.

"The premarket approval process includes review of the device's proposed labeling. "The FDA evaluates safety and effectiveness under the conditions of use set forth on the label, § 360c(a)(2)(B), and must determine that the proposed labeling is neither false nor misleading, §

[4] As the Supreme Court explained in *Riegel*, "[i]n 2005, for example, the FDA authorized the marketing of 3,148 devices under § 510(k) and granted premarket approval to just 32 devices." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008).

360e(d)(1)(A)." *Riegel,* 552 U.S. at 318. The FDA determines the safety and effectiveness of the device,

> (A) with respect to the persons for whose 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). The FDA may "approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives." *Riegel,* 552 U.S. at 318. Once it has completed its review and grants PMA approval, the FDA "may also condition approval on adherence to performance standards, 21 CFR § 861.1(b)(3), restrictions upon sale or distribution, or compliance with other requirements, § 814.82. "The agency is also free to impose device-specific restrictions by regulation. § 360j(e)(1)." *Id.* at 319. Additionally, as an explicit condition of premarket approval,

> [o]nce a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety and effectiveness. § 360e(d)(6)(A)(i). If the applicant wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial application. § 360e(d)(6); 21 CFR § 814.39(c).

Id.; *see also Kemp v. Medtronic, Inc.*, 231 F.3d 216, 235 (6th Cir. 2000) (citing 21 C.F.R. § 814-39). Even after premarket approval, manufactures are required to submit detailed post-PMA reports for the FDA's continuous oversight of the device. *See* 21 U.S.C. § 360i. Under these reporting requirements, the manufacturer of the Class III, PMA device is obligated to:

> inform the FDA of new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know of, 21 CFR § 814.84(b)(2), and to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if recurred, § 803.50(a).

Id. Moreover, Congress granted the FDA "complete discretion" in enforcement of these provisions. *Heckler v. Chaney*, 470 U.S. 821, 835 (1985). Such discretion is necessary "to achieve a somewhat delicate balance of statutory objectives." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001).[5]

C. The History of the Infuse® Device

On July 2, 2002, the FDA conferred Premarket Approval ("PMA") to the Infuse® as a Class III medical device. (ECF No. 52-1 at 6). The purpose of the Infuse® is to create new bone tissue to alleviate spinal pain via an anterior surgical approach or anterior laparoscopic approach. (ECF No. 52-2 at 2). The device is to be used in spinal fusion procedures in patients that suffer from degenerative disc disease at the L_4-S_1 levels of the spine. *See* (ECF Nos. 52-1 at 7; 52-2 at 2). The Infuse® is comprised of two components consisting of three parts: (1) a bone graft substitute known as Bone Morphogenetic Protein ("BMP"), (2) a sponge-like carrier or scaffold, and (3) the LT-Cage carrier for the bone morphogenetic protein. (ECF No. 56 at 9 n.2). As further described in the Important Medical Information ("IMI") for the Infuse®,

> [t]he InFUSE™ Bone Graft component is inserted into the LT-CAGE™ Lumbar Tapered Fusion Device component to form the complete InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device. **These components must be used as a system. The InFUSE™ Bone Graft component must not be used without the LT-CAGE™ Lumbar Tapered Fusion Device Component.**

(ECF No. 57-4 at 2). The IMI further details "Warnings" and "Potential Adverse Effects" for the Infuse®. Specifically, the "Warnings" in the IMI state that,

> [t]he safety and effectiveness of the InFUSE Bone Graft component with other spinal implants, implanted at locations other than the lower lumbar spine, or used in surgical techniques other than open anterior or anterior laparoscopic approaches have not been established. When degenerative disc disease was

[5] *See infra* Part III.A.

> treated by a posterior lumbar interbody fusion procedure with cylindrical threaded cages, posterior bone formation was observed in some instances.

(ECF No. 57-4 at 5). Lastly, the IMI outlines the various "Potential Adverse Events" that can occur because of the Infuse®, such as bone fracture, cessation of any potential growth of the operated portion of the spine or loss of spinal function, ectopic and/or exuberant bone formation, infection, neurological system compromise, tissue or nerve damage, scar formation, or retrograde ejaculation. (ECF No. 57-4 at 10-11).

D. Plaintiffs' Claims

Between 2002 and 2013, the various Plaintiffs named in this lawsuit underwent spinal fusion procedures for various back issues. (ECF No. 52-1 at 3). Plaintiffs state that Plaintiffs were implanted with a debased version of the Infuse® device by, *inter alia*, substitution of the cage component, implantation at unapproved levels of the spine, or utilization of a posterior approach. *Id.* at 11-12. Specifically, Plaintiffs allege that, "[a]lthough the FDA approved as safe and effective the use of the BMP/Sponge together with the LT-Cage™ in anterior approach (from the front) surgeries, ***none*** of the Plaintiffs' surgeons used the LT-Cage™ in their surgery and the surgeries were ***not*** from an anterior approach." *Id.* at 8. Instead of utilizing the LT-Cage® component, Plaintiffs allege that the fusion cages used in their surgeries were Class II medical devices not subject to the same PMA process. *Id.* at 17, 19 ("In all but two cases, P[laintiffs'] Cages had been approved for marketing by the FDA via a 510(k) procedure, which allowed for approval merely by showing that the cage was 'substantially equivalent' to other products like it, already on the market. . . . P[laintiffs'] Cages, in contrast to the LT-Cage™ approved as part of the Infuse® device, are differently designed, are for different surgical approaches, and are made of different materials. Different regulatory approvals from the FDA apply to the use of the LT-Cage™ versus P[laintiffs'] Cages"). Plaintiffs allege they have

suffered "additional, new and/or in some cases worse pain, suffering, symptoms and disability" such as ectopic bone growth, impingement on the nerve roots and the spinal cord, radiculitis, osteolysis, and cage migration. *Id.* at 20.

Plaintiffs allege that such "off-label" use was initiated by Defendants' systematic corruption of medical literature, medical conferences, sales representatives, and "consulting with peers in the spine surgery community . . . . either through explicit misrepresentations of fact or through the withholding of information . . . ." *Id.* at 14. Furthermore, Plaintiffs allege that when Defendants promoted the Infuse® as components and not as a single entity, they created a new device, unapproved by the FDA. *Id.* at 11-12 ("The separate components and parts of the Infuse® are not Infuse®. The Infuse® PMA requirements do not attach to these components when used separately, because these components, when used separately, are a different and distinct biologic, and different and distinct devices").

Due to Defendants' alleged illegal, off-label promotion of the Infuse® device, Plaintiffs pursue seven causes of action: (1) fraudulent concealment, misrepresentation and fraud; (2) failure to warn; (3) strict products liability—design defect; (4) negligent misrepresentation; (5) product liability—negligence; (6) breach of express warranty; and (7) breach of implied warranty. *Id.* at 173-85.

E. Defendants' Motion to Dismiss

Defendants argue three major contentions for why Plaintiffs' Amended Master Complaint should be dismissed: (1) Plaintiffs' claims are expressly preempted by 21 U.S.C. § 360k(a); (2) Plaintiffs' claims for violations of FDA regulations are impliedly preempted and barred by 21 U.S.C. § 337(a); and (3) Plaintiffs' claims each have independent grounds for dismissal. (ECF

No. 56). Defendants specifically contend that Plaintiffs' claims are either inadequately pled, untimely, or otherwise legally deficient. *Id.*

However, Plaintiffs primarily argue that a manufacturer cannot protect itself under the guise of preemption while, at the same time, allegedly violating the central tenants of the FDA and FDCA regulations. Therefore, Plaintiffs argue that: (1) preemption does not apply to Class II cages; (2) preemption does not apply to a single component of an FDA "device"; (3) preemption does not apply when the Defendant violates federal law; (4) the Court should adhere to the judicial presumption against preemption; (5) Plaintiffs' state-law claims are "parallel" allowing them to survive preemption under 21 U.S.C. § 360k(a); (6) Plaintiffs' state-law claims have a basis independent of federal law allowing them to survive preemption under 21 U.S.C. § 337(a); and (7) Plaintiffs' claims survive all other independent grounds for dismissal. (ECF No. 57). Defendants' Reply, (ECF No. 59), primarily reiterates the arguments found within Defendants' original motion. Additionally, Defendants contend that 21 U.S.C. 360k(a) applies to devices and not intended uses of the devices. *Id.* at 9-13. Moreover, Defendants contend that allegations of Defendants' violations of the FDCA does not affect preemption. *Id.* at 14-15.

The arguments of counsel at the hearing of August 13, 2014, and the supplemental filings echo and expand upon the foregoing contentions of the parties. *See* (ECF Nos. 68, 70-71).

II. LEGAL STANDARD

Fed. R. Civ. P. 12(b)(6) provides for dismissal of a complaint that "fail[s] to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). This allows the "defendant to test whether, as a matter of law, the plaintiff is entitled to legal relief even if *everything alleged* in the complaint is true." *Mayer v. Mylod*, 988 F.2d 635, 638 (6th Cir. 1993) (emphasis added) (citing *Nishiyama v. Dickson Cnty.*, 814 F.2d 277, 279 (6th Cir. 1987)).

When evaluating a motion to dismiss under Fed. R. 12(b)(6), the Court must determine whether the complaint alleges "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)); *see also Keys v. Humana, Inc.,* 684 F.3d 605, 608 (6th Cir. 2012) (The court must "construe the complaint in the light most favorable to the plaintiff and accept all allegations as true." (citing *Harbin-Bey v. Rutter*, 420 F.3d 571, 575 (6th Cir. 2005))). The "[f]actual allegations must be enough to raise a right to relief above [a] speculative level." *Ass'n of Cleveland Fire Fighters v. City of Cleveland*, 502 F.3d 545, 548 (6th Cir. 2007) (first alteration in original) (quoting *Twombly*, 550 U.S. at 555). A claim is plausible on its face if "the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 556). Although the complaint need not contain detailed factual allegations, a plaintiff's "[]bare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* (citing *Twombly*, 550 U.S. at 555) ("[T]he tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions."). "[D]etermining whether a complaint states a plausible claim is context-specific, requiring the . . . court to draw on its experience and common sense." *Id.* at 663-64 (citing *Twombly*, 550 U.S. at 556). When undertaking a motion to dismiss, pursuant to Fed. R. Civ. P. 12(b)(6), the Court may look to "'matters of public record, orders, items appearing in the record of the case, and exhibits attached to the complaint'" for guidance. *Barany-Synder v. Weiner,* 539 F.3d 327, 332 (6th Cir. 2008) (quoting *Amini v. Oberlin Coll.*, 259 F.3d 493, 502 (6th Cir. 2001))).

In the context of MDA preemption—as is the issue in this case—"a plausible cause of action requires, among other things, a showing that the alleged violation of state law parallels a violation of federal law." *White v. Stryker Corp.*, 818 F. Supp. 2d 1032, 1037 (W.D. Ky. 2011). If the complaint merely pleads facts that are parallel to the defendant's liability, then the complaint "stops short of the line between possibility and plausibility of 'entitlement to relief.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 557).

III. ANALYSIS

Based upon the above regulations, statutes, and arguments from both parties, this Court must determine whether Plaintiffs' seven causes of action must be preempted and/or barred, pursuant to: (1) 21 U.S.C. § 360k(a), (2) 21 U.S.C. § 337(a); or (3) independent grounds, such as untimely filing, insufficient pleading, or legal deficiency. For the foregoing reasons, this Court finds that Plaintiffs' claim for: (1) fraudulent concealment, misrepresentation, and fraud is not preempted; (2) failure to warn is preempted; (3) strict products liability—design defect is preempted; (4) negligent misrepresentation is not preempted; (5) product liability—negligence is preempted; (6) breach of express warranty is not entirely preempted; and (7) breach of implied warranty is preempted.

A. Preemption Generally

i. Express Preemption

The MDA includes the following express preemption provision:

> 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 and 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); *see also* 21 C.F.R. § 808.1(d). *Reigel* provides this Court with a two-step analysis for determining whether state law claims are preempted. *Riegel*, 552 U.S. at 321-23.

First, this Court must consider whether the FDA imposes federal "requirements" on the device. *Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206, 1213 (W.D. Okla. 2013) (citing *Riegel*, 552 U.S. at 321-23). Specifically, *Riegel* states that,

> [p]remarket approval, in contrast [to the § 510k process] imposes "requirements" under the MDA as we interpreted it in *Lohr*. Unlike general labeling duties, premarket approval is specific to individual devices. And it is in no sense an exemption from federal safety review—it *is* federal safety review. . . . While § 510k is "focused on equivalence, not safety." . . . premarket approval is focused on safety, not equivalence.

Riegel, 552 U.S. at 322-23 (emphasis in original); *Brady v. Medtronic, Inc.*, No. 13-cv-62199-RNS, 2014 U.S. Dist. LEXIS 52151, at *10 (S.D. Fla. April 8, 2014); *Ledet v. Medtronic, Inc.*, No. 1:13CV200-LG-JMR, 2013 U.S. Dist. LEXIS 182448, at *8 (S.D. Miss. Dec. 30, 2013) ("Devices that have received premarket approval automatically satisfy the federal requirement prong of [the] preemption analysis." (citing *Bass v. Stryker Corp.*, 669 F.3d 501, 507 (5th Cir. 2012))). *But see Lohr*, 518 U.S. 470 (finding that the 510k process did not impose federal requirements on a device).

Second, the Court must consider whether the state law claims impose any requirements "different from, or in addition to" the federal requirements. *Caplinger*, 921 F. Supp. 2d at 1213 (citing *Riegel*, 552 U.S. at 322-23). "State law tort duties . . . impose 'requirements' applicable to the device." *Hawkins v. Medtronic, Inc.*, No. 1:13-CV-00499 AWI SKI, 2014 U.S. Dist. LEXIS 11779, at *8-9 (E.D. Cal. Jan. 30, 2014) (citing *Riegel*, 552 U.S. at 323-24); *see also Houston*, 957 F. Supp. 2d at 1174 ("'State tort law . . . disrupts the federal scheme no less than state regulatory law to the same effect.'" (quoting *Riegel*, 552 U.S. at 324-25)). If the state law claim merely parallels federal requirements, express preemption does not apply. *Riegel*, 552

U.S. at 330; *see also Lohr*, 518 U.S. at 495 ("[N]othing in § 360k denies [the states] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements."). "State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law." *Houston*, 957 F. Supp. 2d at 1174 (citing *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1300 (11th Cir. 2011); *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005)).

As such, "without the FDA's central oversight, juries would 'apply the tort law of 50 States to all innovations.'" *Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 693, 699 (S.D. Tex. 2014) (quoting *Riegel*, 552 U.S. at 326). Congress determined that those injured by FDA-approved devices were outweighed by "those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations." *Riegel*, 552 U.S. at 326; *see generally Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013).

> The Supreme Court acknowledged that "[t]he dissent would narrow the pre-emptive scope . . . on the grounds that it is 'difficult to believe that Congress would, without comment, remove all means of judicial recourse' for consumers injured by FDA-approved devices. But, as we have explained, this is exactly what a pre-emption clause for medical devices does by its terms."

Scanlon v. Medtronic Sofamor Danek USA Inc., No. 13-224-SLR, 2014 U.S. Dist. LEXIS 102387, at *12-13 (D. Del. July 28, 2014) (quoting *Riegel*, 552 U.S. at 326); *see also Riegel*, 552 U.S. at 325 ("A jury . . . sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.").

ii. Implied Preemption

The FDCA states that an action for "enforcement, or to restrain violations, of th[e] [FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a). The Supreme Court found "clear evidence that Congress intended that the MDA be enforced exclusively by the

Federal Government." *Buckman*, 531 U.S. at 352. [A]lthough [*Lohr*] can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim." *Id.* at 353. A plaintiff cannot bring a state-law claim that is in substance a claim to enforce the FDCA. *See Caplinger*, 921 F. Supp. 2d at 1214.

Any claim based solely on off-label promotion would thereby be impliedly preempted. *See id.* at 1219-20, 1224 ("[E]ven the concept of 'off-label use' is a creature of the FDCA, is defined by the FDCA, and is not a part of [state] substantive law."); *Blankenship v. Medtronic, Inc.*, 6 F. Supp. 3d 979 at 990 (E.D. Mich. 2014) ("[T]he very concept of 'off-label' use and promotion is derived from the regulatory system imposed by the MDA and the FDCA." (quoting *Gavin v. Medtronic, Inc.*, No. 12-cv-0851, 2013 U.S. Dist. LEXIS 101216, at *54-55 (E.D. La. July 19, 2013))); *Hawkins*, 2014 U.S. Dist. LEXIS, at *51 ("Off-label promotion itself exists only as a creation of the FDCA scheme."); *Montana ex rel. McGrath v. Eli Lilly & Co.*, No. 07-CV-1933 (JBW), 2008 U.S. Dist. LEXIS 10355, at *14 (E.D.N.Y. Feb. 12, 2008) ("[T]here is no state-law equivalent of 'off-label." The concept is entirely federal.").

> The statute's public enforcement mechanism is thwarted if savvy plaintiffs can label [their claim] as arising under a state law . . . . therefore, private litigants may not "bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA."

Loreto v. Proctor & Gamble Co., 515 F. App'x 576, 579 (6th Cir. 2013) (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 779 (D. Minn. 2009)); *see also Buckman*, 531 U.S. at 352-53.

As such, "a narrow gap" is created by *Riegel* and *Buckman*. *Sprint Fidelis Leads Prods. Liab. Litig. v. Medtronic, Inc.*, 623 F.3d 1200, 1204 (8th Cir. 2010); *see also Perez*, 711 F.3d at 1120. "The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct

violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *Sprint*, 623 F.3d at 1204 (citing *Riley*, 625 F. Supp. 2d at 777).

iii. Allegations of Off-Label Promotion does not Shield Against Preemption[6]

Under 21 U.S.C. § 360k(a)(1), "the question is not whether there are federal requirements applicable to a particular *use* of a device; the question is whether there are federal requirements applicable 'to the device.'" *Caplinger*, 921 F. Supp. 2d at 1218 (emphasis in original) ("Nothing in the statute suggests that the preemption analysis somehow depends on how the device is used." (citing *Riley*, 625 F. Supp. 2d at 779)); *see also Brady*, 2014 U.S. Dist. LEXIS 52151, at *13-14 ("There is nothing in [§ 360k(a)] that suggests that the applicability of the preemption analysis turns on either how the device was used or marketed, or on the conduct of the manufacturer." (citing *Gavin*, 2013 U.S. Dist. LEXIS 101216, at *34)). As such, if there are requirements applicable to the device, off-label use/promotion will not remove federal preemption. *See Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 29 (1st Cir. 1995) ("We find nothing to indicate that preemption is conditional upon satisfactory compliance with the federal standard.").

The use of medical devices in an off-label manner "is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." *Buckman*, 531 U.S. at 350 ("'[N]othing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practioner-patient relationship.'" (quoting 21 U.S.C. § 396)).

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[6] This Court finds the reasoning within *Bausch v. Stryker Corp.*, 630 F.3d 546, 550 (7th Cir. 2010), unpersuasive. Primarily, the Court takes issue with the idea that a violation of federal law removes preemption concerns. Specifically, the Court finds this inconsistent with 21 U.S.C. § 337(a)'s grant of exclusive authority in the United States to enforce the FDCA. This Court is constrained by the plain language of the pertinent statutes.

B. Whether There are Device Specific Requirements

Before the Court can properly determine whether the PMA places federal requirements upon the device, the Court must first determine what the device is. 21 U.S.C. § 321(h) defines device as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, *including any component*, part, or accessory . . . ." 21 U.S.C. § 321(h) (emphasis added). The BMP/Sponge is a component of the premarket approved Infuse® device. *See* (ECF No. 56 at 9 n.2). "The component parts of a device are subject to federal safety review through the premarket approval process." *Hawkins*, 2014 U.S. Dist. LEXIS 11779, at *14 (citing 21 U.S.C. § 360e(c)); *see also Smith v. Depuy Orthopaedics, Inc.*, 552 F. App'x 192, 196 (3d Cir. 2014) (finding that the "components were also subject to PMA preemption"); *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 487 (W.D. Pa. 2012) ("[A] device receiving premarket approval cannot be separated into its component parts to avoid application of express preemption."). The component was designed and sold in accordance with the PMA. (ECF No. 57-4 at 2) ("The LT-Cage™ Lumbar Tapered Fusion Device Component is sold separately from the InFUSE™ Bone Graft Component . . . ."). As such, the Court finds that the PMA does impose federal requirements upon the BMP/Sponge. *See Riegel*, 552 U.S. at 322-23; *Houston*, 957 F. Supp. 2d at 1176. The Court will not go as far as to say that every component under a PMA is automatically covered, but where, as in here, it is the primary component that received the majority of the FDA's attention and balancing of interests, the Court finds no issue with finding it subject to the PMA. *See* (ECF No. 52-4 at 132-480) (FDA hearing focusing almost exclusively on BMP research and considering for labeling purposes, *inter alia*, off-label use and selling Infuse® as a package).

Further, the Court finds the gravamen of Plaintiffs' claims is against the "off-label" use of the BMP/Sponge. As shown by Plaintiffs' Master Complaint, some of the Plaintiffs did not even claim the use of a Class II Cage. (ECF No. 52-1 at 19 n.2). Nor were the Class II Cages solely manufactured by Defendants. (ECF No. 52-3 at 14). Additionally, the Amended Master Complaint does not refer to a specific misrepresentation as to any specific Class II Cage for this Court to consider the Class II Cage as a primary focus of Plaintiffs' injuries. *See generally* (ECF No. 52). Moreover, preemption is not defined by a single component of a unit used, but by the unit as a whole. *See Gross*, 858 F. Supp. 2d at 487 ("[A] device receiving premarket approval cannot be separated into its component parts to avoid application of express preemption."); *see also Bertini v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 246, 254 (E.D.N.Y. 2014) (applying the preemption analysis to the whole unit unless the component "alone proximately caused plaintiffs' injuries"); *Eidson v. Medtronic, Inc.*, 981 F. Supp. 2d 868, 881 n.3 (N.D. Cal. 2013) ("[T]he preemption analysis should not be applied differently to the component parts of a medical device and the medical device that received PMA.").

C. Whether the State Law Claims Impose Requirements "Different from, or in Addition to" Federal Requirements

i. *Claim One- Fraudulent Concealment, Misrepresentation, and Fraud is not Expressly nor Impliedly Preempted*

Plaintiffs' first claim for relief involves Defendants' fraudulent concealment, misrepresentation and fraud. (ECF No. 52-1 at 173-77). Primarily, Plaintiffs assert that Defendants had an affirmative duty to warn/disclose and that Defendants, to the contrary, fraudulently and intentionally misrepresented and/or fraudulently concealed important material. *Id.* at 173-77. To the extent that Plaintiffs claim that such misrepresentations were contained within the FDA-approved label, the Court finds such claim preempted under 21 U.S.C. §

360k(a). *Caplinger*, 921 F. Supp. 2d at 1219; *see also Ledet*, 2013 U.S. Dist. LEXIS 182448, at *11-12. Such claim would not only provide requirements "different from, or in addition to" but would directly contradict the safety analysis of the FDA. *Brady*, 2014 U.S. Dist. LEXIS 52151, at *20. Further, any claim premised on a "fraud-on-the-FDA" in production of the label is clearly preempted by *Buckman*.

Plaintiffs' claims regarding alleged misrepresentations of Defendants during promoting and marketing of the Infuse® device, however, do not provide requirements "different from, or in addition to" federal requirements, and thus avoids express preemption. *Brady*, 2014 U.S. Dist. LEXIS 52151, at *20; *see also Schouest*, 13 F. Supp. 3d at 704 ("[S]tate fraud-based claims 'are parallel or genuinely equivalent to federal law.'" (quoting *Houston*, 957 F. Supp. 2d at 1179-80)). Additionally, Plaintiffs' claim is independently supported by traditional state laws against false and misleading advertising, thereby avoiding implied preemption. *Brady*, 2014 U.S. Dist. LEXIS 52151, at *21 (citing *Eidson*, 981 F. Supp. at 885).

However, although Plaintiffs avoid preemption as to affirmative misrepresentations made during marketing of the Infuse® device, Plaintiffs fail to allege fraud with the particularity required by Fed. R. Civ. P. 9(b). *See Perez*, 711 F.3d at 1118-19 ("[F]raud by omission . . . is expressly preempted under the FDCA."). Specifically, Plaintiffs have failed to state with particularity which misrepresentations that the Plaintiffs (or their doctors) relied upon.[7] *See, e.g.*, *Sanderson v. HCA- The Healthcare Co.*, 447 F.3d 873, 877 (6th Cir. 2006) ("Rule 9(b) requires that a plaintiff allege[] the time, place, and content of the alleged misrepresentation on which he

[7] When referenced during the hearing of August 13, 2014, Plaintiffs' counsel stated that he "can't get into a doctor's office, [they don't] want to talk to [hi]m[]." (Transcript for ECF No. 68 at 49) "Now am I going to be able to say that Dr. X read this article, that's what they want me to say here. No, of course not." *Id.* at 51. In the case of fraud, such information is readily in the hand of Plaintiffs, as Plaintiffs should be aware of what representations they relied upon.

or she relied . . . ."); *Murphy v. Sofamor Danek Grp.*, 123 F.3d 394, 403-04 (6th Cir. 1997) (applying Tennessee law found that the "fraud-on-the-market" theory is insufficient to establish the reliance requirement for fraud and required "a showing of actual reliance as a condition of recovery for common law fraud or negligent misrepresentation"); *see also Hawkins*, 2014 U.S. Dist. LEXIS 11779, at *34. Although Fed. R. Civ. P. 8 requires mere notice, Fed. R. Civ. P. 9(b) requires particular facts as to fraud and misrepresentation. *See Glassner v. R.J. Reynolds Tobacco Co.*, 223 F.3d 343, 346 (6th Cir. 2000) ("[A] complaint alleging fraud must allege with particularity those circumstances constituting fraud." (citing *VanDenBroeck v. CommonPoint Mortgage Co.*, 210 F.3d 696, 701 (6th Cir. 2000))). The Court will allow the Plaintiffs to file an amended master complaint to allege with particularity as to the individual Plaintiffs' (or their doctors') reliance.[8]

ii. *Claim Two- Failure to Warn is Expressly Preempted*

Plaintiffs allege that "Defendants had a duty to warn Plaintiffs and their physicians about the risks and benefits" of using their medical devices. (ECF No. 52-1 at 177-78). Specifically, "[t]he warnings and instructions accompanying the BMP/Sponge failed to provide the level of information that an ordinarily prudent physician or consumer would expect when using the product in such a reasonably foreseeable manner." *Id.* at 178.

[8] In *Beavers-Gabriel v. Medtronic, Inc.*, 15 F. Supp. 3d 1021, 1038 (D. Haw. 2014), the Court similarly granted leave to amend the complaint to allow Plaintiff to properly allege reliance. After Plaintiff's amendment, the Court ruled that Plaintiff's fraud and negligent misrepresentation claims were adequately alleged, but only after Plaintiff showed particularity in what the doctor relied upon. *Beavers-Gabriel v. Medtronic, Inc.*, No. 13-00686 JMS-RLP, 2015 U.S. Dist. LEXIS 2522, at *5, *19-22, *26 (D. Haw. Jan. 9, 2015) ("Plaintiff's counsel subsequently took the deposition of Dr. Graham to obtain evidence in support of an amended complaint and in particular, to determine whether Plaintiff could establish the connection between Defendant's alleged misrepresentations and omissions, and Dr. Graham's decision to use the Infuse Device in an off-label manner for Plaintiff's surgery."); *see also Houston v. Medtronic, Inc.*, No. 2:13-cv-01679-SVW-SHx, 2014 U.S. Dist. LEXIS 50613, at *23-29 (C.D. Cal. Apr. 2, 2014) (allowing plaintiff to proceed on fraud claims after specific allegations related to the doctor's reliance).

The Court finds this claim clearly preempted under 21 U.S.C. § 360k(a), as it would impose labeling requirements "different from, or in addition to" the federal requirements. *See Sprint*, 623 F.3d at 1205; *Cupek v. Medtronic, Inc.*, 405 F.3d 421, 424 (6th Cir. 2005) (citing *Kemp*, 231 F.3d at 235). The FDA-approved label clearly warns of the risks associated with use of the BMP/Sponge—both off-label and on-label—experienced by Plaintiffs.[9] *See* (ECF No. 57-4 at 10-11) (including warnings regarding bone fracture, cessation of any potential growth of the operated portion of the spine or loss of spinal function, ectopic and/or exuberant bone formation, infection, neurological system compromise, tissue or nerve damage, scar formation, or retrograde ejaculation). The only possible course of action would require the Defendants "to provide warnings above and beyond those . . . that were specifically approved by the FDA as part of the PMA process." *Caplinger*, 921 F. Supp. 2d at 1221.

Moreover, to the extent that Plaintiffs seek recourse for Defendants' failure to file adverse event reports with the FDA, the Court finds such claim impliedly preempted under *Buckman*. *See Blankenship*, 6 F. Supp. 3d at 989 ("'[T]hese claims are simply an attempt by private parties to enforce the MDA, claims foreclosed by 337(a) as construed by *Buckman*.'" (quoting *Sprint*, 623 F.3d at 1205-06)); *see also Hawkins*, 2014 U.S. Dist. LEXIS 11779, at *10-11 ("[R]eporting of adverse events directly to doctors would be preempted." (citing *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1234 (9th Cir. 2013) (Watford, J. concurring); "[A] duty to disclose lack of FDA approval for [an] off-label procedure [is] not required by [the] FDCA and [is] therefore preempted." (citing *Perez*, 711 F.3d at 1118-19)).

> For Plaintiff to prevail, a jury would have to find either that Defendants were required to include warnings beyond those in the FDA-approved label for the Infuse Device, or that Defendants were obligated to issue post-sale warning about

[9] *See generally supra* Part I.C.

> potential adverse effects of using the Infuse Device in an off-label manner. While FDA regulations *permit* Defendants to issue such post-sale warnings, those regulations do not require such warnings.

Houston, 957 F. Supp. 2d at 1177. The Court GRANTS Defendants' Motion to Dismiss on Plaintiffs' Failure to Warn Claim.

iii. Claim Three- Strict Liability Design Defect is Expressly Preempted

Plaintiffs allege that the BMP/Sponge without the LT-Cage™ "was defectively designed." (ECF No. 52-1 at 179). Such a claim is similarly expressly preempted by 21 U.S.C. § 360k(a). Plaintiffs have not properly alleged that the BMP/Sponge varied from the requirements of the PMA. *See* (ECF No. 57-4 at 2) ("The LT-Cage™ Lumbar Tapered Fusion Device Component is sold separately from the InFUSE™ Bone Graft Component . . . ."). To allow such a claim "would permit a finding that . . . the Infuse Device [is] unreasonably dangerous, even if defendants complied with all FDA regulations addressed to design," which in turn would provide requirements "different from, or in addition to" federal requirements. *Caplinger*, 921 F. Supp. 2d at 1222; *see also Schouest*, 13 F. Supp. 3d at 707 ("[A] design defect claim [is] subject to preemption because it would 'attack[] the risk/benefit analysis that led the FDA to approve an inherently dangerous Class III Device.'" (quoting *Houston*, 957 F. Supp. 2d at 1177 (citing *Bryant v. Medtronic, Inc.*, 623 F.3d 1200, 1206 (8th Cir. 2010); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 913-14 (7th Cir. 1997)))). When state tort law requires a design to "be safer, but . . . less effective" than that of the FDA-approved model, it "disrupts the federal scheme." *Riegel*, 552 U.S. at 325; *Walker v. Medtronic, Inc.*, 670 F.3d 569, 580 (4th Cir. 2012) ("A common law tort claim that presupposes a Class-III device should have been designed in a manner other than that contemplated by its premarket approval is . . . expressly preempted by the MDA as interpreted by *Riegel*."); *Gomez v. St. Judge Med. Daig*

Div., Inc., 442 F.3d 919, 930 (5th Cir. 2006) ("To permit a jury to second-guess the . . . design would risk interference with the federally-approved design standards and criteria."). A requirement that the Defendants sell the device as a package would be "different from, or in addition to" federal requirements, and such requirement would further inhibit the practice of medicine. *See generally* 21 U.S.C. § 396; see also (ECF No. 52-4 at 434-38, 472-76) (voting down packaging the Infuse® as a single unit). The Court GRANTS Defendants' Motion to Dismiss on Plaintiffs' Design Defect Claim.

iv. *Claim Four- Negligent Misrepresentation is not Expressly nor Impliedly Preempted*

Plaintiffs allege that "[i]n the course of marketing these products, the Defendants made untrue representations of material facts and/or omitted material information to Plaintiffs, their physicians, and the public at large." (ECF No. 52-1 at 181).

Similar to Claim One, a cause of action against misrepresentations made during off-label promotion survives both express and implied preemption, while claims related to the FDA-approved label remain preempted. *Hawkins*, 2014 U.S. Dist. LEXIS 11779, at *46-47. Moreover, "[l]ike fraud, allegations of negligent misrepresentation must be pled with particularity." *Republic Bank & Trust Co. v. Bear Stearns & Co.*, 683 F.3d 239, 247 (6th Cir. 2012) (internal quotation marks omitted) (applying Kentucky law). Likewise, Plaintiffs fail to state with particularity which misrepresentations that the Plaintiffs (or their doctors) relied upon. As such, the Court will allow the Plaintiffs to file an amended master complaint to allege with particularity as to the individual Plaintiffs' reliance.[10]

v. *Claim Five- Product Liability Negligence is Expressly Preempted*

[10] *See supra* Part III.C.i.

Plaintiffs allege that Defendants failed to "exercise reasonable or ordinary care under the circumstances in light of the generally recognized and prevailing scientific knowledge at the time the product was sold." (ECF No. 52-1 at 182). Without a more precise statement, it is unclear to the Court what Plaintiffs claim as Defendants' negligence. If Plaintiffs claim that Defendants were negligent in failing to warn, see *supra* Part III.C.ii. To the extent that Plaintiffs claim negligence in design, see *supra* Part III.C.iii. *See also Scovil v. Medtronic, Inc.*, 995 F. Supp. 2d 1082, 1096 (D. Ari. 2014) ("Negligence in researching, manufacturing, selling, labeling, testing, distributing, and analyzing infuse are claims preempted by federal law because they all address the safety of the device in ways that the FDA considers as part of the PMA process."); *Cooley v. Medtronic, Inc.*, No. 09-30-ART, U.S. Dist. LEXIS 55878, at *12 (E.D. Ky. Apr. 20, 2012) ("'To permit a jury to find Medtronic negligent for failing to manufacture [an approved medical device] with [a component different than what the FDA approved] would be to impose a requirement different from and in addition to those established by the FDA.'" (quoting *Kemp*, 231 F.3d at 220)). Further, the Court previously found that a claim based on negligent misrepresentation survives, but such a claim must be plead with particularity. *See supra* Part III.C.iv.

If Plaintiffs claim negligence based solely on Defendants' failure to comply with federal law or solely on illegal off-label promotion (i.e. negligence per se), Plaintiffs' claims are impliedly preempted under *Buckman*. *See Brady*, 2014 U.S. Dist. LEXIS 52151, at *21-22; *see, e.g.*, *Cupek*, 405 F.3d at 424-25; *Franklin v. Medtronic, Inc.*, No. 09-cv-02301-REB-KMT, 2010 U.S. Dist. LEXIS 71069, at * (D. Colo. May 12, 2010) ("[T]o the extent that Plaintiff seeks to ground her negligence per se and misrepresentation claims on allegations that Defendant violated the FDCA—namely, by selling a misbranded and adulterated product—these claims are

impliedly preempted pursuant to 21 U.S.C. § 337(a).”). Moreover, Plaintiffs acknowledge that they do not wish to move forward under a negligence per se theory. *See* (ECF No. 52-1 at 170) (“Plaintiffs are not asserting any cause of action for negligence per se, but instead are only asserting those state law causes of action enunciated below.”). *But see Wolicki-Gables*, 634 F.3d at 1301 (“[Plaintiffs] cannot simply incant the magic words ‘[Defendants] violated FDA regulations’ in order to avoid preemption.”). As such, any claim based on Defendants’ failure to seek a supplemental PMA would similarly fail. *See generally Marsh v. Genetech, Inc.*, 693 F.3d 546 (6th Cir. 2012); *Purchase v. Advanced Bionics, LLC*, 896 F. Supp. 2d 694 (W.D. Tenn. 2011). The Court GRANTS Defendants’ Motion to Dismiss on Plaintiffs’ Negligence Claim with leave to amend related to negligent misrepresentation.

vi. *Claim Six and Seven- Breach of Express and Implied Warranties are Expressly Preempted*

Plaintiffs allege that “Defendants utilized journal articles, advertising media, sales representatives, and paid Key Opinion Leaders to promote, encourage, and urge the use, purchase, and utilization of the BMP/Sponge and/or P[laintiffs’] Cages by representing the quality to health care professionals, Plaintiffs, and the public in such a way as to induce its purchase or use.” (ECF No. 52-1 at 183). “More specifically, [Defendants] represented that the BMP/Sponge when used with P[laintiffs’] Cages, and other surgical cages like them, or without a cage at all, was safe and effective, that it was safe and effective for use by individuals such as Plaintiffs, and/or that it was safe and effective to treat their condition.” *Id.* Further, Plaintiffs allege that “[t]he BMP/Sponge and/or P’s Cages were not reasonably fit for the ordinary purposes for which such goods are used and did not meet the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manner.” *Id.* at 184.

Although an express warranty claim might survive preemption, Plaintiffs' allegations of a breached warranty of safety and effectiveness directly contradict the FDA's analysis of safety and effectiveness. To succeed on such a claim, Plaintiffs "must persuade a jury that the Infuse Device was *not* safe and effective, a finding that would be contrary to the FDA's approval." *Caplinger*, 921 F. Supp. 2d at 1222 (emphasis added); *see Williams v. Cyberonics, Inc.*, 388 F. App'x 169, 171 (3d Cir. 2010); *Gomez*, 442 F.3d at 932; *Gavin*, 2013 U.S. Dist. LEXIS 101216, at *15-16; *see also Sprint*, 623 F.3d at 1208 ("A state common law claim is preempted if it 'actually conflicts with the federal requirement—either because compliance with both is impossible, or because the state requirement stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" (citing *Lohr*, 518 U.S. at 507 (Breyer, J. concurring))). Further, such a finding by the jury as to implied warranties "would be based on statements that Medtronic did not actually make" and thus provide a requirement "different from, or in addition to" federal requirements. *Schouest*, 13 F. Supp. 3d at 707. The Court GRANTS Defendants' Motion to Dismiss on Plaintiffs' Implied Warranty Claim and Express Warranty Claim premised on the FDA-approved label.

To the extent that Plaintiffs claim warranties voluntarily made to individual Plaintiffs, such a claim would not be preempted. *Brady*, 2014 U.S. Dist. LEXIS 52151, at *23; *see also Schouest*, 13 F. Supp. 3d at 707 ("'Federal law permits, but does not require, manufacturers like [Defendants] to make warranties, as long as those warranties are truthful and accurate.'" (quoting *Riley*, 625 F. Supp. 2d at 788)); *Houston*, 957 F. Supp. 2d at 1180-81 ("[S]eek[ing] to impose liability on Defendants for voluntarily making misleading warranties outside the label, [does not] . . . impos[e] any requirement different from or additional to what federal law already requires.").

However, Plaintiffs have failed to adequately allege that such warranties were made.[11] *See Beavers-Gabriel v. Medtronic, Inc.*, 15 F. Supp. 3d 1021, 1042-43 (D. Haw. 2014) ("[Plaintiffs] fail[] to include any facts suggesting that those representations became the 'basis of the bargain' . . . ."). Similar to Plaintiffs' fraud and misrepresentation claims, Plaintiffs have failed to allege facts "demonstrating that Defendants made any affirmations *specifically* to Plaintiff[s] or [their] physician[s] so as to form the basis of the bargain." *Houston*, 957 F. Supp. 2d 1181 (emphasis added) (applying California law); *see also Brady*, 2014 U.S. Dist. LEXIS 52151, at *23 (applying Florida law). Without such facts to provide Defendants with proper notice, Plaintiffs have failed to allege plausibility as required by Fed. R. Civ. P. 8. *See Schouest*, 13 F. Supp. 3d at 707 ("[W]hat is missing from [Plaintiffs'] complaint, in its current form, is a description of what specific warranties [Defendants] made to [Plaintiffs] or [their] physicians."). As such, the Court will allow the Plaintiffs to file an amended master complaint to allege plausible facts that demonstrate what specific "affirmations" became the "basis of the bargain."[12]

D. Statutes of Limitation/Repose

Defendants assert that many Plaintiffs are time barred. (ECF No. 56 at 50-51). With statute of limitations being an affirmative defense, this Court cannot properly consider the matter without proper briefing on the correct choice of law, relevant discovery rules, and specific facts as to each individual Plaintiff. Further, Plaintiffs' complaint alleges that equitable tolling is

[11] The Court does not find Plaintiffs' conclusory statement that "[t]he representations . . . contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises" sufficient under Fed. R. Civ. P. 8. *Id.* ("[B]are recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." (citing *Twombly*, 550 U.S. at 555)).

[12] *See, e.g.*, *supra* note 8.

applicable to this case. (ECF No. 52-1 at 159-61). The Court will therefore defer this issue until properly briefed as to each Plaintiff by Defendants within 30 days of this Order.

IV. CONCLUSION

For the reasons stated above, the Court GRANTS Defendants' Motion to Dismiss with leave to amend as to Claims One, Four, Five, and Six. Plaintiffs may file an Amended Master Complaint as to Claims One, Four, Five, and Six. Failure to file an Amended Master Complaint will result in dismissal of such claims without prejudice.

IT IS SO ORDERED this 13th day of April, 2015.

s/ John T. Fowlkes, Jr.
JOHN T. FOWLKES, JR.
United States District Judge