Marion et al v. Smith & Nephew Doc. 37

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH, NORTHERN DIVISION

HEIDI MARION and MICHAEL MARION, husband and wife, Plaintiffs, v. SMITH & NEPHEW, INC., a Delaware Corporation, Defendant.	Case No. 1:15-cv-00096-JNP-BCW **MEMORANDUM DECISION & ORDER GRANTING IN PART AND DENYING IN PART DEFENDANT'S MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM** Judge Jill N. Parrish

Before the court is Defendant Smith & Nephew, Inc.'s, Second Motion to Dismiss. (Docket 29). The court held oral argument on the motion on July 12, 2016. At the conclusion of the hearing, the court took the motion under advisement. After considering the written submissions on the motion and the arguments presented at the hearing, the court issues this Order Granting in Part and Denying in Part Defendant's Motion to Dismiss.

BACKGROUND

This case presents products liability claims arising from Smith & Nephew's Birmingham Hip Resurfacing (BHR) System, a medical device implanted in a person's hip to treat damage to the hip joint. To market and sell the BHR device, the law required Smith & Nephew to obtain premarket approval (PMA) from the U.S. Food and Drug Administration (FDA). On May 9, 2006 Smith & Nephew received conditional approval to market and sell the device. On August 7, 2007, Plaintiff Heidi Marion underwent a resurfacing procedure to repair arthritic damage to her left hip during which Ms. Marion's physician implanted Smith & Nephew's BHR System. Six

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years later, Ms. Marion's BHR System failed and toxic levels of cobalt and chromium shed into her body. As a consequence, Ms. Marion underwent revision surgery on August 6, 2013.

Ms. Marion and her husband filed suit alleging various claims for relief against Smith & Nephew relating to the BHR System's alleged premature failure. In July 2015, Smith & Nephew removed the case to federal court and subsequently moved to dismiss all claims on federal preemption grounds. Because the Marion's claims as originally pled were deficient and failed to adequately address the issue of preemption, the court granted Smith & Nephew's motion but gave the Marions leave to file an amended complaint. In granting the Marions leave to amend, the court provided guidance regarding the issues that must be addressed in the amended complaint to adequately plead a claim for relief in light of the Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetics Act (FDCA) and Supreme Court precedent governing preemption under these laws.

The Marions filed an amended complaint. Smith & Nephew has again moved to dismiss all claims against it on grounds that the Marion's claims are either preempted or fail to allege sufficient facts to state a claim on which relief may be granted. The Marions respond that their claims are not preempted and have been properly pled.

ANALYSIS

I. Legal Standard

To survive a Rule 12(b)(6) motion to dismiss, a plaintiff must "state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). To do so, a plaintiff must plead both a viable legal theory and "enough factual matter, taken as true, to make [the] 'claim to relief . . . plausible on its face." *Bryson v. Gonzales*, 534 F.3d 1282, 1286 (10th Cir. 2008) (quoting *Bell Atlantic*

Corp. v. Twombly, 550 U.S. 544, 570 (2007)). In the context of medical devices that have received PMA from the FDA, stating a legally viable state law claim "has been compared to the task of navigating between Scylla and Charybdis." *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1340 (10th Cir. 2015). "Exercising its authority under the Supremacy Clause," *id.* at 1336, Congress enacted a preemption provision as part of the Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetics Act (FDCA):

> 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). Although the language of this provision is "expansive" and could have been applied to preempt "all private state law tort suits," the Supreme Court has adopted a nuanced interpretation of § 360k(a) that is both narrower and more complicated. *See Caplinger*, 784 F.3d at 1337

In *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the Supreme Court held that "tort suits do not impose new 'requirements' on manufacturers and are not preempted so long as the duties they seek to impose 'parallel' duties found in the FDCA." *Caplinger*, 784 F.3d at 1338 (quoting *Lohr*, 518 U.S. at 495). "[S]tate and federal law duties 'parallel' each other not only when they are identical, but also when state law imposes duties on the defendant that are 'narrower, not broader' than those found in the FDCA." *Id.* (quoting *Lohr*, 518 U.S. at 495).

In addition, *Lohr* held that the text of § 360k(a) preempting state laws "to the extent they conflict with 'any [federal] requirement applicable under this chapter to the device'" meant that

only regulations "'specific' to a 'particular device'" were "capable of preempting any different or additional state requirement." *Id.* at 1339 (quoting *Lohr*, 518 U.S. at 498-99). "Put differently, [to be preempted] a device must undergo the premarket approval process . . . [l]awsuits aimed at less highly regulated devices . . . are not preempted.'" *Id.*[1]

The Supreme Court next addressed preemption under the FDCA in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). In *Buckman*, the Supreme Court held that 21 U.S.C. § 337(a) "preempts any state tort claim that exists 'solely by virtue' of an FDCA violation." *Caplinger*, 784 F.3d at 1339 (quoting *Buckman*, 531 U.S. at 353). "At the same time, the Court left undisturbed the portion of *Lohr* allowing state lawsuits based on 'traditional state tort law' that 'predate[s]' the FDCA but happens to 'parallel' it." *Id.* Most recently, in *Riegal v. Medtronic, Inc.*, 552 U.S. 312 (2008), the Supreme Court held that "*any* state requirement, whether device specific or generally applicable, is preempted when it differs from or adds to federal requirements." *Caplinger*, 784 F.3d at 1339 (emphasis in original). At the same time, *Riegal* reaffirmed, that "§ 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." *Riegel*, 552 U.S. at 330.

Thus, to state a legally viable claim that avoids preemption under the FDCA, a plaintiff must first plead either that "there exists [no] device-specific federal requirement[s]," or that "the state law duty is narrower than or equal to the federal duty." *See id.* at 1340. Second, a plaintiff

[1] While the Supreme Court left room for preemption to displace some state tort suits against lesser regulated products, it did not identify the basis for such preemption. *See Caplinger*, 784 F.3d at 1339 ("To be sure, *Lohr* itself wasn't unequivocal on this point: the Court acknowledged the possibility that 'general' federal requirements might sometimes preempt state requirements. But when it comes to when and what kinds of 'general' requirements have preemptive effect, or what sort of device-specific regulations beyond the premarket approval process might bear that same power, *Lohr* told us little." (citations omitted)).

must plead that the state law duty "predates the [federal statutory scheme]." *See id.* Ultimately, if a plaintiff's claims survive the preemption analysis, they must also be supported by sufficient factual allegations to make them "plausible on [their] face." *Bryson*, 534 F.3d at 1286 (quoting *Twombly*, 550 U.S. at 570).

Because the Marion's claims as originally pled failed to address the issue of preemption, the court provided clear guidance with respect to its expectations for the amended complaint. First the court required the Marions to identify with specificity the federal law requirements that parallel the state law claims. Second, the court required the Marions to identify with specificity the state law duties that existed prior to but allegedly parallel the requirements for the BHR System under federal law. Finally, the Marions were required to plead adequate facts to make their parallel state law claims plausible on their face.

Reviewing the Marion's amended complaint in light of the foregoing legal standards and the court's instructions in its order dismissing the original complaint, the court concludes that all claims alleged in the amended complaint are preempted and or fail to state a claim, with the exception of the Marion's negligence claim. The court first addresses the Marion's negligence claim. The court then addresses the remaining claims and identifies the basis for their dismissal.

II. The Marion's Negligence Claim.

The Marions assert that their negligence claim parallels federal law because, under Utah law, a violation of a safety statute or regulation is prima facie evidence of negligence. *See Thompson v. Ford Motor Company*, 395 P.2d 62, 64 (Utah 1964). Moreover, the Marion's amended complaint affirmatively limits the negligence claim to this theory in an effort to avoid preemption under § 360k.

In its order dismissing the initial complaint, the court expressed skepticism about this type of negligence theory in light of *Buckman*'s holding that preemption applies when "the existence of . . . federal enactments is a critical element in [the] case." *See Buckman*, 531 U.S. at 353. In pleading this theory in the amended complaint, the Marions cite the concluding passage in *Riegel* that "§ 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." *Riegel*, 552 U.S. at 330. In support of this assertion, the majority in *Riegel* affirmatively cited Justice O'Connor's concurrence in *Lohr*. *See id.* In her concurrence, Justice O'Connor offered the following additional guidance regarding the scope of preemption under the MDA:

> I also agree that the Lohrs' claims are not pre-empted by § 360k to the extent that they seek damages for Medtronic's alleged violation of federal requirements. Where a state cause of action seeks to enforce an FDCA requirement, that claim does not impose a requirement that is "different from, or in addition to," requirements under federal law. To be sure, the threat of a damages remedy will give manufacturers an additional cause to comply, but the requirements imposed on them under state and federal law do not differ. Section 360k does not preclude States from imposing different or additional *remedies*, but only different or additional *requirements.*

Lohr, 518 U.S. at 513 (O'Connor, J. Concurring). While the foregoing passages in *Riegel* are undoubtedly in extreme tension with the facts and holding in *Buckman*, *Riegel* is the more recent word from the Supreme Court and it allows suits for damages based on alleged violations of the FDCA and associated regulations, where those suits are based on preexisting state law duties.

Here, while the Marion's negligence claim of necessity parallels federal statutory and regulatory requirements, it exists independent of the federal statute and regulations. Under Utah law, the federal safety statutes and regulatory provisions provide only prima facie evidence of

the independent state law duty of reasonable care. And while the duty of reasonable care may be broader than or different from the requirements of federal law, the Marions have expressly limited their claims to the area of potential overlap where there is both a violation of the duty of reasonable care under Utah law and a parallel violation of a federal statute or regulation applicable to the BHR System. If such a claim were not deemed to comply with the Supreme Court's Venn diagram approach to preemption, *see Caplinger*, 784 F.3d at 1340, the holdings in *Lohr* and *Riegel* would be completely eviscerated. The court therefore concludes that the Marion's negligence theory properly parallels federal law.

To avoid preemption, however, the Marions must also identify the specific federal statutory or regulatory requirements applicable to the BHR System that Smith & Nephew violated proximately causing the Marion's injuries. On this front, the Marions appear to have taken literally the direction from *Caplinger* to scour "the heap of federal law" for "parallel provisions . . . to save [their] claims." *See Caplinger*, 784 F.3d at 1342.

The Marion's negligence claim is now replete with citations to federal regulations allegedly applicable to the BHR System. On closer review, and by admission of the Marion's counsel at oral argument, many of these regulations do not apply to the BHR System. Of those that might apply, most of the alleged violations are asserted in conclusory fashion without any factual support to move the allegations from conceivable to plausible. Moreover, several of the alleged violations of federal regulations relate to conduct by Smith & Nephew during the PMA process prior to the final grant of PMA, and because these allegations mirror the fraud on the FDA theory rejected in *Buckman*, the court finds that they are preempted here also.

Despite these significant deficiencies arising from the Marion's shotgun approach to the amended complaint, the Marions adequately allege a parallel negligence claim that is supported by sufficient factual allegations to satisfy the *Twombly* plausibility standard.

Namely, the Marions allege that following the PMA for the BHR System, Smith & Nephew violated post-PMA federal regulatory requirements applicable to the BHR System with respect to establishing a reporting system for adverse events related to the BHR System; *see* 21 C.F.R. § 820.100, § 820.198, training physicians and surgeons regarding the proper use of the BHR System; *id.* § 814.82, § 814.84, and establishing and maintaining procedures for implementing a corrective and preventative action plan to respond to any complaints or adverse event reports; *id.* § 820.100, 822.2, 803.50.

The facts to support these alleged violations include the adverse event reporting chart attached as an exhibit to the Marion's complaint. This chart purports to identify when Smith & Nephew became aware of allegedly adverse events involving the BHR System. While there is much that is unclear regarding the information in this chart, it does show significant time gaps between when the alleged adverse events took place and the timing of Smith & Nephew's awareness of these events. Moreover, Ms. Marion's own injuries and citations to other cases involving failed BHR Systems under similar circumstances provide additional facts to support the theory that adverse events were taking place that needed to be promptly reported. Finally, the voluntary recall in the case is further evidence that at some point even Smith & Nephew recognized that the failure rate of the BHR System warranted removal of the product from the market. Taken together, these facts raise a plausible inference that Smith & Nephew may have violated federal regulatory requirements related to receiving adverse event reports. Had these

regulatory requirements been followed, the complaint alleges a plausible claim that Ms. Marion's injuries might not have occurred or at a minimum may have been mitigated.

For these reasons, after accepting the Marion's factual allegations as true for purposes of this motion to dismiss, the Marions have adequately pled a parallel state law negligence claim that is not preempted by § 360k.

III. Deficiencies in the Marion's Remaining Claims.

A. Strict Product Liability—Defective Manufacture

The Marion's manufacturing defect product liability claim is both preempted and fails to allege sufficient facts to state a claim for relief. "To plead a parallel claim successfully, a plaintiff's allegations that the manufacturer violated FDA regulations must meet the *Twombly* plausibility standard." *Bass v. Stryker Corp.*, 669 F.3d 501, 509 (5th Cir. 2012) (collecting cases for this proposition); *see also Caplinger*, 784 F.3d at 1356 (Lucero, J. concurring in part and dissenting in part) (noting that a plaintiff's claims "need only state a plausible claim for relief" citing *Twombly*). Here, the Marions offer only conclusory allegations of alleged regulatory violations without any factual support. As a consequence of the Marion's vague and conclusory allegations, it is unclear whether the Marion's claim alleges that the product as approved by the FDA was unreasonably dangerous—a claim that would clearly be preempted because it would impose different and additional requirements than those approved by the FDA. Moreover, as alleged, the Marion's manufacturing defect claim fails to explain how the state law requirements of the Utah Product Liability Act, Utah Code § 78B-6-701 et seq., parallel federal requirements for the manufacture of the BHR System. Each of these issues provides the court with

independent grounds for dismissal. Accordingly, the court grants Smith & Nephew's motion to dismiss the Marion's Second Claim for Relief.

B. Strict Product Liability—Failure to Warn

Like the manufacturing defect claim, the failure to warn claim likewise fails to state a claim. The Marion's failure to warn claim is also conclusory and unsupported by factual allegations. On their face, the Marion's allegations appear to assert that the FDA approved labeling failed to warn of the risks associated with Ms. Marion's injuries. Such allegations are clearly preempted. To the extent the Marions intended to allege that state law imposes a requirement to change or add to the FDA approved labeling, that claim is also preempted because it would impose a requirement different from and in addition to those imposed by federal law. Accordingly, the court dismisses the Third Claim for Relief on the grounds that it fails to state a plausible claim for relief and is preempted by federal law.

C. Breach of Express Warranties

The Marion's Fourth Claim for Relief for breach of express warranties fails to state a plausible claim for relief. To state an express warranty claim, the Marions must plead that Smith & Nephew made an express warranty to Ms. Marion and that she actually relied on the alleged warranty in making her decision to have the BHR System implanted. *See Hone v. Advanced Shoring & Underpinning, Inc.*, 291 P.3d 832, 839 (Utah 2012); *Mgmt. Comm. of Graystone Pines Homeowners Ass'n v. Graystone Pines, Inc.*, 652 P.2d 896, 900 (Utah 1982). As alleged, the Marion's complaint fails to provide any factual allegation that an express warranty was made to Ms. Marion prior to having the BHR System implanted. All of the alleged warranties postdate the implantation of the BHR System. While many facts may be outside of the Marion's

possession prior to discovery, what if any warranties were made to Ms. Marion or her doctor should be currently available to Ms. Marion.Thus, the absence of any nonconclusory allegation regarding an express warranty made prior to the implantation of the BHR System is fatal to this claim. Accordingly, the court dismisses the Marion's Fourth Claim for Relief.

D. Breach of Implied Warranties

The Marion's Fifth Claim for Relief for breach of implied warranties is preempted because, as alleged, it would impose different and additional requirements than those imposed by the FDCA. The Marions allege that Smith & Nephew impliedly warranted the BHR System as fit for the particular purpose for which it was intended. Because the device subsequently failed, the Marions allege that Smith & Nephew breached this implied warranty. The FDA granted the BHR System PMA deeming it fit for the particular purposes for which it had been approved. To the extent the Marions seek to argue that despite FDA approval the device was not in fact fit for the particular purpose approved by the FDA, that claim is preempted because it would impose different and additional standards than imposed under federal law. Accordingly, the Fifth Claim for Relief—as alleged in the Marion's complaint—is preempted by § 360k.

E. Negligent Misrepresentation and Fraudulent Concealment

Not only do the Marion's Sixth and Eighth Claims for Relief likely fail the plausibility standard under *Twombly*, they clearly fail to assert the who, what, when, where, and how of the alleged fraud and negligent misrepresentation as required by Federal Rule of Civil Procedure 9(b). *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 726–27 (10th Cir. 2006). Accordingly, these claims are dismissed for failure to meet the heightened pleading standard.

F. Unfair and Deceptive Trade Practices

At oral argument, the Marions voluntarily dismissed this claim without objection from Smith & Nephew.

G. Negligent Infliction of Emotional Distress

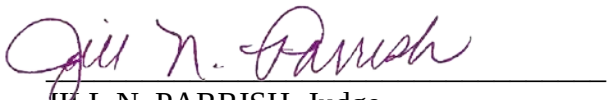
The Marion's allegations under the Ninth Claim for Relief are wholly conclusory and appear to be based entirely on conduct the court has determined to be preempted as outlined in the foregoing sections of this order. Namely, the Marions allege negligence in the development, testing, labeling, marketing, and sales of the BHR System. But the Marions fail to identify specific federal regulations alleged to be violated. And to the extent the Marions contend that the device as approved by the FDA was negligently developed, tested, labeled, marketed, or sold—such an allegation would be preempted by § 360k. Accordingly, the court holds that the Marion's Ninth Claim for Relief must be dismissed for failure to state a claim and, alternatively, on preemption grounds.

CONCLUSION

For the foregoing reasons, the Court GRANTS in PART and DENIES in PART Smith & Nephew's Motion to Dismiss (Docket 29). The court concludes the Marions have adequately pled a negligence claim that is not preempted by § 360k. All other claims are dismissed with prejudice.

Dated this 27th day of July, 2016.

BY THE COURT:



JILL N. PARRISH, Judge
United States District Court