IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(Baltimore Division)

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 THE BHR TRACK AND THE CERTAIN BHR TRACK ACTIONS IDENTIFIED IN EXHIBIT A**

SMITH & NEPHEW, INC.'S REPLY MEMORANDUM IN SUPPORT OF ITS MOTION TO DISMISS CERTAIN TIME-BARRED CLAIMS

Smith & Nephew ("S&N") submits this reply in support of its Motion to Dismiss certain BHR Complaints that are facially untimely. *See* S&N Mem. in Support of Its Motion to Dismiss Certain Time-Barred Claims (June 20, 2018) [D.E. 795-1] ("S&N Mem.").

INTRODUCTION AND SUMMARY

In its opening Memorandum, S&N identified the states in which a Plaintiff's claims accrue when (i) there is an injury, *id.* at 6-8, (ii) the Plaintiff knew of the injury, *id.* at 9-10, or (iii) the Plaintiff knew or should have known of the *factual* cause of the injury, *id.* at 10-13. For the Complaints governed by these state laws, Plaintiffs' claims accrued no later than the date of their surgeries to remove or revise their BHR implants. Unlike cases where the alleged connection between an injury and product (*e.g.*, a prescription drug) may be uncertain, Plaintiffs here all allege that their revision surgeries were "medically necessary" or "medically indicated" to address injuries that they identified in their Short Form Complaints. *Id.* at 4-6. Plaintiffs' claims are untimely because they filed suit well *after* the applicable statute of limitations had run on their claims. *See id.* at 6-14 & nn. 7, 9-10 & Ex. A to S&N Mem. Where claims are time-

barred on the face of the complaint, dismissal under Rule 12(b)(6) is the proper course. Neither the parties nor the Court should have to expend additional resources addressing time-barred claims. Plaintiffs' Opposition [D.E. 853] ("Opp.") does not undermine that showing.

Plaintiffs do not dispute that they allege physical injuries, causally related to the BHR, that occurred no later than the date of their revision surgeries. S&N Mem. 2-6. They advance a variety of objections in an effort to sow confusion, but their principal argument is a legal one. They argue broadly that (i) "every state defines when an injury occurs or accrues in different ways," Opp. 7, (ii) "something beyond a mere physical injury is required" to trigger the statute of limitations, *id.,* and (iii) "the Recall announcement by the FDA should be the earliest possible accrual date," Opp. 2, 4. The precedent that they identify does not support their arguments or undercut S&N's analysis of the relevant accrual standards, S&N Mem. 6-13, and their state-specific analysis confirms that these Complaints are untimely. *See* Ex. D hereto. Further, Plaintiffs cannot postpone the accrual of their claims by identifying an event—*i.e.*, the FDA's Recall announcement—that occurred *after* their claims had already accrued under applicable state law. *See Monroe* v. *City of Charlottesville*, 579 F.3d 380, 385-86 (4th Cir. 2009) ("[T]he court need not accept the legal conclusions drawn from the facts").[1]

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[1] Even under Plaintiffs' theory—*i.e.*, the statute of limitations runs from a Plaintiff's revision date or FDA's September 2015 recall announcement, "whichever is later," MACC ¶ 268; Opp. 9—five Complaints at issue here are time-barred. *Morgan* SFC [D.E. 440], S&N Mem. Ex. B at 62-66 (subject to California's two-year statute of limitations and filed on November 14, 2017, more than two years after September 2015 FDA announcement and nearly five years after Plaintiff's revision surgery); *Carrera* SFC [D.E. 458], S&N Mem. Ex. B at 100-03 (subject to Idaho's two-year statute of limitations and filed on November 29, 2017, more than two years after the FDA announcement and nearly four years after Plaintiff's revision surgeries); *Britt* SFC [D.E. 444], S&N Mem. Ex. B at 281-84 (subject to Utah's two-year statute of limitations and filed on November 17, 2017, more than two years after the FDA announcement and more than three years after Plaintiff's revision surgery); *Aaron* SFC [D.E. 456], S&N Mem. Ex. B at 122-26 (subject to Louisiana's one-year statute of limitations, discussed *infra*); *Stafford* SFC [D.E. 566], S&N Mem. Ex. B at 174-78 (subject to Tennessee's one-year statute of limitations, discussed *infra*).

Moreover, Plaintiffs have failed in the MACC [D.E. 124] or in the Short Form Complaints to allege facts necessary to support tolling of the statute of limitations. *See* Ex. E hereto (addressing requirements for fraudulent concealment/estoppel). This Court has addressed and rejected Plaintiffs' argument that S&N fraudulently concealed that it "did not have legal protection under the FDA's premarket approval" and that S&N "committed fraud" because it "did not inform the medical community or patients about its lost legal protection." March 26, 2018 Memorandum [D.E. 608] ("March 2018 Mem.") 5 n.5. Likewise, allegations that S&N concealed and/or failed to disclose that the BHR was "defective, unsafe, and unfit for the purposes intended" (MACC ¶ 269) are foreclosed by FDA's pre-market approval of the BHR, which (1) is FDA's "recognition of a particular medical device's fitness for the market," March 2018 Mem. 15, and (2) means that, as a matter of federal law, a "device is safe," *id.* at 18. Plaintiffs' reference to one plaintiff's correspondence with Smith & Nephew (Opp. 1-2, 4, Ex. A-B) *confirms* that she understood the BHR was the cause of her alleged injury, thereby triggering the accrual of her claims, which are therefore time-barred.

Finally, with regard to breach of warranty, Plaintiffs' only response to S&N's showing that the identified claims are untimely is to invoke the same inapplicable tolling rules. They do not dispute that their breach of warranty claims are untimely absent tolling. And because tolling does not apply, the breach of warranty claims—like Plaintiffs' other claims—are time-barred.

<u>ARGUMENT</u>

I. PLAINTIFFS' UNTIMELY CLAIMS SHOULD BE DISMISSED.

Throughout their Opposition, Plaintiffs suggest that dismissal of an untimely Complaint should await the completion of discovery at summary judgment. *E.g.*, Opp. 3, 18-19 & Ex. G thereto. Plaintiffs acknowledge, as they must, that a statute of limitations defense "may be reached by a motion to dismiss under Rule 12(b)(6)" where "plaintiffs allege in their complaint

facts sufficient to rule on an affirmative defense." Opp. 3. Indeed, "Rule 12(b)(6) motions to dismiss may properly raise statute of limitations defenses where the defense is apparent from the face of the complaint." *Douglass v. NTI-TSS, Inc.*, 632 F. Supp. 2d 486, 491 (D. Md. 2009); *accord Goodman v. Praxair, Inc.,* 494 F.3d 458, 464 (4th Cir. 2007).

Here, S&N demonstrated that the relevant facts necessary to assess the timeliness of Plaintiffs' Complaints are set forth in the MACC and Plaintiffs' Short Form Complaints. S&N Mem. 2-6. To be clear, S&N does not contend that "a revision surgery is the legal injury as a matter of law." Opp. 7. Rather, the MACC and Short Form Complaints allege that Plaintiffs suffered injury *before* their revision surgeries and that removal or revision of the BHR implant was "medically necessary" to address Plaintiffs' already existing injuries. S&N Mem. 2-6 & nn.2, 4. Plaintiffs' Opposition does not challenge S&N's showing that for each Plaintiff, their alleged physical injury, knowledge of physical injury, and knowledge that the physical injury was causally related to the BHR could have occurred no later than the date of the Plaintiff's revision surgery. Plaintiffs' Opposition does not and cannot dispute their own allegations.

Instead, Plaintiffs argue that state laws governing accrual are murky and therefore factual development is required.[2] That is wrong. S&N identified three categories of state laws

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[2] To streamline the Court's analysis, S&N withdraws from its Motion the following Complaints. *First*, Plaintiff Stranger-McGorrin filed suit in California state court on July 29, 2016, *see* Opp. 6, but never served that complaint on S&N until *after* S&N filed this Motion. Plaintiff instead direct-filed a *separate* federal complaint in this MDL. *See Stranger-McGorrin* SFC [D.E. 281], S&N Mem. Ex. B at 084. The filing in state court does not toll the statute of limitations here, but the parties are in the process of reaching an agreement on dismissal of the state case and the statute of limitations issues, which will be separately presented to the Court and obviates the need for a decision on this Complaint. *Second*, Plaintiffs Hopkins and Berg, both of whom originally filed in Tennessee state court, voluntarily dismissed their claims and subsequently refiled in a different jurisdiction within one year. Opp. 6. Their Short Form Complaints do not claim that Tennessee law applies to their claims, and S&N reserves its right to challenge the applicability of Tenn. Code Ann. § 28-1-105(a) as a basis for tolling the statute of limitations for their claims under Massachusetts and California law. *See* [D.E. 137, 152], S&N Mem. Ex. B at 006, 236 (*Berg* and *Hopkins* Short Form Complaints). *Third*, S&N agrees that Plaintiff Stidham's Complaint, which was added to the MDL before the JPML's January 31, 2018 ruling, is properly addressed in the THA track. *See Stidham* SFC, [D.E. 1 in No. 1:17-cv-2527 (D. Md.)], S&N Mem. Ex. B at 115. *Finally*, S&N withdraws its Motion with respect to Plaintiff Crews. *Crews* SFC [D.E. 147], S&N Mem. Ex. B at 225.

governing accrual of Plaintiffs' claims. In five states, Plaintiffs' claims accrue when there is an alleged physical injury. S&N Mem. 6-8 (Alabama, California, Idaho, Michigan and Virginia).[3] In three other states, Plaintiffs' claims accrue when a plaintiff has knowledge of his or her physical injury. *Id.* at 9-10 (Louisiana, New York and Tennessee).[4] Finally, in twelve other states, a plaintiff's claims accrue when he or she knew or should have known the factual cause of the physical injury. *Id.* at 10-13 (Alaska, Arizona, Arkansas, Indiana, Kentucky, Massachusetts, New Jersey, Ohio, Oregon, Pennsylvania, Utah and Wisconsin).[5]

Without disputing the three groupings, Plaintiffs contend that "every state defines when an injury occurs or accrues in different ways," but that "there is a common thread running through these states' laws: something beyond mere physical injury is required." Opp. 7. For support, Plaintiffs first rely on cases applying California, Wisconsin, Utah, and Louisiana law. *Id.* at 7-8. Next, they argue that "in hip cases, courts have held that a revision date does not automatically cause a claim to accrue." *Id.* at 8. Finally, they contend that "courts have repeatedly held (including against Smith & Nephew) that a product recall date generally triggers the statute of limitations." *Id.* at 9. None of these arguments undercuts S&N's showing that dismissal is appropriate under Rule 12(b)(6). *See* Ex. D hereto.

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[3] *E.g.*, *Tice v. Zimmer Holdings, Inc.*, No. 1:15-CV-134, 2015 WL 4392985, at *5 (W.D. Mich. July 15, 2015) ("[T]he claims accrued when the alleged defects in the Devices harmed Plaintiff. This must have occurred *before* Mr. Tice or his physicians determined that he needed corrective surgery").

[4] *E.g.*, *Potts v. Celotex Corp.*, 796 S.W.2d 678, 680-81 (Tenn. 1990) ("Under the 'discovery rule' applicable in tort actions, . . . the cause of action accrues and the statute of limitations begins to run when the injury occurs or is discovered, or when in the exercise of reasonable care and diligence, it should have been discovered.").

[5] *E.g.*, Utah Code Ann. § 78B-6-706 (The statute runs from the date the party claiming injury "discovered, or in the exercise of due diligence should have discovered, both the harm and its cause."); *Adams v. Am. Med. Sys., Inc.*, 705 F. App'x 744, 745, 747 (10th Cir. 2017) ("Adams does not cite, and we could not find, any Utah Supreme Court decision that § 78B-6-706's two-year limitations period does not run until the plaintiff knows, or should have known, that her harm is caused, not just by the product, but a defect in that product.") (emphasis omitted).

A. Plaintiffs Misconstrue California, Wisconsin, Utah And Louisiana Law.

Plaintiffs point to the laws in California, Wisconsin, Utah and Louisiana law, but each state's laws support dismissal of Plaintiffs' claims. *See* Opp. 7-8.

Plaintiffs acknowledge that in California the statute of limitations "typically begins to run on the date of the plaintiff's injury." *Id.* They insist, however, that (i) California's "discovery rule delays accrual until the plaintiff has, or should have, inquiry notice of the cause of action," *id.* at 8 (citing *Bekins v. AstraZeneca Pharm.,* -- F. App'x --, 2018 U.S. App. LEXIS 17797 (9th Cir. June 28, 2018)), and (ii) S&N's "primary California case [*Bekins*] was reversed by the Ninth Circuit one week after Smith & Nephew's Motion filing in a decision that specifically moots its argument and instead supports Plaintiffs." Opp. 1. Contrary to their argument, the Ninth Circuit in *Bekins* did not modify controlling California law, which dictates that, absent allegations that trigger the discovery rule, a claim generally accrues with "the injury to the future plaintiff." *Fox v. Ethicon Endo-Surgery, Inc.*, 35 Cal. 4th 797, 809 (2005). Indeed, the Ninth Circuit in *Bekins* expressly applied the California Supreme Court's decision in *Fox*, which holds that to invoke the discovery rule, plaintiff must "specifically plead facts to show (1) the time and manner of discovery and (2) the inability to have made earlier discovery despite reasonable diligence." *Id.* at 808; *Bekins,* 2018 U.S. App. LEXIS 17797, at *2 (applying *Fox* to hold that the allegations in plaintiffs' original Complaint were inadequate to invoke the discovery rule but that allegations in the proposed amended Complaint were adequate). In *Bekins*, the court concluded that plaintiff did not have reason to suspect that her kidney failure was caused by the drug when the condition first arose. *Id*. at *5. Here, in contrast, the California plaintiffs' allegations confirm that they knew no later than their revision surgeries that the BHR was the source of their injury and that revision surgery was medically necessary. Unlike *Bekins*, Plaintiffs have not and cannot make

allegations necessary to trigger the discovery rule under California law. *See* S&N Mem. 7 n.8; *cf. Douglass*, 632 F. Supp. 2d at 493 (dismissing claim where plaintiff "failed to allege the requisite diligence in discovering the alleged fraud").[6]

For Wisconsin, Plaintiffs point to the same authority as S&N, which holds that "[a] cause of action cannot be said to accrue until the claimant discovers both the nature of his or her injury and its cause - or at least a relationship between the event and the injury." *Compare* Opp. 8 (quoting *S.J.D. v. Mentor Corp.*, 159 Wis. 2d 261, 266 (Wis. Ct. App. 1990)) *with* S&N Mem. 12 (same). Based on that authority, S&N seeks dismissal of two Complaints governed by Wisconsin law. In the first, Plaintiff Lori Mergener alleges that she had "elevated cobalt and chromium levels" that "made revision surgery medically necessary." *Mergener* SFC ¶ 11 [D.E. 307], S&N Mem. Ex. B at 291. In the second, Plaintiff Kristi Tursky alleges that a "pseudotumor" and "elevated cobalt and chromium levels" made her "revision surgery medically necessary." *Tursky* SFC ¶ 12 [D.E. 238], S&N Mem. Ex. B. at 296. These allegations establish that, no later than the date of the revision surgeries, Plaintiffs Mergener and Tursky were aware of (i) their injury, *i.e.*, their alleged "elevated cobalt and chromium levels" and, for Plaintiff Tursky, her alleged "pseudotumor," and (ii) the relationship between that injury and the BHR implant, for which revision was "medically necessary" to address their respective injuries. *See S.J.D.*, 159 Wis. 2d at 269 (ruling that plaintiff's claim accrued on the date of his surgery).

Likewise, for Utah, Plaintiffs cite the same precedent as S&N, which holds that a claim accrues when the plaintiff "discover[s], or in the exercise of due diligence should have discovered, both the harm and its cause." *Compare* Opp. 8 (quoting *Adams*, 705 F. App'x at

[6] Plaintiffs argue that S&N improperly grouped California with "states that do not" have a discovery rule. Opp. 11. That criticism is baffling because S&N's Memorandum expressly states that "California recognizes a discovery rule," but that Plaintiffs had failed to satisfy their burden "to invoke it." S&N Mem. 7 n.8

746) (emphasis omitted) *with* S&N Mem. 12 (citing *Adams*). S&N's Motion seeks dismissal of two Complaints governed by Utah law. Specifically, Plaintiffs Duane Britt and David James allege that their revision surgeries were "medically necessary" to address "metallosis" and "elevated cobalt and chromium levels," *Britt* SFC ¶ 11 [D.E. 444], S&N Mem. Ex. B at 282, and a "pseudotumor and elevated levels of cobalt and chromium," *James* SFC ¶ 11 [D.E. 262], Ex. B at 286. Given these allegations, the Tenth Circuit's decision in *Adams* is directly on point because there, the statute of limitations began to run when plaintiff "was told she had to undergo a second operation to remove part of the [device] in order to remedy severe pain and bleeding—that she had been harmed by the [device]." 705 F. App'x at 745. Indeed, *Adams* rejected the argument that the statute of limitations did not begin to run until plaintiff knew or should have known "that her harm was caused by a defect in the product." *Id.* (emphasis omitted).

As for Louisiana, the sole Complaint at issue—filed by Plaintiffs Claud and Sherry Aaron—is untimely even under Plaintiffs' own theory of accrual. The Aarons filed suit more than two years *after* the September 2015 Recall announcement, (MACC ¶ 11), *i.e*., well outside Louisiana's one-year statute of limitations. Specifically, Plaintiff Claud Aaron "underwent medically-indicated revision of the RIGHT BHR hip implant on or about June 24, 2013." *Aaron* SFC ¶ 10 [D.E. 456], S&N Ex. B at 123. Plaintiffs filed suit more than four years later on November 27, 2017. *Id.* at 126. The Complaint is untimely even under Plaintiffs' position that the "statute of limitation would have begun to run from the recall date in September 2015, or the date of his revision surgery, whichever is later." MACC ¶ 268; *see also* Opp. 9 ("Rather, as Plaintiffs allege, the key event is the FDA announcement of the Recall, which first put some Plaintiffs who had already had a revision on notice that Smith & Nephew's actions and failures may be causally connected to their revisions."). Under their own analysis, the Aaron Plaintiffs'

claims would have accrued no later than September 2015, and thus, their November 2017 lawsuit is untimely under Louisiana's one-year limitations period. S&N Mem. Ex. A at 2.

B. Plaintiffs Mischaracterize The Relevance Of Plaintiffs' Revision Surgeries Under Applicable Law.

Plaintiffs next argue that "in hip cases, courts have held that a revision date does not automatically cause a claim to accrue." Opp. 8. But the two cases they cite are inapposite. In *Slater v. Biomet*, 244 F. Supp. 3d 803, 809 (N.D. Ind. 2017), the Court analyzed accrual under North Carolina law, which, unlike the state laws at issue here, requires knowledge of wrongdoing by the defendant. *Id*. at 809 (stating that, Under North Carolina law, "[w]here the injury and causation are known, but not that *there has been any wrongdoing*, the action is held to accrue when the plaintiff discovered . . . the wrongdoing" (emphasis added)). And, *Tice*, 2015 WL 4392985, *8, does not even address revision surgery at all. Rather, the *Tice* court held that the date a medical device is *implanted* does not necessarily trigger accrual of the plaintiffs' claim under Michigan law because Michigan law requires a showing of "harm" to plaintiff even if "the plaintiff is not subjectively aware of an injury or its cause." *Id*. at *2-3. Under the standard announced in *Tice*, a Michigan Plaintiff's claims would accrue no later than the date of a revision surgery that is alleged to be medically necessary to address a plaintiff's existing injuries.

C. The Date Of The Recall Announcement Does Not Trigger Or Reset The Statute of Limitations.

Plaintiffs fare no better arguing that a "product recall date" triggers the "statute of limitations." Opp. 9. Specifically, Plaintiffs contend that "before a recall, Plaintiffs could not have known that the device was the *legal* cause of their injury." *Id.* (emphasis added). The state laws identified by S&N in its Motion do not require knowledge of the "legal cause" of Plaintiffs' injuries. *See* Ex. D, hereto. The September 2015 Recall announcement by FDA would have no bearing on the accrual of claims by Plaintiffs at issue in S&N's Motion because their claims

already had accrued by virtue of their allegations of physical injury that necessitated the revision of the BHR well before September 2015.

The cases cited by Plaintiffs are not to the contrary. A number of the cases apply accrual standards under state laws not at issue in S&N's Motion.[7] The others do not support Plaintiffs' argument that the date of a product recall or label change triggers accrual notwithstanding allegations showing that a Plaintiff already was aware of injuries causally related to a challenged medical device. For example, in *In re Fresenius Granuflo/Naturalyte Dialysate Prods. Liab. Litig.*, 111 F. Supp. 3d 79 (D. Mass. 2015), the MDL Court, applying California law, dismissed plaintiff's claim pursuant to Rule 12(b)(6) because plaintiff failed to allege "diligence" necessary to invoke the discovery rule as required by the California Supreme Court. *Id.* at 86 (applying *Fox*, 35 Cal. 4th at 808-09). In *In re Chantix (Varenicline) Prods. Liab. Litig.*, 881 F. Supp. 2d 1333 (N.D. Ala. 2012), the MDL Court expressly *rejected* an argument that "the statute of limitations started running on all neuropsychiatric claims on [the date of the label change]." *Id.* at 1343. Finally, in *Strickland* v. *Gen. Motors Corp.*, 852 F. Supp. 956 (D. Utah 1994), the Court held that a claim accrued at the time of the accident because "[t]he alleged harm should have also been apparent, to some degree, at the time of the accident." *Id.* at 959-60. *Strickland* did not hold that the product recall triggered accrual, but instead explained that plaintiffs' claim was untimely even if measured from the date of a product recall that occurred after the accident. *Id.* at 960.[8]

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[7] *See Creamer v. Gen. Motors*, No. 16-4045, 2016 WL 3197379, at *2 (D. Kan. May 18, 2016) (Kansas law); *Jeffries v. Bos. Sci. Corp.*, No. 15-cv-3480, 2017 WL 2645723, at *2 (D. Md. June 20, 2017) (Maryland law); *Lee v. Wolfson*, 265 F. Supp. 2d 14, 19 (D.D.C. 2003) (District of Columbia law).

[8] Further, *Stratford v. SmithKline Beecham Corp.*, No. 2:07-CV-639, 2008 WL 2491965 (S.D. Ohio June 17, 2008), does not address any statute of limitations defenses, but instead accepts plaintiffs' allegations that their claims accrued on the date of a label change to hold that claims were "preempted" by an Ohio statute enacted before the label change. *Id.* at *4-5. And, in *Nicolosi v. Smith & Nephew, Inc.*, No. L01256-13, 2017 WL 632274, at *3 (N.J. Super. Ct. App. Div. Feb. 16, 2017), the court applied *Cornett* v. *Johnson & Johnson*, 998 A. 2d 543 (N.J. App. 2010), *aff'd as modified*, 48 A.3d 1041 (N.J. 2012), which holds that a claim accrues at the time of injury when a

D. Plaintiffs' State-By-State Analysis Does Not Undermine S&N's Showing.

Plaintiffs' grab-bag of state-specific arguments (Opp. 11-19) does not undermine S&N's showing that the Complaints at issue are untimely. *See* Ex. D hereto (addressing claim accrual rules under state law and allegations by plaintiffs triggering accrual).

Alabama. Plaintiffs acknowledge that "Alabama does not have the discovery rule." Opp. 12; *see Moon v. Harco Drugs, Inc.,* 435 So.2d 218, 220 (Ala. 1983) ("[A] cause of action accrues when the injury occurs, and in so doing, this Court has refused to accept the so-called 'discovery-rule.'"). They argue that the statute of limitations should be addressed at summary judgment and that dismissal is improper under the "continuous tort" doctrine because "actions, which continued post-revision, harmed the Alabama Plaintiffs," Opp. 12. Where, as here, "it appears from the face of the complaint that the plaintiff's claim is time-barred, the defendant is entitled to a dismissal based upon the defense of the statute of limitations." *Payton* v. *Monsanto*, 801 So. 2d 829, 834 (Ala. 2001). Further, "Alabama law does not recognize a continuing tort in instances where there has been a single act followed by multiple consequences," *id.* at 835, and Plaintiffs identify no post-revision actions by S&N that could have caused them harm. Opp. 12.

California. Plaintiffs contend that California applies a discovery rule and they have "sufficiently pled facts to overcome [S&N's] Motion." Opp. 12. As S&N has shown, to invoke the discovery rule, "[a] plaintiff whose complaint shows on its face that his claim would be barred without the benefit of the discovery rule must specifically plead facts to show (1) the time and manner of discovery and (2) the inability to have made earlier discovery despite reasonable diligence." *Fox*, 35 Cal. 4th at 808-09 (explaining that, absent allegations sufficient to invoke

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plaintiff "could have reasonably suspected a possible connection between the medical device and decedent's injury." *Id.* at 553.

the discovery rule, a products liability claim generally accrues with "the injury to the future plaintiff"). Plaintiffs have failed to satisfy that burden either in the MACC or the Short Form Complaints. S&N Mem. 7 n.8 (citing Ex. B at 006–094 (California Short Form Complaints)). The Opposition identifies no allegations in the MACC or Short Form Complaints as to any Plaintiff's "time and manner of discovery" or their "reasonable diligence." As discussed above, the Ninth Circuit in *Bekins* does not alter this requirement of California law. *See* Ex. D hereto.

Idaho. Plaintiffs agree that Idaho recognizes no discovery rule. Opp. 13; *see Theriault v. A.H. Robins Co., Inc.*, 698 P.2d 365, 369-71 (Idaho 1985) (rejecting discovery exception to the statute of limitations contained in Idaho Code § 5-219(4)). Plaintiffs argue that the statute of limitations issue should be resolved at summary judgment to address issues of fraudulent concealment and estoppel. *Id.* But none of the Idaho Plaintiffs makes any allegations in the Short Form Complaints concerning fraudulent concealment. *See* [D.E. 260], S&N Mem. Ex. B at 95-99 (Plaintiff Botkin); [D.E. 458], S&N Mem. Ex. B at 100-103 (Plaintiff Carrera); D.E. 308], S&N Mem. Ex. B at 104-108 (Plaintiffs Kal and Diane Kinghorn). And, as shown below, the MACC does not allege viable grounds for concluding that S&N engaged in fraudulent concealment. *See* Section II, *infra*.[9]

Michigan. Plaintiffs do not dispute that there is no discovery rule under Michigan law. Opp. 14; *Trentadue v. Buckler Lawn Sprinkler, Co.*, 738 N.W.2d 664, 672 (Mich. 2007) ("[C]ourts may not employ an extrastatutory discovery rule to toll accrual"). Instead, they argue that "Michigan law tolls the statute of limitations for fraudulent concealment." Opp. 14. The sole Michigan Plaintiff at issue makes no allegations in her Short Form Complaint to support

[9] The Ninth Circuit's decision in *Allen v. A.H. Robins Co.*, 752 F.2d 1365 (9th Cir. 1985), does not support Plaintiffs' position. In *Allen*, defendant "did more than conceal causation[,] [i]t concealed the damage itself," *id.* at 1371, whereas here, Plaintiffs were aware of the "damage" that gave rise to their revision surgeries.

fraudulent concealment. *See* McLaughlin SFC, S&N Mem. Ex. B at 109-114. And, as discussed below, the MACC does not allege viable grounds for concluding that S&N "fraudulently conceal[ed] the claim . . . from the knowledge of the person entitled to sue on the claim." Mich. Comp. Laws Ann. § 600.5855. *See* Section II, *infra.*[10]

New York. S&N showed that, under New York law, the statute of limitations begins to run when a plaintiff has knowledge of his or her injury. S&N Mem. 9 (citing *Gaillard v. Bayer Corp.*, 986 F. Supp. 2d 241, 246 (E.D.N.Y. 2013) ("'[t]he three year limitations period runs from the date when plaintiff first noticed symptoms, rather than when a physician first diagnosed those symptoms.'")). Dismissal is appropriate for claims governed by New York law where it is clear from the complaint that the claims are time-barred. *See, e.g., Bano v. Union Carbide Corp.*, 361 F.3d 696 (2d Cir. 2004) (affirming dismissal of personal injuries claims under C.P.L.R. § 214-c).

Plaintiffs argue that CPLR § 214-c(4) "extends the statute of limitations for certain tort victims who do not know the cause of their injuries." Opp. 16. The Plaintiffs at issue who are governed by New York law have not alleged any facts that would trigger C.P.L.R. 214-c(4) in their Short Form Complaints. *See* Ex. D hereto. Nor could they trigger § 214-c(4), which requires a plaintiff to plead "that medical knowledge sufficient to ascertain the cause of the injury had not been discovered before the expiration of the otherwise-applicable limitations period." *Gaillard*, 986 F. Supp. 2d at 246. To the contrary, each of the New York Plaintiffs specifically alleged that removal or revision of the BHR implant was "medically necessary" to address the injuries that Plaintiffs already had experienced.[11] There was no medical or "technical

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[10] As discussed in Section I.A. S&N's Motion applies to one Complaint governed by Louisiana law, which is untimely under the analysis advanced by Plaintiffs. S&N Mem. Ex. A at 2 (Aaron SFC [D.E. 456]). In short, Plaintiffs' Complaint, filed on November 27, 2017—more than two years after the Recall and more than four years after the revision—is time-barred under Louisiana's one-year statute of limitations.

[11] *See Aitcheson* SFC ¶ 12 [D.E. 518], S&N Mem. Ex. B at 128; *Colon* SFC ¶ 11 [D.E. 630], S&N Mem. Ex. B at 133); *Cotten* SFC ¶ 11 [D.E. 233], S&N Mem. Ex. B at 137; *DeJohn* SFC ¶ [D.E. 522], S&N Mem. Ex. B at B-142;

knowledge" allegedly lacking in the "scientific and medical communities" to prevent Plaintiffs from determining the cause of their injuries. *Id*.

Tennessee. Tennessee's statute of limitations is triggered when a plaintiff has knowledge of his or her injury. S&N Mem. 9; *see* Tenn. Code Ann. § 28-3-104(b)(1) ("[I]n products liability cases, (1) The cause of action for injury to the person shall accrue on the date of the personal injury"); *see also Potts*, 796 S.W.2d at 680-81 ("[T]he cause of action accrues and the statute of limitations begins to run when the injury occurs or is discovered, or when in the exercise of reasonable care and diligence, it should have been discovered"). Plaintiffs respond that the statute of limitations is tolled until a Plaintiff has "reasonable knowledge of the injury, its cause and origin," and "the pivotal issue is whether [plaintiff] would have discovered the [defendant's] allegedly wrongful acts had he exercised reasonable care and diligence." Opp. 17-18. Even accepting Plaintiffs' position as to Tennessee law, the sole Complaint involving Tennessee law at issue here is untimely even under Plaintiffs' arguments. Plaintiff Chad Stafford filed suit on March 9, 2018, [D.E. 566], S&N Mem. Ex. B at 178, more than 5 years after his revision surgery in 2013, *id.* at 175, ¶ 6, and almost 2.5 years after the September 2015 FDA Recall announcement that Plaintiffs insist triggers Tennessee's one-year statute of limitations. *See* MACC ¶ 268 ("Plaintiffs' statute of limitation would have begun to run from the recall date in September 2015, or the date of his revision surgery, whichever is later"); *see also* Opp. 9. Plaintiff Stafford's Complaint is untimely and should be dismissed.

Durdon SFC ¶ 12 [D.E. 246], S&N Mem. Ex. B at 147; *Leung* SFC ¶ 12 [D.E. 1 in No. 17-2508], S&N Mem. Ex. B at 151); *McCormick* SFC ¶ 12 [D.E. 341], S&N Mem. Ex. B at 159); *Palmquist* SFC ¶ 12 [D.E. 158], S&N Mem. Ex. B at 163; *Parrish* SFC ¶ 12 [D.E. 292], S&N Mem. Ex. B at 169).

II. PLAINTIFFS HAVE NOT ALLEGED FACTS TO TOLL OR EXTEND THE LIMITATIONS PERIOD.

A. Plaintiffs' Have Not Adequately Alleged Fraudulent Concealment.

Plaintiffs seek to avoid dismissal by arguing that S&N's "conduct supports tolling the statute of limitations." Opp. 10-11 (citing MACC ¶¶ 265-271). Plaintiffs cannot toll the limitations period applicable to their claims because they have not adequately alleged facts that would support fraudulent concealment or estoppel under various states' laws. *See* Ex. E hereto (addressing requirements for fraudulent concealment and estoppel); *Douglass*, 632 F. Supp. 2d at 493 (dismissing claim as untimely where plaintiff failed to allege facts necessary to trigger tolling provision for fraudulent concealment); *see also Grant v. Shapiro & Burson, LLP*, 871 F. Supp. 2d 462, 470 (D. Md. 2012) (ruling that equitable tolling and fraudulent concealment inadequately pleaded); *Epstein v. C.R. Bard, Inc*., 460 F.3d 183, 189 (1st Cir. 2006) (fraudulent concealment must be pled pursuant to Rule 9(b)).[12]

First, none of the Short Form Complaints at issue in S&N's Motion says anything about fraudulent concealment or equitable tolling of the statute of limitations. Nor do the Short Form Complaints identify what information was allegedly concealed that prevented Plaintiffs from filing their lawsuits after their revision surgeries.

Second, although the MACC does purport to address fraudulent concealment, its allegations cannot support tolling of the statute of limitations. Opp. 11 (citing MACC ¶¶ 265-71). Specifically, paragraphs 265 and 266 allege that S&N "fraudulently concealed" and "withheld from consumers the fact that it no longer enjoyed PMA protection." MACC ¶¶ 265-66. Those allegations are inadequate because "[i]n the context of an adversarial communication,

[12] Even if Plaintiffs had adequately alleged fraudulent concealment, the three Idaho complaints subject to S&N's motion would be untimely even under Plaintiffs' theory, as they were filed more than one year after FDA's September 2015 announcement. *See* Ex. E hereto at 2 n.2.

such vague assurances that the defendant is not to blame for the plaintiff's injuries are insufficient to allege or constitute the kind of fraud necessary to toll the statute of limitations on the basis of fraudulent concealment." *Douglass*, 632 F. Supp. 2d at 492. Moreover, this Court has expressly rejected the legal premise underlying these allegations: That S&N could not invoke preemption of state law claims based upon FDA's approval of the BHR.

Specifically, in its March 26, 2018 Order, this Court first noted that "[t]he FDA may withdraw approval from a device if it determines, based on existing or new information, that 'such device is unsafe or ineffective under the conditions prescribed, recommended, or suggested in the labeling thereof.'" March 2018 Mem. 5 (quoting 21 U.S.C. § 360e(e)(1)(A)-(B)). The Court explained that this statutory authority was "critical" because it refuted Plaintiffs' argument that S&N "did not have legal protection under the FDA's premarket approval because of their alleged violations of the conditions of that approval" and that S&N committed fraud when it "did not inform the medical community or patients about its lost legal protection." *Id.* at 5 n.5. Contrary to these allegations, the Court held that "[o]nly the FDA has the authority to withdraw approval from a device, *and it did not do so here*." *Id*. (emphasis added).

In addition, in paragraph 269, the MACC alleges that S&N "fraudulently concealed from and/or failed to disclose to Plaintiffs, Plaintiffs' healthcare providers, and the medical community that its BHR resurfacing products were defective, unsafe, and unfit for the purposes intended, and that they were not of merchantable quality." MACC ¶ 269. These allegations of fraudulent concealment likewise cannot toll the statute of limitations because they are premised on characterizations of the BHR that are foreclosed by FDA's PMA approval. Specifically, PMA approval by FDA forecloses any claim under state law that the BHR suffers from a design "defect." *Williams* v. *Smith & Nephew, Inc.*, 123 F. Supp. 3d 733, 742 (D. Md. 2015).

Similarly, this Court has foreclosed any claim of manufacturing defect. *See* March 2018 Mem. 28 ("[P]laintiffs' manufacturing defect claim does not survive the motion to dismiss."). Likewise, PMA approval by FDA forecloses any claim that the BHR was "unsafe." *Id.* at 18. Indeed, "[a] manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. *That is exactly what FDA approval means*." *Id.* (emphasis added)). Finally, PMA approval by FDA forecloses any claim that the BHR was unfit for the purposes intended or not of merchantable quality. *See Williams*, 123 F. Supp. 3d at 742 ("'To the extent that the [plaintiffs] allege the breach of the implied warranties of merchantability or fitness for a particular purpose, their claims are expressly preempted'") (quoting *McCormick v. Medtronic, Inc.*, 101 A.3d 467, 491 (Md. Ct. Spec. App. 2014)); March 2018 Mem. 14 n.9 (explaining that this Court's analysis preempts "any other cause of action that might require proof that the BHR device was unreasonably dangerous").[13]

B. Plaintiffs' Arguments About Plaintiff Cannan Confirm That Dismissal Is Warranted.

Plaintiffs argue that S&N's Motion is premature because "discovery will likely demonstrate how other plaintiffs' experiences were similar to Ms. [Eleanor] Cannan's." Opp. 4. Contrary to their arguments, *id.* at 4-5, Plaintiff Cannan's experience supports dismissal.

In her Short Form Complaint, Ms. Cannan makes no allegations of fraudulent concealment. Instead, she alleges that she underwent a BHR implant in her right hip on November 11, 2008 in Tucson, Arizona. *See* SFC ¶¶ 8-9 [D.E. 265], S&N Mem. Ex. B at 185.

[13] Plaintiffs argue that S&N has "engaged in an extensive campaign to mislead plaintiffs, the public, and the medical community about the relative safety of the BHR to other devices." Opp. 11. Allegations regarding statements of "relative safety" of the BHR in no way support the conclusion that S&N concealed any cause of action or the basis of any asserted claims from Plaintiffs. *Douglass*, 632 F. Supp. 2d at 491 (requiring "specific allegations of how the fraud kept the plaintiff in ignorance of a cause of action"). To the contrary, Plaintiffs rely on allegations regarding S&N statements concerning "relative safety" not as concealment, but as the affirmative basis for claims that they have brought here. *See* March 2018 Mem. 18-19.

Like other Plaintiffs, Ms. Cannan alleges that revision of her BHR was "medically necessary" because she had experienced "metallosis due to loosening, pseudotumor, and elevated levels of cobalt and chromium." *Id.* ¶ 12 (B-186). On November 3, 2014, to address these injuries, Plaintiff Cannan underwent a "revision surgery" to remove the BHR. *Id.* ¶ 10. As Plaintiffs acknowledge, Opp., Ex. D [D.E. 853-4] at 1, under Arizona law, a plaintiff's claims accrue when the plaintiff "know[s] that the product was in some way causally connected to [her] injuries." *Murrell v. Wyeth, Inc.*, No. 13-cv-0290, 2013 WL 1882193, at *3 (D. Ariz. May 3, 2013) (cited in S&N Mem. 10). Plaintiff filed suit on September 8, 2017, nearly three years after her revision surgery, and outside of Arizona's two-year statute of limitations. Ms. Cannan's claims are untimely on the face of her Complaint.

To divert attention from these dispositive allegations, Plaintiffs' counsel attach (i) a string of emails from December 2014 to December 2015 in which Ms. Cannan seeks recovery from S&N relating to the removal of her BHR implant, *see* Ex. B to Opp. [D.E. 853-2], and (ii) a December 3, 2015 letter from S&N explaining that it "cannot agree to a settlement to resolve [her] claim," Ex. A to Opp [D.E. 853-1]. The December 3, 2015 Letter informs Ms. Cannan that (i) the BHR received pre-market approval from FDA, (ii) "the United States Supreme Court has held that claims regarding medical devices approved by FDA through this pre-market approval process are preempted," and (iii) if Plaintiff filed suit, S&N would "seek to have it dismissed on the basis of federal pre-emption." *Id.* Plaintiffs omit that the December 3, 2015 letter recommended that if Ms. Cannan had further questions about federal preemption, then she should "speak with [her] legal advisor." *Id.* The correspondence confirms what is alleged in her Short Form Complaint: No later than her revision surgery, Ms. Cannan was aware "that the [BHR] was in some way causally connected to [her] injuries." *Murrell*, 2013 WL 1882193, at

*3.[14] Indeed, her correspondence with S&N confirmed that she understood the BHR was the cause of her alleged injury. That S&N declined her request for payment does not alter Plaintiffs' knowledge of her injury or toll the running of the statute of limitations.

III. THE BREACH OF WARRANTY CLAIMS SHOULD BE DISMISSED.

S&N has shown that Plaintiffs' breach of warranty claims in the Complaints identified in S&N's motion are time-barred. S&N Mem. 13–14.[15] Plaintiffs' only response is that some—but not all—of the states at issue apply the same tolling doctrines to breach of warranty claims that they apply to the rest of Plaintiffs' claims. Opp. 19. Plaintiffs thus do not dispute that these claims are untimely absent the application of tolling.[16]

For the reasons explained above, those doctrines do not extend the statute of limitations beyond the revision date. Specifically, this Court has rejected Plaintiffs' fraudulent concealment allegations based on S&N's alleged statements about preemption, safety, and merchantability. And the only other basis for tolling Plaintiffs posit in their opposition brief—statements about relative safety—has no bearing on whether Plaintiffs should have known of their injury or its factual cause. The limitations period for Plaintiffs' breach of warranty claims is not tolled, and thus these claims are untimely.

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[14] Plaintiffs argue that S&N's December 2015 letter is "shocking" because it states that "Smith & Nephew does not accept that the BHR system is defective," Opp. 1, but this Court has dismissed Plaintiffs' claims of manufacturing defect and any claim that the BHR was "unreasonably dangerous." March 2018 Mem. 14-15 & n.9; *id.* at 18 (explaining that premarket approval by FDA means that the device "is safe").

[15] S&N does not at this stage challenge the timeliness of the breach of warranty claims of certain plaintiffs. S&N Mem. 13-14. Contrary to Plaintiffs' characterization, however, S&N does not "concede" that these claims "are properly alleged to fall within the applicable statutes of limitations." Opp. 19. Rather, S&N omitted these claims from its Motion to simplify the task before the Court because the state laws at issue "*arguably* apply a four-year" limitations period to warranty claims, noting that S&N "does not *now* contend" that those claims are time-barred on the face of the complaints. S&N Mem. 13-14 (emphases added).

[16] Plaintiffs also do not dispute that the state laws at issue (other than Alabama, New York, Pennsylvania, and Tennessee) apply the same limitations period to all personal injury claims including breach of warranty.

Finally, Plaintiffs contend that S&N has not shown that the states at issue do not apply their tolling doctrines to breach of warranty claims. *Id*. But the party seeking to gain the benefit of tolling has the burden to show that tolling applies. *See, e.g*., *Redwing v. Catholic Bishop for Diocese of Memphis*, 363 S.W.3d 436, 460–63 (Tenn. 2012) ("The party invoking the doctrine of equitable estoppel has the burden of proof."); *Weaver v. Firestone*, 155 So. 3d 952, 957 (Ala. 2013) ("'[A] litigant seeking equitable tolling bears the burden of establishing two elements: (1) that he has been pursuing his rights diligently, and (2) that some extraordinary circumstance stood in his way' as to the filing of his action."). In all events, this Court's rulings and Plaintiffs' own allegations confirm that there is no basis for tolling the statute of limitations for Plaintiffs' breach of warranty claims.

CONCLUSION

For these reasons, and those set forth in S&N's Memorandum, S&N's Motion to Dismiss should be granted.

Dated: August 21, 2018

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I, Sara J. Gourley, hereby certify that on this 21st day of August, 2018, I electronically filed the foregoing with the Court using the CM/ECF system, and thereby delivered the foregoing by electronic means to all counsel of record.

/s/ Sara J. Gourley
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