UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
LOUISVILLE DIVISION
CIVIL ACTION NO. 3:13-CV-01106-TBR

SHAWN WALTENBURG, *et al.* Plaintiffs

v.

ST. JUDE MEDICAL, INC., *et al.* Defendants

MEMORANDUM OPINION AND ORDER

This matter is before the Court upon Defendants St. Jude Medical, Inc., and Pacesetter, Inc.'s Motion to Dismiss. (Docket No. 13.) Plaintiffs Shawn Waltenburg and Jamie Waltenburg have responded, (Docket No. 16), and Defendants have replied, (Docket No. 19). This matter now is ripe for adjudication. For the reasons that follow, Defendants' Motion will be GRANTED IN PART and DENIED IN PART.

BACKGROUND

Implantable cardioverter defibrillators (ICDs) are life-saving devices used to detect and treat irregular heart rhythms. An ICD can correct slow heart rates, pace rapid heart rates, and administer electrical impulses to stabilize a heart and allow it to return to an appropriate rhythm. Wires called "leads" are attached to an ICD and then inserted through a major vein and attached directly to the muscle on the inside of the heart, thereby connecting the ICD to the heart. Electrodes that sense the heart's rhythm are built into the leads and are positioned where they can monitor the heartbeat. Lower voltage electrodes can provide pacing therapy to correct irregular

heart rhythms. Electrical impulses for defibrillation are provided through higher voltage conducting leads.

Plaintiff Shawn Waltenburg (Mr. Waltenburg) was implanted with a St. Jude "Riata" lead, model number 1580, on September 9, 2004. Plaintiffs claim that shortly after implantation, Mr. Waltenburg began to experience recurring unexplained episodes of defibrillator discharge in which he received electrical shocks from the defibrillator. Mr. Waltenburg states that he was advised by his physicians in October 2012 that "his Riata lead showed signs of inside-out erosion of the conductors." (Docket No. 16, at 2.) Mr. Waltenburg says his physicians continue to monitor the lead but have not recommended removal because of the serious risks associated with such a procedure. Plaintiffs allege that Mr. Waltenburg has suffered both physical and emotional injuries, including "inappropriate electrical shocks, medical treatment including diagnostic testing, compromised lead insulation, increased lead impedance, and electrical abnormalities in his Riata lead which have caused him physical pain and discomfort and ha[ve] resulted in medical treatment and hospitalization, as well as severe mental anguish." (Docket No. 16, at 3.)

Plaintiffs originally filed this action in Jefferson Circuit Court on October 18, 2013. (*See* Docket No. 1-1, at 4.) Defendants subsequently removed to this Court on November 11, 2013. (Docket No. 1.) Defendants filed their first motion to dismiss on December 16, 2013. (Docket No. 5.) Plaintiffs responded and requested leave to amend their Complaint. (Docket No. 8.) The Court granted Plaintiffs' request and denied Defendants' first motion to dismiss with leave to refile after the filing of Plaintiffs' Amended Complaint. (Docket No. 9.) Plaintiffs thereafter filed their

Amended Complaint on February 14, 2014. (Docket No. 10.) In their Amended Complaint, Plaintiffs assert four primary claims: (1) strict liability manufacturing defect; (2) negligent manufacture; (3) negligence *per se*; and (4) negligent failure to warn. (Docket No. 10, at 28-32.) Plaintiffs also assert a claim for punitive damages, and Jamie Waltenburg asserts a derivative claim for loss of consortium. (Docket No. 10, at 32.) Defendants now renew their Motion to Dismiss, arguing that Plaintiffs have failed to state a plausible claim for relief and that Plaintiffs' claims are preempted by federal law.

STANDARD

The Federal Rules of Civil Procedure require that pleadings, including complaints, contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). A complaint may be attacked for failure "to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). When considering a Rule 12(b)(6) motion to dismiss, the court will presume that all the factual allegations in the complaint are true and will draw all reasonable inferences in favor of the nonmoving party. *Total Benefits Planning Agency v. Anthem Blue Cross & Blue Shield*, 552 F.3d 430, 434 (6th Cir. 2008) (citing *Great Lakes Steel v. Deggendorf*, 716 F.2d 1101, 1105 (6th Cir. 1983)).

Even though a "complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citations omitted). Instead, the plaintiff's "[f]actual

allegations must be enough to raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Id.* (citations omitted). That is, a complaint must contain enough facts "to state a claim to relief that is plausible on its face." *Id.* at 570. A claim becomes plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556). If, from the well-pleaded facts, the court cannot "infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Id.* at 679 (alteration in original) (quoting Fed. R. Civ. P. 8(a)(2)). "[O]nly a complaint that states a plausible claim for relief survives a motion to dismiss." *Id.*

When resolving a motion to dismiss pursuant to Rule 12(b)(6), the Court may consider the complaint and any exhibits attached thereto, public records, items appearing in the record of the case, and exhibits attached to the defendant's motion to dismiss provided such are referenced in the complaint and central to the claims therein. *Bassett v. Nat'l Collegiate Athletic Assoc.*, 528 F.3d 426, 430 (6th Cir. 2008); *see also Stringfield v. Graham*, 212 F. App'x 530, 535 (6th Cir. 2007) (explaining that documents "attached to and cited by" the complaint are "considered parts thereof under Federal Rule of Civil Procedure 10(c)").

DISCUSSION

Defendants argue that the Plaintiffs' Amended Complaint should be dismissed because their principal claims in Counts I through IV are preempted by federal law and, even if such claims are not preempted, Plaintiffs have failed to sufficiently state

their claims under the requirements of *Twombly* and *Iqbal*. The Court will begin by discussing the relevant statutory and regulatory background before turning to the issue of preemption and the Plaintiffs' particular claims.

I. Statutory and Regulatory Background

In 1976, Congress enacted the Medical Device Amendments (MDA), 21 U.S.C. § 360c *et seq.*, to the Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.* The MDA established various levels of oversight for medical devices depending on the degree of risk posed. Class I, which is subject to the lowest level of oversight and requires only "general controls," includes such devices as elastic bandages and examination gloves. *See* § 360c(a)(1)(A). At the other end of the spectrum are Class III devices, which receive the highest level of federal oversight and require "premarket approval." *See* § 360c(a)(1)(C). A device is classified under Class III where the device "is purported or represented to be for a use in supporting or sustaining human life . . . or presents a potential risk of illness or injury" and it cannot be established that a less stringent classification "would provide reasonable assurance of its safety and effectiveness." § 360c(a)(1)(C)(i)–(ii). It is undisputed that the Riata lead at issue here is a Class III device.

A. Premarket approval generally

As noted above, Class III devices must undergo premarket approval prior to marketing and sale. *See id.* Premarket approval, or "PMA," has been described by the Supreme Court as a "rigorous" process. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996). A manufacturer must submit what is typically a multivolume application that includes, among other things, full reports of all studies and investigations of the

device's safety and effectiveness that have been published or should reasonably be known to the applicant; a "full statement" of the device's "components, ingredients, and properties and of the principle or principles of operation"; "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device"; samples or device components required by the Food and Drug Administration (FDA); a specimen of the proposed labeling; and any other relevant information. 21 U.S.C. § 360e(c)(1)(A)–(H). After completing its review, the FDA may grant or deny premarket approval, and may condition approval on adherence to performance standards, restrictions on sale and distribution, and/or compliance with other requirements. *See* 21 C.F.R. §§ 814.82, 861.1(b)(3). The FDA also is free to impose device-specific restrictions by regulation. *See* 21 U.S.C. 360j(e)(1). The FDA spends an average of 1,200 hours reviewing each application, *Lohr*, 518 U.S. at 477, and will grant premarket approval only if it finds there is a reasonable assurance of the device's safety and effectiveness, *see* 21 U.S.C. § 360e(d).

Once a device has received premarket approval, it "may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. § 814.80. Thus, a manufacturer is forbidden to make, without the FDA's permission, any changes in design specifications, manufacturing processes, labeling, or any other attribute that would affect safety or effectiveness. *See* 21 U.S.C. § 360e(d)(6)(A)(i); 21 C.F.R. § 814.39(a)-(b). If the manufacturer wishes to make any such changes, it must submit, and the FDA must approve, an application for

supplemental premarket approval, or a "PMA supplement." *See* 21 U.S.C. § 360e(d)(6); 21 C.F.R. § 814.39(a). The same procedures that apply to applications for a PMA also apply to applications for PMA supplements. *See id.*; 21 C.F.R. § 814.39(c).

After premarket approval, a device is subject to continued reporting requirements. *See* 21 U.S.C. § 360i; 21 C.F.R. § 814.84. These requirements include the obligation to submit periodic reports to the FDA informing the agency of any "[u]npublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device" as well as any "[r]eports in the scientific literature concerning the device" that the applicant knows of or reasonably should know of. 21 C.F.R. § 814.84(b)(2). The applicant also must report to the FDA no later than 30 days after "receiv[ing] or otherwise becom[ing] aware of information, from any source, that reasonably suggests that a device . . . (1) [m]ay have caused or contributed to death or serious injury; or (2) [h]as malfunctioned and this device . . . would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." 21 C.F.R. § 803.50(a)(1)–(2). The FDA has the power to withdraw premarket approval where it determines that a device is unsafe or ineffective, 21 U.S.C. § 360e(e)(1), and to order the recall of a device where there is a reasonable probability that the device would cause serious adverse health consequences or death, § 360h(e).

B. Premarket approval of the Riata leads

The PMA process for the Riata leads began in 1995 with the submission of an application to market the Riata's predecessor, the "Ventritex TVL." The FDA granted premarket approval to the Ventritex TVL lead in May 1996.[1] In 2002, Defendants submitted, and the FDA approved, a PMA Supplement in which Defendants sought approval to modify the Ventritex TVL lead and to market versions of the modified lead under the trade name "Riata Series 1500 Defibrillation Lead System," which included Riata model 1580.[2] Between the approval of that supplement, PMA Supplement 14, and the implantation of Mr. Waltenburg's Riata lead in September 2004, the FDA approved four additional supplements, PMA Supplements 15 through 18.[3]

II. Preemption

Federal preemption derives from the Supremacy Clause of the United States Constitution. The Constitution establishes the laws of the United States as "the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. CONST. art. VI, cl.2. Thus, state laws that

[1] The parties identify this premarket approval as PMA No. P950022. (*See* Docket Nos. 10, at 7; 13-1, at 8.)

[2] This PMA Supplement was the fourteenth supplement to PMA No. P950022 and is identified as "S014." For purposes of this Opinion, the Court will refer to this supplement as "PMA Supplement 14." Subsequent PMA Supplements will be referred to in a similar fashion using their numerical identifier (*e.g.*, "PMA Supplement 15," "PMA Supplement 16," and so on).

[3] PMA Supplement 15 approved an extension of the shelf life for Riata leads; PMA Supplement 16 approved two new Riata models; PMA Supplement 17 approved the addition of a fluoroscopic marker in the helix tip, the addition of new lead lengths, and minor modifications to the suture sleeve; and PMA Supplement 18 approved modification to the Riata lead family to include integrated bipolar leads in Riata model numbers 1560, 1561, 1562, 1590, 1591, and 1592. Summaries of each of these PMA Supplements can be found on the FDA's website at FDA.GOV, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm (search PMA number "P950022") (last updated July 14, 2014). To date, the FDA has approved more than 80 supplements to PMA No. P950022.

conflict with federal laws or regulations are preempted. *E.g.*, *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978). A court considering a preemption challenge "is not to pass judgment on the reasonableness of state policy," but "is instead to decide if a state rule conflicts with or otherwise stands as an obstacle to the accomplishment and execution of the full purposes and objectives of the federal law." *Livadas v. Bradshaw*, 512 U.S. 107, 120 (1994) (citations omitted) (internal quotation marks omitted). To do so, the Court must "ascertain Congress' intent in enacting the federal statute at issue." *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 738 (1985). Preemption "is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose." *Id.* (citations omitted).

Preemption therefore comes in two forms: express and implied. Express preemption is found when Congress declares a clear intent to preempt state law. *Hillsborough Cnty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 712-13 (1985); *see also State Farm Bank, FSB v. Reardon*, 539 F.3d 336, 341-42 (6th Cir. 2008) (explaining that express preemption exists "where either a federal statute or regulation contains explicit language indicating that a specific type of state law is preempted"). Implied or implicit preemption is subdivided into two categories: conflict preemption and field preemption. *Reardon*, 539 F.3d at 342 (citation omitted). The former exists "where compliance with both federal and state regulations is a physical impossibility, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress"; the latter exists when "the scheme of

federal regulation is so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it." *Id.*

A. Preemption under the MDA

The MDA contains an express preemption clause, which provides:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). Since its enactment, the Supreme Court has decided three principal preemption cases involving the MDA. But despite the guidance offered by those decisions, courts have struggled to discern the precise scope of MDA preemption.

The first case addressing preemption under the MDA was *Medtronic, Inc. v. Lohr*, decided in 1996. 518 U.S. at 470. There, after her pacemaker failed, the plaintiff alleged a number of negligence claims under state law against the pacemaker's manufacturer. Among those claims, the plaintiff alleged that the manufacturer breached its duty to use reasonable care in the sale of the pacemaker by its failure to warn her or her physicians of the pacemaker's tendency to fail, despite the manufacturer's knowledge of earlier failures. *Id.* at 481. The Court held that none of the plaintiff's state-law claims were preempted, writing: "Nothing in § 360k denies [a state] the right to provide a traditional damages remedy for violations of common-

law duties when those duties parallel federal requirements." *Id.* at 495. In regard to her failure-to-warn claim, the Court focused on the generality of the state-law duty to warn, explaining:

> [T]he predicate for the failure to warn claim is the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use. These general obligations are no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a work force. These state requirements therefore escape pre-emption, not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k envisioned to be "with respect to" specific devices such as pacemakers.

Id. at 501-02.

Buckman Co. v. Plaintiffs' Legal Committee was the second case to address preemption under the MDA. 531 U.S. 341 (2001). The *Buckman* plaintiffs brought state-law negligence claims alleging injuries from the implantation of orthopedic bone screws, a Class III medical device. In regard to defendant Buckman, which was a consulting company and did not manufacture the screws, the plaintiffs alleged that Buckman had made fraudulent misrepresentations to the FDA in the course of obtaining PMA approval for its client, the screws' manufacturer. *Id.* at 343-44. The Court characterized these claims against Buckman as "fraud-on-the-FDA claims" and, as such, concluded that they "conflict with, and are therefore impliedly pre-empted by, federal law."[4] *Id.* at 348. The Court explained:

[4] The *Buckman* Court expressly limited its holding to the issue of implied preemption, noting: "[W]e express no view on whether these claims are subject to express pre-emption under 21 U.S.C. § 360k." 531 U.S. at 348 n.2.

> Th[is] conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law.

Id.

The *Buckman* Court distinguished the claims in *Lohr*, which arose from the manufacturer's alleged breach of state-law duties, from those asserted by the *Buckman* plaintiffs, which alleged no state-law claim and instead focused exclusively on Buckman's alleged fraud on the FDA during the PMA process. *See id.* at 352 (discussing *Lohr*, 518 U.S. at 481). After noting that "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law," the Court concluded:

> In the present case . . . the fraud claims exist solely by virtue of the FDCA disclosure requirements. Thus, although [*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.
>
> In sum, were plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in questions [sic]. On the contrary, the existence of these federal enactments is a critical element in their case.

Id. at 352-53.

The third and most recent case to address MDA preemption is *Riegel v. Medtronic, Inc.*, which was decided in 2008. 552 U.S. 312 (2008). There, the

plaintiffs sued Medtronic under state law after a catheter in the lead plaintiff's coronary artery ruptured. The catheter, an FDA-approved Class III device, had been inflated to a higher pressure than recommended on the FDA-approved label. *Id.* at 320. The plaintiffs claimed that the catheter was defective under state law. The Court held that the plaintiffs' claims were expressly preempted by the MDA because state law imposed more stringent safety requirements than did federal law. *Id.* at 325. Still, the Court was careful to state that *Lohr* remained good law:

> State requirements are pre-empted under the MDA only to the extent that they are "different from, or in addition to" the requirements imposed by federal law. § 360k(a)(1). Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case "parallel," rather than add to, federal requirements. *Lohr*, 518 U.S. at 495.

Id. at 330.

B. MDA preemption in the context of Rule 12(b)(6)

Collectively, *Lohr*, *Buckman*, and *Riegel* provide a framework for the appropriate preemption analysis. Nevertheless—and, frankly, understandably—lower courts have struggled to resolve one of the major preemption questions that has arisen since *Riegel*: In the context of a Rule 12(b)(6) motion to dismiss, what degree of particularity is required to establish a parallel claim and avoid preemption?

The first major post-*Riegel* decision to address this issue was *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, a case in which the Eighth Circuit, in a divided opinion, affirmed a multidistrict litigation court's dismissal of failure-to-warn, design-defect, and manufacturing-defect claims on the basis of express preemption. 623 F.3d 1200 (8th Cir. 2010) (2-1 decision). That court read

Riegel and *Buckman* as "creat[ing] a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption." *Id.* at 1204 (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009)). The Eighth Circuit found that each of the plaintiffs' claims were expressly preempted under § 360k(a) because the plaintiffs did not allege with sufficient specificity a deviation from the specific federal requirements in the PMA. *See id.* at 1205-07.

The Sixth Circuit has yet to weigh in directly on this issue, and, since *Riegel* and *In re Medtronics*, different circuit courts have adopted different approaches as to the required pleading specificity in the context of MDA preemption.

On one end of the spectrum is the Seventh Circuit's decision in *Bausch v. Stryker Corp.*, which thus far has required the least specificity to plead a claim that will survive a motion to dismiss. 630 F.3d 546 (7th Cir. 2010), *cert. denied*, 132 S. Ct. 498 (2011). There, the district court granted the defendants' motion to dismiss, holding that the plaintiff's common-law claims were preempted by the MDA. The district court also denied the plaintiff's motion to amend her complaint. The Seventh Circuit reversed, finding that the plaintiff's claims that she was injured by the defendants' alleged violations of federal law were not preempted. In so doing, the *Bausch* panel made clear that a plaintiff need not identify the precise defect or the specific federal regulatory requirements that were allegedly violated in order to comply with Rule 8. *Id.* at 560. In this regard, the *Bausch* panel wrote:

> Defendants object that the original complaint does not specify the precise defect or the specific federal regulatory requirements that were allegedly violated. Although the complaint would be stronger with such detail, we do not believe the absence of those details shows a failure to comply with Rule 8 of the Federal Rules of Civil Procedure or can support a dismissal under Rule 12(b)(6).

Id.

The Seventh Circuit based its decision in part on the fact that "in the context of Class III medical devices, much of the critical information is kept confidential as a matter of federal law [and] there is no public access to complete versions of [the FDA's premarket approval] documents." *Id.* at 560. Thus, the court reasoned that "[i]f plaintiffs must allege that the defendant violated a particular FDA-approved specification before discovery, then it is difficult to appreciate how any plaintiff will ever be able to defeat a Rule 12(b)(6) motion." *Id.* at 561 (quoting *In re Medtronic*, 623 F.3d at 1212 (Melloy, J., dissenting)).

On the other end of the spectrum is the Eleventh Circuit's decision in *Wolicki-Gables v. Arrow International, Inc.*, a decision which set forth a standard requiring the highest degree of pleading specificity. 634 F.3d 1296 (11th Cir. 2011). Adopting an approach embraced by many district courts,[5] the *Wolicki-Gables* panel held that a plaintiff must allege a PMA-specific violation in order to survive preemption under § 360k(a):

> Plaintiffs cannot simply incant the magic words '[defendants] violated FDA regulations' in order to avoid preemption. Parallel claims must be specifically stated in the initial pleadings. A plaintiff must allege that [the] defendant violated a particular federal specification referring to the device at issue. To properly allege parallel claims, the complaint must set forth facts pointing to specific PMA requirements that have been violated.

[5] *See, e.g., Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 589 (E.D.N.Y. 2009); *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009), *aff'd*, 623 F.3d 1200 (8th Cir. 2010) (2-1 decision); *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008); *Rollins v. St. Jude Med.*, 583 F. Supp. 2d 790, 799-800 (W.D. La. 2008).

Id. at 1301 (second alteration in original) (citations omitted) (internal quotation marks omitted).

Though the approaches taken in these cases are not perfectly aligned, the extent to which they differ is not beyond reconciliation.[6] The Fifth Circuit effectively synthesized *In re Medtronic*, *Bausch*, and *Wolicki-Gables* in *Bass v. Stryker Corp.*, a case in which the plaintiff asserted strict liability and negligence claims based on manufacturing defects:

> Although the circuits are not in complete agreement as to what constitutes a sufficient pleading . . . [t]he key distinction between complaints that are sufficient to withstand a motion to dismiss and those that are not is . . . the existence of a manufacturing defect caused by a violation of federal regulations *and* allegations connecting a defect in the manufacture of the specific device to that plaintiff's specific injury.

669 F.3d 501, 511-12 (5th Cir. 2012) (emphasis in original). The Fifth Circuit went on to offer the following illustration:

> [S]uppose a manufacturer had represented to the FDA in its pre-approval documentation that each hip implant component would be sterilized for ten minutes at 800 degrees. We would accept a parallel claim that pleaded that the manufacturer instead sterilized the component at only 200 degrees for five minutes, as that would "violate" what it told the FDA. However, if the plaintiff's claim was that proper sterilization required twenty minutes at 1000 degrees or some other method of sterilization altogether, this claim would not be allowed, as it would "add to" the regulatory requirements.

Id. at 512-13.

[6] This point previously was recognized by this Court in *White v. Stryker Corp.*: "These cases reveal the different approaches to resolving MDA preemption issues, though one can overstate the differences. No doubt, specific factual and procedural differences among the cases partially explain the different results." 818 F. Supp. 2d 1032, 1039 (W.D. Ky. 2011) (discussing *Bausch* and *Wolicki-Gables*, among other decisions).

Yet despite the possibility of reading these seemingly incongruous decisions as somehow in sync, the precise question presently before this Court remains unanswered—namely, is it sufficient to allege that the Defendants violated FDA regulations by deviating from the FDA-approved processes and procedures in the PMA or, instead, must the Plaintiffs identify the particular FDA regulations and set forth facts pointing to the particular PMA requirements that are alleged to have been violated? The Court has found no clear answer to this question, as there appears to be case law supporting both possibilities.[7]

Several recent decisions—two by this Court and one by the Eastern District of Kentucky—provide useful points of comparison. In the first case, *White v. Stryker Corp.*, this Court granted the defendant's motion to dismiss upon finding that the plaintiff had failed to plead the degree of specificity required to establish a parallel claim and avoid preemption. 818 F. Supp. 2d 1032 (W.D. Ky. 2011). The plaintiff in *White* underwent a total hip arthroplasty in which a medical device known as the "Trident System" was implanted. Several years later, the plaintiff learned that the Trident System had failed and sued the manufacturer, alleging that "defendants failed to manufacture [the Trident System] according to FDA approved standards and

[7] *Compare Franzese v. St. Jude Med., Inc.*, 2014 WL 2863087, at *3 (E.D.N.Y. June 23, 2014) (noting that "the law is clear that Plaintiffs must identify a specific federal regulation allegedly violated"), *and Simon v. Smith & Nephew, Inc.*, 2013 WL 6244525, at *4 (S.D.N.Y. Dec. 3, 2013) ("To avoid preemption and satisfy the *Twombly* and *Iqbal* pleading standards, plaintiffs suing with regard to a PMA-approved device cannot simply make the conclusory allegation that defendant's conduct violated FDA regulations."), *with Hawkins v. Medtronic, Inc.*, 909 F. Supp. 2d 901, 906 (S.D. Ohio 2012) (citing the Supreme Court's decision in *Lohr*, 518 U.S. at 495, for the proposition that "to avoid preemption, the complaint need not define 'the precise contours of [the plaintiff's] theory of recovery,' if it alleges that the defendant has violated FDA regulations" (alteration in original)); *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830, 838-39 (S.D. Ind. 2009) (discussing *Lohr* to suggest that the district court's decision in *In re Medtronic* "is an unusually stringent application of *Twombly* and Rule 8 of the Federal Rules of Civil Procedure at the motion to dismiss stage").

procedures for medical devices." *Id.* at 1033 (alteration in original). A review of the docket in that case reveals that the plaintiff's complaint and amended complaint merely alleged that the device was defective and that the defendant designed, manufactured, and distributed the device. *See White v. Stryker Corp.*, No. 3:10-CV-544-JGH, Docket No. 1-3 (filed Aug. 16, 2010); Docket No. 7-1 (filed Oct. 1, 2010). The amended complaint did reference FDA standards, but did so in conclusory fashion: "The subject hip replacement device . . . was defective . . . in that the defendants failed to manufacture it according to FDA approved standards and procedures for medical devices including but not limited to the standards and procedures set forth in the [MDA]." *Id.*, Docket No. 7-1, at 1. The same general reference to "FDA approved standards and procedures" also was used in regard to the plaintiff's negligent-manufacture claim. *Id.*, Docket No. 7-1, at 1. This Court, relying on the standards set out in *In re Medtronic* and *Wolicki-Gables*, found the plaintiff's claims insufficiently specific to avoid dismissal, writing:

> The Amended Complaint neither cites any particular federal standard or procedure, nor does it generally state how the alleged defect deviated from a federal standard or procedure.
> . . . .
> . . . [I]t contains only the most general allegations of product liability [and] negligence . . . . It does not identify any particular design flaw, manufacturing impropriety or product defect. It does not assert either a PMA-specific standard or a GMP regulation, the violation of which might form the basis for a state law action. Rather, in a general manner it purports to limit otherwise broad state law claims only to those circumstances involving noncompliance with an FDA standard. In the face of the narrow pleading window required to avoid preemption, Plaintiff has done virtually nothing.

White, 818 F. Supp. 2d at 1033, 1039.

In the second case, *Steiden v. Genzyme Biosurgery*, this Court reached the opposite conclusion and denied the defendant's motion to dismiss. 2012 WL 2923225 (W.D. Ky. July 18, 2012). The plaintiff in *Steiden* received an injection of "Synvisc-One," a Class III medical device, and immediately suffered an adverse reaction. In his original complaint, he sued the device's manufacturer, Genzyme, alleging strict liability. The defendant moved to dismiss, and the plaintiff moved to amend his complaint to add allegations that "Genzyme failed to comply with the FDA's premarket approval requirements in the continued manufacture, distribution and sale of Synvisc-One®" and that "Genzyme manufactured, held, sold, and delivered an adulterated dose of Synvisc-One®." *Id.* at *1-2. In contrast to *White*, the *Steiden* decision made no mention of *Wolicki-Gables* and instead relied primarily on the Seventh Circuit's decision in *Bausch*. The Court read *Bausch* as holding "that although the original complaint did not specify the precise defect or the specific federal regulatory requirements that were allegedly violated, the absence of those details did not provide a valid basis for dismissal under Rule 12(b)(6)." *Id.* at *3 (citing *Bausch*, 630 F.3d at 560). The Court then likened the facts before it to those in *Bausch* and distinguished them from those in *White*:

> [T]he facts appear to be fairly simple and straightforward. It is claimed that on a particular date, both of Steiden's knees were injected with Synvisc–One®, and he allegedly suffered an immediate adverse reaction in one of them. He claims that the product was adulterated, that Genzyme violated federal [current good manufacturing practices], the PMA for the device, and state law prohibiting the manufacture and sale of adulterated medical devices.
>
> We find the factual allegations before us indistinguishable from those in *Bausch* where the plaintiff cited to the above-referenced FDA letter stating that the device was "adulterated." Nothing more

> specific was required in *Bausch* to state a plausible claim for adulteration. Similarly, we find that the allegation of adulteration based on the occurrence of an immediate adverse reaction in one knee to the injection of Synvisc–One® contains sufficient specificity to satisfy *Iqbal* and *Twombly.*
>
> In *White*, the plaintiff did not allege any specific manufacturing failure or violation of any federal standard. He alleged general claims of product liability, negligence and warranty. By contrast, Steiden has alleged that the means by which he was injured was the injection into his knee of an adulterated dose of Synvisc–One®. He claims that . . . the PMA . . . w[as] violated thereby.

Id. at *5 (citations omitted).

Finally, in the third case, *Kitchen v. Biomet, Inc.*, the Eastern District of Kentucky followed this Court's reasoning in *White* and granted the defendant's motion to dismiss. 2014 WL 694226 (E.D. Ky. Feb. 21, 2014). The plaintiff in *Kitchen* underwent surgery to receive an "Oxford" partial knee implant. The implant subsequently failed, and the plaintiff had to undergo further surgery. She sued the implant's manufacturer alleging, among other things, negligence and strict liability. *Id.* at *1. In regard to her negligence claim, the plaintiff's amended complaint alleged:

> 18. The Oxford partial knee implant was defective in one or more of the following respects:
>
> . . . .
>
> (f) failure to comply with Quality System Regulation and Current Manufacturing Practices required by the FDA in 21 C.F.R. § 820.72 to 820.90. Among other things, these regulations require manufacturers to put in place suitable processes to test products for compliance with product specifications, to check and document compliance with product specifications before products are accepted for sale and use, and to identify and control non-conforming products;
>
> . . . .

> 19. Because of these effects, the knee implant failed to comply and operate within the terms of its Pre-Market Approval from The Food and Drug Administration.

Id. at *2 (alterations in original). The plaintiff's strict liability claim similarly alleged that "[b]ecause of its defects, the knee implant failed to comply and operate in terms of its Pre-Market Approval." *Id.* Relying on *White*, the Eastern District concluded: "Plaintiff refers to a broad category of federal regulations and fails to allege how the device violated those regulations or how that deviation caused her injuries. This lack of specificity is fatal to her claim." *Id.* at *5. The court punctuated its conclusion further by distinguishing this Court's decision in *Steiden*: "In this case, as in *White* and in contrast to *Steiden*, Plaintiff fails to identify the federal regulation violated by Defendants, how the product deviated from the FDA approved process and how such deviation caused her injury. Simply incanting that a manufacturer violated federal regulations does not pass *Iqbal/Twombly* muster."[8] *Id.* at *6.

The Court has reviewed the dockets of these three cases and compared the claims and allegations pleaded in each with those of the Plaintiffs here.[9] The factual

[8] Based on this Court's review of the dockets in *White*, *Steiden*, and *Kitchen*, the comparisons drawn by the court in *Kitchen* are somewhat puzzling. For example, the *Kitchen* decision seems to state that the *Steiden* plaintiff identified specific federal regulations alleged to have been violated. *See Kitchen*, 2014 WL 694226, at 6. However, neither the complaint nor the amended complaint in *Steiden* did, in fact, identify any specific federal regulation. *See Steiden v. Genzyme Biosurgery*, No. 3:11-CV-441-CRS, Docket No. 1-1 (filed Aug. 5, 2011); Docket No. 21 (filed July 18, 2012). Moreover, the *Kitchen* decision seems to gloss over a number of seemingly specific allegations as to why the device in question there was defective. *See Kitchen v. Biomet, Inc.*, No. 0:13-CV-18-HRW, Docket No. 23, at 4, ¶ 18(a) (filed Sept. 26, 2013). Ultimately, this Court's reading of the amended complaint in *Kitchen* appears to reveal allegations that are much more similar to those in *Steiden* than to the meager allegations presented in *White*.

[9] As referenced above, the complaint and amended complaint in *White* appear at Docket No. 1-3 and Docket No. 7-1, respectively, in Civil Action No. 3:10-CV-544-JGH (W.D. Ky); the complaint and amended complaint in *Steiden* appear at Docket No. 1-1 and Docket No. 21, respectively, in Civil

allegations presently before this Court unquestionably are more specific than those in *White* and *Kitchen*. They also are appreciably more specific than those that survived dismissal in *Steiden*. Here, Plaintiffs assert claims sounding in strict liability and negligence, in essence alleging that the Riata leads were defective because the actual manufacture of those leads deviated from the specifications and protocols set forth in the federal regulations and the PMA. (*See* Docket No. 10, at 28-32.) Nothing more specific was required in *Steiden* to overcome dismissal under Rule 12(b)(6). And unlike the scant factual allegations in *White*, here, the Plaintiffs support their claims with a number of specific allegations as to how Defendants deviated from the specifications in the PMA. (*See* Docket No. 10, at 21-24, ¶¶ 75-81, 84.)

Furthermore, in considering the sufficiency of the pleadings, the Court finds much of the Seventh Circuit's reasoning in *Bausch* particularly persuasive. Although the Plaintiffs' Amended Complaint does not make specific reference to the precise PMA requirements allegedly violated, the absence of such details can hardly provide a solid basis for dismissing their claims at this stage. *See Bausch*, 630 F.3d at 560 ("If plaintiffs must allege that the defendant violated a particular FDA-approved specification before discovery, then it is difficult to appreciate how any plaintiff will ever be able to defeat a Rule 12(b)(6) motion."). Indeed, Plaintiffs do not appear to have had access to PMA Supplements 14 through 18 prior to the filing of Defendants' Motion to Dismiss,[10] and there is nothing to indicate that Plaintiffs had access to the

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Action No. 3:11-CV-441-CRS (W.D. Ky.); and the amended complaint in *Kitchen* appears at Docket No. 23 in Civil Action No. 0:13-CV-18-HRW (E.D. Ky.).

[10] PMA Supplements 14 through 18 were filed under seal as attachments to Defendants' Motion to Dismiss. (*See* Docket Nos. 15; 15-1 through -18.)

original PMA when either their Complaint or Amended Complaint was filed. *See id.* (noting that "in the context of Class III medical devices, much of the critical information is kept confidential as a matter of federal law [and] there is no public access to complete versions of [the FDA's PMA] documents.").

For these reasons, the Court is satisfied that the claims in Plaintiffs' Amended Complaint are pleaded with sufficient particularity to satisfy the notice-pleading requirements of Rule 8 and to survive dismissal under Rule 12(b)(6).[11]

III. Preemption and Plaintiffs' Particular Claims

Having found that Plaintiffs' claims pass muster under Rule 8, the Court still must determine whether those state law claims are preempted, either expressly or impliedly, by federal law. Therefore, the Court now turns to the particular claims asserted in Plaintiffs' Amended Complaint. Defendants argue that Plaintiffs' manufacturing-defect claims are expressly preempted because Plaintiffs have failed to state parallel claims. Defendants also argue that Plaintiffs' failure-to-warn claim is both expressly and impliedly preempted. And, finally, Defendants argue that Plaintiffs' negligence *per se* claim is not cognizable under Kentucky law and, even if it was, is impliedly preempted. The Court will consider each of these claims in turn.

[11] The Court's conclusion on this point is consistent with at least one other decision in this Circuit. *See Hawkins*, 909 F. Supp. 2d at 906 ("[T]o avoid preemption, the complaint need not define 'the precise contours of [the plaintiff's] theory of recovery,' if it alleges that the defendant has violated FDA regulations." (quoting *Lohr*, 518 U.S. at 495)).

A. Strict liability manufacturing defect

Defendants argue that Plaintiffs' manufacturing-defect claims are expressly preempted under § 360k(a). Preemption analysis under § 360k(a) involves two inquiries: (1) whether the Federal Government has established requirements applicable to the device in question; and (2) whether the asserted state-law claims impose any requirements with respect to the device that are different from, or in addition to, the federal requirements. *Riegel*, 552 U.S. at 321-22. The Supreme Court recognizes that the extensive PMA process that Class III devices must endure imposes requirements under the MDA, thus satisfying the first part of this inquiry. *See id.* at 322-23. Plaintiffs do not dispute that the FDA has established requirements for the Riata leads. (*See* Docket No. 16, at 7.) Thus, the Court's inquiry here is limited to whether the Plaintiffs' claims would impose state-law requirements "different from, or in addition to," the requirements imposed by the FDA through the PMA process.

In *Riegel*, the Supreme Court offered some guidance as to what it means for a state requirement to be different from, or in addition to, an MDA requirement, explaining that state-law claims "premised on a violation of FDA regulations" are "parallel" claims that do not impose requirements different from, or in addition to, federal requirements. Accordingly, § 360k(a) does not preempt these parallel claims. The Court therefore must determine whether Plaintiffs have established "parallel" claims.

Count I of Plaintiffs' Amended Complaint asserts a claim in strict liability, alleging that the Riata leads possess a manufacturing defect because the actual manufacture of those leads deviated from the specifications set forth in the federal

regulations and required by the PMA and PMA Supplements. Earlier in their Amended Complaint, Plaintiffs specifically identify some eight alleged deviations from those approved specifications that they say make the Riata leads defective: (1) "failure to manufacture the internal conductors, or cables, at sizes consistent with the specifications. . . . result[ing] in increased movement of the conductors, or cables, within the insulation thereby causing inside out abrasion;" (2) "[f]ailure to manufacture insulation diameters consistent with the specifications lead[ing] to increased movement of the cables within the outer silicone as well as an increased risk of abrasion at thinner insulation sites, leading to an increased risk of device failure;" (3) "failure to consistently apply a lubricious interface inside the lumen between the inner and outer insulation [which] may have led to increased friction within the lead body, promoting abrasion and/or externalization;" (4) "fail[ure] to comply with the approved methods and/or specifications of curing and sterilization during the manufacture [which] resulted in reduced tensile strength of the silicone insulation;" (5) "process[ing] the leads in a solution which caused the cables and/or conductors to stretch and then vibrate when exposed to electrical charge thru [sic] silicone, further increasing the risk of abrasion to the leads;" (6) "fail[ure] to consistently trim and/or remove excess adhesive and/or silicone from the outer lead body [which] result[ed] in both inconsistent thickness and less smooth insulation both of which contribute to the abrasion of the lead;" (7) "fail[ure] to crimp with a controlled, uniform, degree of force [which] resulted in insecure crimps over the length of the [l]ead, which also leads to increased movement of the lead and diminishes the integrity of the insulation—both of which lead to abrasion"; and (8) "fail[ure] to adequately inspect

and/or test the leads and their component parts to ensure consisten[cy] with approved specifications and procedures." (Docket No. 10, at 21-24, ¶¶ 75-81, 84.)

Defendants argue that Plaintiffs' manufacturing-defect claims are expressly preempted because they fail to state a parallel claim. More specifically, Defendants state that at least six of these alleged requirements do not appear in PMA Supplements 14 through 18. According to Defendants, "the alleged requirements upon which [Plaintiffs] base their manufacturing-defect claims simply do not exist." (Docket No. 13-1, at 24.) Defendants therefore urge that any manufacturing-defect claim predicated on the existence of these purported requirements is expressly preempted because it necessarily would impose state-law requirements in addition to, or different than, those imposed by the FDA through the PMA process.

As an initial matter, Defendants may be correct that the specifications they are alleged to have deviated from do not appear in PMA Supplements 14 through 18. Notably absent from Defendants' argument, however, is any mention of the original PMA for the Riata's predecessor, the Ventritex TVL, or of the previous PMA Supplements thereto. While the Riata brand may not have appeared until PMA Supplement 14, the specifications applicable to those leads include the specifications approved in the original PMA as well as those approved in earlier PMA Supplements. *See Kemp v. Medtronic, Inc.*, 231 F.3d 216, 227 (6th Cir. 2000) ("[T]he PMA Supplement process . . . builds upon the rigorous PMA process . . . . Hence, because the FDA has already made a determination as to the safety and effectiveness of the underlying device in the original PMA, it can evaluate only the proposed modifications presented in the PMA Supplement while relying on its earlier approval

of the original device."), *cert. denied*, 534 U.S. 818 (2001). In *Kemp v. Medtronic, Inc.*, the Sixth Circuit explained:

> [T]he PMA process establishes specific federal requirements for a Class III device. It is true that in granting approval for a Class III device, the FDA does not set forth the reasons justifying its decision. Impliedly, however, the FDA has relied upon both the PMA submission approved for the original Class III device and the PMA Supplement providing specific information on the proposed modification in question. These specific submissions form the basis of the FDA's approval of the PMA Supplement. *Thus, we conclude the specific requirements applicable to the* [*medical device*] *include the entire relevant PMA and accompanying PMA Supplement, rather than certain portions thereof. . . .* [*T*]*he information submitted to and approved by the FDA in both the . . . PMA and as modified by the . . . PMA Supplement comprise the specific federal requirements applicable to* [*the medical device*].

231 F.3d at 228 (emphasis added). Therefore, the PMA Supplements for the Riata leads *supplemented*, rather than *supplanted*, the PMA requirements for its predecessor, the Ventritex TVL. On this point, the District of New Jersey, applying the Sixth Circuit's decision in *Kemp*, succinctly noted:

> Moreover, DePuy's PMA supplement for the LCS–P/S Knee's "tibial" component supplemented, rather than supplanted, the PMA requirements for its predecessor, the LCS–Knee. As one court of appeals has explained, "a PMA Supplement proposes changes to a device that has already received rigorous review and approval during the original PMA process." Hence, because "the PMA Supplement process builds upon the rigorous PMA process," the FDA evaluates "the proposed modifications presented in the PMA Supplement while relying on its earlier approval of the original device." In determining whether FDA regulations impose specific requirements applicable to the LCS–P/S Knee, this Court considers the FDA's approval of the PMA for the LCS–Knee as well as its approval of the PMA supplement for the LCS–P/S Knee.

Steele v. DePuy Orthopaedics, Inc., 295 F. Supp. 2d 439, 449 n.9 (D.N.J. 2003) (internal citations omitted) (quoting *Kemp*, 231 F.3d at 227). To be sure, this Court and a number of other district courts have recognized that the federal requirements established by FDA approval "consist[] of 'the totality of the design, manufacturing processes, and labeling when coupled with the prohibition against modifying them' as found in the 'entire relevant PMA and accompanying PMA Supplement[s].'" *Enlow v. St. Jude Med., Inc.*, 210 F. Supp. 2d 853, 858 (W.D. Ky. 2001) (quoting *Kemp*, 231 F. 3d at 228); *accord Purchase v. Advanced Bionics, LLC*, 896 F. Supp. 2d 694, 697 (W.D. Tenn. 2011); *Hughes v. Cook*, 452 F. Supp. 2d 832, 841 (W.D. Tenn. 2006); *In re Medtronic, Inc., Implantable Defibrillators Litig.*, 465 F. Supp. 2d 886, 893 (D. Minn. 2006); *Moore v. Sulzer Orthopedics, Inc.*, 337 F. Supp. 2d 1002, 1008 (N.D. Ohio 2004).

As noted above, state-law claims premised on violations of FDA regulations are parallel—and thus not preempted under § 360k(a)—to the extent they do not impose state-law requirements different from, or in addition to, federal requirements. Under Kentucky law, a manufacturing defect exists when a product leaves the hands of the manufacturer in a defective condition because it was not manufactured or assembled in accordance with its specifications. *Gentry v. Gen. Motors Corp.*, 2006 WL 1382293, at *1 (W.D. Ky. May 15, 2006) (referencing *Greene v. B.F. Goodrich Avionics System, Inc.*, 409 F.3d 784, 788 (6th Cir. 2005)); *Ford Motor Co. v. McCamish*, 559 S.W.2d 507, 509-11 (Ky. Ct. App. 1977). Kentucky has adopted the RESTATEMENT (SECOND) OF TORTS § 402A, *Greene*, 409 F.3d at 788 (citing *Dealers Transp. Co. v. Battery Distrib. Co.*, 402 S.W.2d 441, 446-47 (Ky. 1965)), under which

a defendant is held strictly liable if the plaintiff proves the product was "in a defective condition unreasonably dangerous to the user or consumer," *id.* (quoting *Montgomery Elevator Co. v. McCullough ex rel. McCullough*, 676 S.W.2d 776, 780 (Ky. 1984)). "Unreasonably dangerous" means "a product that is 'dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics.'" *Greene*, 409 F.3d at 789 (quoting RESTATEMENT (SECOND) OF TORTS § 402A cmt. i). "Defective" means "that the product does not meet the reasonable expectations of the ordinary consumer as to its safety." *Greene*, 409 F.3d at 789 (quoting *Worldwide Equip., Inc. v. Mullins*, 11 S.W.3d 50, 55 (Ky. Ct. App. 1999)).

Thus, to state a parallel claim and avoid preemption under § 360k(a), Plaintiffs' state-law manufacturing-defect claim must not impose requirements different from, or in addition to, federal requirements. At this early stage in the litigation, it would be difficult, if not impossible, for the Plaintiffs to allege specific deviations from the confidential PMA documentation that they could only obtain through the discovery process. As such, it similarly is difficult, if not impossible, for the Court to determine whether Plaintiffs have failed to allege specific deviations from the PMA and PMA Supplements because, at least at this stage in the litigation, the Court simply is unable to compare the particular state and federal requirements at issue. The Southern District of Ohio faced an analogous situation in *Hawkins v. Medtronic, Inc.*, a case also decided in the context of a Rule 12(b)(6) motion to dismiss. 909 F. Supp. 2d 901 (S.D. Ohio 2012). There, the court noted that "[b]ecause the preemption issue here must be decided on the pleadings, and the complaint has not defined 'the precise

contours of [the plaintiff's] theory of recovery,' the Court can not engage in a detailed comparison of the specific state and federal requirements at issue." *Id.* at 908 (quoting *Lohr*, 518 U.S. at 495). The court then went on to reject the defendant's arguments that the plaintiff's strict liability claims were preempted, concluding: "[I]t is clear from the allegations that Plaintiff's claim is in fact premised on the theory that Defendant violated federal law. The Court therefore DENIES Defendant's motion as to Plaintiff's manufacturing defect claim." *Id.* (citing *Riegel*, 552 U.S. at 330; *Lohr*, 518 U.S. at 495).

The Court reaches the same conclusion here as did the court in *Hawkins*. Plaintiffs' Amended Complaint alleges that Defendants' manufacture of the Riata leads deviated from the PMA and PMA Supplements. Plaintiffs' strict liability manufacturing-defect claim is therefore predicated on violations of federal regulations. *See, e.g.*, *Bass*, 669 F.3d at 512 ("To the extent a plaintiff can show that the FDA-approved processes and procedures were not followed, and that the injury was caused by this deviation, the plaintiff's claim will be parallel."). Thus, at this early stage in the litigation, and to the extent Plaintiffs claim that the device was defectively manufactured because it did not comply with the FDA-approved specifications, the Court finds that Plaintiffs have successfully alleged a parallel claim sufficient to survive preemption under § 360k(a). However, the Court notes that if after the completion of discovery it appears that Plaintiffs cannot maintain a manufacturing-defect claim based on state requirements that parallel federal requirements, Defendants are certainly free to move for summary judgment, at which point the Court will reevaluate the issue of preemption.

B. Negligent manufacture

Count II of Plaintiffs' Amended Complaint alleges that Defendants had a duty to manufacture the Riata leads consistent with the applicable specifications set forth in the PMA and PMA Supplements, that Defendants breached that duty, and that Mr. Waltenburg has sustained and continues to sustain injury as a result. Under Kentucky law, a plaintiff can advance both a strict-liability claim and a negligence claim against the manufacturer of a product for injury suffered by that product. *See Ostendorf v. Clark Equip. Co.*, 122 S.W.3d 530, 535 (Ky. 2003) (referencing *Williams v. Fulmer*, 694 S.W.2d 411, 413 (Ky. 1985)). A negligence claim requires proof that "(1) the defendant owed the plaintiff a duty of care, (2) the defendant breached the standard by which his or her duty is measured, and (3) consequent injury." *Pathways, Inc. v. Hammons*, 113 S.W.3d 85, 88 (Ky. 2003) (citing *Mullins v. Commonwealth Life Ins. Co.*, 839 S.W.2d 245, 247 (Ky. 1992)). Because Plaintiffs' negligent-manufacture claim essentially is premised on the same allegations as their strict liability manufacturing-defect claim, much of the Court's analysis above is equally applicable here. To the extent the duty of care owed and the breach of that duty derive from federal law violations, Plaintiffs' negligent-manufacture claim does not impose different or additional requirements. This claim therefore survives preemption, at least at this juncture. Again, however, if it appears that after the completion of discovery Plaintiffs cannot maintain their negligent-manufacture claim based on state requirements that parallel federal requirements, the Court may revisit the issue of preemption at the summary judgment stage.

C. Negligence *per se*

Count III of Plaintiffs' Amended Complaint asserts a claim of negligence *per se* and references a litany of federal regulations as defining the applicable standard of care. Defendants argue that this claim fails for several reasons, principally because Kentucky law does not recognize a negligence *per se* claim premised on a violation of federal law. Plaintiffs seem to have conceded this point as they have not responded in opposition to this argument.

Defendants are correct that a negligence *per se* claim premised on violations of federal law is not cognizable under Kentucky law. Kentucky Revised Statute § 446.070 codifies the common-law claim of negligence *per se* in Kentucky.[12] "In accord with traditional legal principles related to the common-law concept of negligence per se, the statute applies when the alleged offender violates a statute and the plaintiff comes within the class of persons intended to be protected by the statute." *St. Luke Hosp., Inc. v. Straub*, 354 S.W.3d 529, 534 (Ky. 2011). However, "Kentucky courts have held that the 'any statute' language in KRS 446.070 is limited to Kentucky statutes and does not extend to federal statutes and regulations." *Young v. Carran*, 289 S.W.3d 586, 589 (Ky. Ct. App. 2008) (citing *T & M Jewelry, Inc. v. Hicks*, 189 S.W.3d 526, 530 (Ky. 2006)); *see also Pace v. Medco Franklin RE, LLC*, 2013 WL 3233469, at *2 (W.D. Ky. June 25, 2013); *Cummings v. BIC USA, Inc.*, 2011 WL 1399768, at *3 (W.D. Ky. April 13, 2011). "The Kentucky General Assembly did not intend for KRS 446.070 to embrace the whole of federal laws and the laws of other states and thereby

[12] Kentucky Revised Statute § 446.070 provides: "A person injured by the violation of any statute may recover from the offender such damages as he sustained by reason of the violation, although a penalty or forfeiture is imposed for such violation."

confer a private civil remedy for such a vast array of violations." *Hicks*, 189 S.W.3d at 530; *see also Alderman v. Bradley*, 957 S.W.2d 265, 266 (Ky. Ct. App. 1997) (holding that the "reach [of § 446.070] is limited to violations of Kentucky statutes and does not extend to federal regulations"). Thus, the law of Kentucky is clear that "[v]iolations of federal laws and regulations and the law of other states do not create a cause of action based on KRS 446.070." *St. Luke Hosp.*, 354 S.W.3d at 534. Accordingly, Plaintiffs' negligence *per se* claim fails as a matter of law and will be dismissed.[13]

D. Negligent failure to warn

Count IV of Plaintiffs' Amended Complaint alleges that Defendants had a continuing duty to monitor the Riata leads after FDA approval and to discover and report to the FDA any complaints and issues regarding the device's performance of which they became aware. Plaintiffs allege that Defendants breached that duty by failing to provide timely and adequate postapproval reports, and by failing to conduct adequate risk analyses and investigations regarding safety issues and potential defects. Plaintiffs claim that they have suffered and continue to suffer injury as a direct result of Defendants' breach. Plaintiffs further allege that had Defendants complied with their duties as required by federal law, this information would have reached the public, including Plaintiffs and/or Mr. Waltenburg's physicians, in time to prevent Plaintiffs' injuries.

[13] Because the Court finds that Plaintiffs' negligence *per se* claim is not cognizable under Kentucky law, the Court need not address Defendants' alternative argument that this claim is impliedly preempted under 21 U.S.C. § 337(a) and *Buckman*.

Defendants read Count IV as asserting two failure-to-warn theories: (1) that Defendants had a continuing duty to provide ongoing warnings, and (2) that Defendants had a continuing duty to monitor the device postapproval and to discover and report to the FDA information about device safety and performance. (*See* Docket No. 13-1, at 33.) Defendants argue that under either theory Plaintiffs' failure-to-warn claim is both expressly and impliedly preempted.

To state a parallel claim and avoid express preemption under § 360k(a), Plaintiffs' negligent failure-to-warn claim must not impose a state-law duty different from, or in addition to, the federal-law duties under the MDA. "Kentucky law imposes a general duty on manufacturers and suppliers to warn of dangers known to them but not known to persons whose use of the product can reasonably be anticipated." *Watters v. TSR, Inc.*, 904 F.2d 378, 381 (6th Cir. 1990) (citing *Garrison v. Rohm & Haas Co.*, 492 F.2d 346, 352 (6th Cir. 1974); *Post v. Am. Cleaning Equip. Corp.*, 437 S.W.2d 516 (Ky. 1968)); *see also Smith v. Parker-Hannifin Corp.*, 2014 WL 1418288, at *7 (W.D. Ky. Apr. 14, 2014). This duty may arise under general negligence principles; however, "[a] defendant's duty to warn is confined to risks either known or knowable by the exercise of reasonable care." *Prather v. Abbott Labs*, 960 F. Supp. 2d 700, 712 (W.D. Ky. 2013) (citing *C & S Fuel, Inc. v. Clark Equip. Co.*, 552 F. Supp. 340, 347 (E.D. Ky. 1982)). In *Smith v. Louis Berkman Co.*, this Court further recognized that the duty to warn may be ongoing:

> A continuing duty to warn may arise after manufacture or distribution, where something changes about the product, the experience with its use, or the knowledge of the manufacturer or user. This duty may arise if the manufacturer learns of significant product failures . . . . The issue is whether the manufacturer knew

> of an increased risk for any reason. As a consequence, requiring the manufacturer to undertake the duty to notify users of such new developments may be warranted.

894 F. Supp. 1084, 1092 (W.D. Ky. 1995) (internal citation omitted) (citing *Watters*, 904 F.2d at 381). As for the federal requirements, after PMA approval, a manufacturer of a Class III device is required to comply with certain medical-device-reporting requirements. For instance, under 21 U.S.C. § 360i and 21 C.F.R. § 803.50, a device manufacturer is required to report to the FDA device failures and adverse health events of which the manufacturer is aware.

Plaintiffs argue that the reports required under the applicable federal regulations are collected and published to the public so that both medical professionals and the general public can obtain safety data on medical devices. Plaintiffs insist that "through this procedure, the FDA imposes a duty to warn equivalent to that under Kentucky law." (Docket No. 16, at 17.) Defendants argue that Plaintiffs' failure-to-warn claim is expressly preempted because "the duty to submit adverse-event reports to the FDA is not identical to the state law duty to warn doctors." (Docket No. 13-1, at 36.)

Not surprisingly, courts have reached divergent results as to whether a failure-to-report claim such as that alleged here will survive preemption under § 360k(a). For example, in a thoroughly reasoned decision, the District of Minnesota concluded that the plaintiffs' failure-to-warn claim was expressly preempted because the state common-law duty to warn was not equivalent to the federal duty to properly issue reports to the FDA. *See Pinsonneault v. St. Jude Med., Inc.*, 953 F. Supp. 2d 1006, 1015 (D. Minn. 2013). Contrarily, the Ninth Circuit, in an *en banc* decision also

handed down last year, found that the plaintiffs' negligent failure-to-warn claim was not preempted because the claim was premised on a state-law duty that paralleled the manufacturer's duty under the MDA. *See Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013) (en banc), *cert. denied*, --- S. Ct. ---, 2014 WL 2807193 (June 23, 2014). The Ninth Circuit's decision in *Stengel* comports with recent decisions by the Fifth and Seventh Circuits. *See Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 769-771 (5th Cir. 2011); *Bausch*, 630 F.3d at 555-58.

Upon reviewing the relevant caselaw, the Court finds particularly persuasive the Ninth Circuit's *en banc* decision in *Stengel* and the Fifth Circuit's in *Hughes v. Boston Scientific Corp*. Significantly, both of those decisions are clearly supported by the Supreme Court's decision in *Lohr*, which held that a state-law negligence claim based on the manufacturer's duty to warn about dangers of a medical device was parallel and thus not preempted by § 360k(a). *See* 518 U.S. at 481, 501-02. Like the plaintiffs in *Stengel*, *Hughes*, and *Lohr*, the Plaintiffs here assert a negligence claim based on the manufacturer's violation of the state-law duty to warn. Under the precedent set by those decisions, the Plaintiffs' failure-to-warn claim will be preempted only to the extent that it purports to impose liability despite Defendants' compliance with FDA regulations. It follows that to the extent their claim is based on Defendants' failure to comply with FDA regulations, that claim is not preempted by § 360k(a). At this early stage of the litigation, the Court is satisfied that the Plaintiffs' failure-to-warn claim does not impose any requirements different from, or in addition to, the federal reporting requirements. Accordingly, to the extent their claim is based

on Defendants' violation of the applicable federal reporting requirements, the Court finds that the Plaintiffs' failure-to-warn claim is not expressly preempted.

The Court reaches a similar conclusion on the issue of implied preemption. Again, there is certainly caselaw to support the argument that Plaintiffs' failure-to-warn claim is impliedly preempted under 21 U.S.C. § 337(a) and the Supreme Court's decision in *Buckman*.[14] *See, e.g., Pinsonneault*, 953 F. Supp. 2d at 1016-17. But, at least at this juncture, the Court remains of the opinion that the most compelling authorities on this issue are the Ninth and Fifth Circuit's decisions in *Stengel* and *Hughes*, respectively. *Hughes* concluded that a plaintiff's negligent failure-to-warn claim was not impliedly preempted because such a "claim is not analogous to the 'fraud-on-the-FDA' theory in *Buckman*" where the plaintiffs "were attempting to assert a freestanding federal cause of action based on violations of the FDA's regulations [and] did not assert violation of a state tort duty." *Hughes*, 631 F.3d at 775. Here, much like the plaintiff in *Hughes*, Plaintiffs are alleging a recognized state tort claim based on the underlying state-law duty to warn about the dangers or risks of a product. They seek to prove Defendants' breach of that duty by showing that Defendants violated the applicable federal reporting requirements. As such, the Court is satisfied that Plaintiffs' claim is not impliedly preempted by § 337(a) as construed in *Buckman*.

[14] Section 337(a) generally provides that all actions for enforcement or to restrain violations of the FDCA "shall be by and in the name of the United States." In *Buckman*, the Supreme Court held that the plaintiffs' claims were impliedly preempted by federal law, noting that "the FDA . . . has at its disposal a variety of enforcement options," and that "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." 531 U.S. at 348-49 & n.4 (interpreting 21 U.S.C. § 337(a)).

E. Remaining claims

Defendants move for dismissal of Plaintiffs' final two claims for loss of consortium and punitive damages on the basis that these claims are dependent on Plaintiffs' other claims. Because the Court will allow Plaintiffs' claims for strict liability manufacturing defect, negligent manufacture, and negligent failure to warn to proceed, there is no basis to dismiss Plaintiffs' derivative claims at this time.

CONCLUSION

Therefore, having considered Defendants' Motion and being otherwise sufficiently advised, consistent with the foregoing;

IT IS HEREBY ORDERED that Defendants' Motion to Dismiss, (Docket No. 13), is GRANTED IN PART and DENIED IN PART. Defendants' Motion is GRANTED as to Plaintiffs' claim in Count III for negligence *per se*. Defendants' Motion is DENIED with respect to Plaintiffs' other claims.

IT IS SO ORDERED.

Date: July 18, 2014

cc: Counsel

Thomas B. Russell

Thomas B. Russell, Senior Judge
United States District Court