

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

HELEN McLAUGHLIN	:	CIVIL ACTION NO. 14-7315	
	:		
v.	:		
	:	NO. 14-7316 (Ruble)	NO. 16-3732 (Gross)
BAYER ESSURE, INC., et al.	:	NO. 14-7318 (Stelzer)	NO. 16-3733 (Johnson)
	:	NO. 14-7317 (Strimel)	NO. 16-3766 (Summerlin)
And Related Actions	:	NO. 15-0384 (Walsh)	NO. 16-3767 (Rodvill)
	:	NO. 16-1458 (Dunstan)	NO. 16-3769 (Bennett)
	:	NO. 16-1645 (Clarke)	NO. 16-4081 (Quinton)
	:	NO. 16-1921 (Souto)	NO. 17-2915 (Wistrom)
	:	NO. 16-2166 (Bailey)	NO. 17-3968 (Bobo)
	:	NO. 16-2154 (Campos)	NO. 17-4417 (Guess)
	:	NO. 16-2717 (Bolds)	NO. 17-4936 (Gonzalez)
	:	NO. 16-3049 (Tulgetske)	NO. 18-37 (Jenson)
	:	NO. 16-3409 (Abeyta)	NO. 18-836 (Morua)
	:	NO. 16-3589 (Burgis)	NO. 18-837 (Galan)
	:	NO. 16-3710 (Dong)	NO. 18-838 (Alfaro)
	:	NO. 16-3730 (Mantor)	NO. 18-908 (Archer)
	:	NO. 16-3731 (Olague)	

**MEMORANDUM**

**Padova, J.**

**April 2, 2020**

Each female Plaintiff in these consolidated actions seeks compensation for injuries she sustained in connection with her purchase and use of Essure, a birth control device that was manufactured, sold, and marketed by Defendants Bayer Essure, Inc. and other related Bayer entities (collectively, “Bayer”). Presently before the Court are Plaintiffs’ and Bayer’s Objections to the October 21, 2019 Amended Report and Recommendation of the Special Discovery Master, which makes recommendations concerning the timeliness of the claims of fifty individual plaintiffs. For the following reasons, we sustain in part and overrule in part both Bayer’s Objections and Plaintiffs’ Objections.

**I. PROCEDURAL BACKGROUND**

On March 27, 2019, we issued a summary judgment opinion that addressed Bayer’s arguments that the tort and warranty claims of twelve exemplar plaintiffs were barred on statute

of limitations grounds. McLaughlin v. Bayer Essure, Inc., Civ. A. No. 14-7315, 2019 WL 1382710 (E.D. Pa. March 27, 2019). That opinion set forth a factual and legal framework for resolving timeliness challenges to the claims of the other plaintiffs in these consolidated actions, and the parties agreed to use that framework as guidance in negotiating the resolution of statute of limitations issues with respect to the other plaintiffs. The parties, however, were unable to agree as to the timeliness of numerous plaintiffs' claims and, in consultation with our Special Discovery Master, David Sonenshein, Esq., Bayer filed a Motion for an Order to Show Cause as to why the claims of fifty additional plaintiffs should not be dismissed on statute of limitations grounds. On June 25, 2019, we granted that Motion and ordered Plaintiffs to show cause as to why the claims of those fifty plaintiffs should not be dismissed as untimely.

Thereafter, the parties briefed the timeliness issues with respect to the fifty plaintiffs, and the issues were submitted to the Special Master for a Report and Recommendation. After the Special Master issued his Report and Recommendation on September 12, 2019, Bayer filed a Motion for Reconsideration and Plaintiffs filed Objections. The Special Master issued an Amended Report and Recommendation on October 21, 2019. Both Plaintiffs and Bayer have now filed Objections to the Amended Report and Recommendation. We review *de novo* all objections to findings of fact and conclusions of law made or recommended by a special master. See Fed. R. Civ. P. 53(f)(3)-(4).

## **II. LEGAL STANDARDS**

### **A. Summary Judgment Standard**

Summary judgment is appropriate “if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). An issue is “genuine” when “the evidence is such that a reasonable jury could return a

verdict for the nonmoving party.” Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A factual dispute is “material” if it “might affect the outcome of the suit under the governing law.” Id. In ruling on a summary judgment motion, we consider “the facts and draw all reasonable inferences in the light most favorable to . . . the party who oppose[s] summary judgment.” Lamont v. New Jersey, 637 F.3d 177, 179 n.1 (3d Cir. 2011) (citing Scott v. Harris, 550 U.S. 372, 378 (2007)). If a reasonable fact finder could find in the nonmovant’s favor, summary judgment may not be granted. Congregation Kol Ami v. Abington Twp., 309 F.3d 120, 130 (3d Cir. 2002) (citation omitted).

“[A] party seeking summary judgment always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact.” Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). Where the nonmoving party bears the burden of proof on a particular issue at trial, the movant’s initial Celotex burden can be met simply by “pointing out to the district court . . . that there is an absence of evidence to support the nonmoving party’s case.” Id. at 325. After the moving party has met its initial burden, the adverse party’s response “must support the assertion [that a fact is genuinely disputed] by: (A) citing to particular parts of materials in the record . . . ; or (B) showing that the materials [that the moving party has cited] do not establish the absence . . . of a genuine dispute.” Fed. R. Civ. P. 56(c)(1). Summary judgment is appropriate if the nonmoving party fails to respond with a factual showing “sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial.” Celotex, 477 U.S. at 322. “While the evidence that the non-moving party presents may be either direct or circumstantial, and need not be as great as a preponderance, the evidence must be more than a scintilla.” Galli v. New Jersey Meadowlands Comm’n, 490 F.3d 265, 270 (3d Cir.

2007) (quoting Hugh v. Butler Cty. Family YMCA, 418 F.3d 265, 267 (3d Cir. 2005)).

## **B. Statute of Limitations**

The Pennsylvania statute of limitations for actions grounded on negligence and/or fraud is two years. 42 Pa. Cons. Stat. §§ 5524(2), 5524(7). The statute of limitations for warranty claims is four years. 13 Pa. Cons. Stat. § 2725. Under Pennsylvania law, the statute of limitations begins to run on the date that “the cause of action accrued.” 42 Pa. Cons. Stat. § 5502(a). A tort cause of action generally accrues when an injury is inflicted. Fine v. Checcio, 870 A.2d 850, 857 (Pa. 2005). A warranty claim generally accrues “on the date that the seller tenders delivery of the goods.” Hartey v. Ethicon, Civ. A. No. 04-5111, 2006 WL 724554, at \*5 (E.D. Pa. Mar. 20, 2006) (quotation omitted); 13 Pa. Cons. Stat. § 2725(b). “Once a cause of action has accrued and the prescribed statutory period has run, an injured party is barred from bringing his cause of action.” Nicolaou v. Martin, 195 A.3d 880, 892 (Pa. 2018) (quoting Fine, 870 A.2d at 857). The defendant bears the initial burden of proof to establish that the statute limitations has run. Billeci v. Merck & Co., Civ. A. No. 17-486, 2018 WL 1635242, at \*4 (E.D. Pa. Apr. 5, 2018) (citing Cochran v. GAF Corp., 666 A.2d 245, 249 (Pa. 1995)) (additional citation omitted).

The discovery rule is an exception to the statute of limitations for tort claims that will toll the statute of limitations “[i]n certain cases involving latent injury, and/or instances in which the causal connection between an injury and another’s conduct is not apparent.” Wilson v. El-Daief, M.D., 964 A.2d 354, 361 (Pa. 2009) (citing Fine, 870 A.2d at 859); In re Risperdal Litig., No. 22 EAP 2018, 2019 WL 61391989, at \*5 (Pa. Nov. 20, 2019) (citing Wilson, 964 A.2d at 361). Where the court concludes that the “injury or its cause was neither known nor reasonably knowable,” Fine, 870 A.2d at 858, the discovery rule tolls the statute until “the plaintiff knows, or reasonably should know: (1) that he has been injured, and (2) that his injury has been caused by another party’s

conduct.” Cathcart v. Keene Indus. Insulation, 471 A.2d 493, 500 (Pa. Super. Ct. 1984) (footnote omitted), abrogated on other grounds by Daley v. A.W. Chesterton, Inc., 37 A.3d 1175 (Pa. 2012). Thus, the tolled statute recommences when the plaintiff has ““actual or constructive knowledge of at least some form of significant harm and of a factual cause linked to another’s conduct, without the necessity of notice of the full extent of the injury, the fact of actual negligence, or precise cause.”” Gleason v. Borough of Moosic, 15 A.3d 479, 484 (Pa. 2011) (quoting Wilson, 964 A.2d at 364); Zeleznik v. United States, 770 F.2d 20, 23 (3d Cir. 1985) (stating that the limitations period is “not postponed until the injured party knows every fact necessary to bring his action”). This is sometimes called “inquiry notice.” Gleason, 15 A.3d at 484; Nicolaou, 195 A.3d at 892. The knowledge necessary to start the limitations clock is also described as an “unrebutted suspicion” of an injury “which is . . . caused by another.” Debiec v. Cabot Corp., 352 F.3d 117, 132 (3d Cir. 2003). “Pennsylvania’s formulation of the discovery rule is a more narrow approach than is mandated in some other jurisdictions, as it places a greater burden on plaintiffs.” In re Risperdal Litig., 2019 WL 6139189, at \*5 (citing Nicolaou, 195 A.3d at 893).

In the context of this case, a plaintiff will be on inquiry notice with respect to her tort claims when she knew or reasonably should have known that she was injured by Essure. See McLaughlin, 2019 WL 1382710, at \*9. A plaintiff will be on inquiry notice with respect to a warranty claim when she knew or reasonably should have known that the warranty was breached and that she suffered an injury as a result of the breach. Id.

In determining what a plaintiff reasonably should have known, Pennsylvania applies a standard of reasonable diligence. In re Risperdal, 2019 WL 6139189, at \*5. “The requirement of reasonable diligence is not an absolute standard but, rather, is ‘what is expected from a party who has been given reason to inform [herself] of the facts upon which [her] right of recovery is

premised.” Id. (quoting Wilson, 964 A.2d at 366). “In determining whether reasonable diligence has been exercised, a court must determine whether the plaintiff exhibited ‘those qualities of attention, knowledge, intelligence and judgment which society requires of its members for the protection of their own interests and the interests of others.’” Id. (quoting Fine, 870 A.2d at 858.).

The injured party need not have obtained a precise medical diagnosis or “understand that she has a cause of action” in order to be on inquiry notice of her injury and its cause. Wilson, 964 A.2d at 364 n.10, 365. At the same time, “a lay person is only charged with the knowledge communicated to him or her by the medical professionals who provided treatment and diagnosis.” Nicolaou, 195 A.3d at 893 (citing Wilson, 964 A.2d at 365); see also Bohus v. Beloff, 950 F.2d 919, 929 (3d Cir. 1991) (“[L]ay persons should not be charged with greater knowledge of their physical condition than that possessed by the physician on whose advice they must rely.” (citations omitted)). Indeed, the Pennsylvania Supreme Court has “expressly declined to hold, as a matter of law, that a layperson may be charged with knowledge greater than that which was communicated to her by the medical professionals who provided treatment and diagnosis.” In re Risperdal Litig., 2019 WL 6139189, at \*5 (citing Wilson, 964 A.2d at 365). While there is “some point in time when a patient’s own ‘common sense’ should lead her to conclude that it is no longer reasonable to rely on the assurances of her doctor,” we must nevertheless be “mindful that ‘[t]o put upon [a patient] the duty of knowing the nature of her ailment and its relation to her prior treatment before it is ascertained with a degree of certainty by the medical profession is a great burden to impose upon her.’” Bohus, 950 F.2d at 930 (first quoting DeMartino v. Albert Einstein Med. Ctr., No. Div., 460 A.2d 295, 302 (Pa. Super. Ct. 1983), then quoting Stauffer v. Ebersole, 560 A.2d 816, 818 (Pa. Super. Ct. 1989)).

“Plaintiffs seeking the benefit of the discovery rule bear the burden of establishing its applicability.” Vitalo v. Cabot Corp., 399 F.3d 536, 543 (3d Cir. 2005) (citing Dalrymple v. Brown, 701 A.2d 164, 167 (Pa. 1997); Cochran, 666 A.2d at 250). Thus, “[a] plaintiff invoking the discovery rule bears the burden of proving her inability to know sufficient facts” that would “put [her] on notice that a wrong has been committed and that [she] need investigate to determine whether [she] is entitled to redress.” Wawrzynek v. Statprobe, Inc., Civ. A. No. 05-1342, 2007 WL 3146792, at \*6, \*5 (E.D. Pa. Oct. 25, 2007) (citing Dalrymple, 701 A.2d at 167, and quoting Cooney v. Booth, 210 F. App’x 213, 218 (3d Cir. 2007)); Wilson, 964 A.2d at 362 (“The party relying on the discovery rule bears the burden of proof” (citing Cochran, 666 A.2d at 249)).

“[T]he determination concerning the plaintiff’s awareness of the injury and its cause is fact intensive, and therefore ordinarily is a question for a jury to decide.” Wilson, 964 A.2d at 362 (citation omitted); see also Bohus, 950 F.2d at 925 (“The question whether a plaintiff has exercised reasonable diligence is usually a jury question.” (citation omitted)). “However, courts may resolve the matter at the summary judgment stage where reasonable minds could not differ on the subject.” Wilson, 964 A.2d at 362 (citations omitted).

### **III. DISCUSSION**

#### **A. Bayer’s Objections**

Bayer objects to the Special Master’s recommendations, arguing that the Special Master erred in recommending that (1) we not apply the sham affidavit rule to disregard affidavits submitted by four plaintiffs (K.B., C.H., S.H., J.D.A.) and that we therefore permit those plaintiffs’ tort claims to proceed; (2) we apply separate limitations periods for pregnancy and non-pregnancy-related tort injuries with respect to eight plaintiffs (D.M., L.B., L.C., S.G., R.C., M.B., J.H., and J.D.S.), and decline to find the non-pregnancy-related tort claims to be time-barred; (3) we not

dismiss the tort claims of three plaintiffs (A.N., J.D.S., J.H.) because there are genuine disputes of material fact as to whether they had actual knowledge or medical confirmation that their injuries were caused by Essure; and (4) we decline to find Plaintiff C.P.’s claims to be time-barred in spite of her expulsion of one Essure coil long before she filed suit. Notably, Bayer’s objections pertain exclusively to the Special Master’s recommendations regarding the specified plaintiffs’ tort claims; Bayer does not contest any of the recommendations regarding plaintiffs’ warranty claims.

### 1. Application of the Sham Affidavit Rule

In Plaintiffs’ response to our June 25, 2019 Show Cause Order, numerous Plaintiffs submitted Declarations that Bayer argues we should disregard pursuant to the sham affidavit rule. The Special Master, however, recommends that the sham affidavit rule is:

inapplicable to the Declarations here as the affiants were never deposed (a generally accepted requirement to apply the sham affidavit rule for the very good reason[] that in depositions, the deponent is carefully questioned under oath with ready access to relevant independent evidence at the time), the Declarations generally clarify PFS answers, rather than contradicting the PFS, . . . [and] a reasonable juror could choose to believe the testimony of any witness despite being impeached with a prior inconsistent statement.

(Amended R&R at 3.) Bayer objects to this recommendation, arguing that, under Third Circuit precedent, the sham affidavit rule applies not only to declarations that contradict previous deposition testimony, but also to declarations that contradict Plaintiff Fact Sheet (“PFS”) responses, which are the equivalent of interrogatory responses.<sup>1</sup> It further notes that that a plaintiff has greater ability to carefully consider and shape her answers to written discovery, such as

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<sup>1</sup> There is no dispute in this case that the PFS answers are the equivalent of interrogatory responses and, thus, we treat the PFS answers as interrogatory responses for purposes of the sham affidavit rule. (See 2/15/18 Ord. ¶ 1.b, ECF No. 207, McLaughlin v. Bayer Essure, Inc., Civ. A. No. 14-7315 (stating that “completed PFS[s] shall be considered responses to interrogatories pursuant to Rule 33 of the Federal Rules of Civil Procedure . . . and shall be governed by the standards applicable to written discovery under [the Rules]”).)

interrogatories and PFSs, than she has to consider and shape her answers to deposition questions, thereby undermining any rationale for treating depositions differently than interrogatory responses and PFSs.

In Jiminez v. All American Rathskeller, Inc., 503 F.3d 247 (3d Cir. 2007), the United States Court of Appeals for the Third Circuit articulated the sham affidavit doctrine as providing that “a party may not create a material issue of fact to defeat summary judgment by filing an affidavit disputing his or her own sworn testimony without demonstrating a plausible explanation for the conflict.” Id. at 251 (quoting Baer v. Chase, 392 F.3d 609, 624 (3d Cir. 2004)). In discussing the scope of the doctrine, the Third Circuit quoted with approval a case from the United States Court of Appeals for the Second Circuit, which observed that “[i]f a party who has been examined at length on deposition could raise an issue of fact simply by submitting an affidavit contradicting his own prior testimony, this would greatly diminish the utility of summary judgment as a procedure for screening out sham issues of fact.” Id. at 252 (alteration in original) (quoting Perma Research & Dev. Co. v. Singer Co., 410 F.2d 572, 577-78 (2d Cir. 1969)). The Third Circuit went to explain that, in the context of the established Rule 56 summary judgment standard, “[a] sham affidavit cannot raise a genuine issue of fact because it is merely a variance from earlier deposition testimony, and therefore no reasonable jury could rely on it to find for the nonmovant.” Id. at 253 (citing Anderson v. Liberty Lobby, 477 U.S. 242, 252 (1986)). The court further explained that “[t]he main practical reason supporting the sham affidavit doctrine is that prior depositions are more reliable than affidavits.” Id.

The Third Circuit observed that “[s]ome federal courts have adopted a particularly robust version of the sham affidavit doctrine, holding that, whenever a subsequent affidavit contradicts prior deposition testimony, it should be disregarded.” Id. at 254 (citations omitted). It emphasized,

however, that it had adopted “a more flexible approach” that recognizes that “not all contradictory affidavits are necessarily shams.” Id. (citations omitted). It therefore encouraged courts to consider whether “there is independent evidence in the record to bolster an otherwise questionable affidavit,” observing that such “evidence may establish that the affiant was ‘understandably’ mistaken, confused, or not in possession of all the facts during the previous deposition.” Id. (citing Baer v. Chase, 392 F.3d 609, 625 (3d Cir. 2004)). Thus, an affiant should be given the “opportunity to offer a ‘satisfactory explanation’ for the conflict between the prior deposition and the affidavit.” Id. (quoting Hackman v. Valley Fair, 932 F.2d 239, 241 (3d Cir. 1991)). It is only appropriate to disregard the subsequent affidavit and to label the factual issue a sham if the party does not “explain the contradiction between the subsequent affidavit and a prior deposition.” Id. (citing Hackman, 932 F.2d at 241).

In spite of the Third Circuit’s clear focus in Jiminez on inconsistencies between deposition testimony and subsequent affidavits, Bayer argues that the sham affidavit rule is equally applicable in situations in which there are inconsistencies between interrogatory responses and subsequent affidavits. In support of that argument, Bayer cites two Third Circuit opinions. In the first, Martin v. Merrell Dow Pharmaceuticals, Inc., 851 F.2d 703 (3d Cir. 1988), the Third Circuit considered whether a plaintiff’s affidavit that contradicted both prior deposition testimony and prior sworn interrogatory answers could be disregarded. Id. at 704-06. In concluding that it “was permissible for the district court to disregard the affidavit for purposes of determining whether there was a material dispute of fact,” the court noted that the affidavit was contradicted by “no less than eight . . . prior sworn statements” (at least five of which were made at the affiant’s deposition), and that the plaintiff offered no explanation for the contradiction. Id. at 705-06. The Third Circuit ultimately concluded that “[w]hen . . . the affiant was carefully questioned on the issue, had access

to the relevant information at the time, and provided no satisfactory explanation for the later contradiction, . . . the subsequent affidavit does not create a [genuine] issue of material fact.” Id. at 706. Thus, while Bayer relies on Martin to support its assertion that the sham affidavit rule can apply when an affidavit contradicts only prior interrogatory answers, Martin provides only negligible support for that proposition as the affidavit at issue in that case also contradicted prior deposition testimony.

The second Third Circuit case on which Bayer relies is Zavala v. Wal Mart Stores, Inc., 691 F.3d 527 (3d Cir. 2012). In that case, one of the plaintiffs alleged that his manager had falsely imprisoned him when the manager refused to allow him leave work on account of a toothache. Id. at 545. In a third supplemental declaration that the plaintiff submitted after the defendant had moved for summary judgment, the plaintiff mentioned for the first time that he thought that “his manager might randomly assault him” if he left work after being instructed to stay. Id. at 547. Citing the sham affidavit rule, the Third Circuit observed that it “need not credit a declaration contradicting a witness’ prior sworn statements” and stated that the plaintiff’s omission “of such a crucial fact” was “highly questionable,” if not “precisely contradictory.” Id. (citing Martin, 851 F.2d at 705; Jiminez, 503 F.3d at 251-54. The court concluded, however, that “even absent these suspicious circumstances, . . . no reasonable jury could credit [plaintiff’s] speculative statement that his manager would assault him [if he] had . . . tried to leave” because plaintiff offered no evidence to support that statement and did not allege that his manager either had a propensity for violence or “overtly or impliedly threatened him.” Id. Thus, while Zavala suggests that the sham affidavit rule might be applicable to declarations that contradict prior declarations, its suggestion in that regard is dicta, because the court ultimately considered the third declaration and concluded that it was simply not credible.

Based on these Third Circuit precedents, we cannot conclude that the sham affidavit rule is strictly limited to circumstances in which an affidavit or declaration contradicts prior deposition testimony and never applies to circumstances in which the affidavit or declaration contradicts a prior interrogatory answer. Nevertheless, we will only apply the rule to exclude a declaration that directly and unambiguously contradicts a prior interrogatory answer, and only when other evidence in the record undermines and/or fails to lend credibility to the declaration. With these guidelines, we consider the four plaintiffs that Bayer identifies as having benefitted from the Special Master's slightly more restrictive interpretation of the sham affidavit rule.

a. K.B.

Bayer argues that the Special Master erred in failing to recommend that we disregard Plaintiff K.B.'s Declaration, which states that she underwent a hysterectomy as treatment for endometriosis, when, in Bayer's view, her PFS had established that she had a hysterectomy to remove her Essure coils, which she and her doctor agreed were injuring her. Bayer points to a section of the PFS that inquired about communications that K.B. had with her healthcare provider concerning removal of her Essure device. In response to that question, K.B. wrote: "Plaintiff discussed removal with [Doctor] in approximately 02/2012. Plaintiff explained her belief that her injuries were caused by Essure and her desire for removal, and [Doctor] agreed. He performed a partial hysterectomy on 05/24/2013." (Defs.' Objs. to Amended R&R ("Defs.' Objs."), ECF No. 521, McLaughlin v. Bayer Essure Inc., Civ. A. No. 14-7315, Ex. A ¶ IV.1 (emphasis added).) In her subsequent Declaration, K.B. wrote that her doctor "told [her] that [she] had to have a hysterectomy B/c of . . . Endometriosis" and that she "did not choose to have [the Essure inserts] out." (Defs.' Objs., Ex. B ¶¶ 11-12.)

Bayer maintains that the PFS and Declaration are irreconcilable because the PFS states that K.B.'s doctor agreed that removal was required to address Essure-related injuries and the Declaration says otherwise. Bayer essentially argues that the Special Master erred in failing to (1) disregard K.B.'s Declaration, (2) conclude based on her PFS that her doctor removed Essure to address Essure-related injuries, and (3) dismiss K.B.'s 2018 tort claims as untimely. However, on de novo review, we reach the same conclusion as the Special Master did, that is, that "it is unclear [from the PFS] if the doctor 'agreed' [with] Plaintiff's lay opinion that Essure was the cause of her problems or 'agreed' to perform the surgery." (Amended R&R at 9.) Moreover, we note that K.B. states elsewhere in her PFS that no doctor ever told her that any of her injuries were Essure-related. (Defs.' Objs., Ex. A ¶ V.4.) Under these circumstances, a factfinder could reasonably interpret her statement regarding her doctor's agreement to mean that her doctor agreed only to her request for removal, not that Essure caused her injuries. Moreover, by acknowledging this reasonable interpretation of K.B.'s PFS statements, we can reasonably view the PFS and subsequent Declaration as entirely consistent and supportive of an overall narrative that the doctor agreed to perform a surgery that would result in the removal of the Essure devices, and that K.B. wanted the surgery to remove the devices while the doctor believed surgery to be necessary to treat her endometriosis.

We therefore reject Bayer's arguments that the Special Master erred in recommending that we not apply the sham affidavit rule to bar consideration of K.B.'s Declaration and thereby erred in recommending that we not dismiss K.B.'s tort claims on statute of limitations grounds. Consequently, we overrule Bayer's objection to the Special Master's ultimate recommendation that there is a genuine dispute of material fact concerning the timeliness of K.B.'s tort claims that prevents dismissal of those claims on statute of limitations grounds at this time.

b. C.H.

Bayer argues that the Special Master erred in failing to recommend that we disregard Plaintiff C.H.'s Declaration, which states that she underwent a hysterectomy due to fibroids when, in Bayer's view, her PFS had established that she had a hysterectomy to remove her Essure coils. Bayer points to C.H.'s statement in her PFS that she suspected in December of 2006 that Essure was the cause of various symptoms that she was experiencing and that she underwent a hysterectomy in May of 2007 to have Essure removed. (Defs.' Objs., Ex. C ¶¶ IV.2.1. V.4.) In a subsequent Declaration, C.H. states that the heavy bleeding and pain that she was experiencing was due to fibroids, that she "needed a complete hysterectomy due to . . . fibroids," and that she asked her doctor if he thought that [her symptoms were] due to the Essure device [and] he said he didn't think so." (Defs.' Objs., Ex. D ¶ 2.)

Bayer argues that the Special Master erred in declining to recommend that we (1) disregard the Declaration, (2) conclude based on C.H.'s PFS statement that she had an hysterectomy to remove Essure that she knew or should have known that she was injured by Essure when she underwent her hysterectomy, and (3) dismiss C.H.'s 2017 tort claims as untimely. Upon de novo review, however, we agree with the Special Master that the sham affidavit rule should not be applied to disregard C.H.'s Declaration in this case. Most critically, Bayer takes C.H.'s statement in her PFS out of context. C.H.'s statement that "she underwent a hysterectomy to have the device removed" was in response to a series of two questions. (Defs.' Objs., Ex. C ¶ IV.2.) The first question asked if C.H. had her Essure device removed, to which C.H. answered yes. (Id.) The second queried: "If yes, please provide . . . the procedure used to remove your Essure." (Id.) With this critical context, a reasonable factfinder could certainly read C.H.'s statement in response to the second question that "[s]he underwent a hysterectomy to have the device removed" not to

convey the reason that she underwent the hysterectomy but, rather, merely to convey that the procedure by which her Essure was removed was a hysterectomy. (Id.) Under this reasonable interpretation of the record evidence, there is no apparent conflict between C.H.'s PFS statement that her Essure was removed by way of hysterectomy and her subsequent Declaration that she had a hysterectomy for the purpose of addressing fibroids. This interpretation would also be entirely consistent with: (1) C.H.'s statement in her PFS that no doctor ever told her that the symptoms that she was experiencing were Essure-related (Defs.' Objs., Ex. C ¶ V.4); and (2) C.H.'s medical records, which Bayer concedes never mention Essure in connection with her hysterectomy (see Defs.' Objs. at 7 n.3).

We therefore reject Bayer's arguments that the Special Master erred in recommending that we not apply the sham affidavit rule to bar consideration of C.H.'s Declaration and thereby erred in recommending that we not dismiss C.H.'s tort claims on statute of limitations grounds. Consequently, we overrule Bayer's objection to the Special Master's ultimate recommendation that there is a genuine dispute of material fact concerning the timeliness of C.H.'s tort claims that prevents dismissal of those claims on statute of limitations grounds at this time.

c. S.H.

Bayer argues that the Special Master erred in failing to recommend that we disregard Plaintiff S.H.'s Declaration, which, in Bayer's view, states that no doctor ever told her that cysts she had on her ovaries were Essure-related, when her PFS stated otherwise. Bayer points to S.H.'s statement in her PFS that Dr. Alonzo, her obstetrician gynecologist, told her in November of 2013, that the ovarian cysts that she was experiencing were Essure-related.<sup>2</sup> (Defs.' Objs., Ex. E ¶ V.4;

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<sup>2</sup> The PFS states, on a single line, that S.H. suspected that her ovarian cysts were Essure-related in November of 2013, and that Dr. Alonzo told her that they were Essure-related one year before, in November of 2012. It is difficult to reconcile these two dates, particularly when

*id.* ¶ III.7.) She further states in her PFS that another doctor, Dr. Andah, performed a right salpingo-oophorectomy on her on November 15, 2012, as treatment for pain and cramping, and a left salpingo-oophorectomy on December 27, 2013, as treatment for pain, cramping, and ovarian cysts, and that these surgeries resulted in the removal of her Essure devices. (*Id.* ¶ IV.2.) In her subsequent Declaration, S.H. recounts treatment that she received in 2012 and 2013 from an unnamed ER doctor and Dr. Andah (without mentioning Dr. Alonzo). (Defs.’ Objs., Ex. F ¶¶ 2-3, 11-12.) She states that, in November 2012, she had her right ovary and right fallopian tube removed because of a large ovarian cyst on her right ovary, and that, in December of 2013, she had additional surgery due to a cyst on her left ovary. (*Id.* ¶ 2.) She also states in her Declaration that, when Dr. Andah performed the right salpingo-oophorectomy in December of 2013, “the doctor . . . never told [her] that [Essure] was the cause of [her] cysts.” (Defs.’ Objs., Ex. F ¶ 11.) The symptoms of cramping and abdominal pain that S.H. had been experiencing resolved after the 2012 and 2013 surgeries. (Defs.’ Objs., Ex. E ¶ IV.4.) S.H. filed her claims in this action on September 5, 2017.

Bayer argues that S.H.’s Declaration contradicts her PFS because the PFS states that Dr. Alonzo told her that her cysts were Essure-related in November of 2012, while S.H. states in her Declaration that that “the doctor . . . never told [her] that [Essure] was the cause of her cysts.” (Defs.’ Objs., Ex. F ¶ 11.) However, a reasonable factfinder could interpret those statements as consistent with one another. Indeed, S.H.’s statement in the Declaration that Dr. Andah or the ER

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Plaintiffs argue that S.H. was not diagnosed with ovarian cysts, and did not seek treatment from Dr. Alonzo for those cysts, until November 2013. (See Pls.’ Resp. to Order to Show Cause, ECF No. 465, McLaughlin v. Bayer Essure, Inc., Civ. A. No. 14-7315, at 57 (“In approximately November 2013 Plaintiff [S.H.] was diagnosed with ovarian cysts and sought treatment from Dr. Alonzo for these injuries.”).) We therefore suspect that one date is a typographical error. However, in the absence of any explanation for the apparent discrepancy, we will simply take the dates presented at face value.

doctor (i.e., the only doctors mentioned in the Declaration and thus, under a reasonable interpretation, the only doctors to whom the phrase “the doctor” in the Declaration refers) did not tell her that the cysts were caused by Essure is not inconsistent with Dr. Alonzo separately telling her that the cysts were Essure-related a year before. We therefore reject Bayer’s argument that the PFS and Declaration are necessarily inconsistent, overrule Bayer’s objection to the Special Master’s application of the sham affidavit rule, and will not disregard S.H.’s Declaration.

Bayer also argues, however, that the Special Master erred in stating that “the PFS states that the doctor never mentioned Essure as a cause of her symptoms or reason for her surgery.” (Amended R&R at 10.) We agree that this statement appears to overlook S.H.’s admission that Dr. Alonzo told her that her cysts were Essure-related in November of 2012. Accordingly, on de novo review, we disagree with the Special Master’s recommendation that there is a genuine issue of material fact as to when S.H. knew or reasonably should have known that she had been injured by Essure. We conclude, to the contrary, that the undisputed record evidence supports only the conclusion that S.H. knew or should have known that she had been injured by Essure no later than December 2013, because the undisputed evidence reflects that Dr. Alonzo told her that her ovarian cysts were Essure-related in November 2012, and S.H. states in her Declaration that, in December of 2013, she attributed to her left Essure her symptoms that were “new or worsening” following the removal of her right Essure. (Defs.’ Objs., Ex. E ¶ V.4; Defs. Objs., Ex. F ¶ 9.) We therefore conclude that the two-year statute of limitations on S.H.’s tort claims began to run no later than December of 2013 and expired no later than December of 2015, long before she filed her Complaint against Bayer on September 5, 2017. Thus, we sustain Bayer’s objection to the Special Master’s recommendation that we not find S.H.’s tort claims to be time-barred, and instead conclude that S.H.’s tort claims, like her warranty claims, are time-barred.

d. J.D.A.

Bayer argues that the Special Master erred in failing to recommend that we disregard Plaintiff J.D.A.'s Declaration, which, in Bayer's view, states that J.D.A.'s doctors denied that her various symptoms were Essure-related, when her PFS states that she was told by doctors in both 2009 and 2012 that she was suffering from Essure-related symptoms. Bayer points to J.D.A.'s PFS in which she states that she was told by her neurologist, Dr. Garcha, in July of 2009 that a nickel allergy that she was experiencing was Essure-related, and that she was told by her internal medicine doctor, Dr. Nicholson, in July of 2012 that she had an Essure-related autoimmune disorder. (Defs.' Objs., Ex. G ¶¶ V.4, IX.1.) In her subsequent Declaration, J.D.A. recounts her experiences with Dr. Al-Hussaini, her gynecologist, from 2007 to 2010. (Defs.' Objs., Ex. H ¶¶ 2-5; Defs.' Objs., Ex. G ¶ IX.1.) Dr. Al-Hussaini both implanted J.D.A.'s Essure coils in 2007 and subsequently removed them with a hysterectomy in 2010. (Defs.' Objs., Ex. H ¶¶ 2-5; Defs.' Objs., Ex. G ¶¶ III.4, IV.2.) J.D.A. states that Dr. Al-Hussaini told her that her "hysterectomy was for treatment of [her] severe pain, bleeding & headaches which were probably from endometriosis and hormonal issues." (Defs.' Objs., Ex. H ¶ 2.) According to the Declaration, Dr. Al-Hussaini told her that "the implants had 'absolutely nothing to do with all of [her] medical issues' and that it was 'merely coincidental that [her] health began to fail shortly after [she] got the implants.'" (Id.) J.D.A. adds in the Declaration that "[a]nytime I questioned my doctor [i.e., Dr. Al-Hussaini, the only doctor mentioned in the Declaration] about the implants, the very notion that they were the cause of the conditions I developed subsequent to their placement was met with vehement denial and positive accolades about Essure." (Id. ¶ 5; see also Defs.' Objs., Ex. G ¶ IV.1 (stating that Dr. Al-Hussaini was "adamant that the injuries were not Essure related").

Bayer argues that the PFS and Declaration are inconsistent but, again, a reasonable factfinder could conclude that there is no clear inconsistency. J.D.A. states in her PFS that two doctors told her that her autoimmune disorder and nickel allergy were Essure-related, while she states in her Declaration that a third doctor, Dr. Al-Hussaini, her Essure doctor, told her that her symptoms were not related to the device. We therefore overrule Bayer's objection to the Special Master's recommendation that we refuse to apply the sham affidavit rule, and we will not disregard J.D.A.'s Declaration.

Bayer also argues, however, that the fact that J.D.A. received confirmation from two doctors, one in 2009 and one in 2012, that she was experiencing injuries that were Essure-related, was sufficient to start the statute of limitations clock no later than 2012 and, thus, her June 29, 2017 tort claims against Bayer are untimely. However, in 2009, J.D.A. was under the simultaneous care of Dr. Garcha and Dr. Al-Hussaini, and the two doctors were providing different diagnoses regarding the cause of her symptoms at the time. See Adams v. Zimmer U.S.A., Inc., 943 F.3d 159, 165 (3d Cir. 2019) (stating that "instance[s] of diagnostic uncertainty usually create[] a jury question"). Moreover, while the record evidence is that J.D.A.'s internal medicine doctor told her in 2012 that her auto-immune disorder, which had an onset date of February of 2008 (Defs.' Objs., Ex. G ¶ V.1), was Essure-related, this diagnosis conflicted with Dr. Al-Hussaini's earlier assurances that "the implants had 'absolutely nothing to do with all of [her] medical issues.'" (Defs.' Objs., Ex. H ¶ 2.) Under these circumstances, we conclude that there is a genuine dispute of material fact as to whether J.D.A. knew or had reason to know with reasonable diligence as early as 2012 that she had been injured by Essure. Thus, we overrule Bayer's objections to the Special Master's recommendation that we not find J.D.A.'s tort claims to be barred by the two-year statute of limitations.

## 2. Pregnancy/Non-Pregnancy Injuries

Bayer argues that the Special Master erred in applying separate limitations periods for pregnancy-related injuries and non-pregnancy-related injuries. Bayer argues that a plaintiff knows that she has suffered an injury on account of Essure when she becomes pregnant and, thus, the statute of limitations clock begins to run on all Essure-related injuries at that time. In contrast, the Special Master recommends that pregnancy does not, without more, give rise to inquiry notice as to non-pregnancy-related tort injuries.

In our prior statute of limitations opinion, we considered two plaintiffs who had become pregnant while using Essure, Plaintiff 6 and Plaintiff 7. McLaughlin, 2019 WL 1382710, at \*17-20. In each of those two cases, the plaintiff learned more than two years before she filed suit both that she was pregnant and that her Essure device had migrated. Id. We concluded that, under those circumstances, all of the plaintiffs' tort claims were time-barred, whether based on pregnancy, migration, pain, or other alleged injuries. Id.

Bayer now contends that we should reach the same result in every circumstance in which a plaintiff becomes pregnant more than two years before filing suit, even if she does not know or have reason to know using reasonable diligence that other injuries she may be suffering are also related to Essure. It points to Pennsylvania law that we cited in connection with Plaintiffs 6 and 7, which states "that the statute of limitations begins to run when a plaintiff has 'actual or constructive knowledge of at least some form of significant harm and of a factual cause linked to another's conduct, without the necessity of notice of the full extent of the injury.'" McLaughlin, 2019 WL 1382710, at \*18 (quoting Gleason, 15 A.3d at 484 (internal quotation marks omitted)) (additional citation omitted). It also notes that we expressly rejected Plaintiffs' argument in our

March 2019 Opinion that Plaintiffs 6 and 7 were entitled to a new statute of limitations period for each separate injury they experienced on account of Essure. See id. at \*18-19.

In our prior Opinion, we expressed considerable skepticism that Pennsylvania law allows for separate limitations periods for different injuries arising from a single medical device. See id. We nevertheless allowed for the possibility of a “very narrow exception to the rule that the statute begins to run at the same time on all claims for injuries arising from the same negligent conduct, excepting only those injuries that can be attributed to completely separate ‘chain[s] of causation’ and where one injury is not a ‘reasonably certain consequence’ of the other.” Id. at \*18 n.23 (alteration in original) (quoting Place v. Ortho Pharm. Corp., 595 F. Supp. 1009, 1012 (W.D. Pa. 1984)). And, in fact, we applied, and Bayer expressly agreed to, a separate injury analysis under circumstances in which a plaintiff suffered separate injuries from two different Essure coils. Id. at \*21 (“Bayer does not dispute that the migration of the second coil is a separate and distinct injury that is subject to a separate statutory limitation period.” (citing N.T. 2/11/19, at 64-65)); see also id. \*21 n.27. Thus, in spite of our skepticism regarding separate and distinct injuries from a single medical device, we did not foreclose the possibility that the statute of limitations can start to run at different times for different injuries that arise through different chains of causation.

Moreover, since we issued our March 2019 Opinion, the Third Circuit has opined that, under Pennsylvania law, a reasonably diligent plaintiff who suffers complications from a medical device that she attributes to her body’s poor adjustment to the device is not, as a matter of law, on inquiry notice that the device itself has caused her harm. Adams, 943 F.3d at 166-67. Rather, as the Third Circuit explained, a jury could conclude that the plaintiff “believed she had a bad reaction to the device without yet understanding she had an injury ‘caused by another party’s conduct.’” Adams, 943 F.3d at 167 (quoting Nicolaou, 195 A.3d at 892). A similar logic can apply to women

who suffer Essure pregnancies that may be the result of poor adjustment, or a bad reaction, to Essure, and do not yet have constructive knowledge that the device has otherwise caused them injury. We therefore conclude that a woman who learns that Essure has failed its contraceptive purpose but does not yet know or have reason to know with reasonable diligence that the device has otherwise injured her – by, for example, migrating, perforating other organs, or causing an allergic reaction – may satisfy the discovery rule to delay the start of the statute of limitation clock on non-pregnancy-related injuries.

This approach is consistent with our March 2019 Opinion, in which we ultimately held only that the statute of limitations starts to run on all of a plaintiff's tort claims at that point in time that the plaintiff knows or has reason to know with reasonable diligence both that she is pregnant and that her Essure device has migrated. In contrast, we in no way held in that opinion that a plaintiff's knowledge that Essure failed its contraceptive purpose is independently sufficient to start the statute of limitations clock on claims for other injuries that the plaintiff may suffer as a result of a coil's as-yet-undetected or unknown migration or other non-pregnancy-related injuries. Accordingly, we reject Bayer's argument that the Special Master erred in recommending that a separate statute of limitations can apply to pregnancy-related and non-pregnancy-related injuries.

With this clarification, we consider the facts concerning each of the plaintiffs who became pregnant while on Essure, for whom Bayer objects to the Special Master's recommendation.<sup>3</sup>

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<sup>3</sup> Bayer advances its pregnancy arguments with respect to eight plaintiffs. With regard to two of those plaintiffs – J.D.S. and J.H. – Bayer also argues that the Special Master misapplied the knowledge requirement of the discovery rule. We will therefore discuss all of Bayer's arguments regarding J.D.S. and J.H. in the next section in which we address actual versus constructive knowledge, and we will discuss only the six other plaintiffs here.

a. D.M.

Plaintiff D.M. had her Essure placed in October of 2006. (Addendum to Mots. Regarding Rule to Show Cause (“Show Cause Addendum”), Ex. XII.A ¶ III.2.) In November, she began experiencing pelvic and lower stomach pain, as well as heavy and constant menstrual cycles. (Id. ¶ V.1.) She underwent an HSG test in January of 2007, which showed that “there [were] bilateral essure devices in place and there [was] no free spill,” and her doctor told her that her Essure was correctly placed. (Id. ¶ III.10; id., Ex. XII.C at 50.) D.M. believed that she suffered a miscarriage in either 2008 or 2013, but there is no evidence in the record that a doctor verified her pregnancies. (Id., Ex. XII.A ¶ V.7; id., Ex. XII.C at 45-46; id., Ex. XII.B ¶ 8.) In February of 2014, D.M. underwent a supracervical partial hysterectomy with bilateral salpingectomy as treatment for fibroids. (Id., Ex. XII.A ¶ IV.2; id., Ex. XII.B ¶ 10; id., Ex. XII.C at 4.) The pathology report from that procedure notes that there was a “metallic wire-like structure present[ly] embedded in the myometrium (essure) in the anterior right cornual area [that] measures 5 cm in length.” (Id., Ex. XII.C at 3.) Four months later, in June of 2014, D.M. underwent a bilateral oophorectomy and had her cervix and remaining left fallopian tube removed as treatment for endometriosis. (Id., Ex. XII.A ¶ IV.2; id., Ex. XII.B ¶ 13; id., Ex. XII.C at 17.) There is no reference to the left Essure coil in D.M.’s surgical records. (See id., Ex. XII.C at 14-26.) D.M. filed her claims in February 2018.

The Special Master recommends that we refuse to find D.M.’s non-pregnancy-related tort claims to be time-barred because D.M. “was never informed of a migration or perforation and was consistently given alternative (other than Essure) medical causes for her injuries.” (Amended R&R at 6.) Bayer objects to this recommendation, arguing that D.M.’s pregnancy in 2013 (at the latest) was sufficient to start the limitations period on all of her tort claims, and that all of her tort claims, both pregnancy-related and non-pregnancy-related, are time-barred. However, for the

reasons set forth above, we conclude that D.M.’s apparent pregnancy alone did not start the statute of limitations clock on her non-pregnancy-related tort claims, and a reasonable factfinder could conclude, based on the summary judgment record, that while D.M. knew that Essure had failed its contraceptive purpose, she neither knew nor had reason to know with reasonable diligence that her Essure coils had migrated – or that she was otherwise suffering from non-pregnancy-related Essure injuries – more than two years before she filed suit. We therefore overrule Bayer’s objection to the Special Master’s recommendations regarding D.M.

b. L.B.

Plaintiff L.B. had her Essure placed in 2009. (Defs.’ Objs., Ex. O ¶ III.2.) She underwent an Essure confirmation test in March of 2010 and was told that her Essure was properly placed and that both tubes were successfully occluded. (Id. ¶ III.9; Defs.’ Objs., Ex. P ¶ 5.) Beginning shortly after placement, she began suffering from cramping, bleeding, skin rashes, and fatigue. (Defs.’ Objs., Ex. O ¶¶ IV.4, V.1; Defs.’ Objs., Ex. P ¶ 6.) She became pregnant in 2012, and delivered a baby in October of 2012. (Defs.’ Objs., Ex. O ¶ V.1.) Her doctor told her that her pregnancy was Essure-related in October of 2012. (Id. ¶ V.4.) At the same time, her doctor told her there was no problem with her Essure devices or their placement (and ultrasounds repeatedly showed that the coils were in the correct location), and he simply told her that no birth control is 100% effective. (Defs.’ Objs., Ex. P ¶¶ 9-11.) After delivery of her baby, L.B. had a tubal ligation without removing the Essure coils. (Id. ¶ 13.) She consulted with attorneys about her Essure pregnancy, but the lawyers told her that did not have a case “because no birth control is 100% effective.” (Id. ¶ 14.) She retained a lawyer in November 2014. (Id. ¶ 19.)

To the best of L.B.’s recollection, she first suspected that her irregular bleeding, rash, migraines, and nickel allergies were Essure-related in December of 2009, but her doctors denied

that there was a connection until June of 2016. (Defs.' Objs., Ex. O ¶ V.4; Defs.' Objs., Ex. P ¶ 7.) L.B. filed her lawsuit in July of 2016. (Defs.' Objs., Ex. P ¶ 19.) She had a hysterectomy in April of 2017, and her Essure devices were removed at that time. (Defs.' Objs., Ex. O ¶ IV.2.) L.B.'s symptoms, including pelvic pain, resolved after removal of Essure. (Id. ¶ VII.3.)

The Special Master recommends that there are genuine issues of material fact as to whether L.B.'s non-pregnancy-related claims are time-barred. He reasons that a reasonable jury could conclude that L.B. did not know or have reason to know with reasonable investigation that her non-pregnancy-related injuries were Essure-related more than two years before filing suit because she was told on numerous occasions that her Essure device was properly placed and her fallopian tubes occluded and because various doctors declined to blame Essure for her non-pregnancy-related injuries.

Bayer objects to the Special Master's recommendation regarding the non-pregnancy-related tort claims, arguing that the statute of limitation on all of L.B.'s claims began to run when she became pregnant in 2012 and that all of her tort claims are therefore time-barred. In the alternative, Bayer contends that L.B.'s consultation with attorneys at some point before November of 2014 began the two-year clock and made her July 2016 legal claims untimely.

However, for the reasons set forth above, we will not find the mere fact of L.B.'s Essure pregnancy to start the clock on all tort claims for injuries not associated with the pregnancy where, as here, a reasonable jury could conclude based on the facts in the summary judgment record that she neither knew nor had reason to know that she was suffering from other non-pregnancy-related injuries that her apparently-intact Essure had caused. Moreover, we do not find L.B.'s consultation with attorneys as to whether she had a cognizable claim for damages in connection with her Essure pregnancy to undisputably demonstrate that she knew or reasonably should have known that other

non-pregnancy-related problems that she was experiencing were tied to her use of Essure. We therefore overrule Bayer's objection to the Special Master's recommendations regarding L.B.

c. L.C.

L.C. had Essure placed in March of 2007. (Defs.' Objs., Ex. Q ¶ III.2.) She did not undergo an Essure confirmation test. (Id. ¶ III.9.) L.C. began experiencing severe and persistent pelvic pain and irregular bleeding in late 2007. (Id. ¶¶ V.1 -V.3.) She became pregnant twice - in 2010 and 2013. (Defs. Objs., Ex. S ¶ 4.) After conducting an ultrasound in 2010, her doctor told her that she was miscarrying. (Id.; Defs.' Objs., Ex. R at 2 (stating that L.C. has a "missed abortion" in 2010); Defs.' Objs., Ex. Q ¶ V.1.) A July 2013 ultrasound in connection with her second pregnancy showed that her left coil was "not . . . in place." (Defs.' Objs., Ex. R at 4.) Indeed, L.C. admits that her doctors told her after each pregnancy that her left coil was lower than her right coil, and she understood this to mean that there was a problem with her left coil. (Defs.' Objs., Ex. S ¶¶ 4-5.) She gave birth to a baby in March of 2014 in connection with her second pregnancy. (Defs.' Objs., Ex. Q ¶ V.1.) Her doctor did not want to remove the Essure coils, so the doctor suggested that she have a tubal ligation. (Id. ¶ IV 1.) L.C. had a tubal ligation in March of 2014. (Defs.' Objs., Ex. Q, ¶ V.1.) She states in her Declaration that a new doctor eventually "agreed that Essure was the cause of [her] problems" and performed removal surgery in August of 2014, but only removed the right coil. (Defs.' Objs., Ex. S ¶¶ 7, 14; Defs.' Objs., Ex. Q ¶ IV.2.) L.C. had a full hysterectomy in November of 2014 "due to the left coil being embedded in [her] uterus." (Defs.' Objs., Ex. S ¶¶ 2-4, 7.) Her severe and persistent pelvic pain resolved following the hysterectomy. (Defs.' Objs., Ex. Q ¶ V.11.) L.C. filed suit on June 29, 2016.

The Special Master recommends that there are genuine disputes of material fact as to whether L.C.'s non-pregnancy-related tort claims are time-barred, noting that L.C. asked

numerous doctors whether Essure was the cause of her pain and none of the doctors told her that it was. He further recommends that the fact that L.C. was told that one coil was lower than the other is not the equivalent of a migration and that, even if it were, her doctors told her that the location of the Essure was not the cause of her problems and L.C. was entitled to rely on that. Finally, he observes that the record reflects that L.C. was not diagnosed with an actual migration until less than two years before she filed suit.

Bayer objects to the Special Master's recommendation, arguing that the pregnancies were sufficient to start the statute of limitations clock on all of L.C.'s tort claims. It further argues that a reasonable person exercising diligence would have consulted her medical records, particularly when she suspected that Essure was the cause of her injuries and her doctor told her that her left coil was oriented lower in her fallopian tube than her right coil, and that, here, those records revealed that her left Essure was "not . . . in place." (Defs.' Objs., Ex. R at 4.)

Upon de novo review of the record before us, we reach the same conclusion as the Special Master, i.e., that there is a genuine dispute of material fact as to whether L.C.'s non-pregnancy-related tort claims are barred by the two-year statute of limitations. First, as explained above, we will not find mere knowledge of an Essure pregnancy (or pregnancies) to start the clock on all tort claims for injuries not associated with the pregnancy. Moreover, we conclude that a factfinder could reasonably conclude that a plaintiff's knowledge that her coils are situated slightly differently in her two fallopian tubes is not sufficient to trigger inquiry notice of non-pregnancy-related injuries in the absence of any suggestion that the differently-situated coils were in any way problematic. And while the July 2013 ultrasound report reflects that one coil was "not . . . in place," there is no indication in the record that this information was conveyed to L.C., and a reasonable factfinder could conclude that reasonable diligence did not demand that L.C. request

those records. Under these circumstances, we conclude that there is a genuine dispute of material fact as to whether L.C. was on inquiry notice that she had incurred non-pregnancy-related Essure injuries prior to August or November of 2014, when a new doctor confirmed that Essure was causing her injury and she learned that her left Essure had migrated out of her fallopian tubes and was embedded in her uterus. We therefore overrule Bayer's objection to the Special Master's recommendations regarding L.C.

d. S.G.

Plaintiff S.G. had her Essure placed in March of 2008. (Defs.' Objs., Ex. T ¶ III.2.) She did not undergo an Essure confirmation test. (Defs.' Objs., Ex. T ¶ III.9.) She had a miscarriage in October of 2011. (Defs.' Objs., Ex. T, ¶ V.7; Show Cause Addendum, Ex. XXXVIII.B ¶ 6.) Both before and after her Essure implantation, S.G. was treated for endometriosis. (Show Cause Addendum, Ex. XXXVIII.B ¶ 5.) In November of 2011, she visited her doctor, complaining of chronic abdominal pain that she believed was related to her endometriosis or chronic interstitial cystitis. (Show Cause Addendum, Ex. XXXVIII.B ¶ 7.) She stated in her PFS that she learned she had an Essure perforation on November 18, 2011. (Defs.' Objs., Ex. T ¶ V.1.) As treatment for the perforation, she underwent a hysterectomy, bilateral salpingectomy, and removal of her right ovary on November 18, 2011. (Id. ¶¶ IV.2., V.8.) In S.G.'s Declaration, she states that she did not learn until December of 2012 that the hysterectomy had not removed the Essure coils. (Show Cause Addendum, Ex. XXXVIII.B ¶ 10.) At that same time, she learned that Essure had perforated her "[r]ight side, upper pelvis," which was causing pain in her "[u]pper pelvis." (Defs.' Objs., Ex. T ¶ V.8.) S.G.'s medical records from April of 2013 also reflect that her Essure implants were "deposited in the pelvis." (Defs.' Objs., Ex. U at 4.) In May of 2013, S.G. had surgery to remove the implants and to also treat ongoing endometriosis. (Show Cause Addendum, Ex.

XXXVIII.C at 5; id., Ex. XXXVIII.B ¶ 11; see also Defs.’ Objs., Ex T ¶ V.1 (stating that S.G. had “Multiple surgeries to remove Essure and Essure fragments (5/8/13)”). At that time, her doctor did not associate her abdominal pain with the misplaced Essure coils. (Show Cause Addendum, Ex. XXXVIII.B ¶ 11.) On the other hand, S.G. states in her PFS that her doctor told her in June of 2013 that an injury to her stomach and gastroesophageal reflux disease (GERD) were Essure-related. (Defs.’ Ex. T ¶ V.4.) She filed suit on July 6, 2016. (Show Cause Addendum, Ex. XXXVIII.B ¶ 13.)

The Special Master recommends that there is a genuine dispute of material fact as to whether S.G.’s non-pregnancy-related tort claims are time-barred because S.G.’s doctor never informed her that Essure may have been the cause of her pain, but rather, attributed her pain to other medical issues, and because her doctor never diagnosed her with a migration or other Essure-related problems. Bayer argues that the statute of limitations began to run on all of S.G.’s tort claims in October of 2010, after she became pregnant and suffered a miscarriage and, as a result, all of her tort claims are untimely. In the alternative, Bayer argues that, because S.G. was diagnosed with a perforation in 2011 and a migration in 2013, the statute began to run no later than 2013 and her 2016 claims were therefore untimely on that basis.

While we disagree with Bayer’s assertion that the statute on all of S.G.’s tort claims began to run when she had a miscarriage in October of 2010, we are persuaded by its alternative argument. Contrary to the Special Master’s assertion in his Amended Report and Recommendation, the undisputed evidence in the summary judgment record is that S.G. learned of an Essure perforation in November of 2011, or, at the latest, in December of 2012. (Defs.’ Objs., Ex. T ¶¶ V.1, V.8.) She specifically admits that she learned in December of 2012 that Essure had perforated her pelvis. (Id. ¶ V.8.) The Essure implants were removed from her abdomen in a

May 2013 surgery. (Show Cause Addendum, Ex. XXXVIII.C at 6 (documenting the removal of Essure implants from the “left upper quadrant of the abdomen.”); see also Defs.’ Objs., Ex T ¶ V.1.) In light of the known Essure perforation, the undisputed evidence demonstrates that S.G. know or, with reasonable diligence, should have known that she was injured by Essure as early as November of 2011 and no later than May of 2013. Moreover, S.G. admits that her doctor told her in June of 2013 that she was suffering a non-pregnancy-related Essure injury. (Defs.’ Objs., Ex T ¶ V.4.) Because she did not file suit until July of 2016, her non-pregnancy-related tort claims, just like her pregnancy-related tort claims are time barred. We therefore sustain Bayer’s Objections to the Special Master’s recommendation concerning S.G. and conclude that S.G.’s non-pregnancy-related tort claims are time-barred.

e. R.C.

Plaintiff R.C. had Essure placed in September of 2010. (Defs.’ Objs., Ex. V ¶ III.2.) She had an HSG test in December of 2010, and was not told that her Essure devices were not in the correct location in her fallopian tubes. (Id. ¶ III.10.D; see also Defs.’ Objs., Ex. W at 11 (noting that R.C. had “confirmatory testing with HSG”).) She learned that she was pregnant in April of 2012 and again in March of 2014. (Defs.’ Objs., Ex. V ¶¶ V.1, V.7.) She had conversations with her doctors in 2012 and 2014 about having a hysterectomy to stop the pain, unintended pregnancies and unusual bleeding. (Id. ¶ IV.1.) Her medical records reflect that her pregnancies were the result of “Essure failure.” (Defs.’ Objs., Ex. W at 4; see also id. at 9-10.) R.C. underwent tubal ligation in March of 2015. (Id. at 10.) In connection with that surgery, the doctor observed that “right and left Essure coil noted to be within the tube along the ampulia portion.” (Id. at 9.) R.C. filed suit on March 2, 2018.

The Special Master recommends that a reasonable jury could find that R.C. neither knew or reasonably should have known that Essure was the cause of her non-pregnancy-related injuries because she was never diagnosed with a migration or expulsion or informed that Essure might be the cause of her non-pregnancy-related injuries. Bayer objects to this recommendation, arguing that the statute of limitations began to run on all of R.C.'s tort claims no later than 2014, after she had twice become pregnant and was diagnosed with a "failed Essure." (Id.)

However, as explained above, evidence that R.C. knew in 2014 that Essure had twice failed its contraceptive purpose is not independently sufficient to start the statute of limitations clock on tort claims for non-pregnancy-related Essure injuries. Moreover, a reasonable jury could find, based on the evidence in this record, including that the Essure coils remained properly placed in R.C.'s fallopian tubes and had never migrated, that R.C. did not know and could not have known with reasonable diligence that Essure was the cause of her other non-pregnancy-related injuries. We therefore overrule Bayer's objection to the Special Master's recommendations regarding R.C.

f. M.B.

Plaintiff M.B. had her Essure placed in February of 2008. (Defs.' Objs., Ex. X ¶ III.2.) She underwent an HSG test in June of 2008, which "showed 'evidence [o]f bilateral blocked tubes.'" (Id. ¶ III.9; Show Cause Addendum, Ex. XLIII.C at 1.) She began suffering from abdominal pain and lower back pain in August of 2008. (Defs.' Objs., Ex. X ¶ V.6.) In September of 2008, M.B. learned that she was pregnant with an ectopic pregnancy. (Id. ¶ V.7.) She had a tubal ligation in March of 2012. (Id. ¶ VII.4.) She has not had her Essure removed. (Id. ¶ IV.1.) M.B. filed suit in January of 2018.

The Special Master recommends that a reasonable jury could find that Plaintiff did not know nor reasonably should have known that Essure was the cause of her non-pregnancy-related

problems more than two years before filing suit in the absence of any evidence that she also suffered a migration or perforation. Bayer argues that M.B.'s ectopic pregnancy in 2008 was sufficient to start the statute of limitations on all of M.B.'s tort claims, and that her 2018 claim was therefore untimely.

We conclude, however, that in spite of M.B.'s knowledge that Essure had failed its contraceptive purpose in 2008, there is a genuine issue of material fact as to whether she knew or could have known that Essure was the cause of her non-pregnancy-related injuries. We therefore overrule Bayer's objections to the Special Master's recommendations regarding M.B.

### **3. Actual Versus Constructive Knowledge**

Bayer argues that the Special Master erred in how he applied the discovery rule knowledge requirement. Specifically, it contends that, instead of asking whether there is a genuine issue of material fact as to whether a plaintiff knew or, exercising reasonable diligence, should have known that she had been injured by Essure, the Special Master occasionally required the evidence to unequivocally demonstrate that the plaintiff actually knew that Essure had injured her. Put another way, Bayer contends that the Special Master failed to consistently recognize that a plaintiff's constructive knowledge of here injury and its cause can trigger the start of the statute of limitations period. Bayer argues that, as a result of this error in applying the discovery rule, the Special Mater erroneously recommends that we should find that the tort claims of three particular plaintiffs were not time-barred. We consider each of these plaintiffs in turn.

#### **a. A.N.**

Plaintiffs have limited their claim with respect to Plaintiff A.N. to only injuries associated with her right Essure coil and do not assert a claim with respect to her left coil, which migrated and was removed in January of 2012. (See Pls.' Resp. to Ord. to Show Cause, ECF No. 465,

McLaughlin v. Bayer Essure, Inc., Civ. A. No. 14-7315, at 33.) No later than September of 2013, A.N. complained to her doctors about pelvic pain, was “very anxious,” and wanted to know what was causing the pain. (Show Cause Addendum, Ex. XIV.C at 1, 3.) She underwent a diagnostic laparoscopy on October 11, 2013, which identified a likely sebaceous cyst. (Id. at 4-5.) A.N. underwent imaging on January 24, 2014 to “ck lt side for ? of fragmented Essure” and to “ck if rt side essure is still there & intact.” (Id. at 8.) The imaging indicated: “Essure noted on the right. Left Essure is not identified.” (Id.) On February 12, 2014, A.N. met with her doctor to discuss having a “[s]upracervical hysterectomy with bilateral salpingectomies.” (Defs.’ Objs., Ex. J at 1.) Notes from that visit state: “Surgery is not guaranteed to resolve abdominal pain issues. Left essure coil is out and the right is the focus of removal.” (Id. at 3.) A March 2, 2014 pre-operative report repeats that “she has had her left Essure coil removed and the right side is the focus of removal” and states that A.N. suffers from “pain in the deep pelvis mid to the right side.”<sup>4</sup> (Id. at 4.) A.N. had the surgery on March 7, 2014, and that surgery resulted in the removal of the right coil. (Show Cause Addendum, Ex. XIV.C at 14-15.)

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<sup>4</sup> Elsewhere, the same report identifies the location of the pain and remaining Essure as being on the left side, stating that A.N. “has had significant pain and discomfort that persists particularly on [her] left pelvic side” and also stating that “[s]he has an Essure that still remains on that side.” (Id. at 4 (emphasis added).) The post-operative report likewise repeats that there is a “Prior [Essure] remaining in the left tube.” (Show Cause Addendum, Ex. XIV.C at 14.) These references conflict with the evidence that the left Essure had been removed, leaving only a right-side Essure, and with other references in the same pre-operative and post-operative reports that that her pain is “in the deep pelvis mid to the right side” and that she was suffering from “Pelvic pain, right worse than left.” (Defs.’ Objs., Ex. J at 4; Show Cause Addendum, Ex. XIV.C at 14.) Because A.N.’s January 2014 imaging report identified only a right Essure coil remaining, and her March 2014 post-operative report documented Essure in the right fallopian tube, the only reasonable conclusion is that the references to an Essure coil remaining in the left tube are errors. (Show Cause Addendum, Ex. XIV.C at 8, 15.) Nevertheless, the records support a reasonable conclusion that A.N. was suffering both left and right side pain.

The post-operative notes describe the procedure as a “supracervical hysterectomy, bilateral salpingectomy, and removal of right hemorrhagic cyst.” (Id. at 14.) The notes describe removal of both the left and right fallopian tubes and state: “The remaining portion of the [Essure] could be palpated in the cornu area of the [right] tube. This was avoided with dissection.”<sup>5</sup> (Id. at 15.) They subsequently recount that “[a]ttention [was] focused on the right ovary,” and a cyst was removed from that ovary. (Id.) A.N. states in a Declaration that she “believed that [her] longstanding history with ovarian cysts was the most likely cause of [her] abnormal bleeding and pain symptoms” and that she “was never told that these symptoms were related to Essure.” (Id., Ex. XIV.B ¶ 12.) A.N. filed suit in July of 2016.

Bayer argues that the Special Master erred in failing to recommend that A.N. knew or should have known that she had injuries caused by Essure in January of 2012, after she was diagnosed with the migration of the left coil and had surgery that removed the left coil. (See Defs.’ Objs., Ex. I ¶ IV.2.) In Bayer’s view, the diagnosis of the left Essure migration and its removal “was sufficient to start the limitations period for all claims.” (Defs.’ Objs. at 11.) However, Bayer conceded in connection with the exemplar plaintiffs that we addressed in our March 2019 Opinion that a woman’s claim for injuries from one coil may be subject to a different limitations period than that applicable to her claim for injuries from the other coil when there are separate and distinct injuries from the two separate coils. See McLaughlin, 2019 WL 1382710, at \*21 n.27. In A.N.’s case, the undisputed evidence is that A.N. knew in 2012 that she had been injured by the left coil because it had migrated and been surgically removed. However, the record evidence is that the right coil remained intact and, thus, a reasonable jury could conclude that any

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<sup>5</sup> Instead of Essure, the post-operative notes twice use the word “eschar.” (Id. at 14-15.) We can only conclude that “eschar” is an incorrectly transcribed reference to Essure.

injury that she sustained in connection with the right coil was separate and distinct from any caused by the removed left coil. Accordingly, we reject Bayer's assertion that the migration and removal of the left coil necessarily started the statute of limitations running on claims for injuries from the right coil as well.

We must therefore determine only whether there is a genuine dispute of material fact as to whether A.N. knew or reasonably should have known that she was injured by the right coil more than two years before she filed suit in July of 2016. The Special Master recommends that there is a genuine dispute as to this issue, because the record "does not dispel A.N.'s claim that she was never advised that Essure was the cause of her right side pain prior to filing suit."<sup>6</sup> (Amended R&R at 7.) Thus, the Special Master recommends that "[o]ne cannot say that a reasonable juror would be required to find that Plaintiff knew or should have known that Essure was the cause of her right side pain." (Id.)

Upon de novo review, we agree with the Special Master that it would be premature at this point in time to find A.N.'s tort claims concerning her right Essure to be barred on statute of limitations grounds. While the records reflect that A.N. was experiencing pain in her right side and the medical records suggest that her doctors planned to – and did – remove the right Essure coil, the records also reveal that the doctors were addressing and removing a cyst on her right ovary and that A.N. was also experiencing left side pain, where she no longer had an Essure coil.

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<sup>6</sup> In making this recommendation, the Special Master relies in part on "[t]he confusing and unreliable nature of the medical record." (Amended R&R at 7.) This assessment of the state of the record appears to be primarily due to (1) the aforementioned misspelling of Essure as "eschar," which led the Special Master to observe that "the post-operative report in March, 2014 . . . makes no mention of Essure"; and (2) what we regard as errors in the medical records concerning whether, in 2014, A.N.'s remaining Essure coil was in the right or left fallopian tube. (See supra notes 5-6.) As we have made sense of these aspects of the medical records, we do not rely on any confusion in the medical records in assessing the extent of A.N.'s actual or constructive knowledge.

Moreover, A.N. maintains in her Declaration that she was never told that her pain was the result of the still-in-place right Essure coil. Under these circumstances, a reasonable jury could conclude that A.N. did not know, and could not have known with reasonable diligence, that her intact right Essure was the cause of her ongoing problems. See Adams, 943 F.3d at 165 (stating that “instance[s] of diagnostic uncertainty usually create[] a jury question”).

Accordingly, we reject Bayer’s argument that the Special Master applied an incorrect knowledge standard with regard to A.N.’s right coil tort claims, and we overrule its objections to the Special Master’s recommendation that the existing record presents a genuine dispute of material fact as to whether, more than two years before she filed suit in July 2016, A.N. was on inquiry notice that her right Essure was the cause of her ongoing pain and other symptoms or was otherwise injuring her.

b. J.D.S.

Plaintiff J.D.S. had Essure placed in July of 2005. (Show Cause Addendum, Ex. XLIV.A ¶ III.2.) In the months following implantation, she began experiencing various symptoms, including abdominal pain, heavy bleeding, and pain during intercourse. (Show Cause Addendum, Ex. XLIV.B ¶ 5.) She learned that she was pregnant in December of 2005 and subsequently gave birth. (Id. ¶ 7.) According to her Declaration, J.D.S. asked her doctor about having the Essure coils removed, but her doctor told her not to worry about that. (Id. ¶¶ 7-8.) In June 2012, J.D.S. underwent a partial hysterectomy based on a preoperative diagnosis of “Dysmenorrhea and heavy menses; uncontrolled medical management.” (Show Cause Addendum, Ex. XLIV.C at 1.) Her postoperative diagnosis added that she had “extensive adhesive disease essentially involving the omentum and the anterior abdominal wall.” (Id.) J.D.S.’s medical records reflect that, in May of 2013, she was continuing to suffer from bleeding/pelvic pain and her doctor removed an

endocervical polyp. (Id. at 8-9.) In August 2013, J.D.S. had a bilateral salpingo-oophorectomy with trachelectomy based on a preoperative diagnosis of abnormal uterine bleeding, persistent vaginal bleeding after hysterectomy, and pelvic pain. (Id. at 13.) Although J.D.S.’s Essure coils were removed in the course of her June 2012 and August 2013 surgeries, there is no indication in the medical records that Essure removal was the purpose of the surgeries; indeed, none of the records from the surgeries even mention Essure. (See id., Ex. XLIV.A ¶ IV.2.) Plaintiff states in her Declaration that she believed that her pain and other symptoms were related to Essure, but also states that no doctor ever told her that Essure was the cause of her pain or symptoms. (Id., Ex. XLIV.B ¶¶ 6, 12; id., Ex. XLIV.A ¶ V.4.)

The Special Master acknowledges that J.D.S. suspected that Essure was the cause of her continuing pain symptoms but emphasizes that the record reflects that her suspicions were never confirmed by medical personnel. He therefore recommends that the record can support a reasonable conclusion that J.D.S. did not know or have reason to know with reasonable diligence that Essure was the cause of her injuries more than two years before she filed suit.

Bayer argues that this analysis misapplies the discovery rule because the statute of limitations may begin to run before a prospective plaintiff receives a definitive medical diagnosis.<sup>7</sup> See Billeci v. Merck & Co., Civ. A. No. 17-486, 2018 WL 1635242, at \*5 (E.D. Pa. Apr. 5, 2018). While it is correct that a plaintiff can be on inquiry notice in the absence of a definitive medical diagnosis, the law also provides that “a lay person is only charged with the knowledge

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<sup>7</sup> Bayer argues in the alternative that the statute of limitations began to run on all of J.D.S.’s tort claims when she learned that she was pregnant and thus knew that Essure had injured her. However, as we explain at length above, see supra § III.A.2, we do not find the mere fact of a pregnancy, without knowledge of migration, perforation, or other information that non-pregnancy-related injuries are caused by Essure, to suffice to start the statutory period for non-pregnancy-related tort claims. Thus, we overrule this aspect of Bayer’s objections to the Special Master’s recommendation concerning J.D.S.

communicated to him or her by the medical professionals who provided treatment and diagnosis.” McLaughlin, 2019 WL 1382710, at \*6 (quoting Nicolaou, 195 A.3d at 893) (additional citations omitted); see also Adams, 943 F.3d at 163 (“Plaintiffs generally will not be charged with more medical knowledge than their doctors or health care providers have communicated to them.” (citing Wilson, 964 A.2d at 365)).

Here, J.D.S. had only a lay suspicion that Essure was causing her pain, and the record evidence does not indicate that any medical professional who examined her or performed her surgeries also believed – and conveyed to her – that her symptoms were related to Essure. Moreover, she had been diagnosed with “extensive adhesive disease essentially involving the omentum and the anterior abdominal wall” and also had an endocervical polyp, and the medical records suggest that both of these conditions might have caused her symptoms. (Show Cause Addendum, Ex. XLIV.C at 1, 8-9.) Accordingly, on de novo review, we conclude, like the Special Master did, that a reasonable factfinder could conclude that J.D.S. did not have constructive knowledge that Essure was causing her pain and/or bleeding more than two years before she file suit. We therefore overrule Bayer’s objection to the Special Master’s recommendation that there are genuine disputes of material fact as to whether J.D.S.’s tort claims are time-barred.

c. J.H.

Plaintiff J.H. had Essure placed in December of 2009. (Show Cause Addendum, Ex. XLV.A ¶ III.2.) In the months following implantation, she began experiencing pelvic pain, heavy bleeding, and pain during intercourse. (Id., Ex. XLV.B ¶ 5.) On September 27, 2010, she underwent an HSG confirmation test, which revealed that her right fallopian tube was not occluded. (Defs.’ Objs., Ex. M at 14 (noting that there was “contrast flowing from the right fallopian tube to the pelvis”); Show Cause Addendum, Ex. XLV.B ¶ 4.) In addition, the HSG

report states that the “left Essure . . . is not in the appropriate location of the proximal aspect of the fallopian tube.” (Defs.’ Objs., Ex. M at 14.) On October 18, 2010, J.H. underwent a laparoscopic fulguration of the right fallopian tube on account of the “failed Essure sterilization.” (Show Cause Addendum, Ex. XLV.C at 1; id., Ex. XLV.B ¶ 6.) Medical records reflect that the laparoscopy found that “[a]n Essure system protrudes from the right conual area. It is adhered to the omentum. This is the misplaced Essure system that had failed to work on the right side. The uterus shows a small fundal perforation . . . .” (Id., Ex. XLV.C at 1; see also id., Ex. XLV.B ¶ 6.)

In April 2011, J.H. learned that she was pregnant. (Id., Ex. XLV.B at ¶ 8.) On December 13, 2011, after giving birth, she underwent a “bilateral tubal ligation with removal of Essure suture device from right broad ligament peritoneum.” (Id., Ex. XLV.C at 3; id., Ex. XLV.B ¶ 9.) The medical records also note that no Essure device could be felt in the left tube. (Id., Ex. XLV.C at 3; see also id., Ex. XLV.B ¶ 9.) In 2013, J.H. wrote on social media that her pregnancy had been high risk because the doctor “found the essure from the right side was embedded in [her] uterus” and that, after she had her son, “the dr removed as much essure as possible from [her] uterus.” (Defs.’ Objs., Ex. M at 4.) She further explained that “the coil that migrated from the right tube to [her] uterus was [only] partially removed” because “it was fully embedded [and the doctor] was afraid of digging to remove the entire thing.” (Id.)

Subsequently, in July of 2014, during an appendectomy, the surgeon “observed 2 Essure fallopian tubal implants,” one “in the uterovesical pouch with thin film of tissue over that and another one . . . protruding through the uterus in the fundal area.” (Show Cause Addendum, Ex. XLV.C at 6.) The surgeon “removed the Essure implant tube from the uterovesical pouch.” (Id.) He took a picture of the other Essure coil, i.e., the remainder of the right coil, which was “between the tissues of the uterus with minimal protrusion” and documented that he would advise J.H. to

follow up with her gynecologist for further management of that device. (Id.; id., Ex. XLV.B ¶ 11.) J.H. filed her claims on June 17, 2016.

The Special Master recommends that we find J.H.'s claims for all pregnancy-related injuries to be time-barred because J.H. learned that she was pregnant in 2011. He also recommends that we find any non-pregnancy-related tort claims for injuries from the right coil migration to be time-barred because she was advised of the right coil migration in 2010.<sup>8</sup> In contrast, he recommends that a reasonable jury could find on the summary judgment record that J.H. did not know or have reason to know by the exercise of reasonable diligence that she had been injured by the left Essure coil until July 2014, when she was told that the left coil had migrated. Thus, he recommends that we not dismiss the tort claims for injuries arising from the left coil migration on statute of limitations grounds. Bayer argues that the Special Master erred in requiring J.H. to have actual knowledge of the left coil migration in order for the statute of limitations to begin running on her left coil claim, and that the diagnosis of right coil migration was sufficient to put J.H. on inquiry notice. In the alternative, Bayer argues that the record evidence that J.H. became pregnant in 2011, and knew at that time that the Essure from the right side was embedded in her uterus was sufficient to start the limitations period on all of her tort claims.

We disagree with Bayer's assertion that the Special Master utilized an improper actual knowledge standard, but also disagree with the Special Master's recommendation that there is a genuine issue of material fact that precludes a finding that the non-pregnancy-related left coil claims are time-barred. First, and significantly, unlike the situation with Plaintiff A.N., Plaintiffs

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<sup>8</sup> The Special Master appeared to believe that the right Essure coil was fully removed in 2011 but, in fact, the record reflects that part of the right Essure coil remained in J.H.'s uterus even after the left coil was removed in 2015. (See Defs.' Objs., Ex. M at 4; Show Cause Addendum, Ex. XLV.C at 6.)

do not argue that J.H. suffered separate injuries from the left and right coils and have not asked us to apply separate statute of limitations to the injuries arising from the two separate coils. Rather, Plaintiffs take the position that migration of the right coil simply did not start the statute of limitations running on J.H.'s non-pregnancy-related injuries because, instead of blaming a defect of the medical device for the migration, J.H. blamed her doctor for not implanting it properly. However, we have rejected the argument that a plaintiff's belief that her doctor's malpractice caused her Essure to migrate can prevent the statute of limitation from running on a claim against Bayer for an Essure injury. McLaughlin, 2019 WL 1382710, at \* 11 ("While Plaintiff 1 also believe that she had been injured by her surgery and, thus, had a potential malpractice claim against her doctor, this belief could not reasonably prevent her from understanding that the device itself had also injured her when it migrated and lodged in her uterus." (citations omitted)). Moreover, as explained above, we have concluded that the combination of a pregnancy and migration are sufficient to start the statute of limitations on all of a plaintiff's tort claims.

Here, a reasonable jury could only conclude that J.H. knew that she had suffered pregnancy-related and non-pregnancy-related Essure injuries no later than 2011, after she had learned both that her right coil was embedded in her uterus and that she was pregnant. Accordingly, we sustain Bayer's objections to the Report and Recommendation insofar as the Special Master recommends that we not dismiss the tort claims arising from the migration of the left coil, and we conclude that all of J.H.'s tort claims are time-barred.

#### **4. C.P.**

Bayer separately objects to the Special Master's recommendation that Plaintiff Carmen C.P.'s tort claims are not time-barred. C.P. had Essure placed in August of 2008. (Show Cause Addendum, Ex. XI.A ¶ III.2.) In November 2009 or 2010, one of C.P.'s coils was expelled from

her body during her menstrual period. (Id. ¶¶ IV.1-IV.2.) In July of 2011, she had a total abdominal hysterectomy and right salpingo-oophorectomy as treatment for endometrial hyperplasia and a right ovarian cyst. (Id., Ex. XI.C at 1.) Her post-operative pathology report describes C.P.’s removed uterus as including a “spring coil device . . . at the fallopian tube junction area at the left cornu.” (Id. at 6.) Severe and persistent abdominal cramping that she had experienced before the surgery diminished within a few months afterwards. (Id., Ex. XI.A ¶¶ V.1, IV.4.) However, new symptoms arose over time, including back pain in 2012, migraines in 2015, and neuropathy in 2017. (Id. ¶ V.1.) C.P. attributes both her pre-surgery symptoms and her new symptoms to Essure. (Id.) C.P. filed her claims in July of 2016.

The Special Master recommends that there are genuine issues of material fact as to the timeliness of all of C.P.’s tort claims. While he acknowledges that one Essure coil was expelled, he notes that she had no pain or other symptoms for two years after the expulsion. When she did experience symptoms, her doctor did not tell her that her problems were caused by either her previously-expelled Essure coil or her remaining Essure coil. Bayer objects to this recommendation, arguing that C.P.’s 2009 expulsion of one coil alone is sufficient to start the statute of limitations clock on all of C.P.’s tort claims.

On de novo review, we reach the same conclusion as the Special Master, i.e., that the expulsion of Essure, without any other accompanying symptoms, did not start the statute of limitations running on C.P.’s tort claims. Rather, given that the existing record supports a reasonable conclusion that C.P. suffered no identifiable side-effects from the expulsion of her Essure coil, a reasonable jury could conclude that she did not know and could not have known with reasonable diligence that she had been injured by Essure at the time of the expulsion (other than losing Essure’s contraceptive protection). Moreover, a reasonable jury could conclude that

the existing evidence, including C.P.'s medical records, does not support a conclusion that C.P. knew or should have known subsequent to the expulsion that her developing symptoms were the result of her remaining Essure coil. We therefore overrule Bayer's objections to the Special Master's recommendation regarding C.P.

## **B. Plaintiffs' Objections**

Plaintiffs object on various grounds to the recommendations that we dismiss claims of seven Plaintiffs: E.H., S.C., A.M., T.M., S.J., S.P. and R.C.<sup>9</sup>

### **1. E.H.**

Plaintiff E.H. had Essure placed in April of 2010. (Show Cause Addendum, Ex. XXVII.B ¶ 3.) She learned that she was pregnant in June of 2011, and delivered a child in January of 2012. (Id. ¶ 7.) E.H. joined the Essure Problems Facebook group in 2012, and began posting online about her Essure experience in January of 2012. (Id., Ex. XXVII.A ¶¶ VI.3, VI.4.) E.H. began experiencing pelvic, back, and joint pain, as well as irregular bleeding in 2013. (Id., Ex. XXVII.B ¶ 11.) She visited her doctor in October of 2013 and expressed concern about the location of her Essure coils. (Id. ¶ 12.) Her doctor ordered an ultrasound and told E.H. that her coils appeared to be in the correct position, and that she did not think that E.H.'s pain was Essure-related. (Id. ¶ 14.)

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<sup>9</sup> Plaintiffs also object to the dismissal of one or more of the claims of seventeen additional plaintiffs, but they do not make any specific arguments with respect to those plaintiffs and, instead, simply ask us to consider the arguments and evidence that they presented to the Special Master. Under these circumstances, on de novo review, we approve and adopt the Special Master's report and recommendations as to these seventeen plaintiffs.

Plaintiffs have lodged no objections to the Special Master's recommendations that we dismiss certain claims and/or all of the claims of twenty-five other plaintiffs, recognizing that our prior rulings, which set forth the law of the case, foreclose those claims. However, they reserve the right to challenge our prior rulings on appeal by appealing the dismissal of those claims at a later date.

To this day, E.H. has not been told by her doctor that she has a problem with her Essure device. (Id. ¶ 15.) E.H. filed her claims against Bayer in 2016.

The Special Master recommends that we dismiss all of E.H.'s tort claims as untimely because she only asserts claims for pregnancy-related injuries and she knew that she was pregnant in 2012 but did not file suit until 2016. Plaintiffs object to this recommendation, contending that, contrary to the Special Master's recommendation, E.H. asserts claims for non-pregnancy-related injuries as well as pregnancy-related injuries. Indeed, as noted above, E.H. contends that she has experienced not only an Essure-related pregnancy, but also joint, pelvic, and back pain and irregular menstrual cycles as a result of her use of Essure. (Id., Ex. XXVII.A ¶ V.1.) Moreover, in spite of E.H.'s documented suspicions that these symptoms are Essure-related, the record does not reflect that any doctor has ever confirmed these suspicions and, instead, reflects that E.H.'s doctor expressly told her that she did not think that her symptoms were Essure-related. (Id., Ex. XXVII.B ¶ 14.) Accordingly, we sustain Plaintiffs' objections to the Special Master's recommendation that E.H.'s non-pregnancy-related tort claims are time-barred and instead conclude that there is a genuine issue of material fact as to whether she knew or should have known with reasonable diligence that her non-pregnancy-related injuries were caused by her Essure implants more than two years before she filed suit.<sup>10</sup>

## 2. S.C.

Plaintiff S.C. had Essure placed in June of 2005. (Show Cause Addendum, Ex. XXXII.A ¶ III.2.) Beginning in 2006, she experienced abdominal pain in her right lower quadrant, which

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<sup>10</sup> Bayer urges us to conclude that all of E.H.'s tort-claims are time barred because she knew that she was pregnant in 2011. However, as explained above, we will not bar her claims for non-pregnancy-related injuries merely because she knew that Essure had failed its contraceptive purpose long before she filed suit.

was sometimes severe. (Id., Ex. XXXII.B ¶ 5; id., Ex. XXXII.C at 1, 7, 9.) Her doctors considered different reasons for the abdominal pain, including appendicitis, pyelonephritis, and a tubo-ovarian abscess. (Id., Ex. XXXII.C at 19.) Because of her pain, on October 6, 2008, S.C. underwent an “Operative laparoscopy with right salpingectomy and removal of Essure coil, also cystotomy with drainage of right ovarian cyst.” (Id. at 21.) The October 6, 2008 surgical report detailed under the heading “Indications for Procedure” that S.C. had been having right lower quadrant pain since having the Essure sterilization procedure, and that an ultrasound and MRI had shown “a metallic object in the right parametrium.” (Id.) It further detailed that the doctor would also perform an appendectomy due to S.C.’s chronic pain. (Id.) She was told on the day of the surgery that her right coil had perforated her fallopian tube. (Id., Ex. XXXII.A ¶ V.8; id., Ex. XXXII.B ¶ 11.) The right coil was removed in the course of the surgery. (Id., Ex. XXXII.C at 22.) S.C. states in her PFS that, in connection with her surgery, she spoke with her gynecologist concerning “Pain with perforation of right fallopian tube.” (Id., Ex. XXXII.A ¶ IV.1.) S.C. still has her left coil in her body, and she continues to experience pain, headaches, and depression. (Id., Ex. XXXII.B ¶ 12.) Indeed, she states in her PFS that her symptoms did not decrease or resolve as a result of her October 2008 surgery in which her right coil was removed. (Id., Ex. XXXII.A ¶ IV.4.) Although S.C. believes that Essure is the cause of her continuing symptoms, she states in a Declaration that no doctor has ever told her that Essure is the cause of her symptoms. (Id., Ex. XXXII.B ¶¶ 12-13.)

The Special Master recommends, without elaboration, that we dismiss all of S.C.’s claims as time-barred, presumably because S.C. was diagnosed with an Essure perforation in 2008 and did not file her claims until 2016. Plaintiffs object to this recommendation, arguing that her tort claims should not be dismissed as untimely because “no doctor ever told her that her pain or right

fallopian tube perforation were related to Essure.” (Pls.’ Objs. to Amended R&R (“Pls.’ Objs.”), ECF No. 525, McLaughlin v. Bayer Essure, Inc., Civ. A. No. 14-7315, at 6.) Moreover, Plaintiffs contend that S.C.’s gynecologist specifically told her that Essure was not the cause of her pain. The record, however, provides no support for these assertions. Rather, as noted above, S.C. stated in her PFS that she learned of her Essure perforation in October 2008, and that her gynecologist communicated to her at the same time that she had “[p]ain with perforation of right fallopian tube.”<sup>11</sup> (Show Cause Addendum, Ex. XXXII.A ¶¶ IV.1, V.8.) On this record, a reasonable jury could only conclude that once S.C. learned in October of 2008 that her Essure had perforated her right fallopian tube, she knew or had reason to know that she had been injured by the right Essure device. The two-year statute of limitations therefore began to run on her tort claims associated with her right Essure coil at that time, and that statute had long-expired when she filed her claims against Bayer in 2016.

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<sup>11</sup> S.C. states in her Declaration that her general surgeon wrote the following in an operative report following the October 2008 surgery:

[W]e really have not been able to come up with a clear-cut reason for the [right lower quadrant abdominal] pain. . . . [S]he had a NovaSure [sic] device placed which appeared to be eroding through the right tube where it had been placed, and therefore there was some concern that that might be causing her pain, but [her gynecologist] was not convinced that this should be that painful. Our intention was therefore to carefully inspect the appendix and probably remove it regardless of what we found just to eliminate that as the differential diagnosis since her pain is mostly in the right lower quadrant, and then of course to perform a thorough diagnostic laparoscopy.

(Show Cause Addendum, Ex. XXXII.B ¶ 8.) Although this quotation is quite specific, and Plaintiffs repeat it in their briefing, we were unable to find it in any of the medical records in the summary judgment record. Moreover, even assuming arguendo that this quotation is genuine and accurate, it does not support S.C.’s assertion that she did not know or have reason to know with reasonable diligence that Essure had perforated her fallopian tube or that it was a possible cause of her lower quadrant pain. Rather, this quotation confirms that S.C.’s doctors diagnosed a perforation and, like S.C., suspected that the perforation was causing her pain, even if her gynecologist questioned whether the perforation was causing the full extent of the pain.

Plaintiffs nevertheless argue that we should permit S.C.'s tort claims concerning her left coil to proceed, even if her claims with respect to her right coil are dismissed as untimely. Because the record evidence is that S.C. has experienced pain, headaches and depression since the removal of her right coil, that she attributes those symptoms to her remaining left coil, and that she continues to experience symptoms that she links to her left coil, we conclude that there are genuine disputes of material fact as to whether the left Essure coil has caused an injury separate and discrete from that caused by the right Essure coil and whether S.C. knew or should have known that she had been separately injured by her left Essure coil more than two years before she filed suit. We therefore overrule Plaintiffs' objections to the Special Master's recommendations concerning S.C.'s tort claims regarding her right coil, but sustain their objections concerning S.C.'s tort claims regarding her left coil. We therefore dismiss S.C.'s tort claims concerning injuries associated with the right coil as time-barred and permit her tort claims concerning injuries associated with the left coil to proceed.

### 3. A.M.

Plaintiff A.M. had her Essure placed on September 11, 2012. (Show Cause Addendum, Ex. XV.B ¶ 3.) Prior to this time, as early as 2009, she suffered from pelvic pain due to endometriosis. (Id. ¶ 3.) However, the pelvic pain increased following her Essure procedure. (Id., Ex. XV.C at 10 (stating that "had the Essure procedure done that seemed to increase her pain especially on the right side"); id. at 20 ("Essure placement . . . led to significant increase of her right sided pain.")) After implantation, A.M. underwent an ultrasound that confirmed that her coils were correctly placed. (Id. at 11-12; id., Ex. XV.B ¶ 6.) Her doctor recommended a total hysterectomy to alleviate her ongoing pain. (Id., Ex. XV.B ¶ 6.) On November 9, 2012, less than nine weeks after having Essure implanted, A.M. underwent a total laparoscopic hysterectomy with

bilateral salpingectomies, along with laparoscopic destruction of endometriosis. (Id., Ex. XV.C at 17.) She states in her PFS that she had Essure removed in connection with her hysterectomy “due to the pain it caused.” (Id., Ex. XV.A ¶¶ IV.1-IV.2.) Her symptoms completely resolved for about a year, then slowly began to return and, in February of 2017, her doctor suspected a return of her endometriosis. (Id., Ex. XV.C at 26-27.) A.M. filed her claims in this case on February 23, 2018.

The Special Master recommends that we dismiss all of A.M.’s claims as untimely. He emphasizes A.M.’s statement in her PFS that her doctor removed the Essure device just two months after implantation “due to the pain Essure caused” and that her physician states in the medical records that he discussed A.M.’s Essure-related pain with her on numerous occasions in 2012. (Amended R&R at 8.) The Special Master therefore recommends that A.M. had actual notice of Essure as a cause of her symptoms more than two years before she filed suit in 2018.

Plaintiffs object to the recommendation that A.M.’s tort claims are untimely, pointing to the record evidence that A.M.’s Essure coils were correctly placed, that she had pain caused by endometriosis that predated her Essure implantation, and that, during her hysterectomy, the doctors observed endometriosis as well as a “thickened and shortened right round ligament,” which could have also caused her pain. (Show Cause Addendum, Ex. XV.C at 23.) They therefore argue that there is a genuine dispute of material fact as to when she knew or reasonably should have known that her pain was caused by Essure, as opposed to her other ailments.

However, upon de novo review, we reach the same conclusion that the Special Master reached – that the undisputed record evidence establishes that A.M. knew or had reason to know with reasonable diligence that her Essure coils were causing her additional pelvic pain in 2012. As the Special Master recognized, A.M.’s medical records specifically recount conversations that A.M. had with her doctor in which they discussed that that her pain had increased after the

implantation of Essure. While the onset of pain shortly after implantation is not ordinarily sufficient to put a plaintiff on notice that she has been injured by Essure, in this case, A.M., in consultation with her doctor about her pain, opted to have a hysterectomy, thereby removing the Essure implants, just weeks after having her Essure placed. Moreover, A.M. specifically states in her PFS (in response to a question about communications with her healthcare provider) that she had the Essure inserts removed due to the pain that that they were causing her. (Id., Ex. XV.A ¶¶ IV.1-IV.2.)

Under these circumstances, no reasonable juror could conclude that A.M. did not know or have reason to know with reasonable diligence in November of 2012 that she had been injured by Essure. Thus, her tort claims, which were not filed until over five years after the removal of both coils, are time-barred.<sup>12</sup> We therefore overrule Plaintiffs' objection to the Report and Recommendation as to A.M. and we dismiss A.M.'s claims as time-barred.

#### 4. T.M.

Plaintiff T.M. had Essure placed in the summer of 2008. (Show Cause Addendum, Ex. XLVII.A ¶ III.2.) In the Fall of 2008, she had an HSG test that confirmed that both tubes were properly occluded. (Id. ¶¶ III.9, III.10; Id., Ex. XLVII.C at 11.) However, in January of 2011, she learned that she was pregnant. (Id., Ex. XLVII.B at ¶ 6.) She had an ultrasound on January 17, 2011, which showed that "one of the Essure coils appeared to be in the mid line of the uterus." (Id., Ex. XLVII.C at 10; id., Ex. XLVII.B ¶ 7.) T.M. states in her Declaration that when she asked her doctor how she became pregnant, her doctor told her that "she did not know but that nothing

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<sup>12</sup> Plaintiffs also argue that the evidence that A.M. suffered a recurrence of pain a year after Essure was removed supports a reasonable conclusion that she could not have known that her pain preceding her hysterectomy was caused by Essure. However, the evidence of A.M.'s post-removal experience does not undermine the undisputed evidence that, at the time of the removal, she knew or had reason to know that Essure had injured her.

is 100%.” (Id., Ex. XLVII.B ¶ 8.) In late 2011, she underwent a laparoscopic tubal ligation on account of her “failed Essure.” (Show Cause Addendum, Ex. XLVII.C at 9; id., Ex. XLVII.B ¶ 10.) Her doctor told her that, during the procedure, she had “observed one coil embedded in [T.M.’s] uterus and the other had perforated the fallopian tube.” (Id., Ex. XLVII.B ¶ 10.) In fact, her doctor “showed [her] pictures of [her] perforated uterus and tube and told [her] it was a result of Essure perforating [her] tube and uterus.” (Id., Ex. XLVII.A ¶ V.4.) However, her doctor also told her “that the small, flexible coils were made of safe material and would not cause [her] any medical problems but that removing them could.” (Id., Ex. XLVII.B ¶ 10; see also id., Ex. XLVII.A ¶ IV.1 (“[A]fter the birth of my 4th child . . . I requested removal but I was told it was too risky because Essure had ruptured my tube and uterus.”))

In 2014, T.M. was experiencing chronic fatigue, persistent and severe pelvic and abdominal pain, and other symptoms. (Id., Ex. XLVII.B ¶ 12.) She asked her doctor if the Essure coils were causing the problems, expressing “concern[] about the extruded Essure coils,” and her doctor told her that Essure was not the cause. (Id. ¶ 12; id., Ex. XLVII.C at 8.) Instead, her doctor suggested that her “symptoms were most likely GI in nature” and “possibly due to fibroids.” (Id., Ex. XLVII.B ¶ 12; id., Ex. XLVII.C at 5-6 ) After multiple trips to the doctor and an increase in the severity of her symptoms, her doctor scheduled a hysterectomy to address her “pelvic pain, menorrhagia, [and] displaced Essure.” (Id., Ex. XLVII.C at 8.) The doctor performed a hysterectomy and bilateral salpingectomy on May 22, 2014, which resulted in removal of the Essure coils. (Id., Ex. XLVII.B ¶¶ 13-14; id. Ex. XLVII.C at 8.) Within a few months, nearly every symptom had resolved and, according to T.M.’s own account, she “finally felt like [herself] again which confirmed that Essure was the cause of [her] pain and suffering.” (Id., Ex. XLVII.B ¶ 15.) At the same time, she states in her July 9, 2019 Declaration that she was contacted “several

years ago by a Conceptus and/or Bayer representative,” who told her that Essure was FDA approved and “convinced her that lawsuits related to FDA approved medical devices were impossible to maintain.” (*Id.* ¶¶ 16-17; but see *id.*, Ex. XLVII.A ¶ VI.6 (stating that T.M. had no communication oral or written with Defendants or their representatives).) She therefore states that she delayed contacting a lawyer until mid to late summer of 2014. (*Id.*, Ex. XLVII.B ¶ 17.) T.M. filed her claims on July 8, 2016.

The Special Master recommends that all of T.M.’s claims are time-barred. Specifically with regard to the tort claims, he recommends that we reject Plaintiffs’ argument that the two-year tort statute of limitation is tolled based on fraudulent concealment, observing that the alleged fraudulent concealment, i.e., the call with a Conceptus and/or Bayer representative, could not amount to fraudulent concealment as a matter of law because it does not relate to the cause of T.M.’s injuries.

Plaintiffs object to the Special Master’s recommendations concerning the timeliness of T.M.’s tort claims, arguing that the record presents a genuine dispute of material fact as to when T.M. knew or had reason to know with reasonable diligence that she had been injured by Essure, pointing to T.M.’s statement in her Declaration that her doctors “told [her] over and over that Essure was not the cause [of her fatigue, pain, and other symptoms in 2014].” (*Id.*, Ex. XLVII.B ¶ 12.) They argue, in the alternative, that the doctrine of fraudulent concealment operated to toll the limitations period because T.M.’s conversation with the Conceptus and/or Bayer representative caused her to delay contacting a lawyer. Plaintiffs specifically argue that the Special Master erred in reasoning that the statements by the company representative did not amount to fraudulent concealment because they did not cause her to relax her vigilance about the cause of her injuries,

asserting that the doctrine of fraudulent concealment applies any time that a statement causes a plaintiff to relax her vigilance or deviate from her right of inquiry into the facts.

We conclude, however, that, consistent with our March 2019 Opinion, when T.M. learned that she was pregnant and subsequently learned that one Essure coil was embedded in her uterus and the other had perforated her fallopian tube, she knew that she had been injured by Essure and the statute of limitations began to run. Although her doctor may have been telling her that her pain, fatigue and other symptoms were not caused by Essure, the fact that T.M. had not connected these additional injuries to her migrated coil and the second coil that had perforated her fallopian tube is inconsequential under Pennsylvania law, which states that the statute begins to run when a plaintiff has “‘actual or constructive knowledge of at least some form of significant harm and of a factual cause linked to another’s conduct, without the necessity of notice of the full extent of the injury.’” Gleason, 15 A.3d at 484 (quoting Wilson, 964 A.2d at 364.) Thus, a reasonable jury could only conclude that the statute of limitations began to run on Plaintiff’s tort claims in 2011, when she knew that she had suffered significant injuries (migration and perforation) as a result of Essure.

We also reject Plaintiffs’ argument that T.M.’s conversation with a Conceptus and/or Bayer representative “several years before 2019” constituted fraudulent concealment that renders her tort claims timely. As we explained in our March 2019 opinion, “a statute of limitations that is tolled by virtue of fraudulent concealment begins to run when the injured party knows or reasonably should know of [her] injury and its cause.” Fine, 870 A.2d at 861; see also Urland By & Through Urland v. Merrell-Dow Pharms., Inc., 822 F.2d 1268, 1273 (3d Cir. 1987) (stating that “the [Pennsylvania] Supreme Court . . . views tolling of the statute of limitations in terms of the same ‘knew or should have known’ standard whether the statute is tolled because of the discovery rule

or because of fraudulent concealment”). “Indeed, as a matter of pure logic, there can be no fraudulent concealment of something that is either already known or is reasonably knowable.” McLaughlin, 2019 WL 1382710, at \*9. Accordingly, because we have found that a reasonable jury could only conclude that T.M. knew in 2011 that she had been injured by Essure, even if a Conceptus or Bayer representative made a statement to her at some point in time that constituted fraudulent concealment and temporarily tolled the statute, the statute of limitations began to run in 2011 and expired long before T.M. filed suit in 2016. We therefore overrule Plaintiffs’ objections to the Special Master’s recommendations as to T.M., and we dismiss all of her claims as time-barred.

#### **5. S.J., R.C., and S.P.**

Plaintiffs briefly object to the Special Master’s recommendations regarding S.J., R.C., and S.P., asserting only that the Special Master found with respect to each of these plaintiffs in his September 2019 Report and Recommendation that there were genuine issue of material fact that precluded a time-bar, and then changed that recommendation in his October 2019 Amended Report and Recommendation. According to Plaintiffs, “[t]he very fact that he reached a different conclusion on two readings of the same record demonstrates that there are indeed genuine issues of fact for the jury.” (Pls.’ Objs. at 10.) Plaintiffs do not elaborate any further on their arguments. Nevertheless, we have conducted a de novo review of these three plaintiffs’ claims and the records underlying them, and we overrule Plaintiffs’ objections to the Special Master’s amended recommendations as to these three plaintiffs.

##### **a. S.J.**

With respect to Plaintiff S.J., the Special Master initially recommended, without explanation, that there was a genuine dispute of material fact that prevented S.J.’s tort claims from

being dismissed as time-barred. In his Amended Report and Recommendation, he recommends, based on a “close and fair reading of th[e] record,” that there is no genuine dispute of material fact that the tort claims are time-barred, stating that the undisputed evidence is that S.J. was advised by her doctor that her injuries were Essure-related more than two years before she filed suit, and that no doctor ever informed her that there was another cause for her injuries. (Amended R&R at 10) While the Special Master also notes that S.J. states in a Declaration that she had a hysterectomy because of an infection (a point that Plaintiffs emphasized in their earlier briefing), he recommends that she at no point states that the infection was not Essure-related and, thus, this Declaration statement does not create a genuine dispute of material fact.

On de novo review, we reach the same conclusion as the Special Master reached in his Amended Report and Recommendation. S.J. had her Essure placed in June of 2010. (Show Cause Addendum, Ex. XXIII.A, ¶ III.2.) She asserts that she “had an allergic reaction to the Essure coils six hours after the Essure were implanted.” (Id. ¶ V.9.) She “became ill immediately, developed a skin rash, and had a fever of 103 degrees” and was treated with antibiotics. (Id.) Also in June of 2010, she began experiencing unusual bleeding, back pain, abdominal pain, and cramping that she suspected were Essure-related. (Id. ¶¶ V.1, V.4.) In July of 2012, her doctor confirmed that her unusual bleeding was Essure-related. (Id. ¶ V.4.) Her doctor conducted an ultrasound and concluded that she had an enlarged uterus and had developed an infection, for which he prescribed antibiotics. (Id., Ex. XXIII.B ¶ 2.) However, the infection got worse, and her doctor subsequently told her that a hysterectomy was necessary. (Id.) In July of 2012, she had a hysterectomy that removed the Essure coils. (Id., Ex. XXIII.A ¶¶ V.2, IV.2.) As S.J. explains: “I only had the coils

in for 11 months. I developed [an] infection and had them removed.”<sup>13</sup> (Id. ¶ 5.) She states that the reason for the hysterectomy was an “Enlarged Uterus, abnormal bleeding and Essure removal.” (Id., Ex. XXIII.A ¶¶ VII.4, IV.2.) S.J. states in her Declaration that, prior to the removal of Essure, no doctor had informed her that the need for removal was for a reason independent of her Essure coils or for any reason unrelated to Essure. (Id., Ex. XXIII.B ¶ 1.) The unusual bleeding, back pain, abdominal pain and cramping that she had been experiencing ceased immediately after the removal. (Id., Ex. XXIII.A ¶¶ IV.4, V.11.) She filed her claims five and a half years later, in January of 2018.

Under these circumstances, the undisputed evidence establishes that S.J. had an unrebutted suspicion that she had been injured by Essure and that her doctor performed a hysterectomy in July of 2012 to, among other things, remove the Essure coils and address unusual bleeding that he told her was Essure-related. Thus, a reasonable jury could only conclude that, no later than July of 2012, S.J. was on inquiry notice that she had been injured by Essure. We therefore overrule Plaintiffs’ objections to the Special Master’s recommendation in his Amended Report and Recommendation that S.J.’s tort claims are untimely.

b. R.C.

With regard to Plaintiff R.C., the Special Master initially recommended that there was a genuine dispute of material fact as to R.C.’s non-pregnancy-related tort claims as well as her warranty claims, such that none of those claims should be time-barred. He provided no explanation as to his recommendation regarding the warranty claims. In his Amended Report and

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<sup>13</sup> It is not clear why S.J. states that she only had the coils for eleven months, when the remainder of the record supports only the conclusion that she had the coils for more than two years (June 2010-July 2012). However, this factual disparity is not material to the issues presently before us.

Recommendation, the Special Master recommends, again without explanation, that there is no genuine issue of material fact as to the warranty claims.

On de novo review, we agree with the Special Master's amended recommendation regarding the warranty claims. As we explained in our March 2019 Opinion, we apply a four-year statute of limitation to warranty claims, and the statute begins to run for all claims involving non-extended warranties on the date of implantation. See Mclaughlin, 2018 WL 1382710, at \*7-9 (citing 13 Pa. Cons. Stat. § 2725(b)) (additional citations omitted). On the other hand, we held that warranties that promise permanent birth control are extended warranties for which the statute of limitations begins to run when the breach of the warranty is discovered. See id. Here, the undisputed evidence is that R.C. had her Essure device placed in September of 2010, first got pregnant in 2012, and filed suit in March of 2018. (Show Cause Addendum, Ex. XL.A ¶¶ III.2, V.7.) Thus, her non-extended warranty claims are time-barred because they were filed more than four years after implantation of the Essure device, and her extended warranty claims are time-barred because they were filed more than four years after R.C. learned that she was pregnant.<sup>14</sup>

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<sup>14</sup> Plaintiffs had previously argued that the statute of limitations on R.C.'s warranty claims was tolled on account of fraudulent concealment. They pointed to evidence that R.C. had a conversation with a Conceptus representative about becoming pregnant in 2014, after R.C. had twice become pregnant, in which the representative told R.C. that it was impossible to become pregnant while implanted with Essure, that Essure did not cause pregnancies, and that, if she had become pregnant, it was due to her doctor improperly implanting the devices. (Show Cause Addendum, Ex. XL.B. ¶ 20; but see Defs.' Objs., Ex. V ¶ VI.6 (stating that R.C. had no communications with Defendant or their representatives).) These statements, on their face, only concern warranties concerning permanent birth control, and thus have no relevance to R.C.'s claims concerning the non-extended warranties. Moreover, they cannot constitute fraudulent concealment that tolls the statute of limitations on the extended warranty claims because, even accepting that they were made, a reasonable jury could only conclude that R.C. knew in 2012 that the Essure warranties promising permanency had been breached and that she had been injured as a result of that breach insofar as she had become pregnant. Fine, 870 A.2d at 861 (“[A] statute of limitations that is tolled by virtue of fraudulent concealment begins to run when the injured party knows or reasonably should know of his injury and its cause.”) Thus, the Special Master did not

Accordingly, we overrule Plaintiffs' objection to the Special Master's amended recommendation regarding R.C.'s warranty.

c. S.P.

With respect to Plaintiff S.P., the Special Master initially recommended, with no explanation, that there was a genuine dispute of material fact as to S.P.'s tort claims concerning her left coil and that, as a result, we should not find those claims to be time-barred. In his Amended Report and Recommendation, the Special Master recommends that there is no genuine issue of material fact as to S.P.'s left coil tort claim and that those claims are therefore time-barred. In making his amended recommendation, he emphasizes that S.P.'s medical notes reflect that her doctor recommended removal of the left coil on July 1, 2014, after speaking with an out-of-town specialist who suggested that removal of the left coil might alleviate S.P.'s symptoms. The Special Master recommends that this conversation put S.P. on inquiry notice that Essure was causing her ongoing symptoms, and that because she did not file suit until two years and seven days later, her tort claims related to her left coil are time-barred. (Amended R&R at 16.) Plaintiffs are not pursuing claims with regard to S.P.'s right coil and, thus, only challenge the Special Master's recommendations regarding the tort claims associated with the left coil.

S.P. had her Essure placed on June 12, 2010. (Show Cause Addendum, Ex. XLVI.A ¶ III.2.) She had an HSG test on September 27, 2010 and was told that both fallopian tubes were obstructed. (Id., Ex. XLVI.B ¶ 6.) After experiencing pain and bleeding, she had a hysterectomy and a dilation and curettage (D&C) on January 19, 2011, during which her doctor "observed an Essure guidewire in the right fallopian tube and that the end of the right Essure may have been

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err in failing to find that R.C.'s warranty claims might be saved from the time-bar on account of fraudulent concealment.

misplaced as it appeared to be doubled over.” (Id. ¶¶ 5, 7, 16; id., Ex. XLVI.A ¶ IV.2 (stating that right Essure coil had “migrat[ed] into [her] uterus”).) The doctor therefore removed the right Essure guidewire and coil in that procedure. (Id., Ex. XLVI.B ¶ 8.) S.P. subsequently became pregnant twice, in 2011 and 2013. (Id. ¶¶ 12, 15.)

On May 20, 2014, S.P. visited her doctor for a pelvic pain consult. (Id., Ex. ¶ XLVI.C at 1.) Her doctor believed that she was suffering from pelvic inflammatory disease/endometriosis or appendicitis. (Id. at 3; see also id., Ex. XLVI.B ¶ 17.) On May 28, 2014, to treat the pelvic pain, S.P. underwent another hysteroscopy and D&C, and a lysis of adhesions. (Id., Ex. ¶ XLVI.C at 4.) Notes from a post-op visit on July 1, 2014, however, state that S.P. attributed her pain and bleeding to a nickel allergy associated with Essure. (Id.) Those same notes state that S.P.’s doctor reached out to an out-of-town doctor who was “familiar with patients with similar adverse reactions to Essure coil inserts. He stated patient[s]’ symptoms resolved following removal of implants, alone or with hysterectomy, as if these patient[s] had a nickel allergy/reaction.” (Id. at 6.) The July 1 notes recount that S.P.’s doctor had “extensive discussion” with S.P. and that the doctor recommended “attempt at salpingectomy . . . with removal of remaining (L) coil.” (Id.; see also id., Ex. XLVI.B ¶ 20 (stating that this discussion took place “[o]n or about July 13, 2014”). S.P. had her fallopian tubes and left Essure coil removed in bilateral salpingectomy surgery on July 16, 2014. (Id., Ex. XLVI.A ¶ IV.2; but see id., Ex. XLVI.B ¶ 21 (stating that she had bilateral salpingectomy on July 16, 2016).) Within a few weeks, all of her symptoms resolved. (Id. ¶ 22.) She filed her claims in this case on July 8, 2016.

Upon de novo review, we reach the same conclusion as the Special Master reached in his Amended Report and Recommendation -- that a reasonable jury could only conclude based on the undisputed evidence that, on July 1, 2014, S.P. knew or had reason to know with reasonable

diligence that she had been injured by her left Essure coil in light of her doctor's advice to have the coil removed to address her pelvic pain and possible nickel allergy.<sup>15</sup> We therefore overrule Plaintiffs' objections to the Special Master's recommendation that the tort claims concerning the left coil that S.P. made on July 8, 2016 were barred by the two-year statute of limitations.

#### IV. CONCLUSION

For the foregoing reasons, we sustain Bayer's Objections in part and overrule them part, and sustain Plaintiffs' Objections in part and overrule them in part. Specifically, we sustain Bayer's Objections as to the Special Master's recommendations that (1) S.H.'s tort claims are not time-barred; (2) S.G.'s non-pregnancy-related tort claims are not time-barred, and (3) J.H.'s tort claims concerning her left coil are not time-barred. We overrule Bayer's objections in all other respects.

We sustain Plaintiffs' Objections as to the Special Master's recommendations that (1) E.H.'s non-pregnancy-related tort claims are time-barred, and (2) S.C.'s tort claims for injuries from her left coil are time-barred. We overrule Plaintiffs' Objections in all other respects.

An appropriate Order follows.

BY THE COURT

/s/ John R. Padova, J.

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John R. Padova, J.

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<sup>15</sup> We recognize that S.P. stated in a Declaration that her doctor advised her "[o]n or about July 13" about her conversation with her colleague and recommended at that time that S.P. undergo a salpingectomy. (Show Cause Addendum, Ex. XLVI.B ¶ 20.) However, given the plainly-dated medical records and the uncertain nature of the date in S.P.'s account ("[o]n or about"), we conclude that the Declaration creates no genuine dispute that the conversation occurred on July 1, which was more than two years before she filed her claims.

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

HELEN McLAUGHLIN	:	CIVIL ACTION NO. 14-7315	
	:		
v.	:		
	:	NO. 14-7316 (Ruble)	NO. 16-3732 (Gross)
BAYER ESSURE, INC., et al.	:	NO. 14-7318 (Stelzer)	NO. 16-3733 (Johnson)
	:	NO. 14-7317 (Strimel)	NO. 16-3766 (Summerlin)
And Related Actions	:	NO. 15-0384 (Walsh)	NO. 16-3767 (Rodvill)
	:	NO. 16-1458 (Dunstan)	NO. 16-3769 (Quinton)
	:	NO. 16-1645 (Clarke)	NO. 16-4081 (Bradford)
	:	NO. 16-1921 (Souto)	NO. 17-2915 (Wistrom)
	:	NO. 16-2166 (Bailey)	NO. 17-3968 (Bobo)
	:	NO. 16-2154 (Campos)	NO. 17-4417 (Guess)
	:	NO. 16-2717 (Bolds)	NO. 17-4936 (Gonzalez)
	:	NO. 16-3049 (Tulgetske)	NO. 18-37 (Jenson)
	:	NO. 16-3409 (Abeyta)	NO. 18-836 (Morua)
	:	NO. 16-3589 (Burgis)	NO. 18-837 (Galan)
	:	NO. 16-3710 (Dong)	NO. 18-838 (Alfaro)
	:	NO. 16-3730 (Mantor)	NO. 18-908 (Archer)
	:	NO. 16-3731 (Olague)	

**ORDER**

**AND NOW**, this 2nd day of April, 2020, upon consideration of “Plaintiffs’ Objections to Portions of the Special Master’s October 21, 2019 Amended Report and Recommendation” (Docket No. 525 in McLaughlin), “Defendants’ Objections to Special Master’s Amended Report & Recommendation” (Docket No. 521 in McLaughlin), and all documents filed in connection with both sets of Objections, and for the reasons set forth in the accompanying Memorandum, **IT IS HEREBY ORDERED** that both sets of Objections are **GRANTED IN PART** and **DENIED IN PART** as follows:

1. Plaintiffs’ Objections are **SUSTAINED** insofar as they object to the Special Master’s recommendations that (1) E.H.’s non-pregnancy-related tort claims are time-barred; and (2) S.C.’s tort claims for injuries from her left coil are time-barred.
2. Plaintiffs’ Objections are **OVERRULED** in all other respects.

3. Bayer's Objections are **SUSTAINED** insofar as they object to the Special Master's recommendations that (1) S.H.'s tort claims are not time-barred; (2) S.G.'s non-pregnancy-related tort claims are not time-barred; and (3) J.H.'s tort claims concerning her left coil are not time-barred.
4. Bayer's Objections are **OVERRULED** in all other respects.

BY THE COURT

/s/ John R. Padova, J.

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John R. Padova, J.