UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OKLAHOMA

BRIAN C. HOWARD, M.D. and SUZANNE HOWARD,	)	
Plaintiffs,	)	
v.	)	**Case No. 02-CV-0564-CVE-FHM**
SULZER ORTHOPEDICS, INC., SULZER MEDICA USA HOLDING CO., SULZER MEDICA USA, INC.,[1] and ZIMMER, INC.,	)	
Defendants.	)	

OPINION AND ORDER

Now before the Court are Centerpulse Orthopedics Inc.'s Renewed Motion for Summary Judgment on Plaintiff's [sic][2] Negligence *Per Se* Claim (Dkt. # 136) and Plaintiffs' Response and Objection to Sulzer's "Renewed Motion for Summary Judgment on Plaintiff's [sic] Negligence *Per Se* Claim" and Plaintiffs' Counter-Motion for Partial Judgment on Liability (Dkt. # 139). Defendants filed Centerpulse Orthopedics Inc.'s Reply in Support of its Renewed Motion for Summary [Judgment] and Opposition to Plaintiff's [sic] Counter-Motion for Partial Judgment on

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[1] Plaintiffs' complaint was filed against Centerpulse, Ltd., Centerpulse AG, Sulzer Orthopedics, Inc., Sulzer Orthopedics, Ltd., Sulzer AG, Sulzer Medica USA Holding Co., Sulzer Management AG, Sulzer Medica Management AG, and Sulzer Medica USA, Inc. (collectively referred to as "Sulzer"). However, the parties have since stipulated that the proper defendant in this case is now Zimmer, Inc. Dkt. # 159, at 1. Zimmer, Inc. is a Delaware corporation, with its principal place of business in Indiana, Case No. 10-cv-00511-CVE-FHM, Dkt. # 2, at 2, and the Court therefore retains jurisdiction under 28 U.S.C. § 1332.

[2] The parties have stipulated that both Brian Howard and Suzanne Howard are proper parties in this case. Dkt. # 159, at 1.

Liability (Dkt. # 140), and plaintiffs filed Plaintiffs' Reply Brief in Support of Their Counter-Motion for Partial Judgment on Liability (Dkt. # 142).

I.

The Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq., has long required approval by the Food and Drug Administration (FDA) for the introduction of new drugs into the market. Riegel v. Medtronic, 552 U.S. 312, 315 (2008). However, until the passage of the Medical Device Amendments of 1976 (MDA), 21 U.S.C. § 360c et seq., supervision of medical devices was left largely to individual states. Id. In the wake of large-scale failures of complex devices in the 1960s and 1970s, Congress passed the MDA, which "imposed a regime of detailed federal oversight." Id. at 316. As part of that federal regime, the MDA contains an express preemption clause that 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 –
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> (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 preemption." Riegel, 552 U.S. at 316.

The MDA regulatory regime "establishe[s] various levels of oversight for medical devices, depending on the risks they present:" Class I, subject only to "general controls" such as labeling requirements, for devices like elastic bandages and examination gloves; Class II, subject to "special controls" such as performance standards and postmarket surveillance measures, for devices such as

powered wheelchairs and surgical drapes; and Class III, subject to the most federal oversight. Id. at 316-17 (citing 21 U.S.C. §§ 360c(a)(1)(A-C)). "In general, a device is assigned to Class III if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness, and the device is 'purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health,' or 'presents a potential unreasonable risk of illness or injury.'" Id. at 317 (quoting 21 U.S.C. § 360c(a)(1)(C)(ii)). Class III devices are subject to a "rigorous regime of premarket approval [PMA]." Id.

Plaintiffs' complaint was filed on July 16, 2002, in the Northern District of Oklahoma. Dkt. # 1. In it, they allege that defendants[3] were manufacturers of a prosthesis known as the Sulzer Natural Knee II Tibial Baseplate (NK-II), which was implanted in Brian Howard (Howard) during a knee replacement surgery on or about June 13, 2000. Id. at 5-7. Plaintiffs allege that the NK-II implanted in Howard had residue on it that should have been removed during the manufacturing process. Id. at 2. They claim that the residue "prevented the tibial baseplate from bonding with Dr. Howard's bone and triggered a painful inflammatory response, including extensive inflammation, membrane formation, and bone loss." Id. They further allege that the residue was present because defendants "made changes in the manufacturing process of [the] tibial baseplates to a process that included, but was not limited to, machining them after the porous coating was applied." Id. at 2-3. Howard underwent surgery to replace the implant, after which he allegedly suffered "skin complications." Id. at 7. Plaintiffs' claims are based on those flaws in the manufacturing process that allegedly caused Howard's knee implant to fail. Id. at 2-5, 10-19. Specifically, they initially

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[3] The Court employs the term "defendants" based on the allegations in plaintiffs' complaint, but acknowledges that there is now only one party defendant.

alleged claims for relief based on: strict liability for design defect, manufacturing defect, and failure to warn; negligence; breach of implied warranty; breach of express warranty; deceit by concealment; negligence per se; injunctive and equitable relief in the form of medical monitoring; and loss of consortium. Id. at 10-19.

At the time of plaintiffs' complaint, a number of similar complaints based on the defendants' manufacturing process were being filed As a result, the Judicial Panel on Multidistrict Litigation transferred all federal cases based on the failure of the NK-II to the Northern District of Ohio for multi-district litigation (MDL) pre-trial proceedings. Dkt. # 134, at 2. After identifying which implants had been manufactured with the new process, defendants entered into a settlement agreement with patients who had received them. Id. Plaintiffs' case was not included in the settlement because Howard's device was not in a designated "affected lot." Id. However, plaintiffs allege that Howard's device was similarly affected by flaws in the manufacturing process.

Defendants moved for summary judgment on plaintiffs' claims based on the NK-II's PMA application. They argued that they had properly complied with the PMA process mandated by the MDA, and that plaintiffs' claims were therefore barred by the MDA's express preemption clause. In re Sulzer Hip Prosthesis and Knee Prosthesis Liab. Litig., 455 F. Supp. 2d 709, 711 (N.D. Ohio 2006). The MDL court granted summary judgment for defendants on most of plaintiffs' claims, finding that those based on strict liability, breach of implied and express warranty, and deceit by concealment were preempted by § 360k of the MDA. Id. at 716. It found that plaintiffs' medical monitoring and loss of consortium claims were derivative and, therefore, were preempted to the extent the underlying substantive claims were preempted. Id. at 720 n.13. Thus, the only claim remaining was plaintiffs' negligence per se claim. Id. at 722.

Defendants renewed their summary judgment motion on the negligence per se claim after further discovery. Dkt. # 134, at 3. They argued that plaintiffs lacked sufficient evidence of a genuine issue of material fact that defendants had violated any FDA requirement. Id. Plaintiffs presented several theories as to how defendants had violated FDA requirements, including that Howard's NK-II was actually part of an affected lot, and that Sulzer did not follow the manufacturing process outlined in the NK-II PMA. Id. They also argued that the NK-II PMA required defendants to follow not only the specific manufacturing steps listed in the PMA, but also the more general Good Manufacturing Practices (GMPs)[4] that the PMA incorporated. Id. at 4. The GMPs require, among other things, a process to remove manufacturing materials like lubricating oil. Id. Defendants argued that the GMPs were incorporated into the PMA, and that they were not required to take any steps beyond those outlined in the PMA. Id. The district court rejected most of plaintiffs' arguments as unsupported by the evidence. Id. at 3. It also found that the GMP imposed obligations beyond those in the PMA, and that any claim based on it was preempted. Id. at 4. The district court therefore granted summary judgment on plaintiffs' negligence per se claim.

On August 12, 2010, the Sixth Circuit Court of Appeals reversed the district court's second summary judgment decision, finding that plaintiffs' negligence per se claim was not preempted by federal law. Dkt. # 134, at 5-8. It looked to the GMP relied upon by plaintiffs, which provides that:

> Where a manufacturing material could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount that does not adversely affect the device's quality. The removal or reduction of such manufacturing material shall be documented.

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[4] GMPs are FDA regulations based upon manufacturing standards that apply to all FDA-regulated medical devices. Dkt. # 134, at 4 (citing 21 C.F.R. § 820).

21 C.F.R. § 820.70(h). The Sixth Circuit noted plaintiffs' argument that the "presence of hydrocarbon components that are normally associated with mineral oil on his NK-II me[ant] that [defendants] failed to 'ensure' that [they] had removed manufacturing material in compliance with § 820.70(h)," and noted defendants' contention that they were bound to follow only the PMA-prescribed process for removing oil. Dkt. # 134, at 6. The court thus considered whether compliance with § 820.70(h) requires compliance with a particular process, or whether it requires a specific result – namely, actual removal. Id. at 7. It recognized that, facially, the subsection could be read to support either result. Id. Because the FDA had not interpreted the regulation, the court turned to comments made during rulemaking, as well as FDA guidance documents pertaining to GMPs generally. Id. It found support in both for the view that actual removal is required, and held that "the better reading of [21 C.F.R. § 820.70(h)] . . . is that it requires actual removal." Id. at 8. Therefore, it reversed the district court's finding of preemption as to the negligence per se claim. Id. For purposes of remand, it left open the question of fact as to whether oil was left on the device, as well as whether Oklahoma law recognizes such a negligence per se action. Id. at 9.

Following the decision by the Sixth Circuit, the Judicial Panel on Multidistrict Litigation suggested that the case be remanded to the Northern District of Oklahoma because the class-action lawsuit against defendants had long been settled, and there would be therefore be no continued efficiencies to deciding plaintiffs' claims in the Northern District of Ohio. Dkt. # 143, at 2, 4. It further justified remand by noting that, to the extent additional discovery might be appropriate, the transferor and transferee courts were equally capable of oversight, plaintiffs were never part of the MDL settlement class, and the transferor court had greater familiarity with Oklahoma law. Id. at

4. Thereafter, defendants renewed their motion for summary judgment on plaintiffs' negligence per se claim. Dkt. # 136.

II.

Summary judgment pursuant to Fed. R. Civ. P. 56 is appropriate where there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250 (1986); Kendall v. Watkins, 998 F.2d 848, 850 (10th Cir. 1993). The plain language of Rule 56(c) 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, 477 U.S. at 317. "Summary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed 'to secure the just, speedy and inexpensive determination of every action.'" Id. at 327.

"When the moving party has carried its burden under Rule 56(c), 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. v. Zenith Radio Corp., 475 U.S. 574, 586-87 (1986) (citations omitted). "The mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the [trier of fact] could reasonably find for the plaintiff." Anderson, 477 U.S. at 252. 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." Id. at 250. In its review,

the Court draws "all justifiable inferences," id. at 254, and construes the record in the light most favorable, Garratt v. Walker, 164 F.3d 1249, 1251 (10th Cir. 1998), to the party opposing summary judgment.

III.

Defendants move for summary judgment on plaintiffs' claim for negligence per se. Dkt. # 136, at 6. Plaintiffs object to the motion for summary judgment, and have filed a counter-motion for partial judgment on liability.[5] Dkt. # 139. Defendants argue that they are entitled to summary judgment on plaintiffs' negligence per se claim because it is not recognized under Oklahoma law. In support, they argue that the claim fails because: 1) Oklahoma law does not recognize negligence per se claims based on violations of FDA regulations; 2) the FDCA does not contain a private right of action; 3) the GMP at issue does not create a clear standard of conduct; and 4) the Court should not expand Oklahoma law to allow negligence per se claims based on FDA regulations. Dkt. # 136, at 7-14.

Plaintiffs' surviving negligence per se claim is based on defendants' alleged violation of FDA requirements as set out in the GMPs. Dkt. # 134, at 4. In Riegel, the Supreme Court of the United States concluded that state-law claims are preempted under § 360k(a) of the MDA "to the extent that they are 'different from, or in addition to,' the requirements posed by federal law." 552 U.S. at 330. Prior to remand, the Sixth Circuit concluded that plaintiffs' negligence per se claim is not preempted by § 360k(a); that determination is law of the case, and is binding on the Court. See United States v. West, 2011 WL 1844112, at * 2 (10th Cir. May 17, 2011). The Sixth Circuit also decided that the GMP at issue was specific enough to be enforceable, a determination that is

[5] Plaintiffs also include in their motion a request for remand to the Northern District of Oklahoma. Dkt. # 139, at 8. As the case has been remanded, the request is moot.

similarly binding. Dkt. # 134, at 6. However, left undecided by the Sixth Circuit was whether plaintiffs' negligence per se claim is cognizable under Oklahoma law.

The Court will assume, without deciding, that Oklahoma courts would recognize a claim for negligence per se based on a federal regulation. Defendants rely on Alexander v. Smith & Nephew, P.L.C., 98 F. Supp. 2d 1310 (N.D. Okla. 2000), to support their claim that such a claim is not recognized. However, the Alexander court did not reject the plaintiff's claim because it was based on federal regulations, but because of other aspects of those particular regulations. Similarly, in Claborn v. Plains Cotton Cooperative Association, 211 P.3d 915 (Okla. Civ. App. 2009), and Rosson v. Coburn, 876 P.3d 731 (Okla. Civ. App. 1994), the plaintiffs stated claims for negligence per se based on violations of federal regulations. Although those claims were unsuccessful in both Claborn and Rosson, it was not because the claims were based on federal regulations but because of other problems on the merits. The only cases where Oklahoma courts have allowed claims based on federal regulations have been those where the regulation was adopted by the state. See, e.g., Woodis v. Okla. Gas & Elec. Co., 704 P.2d 483 (Okla. 1985). And, as defendants argue, the Oklahoma Uniform Jury Instruction on negligence per se refers to violations of a "state statute or city ordinance," and "makes no reference to regulations, federal or otherwise." Dkt. # 140, at 14. However, because the Court finds no direct support for a bar on the use of federal regulations to establish the standard of care for negligence per se claims under Oklahoma law, for purposes of this opinion, it will assume that such a claim is not barred on its face.

Courts are divided as to whether a negligence per se claim may be based on a standard of care derived from the FDCA, its amendments, or its corresponding regulations. See Ellis v. C.R. Bard, Inc., 311 F.3d 1272, 1284 (11th Cir. 2002)("There is a split of authority among the states as

to whether a violation of the FDCA or its regulations can serve as a predicate for a negligence per se claim under state law."). The FDCA states that an action for "enforcement, or to restrain violations, of th[e] [FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a). The Supreme Court interpreted that section in Buckman Company v. Plaintiffs' Legal Committee, 531 U.S. 341 (2000), where it found "clear evidence that Congress intended that the MDA be enforced exclusively by the Federal Government," and, consequently, ruled that state-law claims that "exist[ed] solely by virtue of the FDCA," as opposed to being based on traditional state tort law, were impliedly preempted by § 337. Id. at 352-53. It explained that to hold otherwise would "dramatically increase the burdens facing [those regulated by the FDA] – burdens not contemplated by Congress in enacting the FDCA and MDA." Id. at 350. Thus, read together, "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." Riley v. Cordis Corp., 625 F. Supp. 2d 769, 777 (D. Minn. 2009)(emphasis in original).

Based on the lack of a private cause of action in the FDCA, "many courts have held plaintiffs cannot seek to enforce it through negligence per se tort actions." Bartlett v. Mut. Pharmaceutical Co., Inc., 731 F. Supp. 2d 135, 154 (D.N.H. 2010)(quoting Hackett v. G.D. Searle & Co., 246 F. Supp. 2d 591, 594 (W.D. Tex. 2002)); see also Rounds v. Genzyme Corp., No. 8:10-cv-2479-T-23TBM, 2010 WL 5297180, at * 3 (M.D. Fla. Dec. 20, 2010)(internal quotations omitted)(noting that "the FDCA strongly evidences legislative intent to prohibit a private right of action," and that, therefore, "a plaintiff cannot use a negligence per se claim to create a private cause of action for a

defendant's alleged violations of the FDCA"); In re Aredia & Zometa Prods. Liab. Litig., No. 3-06-MD-1760, 2010 WL 5092784, at * 2 (M.D. Tenn. Dec. 7, 2010); Vanderwerf v. SmithKlineBeecham Corp., 414 F. Supp. 2d 1023, 1026-27 (D. Kan. 2006); Rogozinsky v. Danek Med., Inc., No. 4:96CV2572, 1999 WL 33537323, at * 1 (N.D. Ohio July 8, 1999). "Other courts, though, have allowed such suits, reasoning that they do not assert private rights of action under the FDCA, but rather a negligence theory long recognized at common law." Bartlett, 731 F. Supp. 2d at 154 (citing In re Orthopedic Bone Screw Prods. Litig., 193 F.3d 781, 788-89 (3d Cir. 1999)); see also Carson v. Depuy Spine, Inc., 365 F. App'x 812, 815 (9th Cir. 2010)(unpublished)("Because the FDCA prohibits private enforcement . . . [the plaintiff] asserts a state law negligence per se theory predicated on violation of federal law."); Ezagui v. Dow Chem. Corp., 598 F.2d 727, 733 (2d Cir. 1979);[6] Franklin v. Medtronic, Inc., 2010 WL 2543579, at * 8 (D. Colo. May 12, 2010)("implied preemption extends only [to] state-law claims brought pursuant to the FDCA itself, and not to state-law claims premised on the FDA's regulations. . . . [t]his interpretation balances the preemptive effect of Section 337(a) against the Supreme Court's strong suggestion in Riegel that claims 'premised on a violation of FDA regulations' would not be preempted"); Valente v. Sofamor, S.N.C., 48 F. Supp. 2d 862, 875-76 (E.D. Wis. 1999).

In Rimbert v. Eli Lilly and Company, 577 F. Supp. 2d 1174 (D.N.M. 2008), the court attempted to predict how the Tenth Circuit Court of Appeals would decide the question of whether state law claims that draw on FDA regulations for the appropriate standard of care are barred by §

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[6] Ezagui's holding that "a private cause of action for per se negligence arises under New York State law upon violation of the FDCA," Sita v. Danek Med., Inc., 43 F. Supp. 2d 245, 262 (E.D.N.Y.1999), may be called into question following Mitaro v. Medtronic, Inc., 886 N.Y.S.2d 71 (N.Y. Sup. Ct. 2009), which found a negligence per se claim to be preempted under § 337(a), "which provides that all proceedings to enforce or to restrain violations of the FDCA are in the domain solely of the federal government." Id. at * 4.

337(a). It relied heavily on Cottrell, Ltd. v. Biotrol International, Inc., 191 F.3d 1248 (10th Cir. 1999), and Braintree Laboratories, Inc. v. Nephro-Tech, Inc., No. 96-2459-JWL, 1997 WL 94237 (D. Kan. 1997), for its conclusion that the Tenth Circuit would find such a claim to be impliedly preempted by § 337(a). In Cottrell, the Tenth Circuit interpreted Environmental Protection Agency (EPA) rules governing pesticide labels and the regulatory framework in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). 191 F.3d at 1250, 1250 n.1. The plaintiff stated a claim based on § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), for allegedly false labeling that misrepresented the product's approval by EPA. Id. at 1250. To find in favor of the plaintiff would have necessitated a finding of a violation of FIFRA, a statute that governs labeling requirements and is "exclusively enforced by the EPA." Id. at 1255 (internal quotations omitted). In deciding whether the plaintiff could rely on a FIFRA violation to support its claim, the Cottrell court looked to Braintree, a Lanham Act case based on noncompliance with FDCA regulations. Id. at 1254-55. The Braintree court concluded that "claims that require direct interpretation and application of the FDCA are not properly recognized," which the Cottrell court applied to claims based on FIFRA. Id. at 1255. The court found that the plaintiff's complaint was "properly characterized as an attempt to enforce FIFRA's labeling requirements," because, "independent of FIFRA, [the] allegation[s] . . . ha[ve] no force because . . . no EPA clearance or approval for label claims would be necessary." Id. Moreover, it decided that a determination of whether the defendant had violated the applicable rule "would require EPA expertise." Id. Consequently, the court ruled that the plaintiff "must not be permitted to bring a FIFRA claim dressed up as a Lanham Act claim." Id. The court did not dismiss two other claims by the plaintiff for which it found sufficient facts to support a Lanham Act claim independent of FIFRA. Id. at 1255-56.

The Rimbert court noted that "[o]n a clean slate, the Court might not be inclined to follow the district court's analysis in [Braintree]." 577 F. Supp. 2d at 1239. However, it interpreted the Tenth Circuit's reliance on Braintree for the quotation that "claims that require direct interpretation and application of the FDCA are not properly recognized" to prohibit negligence per se claims based on the FDCA and its regulations. Id. Thus, because the Rimbert court was "not certain how it could let proceed a negligence per se claim based on the FDCA and its regulations without interpreting and applying in some way the FDA's regulations," it held that the defendant was entitled to summary judgment on plaintiff's negligence per se claim. Id. at 1240.

This case is before the Court in an unusual procedural posture. As noted, the Court is bound by the decisions of the Sixth Circuit in this matter. And that court, upon consideration of defendants' arguments for summary judgment, did not shy away from interpreting the FDA regulation at issue. On the contrary, it relied upon its own analysis that the GMP at issue required actual removal to support its reversal of summary judgment. Dkt. # 134, at 6-8. Without that determination, the statement in Braintree, echoed in Cottrell and Rimbert, that "claims that require direct interpretation and application of the FDCA are not properly recognized" may have had substantial weight. Indeed, determination of whether defendants violated 21 C.F.R. § 820.70(h) requires an express determination of what that section requires. However, that determination has already been made, and this Court does not decide that the FDCA bars all negligence per se claims that would require interpretation of its regulations.

The ultimate question, then, is whether plaintiffs' negligence per se claim is more akin to a private enforcement action, or whether it is merely the type of parallel claim permitted by Riegel. Neither state nor federal courts in Oklahoma have explicitly considered whether Oklahoma law

recognizes a claim for negligence per se where a private right of action does not exist under the relevant statute.[7] "In the absence of [Oklahoma] law directly on point, [the Court] attempt[s] to predict how [Oklahoma's] highest court would rule." F.D.I.C. v. Schuchmann, 235 F.3d 1217, 1225-26 (10th Cir. 2000). In Oklahoma, "[a] statute's violation is deemed negligence per se if the claimed injury (a) was caused by the law's violation, (b) was of the type intended to be prevented by the statute, and (c) the injured party was a member of the class meant to be protected by the statute." Johnson v. Smith & Nephew Richards, Inc., No. 97-CV-363-K, 1999 WL 111705, at * 2 (N.D. Okla. Sept. 30, 1999)(citing Lockhart v. Loosen, 943 P.2d 1074, 1078 (Okla. 1997)). The law does not explicitly require a private right of action in the underlying statute. However, plaintiffs "cannot sue under a negligence per se theory merely as members of the public." Pehle v. Farm Bureau Life Ins. Co., Inc., 397 F.3d 897, 904 (10th Cir. 2005)(interpreting Wyoming negligence per se claim under similar state law). Instead, the Court must "ask whether the policy behind the legislative enactment will be appropriately served by using the policy to impose and measure civil damage liability." Id. (internal quotations omitted). Thus, the question for the Court is whether the duty created by the GMP "runs to individuals, or rather to the public at large." Id. "Discernment of legislative intent is required to place the plaintiff within the class of persons meant to be protected by the ambit" of the GMP and FDCA. Lockhart, 943 P.3d at 1078. "A statute's language, when given its plain and ordinary meaning, is the yardstick for divining the drafters' objective." Id.

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[7] Defendants would have the Court rely on Alexander and Johnson for the proposition that the lack of a private right of action under the FDCA mandates dismissal of plaintiffs' claims. However, although both Alexander, 98 F. Supp. 2d at 1321, and Johnson, 1999 WL 1117105, at * 2, include the lack of a private right of action under the FDCA as a reason for not permitting a negligence per se claim based on that statute, both courts identified it as merely one of several factors motivating the decision not to permit an action. Neither stated that the lack of a private cause of action under the FDCA was independently sufficient to bar the plaintiffs' negligence per se claims.

Although the Court does not today make the finding that plaintiffs' negligence per se claims constitute a private cause of action such that they are preempted by § 337, it does find that the revocation of any private cause of action in the FDCA speaks to the legislative intent behind the scope of its protections. Cf. Estep v. Danek Med., Inc., No. 1:96CV2580, 1998 WL 1041330, at * 1 (N.D. Ohio Dec. 8, 1998)("Absence of a private cause of action under the federal statute is important in considering whether a negligence per se action is available under state law."). As noted in Lockhart, the statute's plain language is the "yardstick" for determining the drafters' objective. And Congress, in drafting the FDCA, could not have been more explicit that it did not intend for that statute's provisions to be enforced by individuals. "When no private cause of action can be discerned, the courts are left on thin ice in basing civil damages on a statutory violation." Pehle, 397 F.3d at 905. Perhaps for that reason, Oklahoma courts have justified denials of negligence per se claims on the lack of a private cause of action in an underlying statute. See Ronson, 876 P.2d at 736 (rejecting negligence per se claim based on violation of the Medicaid Act, "an administrative scheme providing medical assistance . . . implying no private right of action"); see also Shero v. City of Grove, Okla., No. 05-CV-0137-CVE-PJC, 2006 WL 3196270, at * 9 (N.D. Okla. Nov. 2, 2006)(rejecting plaintiff's attempts to use statute as basis for negligence per se liability where no private right of action existed under the statute); Alexander, 98 F. Supp. 2d at 1321; Johnson, 1999 WL 1117105, at * 2. The Court predicts that an Oklahoma court would find that the FDCA was intended to protect the public at large and not individuals. Because plaintiffs are not members of a class meant to be protected by the statute, there is no negligence per se claim, and there are no remaining derivative claims for medical monitoring and loss of consortium. Therefore, defendants are entitled to summary judgment.

IT IS THEREFORE ORDERED that Centerpulse Orthopedics Inc.'s Renewed Motion for Summary Judgment on Plaintiff's [sic] Negligence *Per Se* Claim (Dkt. # 136) is **granted**, and Plaintiffs' Response and Objection to Sulzer's "Renewed Motion for Summary Judgment on Plaintiff's [sic] Negligence *Per Se* Claim" and Plaintiffs' Counter-Motion for Partial Judgment on Liability (Dkt. # 139) is **moot**. A separate judgment is entered herewith.

DATED this 21st day of June, 2011.

Claire V Eagan

CLAIRE V. EAGAN, CHIEF JUDGE
UNITED STATES DISTRICT COURT