IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OKLAHOMA

PAUL LITTLEBEAR, *individually*,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 11-cv-418-GKF-PJC
	)	
ADVANCED BIONICS, LLC,	)	
	)	
Defendant.	)	

OPINION AND ORDER

This matter comes before the court on defendant Advanced Bionics's motion for summary judgment and memorandum of law in support. (Doc. #40).

I. Background

Advanced Bionics manufactures cochlear implants, a medical device for the deaf. The model at issue is the HiRes90K. The HiRes90K is designed to provide useful hearing to people with severe hearing loss via electrical stimulation. The external components include a sound processor, a head piece, and a cable. The internal components include a surgically implanted receiver and electrode array. The HiRes90k contains a "feedthru" assembly that allows contact between the internal and external components. The feedthru need be waterproof or damage to the device and user could occur. *See generally In re Advanced Bionics Corp.*, Administrative Complaint for Civil Penalties (Doc. #73-8).

Advanced Bionics applied for a Supplemental Pre-Market Approval ("PMA") to sell HiRes90K on March 17, 2003. The application included a feedthru supplied by Pacific Aerospace & Electronics, Inc. ("PA&E"). On July 7, 2003, the FDA approved the PMA. Since

that approval, Advanced Bionics has applied for 27 PMA supplements concerning HiRes90K. (Doc. #73-8 ¶4).

After receiving the July 7, 2003 approval, Advanced Bionics contracted with a new supplier, AstroSeal, for the feedthru assembly. Advanced Bionics did not file a supplemental PMA application regarding that change. When the FDA later discovered an excessive moisture problem in the HiRes90K that exposed patients to risk of device failure, surgical intervention, and possible permanent hearing loss, FDA sent a Warning Letter to Advanced Bionics. (*Id.* ¶¶6-7). The February 1, 2005 letter noted the deviations from the Good Manufacturing Practice requirements, and Advanced Bionics determined the moisture problem related to the feedthru assembly. (*Id.* ¶7). Advanced Bionics voluntarily recalled the HiRes90K devices using AstroSeal feedthru assemblies on March 8, 2006. (*Id.* ¶8).

FDA Administrative Complaint. On November 2, 2007, the FDA brought an administrative complaint against Advanced Bionics for "Bionics' failure to file a required PMA supplement for changes to the HiRes90K device, including the failure to seek approval for the change in supplier of the feedthru assembly." (*Id.* at 13). Thus, the FDA claimed each HiRes90K device using an AstroSeal feedthru was an "adulterated" device under FDA regulations and Advanced Bionics did "not have an approved application for premarket approval in effect" for those devices. (*Id.* at 23 ¶28). The FDA and Advanced Bionics settled that proceeding.

Paul Littlebear's HiRes90K Device. Littlebear had a HiRes90K utilizing an AstroSeal feedthru implanted on July 26, 2004. (Doc. #2 ¶181). The HiRes90K was explanted on July 29, 2010. (*Id.* ¶188). Littlebear's device contained 46% water vapor when explanted and failed due to excessive moisture leaking through the AstroSeal feedthru. (*Id.* ¶187). Littlebear alleges the

following causes of action: (1) negligence, (*id.* ¶¶193-202); (2) strict liability – design and/or manufacturing defect, (*id.* ¶¶203-211); (3) negligence per se, (*id.* ¶¶212-226); (4) breach of implied warranties, (*id.* ¶¶227-236); (5) common law fraud, (*id.* ¶¶237-246); and (6) deceptive, unfair, fraudulent, and/or tortious business practices/the Oklahoma Consumer Protection Act, (*id.* ¶¶247-260).[1]

II. The FDA and Preemption

Medical devices are placed in three classes based on the Medical Device Amendments of 1976 to the Food, Drug, and Cosmetic Act ("FDCA"). 21 U.S.C. §§ 360c *et seq.* The HiRes90k cochlear implant falls into the most highly-regulated group, Class III medical devices, which requires "a rigorous process" of pre-market approval before a product may be sold. *Reigel v. Medtronic, Inc.*, 552 U.S. 312, 317-18 (2008). "A supplemental application shall be required for any change to a device subject to an approved application under this subsection that affects safety or effectiveness." 21 U.S.C. § 360e(d)(6)(A)(ii); 21 C.F.R. § 814.39(a)(3); *see also Purcel v. Advanced Bionics Corp.*, 07-cv-1777, 2010 WL 2679988 (N.D. Tex. June 30, 2010) (*Purcel I*) ("Any modification affecting the safety or effectiveness of an approved device… must receive supplemental premarket approval."); *Reigel*, 552 U.S. at 319 ("Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA

[1] Littlebear's allegations for negligent and intentional infliction of emotional distress are no longer pending. First, Littlebear acknowledged that Oklahoma does not recognize an independent claim for negligent infliction of emotional distress. *Kraszewski v. Baptist Med. Ctr. of Okla., Inc.*, 916 P.2d 241, 243 n.1 (Okla. 1996) ("negligent infliction of emotional distress is not an independent tort"). The claim is subsumed by Littlebear's negligence claim. *Lockhart v. Loosen*, 943 P.2d 1074, 1081 (Okla. 1997) ("Under Oklahoma's jurisprudence the negligent causing of emotional distress is not an independent tort, but is in effect the tort of negligence."); Pl.'s Resp. (Doc. #73 at 30) (acknowledging "the negligence [sic] infliction of emotional distress claim is properly subsumed into his negligence claim"). Second, Littlebear withdrew his IIED claim. Pl.'s Resp. (Doc. #73 at 30).

permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness."). Because of the painstaking detail required for premarket approval, "the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application." *Riegel*, 552 U.S. at 323.

After premarket approval, the FDA subjects devices to reporting requirements, *see* 21 U.S.C. §360i, including obliging companies to inform the FDA of "new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know of, 21 CFR § 814.84(b)(2), and to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred, § 803.50(a)." *Riegel*, 552 U.S. at 319-20.

The FDA also requires manufacturers of Class III devices, including cochlear implants, to comply with Current Good Manufacturing Practices ("CGMP"). Devices not satisfying CGMP requirements are considered "adulterated" under 21 U.S.C. § 351(f), (h). *See* 21 C.F.R. § 814.39(a).

The Medial Device Amendments further provided an express preemption provision, 21 U.S.C. § 360k(a), and the Supreme Court has found some state causes of action are impliedly preempted by the FDA's role, *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001).

A. Express Preemption

The Medical Device Amendments express pre-emption clause provides:

> 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 exception contained in subsection (b) permits the FDA to exempt some state and local requirements from pre-emption. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). The court must determine "whether [plaintiff's] common-law claims are based upon [Oklahoma] 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)).

B. Implied Preemption

Because the FDA approval process created numerous new duties and requirements for device makers, plaintiffs filed lawsuits asserting companies had failed to comply with those new duties. In *Buckman*, 531 U.S. at 348, the Supreme Court held that "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law." Thus, any allegations that are functionally a state law claim that a company defrauded the FDA are impliedly preempted. Past decisions "allow certain state-law causes of actions that parallel federal safety requirements, [they] do[] not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim." *Id.* at 352-53.

A recent decision in this court explains the narrow opening for plaintiffs bringing state law claims concerning class III medical devices:

> *Riegel* and *Buckman* 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.

Howard v. Sulzer Orthopedics, Inc., 796 F. Supp. 2d 1305, 1310 (N.D. Okla. 2011) (quoting *Riley v. Cordis Corp.*, 625 F.Supp.2d 769, 777 (D. Minn. 2009) (emphasis in original)).

III. Discussion

A. Summary Judgment

Summary judgment shall be granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Federal Rule of Civil Procedure 56(a) "mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Adler v. Wal-Mart Stores, Inc*., 144 F3d 664, 670 (10th Cir. 1998). A court must examine the factual record in the light most favorable to the party opposing summary judgment. *Wolf v. Prudential Ins. Co. of Am.*, 50 F.3d 793, 796 (10th Cir. 1995).

When the moving party has carried its burden, "its opponent must do more than simply show that there is some metaphysical doubt as to the material facts . . . Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no 'genuine issue for trial.'" *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986) (citations omitted). "An issue is 'genuine' if there is sufficient evidence on each side so that a rational trier of fact could resolve the issue either way. An issue of fact is 'material' if under the substantive law it is essential to the proper disposition of the claim." *Adler*, 144 F.3d at 670. In essence, the inquiry for the court is "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251-52 (1986).

B. Previous HiRes90K Preemption Decisions

Given the many HiRes90K devices that used AstroSeal, the legal issues presented here are not novel. Other patients have brought suit against Advanced Bionics on similar grounds in other district courts.

Those courts have decided the preemption issues differently, although all permitted some claims to proceed. *Purcel v. Advanced Bionics Corp.*, Case No. 07-cv-1777, 2008 WL 3874713 (N.D. Tex. Aug. 13, 2008) ("*Purcel I*") (finding no pre-emption of Texas strict liability or implied warranty of merchantability claims); *Purcel v. Advanced Bionics Corp.*, Case No. 07-cv-1777, 2010 WL 2679988 (N.D. Tex. June 30, 2010) ("*Purcel II*") (finding no pre-emption of Texas products liability, breach of implied warranty of merchantability, breach of express warranty, fraud and some negligence claims; finding pre-emption of fraud by nondisclosure and some negligence claims); *Hearn v. Advanced Bionics Corp.*, 06-cv-1114 (S.D. Miss. Nov. 5, 2007) (finding some claims preempted) ("*Hearn I*"); *Hearn v. Advanced Bionics Corp.*, 06-cv-114, 2008 WL 3896431, at *4 (S.D. Miss. Aug. 19, 2008) (describing *Hearn I* decision as "careful not to detail exactly which state law claims were preempted" and noting if "Advanced Bionics never had properly obtained pre-market approval for the device that injured Hearn, then the pre-emption defense would presumably fail") ("*Hearn II*"); *Lannon v. Advanced Bionics Corp.*, Case No. 09-cv-1192 (W.D. Wash. Jan. 29, 2010) (denying 12(b)(6) motion based on pre-emption for all claims in minute order) ("*Lannon* Order"); *Purchase v. Advanced Bionics, LLC*, 08-cv-2442 (W.D. Tenn. Aug. 4, 2011) ("*Purchase* Order") (finding claims based on failure to submit a supplemental PMA and failure to identify the feedthru change in defendant's annual report are pre-empted; finding claims based on deviation from manufacturing and design requirements in the PMA and failure to perform testing under actual or simulated use conditions

with the AstroSeal feedthru are not pre-empted). None of these cases took place within the Tenth Circuit.

C. Express Preemption

All claims predicated on Advanced Bionics not keeping the moisture level below 0.5% are expressly preempted. The FDA approval did not specify such a requirement. Thus, any such standard would be "different from, or in addition to" the FDA standard. 21 U.S.C. § 360k(a).

All claims predicated on failure to evaluate AstroSeal as a supplier are also expressly preempted. The only relevant FDA regulation on vendor evaluation is a Current Good Manufacturing Practice ("CGMP") requiring manufacturers to "[e]valuate and select potential suppliers… on the basis of their ability to meet specified requirements, including quality requirements." 21 C.F.R. § 820.50(a). This requirement is too vague and generalized to support a parallel claim. *Purchase* Order at 7 (finding several CGMP requirements "too generic to provide a requirement that could support a parallel claim"); *see also Cottrell, Ltd. v. Biotrol Int'l, Inc.*, 191 F.3d 1248, 1255 (10th Cir. 1999) ("claims that require direct interpretation and application of the FDCA are not properly recognized").

Littlebear's claims for common law fraud and violations of the Oklahoma Consumer Protection Act, 15 O.S. § 751 *et seq.* are expressly preempted. Littlebear does not claim Advanced Bionics made any affirmative misrepresentations to him or his doctors, but rather that Advanced Bionics had a duty to inform him or his doctors that the company was using a different feedthru than the FDA approved. This fraud by nondisclosure is expressly preempted. Because Littlebear does not identify an FDA regulation requiring Advanced Bionics to inform him of such changes, this asserted duty would be "different from, or in addition to" the FDA reporting requirements. 21 U.S.C. § 360k(a); *see also Purcel II* at *6 ("claims of fraud by nondisclosure and negligence by failure to warn impose a requirement in addition to those

approved by the FDA–the duty to warn consumers if devices are adulterated–and are therefore pre-empted by § 360k(a)"). The OCPA claim relies on the same fraud by nondisclosure and is preempted for the same reasons.

D. Implied Preemption

All claims predicated on the failure to obtain supplemental PMA approval to use the AstroSeal feethru are impliedly pre-empted. PMA approval is an administrative requirement created by the FDA, not a substantive safety requirement of state law. The MDA and the FDCA do not provide a private right of action. And no pre-existing state law duty existed requiring such supplemental approval. *See Purchase* Order at 3-4; *see also Buckman*, 531 U.S. 341.

All claims predicated on the failure to comply with adverse event reporting requirements are impliedly pre-empted. The adverse event reporting requirements are not substantive safety requirements under state law, but rather administrative requirements. Thus, the claim is impliedly pre-empted. *Cf. Purchase* Order at 4 (failure to notice change in feedthru component in annual report concerned administrative requirement, and thus, was impliedly pre-empted).

E. Not Preempted

Claims predicated on the deviation from the FDA-approved specification by using the AstroSeal feedthru are not preempted. Claims predicated on the failure to comply with specific CGMPs in the manufacturing of the implants are not preempted. And claims predicated on the failure to test under actual or simulated use conditions are not preempted. These claims properly allege state law claims that parallel federal regulatory requirements, 21 C.F.R. §§ 814.39(b), 820.30(g). *See* Purchase Order at 5-7. Thus, they fit in the "narrow gap" between express and implied preemption. *Howard*, 796 F. Supp. 2d at 1310 ("suing for conduct that *violates* the FDCA, but [not] suing *because* the conduct violates the FDCA").

F. Grounds for Summary Judgment Other Than Preemption

1) *Strict Liability (Claim II)*

Advanced Bionics incorrectly argues the cochlear implant is an "inherently unsafe product" exempt from strict liability under Oklahoma law. Oklahoma law prohibits strict liability in cases involving "common consumer product[s] intended for personal consumption" in which the risk was "known by the ordinary consumer." 76 O.S. § 57; *see also* Restatement (Second) of Torts § 402A, cmt. k (1965) ("The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk."). While the exemption applies to medical devices, it only applies when "the product is properly manufactured and contains adequate warnings." *Tansy v. Dacomed Corp.*, 890 P.2d 881, 886 (Okla. 1994). Whether the HiRes90k using an AstroSeal feedthru was properly manufactured is the dispositive–and disputed–issue in this case. Summary judgment is denied on the strict liability claims.

2) *Negligence Per Se (Claim III)*

The FDCA does not provide a private right of action. *Rimbert v. Eli Lilly & Co.*, 577 F. Supp. 2d 1174, 1205 (D.N.M. 2008) ("Private litigants cannot enforce the Federal Food, Drug and Cosmetic Act through private actions."). And the Tenth Circuit

> has indicated that the FDCA does not create a private right of action to enforce or restrain violations of its provisions. While the [District] Court might be prepared to draw a distinction between private rights of action and claims for negligence per se, the Tenth Circuit's quotation from *Braintree* that "claims that require direct interpretation and application of the FDCA are not properly recognized" seems, fairly read, to prohibit negligence per se claims based on the FDCA and its regulations.

Id. at 1239; *see also Howard v. Sulzer Orthopedics, Inc.*, 796 F. Supp. 2d 1305, 1313 (N.D. Okla. 2011) ("[b]ecause plaintiffs are not members of a class meant to be protected by the statute, there is no negligence per se claim"). Summary judgment is granted to Advanced Bionics on the negligence per se claims.

IV. Conclusion

WHEREFORE, Advanced Bionics's motion for summary judgment is granted in part and denied in part. Advanced Bionics is granted summary judgment on Littlebear's claims for negligence per se, common law fraud, Oklahoma Consumer Protection Act violations, negligent infliction of emotional distress, and intentional infliction of emotional distress. Additionally, any claims based on Advanced Bionics not keeping the moisture level below 0.5%, not evaluating AstroSeal as a supplier sufficiently, not obtaining supplemental PMA approval to use the AstroSeal feedthru, and not complying with adverse event reporting requirements are preempted expressly or impliedly by federal law.

Summary judgment is denied as to Littlebear's remaining negligence and strict liability claims based on deviations from the FDA-approved specification, failure to comply with CGMP in the manufacturing of the implants, and failure to test under actual or simulated use conditions.

DATED this 19th day of December, 2012.

GREGORY K. FRIZZELL, CHIEF JUDGE
UNITED STATES DISTRICT COURT