IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

IN RE: SMITH & NEPHEW BIRMINGHAM HIP RESURFACING (BHR) HIP IMPLANT PRODUCTS LIABILITY LITIGATION	*	
	*	Civil Action No. CCB-17-2775
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Memorandum

Plaintiffs from 42 states and jurisdictions[1] have together filed more than 200 suits claiming that the defendant, Smith & Nephew, is liable under eight state common law theories of liability—strict products liability; negligence; strict liability for failure to warn; negligent failure to warn; negligent misrepresentation; negligence per se; breach of express warranty; and manufacturing defect—for, among other things, misrepresenting the safety of the defendant's Birmingham Hip Resurfacing device and failing to report adverse incidents to the FDA.[2] The plaintiffs also claim these facts support awarding punitive damages against Smith & Nephew.[3] Smith & Nephew has filed a motion to dismiss arguing that these claims are either preempted or insufficiently pleaded.

[1] The jurisdictions represented are: Alabama; Arizona; Arkansas; California; Colorado; Connecticut; District of Columbia; Florida; Georgia; Hawaii; Idaho; Illinois; Indiana; Iowa; Kentucky; Louisiana; Maryland; Massachusetts; Michigan; Minnesota; Mississippi; Missouri; Montana; Nevada; New Hampshire; New Jersey; New York; North Carolina; Ohio; Oklahoma; Oregon; Pennsylvania; Rhode Island; South Carolina; Tennessee; Texas; Utah; Virginia; Washington; West Virginia; and Wisconsin.

[2] According to Smith & Nephew, 37 of the short form complaints contain claims not represented by the Master Amended Consolidated Complaint, and fail to provide plaintiff-specific factual allegations.

[3] A claim for punitive damages is derivative and therefore survives if the plaintiffs' underlying claims that support it survive. As to the surviving claims, whether punitive damages may be sought can be addressed in summary judgment motions.

The defendant's motion will be granted in part and denied in part. The plaintiffs' two strict liability claims are preempted because they require the court to impose requirements on Smith & Nephew that differ from or add to FDA requirements. All but one of the plaintiffs' six remaining claims survive the motion because they are traditional state law claims, may be established by conduct that also violates federal regulations, and have been sufficiently pleaded.

Factual Overview

This case concerns the Birmingham Hip Resurfacing Device ("BHR"), an artificial hip, developed, designed, manufactured, and sold by Smith & Nephew. The hip joint is formed by a ball and socket structure: the end of the femur closest to the hip, called the femoral head, is shaped like a ball and sits inside a socket in the hip called the acetabular cup. (Master Amended Consolidated Complaint ("MACC") at ¶ 12). The BHR system replaces the hip joint with metal components—capping the femoral head with a metal covering and inserting a metal cup within the acetabular cup—to recreate the same ball and socket structure that occurs naturally. (*Id.* at ¶¶ 13-14). Unlike the naturally occurring structure, however, friction between the metal components of the BHR system, a consequence of movement within the joint, causes metal debris to accumulate within the joint and, eventually, the bloodstream. (*Id.* at ¶15).

Far from benign, these shavings can cause significant medical complications such as swelling and pain, metallosis, immune reactions, pseudotumors, and premature loosening of the BHR device, that ultimately require serious corrective surgery. (*Id.*). Patients suffering from complications must undergo total hip replacements—surgeries to implant an entirely new ball and socket structure that are decidedly more complicated and invasive than those required to implant the BHR device. (*Id.* at ¶ 16).

Smith & Nephew issued two recalls regarding the BHR device. First, several versions of the system were recalled in 2007 because of, among other things, labeling issues. (*Id.* at ¶ 18). And eight years later, after several of Smith & Nephew's competitors recalled or removed similar metal-on-metal devices from the U.S. market, Smith & Nephew voluntarily recalled some of the BHR devices because of "unreasonably high failure rates" for all women, all men over the age of sixty-five, and for "all men requiring femoral head sizes 46 mm or smaller." (*Id.* at ¶¶ 19-21).

A. Regulatory Background

All this was in the future, however, when the device was approved by the Federal and Drug Administration in 2006. The Medical Device Amendments of 1976 ("MDA") granted the FDA the authority to regulate medical devices. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996). The FDA divides devices into three classes. Class I devices require minimal oversight and are least dangerous, while Class III devices are rigorously reviewed and represent the most dangerous devices. 21 U.S.C. § 360c. The BHR system is a Class III device. (MACC at ¶ 160).

Class III medical devices must receive FDA approval before they may be marketed. 21 U.S.C. § 360e(a). The rigor of the premarket approval process has been well-documented, requiring nearly 1,200 hours of review and substantial filings for each device, *see, e.g.*, *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 344-45 (2001), including "a full statement of the components, ingredients, and properties and of the principle or principles of operation of such device," 21 U.S.C. § 360e(c)(1)(B), "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and

installation of, such device," 21 U.S.C. § 360e(c)(1)(C), and "specimens of the labeling proposed to be used for such device," 21 U.S.C. § 360e(c)(1)(F).

After the device-maker submits information regarding, among other things, the device's design, manufacture, and safety and effectiveness, 21 U.S.C. § 360e(c)(1), the FDA "weigh[s] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use," 21 U.S.C. § 360c(a)(2)(C). If a device receives approval, the manufacturer is forbidden "to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness" unless the manufacturer submits an additional application for FDA review. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 319 (2008); *see also* 21 U.S.C. § 360e(d)(5)(A)(i). A manufacturer may, however, change its labeling without FDA approval through the discretionary Changes Being Effected ("CBE") process to enhance "the safety of the device" with newly acquired information. 21 C.F.R. § 814.39(d)(1).The BHR device received conditional premarket approval from the FDA in 2006. (MACC at ¶¶ 197-200).

As a condition of approval, the FDA required Smith & Nephew "to evaluate the learning curve, training program, and longer-term safety and effectiveness of the BHR System in the United States," to "implement a training program" and "to provide an analysis of adverse events and complaints . . . received regarding the BHR system." (Def's Mot. Ex. A).[4] Smith & Nephew also was subject to reporting requirements: it was to report to the FDA if the BHR caused or contributed to death or serious injury, 21 U.S.C. § 360i(a)(1)(A), to report such adverse events to the FDA within 30 days after Smith & Nephew became aware of their occurrence, 21 C.F.R. §

[4] The court may rely on documents integral to the complaint. *See Zak v. Chelsea Therapeutics Intern., Ltd.*, 780 F.3d 597, 606-07 (4th Cir. 2015).

803.50(a), and to provide all reasonable information Smith & Nephew possessed on any adverse event, 21 C.F.R. § 803.50(b)(1). Smith & Nephew also was obligated to investigate each adverse report, 21 C.F.R. § 803.50(b)(3), and, if it determined that remedial action was required to prevent substantial harm to public health, to report that information to the FDA within five business days. 21 C.F.R. § 803.53. The FDA may withdraw approval from a device if it determines, based on existing or new information, that "such device is unsafe or ineffective under the conditions of use prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 360e(e)(1)(A)-(B).[5]

B. The Birmingham Hip Replacement Device

The plaintiffs claim Smith & Nephew violated the conditions of FDA approval by misrepresenting the safety of the BHR system "to the medical community, patients, and the FDA." (MACC at ¶ 24). The plaintiffs allege that they viewed these misrepresentations and that Smith & Nephew was aware they would do so. (*Id.* at ¶¶ 53-54).

The plaintiffs also claim that the BHR device was improperly manufactured. They cite evidence demonstrating that the linear wear rate—the degree of wear of the device components caused by the ball part of the artificial joint rubbing against the metal insert in the socket—of the BHR system exceeded the rate identified by Smith & Nephew's own studies and, as a result, failed "to meet manufacturing specifications for hardness, durability, composition, and finish" in violation of the FDA approved specifications. (*Id.* at ¶¶ 222-25).

[5] This point is critical. The plaintiffs argue in the MACC that Smith & Nephew did not have legal protection under the FDA's premarket approval because of their alleged violations of the conditions of that approval. They further argue that because Smith & Nephew did not inform the medical community or patients about its lost legal protection it committed fraud. The plaintiffs do not provide any support for this contention. Only the FDA has the authority to withdraw approval from a device, and it did not do so here.

But the heart of the plaintiffs' complaint focuses on Smith & Nephew's unequivocal support for the BHR device's safety despite growing evidence of its risks and Smith & Nephew's failure to report adverse incidents to the FDA.

Smith & Nephew insisted on the BHR's safety: the company (1) sent a letter in 2010 claiming, among other things, that the BHR system was not associated with an increased risk of disease, (*id.* at ¶ 64); (2) ran advertisements to reach members of the medical community and patients that claimed the BHR was safer than the average metal-on-metal device, (*id.* at ¶¶ 72-73); and (3) used Derek McMinn, one of the surgeon-inventors of the device, to claim that the BHR system does not cause metallosis, has a 96% survivorship rate, and, considering all of his surgeries, the device has a low risk of complications. (*Id.* at ¶ 156). On this last point, the plaintiffs claim that Smith & Nephew misrepresented the difficulty of BHR implant surgeries. The complaint cites a corroborated 2012 article that claimed the revision rate of a BHR surgery was three times higher for the general population than it was for the small number of patients operated on by the team that developed the device. (*Id.*at ¶¶ 87-89). Neither this article, nor its corroborating study, was allegedly ever provided to the FDA. (*Id.* at ¶ 90).[6]

The plaintiffs also claim that Smith & Nephew failed to adequately report adverse incidents involving the BHR device to the FDA. Smith & Nephew allegedly delayed reporting "hundreds of adverse reports and complaints regarding the BHR" system, failing to report entirely that the BHR system was "wearing down more quickly" than Smith & Nephew expected. (*Id.* at ¶ 201).When it did report adverse events, Smith & Nephew allegedly

[6] The plaintiffs also dispute the soundness of the methodology used by the development surgeons, claiming even patients under their charge may have had significant revision rates. (*Id.* at ¶¶ 91-93).

underreported or withheld information from the FDA "about the likelihood of [the device's] failure." (*Id.*).

C. Failure of Metal-on-Metal Devices and the BHR System

The plaintiffs claim that because the risks associated with metal-on-metal devices were well-documented, Smith & Nephew knew or should have known of the danger associated with the BHR and, consequently, that the representations described above were false.

An international consensus on the danger of metal-on-metal hip replacement systems, like the BHR, was formed shortly after Smith & Nephew began marketing its device. An Australian study published results indicating that the BHR revision rate was much higher for women in 2007 and 2008; a study by one of Smith & Nephew's paid researchers, Callum W. McBryde, showed that for every 4-mm reduction in femoral head size the risk of device failure increased four-fold; and another article, this one published in 2012, asserted that the BHR system fails in 26% of women after ten years. (*Id.* at ¶¶ 99-102).

The plaintiffs also provide pages of studies detailing the risk associated with metal-on-metal devices more generally. As early as 2006, the United Kingdom's Medicines and Healthcare Products Regulatory Agency, ("MHRA"), warned of shavings caused by friction within metal-on-metal devices, (*id.* at ¶ 117); in 2008, an Australian warning described a three times higher risk of revision for women with femoral heads smaller than 50 mm, (*id.* at ¶ 121); and in 2010 the MHRA recommended blood tests for patients with metal-on-metal hip replacements, (*id.* at ¶ 124), which was supported by a report later that year that detailed the high failure rates in females and indicated that "soft tissue reactions occur[] in 14.2% of revised

metal-on-metal devices," and "an incident rate of 12.5% for the revised total hip resurfacings," (*id.* at ¶ 128). MHRA followed up on its earlier studies in 2012, recommending that patients with metal-on-metal devices receive annual follow-ups for at least five years. (*Id.* at ¶ 132). That year, a Canadian health organization also promulgated information encouraging follow-ups. (*Id.* at ¶ 133). And a year later, the FDA warned doctors and patients about the risks posed by metal shavings produced by metal-on-metal devices. (*Id.* at ¶ 139).

The plaintiffs also note that Smith & Nephew employees attended an FDA advisory panel on the dangers of metal-on-metal devices in 2012. (*Id.* at ¶ 103). And although the defendant's reporting of complaints over about a 12-month period projected a more favorable outlook on the safety of the device, the report was missing thirty complaints, artificially increasing the survivorship rate of the device, according to the plaintiffs. (*Id.* at ¶ 105).

In the face of this information, and the withdrawal of competing metal-on-metal systems—Zimmer in 2008, Johnson & Johnson in 2010, Depuy in 2010, and Stryker in 2012, (*id.* at ¶¶ 120, 122, 126, 136)—Smith & Nephew continued to sell the BHR device, partially removing it from the market only in 2015.

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This is the background of more than 200 separate law suits, consolidated as an MDL, arising out of 42 states and jurisdictions. The plaintiffs' lead counsel have filed a Master Amended Consolidated Complaint to represent the plaintiffs' claims, which alleges that Smith & Nephew committed eight common law violations by misrepresenting the safety of the BHR device, failing to supply adverse incident reports to the FDA, and manufacturing a defective product. (ECF No. 124). They argue that this conduct violated Smith & Nephew's obligations to

report adverse incidents to the FDA, to disseminate only truthful and non-misleading information regarding the BHR device, and to manufacture the device as approved by the FDA.

Smith & Nephew has moved to dismiss these claims, asserting that the plaintiffs' claims are preempted or insufficiently pleaded. (ECF No. 409). Oral argument was heard on January 24, 2018. For the reasons stated below, the motion will be denied in part and granted in part.

Standard of Review

To survive a motion to dismiss, the factual allegations of a complaint "must be enough to raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (internal citations omitted). "To satisfy this standard, a plaintiff need not 'forecast' evidence sufficient to prove the elements of the claim. However, the complaint must allege sufficient facts to establish those elements." *Walters v. McMahen*, 684 F.3d 435, 439 (4th Cir. 2012) (citation omitted). "Thus, while a plaintiff does not need to demonstrate in a complaint that the right to relief is 'probable,' the complaint must advance the plaintiff's claim 'across the line from conceivable to plausible.'" *Id.* (quoting *Twombly*, 550 U.S. at 570). And the plaintiff typically must do so by relying solely on facts asserted within the four corners of his complaint. *Zak v. Chelsea Therapeutics Intern., Ltd.*, 780 F.3d 597, 606-07 (4th Cir. 2015). The same standard applies to pleading a parallel claim under the *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008) preemption standard. *Bass v. Stryker Corp.*, 669 F.3d 501, 509 (5th Cir. 2012) (collecting cases).

Analysis

Smith & Nephew argues that the plaintiffs' claims should be dismissed for three reasons: (1) the claims are expressly preempted under the FDA's statutory framework; (2) if the claims

are not expressly preempted, they are impliedly preempted; and (3) even if the claims are neither expressly nor impliedly preempted, they have not been sufficiently pleaded. The plaintiffs reject all three arguments, and further claim the court should abstain, for legal and prudential reasons, from considering Smith & Nephew's preemption arguments. The court will consider the plaintiffs' abstention arguments before discussing the parties' disputes over preemption and the sufficiency of the pleadings. The court will conclude that the briefing is sufficient to resolve the motion to dismiss; the plaintiffs' two strict liability claims are expressly preempted; the six remaining claims, at least facially, survive preemption; and all but one of the six surviving claims have been sufficiently pleaded.

I. Preemption Analysis on Motion to Dismiss

The plaintiffs insist that this court should leave the preemption analysis to transferor courts on remand, or at least for summary judgment or a jury, because preemption is a fact-specific issue and implicates the laws of 42 states. These arguments are unpersuasive.

Preemption analysis is not fact based. Rather for the purposes of this case, for reasons explained below, this court need only decide whether a state cause of action is parallel to a federal regulation. Answering this question does not require fact finding and, for a facial determination, there is little need to analyze the elements of underlying state laws.[7] Instead, this court can draw boundaries, excluding claims to the extent the plaintiffs are seeking liability on grounds other than a violation of federal regulations and including all others, to guide future

[7] Other courts have decided preemption issues without knowing the exact scope of the underlying state causes of action at issue. *See McMullen v. Medtronic, Inc.*, 421 F.3d 482, 487 (7th Cir. 2005)("We need not decide which law governs or the scope of the applicable common-law duty . . . . For the purposes of our preemption inquiry, we may assume that there is such a state-law duty."); *see also Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 769 (5th Cir. 2011) (assuming without deciding that a state law violation may be established by arguments that survive preemption); *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1284 n.9 (11th Cir. 2002) (assuming without deciding that Georgia law permits a negligence per se claim premised on a violation of FDA regulations).

argument and discovery on the issue. In doing so, the court is merely deciding which claims, and which arguments within those claims, would run afoul of the FDA's express preemption of state requirements that differ from or add to federal regulations. The court is confident it can do that during the motion to dismiss stage.

For the same reasons, preemption is not an issue for the jury, nor does *Wyeth v. Levine*, 555 U.S. 555 (2009) or *In re Fosamax (Alendronate Sodium) Products Liability Litigation*, 852 F.3d 268 (3d Cir. 2017), the cases on which the plaintiffs rely, say otherwise. In these cases, the defendants defended against a state law suit alleging improper labeling by claiming it would be impossible to comply with both federal and state law labeling requirements. This defense requires factual analysis because the Supreme Court has held that in such circumstances the manufacturer must show with "clear evidence . . . that the FDA would have rejected a proposed label change." *Fosamax*, 852 F.3d at 285. Smith & Nephew has not invoked this defense and thus fact-based considerations are not required here.

Finally, preemption is not better left to transferor courts on remand. To avoid conflicting rulings among the courts of 42 states and jurisdictions (to say nothing of wasted resources), MDLs require a single court to decide pretrial disputes like the sufficiency of the pleadings and the scope of discovery. The plaintiffs would have the court ignore this purpose by restricting the court's power to decide these threshold questions. Fidelity neither to the MDL process nor precedent compels that result.

The plaintiffs rely on the decision in *In re: Zofran (Ondansetron) Products Liability Litigation*, 2016 WL 287056 (D. Mass. 2016) to support their argument. There, a district court withheld a ruling on whether certain state law violations were impliedly preempted because there

were more than 200 cases in the MDL. The *In re: Zofran* court, however, expressly noted the absence of a master complaint, its inability to resolve issues under express preemption, and only three pages of briefing on the issue of preemption as several of the factors leading to its decision. *In re: Zofran*, 2016 WL 287056 at *4. A master complaint has been filed in this case, the parties have devoted over one hundred pages to preemption, and express preemption issues can be resolved. To withhold a ruling on these issues would ignore the reasons—indeed, the more than 200 reasons—these suits were consolidated in an MDL.

II. Preemption

Smith & Nephew argues that the plaintiffs' claims are expressly and impliedly preempted by federal law. Federal courts "must not give effect to state laws that conflict with federal laws," *Armstrong v. Exceptional Child Center, Inc.*, 135 S. Ct. 1378, 1383 (2015), for the "Constitution, and the Laws of the United States, which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land," U.S. Const. art. VI, § 2. Thus, "[w]here state and federal law 'directly conflict,' state law must give way." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617 (2011).

The federal government may expressly preempt state law by "withdraw[ing] specified powers from the States by enacting a statute" or may do so impliedly, by positive action—creating a statutory scheme "so pervasive . . . that Congress left no room for the States to supplement it"—or simply by expressing a "federal interest" in a field "so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Arizona v. U.S.*, 567 U.S. 387, 399-400 (2012). State laws also are impliedly preempted "to the extent of any conflict with a federal statute" and when the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby v. National Foreign Trade Council*, 530 U.S. 363, 372-73 (2000) (citing *Hines v. Davidowitz*, 312

U.S. 52, 66-67 (1941)). When deciding whether a particular state law is preempted, the court should be mindful of Congress's purpose. *Wyeth*, 555 U.S. at 565.[8]

A. Express Preemption

Smith & Nephew argues that the plaintiffs' claims are expressly preempted under 21 U.S.C. § 360k, a provision of the FDA's statutory framework which states:

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

21 U.S.C. § 360k(a). State law requirements, including the state's "common-law duties," are "different from, or in addition to," requirements under the statute if: (1) "the Federal Government has established requirements applicable to" the challenged medical device and (2) the state law requirements are "different from, or in addition to" those requirements and "relate to safety and effectiveness." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321-24 (2008). States, however, are free to impose duties that "parallel, rather than add to, federal requirements" such as by "providing a damages remedy for claims premised on a violation of FDA regulations." *Id.* at 330.

There is no doubt that the federal government has regulated the BHR system. As a Class III device it was subject to a rigorous approval process and continues to be regulated even after receiving premarket approval. *See Walker v. Medtronic, Inc.*, 670 F.3d 569, 572-74 (4th Cir. 2012). There is equally no doubt that the plaintiffs' common law claims constitute requirements under *Riegel*. The plaintiffs agree, but they argue that their claims survive express preemption nevertheless because they parallel, rather than differ from or add to, federal requirements.

[8] Recently, the Supreme Court explained that a court should not apply a presumption against preemption when a "statute contains an express pre-emption clause." *Puerto Rico v. Franklin California Tax-Free Trust*, 136 S. Ct. 1938, 1946 (2016). The court does not rely on a presumption against preemption to reach the conclusions stated below.

A state law is parallel to federal requirements if it seeks to impose liability for conduct that also violates an FDA regulation. *See, e.g.*, *Mink v. Smith & Nephew Inc.*, 860 F.3d 1319, 1326 (11th Cir. 2017); *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013); *Walker*, 670 F.3d at 577; *Bass v. Stryker Corp.*, 669 F.3d 501, 510 (5th Cir. 2012); *Bausch v. Stryker Corp.*, 630 F.3d 546, 552 (7th Cir. 2010); *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, 623 F.3d 1200, 1205 (8th Cir. 2010). So, if a plaintiff may succeed on her state law claim by proving conduct that violates federal requirements, then that claim parallels federal requirements. The state law reliance on a federal regulation need not be explicit. Rather the elements of traditional state laws need only be satisfied by conduct leading to a violation of a federal regulation.

a. Strict Liability

The plaintiffs claim Smith & Nephew is liable under two theories of strict liability: strict products liability and strict liability for failure to warn.[9] Smith & Nephew maintains that these claims are expressly preempted because they impose requirements that add to or differ from federal requirements. The court will grant Smith & Nephew's motion to dismiss these two claims because finding a device unreasonably dangerous adds to or differs from federal requirements.

The plaintiffs' argue that their strict liability claims parallel federal requirements in three steps: (1) State law holds defendants strictly liable for, among other things, selling unreasonably dangerous products; (2) Smith & Nephew's failure to fulfill its preexisting federal duty to report adverse incidents to the FDA resulted in an unreasonably dangerous product; and (3) Smith & Nephew is therefore liable under state strict liability laws that only parallel federal reporting

[9] The reasoning in this section applies as well to any other cause of action that might require proof that the BHR device was unreasonably dangerous.

requirements. Of course, imposing liability under a state statute that parallels federal reporting requirements remains faithful to *Riegel*, but permitting a state court to declare the BHR system unreasonably dangerous adds to federal requirements in two ways.

First, as the Supreme Court made clear in *Riegel*, premarket approval is FDA recognition of a particular medical device's fitness for the market. Having received that approval, the BHR system cannot be labeled unreasonably dangerous by state law without imposing requirements on medical devices different from or in addition to federal regulations. *See Riegel*, 552 U.S. at 319. Second, the FDA also has the sole power to declare that a particular device is too dangerous for the market based on new information. 21 U.S.C. § 360e(e)(1)(A)-(B). Under the plaintiffs' theory, courts would have the power to declare medical devices unreasonably dangerous after the FDA already granted the device approval. Indeed, the courts could do so before the FDA was able to review the information allegedly withheld, allowing a court to decide whether the information the FDA should have received is relevant, sufficient, and persuasive. Unlike deciding the simple binary question, "Was a federal regulation violated?," before imposing state liability, analyzing data related to medical devices requires expertise, judgment, and recognition of policy considerations Congress clearly determined the FDA was more fit to decide.

In sum, allowing state tort law claims to proceed that would require finding a device unreasonably dangerous would undermine Congress's decision to leave such questions to the FDA. Such products liability laws add to, or are different from, federal regulations and are therefore expressly preempted. The court will grant Smith & Nephew's motion to dismiss these claims.

b. Plaintiffs' Remaining Claims

The plaintiffs' remaining claims all, at least facially, survive express preemption because their elements may be satisfied by a violation of federal regulations. The plaintiffs argue that Smith & Nephew is liable under their remaining state law theories—negligence and negligence per se, failure to warn, negligent misrepresentation, breach of express warranty, and manufacturing defect—because it failed to report adverse incidents and properly train surgeons, disseminated false information, and manufactured the BHR with defects.[10] They further argue that these theories are not expressly preempted because each rests on a violation of one of several federal requirements: Smith & Nephew's obligation to report adverse incidents, disseminate only truthful information about the device, implement a surgeon training program,[11] and to manufacture the device exactly as approved. Because all of the plaintiffs' claims can, at least facially, be satisfied by Smith & Nephew's alleged failure to comply with duties already required by the FDA, the defendant's motion to dismiss these claims will be denied.

[10] The plaintiffs also make a separate misbranding claim, (MACC at ¶¶ 249-64), that does not fit neatly into any of the eight counts in the complaint. They argue that Smith & Nephew's labeling, and representations outside of its labeling, were false and misleading. At bottom, this claim seems to be no different than the plaintiffs' negligent misrepresentation and breach of express warranty claims and therefore survives preemption to the same extent those two claims survive preemption. The plaintiffs also have argued that an email exchange between Smith & Nephew and an FDA official transformed the discretionary CBE process—the means by which a medical device manufacturer may change its labeling before seeking FDA approval—into a mandatory reporting requirement. The dictates of an agency official, however, cannot overturn federal regulation. Such claims are expressly preempted. That provision is discretionary, not mandatory, and thus any state law that would have required Smith & Nephew to change its labeling adds to, or differs from, federal requirements.

[11] Smith & Nephew argues that it cannot be held liable for failing to train surgeons because no state provides a cause of action for failure to train medical personnel. Assuming that Smith & Nephew's research is correct, its argument still misses the mark. The plaintiffs argue that Smith & Nephew had a duty to properly train surgeons, and that its breach of that duty is cognizable under state common law tort duties. The plaintiffs' argument on this ground survives implied preemption, as further explained below, for similar reasons. To the extent this decision conflicts with the court's decision in *Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733 (D. Md. 2015), it is this decision that controls.

i. Negligence

The plaintiffs' negligence claims should survive express preemption. It is undisputed that under FDA regulations and the PMA Smith & Nephew had duties to disseminate truthful information, to report adverse incidents, and to adequately train surgeons working with the BHR device. Thus, insofar as the plaintiffs pin their negligence claims to conduct that breached those preexisting federal requirements, they avoid express preemption. Indeed, courts already have recognized that violations of those federal requirements may breach state tort duties. *See, e.g.*, *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 588 (6th Cir. 2013) (finding that courts have permitted negligence per se suits involving medical devices to proceed if they are "premised on [a] violation of federal law"); s*ee also De La Paz v. Bayer Healthcare LLC*, 159 F. Supp. 3d 1085, 1096 (N.D. Cal. 2016)(finding that, if properly pleaded, a failure to properly train argument survives preemption if the failure violates requirements of the premarket approval process).[12]

Any claim, however, that Smith & Nephew had a duty to change its labeling or communicate information to patients or the medical community, or any other duty not also imposed by the FDA, should be preempted as an attempt to impose requirements that add to or differ from federal regulations. *See Bass*, 669 F.3d at 515.

ii. Failure to Warn

The plaintiffs' failure to warn claim also parallels federal obligations. As already stated, Smith & Nephew was required by the FDA to report adverse incidents. *See Riegel*, 552 U.S. at 319-20 (listing reporting requirements).Thus, state failure to warn claims that support holding

[12] The plaintiffs argue in their MACC that Smith & Nephew voluntarily assumed a state law duty of care because of its affirmative steps to market and sell the BHR device. It is not clear that this argument is different from their general negligence claim but, in any case, it is preempted insofar as it attempts to impose a duty on Smith & Nephew not also required by federal regulations.

Smith & Nephew liable for its alleged failure to report specific information to the FDA are not expressly preempted. *See Stengel*, 704 F.3d at 1233 (holding that failure to warn claims are not preempted in accordance with the Fifth and Seventh Circuits.). Any claim that Smith & Nephew had a duty to warn the general public or the medical community is, however, expressly preempted because there is no such parallel federal requirement. *See In re Medtronic*, 623 F.3d at 1205.

iii. Negligent Misrepresentation and Breach of Express Warranty

The plaintiffs' negligent misrepresentation and breach of express warranty claims also avoid express preemption. Smith & Nephew was required to make "truthful, accurate, and not misleading" warranty statements under the terms of the FDA's conditional approval of the device. (MACC at ¶ 509). The plaintiffs claim that Smith & Nephew violated the FDA's conditional approval by marketing the BHR device as safer than rival metal-on-metal devices, despite its knowledge that all metal-on-metal devices were causing serious medical complications.

Claims for breach of express warranty and negligent misrepresentation parallel federal requirements insofar as the plaintiffs argue that Smith & Nephew is liable for claiming the BHR device was safer than competing devices. A manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. That is exactly what FDA approval means. But when a manufacturer makes other claims about its device as, for example, that it is safer than competing devices, it steps out of the protected zone of FDA-approved warranties and into its ongoing obligation to disseminate truthful and non-misleading information regarding the device. Thus, any state law claim that imposes liability for making false statements regarding the

device's relative safety parallels federal obligations, and the plaintiffs' claims for negligent misrepresentation and breach of express warranty survive express preemption. *See Wildman v. Medtronic, Incorporated*, 874 F.3d 862, 870 (5th Cir. 2017) (holding that a breach of express warranty claim was not preempted because the plaintiffs were attempting to enforce "a duty that also exists under federal law."); *see also Funke v. Sorin Group USA, Inc.*, 147 F. Supp. 3d 1017, 1028 (C.D. Cal. 2015) (holding that a negligent misrepresentation claim was preempted because the plaintiffs had not identified a violation of a federal statute, unlike the plaintiffs in this case); *Eidson v. Medtronic, Inc.*, 40 F. Supp. 3d 1202,1225-26 (N.D. Cal. 2014)(finding that a negligent misrepresentation claim parallels federal requirements that make it unlawful to make off-label claims).

These claims, however, cannot be supported by representations that the FDA required Smith & Nephew to make because liability would then rely not on Smith & Nephew violating federal regulations but on Smith & Nephew *complying* with federal regulations.

iv. Manufacturing Defect

Last, the plaintiffs' manufacturing defect claim also is parallel to federal requirements. Any deviation from the FDA's approved design of the BHR device would violate federal regulations. *Bausch*, 630 F.3d at 553 (finding that the plaintiff's "claims for defective manufacture in violation of federal law are not expressly preempted by section 360k"); *see also Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 933 (5th Cir. 2006). A state law manufacturing defect claim relying on such deviations therefore would not differ from or add to preexisting federal obligations. *Bausch*, 630 F.3d at 553.[13]

[13] If, however, a state products liability law underlying any of these claims requires the plaintiffs to prove that the manufacturing defect made the BHR system unreasonably dangerous then it would likely be preempted for the same reasons the plaintiffs' strict products liability claims are preempted.

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These conclusions put the court in step with other federal courts considering similar challenges to the BHR device. *See, e.g.*, *Felger v. Smith & Nephew, Inc.*, 222 F. Supp. 3d 746, 753-54 (D. AK 2016) (holding that a manufacturing defect claim and a failure to warn claim based on failure to report adverse events to the FDA may survive express preemption); *Nagel v. Smith & Nephew, Inc.*, 2016 WL 4098715 at *7-8 (D. Ct. 2016) (recognizing the same for negligent misrepresentation claims that allege untruthful marketing); *Ellis v. Smith & Nephew, Inc.*, 2016 WL 7319397 at *6 (D. S.C. 2016) (holding the same for breach of express warranty claims); *Comella v. Smith & Nephew, Inc.*, 2013 WL 6504427 at *2 (N.D. Ill. 2013) (holding the same for failure to warn claims based on failure to report adverse events to the FDA); *Elmore v. Smith & Nephew, Inc.*, 2013 WL 1707956 at *3 (N.D. Ill. 2013) (holding the same for certain negligence claims); *see also Becker v. Smith & Nephew, Inc.*, 2015 WL 4647982 at *3-4 (D. N.J. 2015) (holding that a breach of express warranty claim is expressly preempted if it is based on an FDA approved label and recognizing that "[s]uccess on [strict liability] claims would require" a showing "that the . . . device was unsafe or ineffective despite the PMA process, thereby interfering with the requirements already established by the MDA"); *Bertini v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 246, 256 (E.D.N.Y. 2014) (holding that a claim for failure to warn the public and health care professionals is expressly preempted).

Accordingly, the defendant's motion to dismiss on express preemptions grounds will be granted as to the plaintiffs' strict liability claims but denied as to the plaintiffs' six remaining claims.

B. Implied Preemption

Smith & Nephew argues that even if most of the plaintiffs' claims are not expressly preempted by 21 U.S.C. §360k they are impliedly preempted because they attempt to enforce a right held by the FDA or assert novel causes of action.

A state law is impliedly preempted by FDA regulations if the law "exist[s] solely by virtue of the FDCA . . . requirements" and is not a "traditional state tort law which had predated the federal enactments in question." *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 353 (2001). This does not mean that state law cannot hold Smith & Nephew liable for a violation of FDA regulations.[14] *Id. Riegel* and *Buckman* explicitly reject that position. *See Riegel*, 552 U.S. at 330; *Buckman*, 531 U.S. at 352-53. Rather, *Buckman* prevents a plaintiff from transforming a federal regulation into a private right of action, instructing plaintiffs to rely on preexisting and traditional state tort law to assert their claims. Thus, a plaintiff cannot pursue a claim alleging fraud-on-the-FDA for a defendant's failure to disclose information but may seek relief under traditional state failure to warn causes of action, for example, for violation of those same reporting requirements. *See Buckman*, 531 U.S. at 353.

All of the plaintiffs' claims in the MACC fall within the states' traditional power to regulate matters of health and safety. Not one cause of action tries to enforce a legal right held by a federal agency or relies on the FDA's statutory scheme for its existence—they have all long predated modern medical devices.

In its motion to dismiss Smith & Nephew argues that premising state law claims on violations of federal regulations is precisely the private enforcement of federal rights that

[14] The MDA's express preemption provision does not "bar the ordinary working of conflict pre-emption principles." *Geier v. American Honda Motor Co. Inc.*, 529 U.S. 861, 869 (2000).

Buckman invalidated. Smith & Nephew argues that the plaintiffs' negligence per se claims, therefore, are impliedly preempted because they depend on the existence of regulatory violations. *See, e.g.*, *In re Darvocet, Darvon, and Propoxyphene Products Liability Litigation*, 756 F.3d 917, 936 (6th Cir. 2014) (finding negligence per se claims preempted by *Buckman*). This argument sweeps too broadly for, if correct, every claim that survives express preemption by paralleling FDA regulations would later be impliedly preempted for, paradoxically, paralleling FDA regulations—a result unsupported by *Buckman* which expressly held that traditional state law claims premised on federal regulatory violations were not covered by its holding. *Buckman*, 531 U.S. at 352-53. There is nothing unique to negligence per se claims to alter this conclusion. Such claims predate the federal enactments in question and attempt what any other state law claim paralleling federal regulations attempt: to hold a defendant liable for conduct that also violates FDA regulations. *See McClellan v. I-Flow Corp.*, 776 F.3d 1035, 1039-40 (9th Cir. 2015) (rejecting the district court's refusal to provide a negligence per se jury instruction on implied preemption grounds); *Fulgenzi*, 711 F.3d at 588; *Hughes*, 631 F.3d at 771.

The same is true for the plaintiffs' failure to warn claim. Such claims are traditional state law causes of action that owe their existence to health and safety concerns rather than federal regulation. *See Stengel*, 704 F.3d at 1233. *But see Mink*, 860 F.3d at 1330 (finding a failure to warn claim impliedly preempted because it was based on a duty to report held by the FDA). And here the plaintiffs argue that Smith & Nephew's failure to warn the FDA violated a legal right owed to *them*, not the FDA. In short, the plaintiffs' failure to warn claims do not attempt to

enforce the FDA's right to be warned of information concerning the safety of approved medical devices and are therefore not impliedly preempted.[15]

The plaintiffs' remaining claims fall squarely outside the teeth of *Buckman*. Claims for manufacturing defect, breach of express warranty, negligent misrepresentation, and negligence implicate "matters of health and safety" historically protected by the state. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). As a result, plaintiffs that press such claims vindicate traditional state law duties, rather than legal rights held by the FDA. Other courts have come to a similar understanding. *See, e.g.*, *Mink*, 860 F.3d at 1330 (holding that manufacturing defect claims are not impliedly preempted); *Comella*, 2013 WL at *3 (holding the same for negligence claims); *Laverty v. Smith & Nephew, Inc.*, 197 F. Supp. 3d 1026, 1035 (N.D. Ill. 2016) (holding the same for failure to warn claims). Accordingly, these claims, like the plaintiffs' claims for negligence per se and failure to warn, survive implied preemption.

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In sum, all but two of the plaintiffs' state law claims survive express preemption because each may be satisfied by conduct that also violates federal requirements. These six claims also survive implied preemption as traditional state law duties that predate the FDA's regulation of medical devices. A single question remains: considering the limits imposed by the court's preemption analysis, have the plaintiffs' claims been sufficiently pleaded? For the reasons stated below, the plaintiffs have carried their burden under Rule 8 for all but their manufacturing defect claim.

[15] To the extent the plaintiffs' adopt, or their underlying state failure to warn claims require, a fraud-on-the-FDA claim, that claim would be preempted under *Buckman*.

C. Sufficiency of the Pleadings

Smith & Nephew argues that the plaintiffs' claims should be dismissed because they fail to state a claim under Federal Rule of Civil Procedure 8. As already explained, at this stage in the MDL, and based on the parties' briefing, the court cannot decide the merits of the defendant's arguments as to any individual claim in the MDL, but can, more generally, decide whether a particular cause of action has been sufficiently pleaded. On that view, the law and the factual allegations in the complaint support rejecting Smith & Nephew's arguments for dismissal for two reasons: (1) the court's preemption analysis does not eliminate all viable arguments for establishing liability for the state law claims pursued by the plaintiffs and (2) the specific allegations in the complaint support the plausibility of nearly all those claims.

Despite the paucity of state-specific information in the parties' briefings, it is clear that restrictions imposed by the preemption analysis do not keep the plaintiffs from sufficiently pleading at least some of their claims. Courts considering the same claims, in some of the same states, as the claims brought by the plaintiffs here have held that claims for failure to report adverse incident reports to the FDA, manufacturing defective devices, and disseminating false information asserted within the bounds of *Riegel* and *Buckman* are sufficient to establish liability under state law. One federal circuit court has held that failure to warn claims in Arizona are not preempted because Arizona imposes liability for failure to warn a third-party like the FDA. *See Stengel*, 704 F.3d at 1233; *see also Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733, 742 (D. Md. 2015) (finding that a failure to warn a third party can establish liability in Maryland). Courts also have held that state negligence and negligence per se claims, *Fulgenzi*, 711 F.3d at 588 (Ohio), manufacturing defect claims, *Bausch*, 630 F.3d at 553 (Illinois), breach of express warranty, *Wildman*, 874 F.3d at 870 (Texas), and negligent misrepresentation claims, *Eidson*, 40

F. Supp. 3d at 1225-26 (California), survive preemption because they may be established by conduct that violates FDA regulations.[16]

Further, the plaintiffs' factual allegations support their contention that Smith & Nephew violated federal regulations. The complaint plausibly casts the BHR device, like other metal-on-metal devices, as a health risk of which Smith & Nephew failed to warn the FDA. (*See, e.g.*, MACC at ¶ 201). They further indicate that Smith & Nephew was aware, based on articles and reports from health organizations around the world, that its device was likely to result in harm, and that despite this information, it pursued a marketing campaign for the BHR device that included comparative safety claims undermined by available data. (*See, e.g.*, MACC at ¶¶ 99, 117, 121, 124, 128). The complaint also contains allegations that Smith & Nephew failed to properly train surgeons in violation of the PMA and that it disseminated false information through widely read publications, plausibly suggesting that the plaintiffs, or at least their doctors, had read the information. All of this is clearly alleged in the MACC.[17]

That some short-form complaints fail to expressly assert that an individual plaintiff or her surgeon reviewed these materials overlooks the short-form complaints' adoption of the allegations in the Master Amended Consolidated Complaint. Each short-form complaint, usually but not always in paragraph 17, expressly adopts the allegations made in the MACC. The purpose of the MACC was to provide a set of representative allegations that any individual allegedly injured by the BHR system may adopt to support their claims. It fulfilled that purpose here.

[16] Each state involved in these cases is also involved in this case.

[17] The plaintiffs' factual allegations also provide support for any causation element of these causes of action. Taking the complaint as true, it is plausible that if Smith & Nephew had warned the FDA and not misrepresented the safety of the device compared to other metal-on-metal devices, for example, the plaintiffs would not have selected the BHR device as a remedy for their hip ailments. The plaintiffs also allege that they, or their physicians, viewed the misrepresentations described in the complaint. (MACC at ¶¶ 53-54).

In sum, the plaintiffs allege, with factual support, that Smith & Nephew failed to warn the FDA of adverse incidents, disseminated false information it knew or should have known to be false, and, for all these reasons, and some others, may have breached its duty of care. This is more than enough to raise the plaintiffs' "right to relief above the speculative level." *Twombly*, 550 U.S. at 555.[18]

Nevertheless, Smith & Nephew challenges the sufficiency of the pleadings of (1) the plaintiffs' manufacturing defect claim and (2) the claims alleged in the short-form complaints but not the MACC.[19] As to the manufacturing defect claim, the defendant argues that the plaintiffs fail to allege the FDA-approved design specifications for the BHR device and, consequently, how any one BHR implant deviated from that design.

The plaintiffs allege that manufacturing defects in the BHR device can be inferred from significant wear rates and inadequate clearance distances (exceeding even Smith & Nephew's expectations for those metrics) between the ball and socket parts of the device found after hip revision surgeries. (MACC at ¶ 225). But an error in design performance does not always result from an error in design manufacturing.

Although the plaintiffs concede that wear rates and clearances were not part of the FDA-approved design specifications, they argue that these figures are indicative of a serious defect that must have resulted from improper manufacturing. Without pleading the FDA's specified design of the BHR device or how any single device deviated from those specifications, it is impossible to tell whether the wear rates and clearances identified by the plaintiffs result from a manufacturing defect. That is so because a deviation from expected design performance can just

[18] Fact-sheets containing individualized information to support the short-form complaints can be used to help define the scope of discovery.

[19] Smith & Nephew also disputes the plaintiffs' characterization of the facts. (Def.'s Mot. ECF No. 409, p. 40). Because the allegations in the complaint must be taken as true, *Beck v. McDonald*, 848 F.3d 262, 270 (4th Cir. 2017), the motion to dismiss is not the proper vehicle to resolve factual disputes.

as well indicate a problem with Smith & Nephew's expectations for the BHR's performance as it could a problem with the BHR's manufacture. Put another way, the complaint is not sufficient to allow the court to infer from excessive wear rates and clearance distances that a manufacturing defect is to blame when a device fails, because that failure also could be caused by a perfectly manufactured device that failed to meet design expectations. Without alleging how a particular device diverges from its designated design a plaintiff cannot carry her pleading burden under 12(b)(6). *Williams*, 123 F. Supp. 3d at 747. Accordingly, the plaintiffs' manufacturing defect claim will be dismissed.

Smith & Nephew's final argument, that the causes of action pursued separately by the short-form complaints (as opposed to those claims expressly pursued by the MACC) have been insufficiently pleaded, cannot be decided on the motion papers. To the extent the MACC alleges facts that support some of the 37 claims pursued by the short-form complaints, those supported claims satisfy Rule 8. Some of those claims will meet that standard, others will not, but without further briefing the court cannot decide where each claim falls. The parties should consider the court's analysis above, including possible preemption concerns, and attempt to reach an agreement on the future of those claims. If an agreement cannot be reached, further briefing on those claims will be ordered.

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In sum, there are sufficient factual allegations to support all but the plaintiffs' manufacturing defect claim. Far more than "a formulaic recitation of the elements of a cause of action," *Twombly*, 550 U.S. at 555, the plaintiffs' complaint permits the court "to draw the reasonable inference that the defendant is liable for the misconduct alleged," *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

Conclusion

Smith & Nephew's motion to dismiss will be granted in part and denied in part. The plaintiffs' strict liability claims are expressly preempted because they add to or differ from federal regulations. The plaintiffs' six remaining claims survive express and implied preemption. Each claim imposes a traditional state duty that predates and parallels federal requirements. All but one of those claims has been sufficiently pleaded. The MACC contains pages of factually supported allegations that, if taken as true, plausibly state a claim for relief. The plaintiffs' manufacturing defect claim does not survive the motion to dismiss, however, because the plaintiffs fail to allege how the BHR device deviated from FDA design specification and do not provide other specific factual support for the inference they ask the court to draw. Accordingly, the plaintiffs' failure to warn, negligence and negligence per se, breach of express warranty, and negligent misrepresentation claims are fit for discovery. Whether the 37 claims pursued by some of the short-form complaints but not the MACC survive preemption and Rule 8 cannot be decided on the motion papers. The parties should attempt to reach an agreement on those claims consistent with the conclusions stated in this opinion. A separate order follows.

March 26, 2018
Date

/s/
Catherine C. Blake
United States District Judge