

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

HELEN McLAUGHLIN	:	CIVIL ACTION NO. 14-7315	
	:		
v.	:		
	:		
BAYER ESSURE, INC., et al.	:	NO. 14-7316 (Ruble)	NO. 16-3732 (Gross)
	:	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)	

**MEMORANDUM**

**Padova, J.**

**March 27, 2019**

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 various Bayer entities (collectively, “Bayer”).<sup>1</sup> Bayer has filed a Motion for Partial Summary Judgment, seeking judgment in its favor on the tort and warranty claims of twelve individual Plaintiffs on statute of limitations grounds. Bayer organizes the twelve Plaintiffs into three groups: (1) those who had their Essure devices removed more than two years before filing suit; (2) those who suffered Essure-related injuries more than two years

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<sup>1</sup> Plaintiffs are not consistent as to which Bayer entities they are suing. In McLaughlin v. Bayer Essure, Inc., Civ. A. No. 14-7315, the plaintiff asserts claims only against Bayer Essure, Inc., and Bayer Healthcare Pharmaceuticals, Inc. In contrast, in Bailey v. Bayer Corp., Civ. A. No. 16-2166, the plaintiffs assert claims against Bayer Corp., Bayer Healthcare LLC, Bayer Essure, Inc., and Bayer Healthcare Pharmaceuticals, Inc. The parties do not ask us to distinguish among the various Bayer entities and, therefore, we do not distinguish among them in this Opinion.

before filing suit; and (3) those who believed that their injuries were Essure-related more than two years before filing suit.<sup>2</sup> We held argument on Bayer’s Motion on February 11, 2019. For the following reasons, we grant Bayer’s Motion in part and deny it in part, concluding that the tort claims of six of the twelve Plaintiffs are time-barred, and that some or all of the warranty claims of nine of the twelve Plaintiffs are time-barred.

## I. BACKGROUND

The FDA granted premarket approval for Essure, a Class III medical device, on November 4, 2002. (Defs.’ Ex. A.) At the same time, it approved the 2002 Essure Patient Information Booklet (“PIB”) and 2002 Instructions for Use (“IFU”).<sup>3</sup> (Defs.’ Concise Statement of Material Facts (“SMF”) ¶¶ 6-7.) The 2002 PIB described Essure as “a new method of permanent birth control” that “involves placing a small, flexible device called a micro-insert into each . . . fallopian tube[.]” (Defs.’ Ex. E at 4.) “Once the micro-inserts are in place, body tissue grows into the micro-inserts, blocking the fallopian tubes . . . , thereby preventing pregnancy.” (*Id.*) The 2002 PIB stated that the risks of Essure include the micro-inserts being “poked through the wall of the fallopian tube or uterus (perforation),” “com[ing] out of the body (expulsion),” or being “in the body, but outside the fallopian tube.” (*Id.* at 14.) It also identified as a risk “[p]elvic/back/abdominal pain” and bleeding, but added that “[v]ery few women reported

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<sup>2</sup> Given that there are over 1,000 Plaintiffs in this consolidated action, the parties have agreed to use the Court’s statute of limitations rulings on these twelve exemplar Plaintiffs as guidance in negotiating resolution of statute of limitations issues with respect to the remaining Plaintiffs.

<sup>3</sup> Plaintiffs “dispute whether or not the FDA ‘approved . . .’ [the] document[s] until further discovery is taken.” (Pls.’ Resp. to SMF ¶¶ 6-18.) However, Bayer establishes by way of declaration that both documents were approved by the FDA and are available on the FDA’s website. (Curtin Decl., attached as Ex. A to Defs.’ Reply SMF, ¶¶ 2-3.)

persistent pain” during the clinical trials. (Id. at 16.) The 2002 PIB also stated that “there is a small chance that you can become pregnant.” (Id. at 5; see also id. at 16.) Similarly, the 2002 IFU advised that potential adverse events not observed in the clinical studies included pregnancy and “perforation of internal body structures other than the uterus and fallopian tube” and also stated that “[a] very small percentage of women in the Essure clinical trials reported recurrent or persistent pelvic pain.” (Defs.’ Ex. F at 7, 12.) Both the PIB and the IFU were revised numerous times over the years, with the PIB undergoing revisions in 2004, 2006, 2011, 2012, 2013, 2015, and 2016, and the IFU undergoing revisions in 2008, 2011, 2012, and 2016. (See Defs.’ Exs. G-Q.) Thus, the precise information any woman may have received regarding Essure prior to implantation and after depends upon the precise date on which her Essure was implanted.

On September 24, 2015, the FDA convened an Advisory Committee Meeting. See FDA Activities, U.S. Food & Drug Admin., <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452254.htm> (last visited Mar. 19, 2009). Feedback from that meeting as well as comments from the public “indicated that medical device labeling for permanent birth control methods, including Essure, [was] not clear and many patients do not receive enough information before making a decision.” Id. “Panel members recommended changes to the patient and physician labeling and more aggressive methods to ensure patients are well-informed of risks before choosing a permanent birth control method.” Id. Among other things, the FDA recommended “[a] boxed warning with safety statements to better communicate to patients and providers the significant side effects or complications associated with these devices and information about the potential need for removal.” Id. It also recommended a “Decision Checklist with key items about the device, its use and safety and effectiveness outcomes,

which the patient should be aware of as they consider permanent birth control options.” Id. In 2016, the IFU therefore included the following “black box” warning:

WARNING: Some patients implanted with the Essure System for Permanent Birth Control have experienced and/or reported adverse events, including perforation of the uterus and/or fallopian tubes, identification of inserts in the abdominal or pelvic cavity, persistent pain, and suspected allergic or hypersensitivity reactions. If the device needs to be removed to address such an adverse event, a surgical procedure will be required. This information should be shared with patients considering sterilization with the Essure System for Permanent Birth Control during discussion of the benefits and risks of the device.

(Pls.’ Ex. 49 at 1.)<sup>4</sup>

Plaintiffs are women who allege that they have suffered various injuries on account of their use of Essure. They assert claims for negligent training, failure to warn, negligent risk management, breach of express warranty, negligent misrepresentation, and fraudulent misrepresentation. The negligent training claim alleges that Bayer negligently failed to adequately train the implanting physicians. The failure to warn claim primarily alleges that Bayer failed to “advise the FDA of thousands of adverse events, which in turn were never reported to the public database or the implanting physician.” McLaughlin v. Bayer Corp., 172 F. Supp. 3d 804, 837 (E.D. Pa. 2016). The negligent risk management claim alleges that Bayer failed to adequately investigate and evaluate the risks of Essure and, as a result, failed to report all adverse events and complaints to the FDA. See McLaughlin v. Bayer Corp., Civ. A. No. 14-7315, 2017 WL 697047, at \*7-8 (E.D. Pa. Feb. 21, 2017)

The breach of express warranty claim is grounded on the following 20 alleged warranties:

- “Only FDA approved female sterilization to have zero pregnancies in the clinical trials.” (McLaughlin Am. Compl. ¶ 181(a), ECF No. 242, Civ. A. No. 14-7315.)

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<sup>4</sup> Plaintiffs refer to their exhibits with numbers that do not correspond to the tabs in their Exhibit binder. We refer to the exhibits by the numbers on the corresponding tab.

- “There were [z]ero pregnancies in the clinical trials.” (Id. ¶ 181(b).)
- “Physicians must be signed-off to perform Essure procedures.” (Id. ¶ 181(c).)
- “Worry free: Once your doctor confirms that your tubes are blocked, you never have to worry about unplanned pregnancy” (¶ 181(d).)
- “Essure is the most effective permanent birth control available-even more effective than tying your tubes or a vasectomy.” (¶ 181(e).)
- “Correct placement . . . is performed easily because of the design of the micro-insert.” (Id. ¶ 181(f).)
- “Essure is a surgery-free permanent birth control.” (Id. ¶ 181(g).)
- “Zero pregnancies” in its clinical or pivotal trials. (Id. ¶ 181(h).)
- In order to be identified as a qualified Essure physician, a minimum of one Essure procedure must be performed every 6-8 weeks. (Id. ¶ 181(i).)
- You’ll never have to worry about unplanned pregnancy again. (Id. ¶ 181(j).)
- “[T]he tip of each insert remains visible to your doctor, so proper placement can be confirmed.” (Id. ¶ 181(k).)
- “Worry free” (Id. ¶ 181(l).)
- “The Essure inserts stay secure, forming a long protective barrier against pregnancy. They also remain visible outside your tubes, so your doctor can confirm that they’re properly in place.” (Id. ¶ 181(m).)
- “The Essure inserts are made from the same trusted, silicone free material used in heart stents.” (Id. ¶ 181(n).)
- Step Two: “pregnancy cannot occur”; Step Three: The Confirmation. (Id. ¶ 181(o).)
- “Essure eliminates the risks, discomfort, and recovery time associated with surgical procedures.” (Id. ¶ 181(p).)
- Essure is a . . . permanent birth control procedure-without . . . the risks of getting your tubes tied. (Id. ¶ 181(q).)
- “The inserts are made from . . . safe, trusted material.” (Id. ¶ 181(r).)
- “This viewable portion of the micro-insert serves to verify placement and does not

irritate the lining of the uterus.” (Id. ¶ 181(s).)

- “[T]here was no cutting, no pain, no scars.” (Id. ¶ 181(t).)<sup>5</sup>

The negligent misrepresentation claim is grounded on four of the same statements that are alleged to be warranties (id. ¶ 197(a)-(d)), and the fraudulent misrepresentation claim is grounded on three of those four statements (id. ¶ 213(a)-(c)).

As noted above, Bayer has filed a Motion for Partial Summary Judgment in which it moves for summary judgment on statute of limitations grounds, seeking judgment in its favor on the claims of twelve exemplar Plaintiffs.

## **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).

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<sup>5</sup> We express no opinion at this time as to whether all of these representations constitute enforceable warranties under Pennsylvania law. Rather, we assume that they do for purposes of this Motion and our analysis of the statute of limitations issues.

“[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<sup>6</sup>**

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

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<sup>6</sup> Although the twelve exemplar Plaintiffs hail from eleven different states, the parties have agreed to the application of the Pennsylvania statute of limitations law to resolve this Motion. (See N.T. 2/11/19, at 4-6.)

is four years.<sup>7</sup> 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).

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<sup>7</sup> Bayer has argued that the breach of express warranty claims in this case should be governed by the two-year statute of limitations for tort claims because the warranty claims, like the tort claims, seek damages for personal injury. In support of this argument, Bayer cites two Pennsylvania cases that suggest that any claim seeking damages for personal injuries, even if framed as a breach of warranty, is subject to the two-year statute of limitations for personal injury claims. (Defs.’ Resp. to Pls.’ Sur-Reply at 3 (citing Crumm v. K. Murphy & Co., 10 Pa. D. & C.5th 268, 276-78 (Lancaster Cty. Sept. 16, 2009), and Ritchey v. Patt, 636 A.2d 208, 210 (Pa. Super. Ct. 1994)). However, as the United States Court of Appeals for the Third Circuit has recognized, “[a] suit to recover damages for personal injuries arising from breach of warranty in the sale of goods must be commenced within the four year limitation period” applicable to breach of warranty claims. Jablonski v. Pan American World Airways, Inc., 863 F.2d 289, 291 (3d Cir. 1988) (citing Gardiner v. Phila. Gas Works, 197 A.2d 612 (Pa. 1964)). Indeed, the Pennsylvania Supreme Court, in Williams v. West Penn Power, 467 A.2d 811 (Pa. 1983), explicitly stated that the four-year statute of limitations applies to all breach of warranty actions brought under the Uniform Commercial Code, whether or not the warranty claim seeks to recover for personal injury. Id. at 818; see also White v. Hon Co., Civ. A. No. 11-4919, 2012 WL 1286404, at \*2-3 (E.D. Pa. Apr. 13, 2012) (citing Williams, 467 A.2d at 818)); Hartey v. Ethicon, Civ. A. No. 04-5111, 2006 WL 724554, at \*5 (E.D. Pa. Mar. 20, 2006) (“The statute of limitations for breach of warranty claims is four years, and this period is applicable to breach of warranty claims for personal injury.”). Here, Plaintiffs’ claims concern contracts for the sale of a good, i.e., Essure, and, thus, pursuant to Pennsylvania law as established by the Pennsylvania Supreme Court, the four-year statute of limitations in 13 Pa. Cons. Stat. § 2725 applies to the express warranty claims.



There are two potential avenues to the equitable tolling of claims: the discovery rule and fraudulent concealment. Fine, 870 A.2d at 858. The plaintiff bears the burden of establishing “that the discovery rule applies and that the time for bringing suit has been tolled.” Billeci, 2018 WL 1635242, at \*4 (citing Cochran, 666 A.2d at 858) (additional citation omitted). The plaintiff also bears the burden of establishing fraudulent concealment. Fine, 870 A.2d at 860.

### 1. Discovery Rule – Tort Claims

The discovery rule is an exception to the statute of limitations for tort claims that applies “[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, 365 (Pa. 2009) (citing Fine, 870 A.2d at 859). Where the injury or its cause was neither known nor knowable with the exercise of reasonable diligence, see 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). 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.”<sup>8</sup> Gleason v. Borough of Moosie, 15

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<sup>8</sup> Pennsylvania’s prevailing formulation of the discovery rule is narrow in comparison to that in other jurisdictions. Gleason v. Borough of Moosie, 15 A.3d 479, 484 (Pa. 2011) (“Pennsylvania’s formulation of the discovery rule reflects a narrow approach ‘to determining accrual for limitations purposes’ and places a greater burden upon Pennsylvania plaintiffs vis-à-vis the discovery rule than most other jurisdictions.” (quoting Wilson, 964 A.2d at 364)). For this reason (and others), many of the authorities on which Plaintiffs rely in their briefing – which apply the law of, inter alia, Kentucky, California, and Florida – are simply inapposite. (See Pls.’ Resp. Mem. at 3 n.9, 4-5 (citing, e.g., Patterson v. Bayer, Civ. A. No. 15-48, 2018 WL 1906102 (E.D. Ky. Apr. 23, 2018), and Bianchi v. Bayer Essure Inc., Case No. RG16809860, Slip Op. (Alameda County Super. Ct. Cal. Aug 2. 2016) (attached as Ex. 1 to Pls.’ Resp.)); Pls.’ Sur-Reply Br. at 6

A.3d 479, 484 (Pa. 2011) (quoting Wilson, 964 A.2d at 364); Zelesnik 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 sometimes 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).

In cases involving medical devices, the question regarding cause under Pennsylvania law is whether a plaintiff knows or has reason to know that the device caused her injury, not whether plaintiff has actual or constructive knowledge as to precisely how or why her injury occurred. See Adams v. Zimmer US, Inc., Civ. A. No. 17-621, 2018 WL 3913749, at \*9-10 (E.D. Pa. Aug. 14, 2018) (analyzing when plaintiff knew or should have known that her injuries were caused by hip prosthesis), appeal docketed, No. 18-3011 (3d Cir. Sept. 13, 2018); Hartey v. Ethicon, Inc., 2006 WL 724554, at \*3-4 (E.D. Pa. Mar. 20, 2006) (considering when plaintiff knew or should have known that her injuries were caused by Mersilene mesh); Dreischalick v. Dalkon Shield Claimants Trust, 845 F. Supp. 310, 315 (W.D. Pa. 1994) (considering when plaintiff knew or should have known of a possible causal relationship between her IUD and her ectopic pregnancy); see also Juday v. Merck & Co., 730 F. App’x 107, 110-11 (3d Cir. Apr. 4, 2018) (considering when plaintiff knew or should have known that his injury was caused by Zostavax vaccine); Gleason, 15 A.3d at 484-486 (considering when plaintiffs were on inquiry notice that mold was the factual cause of their injuries); Debiec, 352 F.3d at 120 (considering when plaintiff knew or should have known that their injuries were caused by exposure to beryllium).

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(citing In re Mentor Corp. Obtape Tranobturator Sling Prods. Liability Litig., 748 F. Appx. 212 (11th Cir. 2018)).)

In assessing a plaintiff's discovery rule argument, the critical question is often "not what the plaintiff actually knew of the injury or its cause, but what [s]he might have known by exercising the diligence required by the law." Nicolaou, 195 A.3d at 893 (citing Gleason, 15 A.3d at 485; Fine 870 A.2d at 858-59); Gleason, 15 A.3d at 485 (stating that the question is "whether, during the limitations period, the plaintiff was able, through the exercise of reasonable diligence," to identify her injury and its cause (emphasis added)). The reasonable diligence standard is objective, but "is 'sufficiently flexible . . . to take into account the differences between persons and their capacity to meet certain situations and the circumstances confronting them at the time in question.'" Nicolaou, 195 A.3d at 893 (quoting Fine, 870 A.2d at 858)). Thus, it "is to be applied with reference to individual characteristics." Id. (quoting Wilson, 964 A.2d at 366). In explaining what is meant by "reasonable diligence," the Pennsylvania Supreme Court has explained:

"There are very few facts which diligence cannot discover, but there must be some reason to awaken inquiry and direct diligence in the channel in which it would be successful. This is what is meant by reasonable diligence." Put another way, "the question in any given case is . . . what might [the plaintiff] have known [about the injury done to him], by the use of the means of information within his reach, with the vigilance the law requires of him?" While reasonable diligence is an objective test, "it is sufficiently flexible . . . to take into account the difference[s] between persons and their capacity to meet certain situations and the circumstances confronting them at the time in question." Under this test, a party's actions are evaluated to determine whether he exhibited "those qualities of attention, knowledge, intelligence and judgment which society requires of its members for the protection of their own interest and the interest of others."

Gleason, 15 A.3d at 485 (quoting Fine, 870 A.2d at 858 (fourth and fifth alterations in original) (citations and quotations omitted)); see also Cochran, 666 A.2d at 249 ("Reasonable diligence is just that, a reasonable effort to discover the cause of an injury under the facts and circumstances present in the case." (citation omitted)). Notably, "a diligent investigation may require one to seek further medical examination as well as competent legal representation." Cochran, 666 A.2d at 249.

The injured party need not have obtained a precise medical diagnosis or “understand [that] she has a cause of action” in order for the statute to start running. Wilson, 964 A.2d at 364 n.10, 365. However, “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 “decline[d] to hold, as a matter of law, that a lay person must be charged with knowledge greater than that which was communicated to her by multiple medical professionals involved in her treatment and diagnosis.” Wilson, 964 A.2d at 365 (citing Bohus, 950 F.2d at 929-30). 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 (alterations in original) (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)). A “plaintiff’s reliance on [her doctor’s] assurances bec[omes] unreasonable as soon as she [loses] confidence in the [doctor’s] professional ability.” Bohus, 950 F.2d at 929 (citing Held v. Neft, 507 A.2d 839, 843 (Pa. Super. Ct. 1987)); but see id. at 927, 930 (explaining that where a plaintiff obtains additional opinions that confirm her first doctor’s prognosis, agree that the first doctor’s treatment was “reasonable,” and tell the plaintiff that her symptoms are normal and will subside, the plaintiff may be justified in relying on her first doctor’s assurances).

As noted above, “[p]laintiffs 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” to “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 \*5-6 (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)).

“The 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.”<sup>9</sup> Wilson, 964 A.2d at 362 (citations omitted).

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<sup>9</sup> Bayer suggests that a plaintiff’s discovery rule arguments may be rejected for the simple fact that the plaintiff did not exercise reasonable diligence, irrespective of whether, with reasonable diligence, the plaintiff would have had reason to know of her injury and its cause within the limitations period. Bayer has not cited any compelling and conclusive Pennsylvania authority in support of such a rule. Furthermore, we have considerable difficulty reconciling such an approach with the discovery rule itself, which is premised on the understanding that when an injury or its cause is not discoverable, an injured party should not be penalized for failing to discover it. See, e.g., Ayers v. Morgan, 154 A.2d 788, 789 (Pa. 1959) (“[I]t would be illogical and unintelligent to say that a person who does not know, and cannot know, for example, that a surgeon has negligently left a rubber tube in his body, would be denied damages because his claim for damages was filed . . . more than two years after the operation.”). In any event, the question of whether a party exercised reasonable diligence is fact-intensive and almost always left for the jury, Nicolaou, 195 A.3d at 893 (citing Wilson 964 A.2d at 362), and, as a result, the instant motion presents us with no opportunity to apply the rule that Bayer suggests.

## 2. Warranty Claims – Non-applicability of Discovery Rule

Breach of warranty claims, unlike negligence claims, are not subject to the discovery rule. White v. Hon Co., Civ. A. No. 11-4919, 2012 WL 1786404, at \*4 (E.D. Pa. Apr. 13, 2012) (“The tort discovery rule does not apply to breach of warranty actions.” (citing Northampton Cty. Area Cmty. Coll. v. Dow Chem., U.S.A., 566 A.2d 591, 599 (Pa. Super. Ct. 1989)); Hartey, 2006 WL 724554, at \*5. “[W]arranty claims [generally] accrue on the date that the seller tenders delivery of the goods.” Hartey, 2006 WL 724554, at \*5 (quoting Pitts v. N. Telecom, Inc., 24 F. Supp. 2d 437, 443 (E.D. Pa. 1998)); 13 Pa. Cons. Stat. § 2725(b) (stating that cause of action for breach of warranty accrues when “tender of delivery is made”). “This is true ‘even if the alleged breach is not apparent until after delivery has been tendered.’” Id. (quoting Hornberger v. Gen. Motors Corp., 929 F. Supp. 884, 888 n.2 (E.D. Pa. 1996)); Patton v. Mack Trucks, Inc., 519 A.2d 959, 964-65 (Pa. Super. Ct. 1986) (stating that “the aggrieved party’s knowledge or ability to know [of the breach] is irrelevant,” and it simply does not matter “that the aggrieved party cannot possibly discover the breach until after tender of delivery”).

Where, however, “a warranty explicitly extends to future performance of the goods,” the cause of action will not accrue “until the breach is or should have been discovered.” 13 Pa. Cons. Stat. § 2725(b). “An analysis of whether a ‘warranty explicitly extends to future performance must focus on the express language of the warranty.’” McPhee v. DePuy Orthopedics, Inc., 989 F. Supp. 2d 451, 464 (W.D. Pa. 2012) (quoting Nationwide Ins. Co. v. Gen. Motors Corp./Chevrolet Motor Div., 625 A.2d 1172, 1175 (Pa. 1993)). Thus, “an extension of a warranty ‘will not be permitted except in those instances in which there is a clear and unambiguous expression of an intent that the warranty shall pertain to future performance.’” Zawadski v. Ethicon, Inc., Civ. A. No. 92-6453, 1994 WL 77350, at \*3 (E.D. Pa. March 11, 1994) (quoting Ranker v. Skyline Corp.,

493 A.2d 706, 709 (Pa. Super. Ct. 1985)). Moreover, “[t]he focus of § 2725 is not on *what* is promised, but on the duration of the promise-*i.e.*, the period to which the promise extends.” Nationwide, 625 A.2d at 1176 (citation omitted). In other words, the word “explicitly” modifies the word “extends,” not the word “warranty” and, thus, it is the extension that must be explicit. Id. (citing Safeway Stores, Inc. v. Certainteed Corp., 710 S.W.2d 544, 549 (Tex. 1986)). Applying this understanding, the Pennsylvania Supreme Court has concluded that an automobile warranty that states that it is “for 12 months or 12,000” miles is a warranty that explicitly extends to future performance. Id.

In contrast, other courts have found less explicit warranties not to qualify as extended warranties. In doing so, they emphasize that warranty extensions are an exception to the general rule, which must be “strictly construed.” Zawadksi, 1994 WL 77350, at \*3; Horsmon v. Zimmer Holdings, Inc., Civ. A. No. 11-1050, 2012 WL 423434, at \*4 (W.D. Pa. Feb. 8, 2012) (observing that “nearly all warranties contain ‘promises regarding the manner in which the goods will perform after tender of delivery’” and that “[a]llowing a warranty to extend to future performance merely because it contains such promises ‘would allow the exception to swallow the rule’” (quoting Patton, 519 A.2d at 964)). Thus, “a bare statement of how a good will perform after delivery does not constitute an explicit extension forward,” particularly where it “fails to state clearly and unambiguously a period of time during which the warrant[y] will be in force.” Zawadksi, 1994 WL 77350, at \*5 (citing Patton, 519 A.2d at 964; and Nationwide, 625 A.2d at 1176) (additional citation omitted). Accordingly, a warranty that a suture will provide “lasting strength” without specifying a time period in which it will do so, and various warranties about a hip implant, including that the implant “could be held in place by a single screw,” that “[t]esting had shown that use of [the] implants was safe and effective,” and that the “implant would not fail,” were found

not to qualify as extended warranties under Pennsylvania law. Zawadski, 1994 WL 77350, at \*5; Horsmon, 2012 WL 423434, at \*2-4.

Here, Plaintiffs have argued that certain select warranties on which they base their claims constitute extended warranties. Specifically, they allege that warranties that extend to the future are those that promise “permanent birth control,” that Essure is “worry-free,” that the device is made from “safe, trusted material,” and that the inserts “stay secure.” (See Pls.’ Reply to Defs.’ Resp. to Pls.’ Sur-reply at 5; N.T. 2/11/19, at 75.) However, under the authority cited above, it is plain that the wholly generic warranties that Essure is “worry-free” and is made of “safe-trusted material,” and that the inserts “stay secure” are not extended warranties under Pennsylvania law because they are “bare statement[s] of how [the product] will perform after delivery,” Zawadski, 1994 WL 77350, at \*5 (citation omitted), and do not suggest a specific time-frame in which the promised performance is guaranteed and, as such, do not “explicitly extend to future performance.” 13 Pa. Cons. Stat. § 2725(b). On the other hand, for purposes of this Motion, we will consider the warranties that promise “permanent” birth control to be extended warranties because, at least on their face, they suggest a time frame in which they will be in effect, i.e., permanently.<sup>10</sup> C.f., Marvin Lumber & Cedar Co. v. PPG Indus., Inc., 223 F.3d 873, 880 (8th Cir. 2000) (holding that “[a] warranty for the ‘lifetime’ of a product . . . is enforceable as a future performance warranty” (citations omitted)).

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<sup>10</sup> The parties have not briefed the precise question of whether a warranty promising permanent birth control is an extended warranty under Pennsylvania law. In the absence of thorough briefing, we conclude that the permanence warranties constitute extended warranties for purposes of this Motion only.



### 3. Fraudulent Concealment

Under the rule of fraudulent concealment, “the defendant may not invoke the statute of limitations, if through fraud or concealment, he causes the plaintiff to relax his vigilance or deviate from his right of inquiry into the facts.” Fine, 870 A.2d at 860 (citation omitted). A plaintiff “bears the burden of proving fraudulent concealment by clear, precise, and convincing evidence.” Id. at 860.

Fraudulent concealment need not be intentional and includes unintentional deception. Id.; In re Risperdal Litigation, Nos. 576 EDA 2015, 590 EDA 2015, 2017 WL 5256400, at \*7 (Pa. Super. Ct. Nov. 13, 2017) (“The doctrine does not require proof of intent to deceive, but requires proof of an unintentional deception.”), pet. for allowance of appeal granted, Nos. 75-76 EAL 2018, 189 A.3d 376 (Pa. July 5, 2018). At the same time,

“[t]he defendant must have committed some affirmative independent act of concealment upon which the plaintiffs justifiably relied. Mere mistake or misunderstanding is insufficient. Also, mere silence in the absence of a duty to speak cannot suffice to prove fraudulent concealment.”<sup>[11]</sup>

Risperdal, 2017 WL 5256400, at \*7 (first alteration in original) (quoting McClellan v. Djerassi, 84 A.3d 1067, 1070 (Pa. Super. Ct. 2013)); see also Meehan v. Archdiocese of Phila., 870 A.2d 912, 921 (Pa. Super. Ct. 2005) (requiring plaintiff must show an “affirmative independent act of concealment upon which the plaintiff justifiably relied” (quoting Kingston Coal Co. v. Felton Mining Co., 690 A.2d 284, 290 (Pa Super. Ct. 1997))). Accordingly, to assert a viable claim of

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<sup>11</sup> Plaintiffs may be relying on Bayer’s concealment of information as a basis for their contention that Bayer engaged in fraudulent concealment. However, they do not cite any authority that supports the finding of a special relationship that would impose a duty on Bayer to warn or disclose. Moreover, “[t]o hold that a manufacturer has that type of special relationship with consumers would render the statute of limitations meaningless in a great number of products liability cases.” Arndt v. Johnson & Johnson, 67 F. Supp. 3d 673, 679 (E.D. Pa. 2014). Accordingly, we conclude that Plaintiffs cannot base any fraudulent concealment argument on a mere failure to disclose, without also pointing to an affirmative independent act of concealment.

fraudulent concealment based on affirmative misrepresentations, a plaintiff must identify specific misrepresentations on which she relied to her detriment, i.e., on which she relied in “relax[ing] [her] vigilance or deviat[ing] from [her] right of inquiry into the facts.” Fine, 870 A.2d at 860; Johnson v. SmithKline Beecham Corp., 55 F. Supp. 3d 603, 615-16 (E.D. Pa. 2014). Moreover, because fraudulent concealment must be based on “independent affirmative act[s] of concealment,” Arndt v. Johnson & Johnson, 67 F. Supp. 3d 673, 678 (E.D. Pa. 2014) (emphasis added) (citing Baselice v. Franciscan Friars Assumption BVM Province, Inc., 879 A.2d 270, 278 (Pa. Super. Ct. 2005)), the “affirmative efforts to divert, mislead, or prevent discovery” that give rise to the claim of fraudulent concealment must be “conduct independent of the . . . things about which the plaintiffs complain” in their causes of action. Overfield v. Pennroad Corp., 146 F.2d 889, 896 (3d Cir. 1944); see also Bailey v. Jacobs, 189 A. 320, 330 (Pa. 1937) (stating that fraudulent concealment must be “an act additional to the illegal transaction itself”).

Finally, “[a]s with the discovery rule, [plaintiffs] are held to a standard of reasonable diligence and ‘a statute of limitations that [has been] tolled by virtue of fraudulent concealment begins to run when the injured party knows or reasonably should know of his injury and its cause.’” Risperdal, 2017 WL 5256400, at \*7 (quoting Fine, 870 A.2d at 861); 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.

As noted above, when considering the question of whether a plaintiff knew or should have known of her injury and its cause in connection with a tort claim, we ask when the plaintiff knew

or should have known that she was injured by Essure. See supra p. 10. In contrast, when considering whether a plaintiff knew or should have known of her injury and its cause in connection with a breach of warranty claim, we ask when the plaintiff knew or should have known that a warranty was breached and that she suffered an injury as a result of the breach, because “cause” in the context of a breach of warranty is, by definition, the breach. See McLaughlin v. Bayer Corp., Civ. A. No. 14-7315, 2017 WL 697047, at \*11 n.13 (E.D. Pa. Feb. 21, 2017) (citing Samuel-Bassett v. Kia Motors Am., Inc., 34 A.3d 1, 35 (Pa. 2011) (stating that “[t]o prevail on [a] breach of express warranty claim,” a plaintiff must establish “that the breach was the proximate cause of the harm”)).

### **III. DISCUSSION**

With respect to each of the twelve exemplar Plaintiffs, Bayer argues that the undisputed record evidence demonstrates that Plaintiff’s injury accrued, i.e., the injury was inflicted, more than two years before suit was filed and, thus, Bayer contends that it has met its initial burden of showing that the statute of limitations bars each Plaintiff’s claims. The exemplar Plaintiffs do not dispute that their injuries were inflicted more than two years prior to their filing of their actions; rather, they concede that they all had their devices implanted and began suffering injuries on account of those devices more than two years before filing suit. Plaintiffs nevertheless argue, with respect to each individual Plaintiff, that the discovery rule applies to toll the statute of limitations until within two years of their filing suit. Specifically, Plaintiffs argue that they have proffered evidence from which a reasonable jury could conclude that each Plaintiff neither knew nor was able to discover with the exercise of reasonable diligence her injury and its cause more than two

years before she filed suit.<sup>12</sup> In the alternative, Plaintiffs ask to conduct discovery pursuant to Federal Rule of Civil Procedure 56(d) to develop the facts necessary to establish that the statute of limitations should be tolled based principles of fraudulent concealment, and they provide an affidavit in support of that request.<sup>13</sup> Bayer maintains, however, that a reasonable jury could only conclude, based on the record evidence, that each Plaintiff knew or should have known by exercising reasonable diligence that she was injured by Essure more than two years before filing suit and that we should therefore conclude as a matter of law that each Plaintiff's claims are time-barred, irrespective of any fraudulent concealment claim.

Plaintiffs argue, and we agree, that the warranty claims require a separate analysis, involving application of the four-year statute of limitations and no application of the discovery

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<sup>12</sup> Plaintiffs repeatedly argue that the statute was tolled until they were able to discover that Bayer's deceptive conduct had caused their injuries. However, as stated above, the law does not require a plaintiff to know or have reason to know that she had a cause of action against Bayer – or that Bayer was negligent – in order for the two-year statutory period to begin running. See Wilson, 964 A.2d at 364 n.10, 365 (explaining that an injured party need not “understand [that] she has a cause of action” or have notice of “the fact of actual negligence” in order for a tolled statute to recommence). Rather, it is sufficient for a plaintiff to know or have reason to know that the device caused her injury. See supra p. 10. Accordingly, our analysis will consistently focus on whether each Plaintiff knew or should have known that she was injured by Essure more than two years before she filed suit.

<sup>13</sup> “When a party opposing summary judgment ‘believes that s/he needs additional time for discovery, [Rule 56(d)] specifies the procedure to be followed.’” Pennsylvania, Dep’t of Pub. Welfare v. Sebelius, 674 F.3d 139, 157 (3d Cir. 2012) (alteration in original) (quoting Dowling v. City of Phila., 855 F.2d 136, 139 (3d Cir. 1988)). Rule 56(d) provides:

If a nonmovant shows by affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition, the court may: (1) defer considering the motion or deny it; (2) allow time to obtain affidavits or declarations or to take discovery; or (3) issue any other appropriate order.

Fed. R. Civ. P. 56(d). “An adequate affidavit or declaration specifies ‘what particular information that is sought; how, if disclosed, it would preclude summary judgment; and why it has not been previously obtained.’” Shelton v. Bledsoe, 775 F.3d 554, 568 (3d Cir. 2015) (quoting Dowling, 855 F.2d at 140).

rule. We will, however, for purposes of this Motion, consider the permanent birth control warranties to be extended warranties. In addition, we must also consider whether fraudulent concealment principles have the potential to save warranty claims that might otherwise be barred, such that Plaintiffs may be entitled to Rule 56(d) discovery.

Applying the legal principles and considering the parties' arguments set forth above, we individually consider each of the twelve exemplar Plaintiffs' claims.

#### **A. Plaintiffs Who Had Essure Device Removed Outside the Two-Year Period**

##### **1. Plaintiff 1<sup>14</sup>**

According to Plaintiff 1's Plaintiff Fact Sheet ("PFS"), Plaintiff 1 had her Essure device placed on December 2, 2010. (Plaintiff 1 ("P1") PFS, Defs.' Ex. V, ¶ III.2.) During the procedure, the doctor was unable to deploy the second of two devices and inserted a third device into Plaintiff 1's fallopian tubes. (P1 PFS ¶ III.8.) Sixteen days later, on December 18, 2010, Plaintiff 1 was treated for severe pelvic pain and unusual bleeding. (Id. ¶¶ V.1-2.) Also in December, her doctor informed her that the Essure device had perforated the wall of her uterus. (Id. ¶ V.8.) As a result of the pain, bleeding, cramping, and uterine perforation, Plaintiff 1 underwent a partial hysterectomy on December 22, 2010. (Id. ¶¶ IV.2, IV.5, V.2, V.6; P1 Decl., Pls.' Ex. 10, ¶ 5.) Plaintiff 1's medical records reflect pre- and post-operative diagnoses of "Right lower quadrant pain, secondary to foreign body (Essure devices)." (P1 Med. Rcds., attached as Ex. B to Defs.' Reply to Pls.' Resp. to Defs.' SMF ("Defs.' Reply SMF"), at 1.) The pain, bleeding, and cramping completely subsided following the removal. (P1 PFS ¶ IV.4.)

Plaintiff 1 supplemented her PFS with a Declaration, in which she states that her doctor

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<sup>14</sup> We refer to the Plaintiffs by number to preserve their confidentiality in connection with their medical records.

told her mother after her hysterectomy that when she first placed the device, she could not find one of the two coils moments after placing it and that she therefore placed a third coil. (P1 Decl. ¶ 6; see also P1 Med. Rcds. at 1 (reflecting removal of 3 Essure devices).) Plaintiff 1's mother told Plaintiff 1 what the doctor had said, and Plaintiff 1 therefore "did not believe it was the device that caused [her] injuries; rather, [she] believed that it was the possible malpractice of the implanting OBGYN that caused [her] pain and subsequent hysterectomy." (P1 Decl. ¶¶ 7-8.) In fact, a few years after the hysterectomy, she reached out to a medical malpractice attorney, but he would not take the case because he believed she had waited too long. (Id. ¶¶ 9-10.) In 2017, Plaintiff 1 saw a legal advertisement discussing problems with the Essure device, went online, and conducted research. (Id. ¶ 11.) She then learned about "a new warning issued by the FDA" (apparently, the black box warning), and that other women were claiming to have suffered injuries similar to her own. (Id. ¶ 12.) Plaintiff 1 filed her Complaint against Bayer on September 5, 2017.

Plaintiff 1's claims are time-barred. A reasonable jury could only conclude that once Plaintiff 1 learned in December 2010 that her Essure device had migrated and lodged in her uterus, she knew or had reason to know that she had been injured by the Essure device. See Gleason, 15 A.3d at 484 (stating that the statute begins to run upon the plaintiff's knowledge of her injury "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" (quoting Wilson, 964 A.2d at 364)). While Plaintiff 1 also believed that she had been injured by her surgery and, thus, had a potential malpractice claim against her doctor, see Wilson, 964 A.2d at 369 (identifying surgery as the factual cause of the plaintiff's surgical injury giving rise to malpractice claim), 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. See Hartey, 2006 WL 724554, at \*3 (recognizing that plaintiff's

belief that doctor who implanted pelvic mesh product had committed malpractice did not toll statute against manufacturer of pelvic mesh when plaintiff knew that problematic scarring she suffered was secondary to use of mesh); see also In re Mirena IUD Prods. Liability Litig., 29 F. Supp. 3d 345, 357 (S.D.N.Y. 2014) (explaining that, under Indiana and Texas law, “[a] diligent individual in Plaintiff’s position would have possessed enough information to explore both potential causes, and the mere existence of an alternative explanation for Plaintiff’s injuries – that it was the inserting doctor’s fault, not the device’s – does not mean that the information Plaintiff possessed was insufficient to prompt her to research the device’s role in causing her injuries” (citations omitted)). Thus, Plaintiff 1’s tort claims are time-barred by the two-year statute because they were asserted for the first time in September of 2017.

In addition, because Plaintiff 1 did not institute her claims until almost seven years after she had Essure implanted, her breach of express warranty claims are barred by the four-year statute applicable to those claims. As noted above, a breach of warranty claim typically accrues on the date of the product sale, but can occasionally accrue later in a case in which the warranty extends to future performance. See McPhee, 989 F. Supp. 2d at 464. The only warranties on which Plaintiff 1 relies that we consider extended are those promising “permanent” birth control, see supra Section II.B.2, and Plaintiff 1 plainly knew that Essure had not performed in accordance with that warranty when the device migrated and she had Essure removed in December of 2010. 13 Pa. Cons. Stat. § 2725(b) (providing that statute of limitation begins to run on extended warranty when plaintiff discovers or should have discovered breach).

Moreover, although Plaintiffs ask for leave to conduct Rule 56(d) discovery to establish that fraudulent concealment tolled the applicable statutes of limitations, no such discovery is warranted here, because, even if fraudulent concealment were proven, Plaintiff 1’s claims would

be time-barred because she knew or had reason to know of her injuries and their causes more than two years before her tort claims were filed and more than four years before her warranty claims were filed. 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.”). Specifically, even assuming *arguendo* that Bayer engaged in fraudulent concealment, the statute of limitations on Plaintiff 1’s tort claims began to run when she knew or had reason to know that she was injured by Essure in December of 2010. Likewise, even assuming *arguendo* that there was fraudulent concealment, the statute of limitations on her warranty claims, which include claims based on warranties that Essure “stay[s] secure,” is “worry free,” and “eliminates the risks, discomfort, and recovery time associated with surgical procedures,”<sup>15</sup> also began to run no later than December of 2010, when she knew that such warranties had been breached because her device had migrated, and she had suffered pain, bleeding and cramping that subsided after removal.<sup>16</sup> Accordingly, when Plaintiff 1 instituted suit in September of 2017, the statutes of limitations had long-expired on both her tort and warranty claims. We therefore we deny Plaintiffs’ request for Rule 56(d) discovery with regard to Plaintiff 1’s claims, and grant

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<sup>15</sup> On February 4, 2019, at our request, Plaintiffs filed a list of the precise warranties on which each of the twelve exemplar Plaintiffs base their breach of express warranty claims. (Pls.’ Warranty List, ECF No. 353, McLaughlin v. Bayer Essure, Inc., Civ. A. No. 14-7315.)

<sup>16</sup> Plaintiffs may contend that Plaintiff 1 did not know or have reason to know that other warranties had been breached, such as the warranties that the “inserts were made . . . from safe, trusted material” and that “[p]hysicians must be signed-off to perform Essure procedures.” (See Pls.’ Warranty List at 7-8.) Plaintiffs may therefore take the position that they should be permitted to pursue fraudulent concealment discovery concerning those warranties. However, similar to other exemplar Plaintiffs, Plaintiff 1 has not identified any affirmative misrepresentation that Bayer made to her other than those same warranties on which she is grounding her breach of warranty claims. See infra Section III.A.3. In the absence of any evidence of additional affirmative misrepresentations on which Plaintiff 1 she relied in relaxing her vigilance, we conclude that Plaintiffs have not established any basis for Rule 56(d) discovery. See id.



Bayer's Motion insofar as it seeks judgment in its favor on all of Plaintiff 1's claims, both tort and warranty.

## 2. Plaintiff 2

Plaintiff 2 had her Essure device placed in April 2007. (Plaintiff 2 ("P2") PFS, Defs.' Ex. Z, ¶ III.2.) There was a lot of blood during the implantation procedure. (P2 Decl., Pls.' Ex. 11, ¶ 4.) Shortly after placement, Plaintiff 2 experienced bleeding, pain, and cramping, and she suspected the cramping and bleeding were Essure-related. (P2 PFS, ¶¶ V.1, V.4.) A few months later, one of the coils exited her body via her vagina, and at that time she believed that the coils had not been properly placed inside of her. (P2 Decl. ¶ 6-7; see also id. ¶ 10.) Plaintiff 2 first received treatment for the pain, bleeding, and cramping in July 2007. (P2 PFS ¶ V.2) Believing the coils to have been improperly placed, Plaintiff 2 "specifically chose not to return to [her original doctor]," and opted to consult a new doctor. (P2 Decl. ¶¶ 7-8.) In August of 2007, the new doctor told her that the cramping and bleeding were Essure-related. (P2 PFS ¶¶ IV.1, V.4.) The doctor did not, however, tell Plaintiff 2 that Essure was the cause of her pain. (P2 Decl. ¶ 9.) In August 2007, the doctor told Plaintiff 2 that he would remove the second coil, which he did. (Id.) According to Plaintiff 2's PFS, the removal of the device was her treatment for the cramping she was experiencing. (P2 PFS, ¶ V.6.) Plaintiff 2's symptoms, including her pain, ceased after removal of the device. (Id. ¶¶ IV.4, V.11.) Plaintiff 2 avers that "[a]t no time . . . in August 2007 did [she] think that it was the Essure device that caused [her] injuries but instead thought the device may have been improperly placed . . . ." (P2 Decl. ¶ 10.) Almost ten years later, in May of 2017, Plaintiff 2 saw a legal advertisement discussing Essure-related problems, called the number in the advertisement and retained her current law firm. (Id. ¶ 11.) Plaintiff 2 filed her claims against Bayer on September 5, 2017. (Id. ¶ 12.)

Plaintiff 2's claims, like Plaintiff 1's, are time-barred. As detailed above, the summary judgment record reflects that Plaintiff 2 suffered from pain and cramping after the devices were placed, and one of her inserts came out of her body. Her second doctor told her that the cramping was Essure-related and recommended that her second insert be removed. Moreover, all of her symptoms resolved after removal of the remaining device in August 2007. While Plaintiff 2, like Plaintiff 1, believed that the doctor who placed her devices had committed malpractice and Plaintiff 2 avers in her Declaration that, in August 2007, she did not believe that the Essure device had caused her injuries, the fact remains that a reasonable person in Plaintiff 2's position should have known that she had been injured by Essure because the undisputed record evidence demonstrates that (1) her doctor told her that her cramping and bleeding were Essure-related, (2) one coil exited her body, (3) she had to have the second coil removed, and (4) she suffered pain and cramping that resolved upon Essure's removal. On this record, reasonable minds could not differ that Plaintiff 2 should have known that she had suffered an injury caused by Essure no later than 2007, approximately ten years before she filed suit. Wilson, 964 A.2d at 362 (“[C]ourts may resolve the matter at the summary judgment stage where reasonable minds could not differ on the subject.” (citations omitted)). Meanwhile, the record reflects that Plaintiff 2 did nothing to investigate the possibility of a claim against Bayer for almost ten years. Accordingly, Plaintiff 2's tort claims are barred by the two-year statute of limitations.

In addition, because Plaintiff 2 did not institute her claims until ten years after she had Essure implanted, her breach of express warranty claims are barred by the applicable four-year statute applicable to those claims. This is so even though Plaintiff 2 alleges a warranty claim grounded on breach of a warranty that Essure is permanent birth control, because she plainly discovered that there had been a breach of any such promise when one insert exited her body and

the other was removed.

Moreover, allegations of fraudulent concealment, even if developed in further discovery, would not save Plaintiff 2's claims from the time-bar. Plaintiff 2 knew or had reason to know that she had been injured by Essure no later than 2007, and likewise knew or had reason to know that she had been injured on account of breaches of alleged warranties (e.g., the warranties that Essure "stays secure," is "worry free," and "eliminates the risks, discomfort, and recovery time associated with surgical procedures") no later than 2007 because she knew by that time that one Essure device had migrated and that her symptoms had resolved upon the other's removal.<sup>17</sup> See Fine, 870 A.2d at 861. Accordingly, we deny Plaintiffs' request for Rule 56(d) discovery with regard to Plaintiff 2's claims, and we grant Bayer's Motion insofar as it seeks judgment in its favor on all of Plaintiff 2's claims, both tort and warranty.

### 3. Plaintiff 3

Plaintiff 3 had her Essure device placed on June 26, 2009. (Plaintiff 3 ("P3") PFS, Defs.' Ex. GG, ¶ III.2.) She immediately began suffering from extreme pelvic, abdominal, and ovarian pain, which intensified over the next two years. (P3 PFS ¶ IV.1; P3 Decl., Pls.' Ex. 26, ¶ 6.) She was also diagnosed with fibromyalgia (an autoimmune condition) and was found to have paratubal or abnormally large ovarian cysts. (P3 PFS ¶ V.1; P3 Decl. ¶¶ 7, 9.) Plaintiff 3 consulted with a doctor, who never told her that her pain and other symptoms were caused by Essure. (P3 Decl. ¶ 9.) Rather, the doctor told Plaintiff 3 that she suspected that Plaintiff 3's pain was caused by her cysts. (Id. ¶ 9.) On August 23, 2011, the doctor scheduled surgery to remove and drain the cysts,

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<sup>17</sup> To the extent that Plaintiff 2, like Plaintiff 1, seeks fraudulent concealment discovery based on other warranties that she may not have known or had reason to know were breached, she has not established a basis for such discovery because she has not identified affirmative misrepresentations that Bayer made to her other than the warranties on which she bases her claims. See supra note 16.

and Plaintiff 3 also asked the doctor to remove the Essure devices, in part to restore her fertility. (Id. ¶ 9; P3 Med. Rcds., Pls.’ Ex. 32, at 5, 7.) The doctor later persuaded Plaintiff 3 to have her fallopian tubes removed “because of the risk of ectopic pregnancy.” (P3 PFS ¶ IV.2 (stating that doctor aimed “to prevent tubal pregnancies with a salpingectomy”); P3 Decl. ¶ 9; P3 Med. Rcds. at 7.) As a result of the removal of her fallopian tubes, Plaintiff 3’s fertility was not restored. (P3 Decl. ¶ 9.) Plaintiff 3’s symptoms of severe abdominal pain and fibromyalgia subsided after removal of two cysts, the fallopian tubes, and the Essure devices. (P3 PFS ¶ IV.4; P3 Decl. ¶¶ 10-11.) Her doctors seemed to believe that the pain she had been suffering was caused by the cysts, and Plaintiff 3 does not recall her doctors ever telling her that the pain was causally related to Essure. (P3 Decl. ¶ 12.) Plaintiff 3 subsequently decided to contact an attorney after doing research, discussing her experience with other women on Facebook, and reading reports of other women’s experiences, which caused her to believe that Essure could be the cause of her pelvic, abdominal, and ovarian pain, heart murmur, and fibromyalgia. (Id. ¶ 13.) Plaintiff 3 filed her claims against Bayer on June 29, 2016.

On this record, there is a genuine dispute of material fact as to when Plaintiff 3 knew or should have known that she had been injured by Essure for purposes of the discovery rule. Bayer essentially argues that the record makes plain that Plaintiff 3 knew or should have known that her injuries were Essure-related no later than August of 2011, because she began to have pain immediately upon implantation in 2009, she requested to have Essure removed, and her symptoms subsided after removal of Essure in 2011. However, those facts are simply not determinative where there is also evidence that her doctor told her that her pain and other medical issues were likely caused by cysts, recommended removal of the cysts to resolve her symptoms, and only removed the Essure micro-inserts along with the cysts at Plaintiff 3’s request. Indeed, a reasonable

jury could conclude under these circumstances that Plaintiff 3 reasonably understood that her pain and fibromyalgia, which subsided after removal of the cysts, had been caused by her cysts as her doctor had told her.<sup>18</sup> See Nicolaou, 195 A.3d at 893 (“[A] lay person is only charged with the knowledge communicated to him or her by the medical professionals who provide treatment and diagnosis” (citing Wilson, 964 A.2d at 365)). Bayer also argues that, even if Plaintiff 3 was not on inquiry notice in August of 2011, she has not established that she fulfilled her obligation to proceed with diligence after her surgery to determine whether, in fact, her symptoms had been cause by Essure rather than her cysts. However, we conclude that, in light of the evidence that, in spite of her doctor’s apparent resolve that her symptoms had been caused by her cysts, Plaintiff 3 subsequently read about other women’s experiences with Essure and met with a lawyer, the question of whether Plaintiff 3 acted with reasonable diligence post-surgery is a question of fact for the jury. In sum, on this record, we cannot conclusively determine that Plaintiff 3 knew or had reason to know that her symptoms were Essure-related more than two years before she filed suit in 2016, and we conclude that there is a genuine dispute of material fact as to when she was on such inquiry notice. We therefore deny Bayer’s Motion for judgment in its favor on Plaintiff 3’s tort claims.

In contrast, Plaintiff 3 did not assert her warranty claims until more than four years after

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<sup>18</sup> Bayer points out that Plaintiff 3 states in her PFS that she believes that her cysts were caused by Essure. It contends that, given this assertion, she cannot credibly argue that she thought her symptoms were caused by her cysts, not Essure, reasoning that if Plaintiff 3 thought Essure caused her cysts and that her cysts caused her symptoms, then she necessarily thought that Essure caused her symptoms, although possibly indirectly. However, without discounting Plaintiff 3’s current statement in her PFS, the statement does not resolve the factual question of what Plaintiff 3 knew or should have known more than two years before filing suit, when her doctor had told her that her symptoms were caused by her cysts and recommended removal of only the cysts (not Essure) to resolve her symptoms. Under these circumstances, we have no hesitation in concluding that there is a genuine dispute of fact as to when Plaintiff 3 knew or should have known that her symptoms were caused by Essure.

her Essure devices were implanted and, thus, any claims that are based on non-extended warranties are presumptively barred by the four-year statute of limitations. With respect to warranties that we consider extended – that Essure provides permanent birth control – Plaintiff 3’s Declaration establishes that she wanted to restore her fertility and asked to have Essure removed, in part, to accomplish that purpose. (P3 Decl. ¶ 9.) Accordingly, we have trouble understanding how Plaintiff 3 could be asserting that she was injured on account of any breach of the promise of permanent birth control. Nevertheless, to the extent that Plaintiff 3 seeks to alternatively assert that she had Essure removed not to restore her fertility, but for other reasons, she was certainly on notice that Essure was not providing her with permanent birth control once she had it removed August of 2011. We therefore conclude that Plaintiff 3 discovered any breach of the permanence promise no later than August of 2011, which was more than four years before she filed suit.

Plaintiffs nevertheless contend that we should not grant Bayer’s Motion for judgment in its favor on Plaintiff 3’s warranty claims without first permitting fraudulent concealment discovery on whether Bayer dissuaded Plaintiff 3 from asserting her warranty claims by providing false information about Essure’s effectiveness and safety. However, Plaintiff 3, like most of the other exemplar Plaintiffs, has not identified any affirmative representations from Bayer that dissuaded her from investigating her claims other than the same warranties and representations on which she bases her warranty claims. (See Pls.’ Warranty List; N.T. 2/11/19, at 75-78.) As noted earlier, see supra Section II.B.3, a plaintiff cannot establish fraudulent concealment by relying on the same warranties on which she bases her warranty claims because such warranties are not “independent affirmative act[s] of concealment,” separate and apart from the misrepresentations on which she bases her warranty causes of action. Arndt, 67 F. Supp. 3d at 678; see also Overfield, 146 F.2d at 896; Bailey, 189 A. at 330. While Plaintiffs contend that one of the reasons that they seek Rule

56(d) discovery is to identify Bayer's additional communications to the public, Plaintiffs, or Plaintiffs' doctors that may have misled the Plaintiffs, it is Plaintiff 3's burden to establish by clear and convincing evidence those independent affirmative communications on which she herself justifiably relied, and no one but Plaintiff 3 can identify those communications. Accordingly, we deny Plaintiffs' request to conduct Rule 56(d) discovery as to other communications that Plaintiff 3 has not identified as communications she saw or read and relied upon. Moreover, because Plaintiff 3 has identified no independent affirmative representations that could support a fraudulent concealment argument with respect to her claims, we conclude that she has not established any legitimate basis for further Rule 56(d) discovery as to fraudulent concealment.

For all of these reasons, we conclude that Plaintiffs have not established that additional discovery as to fraudulent concealment is warranted as to Plaintiff 3's warranty claims and further conclude that the warranty claims are barred by the four-year statute of limitations. Thus, while we deny Bayer's Motion for judgment in its favor as to Plaintiff 3's tort claims, we grant Bayer's Motion for judgment in its favor as to Plaintiff 3's warranty claims.

## **B. Plaintiffs Who Suffered Essure-Related Injuries Outside Two-Year Period**

### **1. Plaintiff 4**

Plaintiff 4 had her Essure device placed in March of 2007. (Plaintiff 4 ("P4") PFS, Defs.' Ex. CC, ¶ III.2.) She states in her PFS that "right after the implant," she began to suffer "abnormal bleeding, stabbing, persistent/constant pelvic pain, back pain, . . . [and] numbness in hands and legs."<sup>19</sup> (P4 PFS ¶ V.1.) She states in a Declaration that her primary care physician, gynecologist, chiropractor, and physical therapist all thought that her pain and numbness were due to having

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<sup>19</sup>Plaintiff 4's PFS offers conflicting onset dates, as she states elsewhere in her PFS that the approximate date of the onset of her pelvic pain and back pain was January of 2010, which was close to three years after implantation. (P4 PFS ¶ V.6; see also *id.* ¶ VII.3.)

delivered a large baby several months before having Essure implanted. (P4 Decl., Pls.' Ex. 17, ¶ 6.) Her gynecologist (and implanting physician) ordered x-rays and other tests. (Id. ¶ 7.) Over the next few years, she received treatment from her primary care provider and gynecologist, and attempted to diagnose the cause of her symptoms. (Id. ¶ 8.) Plaintiff 4's PFS indicates that she "first received treatment" for her pelvic pain and bleeding in 2013, noting that her gynecologist recommended an x-ray and physical therapy. (P4 PFS ¶ V.2.) From March of 2013 to 2016, Plaintiff 4 received treatment, including physical therapy, and took analgesic medication, because her doctors believed her problems to be muscular or neurological. (P4 PFS ¶ V.2.; P4 Decl. ¶¶ 8-9.) Plaintiff 4 first suspected that her injuries were Essure-related in May of 2014. (P4 PFS ¶ V.4; P4 Am. PFS, Pls.' Ex. 18, at 3.) In November of 2014, she began researching and reading reports of other women's accounts of their Essure experiences and began to ask her doctors if her symptoms were Essure-related, but her doctors said that they did not believe that Essure was the cause of her symptoms. (P4 Decl. ¶ 12.)

In 2015, Plaintiff 4's primary care physician referred her to another gynecologist for a second opinion, and that gynecologist referred her to yet another gynecologist more familiar with Essure. (P4 Decl. ¶ 13.) In April of 2015, that gynecologist told her that the injuries were, in fact, Essure-related after he performed a second HSG test that disclosed that her Essure device had migrated and was not in the correct position. (P4 PFS ¶ V.4; P4 Decl. ¶¶ 11, 13.) Plaintiff 4 filed her Complaint on July 8, 2016.<sup>20</sup>

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<sup>20</sup> On August 18, 2016, after Plaintiff 4 filed this action, her initial gynecologist performed a hysterectomy to remove her Essure device. (P4 PFS ¶ IV.2; P4 Decl. ¶¶ 14-15.) Plaintiff 4's abnormal bleeding and pelvic pain resolved within a month of the hysterectomy, and the stabbing pelvic pain, pain and numbness in her hands and legs, and bleeding after intercourse also "subsided and went away." (P4 PFS ¶ IV.4.)



On this record, we conclude that there are genuine disputes of material fact both as to when Plaintiff 4 knew or had reason to know that her injuries were Essure-related and whether she could have discovered Essure's causal role in her symptoms earlier than April of 2015. Indeed, as Plaintiffs emphasize, the record does not indicate that any medical professional informed Plaintiff 4 that her symptoms were even potentially Essure-related or recommended that she undergo a second HSG test before April 2015. Instead, the record shows that medical professionals offered alternative explanations for her symptoms. Bayer argues that Plaintiff 4 was not reasonably diligent in investigating causation, arguing that her PFS discloses that she did not conduct any investigation between 2007 and 2013, because it indicates that she "first received treatment" for her pelvic pain in 2013. (P4 PFS ¶ V.2.) However, we do not find this evidence to be determinative of Plaintiff 4's reasonable diligence when her Declaration states that, in the few years following implantation in 2007, she was visiting her primary care physician and gynecologist, attempting to diagnose the cause of her symptoms. (P4 Decl. ¶ 8.) Rather, on this record, we conclude that reasonable minds could differ as to whether Plaintiff 4 was reasonably diligent in investigating the cause of her injuries. Moreover, as noted above, the existing record also shows that between March of 2013 and early 2015, i.e., a period in which Plaintiff 4 was indisputably seeking out treatment and investigating causation, no medical provider attributed her symptoms to Essure. Accordingly, there is a legitimate dispute of material fact as to the point in time at which Plaintiff 4 should have known that Essure was the cause of her injuries with the exercise of reasonable diligence.<sup>21</sup>

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<sup>21</sup> Bayer takes the position that, had Plaintiff 4 acted with reasonable diligence, she would have been able to link her symptoms to the Essure device, because the "publicly available labeling," i.e., the 2002 Instructions for Use, disclosed that patients had submitted adverse events reports of "[p]elvic/lower abdominal pain (severe)" and "[a]bnormal bleeding . . . (severe)" associated with their use of the device. (2002 IFU, Defs.' Ex. F, at 11.) Plaintiffs counter that the patient information available prior to 2014 did not, in fact, alert her to the fact that her symptoms might be related to Essure as the 2002 PIB also stated that "[v]ery few women report persistent

Accordingly, we deny Bayer's Motion for judgment in its favor with respect to Plaintiff 4's tort claims.

With respect to Plaintiff 4's warranty claims, we conclude that some are time-barred and others are timely. Those claims grounded on warranties that do not extend to the future are presumptively time-barred because Plaintiff 4 had her Essure implanted in March 2007, and did not file suit until more than nine years later, in July of 2016. Moreover, as we did with Plaintiff 3, we deny Plaintiff 4's request for discovery to establish fraudulent concealment as to these non-extended warranties because she has failed to identify any statements (other than the alleged contractual warranties on which she relies to support her warranty claims) on which she justifiably relied in failing to investigate her claims. Accordingly, the non-extended warranty claims are time-barred pursuant to a traditional application of the four-year statute.

However, insofar as Plaintiff 4 relies on the warranties that Essure is "permanent" birth control, which we have concluded for purposes of this Motion are extended warranties, we will not find the warranty claims to be time-barred at this stage of the proceedings. This is because the summary judgment record can support a reasonable conclusion that Plaintiff 4 did not discover that such warranties had been breached until she learned in April of 2015 that her Essure device had migrated, which was less than a year before she filed suit.

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pain" (2002 PIB, Defs.' Ex. E, at 16); the 2006 PIB stated that only "[s]ome women in the clinical studies reported one or more episodes of pelvic, back or abdominal pain" (2006 PIB, Defs' Ex. H, at 8); and the 2012 PIB stated only that "you may experience mild to moderate pain" (2012 PIB, Defs.' Ex. L, at 7). Accordingly, we conclude that whether independent review of the publicly available materials concerning Essure would have alerted Plaintiff 4 to the cause of her symptoms is, again, a jury question.

Thus, we deny Bayer's Motion both as to Plaintiff 4's tort claims and her warranty claims that are grounded on promises of permanence, but we grant the Motion insofar as it seeks judgment on the other warranties, which are non-extended warranties.

## 2. Plaintiff 5

Plaintiff 5 had her Essure device placed on June 21, 2012. (Plaintiff 5 ("P5") PFS, Defs.' Ex. HH, ¶ III.2.) She states that "soon after" implantation, she "had sharp and stabbing abdominal pain," which was in her left lower abdomen. (P5 Decl., Pls.' Ex. 27, ¶ 4; P5 PFS ¶¶ V.2, V.6.) Her periods also became heavier. (P5 Decl. ¶ 5.) She suspected in July 2012 that her pain was related to Essure. (P5 PFS ¶ V.4.) Her doctor told her, however, that abdominal pain was normal "for a while after the implantation of Essure." (P5 Decl. ¶ 4.) In September 2012, Plaintiff 5 underwent an Essure Confirmation test, which showed that the Essure devices were not in the correct location in both fallopian tubes.<sup>22</sup> (P5 PFS ¶¶ III.9, III.10.)

In January 2013, Plaintiff 5 complained to her doctor about heavy vaginal bleeding. (P5 Decl. ¶ 5.) According to Plaintiff 5's Declaration, when she asked her doctor if the bleeding could be related to Essure, he said no. (*Id.*) Her medical records reflect that she met with a second doctor on January 18, 2013, and complained to that doctor about both "persistent vaginal bleeding" and "pain and discomfort" since her Essure procedure. (Ex. D to Defs.' Reply SMF, at 3-4.) The second doctor advised her to "consult with [her implanting physician] about surgical options for management." (*Id.* at 4.) She returned to her implanting physician in September of 2013 with

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<sup>22</sup> Plaintiffs' counsel stated at oral argument regarding Plaintiff 5: "[I]n 2012, she's implanted. In 2012, three months later, she has her confirmation test, the HSG test, and it's confirmed. Proper placement." (N.T. 2/11/19, at 39.) However, Plaintiff 5's PFS asked, "Did a physician . . . advise you of any of the following . . . regarding the results of your Essure Confirmation Test (check all that apply)," and Plaintiff 5 checked the box next to "D. That your Essure was **not** in the correct location in both fallopian tubes." (P5 PFS ¶ III.10.) Accordingly, the record evidence does not support counsel's representation at argument.

continued heavy bleeding and asked again if the bleeding could be related to her Essure device, and he again said no. (P5 Decl. ¶ 6.) Her medical records from September 16, 2013, however, reflect that she also complained about pelvic pain during that visit, and she told the doctor that she wanted to have the Essure coils removed. (P5 Med. Rcds, Ex. D to Defs.’ Reply SMF, at 1-2.) The doctor recommended a pelvic ultrasound, indicating in his notes that a sonogram would help to determine if the pain was related to fibroids or Essure and that Plaintiff 5 would “consider her options.” (Id. at 2.)

The summary judgment record reflects no other medical treatment – including the recommended ultrasound – until March of 2015, when, according to her Declaration, Plaintiff 5 again discussed her heavy bleeding with one of her doctors and asked if she could have her Essure device removed because she believed it was the cause. (P5 Decl. ¶ 7.) At that point, her doctor again ordered a pelvic ultrasound. (Id.) In April of 2015, the pelvic ultrasound showed that her left Essure coil was misplaced, as it was located near her ovary instead of at the tubal opening. (P5 Decl. ¶ 8.) Plaintiff 5’s doctor then told her that Essure might be the cause of her abdominal pain, bleeding, and other symptoms and discussed the possibility of removing the device. (Id. ¶ 9.) Plaintiff 5 avers that “this [was] the first time [she] knew that Essure was the cause of [her] abdominal pain and heavy bleeding.” (Id. ¶ 8.) In September of 2015, Plaintiff 5 went to the ER with more abdominal pain and heavy bleeding. (Id. ¶ 10.) Another pelvic ultrasound was performed and confirmed that her left Essure device was “located distally and inferiorly near [her] ovary.” (Id.) Plaintiff 5 filed suit on June 17, 2016. She was scheduled for a partial hysterectomy and bilateral salpingectomy on August 14, 2018. (Id. ¶ 11.)

We conclude that there are genuine disputes of material fact as to whether Plaintiff 5 knew or should have known with the exercise of reasonable diligence that her injuries were Essure-

related more than two years prior to filing suit. Bayer argues that the record conclusively demonstrates that Plaintiff 5's doctor recommended on September 16, 2013, approximately two and a half years before Plaintiff 5 filed her action, that she obtain an ultrasound to determine whether her pelvic pain was the result of Essure, and that Plaintiff did not undergo the recommended ultrasound until April of 2015. (P5 Med. Rcds. at 21.) We cannot conclude as a matter of law on this record that Plaintiff was not reasonably diligent in seeking out the cause of her injuries because she did not get a more prompt ultrasound, but rather, we find that there is room for a jury to conclude otherwise. Moreover, the existing record does not allow for any conclusions as to what an earlier ultrasound would have shown. We therefore conclude that the record presents a genuine dispute as to whether Plaintiff 5, exercising reasonable diligence, could have learned the cause of her injuries before June 17, 2014, i.e., two years before she filed suit. For these reasons, we deny Bayer's Motion for judgment in its favor on Plaintiff 5's tort claims.

We also conclude that Plaintiff 5's warranty claims are not barred by the statute of limitations. As noted above, Plaintiff 5 had her Essure device implanted on June 21, 2012 and filed this action on June 17, 2016. Accordingly, her warranty claims clearly fall within the four-year statute of limitation for breach of warranty claims. We therefore deny Bayer's Motion for judgment in its favor on Plaintiff 5's warranty claims as well.

### **3. Plaintiff 6**

Plaintiff 6 had her Essure device placed in October of 2010. (Plaintiff 6 ("P6") PFS, Defs.' Ex. BB, ¶ III.2.) "[S]oon after Essure was implanted," Plaintiff 6 began having severe and persistent pelvic pain. (P6 Decl., Pls.' Ex. 15, ¶ 8.) Plaintiff 6 tried to have an HSG test done in January 2011, but when she told the nurse that she was experiencing constant bleeding, the nurse told her that she could not have the test done until the bleeding stopped. (*Id.* ¶ 7.) The nurse did

not tell Plaintiff 6 that the bleeding was abnormal or indicative of a problem. (Id.) In February 2011, Plaintiff 6 called her doctor about the pelvic pain. (Id. ¶ 8.) Her doctor ordered blood work and an ultrasound and scheduled an appointment for March 10, 2011. (Id.) At the March appointment, her doctor told her that her symptoms were most likely associated with her discontinuance of her hormonal birth control, an abnormal menstrual cycle, and/or a cyst that he saw on an ultrasound. (Id. ¶ 9; id. ¶ 11 (“[M]y symptoms were attributed to a rupturing cyst”)). He prescribed medication to slow down the bleeding and did not say that her symptoms were Essure-related. (Id. ¶ 9; P6 Med. Rcds., Pls’ Ex. 33, at 2.) The doctor, again, was unable to perform the HSG test because of her bleeding, but he told Plaintiff 6 that, based upon the ultrasound, she did not need an HSG test. (P6 Decl. ¶ 10.)

Plaintiff 6 discovered that she was pregnant on October 9, 2012. (P6 PFS ¶¶ V.2, V.4.) In February 2013, after her original doctor told her that “God wanted [her] to have a baby,” Plaintiff 6 switched doctors. (P6 Decl. ¶ 12.) She delivered a baby boy on May 6, 2013. (Id. ¶ 13.) In August of 2013, she reported to the FDA that her Essure device had failed, believing that it was important to report her unintended pregnancy given that Bayer had reported that no pregnancies had occurred during the clinical trials. (Id. ¶ 15; P6 PFS ¶ VI.7.) However, Plaintiff 6 did not suspect at the time that any wrongdoing by the company had contributed to her pregnancy. (P6 Decl. ¶ 15.) On May 7, 2013, her new doctor performed a tubal ligation to ensure that she would not become pregnant again. (Id. ¶ 16.) The surgical notes state: “The patient has a history of Essure being placed for birth control, which failed, and subsequently the patient became pregnant.” (P6 Med. Rcds. at 4.) After the surgery, the doctor told Plaintiff 6 that she had been able to feel an Essure coil in the right tube but not in the left tube. (P6 Decl. ¶ 16; P6 PFS ¶ IV.1 (“health care provider . . . was unable to locate missing coil during tubal”)). After discharge, Plaintiff 6 became

very bloated and her doctor ordered an x-ray. (P6 Decl. ¶ 16.) The x-ray showed that the left Essure coil had migrated. (*Id.*) In contrast, a June 9, 2014 CT scan showed that “[t]here [were] bilateral metallic filament-like densities in the proximal fallopian tubes compatible with [the] prior Essure procedure.” (P6 Med. Rcds. at 6-7; P6 Decl. ¶ 16.) Plaintiff 6 continues to experience persistent pelvic pain. (P6 Decl. ¶ 17.)

In late 2014, Plaintiff 6 joined a support group for “Parents of Aidia/Essure babies.” (P6 PFS ¶ VI.3; P6 Decl. ¶ 18.) In January 2015, she asked her doctor if removal of Essure would alleviate her pain, and her doctor replied that she did not know enough about Essure to answer her questions. (P6 Decl. ¶ 17.) Plaintiff 6 filed her claims on July 11, 2016.

Plaintiff 6’s tort claims are time-barred. As an initial matter, her tort claims grounded on injuries associated with her pregnancy while on Essure are untimely because she knew that Essure had failed its contraceptive purpose in October of 2012, when she became pregnant, and had tubal ligation to prevent further pregnancies in 2013. *See Braxton-Secret v. A.H. Robins Co.*, 769 F.2d 528, 531 (9th Cir. 1985) (under California law, which has a stricter statute of limitation standard than Pennsylvania, statute of limitations began to run when IUD failed its contraceptive purpose and plaintiff became pregnant). While Plaintiffs ask us to consider Plaintiff 6’s pelvic pain to be a separate injury that is subject to a different timeliness analysis, they do not develop this argument or cite to any relevant legal authority. Moreover, such an separate analysis would be inconsistent with Pennsylvania law, 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.”” *Gleason*, 15 A.3d at 484 (quoting *Wilson*, 964 A.2d at 364)); *see also Orozco ex rel. Orozco v. Children’s Hosp. of Phila.*, 638 F. Supp. 280, 282 (E.D. Pa. 1986) (“[O]nce the statute of

limitations begins to run on an injury claim[,] it also runs with respect to related injuries arising from the same negligent conduct, even if the related injuries are not immediately ascertainable.” (citing Cathcart, 471 A.2d at 507, and Shadle v. Pearce, 430 A.2d 683, 685-86 (Pa. Super. Ct. 1981)). Indeed, the Pennsylvania Superior Court has specifically refused to create a new “concept in the law [that] would permit an injured plaintiff to have a new limitations period commence for the initiation of an action for personal injuries as of the date when each complication or change in condition arose, despite the fact that no ‘new’ negligence has occurred which is attributable to the defendant.”<sup>23</sup> Shadle, 430 A.2d at 685-86 (concluding that where limitation period had run on

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<sup>23</sup> In a footnote in this same Superior Court opinion, the court suggests that it “might very well” recognize a separate limitations period in a case involving “separate and distinct injuries.” Shadle, 430 A.2d at 686 n.3 (citing Bayless v. Philadelphia Nat’l League Club, 579 F.2d 37 (3d Cir. 1978) (considering damages claim for back injury sustained while playing baseball separately from damages claim for mental illness suffered as a result of drug treatment for back injury)); see also Hartey, 2006 WL 724554, at \*4-5 (considering whether scarring and lesions caused by Mesiline mesh were separate and distinct injuries that were subject to different statute of limitations periods, but concluding that they were not). We have found only one case in which a court found separate injuries from a medical device to be subject to separate timeliness analyses. In Place v. Ortho Pharmaceutical Corporation, 595 F. Supp. 1099 (W.D. Pa. 1984), the plaintiff was injured when her IUD migrated, punctured her vaginal wall, and caused an infection. Id., 595 F. Supp. at 1011. Two years later, she was diagnosed with hepatitis and chronic colocolocystitis, which she also attributed to the IUD, and she underwent a colon resection. Id. at 1012. On summary judgment, the court found the tort claims based on the migration and puncture to be time-barred, but declined to find untimely the plaintiff’s tort claims arising from the hepatitis and chronic colocolocystitis. Id. The court reasoned that there was no evidence that the two injuries were the product of the “same chain of causation,” and that the plaintiff “may contend that the two conditions were caused independently from the same IUD.” Id. The court noted that “[w]hile both diseases may be attributable to the same exposure, they are separate and distinct.” Id. Moreover, it stated that there was “nothing . . . to show that the second disease could be a reasonably certain consequence of the first such as to allow damages for future consequences in a timely suit for the first injury or in the alternative to deny recovery on the second illness because of an award in a suit on the first illness.” Id. at 1012.

We are not certain that Place correctly applies Pennsylvania law. However, even assuming *arguendo* that it does, it supports, at most, 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.



plaintiff's malpractice claim for negligent dental procedure that resulted in aortic valve transplant, plaintiff was not entitled to a new limitations period when he subsequently suffered aortic aneurysm as a result of the transplant).

Here, the undisputed record evidence establishes that Plaintiff 6 suffered an unwanted pregnancy because Essure failed and, as a result, she underwent tubal ligation. The undisputed record evidence also establishes that at least one doctor advised Plaintiff 6 in 2013 that her left Essure device had migrated. Under these circumstances, a reasonable jury could only conclude that Plaintiff 6 had actual or constructive knowledge of significant harm and a factual cause linked to Essure no later than 2013 and, thus, at that point in time, the statute of limitations began to run on all of her claims, including claims grounded on pain caused by the device, without the necessity of specific notice that her pain was also the result of her failed Essure and the device's migration.<sup>24</sup> Accordingly, we grant Bayer's Motion for judgment in its favor on all of Plaintiff 6's tort claims

With respect to Plaintiff 6's warranty claims, we conclude that her claims based on non-extended warranties are time-barred and that the claims based on the warranties that we are considering extended for purposes of this Motion may proceed. Plaintiff 6's warranty claims based on non-extended warranties are presumptively time-barred by the four-year warranty statute because she had her Essure implanted in October 2010 and did not file suit until more than five years later, in July of 2016. Moreover, we deny Plaintiff 6's request for discovery to establish fraudulent concealment as to these non-extended warranties because she has failed to identify any statements (other than the contractual warranties on which she relies to support her warranty

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<sup>24</sup> Indeed, even if we were to consider the narrow exception for separate and distinct injuries articulated in Place, it cannot be said – and Plaintiffs do not argue – that Plaintiff 6's pain was not a “reasonably certain consequence” of her device's failure and migration and, thus, was not within “the same chain of causation.” 595 F. Supp. at 1012.

claims) on which she justifiably relied in failing to investigate her claims. We also reject any argument that she needs Rule 56(d) discovery to identify the statements that dissuaded her from investigating her claims as Plaintiff 6 should be able to identify those communications on which she justifiably relied without the need for discovery. Thus, we find Plaintiff 6's claims based on non-extended warranties to be time-barred under a traditional application of the four-year statute.

However, to the extent that Plaintiff 6 relies on extended warranties of permanent birth control, we do not find her claims to be untimely at this stage of the proceedings because the record reflects that she did not learn that she was pregnant (i.e., that the permanence warranties were breached) until October 2012, less than four years before she filed suit. Accordingly, we deny Bayer's Motion for judgment in its favor on Plaintiff 6's warranty claims grounded on warranties promising permanent protection from pregnancy, and grant Bayer's Motion with respect to the other alleged non-extended warranties.

#### **4. Plaintiff 7**

Plaintiff 7 had Essure placed on November 27 or 28, 2007. (Plaintiff 7 ("P7") PFS, Defs.' Ex. II, at III.2; P7 Decl., Pls.' Ex. 29, ¶ 7.) Prior to implantation, her doctor recommended uterine ablation to help with severe menstrual periods but advised that permanent sterilization by either tubal ligation or Essure was necessary before ablation could be done. (P7 Decl. ¶ 3.) Plaintiff opted for Essure after reading an Essure brochure that said that Essure was 99.8% effective against pregnancy and did not say anything about chronic pain, device migration, or irregular bleeding. (Id. ¶¶ 3-5.) Immediately following implantation, Plaintiff 7's physician expressed concern with the placement of the device in her right fallopian tube. (P7 PFS ¶ III.8; P7 Decl. ¶ 9.) Plaintiff 7 underwent an ultrasound Essure confirmation on December 12, 2007, and her physician told her that the Essure devices were properly situated in her fallopian tubes and that the tubes were

properly occluded. (P7 PFS ¶ III.9; P7 Decl. ¶ 10.) In March and April 2008, letters were sent to Plaintiff 7's home, reminding her to schedule an HSG test to confirm sterilization, but she did not receive those letters because she had moved out of her marital home. (P7 Decl. ¶ 11.) During Plaintiff 7's routine exams with her doctor's physician assistant from 2007 to 2013, the HSG test was not mentioned. (Id. ¶ 12.)

In April 2013, Plaintiff 7 discovered that she was pregnant. (P7 PFS ¶ V.2; P7 Decl. ¶ 14.) That same month, Plaintiff 7 called the Essure hotline, "seeking answers about how she had become pregnant, what [she] should do, and asking if it had happened to other people." (P7 Decl. ¶ 24.) The representative told Plaintiff 7 "that in two clinical trials of 745 women, 2.2% of women experienced the loss of one or both coils, and 1.8% experienced a perforation through the fallopian tube."<sup>25</sup> (P7 Decl. ¶ 24.) On April 15, 2013, Plaintiff 7 had an ultrasound that confirmed her pregnancy and also showed that the right Essure coil was missing from her fallopian tube, and the ultrasound tech could not locate it. (P7 Decl. ¶ 14; P7 Med Rcds., Pls.' Ex. 34, at 2, 8.) "Because the pregnancy was life-threatening," Plaintiff 7 terminated the pregnancy at seven weeks gestation. (P7 Decl. ¶ 14.)

On June 6, 2013, her doctor performed another ultrasound and told Plaintiff 7 that she was unable to see the Essure device in Plaintiff 7's right fallopian tube. (P7 Decl. ¶ 15; P7 Med. Rcds. at 5 (reflecting that an ultrasound showed "no obvious coil in the right fallopian tube").) The doctor told Plaintiff 7 that the coil was likely discharged from her body although Plaintiff 7 believed that it had migrated. (P7 Decl. ¶ 15.) Plaintiff 7's medical records reflect "failed Essure."

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<sup>25</sup> In her PFS, Plaintiff 7 describes her communication with the Essure Hotline representative as follows: "Discussed the discovery of my unplanned pregnancy and sought[] medical advice and guidance on medical care. I also wanted to know how this could have happened and if anyone else had this happen too." (P7 PFS ¶ VI.6.)

(P7 Med. Rcds. at 6.) The doctor recommended tubal ligation and a second ablation. (P7 Decl. ¶ 15; P7 Med. Rcds. at 5 (reflecting that Plaintiff 7 was “interested in definitive surgical management for sterilization”).) At that point, Plaintiff 7 lost faith in her doctor, believing that her doctor’s negligence had caused her injuries. (P7 Decl. ¶ 15.) She began seeing another doctor. (Id.) Her doctors could not, however, tell her why the migration or expulsion of the right coil happened, whether it was the fault of her implanting physician or Bayer, or was a “fluke of [her] own body.” (Id. ¶ 17.)

Plaintiff 7 reported her unplanned pregnancy on the FDA MAUDE database on October 31, 2013. (Id. ¶ 21; P7 PFS ¶ VI.7.) Because Bayer had reported no pregnancies in their clinical trials, Plaintiff 7 thought it was important to report her pregnancy, but she had no basis for believing that any negligent or wrongful conduct by Bayer had caused her pregnancy. (P7 Decl. ¶ 21.) In 2013 or 2014, she joined a Facebook group regarding Essure problems and used that forum to advocate for more research on Essure and unplanned pregnancies. (Id. ¶ 23.) Plaintiff 7 had a second pregnancy in December of 2014 and terminated that pregnancy as well. (Id. ¶ 16.) In addition to the two pregnancies, Plaintiff 7 has experienced severe and persistent pain and numbness in her extremities since 2011. (Id. ¶ 20.) Because these symptoms occurred well after implantation, she did not connect them to Essure, but she now believes that they are related. (Id.) Plaintiff 7 filed suit on July 8, 2016.

Plaintiff 7’s tort claims grounded on injuries associated with her pregnancy and the migration of her Essure device are time-barred, because she knew that Essure had failed its contraceptive purpose in 2013 when she became pregnant, and was told by her doctors that same year that her Essure device was not in her fallopian tube and had either migrated or been expelled from her body. Thus, the undisputed evidence establishes that Plaintiff 7 knew in 2013 that her

Essure device had failed and that she had been injured as a result. Accordingly, her 2016 tort claims based on migration and/or pregnancy are plainly untimely. While Plaintiffs ask us to consider Plaintiff 7's pain, which began in 2011, to be a separate injury that is subject to a different timeliness analysis, Plaintiff 7's situation is the equivalent of Plaintiff 6's, i.e., she knew of significant harms that were factually caused by Essure in 2013. Thus, under Pennsylvania law, Plaintiff 7 did not need to have received specific notice that her pain was also the result of her failed Essure and/or the device's migration in order for the statute of limitations to start to run on a claim for damages for her pain. See Gleason, 15 A.3d at 484 (explaining that plaintiff need not know of "the full extent of the injury" in order for statute to begin running (quoting Wilson, 964 A.2d at 364)). Rather, the statute of limitations on any pain claim began to run no later than when Plaintiff 7 discovered that she had been injured insofar as her device had migrated and she had become pregnant. Consequently, just like her migration and/or pregnancy claims, her pain claim is untimely because it was not filed within two years of the statute's commencement. We therefore find all of Plaintiff 7's tort claims to be time-barred, and we grant Bayer's Motion for judgment in its favor on Plaintiff 7's tort claims.

In contrast, at this stage of the proceedings, we will permit all of Plaintiff 7's warranty claims to proceed. The claims based on non-extended warranties are presumptively time-barred because Plaintiff 7 had her Essure implanted in November 2007, and she did not file suit until more than nine years later, in July of 2016. However, we will not enter judgment on them at this time but, instead, will permit Plaintiffs to conduct limited Rule 56(d) discovery. Plaintiff 7, unlike the other exemplar Plaintiffs, has submitted evidence concerning contact with Bayer in April of 2013, after her implantation with Essure. She contends that statements made in connection with this contact support her assertion of potential fraudulent concealment as well as her request for

Rule 56(d) discovery to further develop evidence to support her fraudulent concealment argument. (See N.T. 2/11/19, at 43-44.) As noted above, the summary judgment record reflects that, in answer to Plaintiff 7's questions on an Essure hotline, a Bayer representative told her "that in two clinical trials of 745 women, 2.2% of women experienced the loss of one or both coils, and 1.8% experienced a perforation through the fallopian tube," and also told her that "the risk to a fetus, should the pregnancy proceed, was unknown." (P7 Decl. ¶ 24; see also P7 PFS ¶ VI.6 (stating that she "[d]iscussed the discovery of my unplanned pregnancy and sought medical advice and guidance on medical care. I also wanted to know how this could have happened and if anyone else had this happen too.")) We cannot say with certainty at this point in the proceedings that this statement could not provide a reasonable basis for a fraudulent concealment argument that Bayer made an affirmative representation "to divert, mislead, or prevent discovery" so as to potentially toll the statute of limitations on Plaintiff 7's non-extended warranty claims. Overfield, 146 F.2d at 896. We also do not find Plaintiff 7's claims to be time-barred to the extent that she relies on extended warranties of permanent birth control, because she did not learn that she was pregnant (i.e., that the permanence warranties were breached) until April of 2013, just three years and three months before she filed suit.

Accordingly, although we grant Bayer's Motion insofar as it pertains to Plaintiff 7's tort claims, we deny the Motion insofar as it pertains to Plaintiff 7's warranty claims, and we grant Plaintiffs' request to conduct Rule 56(d) discovery concerning the fraudulent nature of the statements that Plaintiff 7 alleges were made to her in her call to the Essure hotline.

## **5. Plaintiff 8**

Plaintiff 8 had her device placed in September 2006. (Plaintiff 8 ("P8") PFS, Defs.' Ex. U, ¶ III.2; P8 Decl., Pls.' Ex. 9, ¶ 2.) In December 2006, following an HSG confirmation test, her

doctor informed her that her left coil was not in the correct place. (P8 PFS ¶¶ III.10.D, V.8; P8 Decl. ¶ 3.) As a result, Plaintiff 8 underwent tubal ligation in January 2007. (P8 Decl. ¶ 4.) Immediately after that procedure, she was told that the left coil had migrated, and she learned that the coil had perforated her fallopian tube and lodged in her bowel. (P8 PFS ¶ III.10.D; P8 Decl. ¶ 4.) She was not, however, experiencing pain from the perforation. (P8 PFS ¶ IV.8.) Her doctors cut away a portion of her bowel to remove the migrated coil, but Plaintiff 8's understanding was that "pieces of the Essure device still remain[ed] in [her] bowel." (P8 Decl. ¶ 4; P8 PFS ¶¶ III.10.D, V.8.) She was told that the other coil (the right coil) remained in its proper place. (P8 Decl. ¶ 4.) Plaintiff 8's declaration states that "[o]ver the next nine years, [she] experienced severe abdominal and pelvic pain, [and] abnormal bleeding."<sup>26</sup> (P8 Decl. ¶ 5.) Plaintiff 8's PFS clarifies that at least some of the pain was "at the Essure site." (P8 PFS ¶ V.4; see also P8 PFS ¶ V.1 (stating that she experienced pain "where the Essure device was located")). In 2012, Plaintiff 8 was prescribed pain medication for these symptoms. (P8 PFS ¶ V.2.)

Plaintiff 8 did not undergo an ultrasound to help determine the cause of her chronic pain until 2016. (P8 Decl. ¶ 6.) The ultrasound revealed that her remaining (right) Essure device was protruding into her endometrial cavity. (Id. ¶ 6.) On September 28, 2016, Plaintiff 8 spoke with her doctor about having a hysterectomy to remove the rest of the Essure device because of the pain and abnormal bleeding she had been suffering. (P8 PFS ¶ IV.1.) Her doctor "advised that since [they] had tried to manage [her] abdominal and pelvic pain medically for several years and this treatment had failed, a hysterectomy was necessary." (P8 Decl. ¶ 6.) Plaintiff 8 underwent a hysterectomy to remove the second coil in October 2016. (P8 PFS ¶ IV.2; P8 Decl. ¶ 6.) About

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<sup>26</sup> In contrast, Plaintiff 8 stated in her PFS that she first began to experience pelvic pain in January of 2012. (P8 PFS ¶ V.6.)

one month later, most of the symptoms that she had been experiencing (pain, bleeding, painful intercourse) subsided, and her migraines are now “very limited.” (P8 PFS ¶ IV.4; P8 Decl. ¶ 7.) Plaintiff 8 filed suit on September 5, 2017.

At oral argument on the summary judgment motion, Plaintiffs’ counsel stated that Plaintiff 8 is no longer asserting a tort claim for damages arising out of the 2007 migration of the first coil but, rather, is only asserting a tort claim for damages arising out of the migration of the second coil, which was confirmed in the 2016 ultrasound. (N.T. 2/11/19, at 50.) Moreover, Bayer does not dispute that the migration of the second coil is a separate and distinct injury that is subject to a separate statutory limitations period.<sup>27</sup> (*Id.* at 64-65.) Bayer nevertheless maintains that any claim based on the migration of the second coil is time-barred because Plaintiff 8 had been experiencing pain for years prior to the 2016 ultrasound and failed to exercise reasonable diligence to identify the cause of that pain. It appears to reason that, had Plaintiff 8 exercised reasonable diligence regarding her pain, she would have discovered that the second coil had migrated more than two years before she commenced suit and realized that the pain was, at least in part, the result of that migration. However, as noted above, there is record evidence that Plaintiff 8 had pieces of her left Essure device still lodged in her bowel after 2013, had been told that her right coil was properly located in her right fallopian tube, and received some medical treatment for her pain in 2012. In light of this evidence, a reasonable jury could arguably conclude that, prior to 2016, Plaintiff 8 reasonably attributed any pain she experienced to the migration of her left coil. We

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<sup>27</sup> In making this concession, Bayer appeared to be applying the logic of *Place*. See *supra* notes 23-24; (N.T. 2/11/19, at 65 (“In this instance I would say you can have a situation where the right coil starts a chain of events for the statute of limitations and then the left coil starts a separate one.”). Bayer also, however, took the position that the only circumstance that would give rise to two separate limitations periods is that in which there are injuries from two separate coils. (N.T. 2/11/19, at 65.)



therefore conclude that the record presents a genuine dispute of material fact as to whether Plaintiff 8 exercised reasonable diligence in investigating the cause of her pain and whether, with reasonable diligence, she should have discovered before 2016 that her second coil had migrated. Consequently, we grant Bayer's Motion as unopposed insofar as it seeks judgment in its favor on the tort claims arising out of migration of the first coil, but deny the Motion insofar as Bayer seeks judgment in its favor on the tort claim for damages arising out of migration of the second coil.

On the other hand, we find all of Plaintiff 8's warranty claims to be time-barred. Plaintiff 8's non-extended warranties are presumptively time-barred as she had Essure implanted in 2006 and did not file suit until almost 10 years later, in 2016. In addition, to the extent that Plaintiff 8 relies on extended warranties promising permanent contraception, her claims are time-barred because she plainly discovered that this warranty had been breached in 2007, when she underwent tubal ligation because Essure was not providing her the protection from pregnancy that she was promised. See 13 Pa. Cons. Stat. § 2725(b) (stating that cause of action on extended warranty "accrues when the breach is or should have been discovered"). We also decline to permit Plaintiffs' Rule 56(d) discovery on fraudulent concealment because, like the bulk of the other Plaintiffs, Plaintiff 8 has not identified any statement from Bayer on which she justifiably relied other than those on which she bases her warranty claims. Accordingly, we grant Bayer's Motion for judgment in its favor as to all of Plaintiff 8's warranty claims.

## **6. Plaintiff 9**

Plaintiff 9 had her device placed on June 18, 2013. (Plaintiff 9 ("P9") PFS, Defs.' Ex. AA, ¶ III.2; P9 Decl., Pls.' Ex. 13, ¶ 5.) Prior to placement, she had viewed a brochure that informed her that the device "would not migrate from the fallopian tubes, and that it stayed secure." (P9 PFS ¶ III.6.) During the implant procedure, the doctor noted in her records that there was scar

tissue on Plaintiff 9's left fallopian tube. (P9 Decl. ¶ 6; P9 Med. Rcds, Pls' Ex. 35, at 3.) The doctor told Plaintiff 9 that the first coil she inserted did not stay in, so she had to insert a second coil in that tube. (P9 Decl. ¶ 6.) The doctor stated at the end of the procedure, however, that there were properly placed coils in both fallopian tubes. (P9 Decl. ¶ 6; see also P9 Med. Rcds, at 3.) Plaintiff 9's September 2013 HSG confirmation test revealed that the left coil had migrated outside of her fallopian tube. (P9 PFS ¶ III.10; P9 Decl. ¶¶ 7-8; see P9 Med. Rcds. at 7 (stating that the left device "is not located within the tube" and that is it "coiled near the cornua and partially within the uterus").) Her doctor told her that she could either put another Essure coil in the left fallopian tube or remove both tubes. (P9 Decl. ¶ 8.) Plaintiff 9 initially believed that her doctor had incorrectly placed the device. (Id. ¶ 9.) Plaintiff 9's medical records reflect "Failed Essure," and on December 17, 2013, Plaintiff 9 underwent a laparoscopic bilateral tubal ligation to remove both fallopian tubes and the remaining Essure device. (Id. ¶ 11; P9 Med. Rcds at 8, 10-11.) The left device that had migrated, however, was not located. (P9 Decl. ¶ 11; P9 Med. Rcds. at 9 (noting "[a]bsolutely no evidence of left Essure device near the left tubal ostia or in the uterine cavity or in the abdominal cavity").) Plaintiff 9 asked her doctor where the missing coil was, how it could migrate and why it migrated, and the doctor was unable to provide answers. (P9 Decl. ¶ 13.) Plaintiff 9 did not know if it was "because of the Essure device or Bayer's conduct, doctor error, or a fluke of [her] own body." (Id.) Plaintiff 9 filed her action on July 8, 2016.

Plaintiff 9's tort claims are barred by the statute of limitations. As noted above, the evidence is undisputed she knew her coils had migrated in 2013 and, as a result, she had her Essure implants removed that same year. Thus, a reasonable jury could only conclude that Plaintiff 9 knew that she had been injured by Essure in 2013, more than two years before she filed suit. For this same reason, we deny Plaintiffs request for leave to conduct Rule 56(d) discovery as to

fraudulent concealment with regard to her tort claims; even if fraudulent concealment were proven, any tolling would necessarily end when Plaintiff 9 knew of her Essure-related injury more than two years before her tort claims were filed. See Fine, 870 A.2d at 861. We therefore grant Bayer's Motion insofar as it seeks judgment in Bayer's favor on Plaintiff 9's tort claims.

On the other hand, Plaintiff 9's breach of warranty claims are not barred by the statute of limitations because she had her device implanted on June 18, 2013, and filed suit on July 8, 2016, less than four years later. We therefore deny Bayer's Motion insofar as it seeks judgment in its favor on Plaintiff 9's breach of warranty claims.

**C. Plaintiffs Who Believed Injuries were Essure-Related Outside the Two-Year Period**

**1. Plaintiff 10**

Plaintiff 10 had her Essure device implanted on August 15, 2007. (Plaintiff 10 ("P10") PFS, Defs.' Ex. DD, ¶ III.2; P10 Decl., Pls.' Ex. 20, ¶ 5; P10 Amended PFS, Pls.' Ex. 19, at 3.) She underwent an HSG test on January 23, 2008, which confirmed that the devices were properly placed. (P10 Decl. ¶ 6; P10 Med. Rcds., Pls.' Ex. 37, at 3.) Also in January of 2008, she began experiencing persistent pelvic and abdominal pain and heavy bleeding. (P10 PFS ¶¶ V.4, V.6.) She suspected that her heavy periods were Essure-related in January of 2008, but her physician never confirmed the connection. (P10 PFS ¶ V.4; P10 Decl. ¶ 8.) She also asked her doctors if her pelvic pain could be Essure-related, but her doctors told her that they did not know the cause of her pain. (P10 Decl. ¶ 8.) Her doctors ordered tests and referred her to other doctors. (Id. ¶ 8.) Between 2008 and 2018, she searched for the cause of her symptoms and underwent numerous diagnostic tests, including blood tests, imaging tests, and two exploratory surgeries (one in 2012 and one in 2014). (P10 Decl. ¶¶ 9, 12; P10 Med. Rcds. at 6-7.) She also had pelvic and transvaginal ultrasounds and abdominal and pelvic CT scans between 2008 and 2017. (P10 Decl.

¶ 10; P10 Med. Rcds. at 5, 8-9.) Plaintiff 10 has been told that she was pregnant or might be miscarrying; that she had cysts; that she had thickened endometrial lining; and that she had fluid in her posterior cul-de-sac. (P10 Decl. ¶ 10; P10 Med. Rcds. at 5, 9.) Her doctor offered many possible explanations for her symptoms and did not recommend removal of Essure. (P10 Decl. ¶ 11.) Indeed, her doctors have suggested that her symptoms may be the result of thyroid dysfunction, endometriosis, irritable bowel syndrome, ovarian cyst, lesions, or simply her menstrual cycle. (Id. ¶ 15; see, e.g., P10 Med. Rcds. at 13.)

In 2009, Plaintiff 10 filed a claim with the Social Security Administration (“SSA”) for disability benefits, asserted that she was suffering from injuries from Essure, as well as injury/disability due to “anxiety, pain, [and her] heart,” and her disability claim was granted. (P10 PFS ¶ II.7.1.) In 2014, Plaintiff 10 filed a complaint with the FDA, asserting that her Essure device was causing her pain. (Id. ¶ VI.7.) In 2015, Plaintiff 10 joined the Facebook Essure Problems Group. (P10 Decl. ¶ 18; P10 PFS ¶ VI.2.) While she still suspected that Essure might be the cause of her pain and other symptoms, none of the members of the group were receiving confirmation of causation from their doctors. (P10 Decl. ¶ 18.) She read about the new black box warning on Essure in February 2016. (Id. ¶ 19.) However, her doctors still did not tell her that her symptoms were Essure-related. (Id.) Plaintiff 10 filed her claim on July 11, 2016.<sup>28</sup>

We conclude that there are genuine disputes of material fact that preclude a conclusion at this time that Plaintiff 10’s tort claims are time-barred. Indeed, there is sufficient evidence in the

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<sup>28</sup>In October 2016, after Plaintiff 10 filed suit, her family doctor, for the first time, mentioned that she had other patients with Essure who were experiencing similar problems. (P10 Decl. ¶ 20.) Her doctor stated that she could find no other explanation for Plaintiff 10’s cluster of symptoms and therefore thought Essure might be the cause. (Id.) The doctor referred Plaintiff 10 to a gynecologist, who, on October 17, 2016, again told Plaintiff 10 that her problems were not Essure-related and prescribed birth control to suppress menstruation and eliminate her pain. (Id. ¶¶ 20-21.)

record from which a jury could reasonably conclude that Plaintiff 10 exercised reasonable diligence in attempting to identify the cause of her injuries and yet was unable to do so more than two years before filing her tort claims, in large part due to the opinions of her doctors that a variety of other medical issues were causing her symptoms. While Bayer emphasizes evidence that shows that Plaintiff 10's symptoms began immediately after implantation, and that she suspected that her injuries were caused by Essure and even voiced those opinions to the SSA and FDA, we conclude that in the absence of any sort of medical confirmation of those suspicions – and instead, flat-out disagreement from her doctors – a reasonable jury could find that Plaintiff 10 did not have a “unrebutted suspicion” that her symptoms were caused by Essure such that the statute of limitations necessarily began running. Debiec, 352 F.3d at 132. Indeed, a “suspicion can be rebutted and the statute is tolled where a plaintiff reasonably relies on the assurance of her physician or health care provider that her suspicion about the cause of the injury . . . is unfounded.” Billeci, 2018 WL 1635242, at \*5 (citing Debiec, 352 F.3d at 132); id. at \*5-6 (concluding that there was a genuine dispute of material fact as to whether statute of limitations was tolled when plaintiff suspected injuries to be caused by vaccine and even sent accusatory letter to medical department for not warning of side-effects, but trusted response of medical professionals that vaccine had not caused injuries). We therefore deny Bayer's Motion for judgment in its favor on Plaintiff 10's tort claims.

We find Plaintiff 10's warranty claims, unlike the tort claims, to be time-barred. Plaintiff 10's claims based on the warranties that do not extend to the future are presumptively time-barred because she had her Essure implanted in August 2007, and she did not file her claims until July 11, 2016. We further conclude that there is no basis on which to permit Plaintiff 10 Rule 56(d) discovery concerning fraudulent concealment because she has not identified any statements that

Bayer made (and on which she justifiably relied in failing to investigate) other than the warranties on which she bases her warranty claims, which, as explained above, cannot be the statements on which she bases her fraudulent concealment argument. See supra Section II.B.3. In the absence of any evidence that Plaintiff 10 was dissuaded by Bayer's independent and affirmative misrepresentations, there can be no fraudulent concealment, and there is no basis for discovery into whether Bayer may have made other untruthful or misleading statements.

Moreover, while Plaintiff 10 asserts a breach of warranty claim grounded on Bayer's extended warranties promising permanent birth control, there is no evidence in the record to support a conclusion that that Bayer breached a permanence warranty in connection with Plaintiff 10 as Plaintiff 10 never became pregnant, has not been told that her Essure device has migrated or is otherwise ineffective against pregnancy, and has not had Essure removed. We therefore grant Bayer's Motion insofar as it seeks judgment in its favor on Plaintiff 10's warranty claims.

## **2. Plaintiff 11**

Plaintiff 11 had her Essure device implanted on October 25, 2010. (Plaintiff 11 ("P11") PFS, Defs.' Ex. EE, ¶ III.2; P11 Decl., Pls.' Ex. 22, ¶ 3.) Prior to implantation, she confirmed that she had received Essure's patient information booklet, which warned that a woman "should NOT use . . . *Essure* . . . if . . . [she has] a sensitivity to nickel as shown by skin testing." (Defs.' Reply SMF, Ex. C, at 1; Defs' Ex H at 5.) Nevertheless, based on her doctor's recommendation, she was not tested for any metal allergies before implantation. (P11 Decl. ¶ 7.) She began developing rashes and welts soon after implantation. (P11 PFS ¶¶ V.1, V.4, V.9; P11 Am. PFS, Pls.' Ex. 21, at 3, 5; P11 Decl. ¶ 8.) Plaintiff 11 also experienced frequent pelvic pain. (P11 Decl. ¶ 14.) She consulted her primary care provider, her cardiologist, and her gynecologist. (Id. ¶¶ 8-9.) Her cardiologist suggested that her symptoms could be caused by cardio edema, and her

gynecologist told her “in no uncertain terms that her symptoms were not related to Essure.” (*Id.*) Plaintiff 11 subsequently consulted a dermatologist and an allergist. (*Id.* ¶ 10.)

In 2010, she began filing complaints regarding Essure on the FDA MAUDE database and through the MedWatcher application, the latter of which, according to Bayer, allows patients to report device-associated injuries or malfunctions. (P11 PFS ¶ VI.7; Defs.’ Mem. at 26.) She began to suspect that her injury was Essure-related in May of 2011. (P11 Am. PFS at 3.) Plaintiff 11 tested positive for a nickel allergy in December 2011. (P11 Decl. ¶ 10.) When she asked her allergist about a connection to Essure, he said that it was unlikely that Essure was causing her symptoms but that she could have the device removed if she had concerns about it. (*Id.* ¶ 10.) On January 31, 2012, her allergist wrote a letter to another doctor “at [Plaintiff 11’s] request,” conveying that Plaintiff 11 had a “recurrent rash” and stating: “Patient uses Essure device for birth control. This device is known to contain nickel-titanium alloy. Although it is rare, there are case reports of contact dermatitis secondary to this device in nickel sensitivity women. Given the ongoing symptoms and patient’s severe sensitivity to nickel, I have recommended that she consider removal of the device.” (Defs’ Reply SMF, Ex. C, at 2.) In 2012, Plaintiff 11 joined the Essure Problems Group on Facebook. (P11 PFS ¶ VI.2; P11 Am. PFS at 6.) That same year, Plaintiff 11 talked to another doctor about removal of Essure via hysterectomy, but he told her that Essure was not the cause of her problems. (P11 PFS ¶ IV.1; P11 Decl. ¶ 11.) Plaintiff 11 filed suit on July 8, 2016.

We decline to find on the existing summary judgment record that Plaintiff 11’s tort claims are time-barred. Plaintiff 11 states in her Declaration that she did not know of the connection between her symptoms and Essure until 2016. (P11 Decl. ¶ 17.) While Bayer argues that other evidence conclusively establishes that Plaintiff 11 actually knew of the causal link, pointing

primarily to her complaints to the FDA, these complaints are better characterized as suspicions that were arguably rebutted by Plaintiff 11's various treating doctors and, thus, did not necessarily trigger the start of the statute of limitations.<sup>29</sup> Moreover, we reject Bayer's argument that the undisputed record establishes that Plaintiff 11 did not exercise reasonable diligence in seeking out the cause of her symptoms and that, with reasonable diligence, she would have learned that Essure was the cause. Rather, we conclude that there are genuine disputes of material fact as to Plaintiff 11's reasonable diligence because there is record evidence that Plaintiff 11 exercised considerable diligence in seeking out the cause of her symptoms, meeting with numerous medical professionals and undergoing a number of different tests. Bayer faults Plaintiff 11's apparent failure to request her medical records, which would have disclosed her allergist's 2012 letter, but we conclude that, given Plaintiffs' apparent diligence in other respects, it is for a jury to determine whether her failure to request the records or engage in other investigation was unreasonable. Accordingly, we deny Bayer's Motion insofar as it seeks judgment in its favor on Plaintiff 11's tort claims.

In contrast, we find Plaintiff 11's warranty claims to be time-barred. Plaintiff 11's warranty claims grounded on promises that do not extend to the future are presumptively time-barred because she had her Essure implanted in October 2010, and did not file her claims until July

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<sup>29</sup> Bayer also points to Plaintiff 11's PFS, in which she indicated that she was told by a doctor in 2012 that her welts and rashes were Essure-related. (P11 PFS ¶ V.4.) However, in an Amended PFS, Plaintiff 11 amended that response to state that the date on which she was told by a doctor that her rashes and welts were Essure-related is "N/A." (P11 Amended PFS at 3.) We have stated that the "completed PFS 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]." 2/15/18 Ord. ¶ 1.b, ECF No. 207, McLaughlin v. Bayer Essure Inc., Civ. A. No. 14-7315. At the same time, Plaintiff 11 had an obligation under Federal Rule of Civil Procedure 26(e) to "supplement or correct [her] disclosure or response . . . if [she] learns that in some material respect the disclosure or response is . . . incorrect." Fed. R. Civ. P. 26(e). Under these circumstances, for purposes of resolving the current Motion, we read the record in favor of the non-moving party and rely on the N/A response.



2016. We further conclude that there is no basis on which to permit Plaintiff 11 discovery concerning fraudulent concealment because she has not identified any statements that Bayer made (and on which she justifiably relied in failing to investigate) other than the warranties on which she bases her warranty claims, which, as explained above, cannot be the statements on which she bases her fraudulent concealment argument. See supra Section II.B.3. In the absence of any evidence that Plaintiff 11 was dissuaded by Bayer's independent and affirmative misrepresentations, there can be no fraudulent concealment and there is no basis for discovery into whether Bayer may have made other untruthful or misleading statements.

Finally, while Plaintiff 11 (like Plaintiff 10) asserts a breach of warranty claim grounded on Bayer's extended warranties promising "permanent" birth control, there is no evidence in the record to support a conclusion that that Bayer breached such a warranty in connection with Plaintiff 11 as Plaintiff 11 never became pregnant, has not been told that the device has migrated, and has not had Essure removed. Accordingly, we grant Bayer's Motion insofar as it seeks judgment in its favor on Plaintiff 11's warranty claims.

### **3. Plaintiff 12**

Plaintiff 12 had her device placed on July 6, 2009. (Plaintiff 12 ("P12") PFS, Defs.' Exs. FF, ¶ III.2; P12 Decl., Pls.' Ex. 24, ¶ 4.) She was not tested for a nickel allergy prior to implantation. (P12 Decl. ¶ 10.) She began experiencing a variety of adverse symptoms immediately after placement, including vomiting, migraines, cysts, low back pain, metal allergy, rashes, and abdominal and pelvic pain. (P12 PFS ¶ V.1; P12 Decl. ¶ 5.) Her implanting doctor told her that the symptoms were not related to Essure. (P12 Decl. ¶ 5.) She suspected that her symptoms were caused by Essure in 2009. (P12 PFS ¶ V.4.) However, in a hospitalization in 2009, she was told that her symptoms were a result of her diet. (P12 Decl. ¶ 8.) She began

discussing her suspicions with her ex-husband in 2009. (P12 PFS ¶ VI.5.) Starting in “late 2009,” she “persistently sought treatment and searched for the cause of [her] symptoms.” (P12 Decl. ¶ 14.) Among the diagnostic tests she has undergone are x-rays, blood test, and MRIs. (Id.) Her mother, who never finished high school and has no medical training, suggested that she have the device removed in 2010 for health reasons. (P12 PFS ¶ IV.7; P12 Decl. ¶ 20.) That same year, however, her implanting doctor again told her that her problems were definitely not related to Essure. (P12 Decl. ¶ 9.) Plaintiff 12 also saw an allergist in 2010, and she tested positive for a nickel allergy. (P12 PFS ¶ V.9.) The allergist was aware that she had Essure but did not know what the device was or what materials it contained. (P12 Decl. ¶ 11.) The allergist also “thought it was unlikely that an allergy to nickel would have anything to do with Essure,” and similarly, her implanting doctor said there was not enough nickel in the device to cause health problems. (Id. ¶¶ 11-12.) In 2011, Plaintiff 12 was diagnosed with an auto immune disorder. (Id. ¶ 16.) After 2011, she saw other gynecologists, all of whom have told her that her problems are not related to Essure. (Id. ¶ 13.)

In 2014, Plaintiff 12 discovered the Facebook Essure Problems Group and learned of other women experiencing problems with Essure. (P12 Decl. ¶ 18.) On March 19, 2014, Plaintiff 12 posted in the Facebook Essure Problems Group that she “obtained a lawyer today” and was “going in Monday for a b[i]opsy of my uterus and ovaries.” (Defs.’ Mot. to Suppl. Summ. J. Record, Ex. A, at 2.) Furthermore, in a May 6, 2014 post to the same group, Plaintiff 12 writes that she “ha[s] a doctor onboard finally” and that the doctor is sending her back to the allergist. (Id. at 3.) In 2015, she spoke with a friend whose wife was very ill after her Essure coil migrated to her ovary. (P12 Decl. ¶ 18.) She states in her Declaration that her involvement in the Facebook group and

discussions with her friend raised her suspicion that Essure was the cause of her problems.<sup>30</sup> (Id.) Plaintiff 12 filed suit on June 24, 2016.

We conclude that Plaintiff 12's tort claims are barred by the statute of limitations, based on the evidence that, no later than May 6, 2014, she had obtained a lawyer and had a doctor who had confirmed her suspicions that Essure was the cause of her symptoms. While we agree with Plaintiffs that there is a genuine factual dispute as to whether Plaintiff 12 knew or should have known that that Essure was the cause of her symptoms before May 6, 2014, no reasonable jury could conclude that she did not know by May 6, 2014, when she told members of the Facebook Essure Problems Group that she had finally found both a doctor and a lawyer to support her long-held suspicions that she had suffered Essure-related injuries. Under these circumstances, we grant Bayer's Motion for judgment in its favor as to Plaintiff 12's tort claims.

In addition, we conclude that Plaintiff 12's warranty claims are time-barred. The claims based on non-extended warranties are presumptively time-barred because Plaintiff 12 had her Essure implanted in July 2009, and she did not file suit until June 2016. We also conclude that Plaintiff 12 has not established an entitlement to discovery to develop evidence of fraudulent concealment because she has not identified any statements from Bayer on which she justifiably relied other than those on which she bases her breach of extended warranty claims. See supra

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<sup>30</sup> Immediately after recounting in her Declaration both her discovery of the Facebook Essure Problems Group and her 2015 discussions with her friend, Plaintiff 12 states in her Declaration: "This raised my suspicion that Essure could be the cause of my symptoms, and although my doctors still did not agree, I decided to contact a lawyer." (P12 Decl. ¶ 18.) The Declaration is therefore ambiguous as to what precisely prompted Plaintiff 12 to contact an attorney – i.e., whether it was her involvement in the Facebook Essure Problems Group in 2014 or her conversations with a friend in 2015, or both – and precisely when she made that contact. The social media posts clear up that ambiguity and clarify that it was Plaintiff 12's 2014 conversations that prompted her to contact an attorney because they make clear that the contact occurred before 2015. (Defs.' Mot. to Suppl. Summ. J. Record, Ex. A, at 2.)

Section II.B.3. Finally, while Plaintiff 12 (like Plaintiffs 10 and 11) asserts a breach of warranty claim grounded on certain Bayer's extended warranties promising "permanent" birth control, there is no evidence in the record to support a conclusion that that Bayer breached such a warranty in connection with Plaintiff 12, because Plaintiff 12 never became pregnant, has not been told that an insert has migrated, and has not had Essure removed. Accordingly, we grant Bayer's Motion for judgment in its favor on Plaintiff 12's warranty claims as well as her tort claims.

#### **IV. CONCLUSION**

For the foregoing reasons, we grant Bayer's Motion in part and deny it in part. Specifically, we grant the Motion insofar as it seeks judgment in Bayer's favor as to (1) all of the claims of Plaintiffs 1, 2, and 12; (2) the tort claims of Plaintiffs 6, 7, and 9; (3) the tort claims seeking damages for the migration of the left coil of Plaintiff 8; (4) the warranty claims of Plaintiffs 3, 8, 10, and 11; and (5) the non-extended warranty claims of Plaintiffs 4 and 6. We deny the Motion insofar as it seeks judgment in all other respects. Thus, Plaintiffs may proceed on the both the tort and warranty claims of Plaintiff 5; the tort claims of Plaintiffs 3, 4, 10, and 11; the tort claims of Plaintiff 8 that seek damages arising from the migration of her right coil; all of the warranty claims of Plaintiffs 7 and 9; and the extended warranty claims of Plaintiffs 4 and 6. We grant Plaintiffs' request for Rule 56(d) discovery only with respect to fraudulent concealment that might toll the statute of limitations on Plaintiff 7's warranty claims.

An appropriate Order follows.

BY THE COURT:

/s/ John R. Padova, J.

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John R. Padova, J.