

**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: <i>Mosca v. Smith & Nephew, Inc.</i> , No. 1:18-cv- 03520
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MEMORANDUM

Pending before the court is a renewed motion for partial summary judgment in BHR track action *Phylliss Mosca v. Smith & Nephew, Inc.*, No. 1:18-cv-03520. Smith & Nephew moves for summary judgment as to Ms. Mosca's negligence per se cause of action. (ECF 3001). The motion has been fully briefed and oral argument was heard on October 13, 2021. For the reasons below, the motion will be granted.

BACKGROUND

This case concerns alleged injuries suffered by Ms. Mosca as a result of her use of the Birmingham Hip Resurfacing Device ("BHR"), an artificial hip implant developed, designed, manufactured, and sold by defendant Smith & Nephew. The BHR 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. *In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prod. Liab. Litig.* ("In re BHR"), 300 F. Supp. 3d 732, 736 (D. Md. 2018). The friction between the metal components allegedly can cause metal debris to accumulate within the joint and blood stream of the patient. Metal debris

from the device can cause pain, metallosis, and other serious complication that may require corrective surgery or revision to a different device. *Id.* In 2015, Smith & Nephew voluntarily recalled some BHR devices due to unreasonably high rates of failure in women and in men needing femoral head sizes 46 mm or smaller, for reasons including complications due to metal debris. Ms. Mosca claims she was one such patient—her BHR implant required revision to a different implant due, in her surgeon’s and expert’s opinions, to symptoms caused by the accumulation of metal debris.

PROCEDURAL HISTORY

On November 14, 2018, Ms. Mosca filed a complaint including eight counts against Smith & Nephew under Maryland law: strict products liability (Count I), negligence (Count II), strict products liability for failure to warn (Count III), negligent failure to warn (Count IV), negligent misrepresentation (Count V), breach of express warranties (Count VII), manufacturing defect (Count VIII), and punitive damages (Count IX). (ECF 2518-3, Ex. A, Mosca Short Form Compl.). Smith & Nephew moved to dismiss all of the plaintiffs’ claims in the BHR track, arguing they were either preempted or insufficiently pleaded. The court dismissed all strict products liability and strict products liability for failure to warn claims as expressly preempted (Counts I and III) and the manufacturing defect claim (Count VIII) for failure to state a claim. *In re BHR*, 300 F. Supp. 3d at 743, 746, 750.

Following substantial fact and expert discovery, the parties filed cross-motions for summary judgment on March 12, 2021. (ECF 2514, Mosca MSJ; ECF 2518, Smith & Nephew MSJ), which the court granted in part, denied in part, and reserved in part on July 19, 2021. (ECF 2905). On August 26, 2021, Smith & Nephew filed a renewed motion for summary judgment on the late-raised issue of Ms. Mosca’s negligence claim being based on alleged violations of

Maryland law. (ECF 3001, Smith & Nephew MSJ). Ms. Mosca responded (ECF 3056, Mosca Opp'n), and Smith & Nephew replied. (ECF 3133, Smith & Nephew Reply).

STANDARD OF REVIEW

Federal Rule of Civil Procedure 56(a) provides that summary judgment should be granted “if the movant shows that there is no *genuine* dispute as to any *material* fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a) (emphases added). “A dispute is genuine if ‘a reasonable jury could return a verdict for the nonmoving party.’” *Libertarian Party of Va. v. Judd*, 718 F.3d 308, 313 (4th Cir. 2013) (quoting *Dulaney v. Packaging Corp. of Am.*, 673 F.3d 323, 330 (4th Cir. 2012)). “A fact is material if it ‘might affect the outcome of the suit under the governing law.’” *Id.* (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). Accordingly, “the mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment[.]” *Anderson*, 477 U.S. at 247–48. The court must view the evidence in the light most favorable to the nonmoving party, *Tolan v. Cotton*, 572 U.S. 650, 657 (2014) (per curiam), and draw all reasonable inferences in that party’s favor, *Scott v. Harris*, 550 U.S. 372, 378 (2007) (citations omitted); *see also Jacobs v. N.C. Admin. Office of the Courts*, 780 F.3d 562, 568–69 (4th Cir. 2015). At the same time, the court must “prevent factually unsupported claims and defenses from proceeding to trial.” *Bouchat v. Balt. Ravens Football Club, Inc.*, 346 F.3d 514, 526 (4th Cir. 2003) (quoting *Drewitt v. Pratt*, 999 F.2d 774, 778–79 (4th Cir. 1993)). The relevant inquiry is whether the evidence “presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law.” *McAirlaids, Inc. v. Kimberly-Clark Corp.*, 756 F.3d 307, 310 (4th Cir. 2014) (quoting *Anderson*, 477 U.S. at 255).

DISCUSSION

Smith & Nephew raise several arguments in their motion for summary judgment. Most persuasive among these is that § 21-256(6) of the Maryland Food, Drug, and Cosmetic Act (MFDCA) is a law intended to protect the public at large, and thus cannot serve as the statutory basis for a claim of negligence “*per se*.”¹ See Md. Code Ann., Health-Gen. § 21-256(6).

Under Maryland law:

To make out a *prima facie* case of negligence based on a statutory violation, a plaintiff must show: 1) the violation of a statute designed to protect a specific class of persons; 2) that plaintiff is a member of this class of persons; 3) that the harm suffered by plaintiff is of the type that the statute was intended to protect against; and 4) that the violation was the proximate cause of the plaintiff’s injuries.

Hart v. A.C.E. Taxi, 442 F. Supp. 2d 268, 270 (D. Md. 2006). The use of statutory violations to support negligence claims is “carefully circumscribed,” and Maryland courts “have always required the statute or ordinance allegedly violated to set forth mandatory acts that are clearly for the protection of a *particular* class of persons and *not* merely for the public as a whole.” *Blackburn Ltd. P’ship v. Paul*, 438 Md. 100, 116, 116 n.11 (2014) (internal citation omitted). A statute does not create an enforceable tort duty when it merely “protects the public in general.” *Baker v. Montgomery Co.*, 427 Md. 691, 711 n.16 (2012).

There appears to be no binding precedent regarding whether § 21-256(6) of the MFDCA creates an actionable tort duty.² Smith & Nephew contends that the statute is designed to protect the public at large, and thus does not form a statutory duty. See *Hart*, 442 F. Supp. 2d at 270.³ In

¹ Maryland does not recognize negligence *per se* as an independent cause of action; rather, violation of an applicable statute may be evidence supporting a negligence claim. *Bray v. Marriott Int’l*, 158 F. Supp. 3d 441, 445 (D. Md. 2016),

² The statute itself is terse. MFDCA § 21-256(6) (“A person may not. . . [d]isseminate any false advertisement”).

³ Generally, as this is a matter of first impression, declaring a new duty is a policy decision better suited for the Maryland Court of Appeals or the Maryland General Assembly. See *McKiver v. Murphy-Brown, LLC*, 980 F.3d 937, 963-64 (4th Cir. 2020) (quoting *Rhodes v. E.I. du Pont de Nemours & Co.*, 636 F.3d 88, 96 (4th Cir. 2011) (“[I]n a diversity case, a federal court should not

support of this proposition, Smith & Nephew cites *Gourdine v. Crews*, in which the Maryland Court of Appeals rejected the FDCA as a basis of a negligence claim because it served to protect the public in general. 405 Md. 722, 757-58 (2008) (“[A] statutory obligation which ‘runs to everyone in general and no one in particular’ cannot impose a duty between two parties.” (internal citation omitted)). The relevant portion of the FDCA is “parallel” to the MFDCA § 21-256(6), addressing the same subject matter and content, so the analogy is apt. *Compare* 21 U.S.C. § 321, *et seq.* with Md. Code Ann., Health-Gen. § 21-256, *et seq.*

Ms. Mosca notes that *Gourdine* was decided in the context of a third-party motorist who invoked the FDCA after being harmed by a person who used a drug manufactured by the defendant Eli Lilly. 405 Md. at 728. As a recipient of a regulated device who alleges she was directly injured by the device, Ms. Mosca argues she is in a different position than the *Gourdine* plaintiff. The holding of *Gourdine*, however, does not rely on the status of the plaintiff, but on the purpose of the FDCA: to protect the public at large from false advertising of medical products, not only those patients like Ms. Mosca who received the medical device. *Id.* at 790 (“These [FDCA]. . . regulations, however, are framed to protect the public in general”). Further, the statutory language in the MFDCA, like that in the FDCA, is broad and devoid of any mention of a subgroup of individuals it seeks to protect.⁴ Therefore, an alleged violation of the MFDCA may not serve as

interpret state law in a manner that may appear desirable to the federal court, but has not been approved by the state whose law is at issue.”).

⁴ Ms. Mosca argues that the court should follow *Bray v. Marriott Int’l*, 158 F. Supp. 3d at 444-46, wherein the plaintiff, whose disability was covered by the Americans with Disabilities Act (ADA), was allowed to proceed with a negligence action based upon violations of the ADA. Ms. Bray’s case, however, relied on numerous ADA provisions that regulated for the exclusive benefit of people with disabilities in the exact situation she alleged resulted in her injury. *Id.* at 446. These provisions included statements on the inadequacy of certain types of shower grab bars and seats, as well as the necessity of communication devices in showers accommodating people with disabilities. *Id.* The succinct and generalized wording of the MFDCA distinguishes

the basis for a claim of negligence under Maryland law, as it is not intended to protect a specific group of individuals to which Ms. Mosca belongs.

Because the court agrees that violation of the Maryland statute relied on by Ms. Mosca cannot support a finding of negligence, there is no need to address the additional arguments raised by Smith & Nephew in their motion.

CONCLUSION

For the reasons stated herein, Smith and Nephew's motion to dismiss will be granted. A separate Order follows.

10/27/21
Date

CCB
Catherine C. Blake
United States District Judge

this case from *Bray*, where the ADA's specificity and identification of issues affecting only people with disabilities could support a finding of negligence for statutory noncompliance.