UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

SHELLEY EVERS, CHRISTINA PATRAS, RITA MELKONIAN, and TRICIA WILLARD, Plaintiffs, v. HOLOGIC, INC., Defendant.	* * * * * * * * * *	Civil Action No. 22-cv-11895-ADB
JULIE BLOCK, NERISSA BURKE, and KAREN ENSLEY, Plaintiffs, v. HOLOGIC, INC., Defendant.		Civil Action No. 22-cv-12194-ADB

MEMORANDUM AND ORDER

BURROUGHS, D.J.

Plaintiffs Rita Melkonian ("Melkonian"), Tricia Willard ("Willard"), Nerissa Burke ("Burke"), and Karen Ensley ("Ensley") (collectively "Plaintiffs") were each diagnosed with mammary/ductal carcinoma, a form of breast cancer. Each underwent a partial mastectomy, sometimes referred to as a lumpectomy or breast conservation surgery, to remove cancerous lesions. During those surgeries, Plaintiffs were implanted with a BioZorb marker, a device used

to identify breast tissue surrounding the excised cancer tissue to help calibrate for radiation targeting. After the procedures, each Plaintiff alleges that she experienced injuries, which they attribute to the negligence of Defendant Hologic, Inc. ("Hologic") in the manufacture and distribution of the BioZorb device. In the complaints in this case, Plaintiffs each allege four causes of action against Hologic: Negligent Failure to Warn (Count I); Negligent Design Defect (Count II); Breach of Implied Warranty of Merchantability (Count III); and Negligence (Count IV). [See Case No. 22-cv-12194 ("Block"), ECF No. 121 at 12–20 ("Block First Amended Complaint" or "Block FAC"); Case No. 22-cv-11895 ("Evers"), ECF No. 139 at 13–21 ("Evers Second Amended Complaint" or "Evers SAC")].

Plaintiffs are just four of more than eighty plaintiffs, spread across eighteen cases currently pending before the Court,[1] who allege negligence by Hologic in connection with the design and marketing of BioZorb. The Court has entered case management and bellwether orders in the cases, pursuant to which the parties are permitted to file initial motions for summary judgment limited to the applicability of learned-intermediary doctrine, which can disprove the element of causation in failure-to-warn claims involving medical devices. See, e.g., [Evers, ECF No. 84 at 7]. Hologic has moved for summary judgment on Plaintiffs' failure to warn, general negligence, and breach of warranty claims (Counts I, III and IV) under that doctrine. For the reasons set forth below, the motions for summary judgment are **DENIED** on

[1] The cases are Evers v. Hologic, No. 22-cv-11895; Block v. Hologic, No. 22-cv-12194; Chambers v. Hologic, No. 23-cv-10260; Shirkey v. Hologic, No. 23-cv-10579; Stine v. Hologic, No. 23-cv-10599; Baker v. Hologic, No. 23-cv-10717; Slater v. Hologic, No. 23-cv-10888; Rivera v. Hologic, No. 23-cv-11012; English v. Hologic, No. 23-cv-11512; Webb v. Hologic, No. 23-cv-11823; Price v. Hologic, No. 23-cv-12011; Heffner v. Hologic, No. 23-cv-12278; Blanchenay v. Hologic, No. 23-cv-12458; Austin v. Hologic, No. 23-cv-12651; Swafford v. Hologic, No. 23-cv-12687; Bonvillain v. Hologic, No. 23-cv-12833; Ciers v. Hologic, No. 23-cv-13215; Broeder v. Hologic, No. 24-cv-10823; Galaini v. Hologic, No. 24-cv-11939.

all counts as to Rita Melkonian, Tricia Ward, and Karen Ensley, and **GRANTED** on Counts I, III and IV as to Nerissa Burke.[2]

I. BACKGROUND

A. Factual Background

The BioZorb marker is an implantable device approved by the FDA to assist in post-lumpectomy radiation treatment of breast cancer. See, e.g., [Melkonian Responsive Statement of Undisputed Facts ("RSUF") ¶¶ 1–2]. The BioZorb consists of a spiral-shaped bioabsorbable spacer that holds six titanium clips. [Id. ¶¶ 2–3]. Although BioZorb markers come in a range of sizes, the parties agree that the image below depicts an accurate visual representation of the device.

See, e.g., [id. ¶ 2].

[2] Hologic's motions also contend that Plaintiffs have inadequately pled their design defect claims (Count II). See, e.g., [Burke MSJ at 13]. Pursuant to the Court's bellwether order, however, these arguments are not ripe for summary judgment. See [Evers, ECF No. 84 at 7]. In any event, as the Court permitted Plaintiffs to amend their design defect claims and has invited Hologic to file motions to dismiss, see [Evers, ECF No. 168; Block, ECF No. 142], the Court will **DENY** Hologic's motions for summary judgment as to the design defect claims without prejudice.

The BioZorb was approved by the Food and Drug Administration ("FDA") as a Class II medical device to mark sites where cancerous lesions have been surgically removed to facilitate targeted future radiation treatment. [Melkonian RSUF ¶¶ 1, 3–4]. The device is intended to dissolve into the body during a process Hologic calls "resorption." [Id. ¶ 4].

According to the BioZorb's Instructions for Use ("IFU") in effect at the time of the Plaintiffs' operations, the resorption process may take "one or more years." [Melkonian RSUF ¶ 4]. Specifically, the IFU advised that "the spacer material retains its functional integrity for approximately [two] months, while complete resorption may require up to one or more years." [Id.; Evers SAC Ex. 1]. The IFU expressly warns of the following risks and contraindications:

> The Marker should not be placed in a tissue site with clinical evidence of infection . . . The marker should only be used by physicians trained in surgical techniques. The physician is responsible for its proper clinical use. The Marker is shipped sterile; do NOT re-sterilize any portion of the Marker. The Marker is for SINGLE USE only. Do NOT use if the package is open or damaged, or if the temperature indicator has a black center. Use the Marker prior to the expiry date shown on the product label.

[ECF No. 11-1 at 2].

Plaintiffs were diagnosed with breast cancer and had surgery between 2018 and 2019, during which each was implanted with a BioZorb marker. [Melkonian RSUF ¶¶ 5–6; Willard RSUF ¶¶ 5–6; Ensley RSUF ¶¶ 5–6; Burke RSUF ¶¶ 5–6]. Details concerning each Plaintiff's treatment and details of their physicians' deposition testimony are set forth below.

1. Rita Melkonian

Rita Melkonian was diagnosed with breast cancer in her left breast in May 2018. [Melkonian RSUF ¶ 5]. On August 9, 2018, Dr. Lisa Bailey, a surgical oncologist specializing in breast cancer treatment, performed a partial mastectomy and sentinel node excision on

Melkonian at Alta Bates Summit Medical Center in Oakland, California. [Id. ¶ 6]. Prior to the procedure, Dr. Bailey explained to Melkonian that she intended to use a BioZorb device during Melkonian's procedure. [Bailey Dep. at 58:18–59:3]. Melkonian testified that Dr. Bailey told her the device "w[ould] be absorbed within six months to a year." [Melkonian Dep. at 126:8]. Dr. Bailey did not specifically recall discussing an absorption timeline with Melkonian, explaining that she "would normally not say that." [Bailey Dep. at 62:17–18]. Dr. Bailey testified that she typically advised her patients that "BioZorb would reabsorb gradually" and could not recall whether she had "ever give[n] [patients] a time frame." [Melkonian RSUF ¶ 16].Approximately two and a half years after surgery, in March 2021, Melkonian noticed a nodule in her breast that caused a "pulling" sensation at her nipple. [Melkonian Responsive Statement of Additional Undisputed Facts ("RSAF") ¶ 3]. Melkonian testified that she feared the nodule was a recurrence of breast cancer. [Id.]. In May 2021, she received an examination and ultrasound by another physician, Dr. Natalie Marshall. [Evers, ECF No. 81-7 at 1]. Dr. Marshall's patient report stated that, based on a "compar[ison] to prior imaging studies," the "BioZorb markers ha[d] rearranged in a somewhat linear configuration, the most anterior of which [were] in the palpable area of concern." [Id.]. Dr. Marshall also noted "fat necrosis calcification associated with the more posterior markers." [Id.]. At a September 3, 2021 follow-up appointment based on a referral from Dr. Marshall, another physician, Dr. Elizabeth Peralta, reported that Melkonian presented with "tenderness under the surgical scar where the fragmented BioZorb is palpable in a superficial plane." [Evers, ECF No. 81-8 at 1]. Melkonian reported pain "even with light touch such as clothing." [Id.]. Dr. Peralta's report indicates that Melkonian was considering having the BioZorb surgically removed, see [id.], although she ultimately elected not to undergo further surgery, see [Melkonian Dep. at 246:7–12].

Dr. Bailey's 2024 deposition included the following exchange between her and counsel for Hologic:

> Q: Doctor, did you ever review the complaint that was filed . . . by the plaintiffs in this case?
> A: I don't recall, but I don't believe so.
> Q: Doctor, given everything that you know today about BioZorb, do you continue to believe that using the BioZorb was the appropriate option for you to use with Rita Melkonian at the time of her surgery?
> A: Yes.

[Bailey Dep. at 106:1–10].

Hologic's counsel then asked Dr. Bailey about hypothetical additional warnings that Hologic could have included in the IFU:

> Q: If the BioZorb instructions for use indicated that one of the risks associated with using the BioZorb would be a risk of pain, would you still have used the BioZorb?
> A: Well, I would — I generally review whatever literature there is, and I think it would depend on more specifics about risks.
> Q: Okay. And when you say "more specifics about risks," what do you mean?
> A: Well, you have to look at all of the risks. So if a hundred percent of the patients had pain, then that would be an issue, obviously. So you just — you know, I would always review whatever literature there was and look at risk/benefit for the patient.

[Bailey Dep. at 107:6–20]. Dr. Bailey then testified that, although she did not specifically recall reviewing the BioZorb IFU, she "generally" would do so before using a prescription device. [Id. at 109:2–5]. Hologic ended its questioning after that. [Id. at 109:11–12].

2. Tricia Willard

Tricia Willard was diagnosed with cancer in her left breast in September 2019. [Willard RSUF ¶ 5]. On October 29, 2019, Dr. Lindsay Hardley performed a partial mastectomy on Willard at Parkview Packnett Family Cancer Institute in Fort Wayne, Indiana. [Id. ¶ 6].

Dr. Hardley testified that prior to the procedure, she told Willard that she intended to use a BioZorb device in Willard's breast during surgery and advised her that she may be able to feel the BioZorb device in her breast. Willard, however, testified that Dr. Hardley said she would not be able to feel it. [Willard RSUF ¶ 17; Willard Dep. at 64:25–65:3]. Willard also testified during her deposition in this case that Dr. Hardley told her the BioZorb would resorb in about a year, although Hardley testified that she "never gave [her] patients [an] expectation of a specific time frame." [Id. ¶ 19].

According to Willard's testimony, around February 2020, she felt a painful lump in her breast, which diagnostic imaging determined to be near the BioZorb site. [Willard Dep. at 104:5–23, 109:8–11]. Willard discussed removing the BioZorb with Dr. Hardley, who recommended waiting for the marker to resorb. [Id. at 132:2–8]. A physician providing a second opinion also recommended against surgical removal. [Id. at 27:1–10, 132:6–11].

In her deposition in this case, Dr. Hardley was asked whether a variety of warnings would have affected her decision to use BioZorb to treat Willard and, in general, testified that such warnings would not have affected her recommendation. For example, when counsel for Hologic asked whether an IFU that "had specifically stated that patients could feel the device or may be able to palpate the device" would "have changed [her] decision to use the BioZorb for Ms. Willard," Dr. Hardley responded "no." [Willard RSUF ¶ 22]. Counsel for Hologic also asked Hardley whether she believed that, even if BioZorb took more than two years to resorb,

"for the right patient, the benefits of the BioZorb could outweigh the potential side effects or risks." [Id. ¶ 23]. Dr. Hardley said "[y]es." [Id.]. She also testified that notwithstanding Willard's allegations, she continued to believe that she had made the "right decision" by using BioZorb as part of Willard's treatment.[3] [Id. ¶ 24].

3. Karen Ensley

Plaintiff Karen Ensley was diagnosed with cancer in her right breast in September 2018. [Ensley RSUF ¶ 5]. On October 4, 2024, Dr. Jennifer McAlister performed a partial mastectomy on Ensley's right breast at UNC Health Pardee Hospital in Henderson, North Carolina, during which McAlister implanted a BioZorb device. [Id. ¶ 6]. After the procedure, Ensley underwent radiation treatment. [Id. ¶ 7].

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[3] Dr. Hardley engaged in several colloquies with Hologic's attorney on this point, as described below.

> Q: Based on everything you have heard today regarding Ms. Willard's medical records and her allegations in this litigation, do you continue to believe that you made the right decision for Ms. Willard when you implanted a BioZorb?
>
> A: Yes.
>
> Q: Okay. And given everything you've heard today regarding Ms. Willard's allegations and what we've seen in the medical records, do you continue to stand by your decision to use the BioZorb for Ms. Willard?
>
> A: Yes.

[Willard RSUF ¶ 24]. After Willard's attorney questioned Dr. Hardley, on redirect she testified as follows:

> Q: Is there anything you heard today, including from Mr. Cowper in his questions, that changes your prior testimony that you stand by your decision to use the BioZorb for Ms. Willard?
>
> A: No, it does not change it.

[Id. ¶ 25].

In 2021, Ensley developed a new mass in her right breast. See [McAlister Dep. at 148:21–149:2]. By February 2022, Dr. McAlister determined that the mass had grown larger and more palpable. [Id. at 60:4–21]. Dr. McAlister performed an excisional biopsy procedure in March 2022, [id. at 151:12–18], which identified necrotic fat tissue, [id. at 62:4–18], and fragile, solid, white debris around the area of the BioZorb, [id. at 65:7–9]. McAlister testified that the pathology report did not indicate that the BioZorb remained present in Ensley's breast at the time of the biopsy, but Ensley testified that she understood that McAlister had excised remnants of the BioZorb during the biopsy. [Ensley RSUF ¶ 20; Ensley Dep. at 41:12–16].

In her deposition in this case, Dr. McAlister provided testimony regarding her understanding of the risks associated with Ensley's procedure. She testified that she understood "chronic pain" beyond "normal postoperative pain," swelling, scarring, and fat necrosis can be risks associated with lumpectomy procedures. [Ensley RSUF ¶¶ 9, 11–12, 14, 17]. She also testified that she understood that the BioZorb device could be palpable to a patient and could take longer than eighteen months to resorb, but that she believed that the device was nevertheless appropriate for use in Ensley's treatment. [Id. at ¶¶ 19, 21]. Hologic's counsel also asked McAlister whether a warning in the IFU pertaining to scar tissue, palpability, or necrosis would have affected her decision to use the BioZorb with Ensley, and she testified that it would not have. [Id. ¶¶ 23–24]. McAlister ceased using BioZorb after she determined through clinical experience that it associated with firm masses that were difficult to distinguish from malignant masses during subsequent exams. [McAlister Dep. at 78:15–24].

4. Nerissa Burke

Nerissa Burke was diagnosed with cancer in her right breast in July 2018. [Burke RSUF ¶ 6]. On August 9, 2018, Dr. Paul Williams performed a partial mastectomy procedure on Burke

at Heart of Florida Regional Medical Center, after which Burke underwent radiation therapy. [Id. ¶¶ 7–8]. Although Williams testified that he did not discuss using a BioZorb with Burke prior to the procedure, he decided to use the device during the procedure to reduce cosmetic deformity in Burke's breast.[4] [Williams Dep. at 43:6–12, 90:18–25]. Dr. Williams testified that he informed Burke that he had placed a BioZorb after the procedure. [Id. at 49:10–12]. Burke testified that although Dr. Williams had told her that the BioZorb would dissolve in one year or less, [Burke Dep. at 175:7], around the beginning of 2020, she could still feel the BioZorb in her breast and could visualize the shape of the device through her skin when looking in the mirror. [Id. at 146:10–147:4]. Williams testified that he was also able to visualize the device through her skin. [Williams Dep. at 73:14–74:15]. He explained that as her breast tissue healed from surgery and radiation, the BioZorb had become visible and was pressing against her skin. [Id. at 74:2–15].

During Dr. Williams's deposition, he testified that he believed he had made the right clinical decision in using a BioZorb during Burke's procedure. [Burke RSUF ¶ 19]. Burke strongly preferred a lumpectomy to a mastectomy, and Williams understood, at the time, that the BioZorb was the only clinical treatment option to avoid a significant structural and cosmetic deformity in Burke's breast. [Id. ¶¶ 15, 18]. He was not questioned specifically about whether a stronger warning by Hologic would have changed his decision.

[4] Burke testified that Dr. Williams told her he would use a marker prior to her procedure, though she could not recall whether he identified the device as a BioZorb device. [Burke Dep. at 141:17–20]. To the extent the difference in their testimony gives rise to a factual dispute, neither party identifies the factual dispute as material.

B. Procedural History

On November 4, 2022, Melkonian and Willard, along with co-plaintiffs whose summary judgment proceedings are not addressed in this order, sued Hologic in Middlesex County Superior Court. [Evers, ECF No. 1]. Hologic moved for removal on November 10, 2022, [id.], and on December 9, 2022, Plaintiffs agreed to sever and remand a single non-diverse plaintiff and otherwise consented to removal, [Evers, ECF No. 10].[5] Burke, Ensley, and their co-plaintiffs filed an initial complaint in this Court making substantively identical allegations on December 23, 2022. [Block, ECF No. 1].

Plaintiffs' operative complaints set forth the following allegations. Count I alleged that Hologic breached its duty to warn users about foreseeable risks, specifically arguing that Hologic was liable because "the IFU failed to include warnings" concerning four risks:

1. that "the BioZorb device may not ever dissolve in the breast and [may] need to be surgically removed";
2. that "a radiologist might need to use a higher energy electron therapy which can cause scarring on the breast";
3. that "the device could migrate in the breast and cause a painful lump and scarring"; and,
4. that "the device could protrude from the breast creating a hole in the breast, [and] could be expelled from the breast which can lead to drainage and infection."

[Evers, ECF No. 11 ¶ 63; Block, ECF No. 1 ¶ 47]. Plaintiffs asserted design defect, negligence, and breach of implied warranty claims. [Evers, ECF No. 11 ¶¶ 67–97; Block, ECF No. 1 ¶¶ 51–81]. After Hologic answered, [Evers, ECF No. 15; Block, ECF No. 22], with the agreement of the parties, the Court ordered phased discovery and summary judgment proceedings, with the initial discovery process limited to core document discovery and depositions of Plaintiffs and

[5] On remand, the Middlesex County Superior Court found that the learned intermediary doctrine did not support awarding summary judgment to Hologic. Lyons v. Hologic, Inc., No. 2281-cv-4312, slip op. at 2 (Mass. Super. Ct. filed July 10, 2024).

their implanting physicians, as necessary to evaluate the applicability of the learned-intermediary doctrine to the causation analysis of each Plaintiff's claim. See [Evers, ECF Nos. 22, 84]. Hologic moved for summary judgment on the basis of the learned intermediary doctrine against Tricia Willard on February 14, 2024, [Evers, ECF No. 72]; Nerissa Burke on February 20, 2024, [Block, ECF No. 71]; Rita Melkonian on February 21, 2024, [Evers, ECF No. 78]; and Karen Ensley on February 22, 2024, [Block, ECF No. 77]. Plaintiffs timely opposed, and Hologic replied.

II. DISCUSSION

A. Legal Standard

A movant can obtain summary judgment only by demonstrating "that there is no genuine dispute" between the parties "as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). To prevail, a moving defendant must first show "an absence of evidence to support the nonmoving party's case." Pleasantdale Condos., LLC v. Wakefield, 37 F.4th 728, 733 (1st Cir. 2022) (quoting Brennan v. Hendrigan, 888 F.2d 189, 191 (1st Cir. 1989)). "This burden can be satisfied in two ways: (1) by submitting affirmative evidence that negates an essential element of the non-moving party's claim or (2) by demonstrating that the non-moving party failed to establish an essential element of its claim." Nantucket Residents Against Turbines v. U.S. Bureau of Ocean Energy Mgmt., 675 F. Supp. 3d 28, 46 (D. Mass. 2023).

"The burden then shifts to the nonmovant to establish the existence of a genuine issue of material fact." Pleasantdale, 37 F.4th at 733 (citation omitted). The Court must construe "the record and all reasonable inferences therefrom in the light most hospitable" to the nonmoving party. Id. (quoting Houlton Citizens' Coal. v. Town of Houlton, 175 F.3d 178, 184 (1st Cir.

1999)). Still, the Court will not let a case proceed to trial based only on a nonmovant's "bald assertions, empty conclusions, [or] rank conjecture." Hoover v. Hyatt Hotels Corp., 99 F.4th 45, 57 (1st Cir. 2024). Instead, where (as here) "the nonmovant bears the ultimate burden of proof" concerning the issue on which summary judgment is sought, the nonmovant "must present definite, competent evidence to rebut the motion for summary judgment." Pleasantdale, 37 F.4th at 733 (quoting Mesnick v. Gen. Elec. Co., 950 F.2d 816, 822 (1st Cir. 1991)).

B. Learned Intermediary Doctrine

Under settled principles of negligence, a seller or manufacturer is "subject to liability for harm to persons . . . caused by the seller's failure to provide a warning after the time of sale or distribution of a product if a reasonable person in the seller's position would provide such a warning." Restatement (Third) of Torts: Products Liability § 10 (Am. L. Inst. 1998). Although the seller's duty to warn typically runs to the user, in prescription drug and medical device cases, the duty to warn "traditionally has required warnings directed to health-care providers and not to patients." Id. § 6 cmt. b; see also id. § 6(d)(1). "The duty then devolves on the health-care provider to supply to the patient such information as is deemed appropriate under the circumstances so that the patient can make an informed choice as to therapy." Id. § 6 cmt. b.

The key variation among states for purposes of the present motions is whether each state applies a "rebuttable presumption . . . that had there been an adequate warning, the doctor would have heeded it." Motus v. Pfizer, Inc., 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001). This heeding presumption is "a burden-shifting device that makes it easier for a plaintiff to prove causation." Id. Where it applies, "once the plaintiff establishes that the manufacturer provided inadequate warnings, the burden shifts to the defendant to show that an adequate warning would not have affected the doctor's conduct in prescribing the drug." Id. If the manufacturer fails to make that

showing, then "the presumption satisfies the plaintiff's burden of demonstrating that the inadequate warning was the proximate cause of the ingestion of the drug." Id. (quoting Williams v. Lederle Labs., 591 F. Supp. 381, 386 (S.D. Ohio 1984)). "By contrast, in states that have not adopted the rebuttable presumption, the plaintiff in a [medical device] case bears the full burden of proving through affirmative evidence that the inadequate warning was the proximate cause of the injury, or, in other words, that an adequate warning to the prescribing physician would have altered the physician's conduct." Id. (quoting Windham v. Wyeth Labs., Inc., 786 F. Supp. 607, 612 (S.D. Miss. 1992)). Two of the states relevant to these motions have adopted a heeding presumption, see Kovach v. Caligor Midwest, 913 N.E.2d 193, 199 (Ind. 2009); Garside v. Osco Drug, Inc. 976 F.2d 77, 81 (1st Cir. 1992) (applying Massachusetts law), while the other two do not, see Corbo v. Taylor-Dunn Mfg. Co., No. A135393, 2014 WL 576268, at *13 (Cal. Ct. App. Feb. 14, 2014) ("California does not recognize the heeding presumption."); Salinero v. Johnson & Johnson, 995 F.3d 959, 964–65 (11th Cir. 2021) ("[A] plaintiff must show that her treating physician would not have used the product had adequate warnings been provided." (citation omitted)); Richardson v. Smith & Nephew Richards, Inc., No. 5:95-cv-00068, 1998 WL 1166780, at *5 (E.D.N.C. Sept. 22, 1998), aff'd and adopted, 1999 WL 1132962 (E.D.N.C. Jan. 10, 1999) (similar).

C. Conflict of Laws

The Court must first determine which state law governs Hologic's liability.[6] Plaintiffs contend that Massachusetts law should govern this entire case, no doubt hoping to gain the

[6] As noted above, Massachusetts differs from each relevant state's law, with the exception of Indiana, to the extent that it applies a heeding presumption in failure-to-warn cases. Accordingly, there is a real conflict between the contending states' laws that the Court must

benefit of its heeding presumption. Hologic insists that the law of the states where each Plaintiff was injured should control: California for Melkonian's claims, Florida for Burke's claims, North Carolina for Ensley's claims, and Indiana for Willards's claims.[7] The Court concludes that the law of the place of injury should apply to each of their cases.[8]

Sitting in diversity, this Court applies the choice of law rules of Massachusetts to determine which state's law should decide liability. Cheng v. Neumann, 106 F.4th 19, 25 (1st Cir. 2024) ("[F]ederal courts sitting in diversity apply the substantive law of the forum state, . . . including its conflict of laws rules." (quoting Smith v. Prudential Ins. Co. of Am., 88 F.4th 40, 49 (1st Cir. 2023))).

Massachusetts follows a "functional approach" to conflict of laws issues in personal injury cases that reflects the approach set forth in the Restatement (Second) of Conflict of Laws (hereinafter "Restatement"). See McKee v. Cosby, 874 F.3d 54, 60 (1st Cir. 2017) (describing the Restatement as "an 'obvious source of guidance' for choice of law questions." (quoting Bushkin Assocs. v. Raytheon Co., 473 N.E.2d 662, 668 (Mass. 1985))). In general, the Restatement provides that the "law of the state where the injury occurred" should "determine[] the rights and liabilities of the parties, unless, with respect to the particular issue, some other state has a more significant relationship under the principles stated in § 6 to the occurrence and the parties." Robidoux v. Muholland, 642 F.3d 20, 25 (1st Cir. 2011) (quoting Restatement

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resolve. See Smith v. Prudential Ins. Co. of Am., 88 F.4th 40, 49 (1st Cir. 2023) (quoting In re Pioneer Ford Sales, Inc., 729 F.2d 27, 31 (1st Cir. 1984)).

[7] Plaintiffs do not dispute Hologic's factual assertion that each Plaintiffs' injuries occurred at the location where they were implanted with the BioZorb device, and the Court therefore assumes Plaintiffs have conceded this fact.

[8] In their respective opposition filings, Plaintiffs each present identical arguments in favor of application of Massachusetts law, so the Court addresses their arguments collectively.

§ 146). In other words, Section 146 creates a presumption in favor of the law of the place of injury. See Dagi v. Delta Air Lines, 352 F. Supp. 3d 116, 124 n.6 (D. Mass. 2018) (describing Massachusetts law); Murthy v. Abbott Bioresearch Ctr., Inc., No. 080328, 2009 WL 3233360, at *1 (Mass. Super. Ct. Jan. 13, 2009); Kramer v. Acton Toyota, Inc., No. 993733, 2004 WL 2697284, at *3 (Mass. Super. Ct. Nov. 2, 2004); cf. Mason v. S. New Eng. Conf. Ass'n of Seventh-Day Adventists, 696 F.2d 135, 138 (1st Cir. 1982) (same, discussing application of § 146 under Maine law). Following that presumption, the Court should apply Massachusetts law only if Massachusetts bears a relationship to Hologic, Plaintiffs, and their injuries that is more significant than that of the place of the plaintiffs' respective injuries.

Section 6 of the Restatement lays out seven principles for evaluating the significance of each state's relationship to the case:

> (a) the needs of the interstate and international systems, (b) the relevant policies of the forum, (c) the relevant policies of other interested states and the relative interests of those states in the determination of the particular issue, (d) the protection of justified expectations, (e) the basic policies underlying the particular field of law, (f) certainty, predictability and uniformity of result, and (g) ease in the determination and application of the law to be applied.

Robidoux, 642 F.3d at 25 (quoting Restatement § 6).

In addition, when applying Massachusetts conflict of laws principles to product liability cases, the First Circuit examines the following contacts, which are relevant in all tort cases under Section 145(2) of the Restatement:

> (a) the place where the injury occurred, (b) the place where the conduct causing the injury occurred, (c) the domicile, residence, nationality, place of incorporation and place of business of the parties, and (d) the place where the relationship, if any, between the parties is centered.

Id. at 25–26 (quoting Restatement § 145(2)). "Though these sections identify as many as eleven relevant factors, the four highlighted by the First Circuit are paramount to the analysis and are often determinative." Daley v. Mira, No. 18-cv-10353, 2023 WL 3605438, at *3 (D. Mass. May 23, 2023); see also Cohen v. McDonnell Douglas Corp., 450 N.E.2d 581, 583–85 (Mass. 1983); Burleigh v. Alfa Laval, Inc., 313 F. Supp. 3d 343, 353–59 (D. Mass. 2018). The Court therefore begins its analysis with those factors.

The place of injury "usually" prevails over the location of the negligent conduct, even though decisions about "the applicable law become[] more difficult in situations where, as here, the defendant's conduct and the resulting injury occurred in different states." Burleigh, 313 F. Supp. 3d at 353 (internal quotation marks omitted) (quoting Restatement § 145 cmt. e). That is particularly so when the plaintiff has a "settled relationship" with the place of injury. Id. (quoting Restatement § 146 cmt. e); Cohen v. McDonnell Douglas Corp., 450 N.E.2d 581, 586 (Mass. 1983) (same). A "settled relationship" with the place of injury exists if the plaintiff "is domiciled or resides there or because he does business there." Cohen, 450 N.E.2d at 586. By contrast, "the law of the place of injury might not play an important role 'when the place of injury' is 'fortuitous,' such as in a car accident when the non-resident plaintiffs are 'merely passing through' the state where the accident occurred." Burleigh, 313 F. Supp. 3d at 353–54 (quoting Kramer, 2004 WL 2697284, at *3).

It is undisputed that the Plaintiffs' injuries occurred outside of Massachusetts, even though Hologic's alleged negligence in developing BioZorb took place within the state. [Melkonian RSUF ¶ 6; Ensley RSUF ¶ 6; Willard RSUF ¶ 6; Burke RSUF ¶ 7]. Despite Hologic's connection to the forum state, Plaintiffs' have established settled relationships with their respective places of injury, as each Plaintiff except for Ensley is domiciled in the same

place as her state of injury.[9] No Plaintiff contends that they bear any comparable relationship to Massachusetts. Consequently, Massachusetts's conflict-of-laws principles favor the law of the place of injury. Although Massachusetts has an interest in regulating the conduct of its resident defendants, including Hologic, the place of the injury and domicile of the injured "reduce the comparative weight" of Massachusetts's interest. Burleigh, 313 F. Supp. 3d at 355.

To the extent Plaintiffs and Hologic share any relationship relevant to the Restatement analysis, it is centered in the states where they were implanted with the BioZorb, not in Massachusetts. In "failure to warn and product design defect case[s]," it is not unusual for the Plaintiff to "lack any 'preexisting relationship'" to the Defendant. Burleigh, 313 F. Supp. 3d at 355 (quoting La Plante v. Am. Honda Motor Co., Inc., 27 F.3d 731, 741–42 (1st Cir. 1994)). Thus, any relationship Plaintiffs share with Hologic flows through the implanting physicians, each of whom bore "settled relationship[s]" to California, Indiana, North Carolina, and Florida — not Massachusetts. Cohen, 450 N.E.2d at 586 ("settled relationship" with the place of injury exists if the plaintiff "is domiciled or resides there or because he does business there").

In addition, "section 146 requires considering whether a state other than [the place of injury] has a more significant relationship under the principles in section six [of the Restatement] with respect to the occurrence and the parties vis-à-vis the particular issue." Burleigh, 313

[9] Ensley is a citizen of South Carolina, although her injury occurred in North Carolina. See [ECF No. 121 ¶¶ 19–20]. The learned intermediary doctrine in North and South Carolina appears to be identical in all material respects; in particular, neither state applies a heeding presumption to failure-to-warn claims. Compare Richardson, 1998 WL 1166780, at *5 (applying North Carolina law), with Odom v. G.D. Searle & Co., 979 F.2d 1001, 1003 (4th Cir. 1992) (applying South Carolina law). And in any event, Ensley makes no argument that her South Carolina domicile weighs in favor of applying Massachusetts law.

F. Supp. 3d at 355. Plaintiffs invoke just two of the seven factors relevant under § 6 in attempting to refute this conclusion: the justified expectations of the parties, and the ease in the determination and application of the law to be applied. See, e.g., [Willard Opp. at 6–7 (first quoting Fresenius Granuflo/NaturaLyte Dialysate Prods. Liab. Litig., 76 F. Supp. 3d 294, 301 (D. Mass. 2015); then quoting Elliston v. Wing Enters., 146 F. Supp. 3d 351, 354 (D. Mass. 2015))]. Each of the cases relied on by Plaintiffs, however, arises from conflicts between statutes of limitations, a question on which Massachusetts presumptively applies forum law, not the law of the place of injury, as distinct from its approach to product liability claims. Compare Elliston, 146 F. Supp. 3d at 353 (presuming "[t]he forum will apply its own statute of limitations" (quoting Restatement § 142(2))), with Robidoux, 642 F.3d at 25 (presuming that "in personal injury cases, 'the local law of the state where the injury occurred determines the rights and liabilities of the parties'" (quoting Restatement § 146)). In light of these well-settled principles, the Court is unconvinced that Plaintiffs had a justified expectation that forum law would determine liability on their failure-to-warn claims. Nor does the Court believe it is appropriate to apply Massachusetts law out of mere convenience. Cf. Fresenius, 76 F. Supp. 3d at 300 ("[T]he law of the MDL forum itself is not necessarily the proper source for choice of law standards.").

Based on the foregoing, the Court agrees with Hologic that the state where each Plaintiff's injury occurred will provide the negligence standards to be applied in determining Hologic's liability.

D. Rita Melkonian

Rita Melkonian's claims are governed by California law. Under California's learned-intermediary doctrine, "manufacturers have a duty to warn physicians, but not the physicians'

patients, about certain risks accompanying use of . . . medical devices." Himes v. Somatics, LLC, 549 P.3d 916, 922 (Cal. 2024) (citation omitted). A manufacturer must warn physicians of "any non-negligible risks that are generally unknown to the medical community," in order to "allow the health-care provider, and thereby the patient, to make an informed choice whether to utilize the . . . device." Id. (quoting Restatement (Third) of Torts § 6 cmt. d). If a manufacturer has adequately warned the physician, then the duty falls on the physician to advise the patient as necessary "so that the patient can make an informed choice as to therapy." Id. (quoting Restatement (Third) of Torts § 6 cmt. b). Thus, to prevail on summary judgment, Melkonian must identify a genuine dispute of material fact as to whether Hologic's alleged failure to warn her physician "was a substantial factor in causing [her] injury." Id. at 925.

In California, a plaintiff can demonstrate causation on a failure-to-warn claim by showing that an adequate warning would have caused the physician to change their recommendation to use the device. Himes, 549 P.3d at 922. "California does not recognize the heeding presumption," Corbo, 2014 WL 576268, at *13, so the burden of producing evidence that could allow a jury to find that Dr. Bailey would not have recommended BioZorb in the face of a stronger warning rests with Melkonian. Hologic contends that Melkonian has failed to identify evidence indicating that there is a triable issue as to whether Dr. Bailey would have changed her recommendation in the face of an adequate warning. A "product defect claim based on insufficient warnings cannot survive summary judgment if stronger warnings would not have altered the conduct of the prescribing physician." Himes v. Somatics, LLC, No. 21-55517, 2022 WL 989469, at *2 (9th Cir. Apr. 1, 2022) (citation omitted).

Even if, however, Hologic is correct that Melkonian has not identified any evidence indicating Dr. Bailey would have changed her recommendation despite receiving a stronger

warning, under California law, Melkonian can still prevail by showing "the physician would have communicated the stronger warning to the patient and," even if the physician still endorsed the device for treatment, "an objectively prudent person in the patient's position would have thereafter declined." Himes, 549 P.3d at 926. In other words, even if no reasonable jury could find that Dr. Bailey would have changed her recommendation, Melkonian may still defeat summary judgment if the record shows that (a) Melkonian's surgeon would have relayed the warning to Melkonian, and (b) an "objectively prudent person in the patient's position would have declined treatment" in light of the risks notwithstanding the doctor's recommendation. Id. at 930.

Hologic contends that "there is no testimony from [Dr. Bailey] that she would have communicated any additional or different risk information about the BioZorb to [Melkonian] if presented with a different warning," [Evers, ECF No. 157 at 1], but the Court concludes that Dr. Bailey's deposition creates a genuine dispute of material fact. Although Dr. Bailey testified that she advised Melkonian that "BioZorb would reabsorb gradually" and could not recall whether she had communicated to Melkonian or other patients a specific timeframe, Melkonian testified that Dr. Bailey told her the device "w[ould] be absorbed within six months to a year." [Melkonian RSUF ¶ 16]. Melkonian's testimony is consistent with the resorption time contained in the IFU, and Dr. Bailey testified that she likely would have reviewed the IFU before using the BioZorb. [Bailey Dep. at 109:4–5]. Drawing reasonable inferences in Melkonian's favor, the Court believes a reasonable jury could conclude that if Dr. Bailey had relayed the risk information to Melkonian concerning resorption time and other serious risks of complication associated with surgery, she would have relayed these risks to Melkonian, even if she ultimately recommended the use of the BioZorb to Melkonian. Hologic does not suggest or dispute that

such information could have changed Melkonian's decision to allow Dr. Bailey to use BioZorb. See [Evers, ECF No. 157 at 1]. Thus, Hologic has not carried its initial burden of production as to the second avenue of causation under California law.

In sum, summary judgment on Count I as to Rita Melkonian is **DENIED**. To the extent Hologic seeks summary judgment on Counts III and IV on the basis of the learned intermediary doctrine, summary judgment is **DENIED**. To the extent Hologic seeks summary judgment as to any count on a basis other than the learned intermediary doctrine, such request is outside the scope of the pending motions and is **DENIED**.

E. Tricia Willard

Tricia Willard's claims are governed by Indiana law. Under Indiana law, a product may be defective if the seller does not "properly package or label the product to give reasonable warnings of danger about the product . . . when the seller, by exercising reasonable diligence, could have made such warnings or instructions available to the user or consumer." See Kaiser v. Johnson & Johnson, 947 F.3d 996, 1015 (7th Cir. 2020). "Under Indiana's learned-intermediary doctrine, a medical-device manufacturer can discharge this duty by providing adequate warnings to physicians." Id. "[M]anufacturers of prescription medical products have a duty only to warn physicians, rather than patients, of the risks associated with the use of the product." Minisan v. Danek Med., Inc., 79 F. Supp. 2d 970, 978 (N.D. Ind. 1999). In addition, Indiana law does not hold a manufacturer liable "if the plaintiff's physician independently knew of the risks" that allegedly caused the plaintiffs' injuries "and failed to advise the plaintiff" about them. Minisan, 79 F. Supp. 2d at 978.

Indiana recognizes a "presumption that an adequate warning would be heeded." Kovach, 913 N.E.2d at 199 (quoting Ortho Pharm. Corp. v. Chapman, 388 N.E.2d 541, 555 (Ind. Ct. App.

1979)). In other words, "the plaintiff is not required to establish that he would have read the warning and taken the steps to avoid injury." Id. (citing Nissen Trampoline Co. v. Terre Haute First Nat'l Bank, 332 N.E.2d 820, 826–27 (Ind. Ct. App. 1975)). Although the ultimate burden of proving causation remains with the plaintiff, see Roberts v. Wabash Life Ins. Co., 410 N.E.2d 1377, 1383 (Ind. Ct. App. 1980), the heeding presumption requires the defendant to produce "evidence that an adequate warning would not have been heeded," In re Fosamax Prod. Liab. Litig., 688 F. Supp. 2d 259, 266 (S.D.N.Y. 2010) (applying Indiana law). At summary judgment, the heeding presumption requires a defendant moving for summary judgment to produce evidence "establish[ing] that the only reasonable conclusion a trier of fact could draw from the record evidence is that Plaintiff's treating physician would not have changed h[er] course of treatment had [s]he been adequately warned." Id.; see also Kovach, 913 N.E.2d at 198 (explaining that "where reasonable minds cannot disagree as to causation-in-fact, the issue may become a question of law for the court"). Thus, a "party seeking summary judgment on the issue of proximate cause faces a difficult burden." Fosamax, 688 F. Supp. 2d at 266.

Hologic assumes for purposes of its motion that its warnings were inadequate, but nevertheless urges the Court to grant summary judgment based on Dr. Hardley's deposition testimony. [Evers, ECF No. 73 at 13]. In particular, Hologic points to the following questions and answers:

> Q: Based on everything you have heard today regarding Ms. Willard's medical records and here allegations in this litigation, do you continue to believe that you made the right decision for Ms. Willard when you implanted BioZorb?
> A: Yes.
> Q: Okay. And given everything you've heard today regarding Ms. Willard's allegations and what we've seen in the medical records, do you continue to stand by your decision to use the BioZorb for Ms. Willard?
> A: Yes.

> . . .
> Q: Is there anything you heard today, including from Mr. Cowper in his questions, that changes your prior testimony that you stand by your decision to use the BioZorb for Ms. Willard?
> A: No, it does not change it.

[Willard RSUF ¶¶ 24–25].

Hologic contends that this testimony overcomes the heeding presumption and warrants summary judgment because a reasonable jury could only conclude that even having received adequate warnings, Dr. Hardley would have still used a BioZorb to treat Willard. The Court disagrees, however, because the above testimony does not pertain to what Dr. Hardley would have done in the face of a warning that adverted to the injury Willard actually experienced. Hologic's burden under Indiana law is to "establish that the only reasonable conclusion the trier of fact could draw from the record evidence is that Plaintiff's treating physician would not have changed h[er] course of treatment had [s]he been adequately warned." Fosamax, 688 F. Supp. 2d at 266. Willard testified that despite being told the BioZorb would resorb in approximately one year,[10] more than two years after surgery, the BioZorb had not resorbed and remained palpable and painful. [Willard Dep. at 104:5–23, 109:8–11]. Immediately before the testimony cited by Hologic, defense counsel asked Dr. Hardley several questions that elicited

[10] Dr. Hardley contests whether she provided a specific timeframe, but she also testified that it was her recollection that Hologic representatives said the resorption time was one year. [Willard RSUF ¶ 19]. The record would permit a jury to find Willard more credible than Dr. Hardley on this point, and on summary judgment, the Court must draw that inference in Willard's favor. In any event, "[t]o allow summary judgment this court would have to weigh the credibility of the respective deponents and other evidence and to balance the strengths of the parties' proofs to arrive at a factual conclusion. Summary judgment is not the proper vehicle for that kind of a determination on a material fact." Penney v. Deutsche Bank Nat'l Tr. Co., No. 16-cv-10482, 2018 WL 3651349, at *5 (D. Mass. Aug. 1, 2018) (quoting N. Ins. Co. of N.Y. v. AGA Food Serv. Inc., No. 08-cv-11089, 2011 WL 761507, at *4 (D. Mass. Feb. 24, 2011)).

testimony concerning what she would have done if faced with a warning that addressed those complications:

> Q: Okay. If the BioZorb label had stated specifically that for some patients, [the] resorption period has been reported as longer than two years, would that have changed your decision to use the BioZorb for Ms. Willard?
> A: I'm not sure.

[Hardley Dep. at 211:18–23]. This statement was consistent with previous testimony, where she stated that she "didn't expect that [resorption would take two years] based on the information that [she] was given when [she] started using the BioZorb. [She] was under the impression it would be a year." [Id. at 108:13–21].

This question elicited the only testimony Dr. Hardley provided on the potential effect of a stronger warning in the Hologic IFU on her treatment of Willard. Dr. Hardley's equivocation on this question undercuts the notion "that the only reasonable conclusion the trier of fact could draw from the record evidence is that Plaintiff's treating physician would not have changed h[er] course of treatment had [s]he been adequately warned." Fosamax, 688 F. Supp. 2d at 266. The testimony Hologic relies on in support of its motion — in particular, Dr. Hardley's admission that she "continue[s] to stand by" her decision to use BioZorb on Willard — does not provide a basis to conclude otherwise. Given that Dr. Hardley was "not sure" whether she "would have changed [her] decision to use BioZorb for Ms. Willard," a reasonable jury could infer that her subsequent statement that she "stood by" her decision to do so in 2019 simply meant that in the absence of any such warning, she believes she rendered appropriate treatment. The record therefore does not foreclose the conclusion that Dr. Hardley would not have used or recommended BioZorb on Tricia Willard in the face of a stronger warning. Nor does the record indicate that Dr. Hardley "independently knew of the risks" that allegedly caused the Plaintiff's

injuries "and failed to advise" her about them. Minisan, 79 F. Supp. 2d at 978. Rather, Dr. Hardley testified only that she was aware that a risk of chronic pain was associated with breast conservation surgery in general. [Willard RSUF ¶ 8].

Accordingly, Hologic has failed to overcome its burden of production, and summary judgment on Count I as to Tricia Willard is **DENIED**. To the extent Hologic seeks summary judgment on Counts III and IV on the basis of the learned intermediary doctrine, summary judgment is also **DENIED**. To the extent Hologic seeks summary judgment as to any count on a basis other than the learned intermediary doctrine, such request is outside the scope of the pending motions and is **DENIED**.

F. Karen Ensley

Karen Ensley's claims are governed by the laws of North Carolina, where she was implanted with BioZorb and began to suffer from the injuries she alleges the device caused. In North Carolina, a plaintiff alleging a failure to warn ultimately bears the burden of showing that "the defendant unreasonably failed to provide an adequate warning, such failure was the proximate cause of the plaintiff's damages, and the product posed a substantial risk of harm without an adequate warning either at the time of or after leaving the manufacturer's control." Asby v. Medtronic, Inc., 673 F. Supp. 3d 787, 794 (E.D.N.C. 2023) (quoting Carlson v. Bos. Sci. Corp., 856 F.3d 320, 324 (4th Cir. 2017)). In North Carolina, the learned intermediary doctrine expressly applies to pharmaceutical manufacturers. See N.C. Gen. Stat. Ann. § 99B-5. North Carolina state courts have not addressed whether the doctrine also applies to medical device manufacturers, but each federal court to confront the question has presumed that a North Carolina court would apply the doctrine to medical device manufactures as well. See id.; Teague v. Johnson & Johnson, Inc., 578 F. Supp. 3d 743, 750 (E.D.N.C. 2022); Smith v. Ethicon, Inc.,

No. 20-cv-00212, 2020 WL 3256926, at *2 (M.D.N.C. June 16, 2020); Carlson v. Bos. Sci. Corp., Nos. 5:15-cv-00057, 3:15-cv-00211, 2015 WL 5732107, at *2 (W.D.N.C. Sept. 30, 2015). The Court is aware of no North Carolina decision applying a heeding presumption. See, e.g., Richardson v. Smith & Nephew Richards, Inc., No. 5:95-cv-00068, 1998 WL 1166780, at *5 (E.D.N.C. Sept. 22, 1998), aff'd and adopted, No. 5:95-cv-00068, 1998 WL 1132962 (E.D.N.C. Jan. 10, 1999) (no heeding presumption).

Hologic contends that not only did Ensley fail to produce testimony that would allow a jury to find in her favor on causation, but Dr. McAlister also specifically testified that stronger warnings would not have made a difference in her treatment of Ensley. For example, defense counsel engaged in the following colloquy:

> Q: If the BioZorb IFU had . . . said something in there that . . . palpability . . . could be a risk of implanting the BioZorb in there, would that have changed your decision to use the BioZorb with Ms. Ensley?
> A: No, because I discuss that routinely with patients.
> Q: Okay. And if --- if the IFU had said something about scar tissue or fat necrosis being a risk, would that have changed your decision to use BioZorb with Ms. Ensley?
> A: No.

[Ensley RSUF ¶¶ 23-24]. On the basis of this testimony, Hologic maintains that Dr. McAlister acknowledged that stronger warnings in the IFU would not have changed her decision to use the BioZorb.

Ensley disagrees, observing that Dr. McAlister also testified that a warning that the BioZorb could have taken up to five years to dissolve "may" have changed her decision to use it. See [McAlister Dep. at 170:6–11; Ensley Opp. at 11]. In addition, Ensley contends that because Dr. McAlister no longer uses the BioZorb because of scarring tendencies she observed over several years of use, the Court should credit Dr. McAlister's "current actions and beliefs

regarding BioZorb" over "speculative testimony about what she might have done five years ago." [Ensley Opp. at 12].

The Court concludes that a genuine dispute of material fact exists as to whether Dr. McAlister would have changed her decision to use BioZorb in the face of a stronger warning about the risk of scar tissue formation. Hologic contends that "[w]hat matters for the learned intermediary doctrine is whether different ***warnings*** would have made a difference to Dr. McAlister's treatment of the Plaintiff, not whether the doctor would have made a different decision in hindsight based on her own particular clinical experience." [Ensley Reply at 6 (emphasis in original)]. Although Dr. McAlister testified that such a warning would not have affected her decision to use BioZorb, the Court nonetheless agrees with Ensley that Dr. McAlister's subsequent decision not to use the device as a consequence of that risk undermines her testimony. Although "a party cannot raise a genuine dispute merely 'by relying on the hope that the jury will not trust the credibility of the witness,'" courts may find that credibility creates a triable issue where, as here, the non-movant points to "affirmative evidence" demonstrating contradiction in the summary-judgment record. Nunes v. Mass. Dep't of Corr., 766 F.3d 136, 142 (1st Cir. 2014) (citation omitted)). Particularly when the Court affords Ensley the benefit of all reasonable doubts and inferences, as it must at this stage, the conflict Ensley identifies in Dr. McAlister's testimony creates a triable issue of fact on causation. Accordingly, summary judgment on Count I as to Ensley is **DENIED**. To the extent Hologic seeks summary judgment on Counts III and IV on the basis of the learned intermediary doctrine, summary judgment is **DENIED** for the same reasons. To the extent Hologic seeks summary judgment as to any count on a basis other than the learned intermediary doctrine, such request is outside the scope of the pending motions and is **DENIED**.

G. Nerissa Burke

To prevail on a failure to warn claim under Florida law, a "plaintiff must show (1) that the product warning was inadequate; (2) that the inadequacy proximately caused her injury; and (3) that she in fact suffered an injury from using the product." Eghnayem v. Bos. Sci. Corp., 873 F.3d 1304, 1321 (11th Cir. 2017). In cases involving medical devices, a device manufacturer satisfies its duty to warn users if it provides "adequate warning[s] to the [prescribing physician]." Salinero v. Johnson & Johnson, 995 F.3d 959, 964 (11th Cir. 2021) (quoting Buckner v. Allergan Pharms., Inc., 400 So. 2d 820, 823 (Fla. 5th DCA 1981)). The prescriber serves as "a 'learned intermediary' between the manufacturer and the consumer, weigh[ing] the potential benefits [of a device] against the dangers in deciding whether to recommend [it] to meet the patient's needs." Felix v. Hoffman-LaRoche, Inc., 540 So.2d 102, 104 (Fla. 1989). Florida has not adopted a heeding presumption, so Burke must produce evidence that her implanting surgeon, Dr. Williams, would not have used the BioZorb had the manufacturer provided adequate warnings. See Eghnayem, 873 F.3d at 1321 ("[T]o satisfy the causation element, a plaintiff must show that her treating physician would not have used the product had adequate warnings been provided.").

Burke never attempted to put that question to Dr. Williams during his deposition, and Burke does not point to any other evidence in the record that would permit a jury to conclude that an adequate warning concerning the symptoms she experienced would have changed Dr. Williams' decision to use the BioZorb as part of her treatment. Rather, Burke contends that summary judgment is inappropriate because Dr. Williams did not "unequivocally testif[y]" that he still "would have used the [BioZorb on Burke] had he been adequately warned about the specific risks" that caused her injuries. [Burke Opp. at 11]. Burke appears to have been under the impression, as reflected in her opposition to summary judgment, that Massachusetts law and

its heeding presumption apply to this case, thereby placing the burden on Hologic to produce evidence that Dr. Williams would not have changed his use of the BioZorb in the face of a stronger warning.[11] See [id.]. But under Florida law, the reverse is true: to survive summary judgment, Burke must come forth with evidence that would permit a jury to conclude Dr. Williams would not have used the BioZorb had he received an adequate warning. See Eghnayem, 873 F.3d at 1321. Burke has simply pointed to no evidence that would permit such a verdict, nor does the Court's independent review of the Williams deposition reveal any.[12] "[T]here can be 'no genuine issue as to any material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." Celotex Corp. v. Catrett, 477 U.S. 317, 317 (1986). Nor do Burke's conclusory challenges to Dr. Williams's credibility suggest otherwise. A non-movant's "mere challenge to the credibility of [the evidence relied on by the movant] without any supporting evidence does not create a genuine issue of material fact." Moreau v. Local Union No. 247, International Brotherhood of Firemen & Oilers, 851 F.2d 516, 519 (1st Cir. 1988). As a consequence, Burke has failed to identify a genuine dispute of material fact as to causation on her failure to warn claim, and summary judgment on Count I as to Nerissa Burke is **GRANTED**. Summary judgment as to Counts III and IV is **GRANTED IN PART** to the extent such claims are

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[11] For the same reason, the Court takes no position on Burke's contention that, under Massachusetts law, Dr. Williams's credibility as to his hindsight opinion would present a jury question. See [Block, ECF No. 93 at 11–12 (citing Garside v. Osco Drug Inc., 976 F.2d 77, 83 (1st Cir. 1992))].

[12] Burke also contends that "Hologic failed to warn Heart of Florida,'' the hospital at which Burke was implanted with BioZorb, "of the risks associated with BioZorb in the device's IFU," and that "[h]ad the hospital been adequately warned, it may not have approved BioZorb . . . , thus preventing Dr. Williams from using the device." [Burke Opp. at 13]. But Burke points to no case under Florida law that places such a duty on medical device manufacturers.

premised on a failure to warn and **DENIED IN PART**, to the extent such claims are premised on a design defect theory of liability.

III. CONCLUSION

Summary judgment is **DENIED** as to Rita Melkonian, Tricia Willard, and Karen Ensley, and **GRANTED IN PART** and **DENIED IN PART** as to Nerissa Burke.

SO ORDERED.

September 26, 2024

/s/ Allison D. Burroughs
ALLISON D. BURROUGHS
U.S. DISTRICT JUDGE