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 ACTIONS

MEMORANDUM

Now pending are several motions from defendant Smith & Nephew to exclude the opinion testimony of the plaintiffs' three THA-Track expert witnesses: (1) Mari Truman;[1] (2) Harold Pellerite;[2] and (3) Jeffrey Shapiro.[3] Also pending are several motions filed by the plaintiffs to exclude the opinion testimony of Smith & Nephew's three THA-Track expert witnesses: (1) Daniel Goldstein;[4] (2) Brent Kerger;[5] and (3) Kevin Bozic.[6] The motions are fully briefed and oral argument was heard November 22, 2021. By request of the parties, the court subsequently entered

[1] *See* Smith & Nephew's Mot. to Exclude the Op. Test. of Pls.' Expert Witness Mari Truman, ECF 2886-2 ("Truman Mot."); Pls.' Truman Opp'n, ECF 2985; Def.'s Truman Reply, ECF 3200.

[2] *See* Smith & Nephew's Mot. to Exclude the Op. Test. of Pls.' Expert Witness Harold Pellerite, ECF 2888-2 ("Pellerite Mot."); Pls.' Pellerite Opp'n, ECF 2981; Def.'s Pellerite Reply, ECF 3201.

[3] *See* Smith & Nephew's Mot. to Exclude the Op. Test. of Pls.' Expert Witness Jeffrey Shapiro, ECF 2891-2 ("Shapiro Mot."); Pls.' Shapiro Opp'n, ECF 2982; Def.'s Shapiro Reply, ECF 3199.

[4] *See* Pls.' Mot. to Exclude Def.'s Expert Daniel J. Goldstein, ECF 2887-1 ("Goldstein Mot."); Def.'s Goldstein & Kerger Opp'n, ECF 2984; Pls.' Goldstein & Kerger Reply, ECF 3202.

[5] *See* Pls.' Mot. to Exclude Def.'s Expert Brent D. Kerger, ECF 2889-1 ("Kerger Mot."); Def.'s Goldstein & Kerger Opp'n, ECF 2984; Pls.' Goldstein & Kerger Reply, ECF 3202.

[6] *See* Pls.' Mot. to Exclude Def.'s Expert Kevin Bozic, ECF 3153-1 ("Bozic Mot."); Def.'s Bozic Opp'n, ECF 3216.

a litigation stay. *See, e.g.*, Case Management Order No. 23, ECF 3770; Order Extending Stay, ECF 3931. The parties have since requested a ruling on the pending motions to exclude expert testimony. As with its ruling on expert testimony in the BHR Track, the court highlights the difficulty of delineating with precision the acceptable form of the experts' opinions before particular plaintiffs' claims are clearly defined. While the court can establish limits, the finer details of the opinions must depend on the context of the particular case when it reaches summary judgment or trial. With that caveat, and for the reasons stated below, the court will grant in part, reserve in part, and deny in part each of Smith & Nephew's motions, and will deny the plaintiffs' motions.[7]

LEGAL STANDARD

Rule 702 of the Federal Rules of Evidence, which "was intended to liberalize the introduction of relevant expert evidence," *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999), provides that a qualified expert witness "may testify in the form of an opinion or otherwise if . . . [his or her] scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702(a). The expert's testimony must be "based on sufficient facts or data" and must be "the product of reliable principles and methods." Fed. R. Evid. 702(b), (c). And the expert must "reliably appl[y] the principles and methods to the facts of the case." Fed. R. Evid. 702(d).

It is the district judge's responsibility to make an initial determination of an expert's qualifications, *see* Fed. R. Evid. 104(a), and to "ensur[e] that an expert's testimony both rests on a

[7] The court dispenses with a recitation of the facts of the THA-Track cases, which have been described in prior opinions. *See, e.g.*, *In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prod. Liab. Litig.*, 401 F. Supp. 3d 538, 546-47 (D. Md. 2019) [hereinafter, "*THA Preemption Ruling*"].

reliable foundation and is relevant to the task at hand," *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 597 (1993). Relevant evidence is of course that which "helps the trier of fact to understand the evidence or determine a fact in issue." *McKiver v. Murphy-Brown, LLC*, 980 F.3d 937, 959 (4th Cir. 2020) (internal quotation marks omitted). Testimony that relates only to claims that are preempted is not relevant to the remaining claims. *In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prod. Liab. Litig.*, 2021 WL 781682, at *2-4 (D. Md. Mar. 1, 2021) [hereinafter "*BHR Daubert Ruling*"]. Reliable expert testimony is "based on scientific, technical, or other specialized knowledge and not on belief or speculation" and derives any inferences "using scientific or other valid methods." *Id.* at *1 (internal quotation marks omitted). The Supreme Court has identified five factors that the court may consider in evaluating the reliability of an expert's reasoning or methodology: (1) whether the particular scientific theory has been or can be tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error; (4) whether there are standards controlling the method; and (5) whether the technique has gained general acceptance in the relevant scientific community. *See Daubert*, 509 U.S. at 593-94. These factors, which "may or may not be pertinent in assessing reliability," are not meant to be "definitive" or to constitute a "checklist." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 150, 151 (1999) (internal quotation marks omitted).

"As in all questions of admissibility," the party seeking the admission of expert testimony "must come forward with evidence from which the court can determine that the proffered testimony is properly admissible"—i.e., that it is reliable and relevant. *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). Yet the trial court's role as a gatekeeper is not intended to serve as a "replacement for the adversary system, and consequently, the rejection of expert testimony is the exception rather than the rule." *In re Lipitor (Atorvastatin Calcium) Mktg.,*

Sales Pracs. and Prods. Liab. Litig., 892 F.3d 624, 631 (4th Cir. 2018) (internal quotation marks omitted).

ANALYSIS

The court will analyze the defendant's and plaintiffs' motions in turn.

I. Smith & Nephew's Motions to Exclude Expert Testimony

The plaintiffs have retained Mari Truman, Harold Pellerite, and Jeffrey Shapiro as expert witnesses. Smith & Nephew contends that much of the testimony offered by these experts is inadmissible for two independent reasons: (1) it is irrelevant insofar as it only relates to claims preempted from this litigation; and (2) the experts' opinions are not reliable because they are not qualified to offer them or because they are based on unsatisfactory evidence and methods. Because many of Smith & Nephew's arguments turn on the scope of the court's preemption ruling, the court begins by summarizing that ruling before proceeding to evaluate the admissibility of the challenged opinions.

The FDA reviewed the relevant products under one of two regulatory paths: (1) the premarket approval ("PMA") process or (2) the § 510(k) clearance process. "The premarket approval process is demanding." *THA Preemption Ruling*, 401 F. Supp. 3d at 548. The FDA will grant PMA only if the agency, after thousands of hours of review, has reasonable assurances of a device's safety and effectiveness. *Id.* at 548-49. The § 510(k) process, in contrast, is much more lenient. *Id.* at 549-50. Clearing the § 510(k) process does not require an independent or exhaustive review of a device's safety and efficacy; in fact, the FDA on average "spends a mere 20 hours determining whether to approve a device through the § 510(k) process." *Id.* (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 479 (1996)).

Beyond the differences in rigor, the PMA and § 510(k) processes impart distinct preemption consequences. Start with devices granted PMA. As this court has explained, states are expressly preempted from establishing requirements for medical devices that are different from or in addition to requirements imposed by the MDA's PMA. *See, e.g.*, *In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prods. Liab. Litig.*, 300 F. Supp. 3d 732, 742 (D. Md. 2018) (hereinafter "*BHR Preemption Ruling*"); *see also* 21 U.S.C. § 360k (providing preemption framework for devices with PMA). Accordingly, state law may not impose requirements on PMA 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. A state law parallels federal requirements if it seeks to impose liability for conduct that also violates an FDA regulation. *See Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1326 (11th Cir. 2017). 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.

A state law is impliedly preempted by FDA regulations if the law exists "solely" by virtue of the federal requirements and is not a "traditional state tort law which [ ] predate[s] the federal enactments in question[ ]." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001); *see* 21 U.S.C. § 337(a) (subject to a few enumerated exceptions, all proceedings to enforce or restrain violations of the FDA statute must be brought by the federal government). A plaintiff therefore may not transform a federal regulation into a private right of action, even if a plaintiff may rely on preexisting and traditional state tort law to assert his or her claims. *See BHR Preemption Ruling*, 300 F. Supp. 3d at 747.

The § 510(k) approval process has different preemption effects. *THA Preemption Ruling*, 401 F. Supp. 3d at 554 (citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315-16 (2018)) (noting "the premarket-approval and § 510(k) processes have different preemption implications because the § 510(k) process is focused on equivalence, not safety"). Earlier in this multidistrict litigation, the court addressed how the MDA's preemption provisions apply to hybrid systems comprised of components that went through the PMA approval process and components that were approved through the § 510(k) process. *Id.* at 551 ("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."). After analyzing the MDA and competing case law, the court concluded that "§ 360k(a) preempts non-parallel state-law claims that target pre-market 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." *Id.* at 555. Thus, "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 554 (citing *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 775 n.15 (3d Cir. 2018)).

Applying this framework, the court determined that the THA-Track and R3-Track Plaintiffs' claims are preempted to the extent they assert that Smith & Nephew:

(1) is strictly liable for design defects in or failure to warn regarding "either the R3 metal liner or the BHR cup specifically," *THA Preemption Ruling*, 401 F. Supp. 3d at 556;

(2) breached any implied warranty as to the "R3 metal liner specifically," *id.*;

(3) negligently failed to warn "the public or the medical community" about adverse events associated with the BHR cup or R3 metal liner, *id.* at 557-58;

(4) should have amended the labeling of the BHR cup or R3 metal liner, *id.* at 562;

(5) should have conducted a post-approval study of the R3 metal liner, *id.*;

(5) should have recalled the BHR cup or R3 metal liner, *id.* at 562-63; or

(6) had a duty to train surgeons as to the BHR-THA or R3-THA constructs, *id.* at 563.

On the other hand, the court allowed many of the plaintiffs' other claims to continue, including claims that Smith & Nephew:

(1) is strictly liable for design defects in or failure to warn regarding "either the hybrid systems as a whole or the systems' § 510(k)-approved components," *id.* at 556;

(2) breached any implied warranty as to the "BHR-THA or the R3-THA systems as a whole and their § 510(k)-approved components," *id.* at 557;

(3) negligently failed to warn both patients and the medical community about the risks associated with "the hybrid systems as a whole, without impugning the safety or efficacy of the systems' premarket-approved components," or "the systems' § 510(k)-approved component parts," *id.*;

(4) negligently failed to warn the FDA about adverse events associated with the BHR cup or R3 metal liner, *id.* at 557-59;

(5) made false statements, including by failing to warn, rising to the level of negligent misrepresentation, fraud, and deceptive trade practices about "the hybrid systems and their § 510(k)-approved components," *id.* at 559-60;

(6) made "false or misleading statements about the hybrid systems' premarket-approved components," *id.* at 560;

(7) promoted the BHR-THA and R3-THA systems off-label, *id.* at 561-62;

(8) failed to "amend or supplement its labeling of the hybrid systems as a whole and the systems' § 510(k)-approved components," *id.* at 562;

(9) failed to recall the BHR-THA and R3-THA systems "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," *id.* at 562-63.

The parties' preemption arguments here primarily center on whether experts' testimony focuses on the BHR cup and R3 metal liner and is therefore only relevant to the prior class of claims, or whether it attacks the hybrid systems and their § 510(k)-approved components and thus is relevant to the latter class.

With this background in mind, the court will address Smith & Nephew's objections to each expert in turn.

A. Mari Truman

Smith & Nephew argues that Truman's opinions regarding the "use of a BHR acetabular cup or R3 metal liner in combination with an MFH[8] as part of a total hip arthroplasty procedure," Truman Mot. at 14, "labeling for the BHR cup and R3 liner," *id.* at 17, recall process for the BHR cup and R3 liner, *id.* at 19, and the duties of a "reasonable manufacturer" subject to federal regulations, *id.* at 21, relate only to preempted claims and are therefore inadmissible as irrelevant. Additionally, Smith & Nephew challenges Truman's qualifications to testify about regulatory matters, *id.* at 23, or medical and toxicological data and related risks, *id.* at 25. Finally, Smith & Nephew questions the reliability of elements of Truman's report, including her document narratives, opinions as to Smith & Nephew's knowledge, and speculation about how the FDA

[8] An "MFH" is a "modular femoral head." It is a § 510(k) approved component of the BHR-THA and R3-THA constructs. *See* Truman Mot. at 4, 5 ("Plaintiffs allege to have been injured by their physicians' use of the MFH in combination with the BHR acetabular cup or R3 metal liner as part of a total hip arthroplasty procedure.").

would have reacted to different information, as well as any legal conclusions that she asserts. *Id.* at 26-30.

i. Preemption

a. The THA Systems' Safety and Design

Smith & Nephew contends that Truman should not be permitted to "opine that use of a BHR acetabular cup or R3 metal liner in combination with an MFH as part of a total hip arthroplasty procedure is unreasonably dangerous and a defective design" because such opinions "target[] the safety of pre-market approved components" and thereby "impose requirements on the PMA components that are in addition to and different from existing PMA requirements." Truman Mot. at 14-15. According to Smith & Nephew, the PMA approved components of the THA system, the BHR cup or R3 metal liner, "are 'at the heart' of her opinions" that the THA system is unreasonably dangerous because "the alleged injury does not occur without the BHR components." *Id.* at 15.

Claims that the BHR cup and R3 metal liner were unreasonably dangerous or defectively designed are expressly preempted. *THA Preemption Ruling*, 401 F. Supp. 3d at 556. But claims alleging that the THA systems "as a whole" were unreasonably dangerous and defectively designed are not preempted. *Id.* In its THA Preemption Ruling, the court expressly distinguished the two types of claims, explaining that "concluding that the BHR-THA or R3-THA systems 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." *Id.* Smith & Nephew's argument that the safety of the THA systems by its nature implicates the safety of the BHR cup or R3 metal

liner would obliterate this distinction.[9] Truman's testimony is admissible insofar as she opines about the safety and design of the THA systems as a whole. The relevant opinions focus on the THA systems, *see* Truman Report at 7-8, ECF 2886-10, and the court will deny Smith & Nephew's motion on this issue.

b. Labeling

Smith & Nephew argues that Truman improperly opines that "the labeling of the BHR cup and R3 liner, both of which are under the BHR's PMA, were deficient or should have been changed." Truman Mot. at 17. Claims challenging the labeling of PMA components are preempted. *THA Preemption Ruling*, 401 F. Supp. 3d at 562. In her report, Truman's opinions that Smith & Nephew's labeling was insufficient primarily criticize the labeling of the MFH, which is a § 510(k) approved component and therefore not subject to express preemption. *See* Truman Report at 10 ("the BHR-MFH/hemi labeling should have included the risks associated with MoM bearings in THA."); *id.* at 3 (defining BHR-MFH as "the Birmingham modular hemi-arthroplasty head"); *id.* at 12 ("Smith & Nephew should have changed the MFH head label at some point . . . to warn against using with the MFH metal cup in a MoM construct."); *THA Preemption Ruling*, 401 F. Supp. 3d at 562.

[9] Smith & Nephew's reliance on the Third Circuit's ruling in *Shuker* is unavailing. In that case, the Third Circuit noted that the plaintiffs' "negligence, strict liability and breach of implied warranty claims rest on the premise that the R3 System was defective only because it was used with the R3 metal liner." *Shuker*, 885 F.3d at 775. In contrast, the court has already explained that the plaintiffs in this litigation allege "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." *THA Preemption Ruling*, 401 F. Supp. 3d at 556. The plaintiffs' particularized allegations about non-PMA components establish claims that survive preemption.

Nevertheless, Truman's report lacks precision with regard to the PMA and § 510(k) approved components and the scope of her opinions is sometimes confusing. Truman's labeling of the "BHR-MFH" blurs the distinction between the BHR cup's PMA and the MFH's § 510(k) approval. Thus, while on balance it appears that her opinions regarding labeling pertain to the MFH and are therefore admissible, the court reserves ruling on Truman's labeling opinions at this time.

c. Recall

Smith & Nephew argues that Truman cannot "testify that [it] should have recalled the BHR and R3 liner at any time before they did." Truman Mot. at 19. Smith & Nephew correctly explains that claims based on a failure to recall the BHR cup and R3 metal liner are expressly preempted. *See THA Preemption Ruling*, 401 F. Supp. 3d at 562-63. But the court also held that "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 those systems, the plaintiffs may be able to pursue [failure to recall] claims" as to the THA systems. *Id.*

Truman's opinions are again unclear as to what device she suggests should have been recalled. Though she consistently states that Smith & Nephew should have recalled the "BHR-THA" and "R3-THA," she appears to adopt a timeline of actual recall that corresponds to the dates that Smith & Nephew recalled the BHR cup and R3 metal liner. *See* Truman Report at 12 ("A responsible manufacture would closely monitor the clinical outcomes for higher risk MoM devices like R3-THA and BHR-THA, both unapproved, uncleared Class III devices in the USA, and would have withdrawn them from the market earlier than 2012 and 2015 respectively."). Moreover, Truman also focuses on the recalls of the BHR cup and R3 metal liner without explicitly opining that these devices should have been recalled earlier. *See* Truman Report at 12, 13 ("In June of

2012, Smith & Nephew withdrew the R3 metal liners from the global market citing high revision rates for R3-THA and R3 resurfacing . . .” and “[i]f Smith & Nephew had acted as a reasonable medical device company and taken appropriate steps for the BHR, then the BHR-THA would not have been available for surgeons.”). However, Truman also identifies the MFH’s removal from the market as coming too late. Truman Report at 12 (“Prior to withdrawal in 2015, Smith & Nephew did not take any steps in the US to prevent surgeons from using the MFH in BHR-THA, or warning them about poor clinical performance, associated risks, or the removal of the indication for use in THA globally.”).

Truman’s opinions about recalling components of the THA systems appear to substantially implicate the recall dates of the BHR cup and R3 metal liner. To the extent she suggests that the BHR cup and R3 metal liner specifically should have been recalled sooner, her opinion relates to preempted claims and is not relevant. However, given the general lack of specificity and the inclusion of opinions regarding the MFH’s recall, the court will reserve ruling on the remainder of Truman’s recall opinions until they are more clearly defined for summary judgment or trial.

d. Duties of a Reasonable Manufacturer

Smith & Nephew argues that “experts cannot offer opinions regarding purported duties of a reasonable manufacturer that are not based on federal requirements.” Truman Mot. at 21 (citing *BHR Daubert Ruling*, 2021 WL 781682, at *9). This argument misses the distinction between the BHR track, in which the only device at issue received PMA approval and therefore only the claims that paralleled federal requirements survived preemption, *see BHR Preemption Ruling*, 300 F. Supp. 3d at 736-37, 742-43, and the THA track, in which state law claims relating to the THA systems as a whole or their § 510(k)-approved components were not preempted, *THA Preemption Ruling*, 401 F. Supp. 3d at 555. Opinions regarding the THA systems or their § 510(k) components

therefore need not be tied to federal standards. Smith & Nephew does not raise any other argument to challenge Truman's opinions regarding the actions of a "reasonable manufacturer" and the court will deny its motion as to those opinions.

ii. Qualification

a. Regulatory Matters

Smith & Nephew argues that Truman "is not qualified to testify on regulatory matters," but that she "offers . . . a multitude of opinions about Smith & Nephew's regulatory obligations and its compliance with those obligations." Truman Mot. at 23. The opinions Smith & Nephew identifies largely rehash its arguments about preemption. *Id.* at 23-24 (citing opinions about explaining the risks of the THA systems and the components' labels). As explained above, testimony as to the adequacy of labels is admissible to the extent that it focuses on the THA systems as a whole or their non-PMA components. Truman is a biomedical engineer with 40 years of experience, has designed orthopedic devices and performed laboratory evaluations for orthopedic implants, and analyzes effects and risks for such devices. *BHR Daubert Ruling*, 2021 WL 781682, at *11; Truman Opp'n at 3. She is therefore qualified to opine on the risks inherent in the design of orthopedic implants and the adequacy of manufacturers' warnings. *BHR Daubert Ruling*, 2021 WL 781682, at *11-12; *In re Biomet M2a Magnum Hip Implant Prods. Liab. Litig.*, No. RLM-12-md-2391, 2017 WL 10845178, at *11-13 (N.D. Ind. Dec. 21, 2017).[10] To the extent she offers testimony about those matters that are within the realm of her expertise, the court will deny the motion as to this issue in part.

[10] Unpublished opinions are cited for the soundness of their reasoning rather than any precedential value.

Smith & Nephew also identifies two specific areas where it claims Truman draws legal conclusions that she is unqualified to assert. First, Smith & Nephew states that Truman improperly "opines that [it] did not comply with standards promulgated by the International Organization for Standardization." Truman Mot. at 24. Second, Smith & Nephew takes issue with Appendix K to Truman's report, which details "PMA Reporting Violations." Truman Report at App'x K.

Truman's opinion as to International Organization for Standardization compliance is that "Smith & Nephew was not compliant with *the spirit* of ISO EN 13485, ISO 14971 (2007, 2012), and ISO 9001 (2000)." Truman Report at 10 (emphasis added). The plaintiffs argue that, because Truman's opinion is that Smith & Nephew did not comply with the "spirit" of the regulations, it does not actually implicate regulatory violations. As other courts have determined, Truman's experience as a biomedical engineer qualifies her to "opine as to whether the device complied with the goals of ISO testing." *Diaz-Granados v. Wright Med. Tech., Inc.*, No. JA-14-cv-1953, 2016 WL 1337264, at *4 (M.D. Fla. Apr. 1, 2016). Truman's opinions about Smith & Nephew's compliance with ISO standards are admissible.

Appendix K includes opinions relating to Smith & Nephew's compliance with reporting requirements imposed by the PMA process for the BHR cup. As the court held in its *BHR Daubert Ruling*, "[Truman] lacks the regulatory and legal expertise necessary to reliably and helpfully opine so broadly on whether [Smith & Nephew] conformed its conduct to the requirements of the PMA approval letter and the relevant federal statutes." *BHR Daubert Ruling*, 2021 WL 781682, at *14. To the extent she draws legal conclusions about compliance with FDA regulations, federal statutes, or the PMA approval letter, such as "Smith & Nephew repeatedly failed to comply with the Conditions of Approval established in the BHR PMA Approval Letter," Truman Report at 254,

her opinions will be excluded because she is not qualified to offer them. *See BHR Daubert Ruling*, 2021 WL 781682, at *14

b. Medical Matters

Smith & Nephew argues that Truman "purports to interpret medical and toxicological data and expound upon the magnitude and nature of toxicological and other medical risks." Truman Mot. at 25. Smith & Nephew acknowledges that the court has ruled Truman may opine about the BHR system's bioreactive particles when that opinion is "based upon the testimony of experts qualified to express that opinion" and is "offered in support of her conclusion that Smith & Nephew failed to act as a reasonable device manufacturer" for the purposes of a failure to warn claim and not "to establish medical causation." *Id.* at 25 & n.13; *BHR Daubert Ruling*, 2021 WL 781682, at *11-12. Smith & Nephew seeks only "to preserve [the argument] for further review." Truman Mot. at 25 n.13. Truman's opinions as to medical matters in the THA track parallel those in the BHR track and are therefore admissible for the same reasons. *BHR Daubert Ruling*, 2021 WL 781682, at *12.

iii. Reliability

a. Factual narratives

Smith & Nephew asserts that Truman "may not act as a 'human highlighter' who provides summaries of documents and offers her impressions of their contents to the jury." Truman Mot. at 26. The court reserved ruling on the same narrative summary in the BHR track, recognizing that "it is difficult to determine whether such a summary will be offered solely for the purpose of constructing a factual narrative or for some purpose that calls for an expert's specialized knowledge." *BHR Daubert Ruling*, 2021 WL 781682, at *13. For the same reason, the court will reserve ruling here.

b. Smith & Nephew's Knowledge

Smith & Nephew challenges Truman's statements regarding what it "knew." Truman Mot. at 27. In the BHR track, the court ruled that "a party's 'knowledge, state of mind, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury.'" *BHR Daubert Ruling*, 2021 WL 781682, at *13 (quoting *Eghnayem v. Boston Sci. Corp.*, 57 F. Supp. 3d 658, 670 (S.D.W. Va. 2014)). For the same reasons, Truman's opinions regarding Smith & Nephew's knowledge will be excluded in the THA track.

c. The FDA's Reaction to Hypothetical Disclosures

The plaintiffs state that they do not intend to offer testimony speculating about how the FDA would have reacted to additional or different information. Truman Opp'n at 27; *see BHR Daubert Ruling*, 2021 WL 781682, at *13. Such testimony would be improper and, if it were offered, would be inadmissible. *BHR Daubert Ruling*, 2021 WL 781682, at *23. Because the plaintiffs do not intend to offer this testimony, Smith & Nephew's motion is moot as to this issue.

d. Information for Physicians

The plaintiffs concede that Truman cannot opine about how physicians may have reacted to different information but argue that she should be permitted to testify about "the sources of information that physicians rely upon and the types of information that practicing physicians take into account when making decisions about the risks of medical devices." Truman Opp'n at 27-28. As a biomedical engineer with experience drafting warnings included in package inserts for medical devices, Truman Opp'n at 3, Truman is sufficiently qualified to opine as to what sources of information are relevant to providing effective warnings. *Cf.* Truman Reply at 17-18; *Diaz-Granados*, 2016 WL 1337264, at *5. But her testimony may go no further; to the extent that such

testimony includes opinions about how physicians may have reacted to the information they received or would have reacted to different information it is inadmissible. *Diaz-Granados*, 2016 WL 1337264, at *5.

e. Legal Conclusions

Smith & Nephew challenges Truman's opinions that amount to legal conclusions. Truman Mot. at 29-30. As in the *BHR Daubert Ruling*, Truman is not qualified to opine about Smith & Nephew's actual compliance with statutory requirements or those included in the PMA approval letter. *BHR Daubert Ruling*, 2021 WL 781682, at *14. Furthermore, Truman's opinion also states legal conclusions using terms of art, including that "[t]he BHR-THA and R3-THA metal-on-metal (MOM) hip devices are unreasonably dangerous and defective" and "Smith & Nephew failed to warn its customers . . . of [] unreasonable dangers." Truman Report at 8, 11. Although "an opinion is not objectionable just because it embraces an ultimate issue," Fed. R. Evid. 704(a), Truman's opinions here, as in the BHR Track, would "consume" the issues, *BHR Daubert Ruling*, 2021 WL 781682, at *14; *see United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) (quoting *Strong v. E.I. DuPont de Nemours Co.*, 667 F.2d 682, 685-86 (8th Cir. 1981)) ("[C]ourts have held inadmissible testimony . . . that a product was unreasonably dangerous."). Truman may of course describe the evidence that supports these conclusions, and may even express equivalent conclusions using synonymous terminology, *see McIver*, 470 F.3d at 562; *United States v. Perkins*, 470 F.3d 150, 158-59 (4th Cir. 2006), but she may not "invade[] the province of the jury" by outright opining that Smith & Nephew violated the specific standards at issue in this case, *Perkins*, 470 F.3d at 158. The court will therefore grant the motion as to Truman's statements involving legal conclusions.

f. Selective Evidence

Smith & Nephew tacks on a catch-all reliability argument, contending that none of Truman's opinions are admissible because they are based on evidence provided to her by plaintiffs' counsel. Truman Mot. at 29. But the "cherry-picking" Smith & Nephew identifies is not of the type about which courts have expressed concern. Selective evidence issues arise when an expert focuses on evidence that is helpful to her conclusion while ignoring evidence that may be harmful. *In re Lipitor*, 892 F.3d at 634-35 (expert report included results from helpful test but omitted results from harmful test); *see Nikolova v. Univ. of Texas at Austin*, 585 F. Supp. 3d 936, 946 (W.D. Tex. 2022) (expert relied on documents provided by plaintiff's counsel and did not review relevant evidence); *EEOC v. Bloomberg L.P.*, 2010 WL 3466370, at *14 (S.D.N.Y. Aug. 31, 2010) (expert did not independently determine that data provided to him were representative in conducting a social framework analysis); *Eghnayem*, 57 F. Supp. 3d at 673-74. Smith & Nephew explains that Truman "had no role in selecting the documents and depositions that she reviewed for the formulation of her opinions." *Id.* However, Smith & Nephew does not suggest that the data in any of the documents Truman reviewed were incomplete, nor does it identify any unreviewed documents that may have altered her conclusions. Though Truman by her own admission relied on evidence provided by the plaintiffs, *see* Truman Dep. at 253, ECF 2886-4, that fact alone does not render her testimony unreliable. Without a showing that the evidence reviewed was inaccurate or insufficient, the court will not condemn the efficiency of an expert using documents provided by counsel in a case of this complexity. Moreover, the sufficiency of the evidence underlying Truman's opinions can be challenged by cross-examination. *Knight v. Boerhringer Ingelheim Pharms., Inc.*, 323 F. Supp. 3d 837, 852-53 (S.D.W. Va. 2018). The court will deny Smith & Nephew's motion as to this issue.

B. Harold Pellerite

Smith & Nephew asserts preemption challenges to Pellerite's opinions that the BHR cup and R3 metal liner were not legally marketed, Pellerite Mot. at 13, Smith & Nephew should have trained physicians on the BHR-THA and R3-THA, *id.* at 16, Smith & Nephew should have warned that the BHR-THA and R3-THA were off-label, *id.* at 17, and the BHR cup's labeling amounted to improper marketing, *id.* at 20. Smith & Nephew also attacks the reliability of Pellerite's opinions that the BHR-THA and R3-THA are "unapproved devices," *id.* at 21, and that Smith & Nephew engaged in off-label promotion, *id.* at 24, as well as his reliance on foreign actions, *id.* at 27, and his opinions about surgeons' practice and knowledge, *id.* at 28.

i. Preemption

a. "Unapproved" Devices

At the outset, Smith & Nephew argues that "[t]he crux of Mr. Pellerite's report is his opinion that a physician's use of BHR cup or the R3 metal liner, not as part of a complete BHR system, renders the BHR cup or R3 liner itself (and any construct in which it is used) an unapproved device." Pellerite Mot. at 13. Smith & Nephew contends Pellerite's "unapproved" classification of the BHR cup and R3 liner is both legally wrong and causes his opinions to be preempted. *Id.* at 13-14. While Pellerite's report mixes terms of art with common language, he does not specifically opine that the BHR cup or the R3 metal liner were themselves not approved by the FDA. Pellerite instead opines that "Smith & Nephew marketed unapproved devices when it promoted the *BHR-THA* and *R3-THA*," and that "the BHR and R3 components at issue in this matter *were not legally marketed* when used for THA." Pellerite Report at 5, ECF 2888-9 (emphasis added). While that particular phrasing may not be admissible, Pellerite's conclusion that the BHR-THA and R3-THA were "unapproved devices" appears to refer only to FDA's decision

not to approve either system as a whole, while his conclusions regarding the BHR cup and R3 liner focus on Smith & Nephew's marketing of these components as part of a THA system. *See id.* at 6 ("Smith & Nephew ignored FDA's warnings and promoted the BHR for use in THA."). Pellerite's ultimate conclusion is, in essence, that "[Smith & Nephew] *promoted* unapproved devices in the BHR-THA and R3-THA devices, as well as *promoted off-label use* of BHR components and the MFH." Pellerite Report at 8. Pellerite's opinions are therefore not "an attack on PMA components themselves," nor "would [they] impose obligations different from or in addition to the BHR's and R3's PMA." Pellerite Mot. at 14. Instead, Pellerite appropriately opines that Smith & Nephew marketed the BHR and R3 components and the THA systems as a whole in violation of FDA regulations. This opinion could support the non-preempted claim of off-label promotion of the BHR-THA and R3-THA systems and does not inherently impugn the safety of the systems' PMA components. *THA Preemption Ruling*, 401 F. Supp. at 561-62. The court will deny Smith & Nephew's motion to exclude Pellerite's testimony on this basis.

Smith & Nephew advances several other arguments stemming from the idea that Pellerite opines that the BHR cup and R3 liner were "unapproved" when used in the THA systems. As explained, Pellerite's opinion focuses on the unapproved status of the THA systems, and states that the BHR cup and R3 liner were improperly *promoted* for that unapproved use by Smith & Nephew. The remainder of Smith & Nephew's arguments that Pellerite attacks the safety of the PMA components are without merit. However, the court is cognizant of the potential for confusion resulting from Pellerite's imprecise language. Whether a term other than "unapproved" should be used, and what that term should be, must depend on the context of an individual case and the presentation of issues therein. The court will reserve ruling on the appropriateness of precise language at this time.

b. Training Physicians on the BHR-THA or R3-THA

Smith & Nephew challenges as preempted Pellerite's opinion that "Smith & Nephew never advised surgeons that it did not have FDA approval for the resurfacing cup to be used in a THA, and that this 'bailout device' was an unapproved device" because it would impose new training requirements on Smith & Nephew that are not required as part of PMA. Pellerite Mot. at 16-17 (quoting Pellerite Report at 6). Though Smith & Nephew tries to frame this opinion as relating to training, it is more reasonably classified as describing a failure to warn physicians about the BHR-THA and R3-THA systems as a whole, which is not a preempted claim. *THA Preemption Ruling* at 557; *cf.* Pellerite Mot. at 16 (describing Pellerite's opinion as a requirement that Smith & Nephew "train surgeons on the use (*or non-use*) of the BHR-THA or R3-THA") (emphasis added). Pellerite's opinion is not preempted and the court will deny Smith & Nephew's motion on this issue.

c. Warning Physicians that the BHR-THA or R3-THA was "Off-Label"

Smith & Nephew contends that Pellerite's opinions suggesting that it should have proactively warned surgeons that the BHR-THA and R3-THA systems were unapproved devices and involved off-label usage are preempted. Pellerite Mot. at 17. Yet Pellerite's report is more reasonably understood as opining that Smith & Nephew should have responded to physicians' efforts to use the BHR-THA or R3-THA by providing proper warnings. *See* Pellerite Report at 8 ("Smith & Nephew knew that surgeons were implanting the BHR-THA and R3-THA devices . . . and failed to take steps to warn surgeons."); Pellerite Report at 13 ("[Smith & Nephew should have] instruct[ed] sales representatives to respond to any question from a surgeon about the BHR-THA by informing them of [the decision to stop selling the BHR-THA worldwide as a primary implant.]"). Because Pellerite does not opine that Smith & Nephew should have raised the THA

systems without prompting, his opinions are not preempted. The court will deny Smith & Nephew's motion as to this part.

Pellerite also suggests that Smith & Nephew should have "instruct[ed] sales representatives to refrain from bringing the MFH into the operating suite with them for BHR resurfacing procedures." Pellerite Report at 13. Any legal requirement that a manufacturer prohibit its sales representatives from providing certain products to physicians when specifically asked for them would conflict with § 396, the practice of medicine exception, and a claim based on a requirement to withhold the MFH is therefore impliedly preempted. *THA Preemption Ruling*, 401 F. Supp. at 553 (quoting *Shuker*, 885 F.3d at 766). On the other hand, reading Pellerite's report as a whole, he appears to be referring to a practice where "Smith & Nephew sales representatives . . . would bring modular femoral heads into the operating room when a surgeon was performing a BHR resurfacing procedure. If the surgeon decided to convert to a THA that sale representative would *offer the modular head to the physician for use*. . . . [T]he surgeon did not know it was off-label, *and the surgeon did not make an unsolicited request as required by the FDA's practice of medicine exemption*." Pellerite Report at 11. Again, it is hard to determine whether the opinion is admissible without the benefit of understanding how it will be applied to the facts. The court will reserve decision on the remainder of Pellerite's opinion about the obligation of sales representatives regarding the MFH.

d. Labeling

As with Truman, Smith & Nephew argues that Pellerite's opinion describing the color coding of the labels used on the BHR and MFH as promotional is inadmissible. Pellerite Mot. at 20. As stated earlier, such opinions do not necessarily attack the labeling of the BHR, as changing the label of the MFH would similarly resolve the problem the experts identify. Though Smith &

Nephew frames Pellerite's opinion as "attack[ing] the color coding on the BHR cup that parallels the corresponding-sized MFH," Pellerite Mot. at 20, Pellerite focuses his critique on the MFH's label, stating that "the use of color-coded stickers on MFH to match BHR components constitutes off-label promotion of the BHR-THA device as an approved device," Pellerite Report at 10-11. Like Truman's opinion regarding the color-coded stickers, Pellerite's opinion is admissible, and the court will deny Smith & Nephew's motion as to this part.

ii. Reliability

a. "Unapproved" Devices

Smith & Nephew argues that Pellerite's opinion that the THA systems were "unapproved devices and that the use of these constructs is an unapproved use" should be excluded because it is a legal conclusion which he is not qualified to assert and because it is factually incorrect. Pellerite Mot. at 21-23. As explained above, though Pellerite's opinion is at times imprecise, a holistic reading suggests that he is describing the factual circumstances of the FDA's decision not to approve the sale or marketing of the THA systems. *See* Pellerite Report at 5 ("Smith & Nephew sought approval three times for [the BHR-THA] device from FDA, and each time withdrew its request . . ."). Pellerite does not state that the BHR cup or R3 metal liner themselves lacked FDA approval, except when used as part of a THA system. Thus, Pellerite's opinion is not "incorrect as a matter of law." Pellerite Mot. at 21.

Smith & Nephew argues that Pellerite's use of the term "unapproved" constitutes an "an impermissible legal conclusion" because the term "ha[s] a separate, distinct and specialized meaning in the law from that in the vernacular." Pellerite Mot. at 22 (quoting *JFJ Toys, Inc. v. Sears Holdings Corp.*, 237 F. Supp. 3d 311, 324 (D. Md. 2017)). But "approve" alone is not a legal term of art. Indeed, the court's preemption ruling turned on the distinction between different types

of FDA approval (PMA and 510(k)). Though Pellerite's use of "approved" is confusing at times, it is not absolutely improper. Nevertheless, the court will reserve ruling until Pellerite's testimony is presented in the context of an individual case; so long as the type of approval at issue (approval to market the THA systems as a device) is sufficiently clear, Pellerite's opinion should be admitted. *See McIver*, 470 F.3d at 562 ("Although Dr. Storick used terms similar to that which this court has employed to express the underlying issue, none is sufficiently specialized to render his testimony inadmissible.").

b. Off-Label Promotion

Smith & Nephew asserts four reasons why Pellerite's opinions about off-label promotion should be excluded, but none is convincing.

First, Smith & Nephew argues that "determining whether certain facts support a conclusion of off-label promotion is a job for the jury not a paid expert." Pellerite Mot. at 24. But Pellerite's expertise is intended to help the jury reach an informed conclusion about a question of fact and is permissible. Fed. R. Evid. 704(a); *BHR Daubert Ruling*, 2021 WL 781682, at *14.

Second, Smith & Nephew contends that Pellerite's "summary and commentary on the testimony of other witnesses or the import of certain documents," "invades the province of the jury, amounts to mere advocacy on plaintiff's behalf, and thus falls outside the scope of what Rule 702 permits." Pellerite Mot. at 25. But Smith & Nephew does not explain how the impropriety of Pellerite's summary testimony renders his conclusions about off-label promotion improper. Moreover, to the extent Pellerite relies on the documents and testimony that he summarizes to support his conclusion of off-label promotion, such a summary is admissible. *BHR Daubert Ruling*, 2021 WL 781682, at *14; *see* Section I.A.iii.a, *supra*.

Third, Smith & Nephew argues that Pellerite's conclusions are inadmissible because he does not base his opinion regarding off-label promotion on the methods the FDA uses to police off-label promotion, such as "market surveillance . . . review[ing] advertisements, monitoring company websites, visiting manufacturers' exhibit booths at conferences, and investigating formal complaints." Pellerite Mot. at 25. As the plaintiffs point out, however, Pellerite is qualified as an expert on FDA regulations and bases his conclusions on relevant evidence, including the sworn testimony of doctors and Smith & Nephew's documents. *See* Pellerite Report at 8-13. That this evidence was contained in "snippets of transcripts and internal documents" is a necessary byproduct of its production pursuant to litigation. Pellerite Mot. at 25. Any dispute over whether this evidence is sufficient to support Pellerite's conclusions is better suited for trial arguments about the weight of Pellerite's testimony.

Finally, Smith & Nephew generally contends that "Pellerite's characterization of deposition transcripts and record documents as definitively showing off-label promotion should be excluded because many of his conclusions are baseless and providing them with the imprimatur of an expert is likely to mislead the jury and result in unfair prejudice to Smith & Nephew." Pellerite Mot. at 26. Smith & Nephew does not cite case law to support its position. Pellerite's opinions should not be excluded because Smith & Nephew disagrees with the sufficiency of the evidence on which he relies. *Westberry*, 178 F.3d at 261 ("[T]he court need not determine that the expert testimony a litigant seeks to offer into evidence is irrefutable or certainly correct."). Pellerite has identified relevant evidence to support his conclusions, and questions about that evidence's adequacy are the proper subject of argument at trial.

At bottom, Pellerite's opinions regarding off-label promotion of the BHR-THA and R3-THA were reached by applying adequate methods to sufficient evidence. Whether the evidence is

enough to convince a jury to agree with Pellerite's conclusions is a question better resolved through presentation and cross-examination. The court will deny Smith & Nephew's motion as to this issue.

c. Foreign Business and Regulatory Actions

Smith & Nephew argues that Pellerite's opinions "based on his understanding of Smith & Nephew's business and regulatory actions in other countries" is inadmissible because Pellerite is not an expert on foreign regulations and such matters are irrelevant to this case. Pellerite Mot. at 27. As the court has explained, evidence related to foreign regulatory actions may be confusing and irrelevant. Case Specific Evidentiary Ruling at 9-10, ECF 2827. However, when provided to show that Smith & Nephew had notice of its own foreign actions, such evidence is generally admissible. *Id.* at 10. Here, Pellerite's report employs evidence of foreign regulatory actions primarily to support his conclusion that Smith & Nephew should have informed surgeons of its decision to stop selling the BHR-THA worldwide, a purpose that is focused on notice. Pellerite Report at 13.

Nevertheless, some of Pellerite's conclusions, including that Smith & Nephew had a duty to prevent physicians from using the BHR-THA system, do appear to stem from the inference that foreign actions should have been duplicated in the United States, or that these foreign actions are evidence that the BHR-THA was unsafe. *Id.* Any conclusion that Smith & Nephew had a duty to extend its compliance with foreign regulations or business decisions to the United States is not relevant, may confuse the jury, and should not be admitted. *See In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1054 (D. Minn. 2007). The court will reserve ruling on this issue until Pellerite's opinion is presented in the context of an individual case.

d. Surgeons' Practice and Knowledge

Smith & Nephew contends that Pellerite exceeds the limits of his expertise when he opines about the items on which surgeons rely for instructions for use. Pellerite Mot. at 28-29. Though the plaintiffs argue that Pellerite is only describing "his conclusion that surgeons were not generally aware [of known risks associated with the BHR-THA and R3-THA devices]," Pellerite Opp'n at 22-23, Pellerite does opine that "[i]t is well-established that surgeons do not rely on the in-box labeling or instructions for use (IFU) when they choose which firm's device to use," Pellerite Report at 10. Pellerite is an ex-compliance officer at the FDA who held a variety of positions related to medical device marketing and enforcement over a three-decade career, *id.* at 1-2; he is not qualified as an expert to testify about the practice of surgeons, and his opinions asserting that surgeons would not have relied on certain materials are therefore not admissible.

Smith & Nephew also argues that Pellerite cannot testify as to what surgeons knew when they used the THA systems. Pellerite Mot. at 29. Pellerite bases his conclusions on the testimony of several surgeons who were deposed in this litigation. Pellerite Report at 5-8, 10-12. Though the surgeons' testimony is sufficient to support conclusions regarding *their* knowledge, Pellerite is not qualified to opine, based on the testimony of a handful of surgeons, that "surgeons like [the deposed doctors] were not aware that using the BHR-THA device was not approved by the FDA" or "surgeons were not aware that the BHR-THA was denied approval by FDA." Pellerite Report at 8-9. Pellerite's general conclusions about the knowledge of all surgeons are outside his area of expertise and the court will therefore grant Smith & Nephew's motion as to this issue.

C. Jeffrey Shapiro

Smith & Nephew asserts preemption challenges to Shapiro's opinions that the labels for the BHR cup and R3 metal liner were insufficient, Shapiro Mot. at 14, Smith & Nephew should

have used alternative methods to warn physicians because they do not read IFUs, *id.* at 16, Smith & Nephew should have warned that the BHR-THA and R3-THA were off-label, provided additional information to surgeons about IFUs, and ultimately stopped selling components used in the BHR-THA system, *id.* at 17-19, and metal-on-metal devices pose an unacceptable risk of failure and the R3 metal liner's PMA approval was faulty, *id.* at 20. Smith & Nephew also attacks Pellerite's opinions that Smith & Nephew "promoted the 'off-label' use of the BHR cup and R3 metal liner," *id.* at 21, concern regulatory matters, *id.* at 22-23, describe "what a 'reasonable orthopedic surgeon would want to know,'" *id.* at 24, provide a narrative history of hip implants, *id.* at 27, summarize and comment on other witnesses' testimony and documents, *id.* at 27-28, speculate about Smith & Nephew's "knowledge," *id.* at 28, and derive from business and regulatory actions in other countries, *id.* at 28-29, as beyond his expertise and unreliable.

i. Preemption

a. Labeling

Smith & Nephew argues that Shapiro's opinions regarding the BHR cup and R3 metal liner's labeling are inadmissible because they are preempted. Shapiro Mot. at 14. Shapiro's opinions regarding the labeling of the BHR cup and R3 metal liner implicate two aspects of the devices' labels, only one of which is preempted.

Shapiro opines that "[i]t was not enough to include a line in the U.S. version of the IFU for the BHR stating that the company did not have a commercially available modular femoral head for use with a BHR surfacing shell." Shapiro Report at 19. An opinion undermining the adequacy of the BHR's PMA label is expressly preempted. *THA Preemption Ruling*, 401 F. Supp. 3d at 562. Thus, Shapiro's opinion directly impugning the sufficiency of the labels of the BHR cup or R3 metal liner is inadmissible.

Shapiro also states that the color coding used in the BHR cup and MFH "gave [the THA systems] the false appearance of approval and certification." Shapiro Report at 18-19. As with Truman and Pellerite, Shapiro primarily criticizes the MFH's label or the impact of Smith & Nephew's color coding on the systems as a whole. *Id.* As such, his opinion does not relate only to preempted claims and is admissible. *See THA Preemption Ruling*, 401 F. Supp. 3d at 562.

The court will grant Smith & Nephew's motion as to Shapiro's opinions regarding the labels of the BHR cup and R3 metal liner alone, but deny the motion as to opinions relating to the labels of the MFH or the THA systems as a whole.

b. Surgeons' Practice of Reading IFUs

Smith & Nephew argues that Shapiro's opinion that surgeons do not read IFUs is expressly preempted because it impugns the efficacy of PMA labels. Shapiro Mot. at 16. Moreover, Smith & Nephew contends that "Dr. Shapiro's opinion that the IFUs are inadequate because surgeons do not read them undermines the FDA's determination to the contrary" and is therefore also impliedly preempted. *Id.* While Shapiro's opinion is admissible to show that surgeons had notice of the information that was included on the IFU as part of a non-preempted failure to warn claim, *THA Preemption Ruling*, 401 F. Supp. 3d at 556, parts of his opinion also imply that including information on an IFU is not a sufficient warning. Shapiro's opinion is preempted to the extent that it would question the adequacy of the labels on PMA components. *Id.* at 562. The court will reserve ruling on Shapiro's opinion about surgeons' practice of reading IFUs until the opinion is presented in the context of specific claims.

c. Warning Surgeons Against Off-Label Use

Smith & Nephew contends that Shapiro's opinion that it should have "discourage[d]" the "use of the BHR THA configuration" and warned surgeons against off-label use is inadmissible

because it is relevant only to preempted claims and imposes additional obligations on PMA components. Shapiro Mot. at 17. Smith & Nephew attempts to refocus Shapiro's opinions regarding the need for warnings about the THA systems as warnings about the PMA components. But the court has drawn a distinction between the systems and their PMA components, and opinions suggesting that additional warnings were required for the THA systems as a whole are not preempted. *THA Preemption Ruling*, 401 F. Supp. 3d at 557. And Shapiro's statements that Smith & Nephew representatives should have provided warnings to surgeons during implantations always involve a hypothetical circumstance in which a surgeon was attempting to use PMA components with an MFH in a THA. *See* Shapiro Depo. Tr. at 95, ECF 2891-10 (Q: "Smith & Nephew did warn surgeons not to use the BHR cup in a total hip, didn't they?" . . . A: "the representatives being there, okay, who had the opportunity . . . to tell the surgeons *this is not a very good configuration* because it has worse outcome."); *id.* at 216-17 ("So here, you have a stem that says you may use this in a hemiarthroplasty, not to be used in a total hip configuration; okay? . . . Then you have your shell. It's been told you can use this shell in a resurfacing—*BHR resurfacing type of design of a hip, and that's okay*. Problem is *mixing the two of them is like fertilizer and heat*.") (emphasis added).

Secondarily, Smith & Nephew also contends that Shapiro's "opinion that [it] should have affirmatively advised surgeons of the regulatory status of the BHR-THA and R3-THA" is expressly preempted because it would constitute off-label promotion. Shapiro Mot. at 18. However, Shapiro's opinions focus on Smith & Nephew's *advertising* which allegedly promoted the THA systems, Shapiro Report at 19-20, and contend that sales representatives should have warned surgeons about the regulatory status of the THA systems primarily *in response* to surgeons' requests to use an MFH with a PMA component, Shapiro Depo. Tr. at 95. Shapiro's opinions do

not suggest that Smith & Nephew should have affirmatively informed surgeons about the THA systems' regulatory status without prompting and are admissible.

Finally, Smith & Nephew asserts that Shapiro's opinions that it should have warned surgeons about the risks of using the MFH with PMA components when asked for the components during a procedure would constitute interference with the practice of medicine in violation of the FDCA. Shapiro Mot. at 19. Yet Shapiro does not opine that Smith & Nephew representatives should have actually prevented surgeons in the operating room from implanting a THA system. Providing a warning does not interfere with the practice of medicine, and Shapiro's opinions are admissible.

The court will deny Smith & Nephew's motion as to Shapiro's opinions regarding its warnings to surgeons against off-label use.

d. Safety and PMA Approval of BHR Components

Smith & Nephew challenges Shapiro's opinion that "metal-on-metal articulating implants have an unacceptable rate of failure," as preempted because it "challenge[s] the safety and PMA approval of BHR components." Shapiro Mot. at 20. But Shapiro's opinion about the safety of metal-on-metal focuses on the BHR-THA and is therefore not preempted. Shapiro Report at 20. Questioning the safety of the THA systems as a whole does not necessarily impugn the PMA components. *THA Preemption Ruling*, 401 F. Supp. 3d at 556.

Smith & Nephew also attacks Shapiro's opinion regarding the adequacy of its submissions during the process of clearing the R3 metal liner for PMA line extension. Shapiro Mot. at 20. Testimony relating to the PMA approval process is expressly or impliedly preempted under *Buckman*. *BHR Daubert Ruling*, 2021 WL 781682, at *4-5 (citing *Buckman*, 531 U.S. at 348, 351).

Shapiro's testimony questioning the adequacy of Smith & Nephew's submissions for the PMA process, *see* Shapiro Report at 3, relates to preempted claims and is therefore not relevant.

The court will therefore deny in part and grant in part Smith & Nephew's motion on this issue.

ii. Reliability

a. Promoting Off-Label Use of the BHR Cup and R3 Metal Liner

Smith & Nephew argues that Shapiro lacks qualifications to opine on its alleged off-label promotion because "he is not an expert in FDA regulatory matters, nor is he in any sense an expert in the marketing of medical devices." Shapiro Mot. at 21. Though Shapiro is not a regulatory or marketing expert, his experience as an orthopedic surgeon for more than 36 years is sufficient background to support his opinions about whether Smith & Nephew's actions would have promoted off-label usage of the BHR cup and R3 metal liner from the perspective of a surgeon. *See* Shapiro Report at 2; *BHR Daubert Ruling*, 2021 WL 781682, at *12; *Knight*, 323 F. Supp. 3d at 850-52.

Smith & Nephew also contends that Shapiro's opinions on its promotion of the PMA components are not "the product of reliable principles and methods" because he did not understand Smith & Nephew's purported reason for color-coding the BHR and MFH together, relied on a photo of BHR components provided to him by the plaintiffs, and cited an email which Smith & Nephew contends shows that a sales manager discouraged off-label promotion. Shapiro Mot. at 21-22. Smith & Nephew essentially argues that the evidence is insufficient to support Shapiro's conclusion. But such contentions are better suited for testing by cross-examination. *See Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 532 (S.D.W. Va. 2014).

The court will deny Smith & Nephew's motion as to Shapiro's opinions about off-label promotion of the PMA components.

b. Regulatory Matters

Smith & Nephew argues that Shapiro should not be permitted to opine about Smith & Nephew's compliance with FDA regulations and requirements. Shapiro Mot. at 22-23. But the statements Smith & Nephew identifies merely describe historical facts which do not require expertise to understand. *See* Shapiro Report at 21 ("Smith & Nephew failed to provide certain information to the FDA" about the THA construct and "the FDA requested additional information about the safety of the device, which Smith & Nephew did not provide."). Moreover, these statements are not offered to demonstrate that the THA systems are in fact unsafe, but that Smith & Nephew did not provide relevant information to surgeons. *Id.* at 21. The court will deny Smith & Nephew's motion on this issue because Shapiro is not opining about whether Smith & Nephew's compliance with regulatory matters was satisfactory.[11]

c. What a "Reasonable Surgeon" Would Want to Know

Smith & Nephew asserts four reasons why Shapiro's opinions about what a "reasonable orthopedic surgeon would want to know" should be excluded. Shapiro Mot. at 24-25.

Smith & Nephew first argues that Shapiro cannot base his opinions on "common sense." *Id.* at 24. Shapiro's reference to "common sense" is more fairly understood as a reference to intuitions derived from "his extensive experience" as an orthopedic surgeon. *See* Case Specific *Daubert* Ruling at 12, ECF 2717; Shapiro Report at 18 ("Based on my experience and training, any reasonable orthopedic surgeon would want to know this kind of information."). An expert

[11] Smith & Nephew also points out several errors in Shapiro's testimony, including misstating the name of the BHR and the details of the PMA. Smith & Nephew may highlight these errors in cross-examination, but they do not undermine the overall reliability of Shapiro's testimony.

opining based on experience "must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." Fed. R. Evid. 702 advisory committee's note to 2000 amendments. In the relevant deposition testimony, Shapiro explained that "as an orthopedic surgeon, if I am using a device that I think is approved . . . and if marketing makes me think that it's okay to do that . . . I think it's wrong for a company to market and sell a configuration or product . . . knowing that it is performing much more poorly compared to [other devices]." Shapiro Depo. Tr. at 47-48. Shapiro also describes his experience in detail in his report. Shapiro Report at 5-7. Though he does not develop the connections required by FRE 702 in his deposition, the required elements of an acceptable opinion are present and he may be able to explain the basis for his conclusions at a later point.

Second, Smith & Nephew takes issue with Shapiro's failure to base his testimony on "any reliable scientific methodology" such as a "survey of orthopedic surgeons." Shapiro Mot. at 25. But the plaintiffs identify case law approving an experienced medical professional's opinion as to what information a reasonable professional would want to know, and Shapiro is sufficiently qualified to offer his general opinion about information that would be relevant to a reasonable surgeon. *See* Shapiro Opp'n at 24 (citing *In re Bard IVC Filters Prods. Liab. Litig.*, 2017 WL 6554163, at *4-5 (D. Ariz. Dec. 22, 2017); *Knight*, 323 F. Supp. 3d at 850-52. On the other hand, case law also supports the proposition that an expert may not generalize his opinion to all reasonable members of his profession when it is overly conclusory or predictive. *In re Diet Drugs Prods. Liability Litig.*, 2000 WL 876900, at *11 (E.D. Pa. June 20, 2000); *In re Baycol*, 532 F. Supp. 2d at 1069.

Third, Smith & Nephew criticizes Shapiro's opinion as relying "primarily, if not entirely, on his own purported personal preferences." Shapiro Mot. at 25. However, as stated above,

Shapiro's experience qualifies him to speak about the preferences of an experienced orthopedic surgeon.

Finally, Smith & Nephew asserts that Shapiro's "views of what a reasonable surgeon would want to know have no bearing on any issue in any of the individual cases in this MDL" because only an individual plaintiff's own surgeon's understanding is relevant. *Id.* at 26. The court has already reserved ruling on the relevance of Shapiro's opinions regarding the views of a reasonable orthopedic surgeon. Case Specific *Daubert* Ruling at 5-6, ECF 2717.

With all of the above considerations in mind, the court will reserve ruling on the propriety of Shapiro's testimony about what a reasonable orthopedic surgeon would have wanted to know. At a later point, Shapiro may be able to demonstrate the concrete bases for his opinions and clarify the scope of his conclusions. Moreover, the testimony's relevance and potential for prejudice or confusion will be clearer when viewed in context.

d. Historical Narrative

Smith & Nephew challenges Shapiro's narrative of the history of hip implants. Shapiro Mot. at 27. The court ruled that part of Shapiro's historical narrative of hip implants was inadmissible in the BHR Track because it was related to an opinion on a preempted claim, but reserved ruling on the remainder of the historical narrative. *BHR Daubert Ruling*, 2021 WL 781682, at *13. Shapiro's opinion includes some history that is clearly not relevant to any claims, including testimony on early hip replacement designs from the 1920's and 1950's. Shapiro Report at 8. Such irrelevant testimony should be excluded. However, Shapiro's history of the BHR-THA could be relevant to his opinions on many non-preempted claims, and the court will reserve ruling on that portion of the narrative at this time. *See BHR Daubert Ruling*, 2021 WL 781682, at *13.

e. Summary of Other Testimony

Smith & Nephew challenges Shapiro's description of other witnesses' testimony. Shapiro Mot. at 27-28. Summaries of testimony or other documents are admissible when used to support an admissible expert opinion. *BHR Daubert Ruling*, 2021 WL 781682, at *13. The court will reserve ruling on the admissibility of factual summaries until summary judgment or trial to determine whether they are connected to otherwise admissible opinions.

f. Smith & Nephew's Knowledge or State of Mind

Smith & Nephew argues that Shapiro's testimony "speculating as to Smith & Nephew's knowledge or state of mind is inadmissible." Shapiro Mot. at 28. As stated above, the court has ruled that "a party's 'knowledge, state of mind, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury.'" *BHR Daubert Ruling*, 2021 WL 781682, at *13 (quoting *Eghnayem*, 57 F. Supp. 3d at 670). For the same reasons, Shapiro's opinions regarding Smith & Nephew's knowledge will be excluded.

g. Foreign Business and Regulatory Actions

Smith & Nephew opposes Shapiro's testimony regarding the business and regulatory decisions to stop selling the THA in foreign countries. Shapiro Mot. at 28-29. As explained above, foreign actions may be admissible to show notice. Case Specific Evidentiary Ruling at 9-10, ECF 2827. Shapiro's opinion cites foreign actions both to show notice of potential failure rates, Shapiro Report at 16-17, and (arguably) to opine that Smith & Nephew should have taken similar action in the U.S., Shapiro Report at 19 ("[E]ven when it withdrew the BHR-THA system overseas, Smith & Nephew intentionally decided not to warn surgeons in the United States."). To the extent foreign actions are used to demonstrate notice, such opinions are admissible, but opinions that foreign

regulatory actions should have inspired similar actions in the U.S. are inadmissible. The court will grant Smith & Nephew's motion in part and deny it in part as to this issue.

II. The Plaintiffs' Motions to Exclude Expert Testimony

The plaintiffs raise effectively identical challenges to the testimony of each of Smith & Nephew's three THA-Track experts. They contend that each expert is unqualified to testify to THA-Track issues because they do not "have specialized knowledge of the facts specific to the THA devices," Kerger Mot. at 7; Bozic Mot. at 6; Goldstein Mot. at 6, and that the testimony of each is unreliable because it is not based on "specialized knowledge regarding the facts specific to the THA cases," Kerger Mot. at 8; Bozic Mot. at 7; Goldstein Mot. at 7. Fundamentally, the plaintiffs argue that Smith & Nephew's experts should not be permitted to testify because they did not issue new reports specific to the THA Track.

Bozic and Goldstein's opinions are not specific to the BHR Track. Bozic testifies about the utility of registry data, the general availability of information about the dangers of metal-on-metal hip resurfacing, the adequacy of Smith & Nephew's actions regarding metal-on-metal devices, and surgeons' decision-making practices. Bozic Mot. at 3-4. Goldstein testifies about the sufficiency of the Quality System at Smith & Nephew's Warwick facility and rebuts opposing expert testimony about the same. Goldstein Mot. at 3-4. The MFH was manufactured at the Warwick facility along with the BHR cup and the R3 metal liner. Goldstein Opp'n at 7. Bozic and Goldstein's opinions are applicable to issues in the THA Track, and the court will deny the plaintiffs' motions to exclude their testimony.

Though Kerger's testimony does include details specific to the BHR cup, those details are also relevant to the THA Track. Kerger testifies about the metal alloys used in the design of the BHR cup, the release of metal ions from metal-on-metal devices and the BHR cup in particular,

and the toxicological impact of the wear debris produced by metal-on-metal devices and the BHR cup in particular. Kerger Mot. at 3-4. The BHR-THA and R3-THA are both metal-on-metal devices that allegedly produce metal ion debris. Moreover, the BHR-THA system contains the BHR cup. Though Kerger may not have tailored his testimony to the THA systems, his general opinions about the toxicological impact of metal ion debris are relevant to the THA track claims, and he is qualified to offer those opinions. The court will deny the plaintiffs' motion to exclude Kerger's testimony.

CONCLUSION

For the reasons described above, the court will grant, reserve, and deny in part each of Smith & Nephew's motions to exclude expert testimony. The court will deny each of the plaintiffs' motions to exclude. A separate order follows.

10/12/2023
Date

/s/
Catherine C. Blake
United States District Judge