IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

IN RE: SMITH & NEPHEW BIRMINGHAM HIP RESURFACING (BHR) HIP IMPLANT PRODUCTS LIABILITY LITIGATION	*	MDL No. 2775 Master Docket No. 1:17-md-2775
	*	JUDGE CATHERINE C. BLAKE
	*	THIS DOCUMENT RELATES TO ALL THA TRACK CASES
	*	
	*	

MEMORANDUM

Pending before the court is Smith & Nephew's motion to dismiss claims in the THA track. The motion boils down to one core dispute: how does the express preemption provision of the Medical Device Amendments of 1976 (the "MDA") apply to hybrid systems that are comprised of both premarket-approved and § 510(k)-approved components? The Fourth Circuit has yet to address this question, and resolving the issue calls for careful consideration of the interrelated, and sometimes competing, concerns that underlie the U.S. Food and Drug Administration's (the "FDA") premarket approval process and the MDA's preemption provision—namely, ensuring public safety while encouraging innovation. For the reasons outlined below, Smith & Nephew's motion will be granted in part and denied in part.

BACKGROUND

Smith & Nephew seeks to dismiss claims in two of the plaintiffs' Master Amended Consolidated Complaints ("MACCs"). First, the plaintiffs filed a MACC that alleges harm from the use of Smith & Nephew's Birmingham Hip Resurfacing ("BHR") cup with Smith & Nephew's cobalt-chrome modular femoral heads as part of total hip arthroplasties ("THA"). (MACC ["THA MACC"], ECF No. 878). Second, the plaintiffs filed a MACC that alleges harm from the use of

release of metal debris that can occur from metal-on-metal devices, (THA MACC ¶ 97), and the FDA stated that the "R3 metal liner should not be used with the R3 acetabular shell," (R3 MACC ¶¶ 9, 11). Patients who received the BHR-THA and R3-THA systems suffered adverse reactions and underwent revision surgeries. (*See, e.g.*, THA MACC ¶ 32; R3 MACC ¶¶ 60, 65).

In its motion to dismiss, Smith & Nephew sets forth several arguments: (1) the plaintiffs' strict liability, implied warranty, misrepresentation, deceptive trade practices, and fraudulent concealment arguments are preempted by the MDA; (2) several of the plaintiffs' claims are not pled with the particularity required by Rule 8 and Rule 9(b); and (3) the court should reconsider its ruling in the BHR track that several of the plaintiffs' claims at least superficially survive preemption.

STANDARD OF REVIEW

When ruling on a motion under Rule 12(b)(6), the court must "accept the well-pled allegations of the complaint as true," and "construe the facts and reasonable inferences derived therefrom in the light most favorable to the plaintiff." *Ibarra v. United States*, 120 F.3d 472, 474 (4th Cir. 1997). "Even though the requirements for pleading a proper complaint are substantially aimed at assuring that the defendant be given adequate notice of the nature of a claim being made against him, they also provide criteria for defining issues for trial and for early disposition of inappropriate complaints." *Francis v. Giacomelli*, 588 F.3d 186, 192 (4th Cir. 2009). "The mere recital of elements of a cause of action, supported only by conclusory statements, is not sufficient to survive a motion made pursuant to Rule 12(b)(6)." *Walters v. McMahen*, 684 F.3d 435, 439 (4th Cir. 2012) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). 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*, 684 F.3d at 439 (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).

ANALYSIS

The Medical Device Amendments of 1976

In 1976, in response to "mounting consumer and regulatory concern" about the health risks posed by new medical devices, the FDA passed the MDA. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475–76 (1996); *Riegel v. Medtronic, Inc.*, 522 U.S. 312, 315–16 (2018). Expanding the scope of the Federal Food, Drug, and Cosmetic Act (the "FDCA"), the MDA established federal requirements for the introduction of new devices and included an express preemption provision that preempts conflicting state law. *See* Medical Device Amendments of 1976, Pub. L. No. 94-295, sec. 2, §§ 513-516, 521, 90 Stat. 539, 540-60, 562 (codified as amended at 21 U.S.C. §§ 360c-360f, 360k). The MDA established three classes of medical devices, tiering devices based upon the potential risk posed to human health: Class I, Class II, and Class III. 21 U.S.C. § 360c. Class I medical devices are the most benign, while Class III medical devices pose the most potential risk to human life and welfare and, therefore, are subject to the most stringent regulations. *Id.*; *see Riegel*, 522 U.S. at 317.

Premarket Approval Process

Before a manufacturer can release a Class III device to the public, it must proceed through the premarket approval ("PMA") process. *See* 21 U.S.C. § 360c(a)(1)(C). A device will receive

premarket approval only if the FDA determines, after considering "any probable benefit to health from the use of the device against any probable risk of injury or illness from such use," that "there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Riegel*, 552 U.S. at 318 (quoting 21 U.S.C. §§ 360c(a)(2)(C), 360e(d)). The premarket approval process is demanding. On average, before rendering a decision on any Class III device, the FDA spends 1,200 hours reviewing the manufacturer's submissions and data related to the device's safety and efficacy. *Lohr*, 518 U.S. at 477 (first citing Hearings before the Subcommittee on Health and the Environment of the House Committee on Energy & Commerce, 100th Cong., 1st Sess. (Ser. No. 100-34), p. 384 (1987) (hereinafter 1987 Hearings), and then citing Kahan, *Premarket Approval Versus Premarket Notification: Different Routes to the Same Market*, 39 FOOD DRUG COSM. L.J. 510, 512–14 (1984)).

Manufacturers must provide the FDA with a range of information, including "a full statement of the [device's] components, ingredients, and properties," 21 U.S.C. § 360e(c)(1)(B); *Riegel*, 552 U.S. at 317–18, and a "specimen of the proposed labeling" that details "conditions of use," *Riegel*, 552 U.S. at 318; 21 U.S.C. § 360e(c)(1)(F). The FDA also reviews the manufacturer's proposed labeling to ensure that it is not false or misleading. *Riegel*, 552 U.S. at 318; 21 U.S.C. § 360e(d)(1)(A). "Once approved, the device may be manufactured, advertised, and distributed to the public, but those marketing activities may not be done in a manner 'inconsistent with . . . the [premarket] approval order for the device.'" *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 766 (2018) (quoting 21 C.F.R. § 814.80).

And manufacturers are required to inform the FDA of "new clinical investigations or scientific studies concerning the device which the [manufacturer] knows of or reasonably should know of," and to "report incidents in which the device may have caused or contributed to death or

serious injury." *Riegel*, 552 U.S. at 319 (first citing 21 C.F.R. § 814.84(b)(2), and then citing § 803.50(a)). Manufacturers of premarket-approved products are also required to investigate adverse reports to determine if remedial action is required to prevent substantial harm to the public health, 21 C.F.R. § 803.50, and to report these findings to the FDA within five days, 21 C.F.R. § 803.53. If manufacturers want to make changes to a PMA approved device, they must submit an application for "supplemental premarket approval" to the FDA. § 360e(d)(5); 21 C.F.R. § 814.39(c). Finally, the FDA may withdraw premarket approval if it "determines that a device is unsafe or ineffective." *Riegel*, 552 U.S. at 319–20 (first citing § 360e(e)(1), and then citing § 360h(e)).

Importantly, however, not all Class III devices are approved through the PMA process. The MDA provides for two exceptions to the PMA requirement. First, the MDA allowed devices which were already on the market as of 1976 to "remain on the market without FDA approval until such time as the FDA initiates and completes the requisite PMA." *Lohr*, 518 U.S. at 478 (first citing 21 U.S.C. § 360e(b)(1)(A), and then citing 21 C.F.R. § 814.1(c)(1) (1995)). "Second, to prevent manufacturers of grandfathered devices from monopolizing the market while new devices clear the PMA hurdle, and to ensure that improvements to existing devices can be rapidly introduced into the market, the Act [] permits devices that are 'substantially equivalent' to pre-existing devices to avoid the PMA process." *Lohr*, 518 U.S. at 478 (citing 21 U.S.C. § 360e(b)(1)(B)). This approval process for substantially equivalent devices, described in further detail below, is known as the § 510(k) process. *See* 21 U.S.C. § 360(k).

§ 510(k) Approval Process

Today, many Class I, II, and III devices are reviewed through the comparatively lenient § 510(k) process. *See* 21 U.S.C. § 360(k). On average, the FDA spends a mere 20 hours

determining whether to approve a device through the § 510(k) process. *Lohr*, 518 U.S. at 479 (citing 1987 Hearings, at 384). And clearing the § 510(k) process does not require an independent or exhaustive review of a device's safety and efficacy. *Lohr*, 518 U.S. at 479; *Shuker*, 885 F.3d at 767. Instead, manufacturers submit a "premarket notification" to the FDA, and the device may be cleared for the market if it is "substantially equivalent" to an existing device.

In designing the MDA, Congress expected that most Class III devices would be approved for market through the PMA process. *Lohr*, 518 U.S. at 479. But because of the comparative ease of receiving approval through the § 510(k) process, many Class III devices enter the market without proceeding through the PMA process. In fact, by 1983, "nearly 1,000 of approximately 1,100 Class III devices that had been introduced to the market since 1976" were processed through the § 510(k) process instead of the PMA process. *Id.* (citing Medical Device Regulation: The FDA's Neglected Child (Committee Print compiled for the Subcommittee on Oversight and Investigations of the House Committee on Energy & Commerce), Comm. Print 98–F, p. 34 (1983)). By 1990, "80% of new Class III devices were being introduced to the market through the § 510(k) process and without PMA review." *Lohr*, 518 U.S. at 479 (citing H.R.Rep. No. 101-808, p. 14 (1990)).

In 1990 Congress amended the MDA in an attempt to decrease "the FDA's reliance on the § 510(k) process while continuing to ensure that particularly risky devices received full PMA review." *Lohr*, 518 U.S. at 479 n.4 (citing Safe Medical Devices Act of 1990, 104 Stat. 4511). Despite these amendments, the § 510(k) approval process continues to be overwhelmingly preferred. In 2005, for example, the FDA approved 3,148 Class III devices through the § 510(k) process compared to a meager 32 devices through the PMA process. *Riegel*, 552 U.S. at 317 (citing

P. Hutt, R. Merril, & L. Grossman, Food & Drug Law 992 (3d ed. 2007)).[1]

The MDA's Express Preemption Provision

Beyond the differences in rigor between the PMA and § 510(k) approval processes, the processes also impart distinct preemption consequences. The MDA contains an express preemption provision, which reads: "no State . . . may establish or continue in effect with respect to a device . . . any requirement which is different from, or in addition to," any federal requirement that relates either "to the safety or effectiveness of the device" or "to any other matter" included in a federal requirement applicable to the device. 21 U.S.C. § 360k(a). The Supreme Court has held that premarket approval establishes federal "requirement[s]" under the MDA. *Riegel*, 552 U.S. at 322–23. By contrast, the § 510(k) process does not establish federal requirements because it "focuse[s] on *equivalence*, not safety." *Id.* at 323 (citing *Lohr*, 518 U.S. at 493). Accordingly, state law may not impose requirements on PMA approved devices that depart from, or expand upon, federal requirements. But parallel state-law claims that mirror the federal requirements established by the MDA are not preempted. *Lohr*, 518 U.S. at 494–95. Importantly, state claims need not be identical to federal requirements to survive explicit preemption, they need only be "narrower, not broader" than existing federal requirements. *See Lohr*, 518 U.S. at 495 ("While such a narrower requirement might be 'different from' the federal rules in a literal sense, such a difference would surely provide a strange reason for finding preemption of a state rule insofar as it duplicates the federal rule."); *see also id.* (Breyer, J., joining the Court's opinion as to Part V).

Accordingly, determining whether state-law claims are preempted under § 360k(a) requires a two-step analysis: (1) has the federal government established requirements applicable to the specific device?; and (2) if so, do the plaintiffs' state-law claims impose state requirements

[1] The Second Circuit noted that this data was derived from the FDA's website. *See Riegel v. Medtronic*, 451 F.3d 104, 111–12 (2d Cir. 2006).

"with respect to the device that are 'different from, or in addition to,' the federal ones, and that relate to safety and efficacy"? *See Riegel*, 552 U.S. at 321–22 (quoting 21 U.S.C. § 360k(a)). Claims will be preempted only if both of these questions are answered in the affirmative.

Implied Preemption

State-law causes of action may also be impliedly preempted by the MDA. *See Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 348 n.2 (2001). *Buckman* held that state-law claims will be impliedly preempted under the MDA if the claim "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." *Id.* at 353. The claim at issue in *Buckman* was a "fraud-on-the-FDA" claim. *Id.* at 350. The Supreme Court reasoned that the MDA grants the FDA flexibility to prosecute fraud. *Id.* at 349–50. Allowing litigants to bring a state-law fraud-on-the-FDA claim might undercut the FDA's enforcement power. *Id. Buckman*, therefore held that the claim was impliedly preempted.

But as this court has previously held, *Buckman* cannot be read to mean that Smith & Nephew cannot be held liable for a violation of FDA regulations under state law. *In re Smith & Nephew Hip Resurfacing (BHR) Hip Implant Products Liability Litigation ["In re BHR"]*, 300 F.Supp.3d 732, 747 (D. Md. 2018) (first citing *Riegel*, 552 U.S. at 330, and then citing *Buckman*, 531 U.S. at 352–53). After *Buckman* the operative question is whether a traditional state law cause of action imposes the duty a litigant seeks to enforce, or whether the duty arises solely from the MDA. If the former, the claim will survive implied preemption. If the latter, the claim will be impliedly preempted.

Application of § 360k(a) to the BHR-THA and R3-THA Systems

The question at issue in this case is how to apply the MDA's express preemption provision

to hybrid systems that are comprised of not only components that went through the PMA approval process, but also components that were approved through the § 510(k) process. Here, the BHR cup in the BHR-THA system and the R3 metal liner in the R3-THA system received PMA approval, but the remaining elements of both systems were approved through the § 510(k) process. Specifically, the court must determine whether the incorporation of a premarket-approved component in a new medical device, which as a whole has not received premarket approval, extends § 360k(a)'s preemption protection to all claims targeting the device, or whether some state law claims fall outside of the scope of § 360k(a) because they do not directly impugn the safety or efficacy of the premarket-approved component.

The parties' briefing highlights two lines of case law—epitomized by *Shuker* and *Lafountain v. Smith & Nephew, Inc.*, No. 14-cv-1598, 2016 WL 3919796 (D. Conn. July 18, 2016)—which, at first blush, appear to take diametrically opposed approaches. Specifically, *Shuker* sets forth a components-level approach that focuses on whether any of the state-law claims are directed at a premarket-approved component, *see Shuker*, 885 F.3d at 774, while *Lafountain* focuses not only on the individual components, but also on the device that, as a whole, has not received premarket approval, *Lafountain*, 2016 WL 3919796, at *6. These lines of cases are reconcilable with each other and with the statutory text and structure of the MDA.[2] The best reading of § 360k(a) is that it "requires a court to parse a plaintiff's claims to determine whether

[2] And, what differences do exist may be explained, in part, by the different procedural postures of the *Shuker* and *Lafountain* courts. The *Lafountain* court reviewed a motion to dismiss, while the *Shuker* court was, at least in part, reviewing a motion for summary judgment, and, therefore, could conclude, on the basis of a more fully developed record, that the R3 metal liner was "at the heart" of each of Shuker's claims. (*Compare Lafountain*, 2016 WL 3919796, at *1, *with Shuker*, 885 F.3d at 768 n.5, 770). Notably, the FDA disagreed with that conclusion, as stated by the district court. FDA Amicus Br. at *11. The FDA asserted that the district court erred in finding that the R3 metal liner was "at the heart" of each claim, and explained that while "plaintiffs' claims 'generally concern the interaction of the R3 metal liner with the components of the R3 acetabular system,' [] the express-preemption analysis requires the court to further parse those claims to determine if any are directed at one or more of the § 510(k)-cleared components." *Id.*

the state-law requirements that underline them are indeed directed at the premarket-approved component." Brief for FDA ["FDA Amicus Br."] at *10, *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760 (3d Cir. 2018), (No. 16-3785), 2017 WL 4151264. Under this reading, § 360k(a) does not extend to state law claims that target the § 510(k)-approved components or the system as a whole. It only extends to state law claims that are directed at the premarket-approved component. A review of the MDA's text and the principles that underpin the premarket-approval process and the MDA's preemption provision supports this interpretation.

First, the MDA defines a device as an "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory" of that article. 21 U.S.C § 321(h). Because the MDA defines device to include "component" parts, courts have held that once a device as a whole receives PMA approval, the MDA preempts non-parallel state law claims directed at not only the device as a whole, but also at the device's component parts. *See Kubicki v. Medtronic, Inc.*, 293 F. Supp. 3d 129, 174–76 (D.D.C. 2018) (analyzing claims related to a specific insulin pump, which was part of an overall insulin-delivery system that had received premarket approval).[3] Further, courts have frequently held that the MDA's preemption provision applies when a single component of a PMA-approved device is used in isolation. *See e.g.*, *Arvizu v. Medtronic Inc.*, 41 F.Supp.3d 783, 790 (D. Ariz. 2014); *Martin v. Medtronic, Inc.*, 32 F.Supp.3d 1026, 1036 (D. Ariz. 2014); *Beavers-Gabriel v. Medtronic, Inc.*, 15 F.Supp.3d 1021, 1035 (D. Haw. 2014); *Houston v. Medtronic, Inc.*, No. 13-1679, 2014 WL 1364455, at *4 (C.D. Cal. Apr. 2, 2014)). Moreover, in an amicus brief for the

[3] *See also Bentzley v. Medtronic, Inc.*, 827 F. Supp. 2d 443, 452 (E.D. Pa. 2011) (same pump); *Duggan v. Medtronic, Inc.*, 840 F.Supp.2d 466, 471 (D.Mass.2012) (same); *Gross v. Stryker Corp.*, 858 F.Supp.2d 466, 487–88 (W.D.Pa.2012) (analyzing a component of a hip replacement system which had received approval as a whole under the PMA process); *Lewkut v. Stryker Corp.*, 724 F.Supp.2d 648, 656 (S.D.Tex.2010) (same).

Shuker court, the FDA concluded that as a matter of statutory interpretation and policy, components of premarket-approved devices should be considered "devices" even when used in combination with non-premarket-approved devices. *See* FDA Amicus Br. at 7–10.[4]

Based on this review of the text of the MDA and existing case law, it appears to be beyond dispute that components of premarket-approved devices are themselves devices for which the MDA has set forth safety and efficacy requirements. Accordingly, non-parallel state-law claims that target premarket-approved components of hybrid devices are preempted. But the inquiry does not end there. The court must next determine how to handle state-law claims that target the hybrid system as a whole and the system's § 510(k) components.[5]

Section 360k(a) preempts states from imposing safety or efficacy requirements on a device that is already subject to federal requirements under the MDA. Nothing in the text of § 360k(a) suggests that preemption is limited to a particular use of a device. *See Simon v. Smith & Nephew, Inc.*, 18 F. Supp. 3d 423, 428 (S.D.N.Y. 2014) ("In determining whether claims relating to the safety and effectiveness of an FDA-approved device are preempted by the MDA, the question is not whether there are federal requirements applicable to a particular *use* of a device; the question is whether there are federal requirements applicable to the *device*." (internal quotations and citations omitted)). And as *Shuker* emphasized, the MDA implicitly endorses off-label use of devices because it does not "limit or interfere with the authority of a health care practitioner to

[4] The court does not defer to the FDA's interpretation of the MDA, but an agency's interpretation of its operative statute draws upon a "body of experience and informed judgments to which courts and litigants may properly resort for guidance" to the extent it has the "power to persuade." *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944).

[5] Smith & Nephew argues that all claims relating solely to § 510(k)-approved components should be dismissed because they are not properly part of this MDL. (Mem. P. & A. Supp. Def.'s Mot. Dismiss ["Def.'s Mot."] at 17 n.2, ECF No. 1173). The court disagrees. Because the court will consider these claims in conjunction with claims that target the hybrid systems as a whole, and claims targeting only the R3 liner, they are properly part of this MDL. Moreover, powerful considerations of judicial economy weigh against bifurcating these claims at this stage in the litigation.

prescribe or administer any legally marketed device to a patient." *Shuker*, 885 F.3d at 766 (citing 21 U.S.C. § 396); *see also Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1346–47 (10th Cir. 2015) (discussing why Congress may have wanted to establish a preemption provision that does not distinguish between on- and off-label uses in order to promote innovation). "'[O]ff-label' usage" by healthcare providers, "or use 'for some other purpose than that for which [a device] has been approved by the FDA,' is," therefore, "'an accepted and necessary corollary of the FDA's mission to regulate . . . without directly interfering with the practice of medicine.'" *Shuker*, 885 F.3d at 766 (quoting *Buckman*, 531 U.S. at 350).

But while the MDA implicitly encourages the off-label use of devices by physicians, nothing in the text of the MDA or the principles that undergird the PMA approval process suggests that Congress endorsed the off-label promotion of hybrid devices by manufacturers.[6] Quite the opposite. Once approved, a device may not be "manufactured . . . distributed, or advertised in a manner that is inconsistent with" the premarket approval order for the device. 21 C.F.R. § 814.80. And a manufacturer cannot make alterations to a premarket-approved device without first submitting an application to the FDA for supplemental premarket approval, 21 U.S.C. § 360e(d)(5); 21 C.F.R. § 814.39, and the MDA expressly prohibits manufacturers from engaging in false or misleading advertising, 21 U.S.C. §§ 331(b), 352 (q), 21 C.F.R. §§ 99.101, 99.103, § 801.6. Further, holding that manufacturers are immune from state tort liability in the case of off-label promotion of a medical device that rises to the level of misbranding or adulterating

[6] In fact, both *Riegel* and *Caplinger* deal with a different strain of off-label use. In those cases, physicians used a device in a different manner than it was originally designed for. *See Riegel*, 552 U.S. at 320 (device was used on a patient with a diffusely diseased and heavily calcified artery even though the "device's labeling stated that use was contraindicated for patients with diffuse or calcified stenoses," and the physician inflated device "beyond its rated burst pressure"); *Caplinger*, 784 F.3d at 1337 (physician implanted device using posterior approach rather than the anterior surgical approach that it was approved for). But they did not alter the design of the device to craft a new medical device, as occurred here with the BHR-THA and R3-THA systems.

a product "would improperly shift the risk of liability from device companies that intentionally mislead physicians to the physicians who rely upon that misleading advice when deciding to utilize a device off-label." *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1350 (10th Cir. 2015) (Lucero, J., concurring in part and dissenting in part); *see* 21 U.S.C. § 331 (prohibiting "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device . . . that is adulterated or misbranded").

Further, as discussed above, Congress has expressed concern about, and acted to rectify, the over-reliance of both the FDA and manufacturers on the § 510(k) process. *See* 1990 Amendments. And the Supreme Court has been clear that the premarket-approval and § 510(k) processes have different preemption implications because the § 510(k) process is focused on equivalence, not safety. *Riegel*, 552 U.S. at 323; *Lohr*, 518 U.S. at 493. Concluding that the incorporation of a single premarket-approved component into a hybrid device grants the entire device § 360k(a)'s preemption protection flips this finding on its head and would further disincentivize manufacturers from utilizing the PMA process. *See Huskey v. Ethicon, Inc.*, 29 F.Supp.3d 736, 752 (S.D. W.Va. 2014) ("It is difficult to understand why [the] premarket approval of one medical device [means] that claims against an entirely different medical device [are] preempted."). This is particularly true here, where the FDA explicitly declined to grant premarket-approval to the BHR-THA and R3-THA systems and warned against both the use of the metal modular femoral heads with a metal acetabular and the use of the R3 metal liner with the R3 acetabular shell. (THA MACC ¶¶ 63, 70, 97; R3 MACC ¶ 9, 11, 15–16).

What is more, while the FDA considers each component of a PMA-approved medical device to be a distinct premarket-approved device, *see* FDA Amicus Br. at 7–11, it has not suggested that claims that arise out of a "combination of components that includes a premarket-

approved component but [that] was not itself subject to premarket approval" triggers explicit preemption. FDA Amicus Br. at 12 n.4 (citing *Lafountain*, 2015 WL 3919796, at *5–6). In fact, the FDA explicitly left this question open, stating that "[t]he resolution of that question would likely depend on fact-specific considerations, such as whether the manufacturer had marketed the components for use in combination with each other." *Id.* And the *Shuker* and *Lafountain* courts appear to agree, to an extent, on this reasoning, though it ultimately leads the courts to somewhat different conclusions.

Shuker, for example, concludes that a litigant's negligence, strict liability, and breach of implied warranty claims impose requirements on a premarket-approved device because the "'heart of each of [the Shukers'] claims' challenged the safety and effectiveness of the R3 metal liner." *Shuker*, 885 F.3d at 774. But *Shuker* also expressly noted that some claims targeting hybrid systems, such as claims directed at the § 510(k) components of the system or claims that do not impose a new requirement on a premarket-approved component would not be preempted. *Id.* at 775 n.15. Likewise, *Lafountain* acknowledged that non-parallel state-law claims that target a premarket-approved component are preempted by § 360k(a), but concluded that state-law claims targeting a hybrid system's § 510(k) components or the system as a whole do not trigger § 360k(a). *Lafountain*, No. 14-1598, 2016 WL 3919796, at *5–6. The distance between the *Shuker* and *Lafountain* courts is not as great as the parties' briefing suggests. In keeping with the FDA's reading of the MDA, the court concludes that § 360k(a) preempts non-parallel state-law claims that target premarket-approved components, but it does not govern state-law claims that target a hybrid system's § 510(k) components or the system as a whole.

A handful of courts take issue with this approach, concluding either that claims directed at the system as a whole necessarily implicate the system's premarket-approved component, *see*

Simon, 18 F.Supp.3d at 428, or that litigants would not be able to plausibly state a claim for relief as to the system as a whole or the systems' § 510(k)-approved components without alleging claims specific to the premarket-approved component, *see Bertini v Smith & Nephew, Inc.*, 8 F.Supp.3d 246, 254 (E.D.N.Y. 2014). *But see Huskey*, 29 F.Supp.3d at 749–52 (disagreeing with *Bertini* and *Simon*). Under the FDA's reading of the MDA, at least some claims directed at the system as a whole and the systems' § 510(k) process may survive preemption. *See* FDA Amicus Br. at n.3, n.4. And though the Fourth Circuit has yet to weigh in on this issue it has, albeit superficially and in a different factual context, indicated that an analysis of the safety of a device as a whole is not coextensive with an analysis of the safety of a component of that device. *See Huskey v. Ethicon, Inc.*, 848 F.3d 151, 161–62 (4th Cir. 2017) ("evidence regarding the FDA process that the Prolene suture underwent . . . says little about the safety and effectiveness of *the final product*") (quoting *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2015 WL 4944339, at *13 (S.D.W.Va. Aug. 19, 2015)).

By this court's reading of the MDA and the existing case law, a tripartite approach to hybrid devices, which conducts distinct preemption analyses for claims directed at premarket-approved components, § 510(k) components, and the hybrid systems as a whole, to determine whether any claim imposes different state requirements on a device that is subject to federal requirements, is the only way to reconcile the statutory definition of "device" with Congress's fundamental concerns about adulterated and dangerous medical devices.[7]

Strict Liability Claims

The plaintiffs allege two strict liability claims: design defect and failure to warn. (THA

[7] Even if the court were to hold that, in some cases, claims targeting the hybrid system as a whole necessarily implicate the premarket-approved components, these claims would not automatically be preempted. Instead, these claims would survive to the extent the plaintiffs have stated parallel state-law causes of action that predated the MDA.

MACC ¶¶ 129–207; R3 MACC ¶¶ 132–211). Specifically, the plaintiffs allege that "Smith & Nephew designed, distributed, sold, produced, and/or manufactured" the components of the R3-THA system and that "the R3-THA device configuration was in a defective and unreasonably dangerous condition," (*see e.g.*, R3 MACC ¶¶ 133–34), and that Smith & Nephew designed the BHR-THA system, which was "unreasonably dangerous," (*see e.g.*, THA MACC ¶¶ 130–31, 148). The plaintiffs further allege that Smith & Nephew failed to carry out its duty to warn patients and the medical community about the risks of the BHR-THA and R3-THA systems. (*See e.g.*, THA MACC ¶¶ 140–47, 149; R3 MACC ¶¶ 147–51). The plaintiffs' allegations boil down to three types of claims: (1) design defect and failure to warn claims related specifically to the BHR cup and the R3 metal liner; (2) design defect and failure to warn claims related to the remaining BHR-THA and R3-THA system components; and (3) design defect and failure to warn claims related to the BHR-THA and R3-THA systems as a whole. The first group of claims are expressly preempted because they seek to impose state-law requirements on a premarket-approved device which differ from preexisting federal requirements. *See In re Smith & Nephew Birmingham Hip Resurgacing (BHR) Hip Implant Products Liability Litigation* ["*In re BHR*"], 300 F.Supp.3d 732, 743 (D. Md. 2018). Namely, they require a finding that a premarket-approved device is "unreasonably dangerous," which departs from the FDA's conclusion that premarket-approved devices are safe for public use. *Id.*

But the remaining claims are not governed by § 360k(a). Neither the hybrid systems themselves, nor their § 510(k) components received premarket approval. The FDA has, therefore, not established federal requirements as to either the system as a whole or its § 510(k)-approved components. Further, concluding that the BHR-THA or R3-THA systems as a whole were defectively designed or unreasonably dangerous does not necessarily impugn the safety or

effectiveness of the BHR cup or the R3 metal liner in isolation. Accordingly, the court will deny Smith & Nephew's motion as to the plaintiffs' strict liability claims that are directed at either the hybrid systems as a whole or the systems' § 510(k)-approved components and grant Smith & Nephew's motion as to the plaintiffs' strict liability claims that target either the R3 metal liner or the BHR cup specifically.[8]

Breach of Implied Warranty Claims

The plaintiffs allege that Smith & Nephew impliedly warranted that the BHR-THA system and the R3-THA system and its component parts were merchantable and fit for the particular use for which they were intended, and that Smith & Nephew breached this implied warranty. (THA MACC ¶¶ 323–33; R3 MACC ¶¶ 317–25). The plaintiffs' breach of implied warranty claims in the THA MACC are not governed by § 360k(a) because they relate solely to the BHR-THA system as a whole, rather than any of its component parts. (THA MACC ¶¶ 323–33). By contrast, the breach of implied warranty claims in the R3 MACC target not only the R3-THA system, but also its component parts. (R3 MACC ¶¶ 317–25). The claims that allege a breach of implied warranty as to the R3-THA system as a whole and its § 510(k) components fall outside of the scope of § 360k(a) and, therefore, survive preemption. The claims that target the R3 metal liner specifically are preempted.

Smith & Nephew contends that even if these claims survive preemption, they should be dismissed because they "assert only inadequate and conclusory allegations." (Def.'s Mot. at 36). But the plaintiffs adequately allege what Smith & Nephew impliedly promised and how patients

[8] The Court does note, however, that success on the merits of the remaining claims will require, e.g., a showing that Smith & Nephew was responsible for the decision to use the BHR-THA and R3-THA systems, such that they were, in fact, defectively *designed*. *See Simon*, 18 F.Supp.3d at 427. And it may be that, at the summary judgment stage, the BHR cup or the R3 metal liner will be "at the heart" of the plaintiffs' claims such that preemption will be required.

and physicians relied upon these promises. Specifically, the plaintiffs allege that: Smith & Nephew made public representations that the BHR-THA and R3-THA systems were safe, (*see e.g.*, THA MACC ¶¶ 59, 69, 81; R3 MACC ¶ 16); publicly indicated that the R3 metal liner could be used with the R3 acetabular system, (*see e.g.*, R3 MACC ¶ 15); promoted both the BHR-THA and the R3-THA systems through its sales representatives, (*see e.g.*, THA MACC ¶ 121; R3 MACC ¶¶ 17–20, 38); and circulated information to physicians that implied the BHR-THA system was safe yet simultaneously withheld critical safety and efficacy information from physicians, (*see e.g.*, THA MACC ¶¶ 61, 63–64, 68–69, 284–85; R3 MAC ¶¶ 23, 37, 40, 81, 88–89). Further, the plaintiffs allege that patients and physicians relied on this information in deciding to use the BHR-THA and R3-THA systems. (*See, e.g.*, THA MACC ¶¶ 327–29; R3 MACC ¶¶ 319–21). At this stage in the litigation, the plaintiffs have sufficiently pled breach of implied warranty claims as to the BHR-THA and the R3-THA systems and their 510(k)-approved components.

The claims that allege a breach of implied warranty as to the R3 metal liner "are preempted because they implicate the FDA's review of the safety and effectiveness" of the metal liner. *Lafountain*, No. 14-cv-1598, 2016 WL 3919796, at *5.[9] Accordingly, the court will grant Smith & Nephew's motion as to breach of implied warranty claims directed at the R3 metal liner, but deny the motion as to breach of implied warranty claims that address the BHR-THA or the R3-THA systems as a whole and their § 510(k)-approved components.

Negligent Failure to Warn Claims

The plaintiffs allege that Smith & Nephew negligently failed to warn both patients and the

[9] Smith & Nephew has not directly challenged the plaintiffs' breach of express warranty claims. But the court notes that breach of express warranty claims premised on Smith & Nephew's obligation to disseminate truthful and non-misleading information, even as to the R3 metal liner, are neither expressly nor impliedly preempted because they parallel federal requirements and arise out of "'matters of health and safety' historically protected by the state." *In re BHR*, 300 F.Supp.3d at 745, 747; *Houston v. Medtronic, Inc.*, 957 F.Supp.2d 1166, 1180–81 (C.D. Ca. 2013).

medical community about the risks associated with the use of the BHR-THA and R3-THA hybrid systems. (*See e.g.*, THA MACC ¶¶ 214; R3 MACC ¶¶ 212–92). To the extent these claims address the hybrid systems as a whole, without impugning the safety or efficacy of the systems' premarket-approved components, and to the extent these claims target the systems' § 510(k)-approved component parts, they are not subject to § 360k(a)'s purview.[10] Accordingly, the court will deny Smith & Nephew's motion as to these claims.

To the extent that these claims target the BHR cup and the R3 metal liner, they survive only to the extent that they parallel federal requirements and arise out of state law causes of action that predated the MDA. *See In re BHR*, 300 F.Supp.3d at 745; *see also Shuker*, 885 F.3d at 774 n.13 (noting that plaintiffs had "asserted ostensibly parallel [negligence] claims based on violations of federal law" but that these claims had not been revived on appeal). Because the MDA does not impose any requirement that a manufacturer warn the public or the medical community about adverse events, these claims are preempted. *See In re BHR*, 300 F.Supp.3d at 745. The MDA does, however, require manufacturers to report adverse incidents to the FDA. *See Riegel*, 552 U.S. at 319–20. Accordingly, these claims are not expressly preempted. *See Lafountain*, 2016 WL 3919796, at *5 (citing *Rosen v. St. Jude Medical, Inc.*, 41 F. Supp. 3d 170, 185 (N.D.N.Y. 2014)).

Notwithstanding the court's express preemption analysis, Smith & Nephew argues that these claims are impliedly preempted under *Buckman* because they exist solely by virtue of federal regulations. In its ruling on Smith & Nephew's motion to dismiss claims in the BHR track, the court rejected this argument, noting that state law may give rise to a coextensive duty to warn a

[10] By way of example, any claim that Smith & Nephew violated a state requirement in failing to include proper warnings with its BHR-THA and R3-THA system likely would not be preempted so long as the state requirements were limited to cautioning against the use of metal-on-metal systems, or metal liners in general, rather than specifically cautioning against the use of the BHR cup or the R3 metal liner. *See* FDA Amicus Br. at 11 n.3.

federal regulatory body such as the FDA about adverse events. *In re BHR*, 300 F.Supp.3d at 747. Smith & Nephew asks the court to reconsider its ruling, contending that the plaintiffs have pointed to no authority that establishes state law requirements that are "identical" to the federal requirement to report adverse events to the FDA. (*See* Def.'s Mot. at 56). But state requirements need not be identical, so long as they are "narrower, not broader" than federal requirements. *See Caplinger v. Medtronic, Inc.*, 784 F.3d at 1338 (citing *Lohr*, 518 U.S. at 495).

Smith & Nephew also argues that the plaintiffs have not identified state requirements that would require medical device manufacturers to report adverse events to the FDA. And, in fact, developments in the case law since this court's ruling in the BHR track do support the contention that not all states have a traditional cause of action that imposes such a duty on manufacturers. *See Conklin v. Medtronic, Inc.*, 431 P.3d 571, 576–78 (Sup. Ct. Az. 2018) (concluding that in Arizona, "only federal law, not state law, imposes a duty on [the manufacturer] to submit adverse event reports to the FDA"); *see also* Def.'s Mot. at 57 n.33 (compiling cases that have held that no state duty exists to report adverse events to the FDA). At this stage of the litigation, the plaintiffs have at least plausibly alleged that state law may, in some cases, impose a duty on medical device manufacturers to report adverse events to the FDA. To the extent such state duties exist, these claims survive implied preemption.

Finally, Smith & Nephew argues that the plaintiffs' negligent failure to warn claims should be dismissed because the plaintiffs have not "sufficiently pled a causal link between [Smith & Nephew's] failure to report and Plaintiffs' injuries." (Def.'s Mot. at 58). The court disagrees. As to failure to warn claims related to the BHR-THA and R3-THA hybrid systems as a whole and their § 510(k) components, the plaintiffs have sufficiently alleged that physicians and individual plaintiffs acted in reliance upon information they received about the hybrid systems' safety. (*See,*

e.g., THA MACC ¶¶ 217–19; R3 MACC ¶¶ 219–21). Had Smith & Nephew disclosed information about adverse events, physicians and patients may not have used the hybrid systems. At the motion to dismiss stage, these allegations suffice to plead a causal nexus between Smith & Nephew's alleged negligent failure to report and the plaintiffs' injury.

As to claims related to the BHR cup and R3 metal liner specifically, Smith & Nephew argues that the causal link is too tenuous because the FDA has no obligation to share information that manufacturers report about adverse events with the public. (*See* Def.'s Mot. at 59 (citing *Aaron v. Medtronic, Inc.*, 209 F.Supp.3d 994, 1005 (S.D. Ohio 2016), and 21 C.F.R. § 803.9 for the proposition that the FDA *may* but is not *required* to share adverse event reports with the public)). The court disagrees. First, in making this argument, the *Aaron* court did not draw any conclusion about the sufficiency of the plaintiffs' pleadings. Instead, the *Aaron* court concluded that because the FDA was not obligated to disclose adverse event reports to the physicians, the "federal duty to submit adverse-event reports to the FDA is not 'genuinely equivalent' to a state-law duty to warn physicians." But as the court already discussed, Supreme Court precedent dictates that state requirements need not be identical to federal requirements, so long as they are "narrower, not broader" than federal requirements. *Lohr*, 518 U.S. at 495. And based on the plaintiffs' pleadings, it is plausible that Smith & Nephew's alleged failure to report adverse events to the FDA caused plaintiffs' injuries. Specifically, the plaintiffs make extensive allegations about the growing scientific consensus about the dangers of metal-on-metal products. (THA MACC ¶¶ 23–31, 40–54; R3 MACC ¶¶ 47–53). Had the FDA learned of the adverse events related to the BHR-THA and R3-THA systems, it is plausible that the agency would have made those reports public, and that patients and physicians may have adjusted their behavior accordingly. Section 803.9's language, in fact, empowers the FDA to make adverse-event reports public. 21 C.F.R. § 803.9.

Negligent Misrepresentation, Fraud, Fraudulent Concealment, & Unfair & Deceptive Trade Practices Claims

The plaintiffs allege that Smith & Nephew negligently misrepresented the safety and efficacy of the BHR-THA and R3-THA systems and their component parts. (*See, e.g.*, THA MACC ¶¶ 335–39; R3 MACC ¶¶ 327–31). The plaintiffs also allege that Smith & Nephew's misrepresentations regarding the R3-THA system rose to the level of fraud. (R3 MACC ¶¶ 326–46). The plaintiffs further allege that Smith & Nephew fraudulently concealed the dangers associated with the BHR-THA and R3-THA systems and their component parts. (THA MACC ¶¶ 356–62; R3 MACC ¶¶ 121–28). Finally, the plaintiffs allege that Smith & Nephew's deceptive conduct related to the BHR-THA and R3-THA systems and their component parts rose to the level of unfair and deceptive trade practices under state law. (THA MACC ¶¶ 350–55; R3 MACC ¶¶ 347–52).

Smith & Nephew argues that all of the plaintiffs' fraud, negligent misrepresentation, and deceptive trade practices claims should be dismissed to the extent that "they rest on [Smith & Nephew's] alleged failure to provide different warning to patients and the medical community about BHR-THA and R3-THA combinations." (Def.'s Resp. at 29, ECF No. 1328 (citing *In re BHR*, 300 F. Supp. 3d at 745). But this court's ruling in the BHR track, which dealt solely with premarket-approved devices, is not directly on point here. To the extent the plaintiffs' claims rest on Smith & Nephew's alleged failure to provide warnings to patients and the medical community about the hybrid systems as a whole or the systems § 510(k)-approved components, and on Smith & Nephew's negligent or fraudulent statements about the safety of the hybrid systems and their § 510(k)-approved components, the claims are not governed by § 360k(a). Imposing state tort liability for false statements about the safety of § 510(k)-approved components, or the failure to

make statements, does not implicate any device for which there are federal requirements. And claims targeting the hybrid system as a whole can proceed to the extent they allege that Smith & Nephew breached a duty to warn about the dangers of metal-on-metal devices, or made fraudulent statements about the safety of metal-on-metal devices, or acted to conceal information related to the dangers of metal-on-metal devices generally, because these claims would not directly impugn the safety or efficacy of the BHR cup or the R3 metal liner.

To the extent the plaintiffs' claims are premised directly on the BHR cup and the R3 metal liner, they will only survive to the extent plaintiffs have identified parallel state-law causes of action that predated the MDA. Any claim alleging that Smith & Nephew breached a duty to warn patients and the medical community about the BHR cup or the R3 metal liner are expressly preempted because the MDA imposes no such duty. *See In re BHR*, 300 F. Supp. 3d at 745. The preemption consequences for claims premised on Smith & Nephew's alleged failure to warn the FDA are discussed above. Finally, to the extent the plaintiffs' claims are premised on Smith & Nephew's alleged false or misleading statements about the hybrid systems' premarket-approved components, those claims are not preempted. The FDCA expressly prohibits misbranded or adulterated devices from entering the market. 21 U.S.C. §§ 331, 351, 352; 21 C.F.R. § 814.80 (forbidding devices to be "manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any condition to approval specified in the PMA approval order for the device"). And a device is misbranded if "its labeling is false or misleading in any particular," if the manufacturer engages in "false or misleading advertising," or if the device's labeling does not provide "adequate directions for use." 21 U.S.C. §§ 352(a)(1), (f), (q); *see also* 21 C.F.R §§ 99.101, 99.103. Accordingly, parallel state claims based on fraud, fraudulent concealment, negligent misrepresentation, negligence, and unfair and deceptive trade practices are

not expressly preempted. *See Shuker*, 885 F.3d at 776–79; *Ramirez v. Medtronic Inc.*, 961 F.Supp.2d 977, 990–92 (D. Ariz. 2013); *Houston v. Medtronic, Inc.*, 957 F.Supp.2d 1166, 1179–80 (C.D. Ca. 2013). And these claims are not impliedly preempted because state law causes of action imposing liability for false, misleading, or fraudulent statements predated the MDA. *See Caplinger*, 784 F.3d at 1352 (Lucero, J., concurring in part and dissenting in part); *Ramirez*, 961 F.Supp.2d at 991; *Houston*, 957 F.Supp.2d at 1179; *Loreto v. Procter & Gamble Co.*, 515 F.App'x 576, 579–80 (6th Cir. 2013).

Next, Smith & Nephew argues that even if the plaintiffs' claims survive preemption, they fail to meet the pleading standards of Rule 8 and Rule 9(b). To the extent the plaintiffs' claims sound in fraud, they are subject to Rule 9(b)'s heightened pleading standards. *Spaulding v. Wells Fargo Bank, N.A.*, 714 F.3d 769, 781 (4th Cir. 2013). Federal Rule of Civil Procedure 9(b) requires a plaintiff to plead "with particularity the circumstances constituting fraud." Fed. R. Civ. Pro. 9(b). These circumstances include "the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby." *See Spaulding*, 714 F.3d at 781 (citing *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 784 (4th Cir 1999)). But the Fourth Circuit has held that a "court should hesitate to dismiss a complaint under Rule 9(b) if the court is satisfied (1) that the defendant has been made aware of the particular circumstances for which she will have to prepare for trial, and (2) that plaintiff has substantial prediscovery evidence of those facts." *Harrison*, 176 F.3d at 784; *see also McCauley v. Home Loan Inv. Bank, F.S.B.*, 710 F.3d 551, 559 (4th Cir. 2013) (same). Further, Rule 9(b)'s strictures are also relaxed in fraudulent concealment cases because "an omission likely 'cannot be described in terms of the time, place, and contents of the misrepresentation or the identity of the person making the misrepresentation.'" *Piotrowski v. Wells Fargo Bank, N.A.*, No. DKC 11-3758,

2013 WL 247549, at *5 (D. Md. Jan. 22, 2013) (quoting *Shaw v. Brown & Williamson Tobacco Corp.*, 973 F.Supp. 539, 552 (D. Md. 1997)).

Specifically, Smith & Nephew alleges that the plaintiffs do not "identify particular misrepresentations by S&N that were relied upon by any individual Plaintiff (or physician)" in either MACC or in the plaintiffs' short-form complaints, and that the plaintiffs fail to adequately plead reliance. (Def.'s Mot. at 48–49). But the plaintiffs have identified particular misrepresentations that they allege undergird their claims. For example: "BHR is not your average 'metal on metal,'" (THA MACC ¶ 81); Smith & Nephew's Senior Vice President's statement that the BHR is "unlike any other metal-on-metal implant," (THA MACC ¶ 317); a March 2015 advisory notice where Smith & Nephew stated that there was no equivalent data available for metal modular femoral head patients in the United States, though Smith & Nephew was allegedly aware of adverse events related to metal modular femoral heads in the United States, (THA MACC ¶ 314); and a press release announcing "the introduction of the metal liner option for its R3 Acetabular System" and statements that the R3-THA system was "designed to reduce wear and the subsequent need for revision surgery," and "good if not better" than its competitors, (R3 MACC ¶¶ 15–16, 38). The plaintiffs also allege that Smith & Nephew withheld critical information from patients and their physicians, (R3 MACC ¶¶ 15, 16, 23, 26, 37, 40, 81, 88–89, 123, 286–87, 327, 330, 337; THA MACC ¶¶ 63, 65–66, 284–85, 337–38, 340, 360). Further, the court is persuaded that the plaintiffs have sufficiently alleged that patients and physicians relied on these misrepresentations in deciding courses of treatment. (*See, e.g.*, R3 MACC ¶¶ 17, 40; THA MACC ¶¶ 340, 360). Accordingly, at this stage of the litigation, the plaintiffs' claims provide adequate notice to the defendants and satisfy pleading requirements.

Finally, Smith & Nephew contends that the plaintiffs' unfair and deceptive trade practices

claims are impermissibly vague. (THA MACC ¶¶ 350–55; R3 MACC ¶¶ 347–52). But these claims expressly incorporate all of the factual allegations in the MACC, which include off-label promotion of the hybrid systems that arguably rises to the level of misbranding or adulterating a product. Unfair and deceptive trade practices typically include false or misleading oral and written statements. *See* Md. Code Ann., Com. Law § 13-301 (West 2018). These claims also pass muster.

Off-label Promotion Claims

Apart from its arguments directed at particular numbered counts in the THA MACC and R3 MACC, Smith & Nephew argues that all of the claims based on off-label promotion of the BHR-THA and R3-THA systems are expressly preempted. The court disagrees. Even *Shuker*, which Smith & Nephew relies on heavily, concluded that claims of negligence and fraud based on off-label promotion were not expressly preempted. *See Shuker*, 885 F.3d at 776–80; *see also Coleman v. Medtronic, Inc.*, 167 Cal. Rptr. 3d 300, 315–16 (Ct. App. Ca. 2014). And as the court previously detailed, the MDA's tacit approval of off-label use of devices by physicians, 21 U.S.C. § 396, should not be interpreted as an implicit endorsement of off-label promotion of devices by manufacturers, which the MDA expressly prohibits. *See* 21 C.F.R. § 814.80; 21 U.S.C. § 331(a), (b); *see also Caplinger*, 784 F.3d at 1352–53 (Lucero, J., concurring in part and dissenting in part) (discussing how a manufacturer's advertising and oral and written statements can be viewed as evidence that a device was misbranded or adulterated, and detailing why causes of action based on off-label promotion are not expressly or impliedly preempted); *Schouest v. Medtronic, Inc.*, 13 F.Supp.3d 692, 701–03 (S.D. Tex. 2014); *Houston*, 957 F.Supp.2d at 1179–80; *Ramirez*, 961 F.Supp.2d at 991–92.[11] Accordingly, the court sees no reason to alter its preemption analysis when dealing with claims based on off-label promotion.

[11] The court does recognize that not all courts agree with this analysis. *See Otis-Wisher v. Medtronic, Inc.*, 616 F.App'x 433, 435 n.2 (2d Cir. 2015); *see also Caplinger*, 784 F.3d at 1341–45.

Failure to Conduct a Study

The plaintiffs' claim that Smith & Nephew is liable for failing to conduct a post-approval study of the R3 metal liner "pursuant to the FDA's PMA requirements," (R3 MACC ¶¶ 28, 67, 113(f)), is expressly and impliedly preempted. The plaintiffs have not pointed to any federal requirement that imposes a duty to conduct a post-approval study of the R3 metal liner. At most, the plaintiffs point to 21 C.F.R. § 803.50, but this provision relates to manufacturers' duty to report adverse events to the FDA. Conducting a new study is not surveilling the market or reporting existing, pertinent data to the FDA, but instead, developing new data. Further, even if there were a federal requirement to conduct this study, the plaintiffs have pointed to no state-law duty that predated the MDA that would similarly require Smith & Nephew to undertake this research. Accordingly, the court will grant Smith & Nephew's motion as to this claim.

Failure to Supplement/Revise Labeling

Smith & Nephew asks the court to dismiss the plaintiffs' claims that allege Smith & Nephew failed to amend, revise, or supplement its labeling. (THA MACC ¶¶ 132(h), 132(m), 149(h), 149 (m); R3 MACC ¶¶ 134(c), 135(c)-(d), 136(c), 145(h)). Claims alleging that Smith & Nephew was obligated to amend its labeling of the BHR cup and R3 metal liner are expressly preempted by the MDA because they would impose additional, broader requirements on premarket-approved devices. But claims alleging that Smith & Nephew breached a duty to amend or supplement its labeling of the hybrid systems as a whole and the systems' § 510(k)-approved components are not preempted so long as they do not undercut the sufficiency of the FDA-approved labeling for the premarket-approved components. *See, e.g.*, *Shuker*, 885 F.3d at 775 n.15. Accordingly, the court will grant Smith & Nephew's motion as to claims alleging that the labeling of pre-market approved components of the hybrid systems was deficient, and deny the motion as

to the remaining claims.

Failure to Recall

The plaintiffs' claims that allege Smith & Nephew breached a duty in failing to recall the BHR cup and R3 metal liner are expressly preempted by the MDA, which grants the FDA the authority to withdraw premarket-approval from a device. *See In re BHR*, 300 F. Supp. 3d at 737 n.5. Smith & Nephew also contends that the plaintiffs' claims that it breached a duty to recall the BHR-THA and R3-THA systems are "baffling" because these systems were not designed by Smith & Nephew, but instead were chosen by physicians. (Def.'s Mot. at 42). But to the extent the plaintiffs are able to establish through discovery that Smith & Nephew's off-label promotion of the hybrid systems rose to the level of designing these systems, the plaintiffs may be able to pursue these claims. As an example, in an exhibit to their opposition, the plaintiffs detail new allegations that came to light after the filing of the THA-MACC and R3-MACC, including that Smith & Nephew employed a color-coding system to assist physicians in using their products, and that this system intentionally matched the BHR cup with the metal modular femoral head. (Mem. P. & A. Supp. Pls.' Opp'n. Ex. A at 2 ¶ 5, ECF No. 2-1). Accordingly, the court will grant Smith & Nephew's motion as to claims alleging Smith & Nephew breached a duty to recall the BHR cup or the R3 metal liner, but deny the motion as to the remaining claims.

Reconsideration of Rulings in the BHR Track

Smith & Nephew asks the court to reconsider the rulings it made in the BHR track with respect to the plaintiffs' claims that Smith & Nephew failed to report adverse events, failed to train physicians, and that Smith & Nephew's conduct rose to the level of negligence per se, and that the plaintiffs' punitive damages claims at least superficially survive preemption. The court dealt with Smith & Nephew's request for reconsideration as to failure to report adverse events in the

preceding negligent failure to warn section.

Without altering its ruling as to claims that Smith & Nephew breached its duty to train physicians as to the BHR track, the court concludes that any claims that Smith & Nephew had a duty to train physicians as to the BHR-THA and R3-THA systems are preempted. First, the plaintiffs have not identified a federal requirement that mandates manufacturers train physicians as to off-label uses, and such a duty would in fact undercut the plaintiffs' overarching argument that Smith & Nephew misbranded, adulterated, and fraudulently promoted the hybrid systems for off-label use.

Further, the court reaffirms its ruling in the BHR track that negligence per se claims are not impliedly preempted under *Buckman*. In its BHR-track decision, the court concluded that negligence per se claims predated the MDA and are, therefore, not impliedly preempted under *Buckman*. *See McClellan v. I-Flow Corp.*, 776 F.3d 1035, 1039–40 (9th Cir. 2015); *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 588–89 (6th Cir. 2013); *Coleman*, 167 Cal. Rptr. 3d at 315–16. Smith & Nephew does cite to a suite of cases that hold otherwise. *See e.g.*, *In re Bard*, No. MDL 15-02641-PHX0DGC, 2018 WL 4356638, at *2–3 (D.Ariz. Sept. 12, 2018) (collecting cases). These cases argue that negligence per se claims hinge on a violation of the MDA and, therefore, fall within *Buckman*'s ambit. *Id.* But none of these cases are binding on this court and the court does not find their reasoning to be persuasive. Negligence per se is a method of proof, not an independent tort, and accordingly, negligence per se claims do not exist solely by virtue of the MDA, instead they "simply direct[] the trier of fact to the federal requirements to establish the applicable standard of care." *Coleman*, 167 Cal. Rptr. 3d at 316; *see also Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 775 (5th Cir. 2011).

Finally, as the court held in its BHR track ruling "[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." *In re BHR*, 300 F.Supp.3d at 736 n.3. Because the court concludes that many of the plaintiffs' claims survive Smith & Nephew's motion, the court declines to alter its previous ruling.

CONCLUSION

For the reasons stated above the court will grant in part and deny in part Smith & Nephew's motion to dismiss. A separate Order follows.

8/5/19
Date

CCB
Catherine C. Blake
United States District Judge