UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
AT LOUISVILLE

CIVIL ACTION NO. 3:11-CV-00450-H

BRIAN AND MICHELLE SADLER PLAINTIFFS
Individually and on behalf of their
Minor child, B.S.

V.

ADVANCED BIONICS, INC. DEFENDANT

MEMORANDUM OPINION AND ORDER

Breanna Sadler and her parents Michelle and Brian Sadler (collectively, "Plaintiffs") bring this action to recover for injuries Breanna incurred as a result of the malfunctioning of her cochlear implant against Advanced Bionics, the manufacturer of the device. Advanced Bionics now moves for summary judgment of most of Plaintiffs' claims on preemption grounds. Many district and circuit courts have addressed medical device preemption issues from a variety of perspectives. As yet, the Sixth Circuit has not contributed any comprehensive discussion on the precise context presented here. The Court has reviewed relevant approaches and decided upon a reasonable one. For the reasons that follow, the Court sustains the motion in part and denies the motion in part.

I.

The facts particular to this case are straightforward. Breanna Sadler suffered from permanent hearing loss until she underwent open-head surgery to receive a cochlear implant on January 16, 2006. Breanna's cochlear implant device was Advanced Bionics' HiRes 90k. With the assistance of a cochlear implant, the brain learns to decode noise, and over time, implant recipients are able to

distinguish sounds such that they are able to hear again. Although the device is technologically complicated, two principal systems comprise the cochlear implant: an internal component surgically implanted in the skull and an external component that sits outside the ear. The feedthru, which must remain hermetic (waterproof) throughout the life of the device, connects these two parts.

In December 2009, a leak in the feedthru that allowed moisture into the device caused Breanna's cochlear implant to fail, and as a result, she endured an aggressive shock. As Breanna convulsed on the floor, her mother held her down. After Breanna disconnected the device, her mother reconnected it at the urging of a doctor on the telephone. The cochlear implant again shocked Breanna, and Breanna's mother allowed Breanna to once more disconnect the device. The following day, Brian Sadler took Breanna to an audiologist. While Brian held Breanna down, the doctor reconnected the external processor to Breanna's skull. For the third time, the device shocked Breanna. When Breanna underwent replacement surgery in February 2010, the Sadlers chose a competitor cochlear implant for their daughter. The lingering physical and emotional effects of the three shocks are disputed.

Breanna's cochlear implant is subject to significant federal regulation under the Federal Food, Drug, and Cosmetic Act ("FDCA"), which governs medical device manufacturing. The FDCA specifically empowers the Food and Drug Administration ("FDA") to regulate production and labeling practices of medical product manufacturers and distributors. In amending the FDCA several times since its enactment, Congress expanded the federal role in medical product regulation while preserving the applicability of state laws to the manufacture and distribution of medical products. *Wyeth v. Levine*, 555 U.S. 555, 566 (2009).

In 1976, Congress enacted the Medical Device Amendment ("MDA") to broaden the FDCA's regulatory scope to include medical device manufacturing. Anne-Marie Dega, *The Battle Over Medical Device Regulation: Do the Federal Medical Device Amendments Preempt State Tort Law Claims*, 27 LOY. U. CHI. L.J. 615, 625-26 (1996). Because medical devices vary in composition and risk, Congress created three classes of these devices with corresponding varied levels of federal administrative control over the covered devices. For Class III devices, such as Advanced Bionics' cochlear implant, the FDA will grant manufacturers approval to market and distribute their products after obtaining premarket approval ("PMA").[1] PMA "requires that manufacturers conduct extensive testing to obtain clinical results that demonstrate the safety and effectiveness of a device. Both FDA staff members and outside experts must approve the PMA before the FDA will approve the device for commercial use." Dega, *supra,* at 627. This involves over 1,000 hours of FDA review. *Lohr,* 518 U.S. at 478. Once a device receives PMA approval, the manufacturer must

> submit a PMA Supplement for review and approval by FDA before making a change affecting the safety or effectiveness of the device. . . . [C]hanges for which an applicant shall submit a PMA supplement include . . . (6) Changes in the performance or design specifications, circuits, *components*, ingredients, principle of operation, or physical layout of the device.

21 C.F.R. § 814.39(a)(emphasis added). In sum, federal regulations require Advanced Bionics to obtain PMA approval for the initial cochlear implant device and supplemental approval for any

[1] An alternative avenue for FDA medical device approval is called the § 510(k) process, which was designed to grandfather medical devices already on the market into the new medical device regulatory scheme, allowing them "to remain on the market without FDA approval until such time as the FDA initiates and completes the requisite PMA." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 479 (1996)(plurality opinion); 12 U.S.C. § 360e(b)(1)(A). The § 510(k) process also "permits devices that are 'substantially equivalent' to the pre-existing devices to avoid the PMA process" in order "to prevent manufacturers of grandfathered devices from monopolizing the market while new devices clear the PMA hurdle." *Lohr*, 518 U.S. at 479; 21 U.S.C. § 360e(b)(1)(B).

subsequent generation of the device that incorporates changes affecting device safety or effectiveness.

In 1996, Advanced Bionics obtained a PMA for its original cochlear implant, the Clarion Multi-Strategy Cochlear Implant System. Subsequently, Advanced Bionics obtained PMA Supplement #30 for a later generation of the device, called the HiRes 90k. Advanced Bionics manufactured two versions of the HiRes 90k. First, the PMA Supplement #30 approved the device using a Pacific Aerospace and Electronics, Inc. ("PA&E") manufactured feedthru ("Vendor A HiRes 90k"). In July of 2003, Advanced Bionics began commercially selling the Vendor A HiRes 90k.

Shortly thereafter, Advanced Bionics began manufacturing the second version of the HiRes 90k; this cochlear implant contained a feedthru manufactured by AstroSeal, Inc. ("Vendor B HiRes 90k"). Advanced Bionics did not seek a PMA Supplement for the Vendor B HiRes 90k. When Breanna underwent cochlear implant surgery in January of 2006, she received a Vendor B HiRes 90k, manufactured in 2005.

A number of issues relating to the HiRes 90k arose prior to Breanna's implantation surgery. In 2004, Advanced Bionics thoroughly tested failed, explanted cochlear implant devices, and concluded that the devices failed due to excessive moisture concentration in the feedthrus. In September of 2004, Advanced Bionics issued a recall of its unimplanted cochlear implant devices including the HiRes 90k, claiming that moisture sealed into the device during its manufacture caused issues with the proper functioning of the device. After implementing some changes to the device manufacturing process, Advanced Bionics resumed manufacturing and distributing the HiRes 90k. Nevertheless, Advanced Bionics received a warning letter the next year from the FDA informing it of insufficiencies in its operating structure. Because some devices continued to fail, Advanced

Bionics issued another recall in March of 2006, which included a recall of unimplanted Vendor B HiRes 90ks. This time, Advanced Bionics concluded that a leak in the feedthru, rather than moisture being sealed in the device during manufacture, caused the excessive moisture levels.

After the 2006 recall, the FDA conducted an on-site investigation of Advanced Bionics' operations related to the recall. In 2007, apparently as a result of the inspection, the FDA filed a civil complaint against Advanced Bionics and its president and CEO, Jeffrey Grenier, seeking administrative penalties related to Advanced Bionics' violation of the FDCA and its corresponding regulations. The parties agreed to settle the case, and Advanced Bionics and Grenier paid the maximum FDCA fine.

II.

Plaintiffs brought suit arising from the failure of Breanna's Vendor B HiRes 90k in August of 2011, alleging negligence, products liability, negligence *per se*, breach of implied warranty, common law fraud, and punitive damages claims. Plaintiffs have agreed to withdraw their breach of implied warranty claim. Additionally, the parties do not discern the punitive damages. Therefore, the Court's preemption analysis addresses the remaining four claims separately.

Advanced Bionics moves for summary judgment under Federal Rule of Civil Procedure 56 on these four claims. Summary judgment is appropriate where "there is no genuine dispute as to any material fact." FED. R. CIV. P. 56(c). Initially, the moving party bears the burden of proving that no genuine issues of material fact are extant. *Matsushita Electric Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 585-86 (1986). The Court will view the facts in a light most favorable to the nonmoving party. *Id.* Once the moving party satisfies its burden, the nonmoving party may

overcome summary judgment only by designating "specific facts showing that there is a genuine issue for trial." *Celotex Corp v. Catrett*, 477 U.S. 317, 324 (1986).

III.

Advanced Bionics' primary argument is that express and implied medical device preemption void the four claims. The Court will attempt to navigate the murky waters of medical device preemption, relying on controlling precedent and applying relevant and persuasive decisions to the case *sub judice*. As a threshold matter, though, the Supreme Court affirmatively recognizes

> two cornerstones of our pre-emption jurisprudence. First, the purpose of Congress is the ultimate touchstone in every pre-emption case. Second, in all pre-emption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied, we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.

Wyeth, 555 U.S. at 565 (internal citations omitted).

The purpose of the MDA is to provide a comprehensive legislative regime regulating medical device production to protect consumers from the potentially fatal effects of defective medical devices. Prior to enacting the MDA, the FDA maintained an enormous role in ensuring the safety of medical products for consumers. *Dega*, *supra*, at 624-25. With the inclusion of the MDA in the FDCA, this role is even more pronounced as applied to medical devices, because in certain circumstances, the FDA is the only party entitled to reign in unlawful medical device manufacturing practices. *See* 21 U.S.C. § 337(a)(vesting sole power for enforcement of some FDA violations with the federal government, as explained below). With congressional intent in mind, the Court turns to the state of medical device claim preemption.

A.

Federal courts recognize three varieties of preemption: express, implied, and field. *Fadel v. Nationwide Mut. Fire Ins. Co.*, 2012 WL 5878728, at *4 (W.D. Ky. Nov. 21, 2012). Medical device preemption includes both the express and implied varieties. Congress provided an express preemption statute for medical devices in the MDA, codified at 21 U.S.C. § 360k(a). This provision states,

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

21 U.S.C. § 360k(a).

The Supreme Court has decided two major express preemption cases that help define the preemptive scope of § 360k. In *Medtronic v. Lohr*, the Supreme Court addressed "whether [the MDA] pre-empts a state common-law negligence action against the manufacturer of an allegedly defective medical device." 518 U.S. at 474.[2] In holding that § 360k did not preempt the plaintiffs' state law negligence claims as a matter of law, the plurality reasoned that

> [n]othing in § 360k denies [the state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements. . . . The presence of a damages remedy does not amount to the additional or different "requirement" that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing "requirements"under federal law.

[2] In *Lohr*, the device at issue had undergone § 510(k) approval rather than PMA approval. This single fact makes the *Lohr* case distinguishable from the present situation, because this Court's holding as to the preemptive scope of § 360k is based in part on the rigorous approval process required to obtain a PMA.

Id. at 495. The Court maintained that "pre-emption [can] occur only where a particular state requirement threatens to interfere with a specific federal interest." *Id.* at 500. Justice Stevens explained that "the use of the term 'requirement,' rather than the term 'remedy,' indicated that Congress intended to preempt 'device-specific enactments of positive law by legislative or administrative bodies, not the application of general rules of common law by judges and juries.'" *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 223 (6th Cir. 2000)(quoting *Lohr*, 518 U.S. at 489). In so holding, the Supreme Court declared that the FDCA did not preempt any of the claims at issue. *Lohr*, 518 U.S. at 503.

Twelve years later, the Supreme Court retreated from *Lohr*'s relatively broad reading of the scope of § 360k preemption. In *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), the Supreme Court established a two-part test to determine whether § 360k preempts a state common law claim. First, the Court "must determine whether the Federal Government has established requirements applicable to the" medical device at issue. *Id.* at 321. "If so, [the Court] must then determine whether the [plaintiffs'] common-law claims are based upon [state law] requirements with respect to the device that are 'different from, or in addition to' the federal ones, and that relate to safety and effectiveness." *Id.* at 321-22 (quoting 21 U.S.C. § 360k(a)).

As to the first step, Justice Scalia explained that general federal requirements applicable across the board to almost all medical devices "did not pre-empt the common-law claims of negligence and strict liability at issue in *Lohr*." *Riegel*, 552 U.S. at 322. To preempt state law, the federal law violations must be somewhat specific to a particular medical device. For example, and germane to this case, the Supreme Court determined that premarket approval "imposes [federal]

'requirements' under the MDA," *id.* at 322, because "devices that receive FDA premarket approval must be manufactured with 'almost no deviations from the specifications' in the approval application. . . . [A]ny changes to a device's design specifications, manufacturing process, labeling, or other attribute that would affect safety require FDA approval." *Cooley v. Medtronic, Inc.*, 2012 WL 1380265, at *3 (E.D. Ky. Apr. 20, 2012).

As for the state law analysis, Justice Scalia commented on each of the three elements that comprise the second step of the *Riegel* test, which are: (1) the existence of state law requirements applicable to the device, (2) that are different from or in addition to federal requirements, and (3) that relate to safety and effectiveness. Writing for the majority, Justice Scalia determined that plaintiffs' state law claims invariably deal with safety and effectiveness. *Riegel*, 552 at 323. Therefore, "the first critical issue is whether [the state's] tort duties constitute 'requirements' under the MDA." *Id.* Adhering to *Lohr*, Justice Scalia concluded that the plaintiffs' "common-law causes of action for negligence and strict liability do impose 'requirement[s]' and would be pre-empted by federal requirements specific to a medical device." *Id.* at 323-24.

Most importantly, Justice Scalia did not to continue his analysis to the final element of the second step regarding whether the state common law requirements were "different from, or in addition to" federal requirements, as the parties did not raise this argument in the proceedings below. Instead, he wrote,

> State requirements are pre-empted under the MDA only to the extent that they are "different from, or in addition to" the requirement 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.

Id. at 330. Thus, the Supreme Court allows for parallel state law claims to survive express preemption. For the duration of this Opinion where express preemption is raised, this Court will examine whether the federal law cited establishes requirements for the medical device at issue and whether the state law claim imposes additional or different requirements upon the device manufacturers that impact the device's safety or effectiveness.

B.

Turning to implied preemption, Congress included a right of action provision in the FDCA, stating, "Except as provided in subsection (b) of this section [permitting states to bring certain actions], all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). The Supreme Court has interpreted this provision to impliedly preempt private litigants from asserting claims that directly enforce FDCA provisions against a manufacturer. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001)("The 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."). Therefore, private plaintiffs have no right of action to directly enforce the MDA.

In *Buckman,* the Supreme Court broadened the scope of implied preemption to bar some state law claims, holding that "the plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law." *Id.* at 348. The Sixth Circuit has read *Buckman* to proscribe prosecuting medical device manufacturers for fraud against the FDA through state law tort actions. *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 966 (6th Cir. 2004)(holding that *Buckman* "teaches that state tort remedies requiring proof of fraud committed against the FDA are foreclosed

since federal law preempts such claims")(quoting *Garcia v. Wyeth-Ayerst Labs.*, 265 F. Supp. 2d 825, 832 (E.D. Mich. 2003)).[3]

Combining *Buckman* and a plain reading of § 337(a), medical device implied preemption bars state law claims that do not exist independent of FDA statutes and regulations, because "we have clear evidence that Congress intended that the MDA be enforced exclusively by the Federal Government." *Buckman*, 531 U.S. at 352(citing 21 U.S.C. § 337(a)); *Cupek v. Medtronic, Inc.*, 405 F.3d 421, 424 (6th Cir. 2005)(quoting *Buckman* for this proposition).

C.

Construing *Lohr*, *Riegel*, and *Buckman* together, Advanced Bionics quotes the District Court for the District of Minnesota in holding that these cases

> create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption. 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*). For a state-law claim to survive, then, the claim must be premised on conduct that both (1) violates the FDCA and (2) would give rise to recovery under state law even in the absence of the FDCA.

Riley v. Cordis Corp., 625 F. Supp. 2d 769, 776 (D. Minn. 2009). The Court agrees with this conclusion as a general matter. However, the parallel claims that the *Riegel* Court determined could survive preemption may have widespread applicability, as evidenced in the large number of District

[3] The Sixth Circuit reasoned that because the basis for the claim in *Buckman* was a violation of a federal statute or regulation, and the state law claim existed "solely by virtue of the FDCA disclosure requirements," allowing state law causes of actions for violations of these federal regulations "interfere with the FDA's approval process". *Marsh v. Genentech, Inc.*, 693 F.3d 546, 551 (6th Cir. 2012)(quoting *Buckman*, 531 U.S. at 352-53). Therefore, the FDCA preempts such state law claims.

Court and Court of Appeals decisions on the issue.[4] The instant case provides yet another example of how some claims may fall within the gap between express and implied preemption.

Two other federal district courts have considered this preemption gap as it applies specifically to the Vendor B HiRes 90k devices, albeit with different plaintiffs. In *Purcel v. Advanced Bionics Corp.*, 2008 WL 3874713 (N.D. Tex. Aug. 13, 2008) ("*Purcel I*"), District Judge Barbara Lynn held that the MDA did not preempt Plaintiffs' claims under strict liability or for breach of implied warranty. *Id.* at *11-12. Judge Lynn read the *Riegel* and *Lohr* opinions quite literally, explaining that "the MDA does not preempt state law claims which are premised solely on violations of federal law."[5] *Id.* at *4.

Nearly two years later, she determined that most of the remaining claims presented proper parallel state law claims that survive preemption, except for those alleging fraud on the FDA and those where the plaintiffs did not indicate a federal requirement obligating Advanced Bionics to act in a particular way. *Purcel v. Advanced Bionics Corp.*, 2010 WL 2679988 (N.D. Tex. June 30, 2010) ("*Purcel II*"). The former are impliedly preempted, and the latter are expressly preempted. *Id.* at *6.

Judge Jon McCalla of the District Court for the Western District of Tennessee read the scope of medical device preemption more broadly. *Purchase v. Advanced Bionics, LLC*, No. 2:08-cv-

[4] "Though many federal courts have made gallant attempts to assess the viability of common law claims under the 'parallel claim' language used thrice by the Supreme Court, the ambiguity in the preemption provision and the broad ruling of the Supreme Court in Riegel give the courts wide latitude for interpretation of which state common law requirements deserve preemption." Demetria D. Frank-Jackson, *The Medical Device Federal Preemption Trilogy: Salvaging Due Process for Injured Patients*, 35 S. ILL. U. L.J. 453, 470 (2011).

[5] Although this holding seems to contradict this Court's understanding of implied preemption, Judge Lynn was not dealing with a cause of action that *existed* solely because of the FDA regulations; rather, the underlying state law claim was *predicated* solely on violations of federal law. This distinction is important. Where a state law claim exists independent of the FDA regulation or FDCA provision, that state law claim is not impliedly preempted.

02442-JPM (W.D. Tenn. Aug. 4, 2011). First, he held that "[t]o the extent that Plaintiffs' claims are based on Advanced Bionics' purported failure to submit a PMA Supplement Application and obtain PMA approval," this "is an administrative requirement, not a substantive safety requirement." *Id.* at *3-4. Therefore, claims premised on these failures were impliedly preempted. *Id.* at *4.[6]

However, Judge McCalla held that claims based on Advanced Bionics' deviation from the PMA Supplement #30 requirements are parallel. *Id.* at *5. He determined that once the HiRes 90k was approved, "the design, manufacturing process, and labels may not be modified without further FDA approval, unless the modifications do not affect the device's safety or effectiveness." *Id.* (quoting *Kemp*, 231 F.3d at 228). He then found that using the AstroSeal feedthru was a change that affected safety and effectiveness, and accordingly, Advanced Bionics' deviation from the PMA Supplement #30 "is a parallel claim that survives preemption." *Id.* He also found that claims based on Advanced Bionics' failure to perform qualification testing under actual or simulated use conditions, in violation of federal regulations that require manufacturers to comply with Current Good Manufacturing Practices ("CGMPs"), are not preempted. *Id.* at *7.[7]

While *Purcel I*, *Purcel II*, and *Purchase* are not binding decisions on this Court, they are certainly instructive on the present issues.[8]

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[6] Judge McCalla made other preemption rulings in this case not applicable here.

[7] However, Judge McCalla found that all other CGMPs cited in the Complaint are too vague to impose a federal duty on the manufacturer, apparently not satisfying the first *Riegel* step. In such a circumstance, a state law claim thereon would impose an additional requirement and be preempted under § 360k. *Id.* at *8. He did provide that evidence of CGMP violations may be used to demonstrate Advanced Bionics' negligence, but cannot serve as the basis for a negligence *per se* claim. *Id.* at *9.

[8] The Court in *Purcel I* and *Purcel II* examined whether the state law causes of action imposed additional or different requirements that would render the claims expressly preempted. The Court in *Purchase* seemed to focus on the federal law violations, determining whether these federal violations would preempt state law causes of action in general. This Court finds that the proper approach to the preemption analysis is a combination of these two methods, and will proceed by comparing the state law causes of action to the proposed federal regulatory violations.

IV.

As an initial matter, Plaintiffs assert that because Advanced Bionics never obtained a PMA Supplement for the Vendor B HiRes 90k, it is not a PMA-approved device, and the preemption provisions of the MDA, and specifically § 360k, are inapplicable to this case. However, § 360k preempts claims "with respect to a device intended for human use." 21 U.S.C. § 360k(a). Under the FDCA, a device need not be PMA-approved to satisfy the definition of device. 21 U.S.C. § 321(h).[9] Therefore, § 360k preemption applies to a medical device regardless of its status as PMA-approved or not. Moreover, Advanced Bionics did obtain supplemental approval for the HiRes 90k itself. Therefore, this argument fails, and the Court finds that the MDA preemption provisions apply to the Vendor B HiRes 90k.

Advanced Bionics argues that the remaining claims for negligence *per se*, fraud, strict liability, and negligence are expressly or impliedly preempted, each of which the Court will address in successive sections. However, Plaintiffs' negligence *per se* claims are void for a different reason. Under Kentucky law, plaintiffs must bring negligence *per se* claims under KRS § 446.070, which codified the common law negligence *per* se tort.[10] *St. Luke Hosp., Inc. v. Straub*, 354 S.W.3d 529,

[9] The statute provides in full:

> The term "device" (except when used in paragraph (n) of this section and in sections 331(I), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is--
>
> (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
>
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> (3) intended to affect the structure or any function of the body of man or other animals, and
>
> which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

21 U.S.C. § 321(h).

[10] Plaintiffs did not argue that a party can bring a negligence *per se* claim for violations of federal law under some lingering negligence *per se* common law. Nevertheless, those arguments would fail according to Kentucky law, which seems to construe KRS § 446.070 as codifying the entirety of the negligence *per se* common law. *See Young v. Carran*,

534 (Ky. 2011). The Kentucky Supreme Court determined that the General Assembly did not intend KRS § 446.070 "to embrace the whole of federal laws and the laws of other states and thereby confer a private civil remedy for such a vast array of violations." *T&M Jewelry, Inc. v. Hicks* ex rel. *Hicks*, 189 S.W.3d 526, 530 (Ky. 2006). Therefore, violations of federal law do not support negligence *per se* claims under Kentucky law. *See St. Luke Hosp.*, 354 S.W.3d at 534 (holding that "[v]iolations of federal laws and regulations and the laws of other states do not create cause of action based on KRS 446.070.").[11] Plaintiffs' negligence *per se* claims, which are premised upon violations of federal law, are not cognizable as a matter of Kentucky law and must be dismissed.

V.

Plaintiffs allege that Advanced Bionics committed fraud by misrepresentation and omission. Kentucky courts established that plaintiffs must prove different elements to sustain fraud by omission and fraud by misrepresentation claims.[12] *Giddings & Lewis, Inc. v. Indus. Risk Insurers*, 348 S.W.3d 729, 747 (Ky. 2011).

> Fraud through misrepresentation requires proof that: (1) the defendant made a material representation to the plaintiff; (2) the representation was false; (3) the defendant knew the representation to be false or made it with reckless disregard for its truth or falsity; (4) the defendant intended to induce the plaintiff to act upon the

289 S.W.3d 586, 589 (Ky. Ct. App. 2008). As explained in *Young*, Kentucky Courts no longer recognize a common law negligence *per se* claim. *Id.* (rejecting plaintiffs' claim that a federal law "and its corresponding regulations impose a duty of care on Appellees allowing for a Kentucky 'common law' negligence *per se* claim"). For this reason, Plaintiffs' negligence *per se* cause of action is properly brought pursuant to § 446.070, regardless of whether Plaintiff cites to this statute in its Complaint.

[11] Although Plaintiffs cannot bring a negligence *per se* claim based on violations of the FDA regulations and FDCA provisions, Kentucky courts have held that federal laws can support the existence of a duty of care in a negligence action. *See, e.g.*, *T&M Jewelry*, 189 S.W.3d at 532 ("[T]he provisions of the Gun Control Act represent a reasonable and satisfactory duty to impose upon licensed gun dealers in Kentucky."); *Yeager v. Dickerson*, 2013 WL 135718, *5 (Ky. Ct. App. Jan. 11, 2013)(construing *T&M Jewelry* as "allow[ing] the common law negligence claim to go forward and the lower court could use the federal law in establishing the defendant's duty").

[12] It is unclear whether Plaintiffs are pursuing a fraudulent misrepresentation claim in addition to a fraudulent omission claim. The Court will address both types of fraud, as the Complaint can be construed to assert both.

> misrepresentation; (5) the plaintiff reasonably relied upon the misrepresentation; and (6) the misrepresentation caused injury to the plaintiff. By contrast, a fraud by omission claim is grounded in a duty to disclose. To prevail, a plaintiff must prove: (1) the defendant had a duty to disclose the material fact at issue; (2) the defendant failed to disclose the fact; (3) the defendant's failure to disclose the material fact induced the plaintiff to act; and (4) the plaintiff suffered actual damages as a consequence.

Id. (internal citations omitted).

A.

To the extent Plaintiffs are alleging that Advanced Bionics' labels contained false or misleading representations or failed to disclose material information, Plaintiffs are asking the Court to find that FDA-approved labels were in fact unlawful. To sustain such an argument would require the Court to find one of two facts to be true: first, that Advanced Bionics lied to the FDA during its label-approval process, a claim impliedly preempted under *Buckman*; or second, that the labels must include some information in addition to or different from what the FDA and the FDCA prescribe. The latter is expressly preempted under the second step of the *Riegel* analysis. *See Purcel II*, 2010 WL 2679988, at *7 ("§ 360k(a) [] preempt[s] fraud claims based on statements that were approved or required by the FDA, and § 337(a) and *Buckman* preempt claims based on fraud to the FDA."). In sum, Plaintiffs' claims based on labeling improprieties are preempted.

B.

The FDA also contains a comprehensive scheme regulating disclosures. *Marsh*, 693 F.3d at 551. To the extent Plaintiffs are alleging fraudulent misrepresentations or omissions in Advanced Bionics' disclosures *to the FDA*, *Buckman* preempts these claims as fraud-on-the-FDA. *Id.* Insofar as Plaintiffs are alleging that Advanced Bionics' disclosures were misleading *to the public*, these claims as pled in the Complaint are really asserting that Advanced Bionics failed to warn the public

of certain material facts.[13] According to Sixth Circuit precedent, these claims are either impliedly or expressly preempted.

In *Kemp*, the Court held that the scope of implied preemption under *Buckman* encompasses some failure-to-warn claims. 231 F.3d at 236-37. A failure-to-warn claim "could be read as asserting that the warnings found in the label and literature approved by the FDA . . . were inadequate under [state] law. . . . [T]o the extent that plaintiffs' claim is premised on the adequacy of the warnings reviewed and approved by the FDA, our analysis of the 'fraud on the FDA' claim applies equally to the failure to warn claim, and the claim is similarly preempted." *Id.* Therefore, to the extent Plaintiffs are asserting that Advanced Bionics' FDA-approved disclosures are inadequate, these claims are impliedly preempted.[14]

Additionally, recognizing that "the FDA requires continuous updates as part of the pre-market approval application and supplement process . . . [that] specifically address warnings and recalls associated with medical devices", the Sixth Circuit also held that state law failure to warn claims based on fraudulent omissions can be expressly preempted. *Cupek*, 405 F.3d at 424 ("Any claim, under state law, then, that Defendant failed to warn patients beyond warnings required by the

[13] Plaintiffs' Complaint only states one affirmative misrepresentation in the fraud claim section, that "Advanced Bionics made representations via comments to Plaintiffs and/or Breanna's physicians through oral representations and/or written promotional and marketing materials that its products were the most technologically advanced and the safest." Complaint, ECF no. 57, at 50. In the Complaint, Plaintiffs next recount what they believe to be true about the Vendor B HiRes 90k. *Id.* Therefore, the Court views Plaintiffs' only affirmative misrepresentation allegation as a claim for the failure to warn of the true state or condition of the Vendor B HiRes 90k.

[14] *Kemp* reserved the possibility of asserting parallel state law fraudulent omission claims where the "defendant acquired information subsequent to the FDA approval of the [medical device] and before implantation of the device that would lead a reasonable manufacturer to warn patients and the medical community." *Id.* Therefore, not all state law fraud claims are impliedly preempted. Indeed, other Sixth Circuit district courts have held that *Buckman* preemption does not prohibit state law fraud claims alleging "the concealment of information from patients and physicians as the cause of Plaintiff's injuries," because these "claims sound in state tort law and would exist even without these federal regulations." *Fulgenzi v. Wyeth, Inc.*, 686 F. Supp. 2d 715, 724 (N.D. Ohio 2010). While Plaintiffs' fraudulent omission claims arguably fall within this opening, when analyzing these claims through the prism of the corresponding Kentucky law elements of proof, the Court finds that Plaintiffs' fraudulent omission claims are expressly preempted.

FDA . . . would constitute state requirements 'different from' or 'in addition to' the requirements of the federal PMA application and supplement process.").[15]

Applying Kentucky law for fraudulent omissions to these preemption doctrines under the second step of the *Riegel* express preemption test further supports this conclusion. Kentucky law requires that the defendant have a duty to disclose information. *See CertainTeed Corp. v. Dexter*, 330 S.W.3d 64, 79 (Ky. 2010)(noting that product manufacturers can be held to a duty to warn). Plaintiffs cite no federal duty to disclose to the public or to patients the omitted information.[16] Therefore, to the extent Plaintiffs assert that Advanced Bionics was under some state law duty to disclose, this amounts to an additional requirement, which § 360k expressly preempts. *See Purcel II*, 2010 WL 2679988, at *6 ("Plaintiffs cite no federal requirement obligating Bionics to warn them that devices were adulterated. These claims . . . impose a requirement in addition to those approved by the FDA—the duty to warn consumers if devices are adulterated—and are therefore preempted by § 360k."). Accordingly, all of Plaintiffs' common law fraud claims are preempted.

VI.

[15] This Court recognizes that this conclusion is different from the holding as to fraudulent misrepresentation claims in *Purcel II*. In that case, the Texas District Court reasoned that "[t]o hold that voluntary fraudulent statements are preempted 'would turn FDA approval of some statements into a free pass to deceive consumers by making other statements.'" 2010 WL 2679988, at *7 (quoting *Riley*, 625 F. Supp. 2d at 788). This Court disagrees, because the FDCA and MDA endow the FDA with ample power to regulate medical device manufacturers, such that manufacturers cannot have a free pass to deceive customers. Also, Sixth Circuit decisions and Kentucky common law jointly dictate that this Court find the fraudulent misrepresentation claims preempted.

[16] Plaintiffs' Complaint lists five different fraudulent omissions, including Advanced Bionics' failure to notify a) that it did not supplement its PMA Application to include the AstroSeal feedthru; b) that it did not test the HiRes 90k device in a simulated environment; c) that it had commenced life cycle testing in an environment which simulated the human body, and within seventy days, 50% of the test devices had failed; d) that there was a history of device failures related to moisture with the Clarion and Clarion II devices; and e) that the company knew in October 2004 that HiRes 90k devices were leaking at the feedthru. Complaint, ECF no. 57, at 50.

Plaintiffs advance manufacturing and design defect claims under both strict liability and negligence. These are related but distinct inquiries, because in Kentucky, products liability focuses on the strict liability of the defendant for inadequacies in the quality of the product, whereas negligence liability focuses on the conduct of the actor. *Montgomery Elevator Co. v. McCullough by McCullough*, 676 S.W.2d 776, 780 (Ky. 1984). Further,

> under the strict liability theory, a supplier or manufacturer is in effect charged with hindsight. That is, it is legally responsible for risks which could not have been known or appreciated at the time of manufacture, but came to light later . . . . This is not true in a negligence case, where the issues turn on what the manufacturer knew or should have known at the time of distribution.

C & S Fuel, Inc. v. Clark Equip. Co., 552 F. Supp. 340, 343-44 (E.D. Ky. 1982).[17] For this reason, it is easier to prove a claim based on strict liability than one based on negligence, and Plaintiffs tend to focus on this claim. In any event, and due to this distinction, the Court will address strict liability recovery first.

A.

Advanced Bionics argues that Plaintiffs' strict liability claims for the Vendor B HiRes 90k are both expressly and impliedly preempted. To determine express preemption according to the *Riegel* test, this Court must first determine whether federal regulations provide requirements

[17] The Court recognizes that under Kentucky law, design defect claims are not so easily compartmentalized between strict liability and negligence. In Kentucky, a product is defectively designed where

> the design itself selected by the manufacturer amounted to a defective condition which was unreasonably dangerous. . . . "[T]he distinction between the so-called strict liability principle and negligence is of no practical significance as far as the standard of conduct required of the defendant is concerned. In either event the standard required is reasonable care."

Nichols v. Union Underwear Co., Inc., 602 S.W.2d 429, 433 (Ky. 1980)(quoting *Jones v. Hutchinson Mfg., Inc.*, 502 S.W.2d 66, 69-70 (1973)). However, the theories of liability are distinct in that the negligence theory requires the plaintiff to show that the manufacturer knew of the defect at the time of distribution, whereas the strict liability theory assumes so. *Jordan v. Massey Ferguson, Inc.*, 100 F.3d 956, at *2 (6th Cir. 1996).

applicable to this device that caused the device's defective condition.[18] Second, the Court will determine whether the state law strict liability claim imposes an additional or different requirement.

Under the first step, the defect must be premised on a violation of the FDCA or corresponding regulations. *See Purcel I*, 2008 WL 3874713, at *10-11 ("[The MDA does not preempt Plaintiffs' claims under strict liability, which are predicated solely on violations of federal law.").[19] Here, the Court finds that Plaintiffs have presented enough evidence for a reasonable juror to determine that the product was defective due to violations of two federal requirements.

First, according to Plaintiffs, Advanced Bionics failed to manufacture the Vendor B HiRes 90k in conformity with its PMA Supplement, which only approved the device using the PA&E feedthru.[20] The Sixth Circuit has held that the PMA Supplement imposes federal requirements under the MDA. *See Kemp*, 231 F.3d at 228 (holding that "it is the totality of the design, manufacturing processes, and labeling—when coupled with the prohibition against modifying them—that represents the specific federal requirement 'applicable [under the MDA] to the device'")(quoting 21 U.S.C. § 360k(a)(1)). The PMA Supplement obligates the device manufacturer to comply with its provisions. By substituting the AstroSeal feedthru in noncompliance with the

[18] The Court recognizes that medical device preemption thus imposes an additional element of proof, that the defect is premised on violation of a federal law, that is not traditionally required for a prima facie strict liability case under state law, which makes medical device products liability different from other types of products liability cases under Kentucky law.

[19] Advanced Bionics argues that Plaintiffs did not specify which federal regulation it violated in manufacturing or designing a defective device, and therefore these claims must fail. However, Plaintiffs' Complaint does allege specific federal regulatory violations that are incorporated by reference into the strict liability claim. Therefore, the Court will not dismiss the products liability claims on this ground.

[20] This Court is examining a claim for Advanced Bionics' deviation from the PMA Supplement #30, not for Advanced Bionics' failure to file or obtain a PMA Supplement for the Vendor B HiRes 90k, because the latter claim is impliedly preempted. Advanced Bionics' failure to file a PMA Supplement is a violation of an administrative obligation, required in the PMA Supplement #30 and in FDCA regulations. A state law claim seeking a remedy for this violation is a disguised claim to privately enforce the federal law, prohibited under 21 U.S.C.§ 337(a). Any derivative claim that the Vendor B HiRes 90k was adulterated as a result of the failure to obtain a PMA Supplement is likewise preempted for the same reasons. *See Purchase*, No. 2:08-cv-02442-JPM, at *3.

PMA Supplement, Advanced Bionics appears to have evaded the FDA's rigorous investigation and testing of the AstroSeal feedthru's safety and effectiveness. A reasonable juror could conclude deviating from the PMA Supplement requirement caused this device to be defective.[21]

Second, Plaintiffs argue that Advanced Bionics' design and manufacture of the Vendor B HiRes 90k violated certain CGMPs, which rendered the device defective. CGMPs are FDA regulations setting standards for manufacturing practices, which are incorporated by reference into the PMA.[22] Most of these CGMPs impose only administrative standards or flexible guidelines rather than mandate manufacturing requirements. However, the Sixth Circuit recognized that some CGMPs may be specific enough to constitute a valid federal requirement. *Howard v. Sulzer Orthopedics, Inc.*, 382 F. App'x 436, 440-41 (6th Cir. 2005); *see also Lohr*, 518 U.S. at 499-501. In such a case, the CGMP may impose obligations beyond those specifically approved for that device by the FDA in its PMA, *Howard*, 382 F. App'x at 441, and still impose a federal requirement under *Riegel*. The CGMP provision cannot be "so vague as to be incapable of enforcement." *Howard*, 382 F. App'x at 440. Rather, the CGMP must "impose a concrete requirement on a manufacturer that embodies a standard of care related to the safety and effectiveness of the device."

[21] This holding is also consistent with the oft-cited opinion of Judge Richard Kyle in the District Court for the District of Minnesota. *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147 (D. Minn. 2009). In that opinion, Judge Kyle determined that "*Riegel* left open a back door for plaintiffs: claims alleging that a manufacturer failed to adhere to the specifications imposed by a device's PMA are not preempted. Such claims are not preempted because they merely 'parallel' federal requirements–that is, they do not *add to* or *differ from* federal requirements, which is the cornerstone of FDCA preemption." *Id.* at 1152 (internal citations omitted). This decision overall is relatively austere, as Judge Kyle found that only these types of claims can survive preemption. *See id.* at 1161 ("As a result, when Sections 337(a) and 360k–as construed in *Buckman* and *Riegel*, respectively–are read together, nearly all types of claims concerning FDA-approved medical devices are preempted."), *aff'd* 623 F.3d 1200 (8th Cir. 2010).

[22] The CGMPs require medical device manufacturers to adopt procedures and controls, including "1) design control; 2) a quality assurance program; 3) adequate written cleaning procedures and schedules to meet manufacturing process specifications; 4) written manufacturing specifications and processing procedures; 5) process validation; 6) written procedures for finished device inspection to assure that device specifications have been met; and 7) corrective and preventive action." Daniel W. Whitney, *Guide to Preemption of State-Law Claims Against Class III PMA Medical Devices*, 65 FOOD & DRUG L.J. 113, 116 (2010)(internal quotations omitted).

Purchase, 2011 WL 9688280, at *3. The Court finds that the CGMP requiring Advanced Bionics to test products under actual or simulated use conditions is specific enough to support a parallel claim.[23] 21 C.F.R. § 820.30(g).

Even though Advanced Bionics argues that it complied with testing mandated in the PMA Supplement, Plaintiffs have presented sufficient evidence that Advanced Bionics did not conduct testing under actual or simulated use conditions, as 21 C.F.R. § 820.30(g) requires. These testing failures could have caused the implant to be defective and unreasonably dangerous. Other CGMPs cited in the Complaint are too general to impose a federal requirement on medical device manufacturers, such that enforcing a state law claim based on violations of those CGMPs would impose an additional requirement on manufacturers, which is preempted under 21 U.S.C. § 360k.[24]

B.

Having found that Plaintiffs presented two federal requirements that Advanced Bionics allegedly violated in satisfaction of the first *Riegel* step, the Court now examines whether the state law cause of action presents a parallel claim. For strict liability claims, Kentucky courts adopted the Restatement (Second) of Torts § 402A definition for manufacturing defects, under which "the

[23] In *Howard*, the Sixth Circuit addressed a different CGMP, 21 C.F.R. § 820.70(h). The Sixth Circuit reasoned that one could read this CGMP to either impose a federal requirement—that manufacturing materials must be removed during the cleaning process—or to require compliance with the PMA-prescribed cleaning process. 382 F. App'x at 440. The Court read the CGMP to impose a requirement of actual removal. *Id.* at 441. Advanced Bionics argues that the CGMP at issue here merely requires compliance with those testing processes approved by the FDA in the PMA Supplement, and any requirement beyond the PMA-approved testing would thus be expressly preempted. This Court disagrees. Here, the CGMP requires that the medical device be tested under actual or simulated use conditions, while the PMA Supplement required particular methods of testing that were arguably not under actual or simulated use conditions. Therefore, Advanced Bionics could comply with the PMA Supplement-approved testing and still violate 21 C.F.R. § 820.30(g). Accordingly, the Court reads this CGMP to impose a federal requirement that is more than mere compliance with the PMA Supplement-approved testing processes.

[24] To the best of this Court's understanding, Plaintiffs allege manufacturing and design defect claims, as well as negligence claims, on violations of the following CGMPs: 21 C.F.R. § 820.20(c); 21 C.F.R. § 820.22; 21 C.F.R. § 820.25(b); 21 C.F.R. § 820.30(f); 21 C.F.R. § 820.50(a)(1); 21 C.F.R. § 820.70; 21 C.F.R. § 820.75; 21 C.F.R. § 820.90; and 21 C.F.R. § 820.100. This Court finds these CGMPs too vague to be enforceable.

defendant is held strictly liable if the plaintiff proves the product was 'in a defective condition unreasonably dangerous to the user or consumer.'" *Greene v. B.F. Goodrich Avionics Sys., Inc.*, 409 F.3d 784, 788 (6th Cir. 2005)(quoting *Montgomery Elevator Co.*, 676 S.W.2d at 780).[25] Kentucky law considers several factors to determine wether a defect is unreasonably dangerous, including the presence of warnings, the expectations and knowledge of the ordinary consumer, the obviousness of the danger, industry standards, the feasibility of alternative designs, subsequent maintenance and repair, and consumer misuse. *Jordan*, 100 F.3d 956, at *2. Moreover, the plaintiff must prove that the defendant's conduct was a substantial factor in causing the plaintiff's injury, but need not prove that the manufacturer was at fault. *Greene*, 409 F.3d at 788.

In analyzing defective design claims, Kentucky courts inquire into "whether the manufacturer that placed in commerce the product made according to an intended design acted prudently, i.e., was the design a defective condition which was unreasonably dangerous." *Nichols*, 602 S.W.2d at 433. The plaintiff must show that the "'design itself selected by the manufacturer'–the plan, structure, choice of materials, and specifications–was unreasonably dangerous." *Low v. Lowe's Home Centers, Inc.*, 771 F. Supp. 2d 739, 741 (E.D. Ky. 2011)(quoting *Jones*, 502 S.W.2d at 69). Kentucky law allows a risk-utility analysis in design defect cases, which "thereby implicitly require[s] proof of a reasonable alternative design without explicitly doing so." *Toyota Motor Corp. v. Gregory*, 136 S.W.3d 35, 42 (Ky. 2004); *see also Low*, 771 F. Supp. 2d at 741.

[25] The *Greene* Court determined that

> [t]he Restatement (Second) of Torts provides that "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. "Defective" means that the product does not meet the reasonable expectations of the ordinary consumer as to its safety.

Id. at 789 (internal citations and quotations omitted).

The PMA approval process and the CGMPs, like state law strict liability claims, are designed to prevent manufacturers from introducing unreasonably dangerous products into the stream of commerce. Considering all of this, the Court concludes that, as a general matter, Plaintiff's claims under Kentucky common law strict liability do not impose requirements in addition to or different from those mandated under federal law.[26] However, this does not mean that every strict liability claim escapes preemption. The Court finds that Plaintiffs have alleged only two viable parallel claims that are not expressly preempted: (1) that Advanced Bionics violated the FDCA by deviating from the PMA Supplement, and (2) that Advanced Bionics failed to comply with the CGMP mandating actual or simulated use testing.

C.

Finally, the Court must consider whether strict liability under either of these theories may be impliedly preempted. Strict liability arising from a defect caused by the failure to properly test the Vendor B HiRes 90k exists under Kentucky law regardless of whether the FDA enacted 21 C.F.R. § 820.30(g). This theory of strict liability is not impliedly preempted. However, the argument that Kentucky law allows for recovery under strict liability for a defect caused by the failure to adhere to the PMA Supplement independent of the federal law requirement is a bit more attenuated.

According to the medical device implied preemption doctrine, plaintiffs have no private right of action to directly enforce federal regulations. Plaintiffs cannot allege state law causes of action that are in reality veiled attempts to directly enforce federal regulations. Therefore, for a state law

[26] This holding is consistent with the holding of Judge Starrett, District Judge for the Southern District of Mississippi, in an earlier case against Advanced Bionics over the HiRes 90k. *Hearn v. Advanced Bionics Corp.*, 2:06-cv-114, Oral Bench Op., at 9 (S.D. Miss. Nov. 5, 2007)("The manufacturing defect, well, that's the lawsuit. If it was manufactured as set forth in the advanced marketing approval, then there is no claim. If it was not, then there is. So that's an issue of fact that will be determined by the jury.").

cause of action to survive implied preemption, the state law claim must exist regardless of whether the FDA promulgated these regulations. In other words,

> a private litigant cannot 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–that is, when the state claim would not exist if the FDCA did not exist. So, for example, a state-law claim that the defendant made misrepresentations to the FDA is preempted because such a claim would not exist absent the federal regulatory scheme established by the FDCA. . . . [T]he conduct on which the claim is premised must be the type of conduct that would traditionally give rise to liability under state law–and that would give rise to liability under state law even if the FDCA had never been enacted. If the defendant's conduct is not of this type, then the plaintiff is effectively suing for a violation of the FDCA (no matter how the plaintiff labels the claim), and the plaintiff's claim is thus impliedly preempted under *Buckman*.

Riley, 625 F. Supp. 2d at 776-77 (internal citations omitted).

Without the FDCA, corresponding federal regulations, and the PMA Supplement itself all requiring companies to follow the PMA Supplement, this claim, when considered quite literally, may fail. However, the PMA Supplement process involves rigorous investigation and testing. Approval of the PMA Supplement reflects the federal government's determination that the manufacturer had indeed designed a product and established a manufacturing system that ensures the medical device's safety and effectiveness. In essence, like 21 C.F.R. § 820.30(g), the requirement to follow the PMA Supplement provides that manufacturers have undergone certain processes to ensure that the product is not unreasonably dangerous when it enters the stream of commerce. The failure to subject the device to this safety and effectiveness assurance procedure may well have led to the dangerous condition at issue here. State law provides recovery under strict liability for unreasonably dangerous products, and would likely allow plaintiffs to premise the defect upon evidence that the manufacturer failed to submit its product to proper safety and effectiveness testing.

Therefore, the Court concludes that the strict liability claim based upon deviation from the PMA Supplement is not impliedly preempted, because this claim would have existed under state law absent the federal regulations requiring compliance with the PMA Supplement.

VII.

Advanced Bionics next argues that it is entitled to summary judgment as to Plaintiffs' negligence claims for two reasons: 1) Plaintiffs did not allege sufficient factual or legal support for their claims, and 2) these claims are expressly preempted.

A.

Examining the sufficiency of the negligence claim, to the best of the Court's understanding, Plaintiffs' Complaint alleges that Advanced Bionics was negligent in the following ways:

(1) by incorporating a design defect into the design of the HiRes 90k;

(2) by failing to manufacture the HiRes 90k within FDA-applicable standards of care for testing, validating, and qualifying the AstroSeal feedthru;

(3) by manufacturing a defective HiRes 90k;

(4) by failing to warn Plaintiffs of the risk that the HiRes 90k would not be hermetically sealed;

(5) by failing to notify and warn the FDA, Breanna's treating physicians, Plaintiffs, and the public of the manufacturing defects;

(6) by failing to qualify and validate the Hires 90k with an AstroSeal feedthru;

(7) by failing to test the Hires 90k with an AstroSeal feedthru under actual or simulated use conditions; and

(8) by failing to perform life cycle testing on the HiRes 90k with an AstroSeal feedthru.

Plaintiffs do not allude to specific federal regulations in the negligence section of their Complaint. However, the Complaint presents applicable federal requirements in enough detail to specify which acts of negligence violate specific federal laws.[27] Moreover, Plaintiffs provide a wide array of factual evidence to support a reasonable juror's conclusion that Advanced Bionics indeed violated some these regulations.[28] This Court has previously found a complaint inadequate to assert state law claims for violations of the FDCA where the complaint did not "identify any particular design flaw, manufacturing impropriety or product defect" and failed to assert the violation of a PMA-specific standard or CGMP regulation. *White v. Stryker Corp.*, 818 F. Supp. 2d 1032, 1039 (W.D. Ky. 2011). The Complaint here is not subject to these same errors. Accordingly, the Court finds that Plaintiffs alleged sufficient factual and legal support to satisfy their obligations in asserting negligence claims.[29]

B.

Nevertheless, a few of these negligence theories are decidedly preempted. Plaintiffs' negligence claims based on allegations that Advanced Bionics made misrepresentations or material omissions to the FDA, Plaintiffs or the public, are preempted for the reasons stated above. Plaintiffs' negligence claim based on Advanced Bionics' failure to conduct life cycle testing is preempted, because Plaintiffs do not cite any federal regulations that require life cycle testing. To

[27] Plaintiffs cite Paragraph 175 of their Amended Complaint to demonstrate that all factual allegations presented in the previous paragraphs of the Complaint are incorporated by reference into the negligence count. Defendants argue that because Paragraph 175 does not in fact incorporate the preceding paragraphs, Plaintiffs' reliance on that paragraph requires dismissal of the negligence claim. However, this was an apparent typographical error, and Plaintiffs' Paragraph 195 has this effect. The Court will not dismiss the negligence claims on this ground.

[28] The Court notes that both parties have submitted a number of motions *in limine* regarding the admissibility of this evidence, which the Court has taken under submission. The Court refuses to rule on any of these motions at this time.

[29] However, the Court recognizes that Plaintiffs ground some of their theories of negligence on violations of CGMPs that are not specific enough to constitute a federal duty upon which a state law claim can be founded, and therefore these theories of negligence have insufficient legal support. Nevertheless, the evidence of violations of those CGMPs may be relevant for other purposes at trial, and the Court refrains from ruling on their admissibility at this time.

impose an obligation to perform life cycle testing would require an additional duty under state law, which is expressly preempted under § 360k. The remaining claims can be broken down into four categories: negligent design, negligent manufacturing, failure to comply with PMA and FDCA requirements, and failure to test under actual or simulated use conditions.

Beginning with the negligent design and manufacturing claims, according to the first step in the *Riegel* test, the defect must arise from violations of federal law. As best this Court can conceive from the briefs, Complaint, and lengthy telephonic conferences, Plaintiffs' negligent manufacturing and design claims are based on the failure to test under actual or simulated use conditions and failure to comply with PMA and FDA requirements, which are themselves asserted as distinct theories of negligence.

As this Court has already explained, the obligations to follow the PMA Supplement and to test under actual or simulated use conditions pursuant to 21 C.F.R. § 820.30(g) are viable federal requirements under *Riegel*. Negligence claims based on a violation of these requirements also satisfy the second step in the *Riegel* test. In Kentucky, a negligence case 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). Here, the duty of care owed and breach of that duty derive from federal law violations, and therefore, the negligence claims do not impose different or additional requirements. Based on the four remaining and interwoven negligence theories, the Court finds that Plaintiffs' negligence claims survive preemption.[30]

[30] Advanced Bionics does not appear to argue that Plaintiffs' negligence claims are also impliedly preempted. Even in its lengthy section devoted to negating Plaintiffs' negligence *per se* claims, which analyze these four theories under medical device preemption, Advanced Bionics does not argue that these claims are impliedly preempted. For that reason, the Court does not devote another subsection to this issue. Rather, for the reasons indicated above, these

VIII.

Finally, Advanced Bionics argues that Michelle and Brian Sadler cannot recover non-economic damages sustained as a result of the malfunctioning of Breanna's cochlear implant, because Kentucky subscribes to the physical impact rule. Under this rule, plaintiffs are unable to recover for emotional damages unless the plaintiffs sustained some level of physical contact with the source of the injury. *Osborne v. Keeney*, -- S.W.2d ----, 2012 WL 6634129, at *7 (Ky. Dec. 20, 2012). The Kentucky Supreme Court recently abrogated the physical impact rule in favor of a more relaxed rule allowing for recovery irrespective of contact, so long as the plaintiff satisfies the elements of the negligence claim. *Id.* at *8. Still, Plaintiffs must prove "serious" or "severe" emotional injuries, "where a reasonable person, normally constituted, would not be expected to endure the mental stress engendered by the circumstances of the case." *Id.* at *9. Because the Kentucky Supreme Court published its opinion after both parties briefed this motion, the Court will refrain from deciding whether Plaintiffs have alleged sufficient facts to constitute severe emotional injuries as imagined in *Osborne*. Nevertheless, the *Osborne* decision effectively nullifies Advanced Bionics' argument, and accordingly, the Court will deny the motion for summary judgment on Michelle and Brian Sadlers' claims for emotional damages.

Being otherwise sufficiently advised,

IT IS HEREBY ORDERED that Advanced Bionics' motion for summary judgment as to Plaintiffs' claims of fraud, negligence *per se* and breach of implied warranty are SUSTAINED and those claims are DISMISSED.

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claims are not impliedly preempted.

IT IS FURTHER ORDERED that Advanced Bionics' motion for summary judgment as to Plaintiffs' strict liability claims is DENIED as to those theories discussed within this opinion.

IT IS FURTHER ORDERED that Advanced Bionics' motion for summary judgment as to Plaintiffs' negligence claims is SUSTAINED for those claims based on fraudulent misrepresentations, fraudulent omissions, and failure to conduct life cycle testing, and DENIED as to all other grounds as discussed within this opinion.

IT IS FURTHER ORDERED that Advanced Bionics' motion for summary judgment on Michelle and Brian Sadler's emotional damages claims is DENIED.

March 7, 2013

John G. Heyburn II, Judge
United States District Court

cc: Counsel of Record