Evers et al v. Hologic, Inc. Doc. 202

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: BioZorb Device Products Liability Litigation This Order Relates to: No. 23-cv-10260-ADB	Civil Action No. 1:22-cv-11895-ADB

MEMORANDUM AND ORDER

BURROUGHS, D.J.

Presently before the Court is a motion by Defendant Hologic, Inc. ("Hologic") seeking summary judgment as to all four counts alleged against it by Plaintiff Joye Rishell ("Rishell"). See [ECF No. 65].[1] After receiving a breast cancer diagnosis, Rishell underwent a partial mastectomy. During the procedure, her surgeon implanted a BioZorb marker, a device used to identify breast tissue surrounding the excised cancer tissue to target radiation therapy. Rishell subsequently experienced a variety of injuries, which she attributes to negligence by Hologic in the design, manufacturing, and marketing of the BioZorb device. Rishell alleges 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 [ECF No. 120 ("Second Amended Complaint" or "SAC")].[2] She is one of more than eighty plaintiffs spread across twenty-two cases consolidated before the Court that advance similar

[1] Unless otherwise specified, citations to the docket in this opinion are to No. 23-cv-10260-ADB.
[2] On September 6, 2024, after the filing of the pending motion, the Court permitted Plaintiff to file a SAC to amend her design defect allegations. The allegations concerning Plaintiff's failure to warn claim are unchanged. Accordingly, the Court will cite the SAC throughout this motion.

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allegations concerning the BioZorb device.[3] For the reasons set forth below, the motion for summary judgment is **DENIED** on Count I, Count II, and Count IV, and **GRANTED** as to Count III.[4]

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., [ECF No. 86-1 ¶ 1–2]. The BioZorb consists of a spiral-shaped bioabsorbable spacer that holds six titanium clips. [Id. ¶¶ 2–3].

[3] 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; Bates v. Hologic, No. 24-cv-12472; Nudel v. Hologic, No. 24-cv-12495; and Holcomb v. Hologic, No. 24-cv-12784. The Court has ruled on motions for summary judgment in the Block and Evers cases. See In re BioZorb Device Prod. Liab. Litig., Nos. 22-cv-11895, 22-cv-12194, 2024 WL 4309413 (D. Mass. Sept. 26, 2024).

Pursuant to Federal Rule of Civil Procedure 42(a), the Court consolidated these cases under the docket of the first filed case, No. 22-cv-11895, and under the caption In re BioZorb Device Products Liability Litigation. [ECF No. 121 at 1].

[4] Hologic's summary judgment motion also contends that Plaintiff has inadequately pleaded her design defect claim (Count II). See [ECF No. 65 at 1–2]. The pleading defects Hologic alleges are unrelated to the learned intermediary doctrine. Therefore, these arguments fall outside the scope of the summary judgment filings permitted by the Court's bellwether order at this stage. See [ECF No. 48 at 7]. In any event, as the Court allowed Plaintiff to amend her design defect claims and Hologic to file a motion to dismiss, see [ECF Nos. 112, 119 at 7], the Court will **DENY** without prejudice Hologic's motion for summary judgment as to the design defect claim.

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 [id. ¶ 2].

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 ("radiographic marking"). [ECF No. 86-1 ¶¶ 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 Plaintiff's operation, the resorption process may take "one or more years." [ECF No. 86-1 ¶ 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.]. 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.

[SAC Ex. A].

In April 2022, Joye Rishell was diagnosed with cancer in her right breast. [ECF No. 86 at 7]. On May 27, 2022, Dr. John Turner, a surgeon at Evangelical Community Hospital in Lewisburg, Pennsylvania, "performed a partial mastectomy and sentinel lymph node excision on Plaintiff . . . and implanted a BioZorb device in her right breast. [ECF No. 86-1 ¶ 6]. After the implantation, Rishell reported pain at the site of insertion, felt the device pressing against her skin, and observed a wound forming in the affected area. [SAC ¶ 19].

In August of 2022, only a few months after initial implantation, Rishell required surgery to remove the BioZorb device due to an infection and the device physically breaking through her skin and protruding from her breast. [SAC ¶ 20]; [ECF 96-1 ¶¶ 2–3, 17]; [ECF No. 86-3 ("Turner Deposition" or "Turner Dep.") at 51:17–52:9]. In her Complaint, she alleges this procedure caused her significant pain, disfigurement, non-absorption, adverse tissue reaction, and delay in receiving vital radiation therapy. [ECF No. 86-1 ¶ 7; SAC ¶ 20].

Dr. Turner began using the BioZorb device in his practice "sometime in 2020," but has since stopped using it because, among other compounding reasons, there were "several patients that [he] had to remove the device on, typically because of discomfort." [Turner Dep. at 20:8–15]. At the time of the surgery, the BioZorb IFU did not warn Dr. Turner that the device can "erode through a patient's skin," "cause cellulitis or infection," or "cause pain above and beyond th[e] pain caused by surgery." [Turner Dep. at 68:13–69:3].

During his deposition in this case, Dr. Turner testified that using the BioZorb was the right treatment choice for Rishell "based on the information [he] had at the time," [Turner Dep. at 162:21–22], that Hologic never alerted him to the risk that the device could erode through a patient's skin, although he recognized as a matter of common sense that such erosion was "within the realm of possibility." [id. at 69:17–70:3]. Dr. Turner also testified that if he had been

warned about the risk of these side effects, he would have "analyze[d] the risk-benefit ratio" differently taking into account the additional information, which "would have been a thought process." [Id. at 70:9–12]. Such warnings would have led him to "inform Ms. Rishell of that risk" in their pre-operation discussion. [Id. at 70:17–20]. The additional risk factors "could have" led him "not [to] implant the BioZorb device in Ms. Rishell." [Id. at 71:8–12]. He also attested that once he had observed erosion and other side effects of the BioZorb device in several patients, and after observing the need to remove the device from Rishell and others, he began "searching for other alternatives." [Id. at 70:5–14]. As of the time of his deposition, he testified that he no longer uses BioZorb in his practice and opts for a "VeraForm" instead because it is "not something the patients feel[,] [b]ut it does achieve the same goal." [Id. at 20:8–21:9].

B. Procedural History

On January 31, 2023, Rishell, along with four other co-plaintiffs whose summary judgment proceedings are not addressed in this order, filed a complaint against Hologic. See [ECF No. 1 ("Complaint" or "Compl.")]. After Hologic answered, [ECF No. 6], with the agreement of the parties, the Court ordered phased discovery, with the initial discovery limited to core document discovery and depositions of plaintiffs and their implanting physicians, as necessary to evaluate the applicability of the learned-intermediary doctrine to the causation analysis of each plaintiff's claim. See [ECF No. 48 at 7].

On May 30, 2024, Hologic moved for summary judgment as to Rishell based on the learned intermediary doctrine, [ECF No. 65], supported with a memorandum of law, [ECF No. 66], and a statement of undisputed facts, [ECF No. 67]. Plaintiff filed a timely opposition on July 15, 2024, [ECF No. 86], and Hologic replied on August 5, 2024. [ECF Nos. 95–96].

Plaintiff's operative complaint sets forth the following allegations. Count I alleges that Hologic breached its duty to warn users about foreseeable risks, specifically arguing that Hologic was liable because "[t]he IFU failed to include" warnings concerning three risks:

1. that "the BioZorb Markers take far longer than one year to resorb and could require surgical removal";
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 protrude from the breast creating a hole in the breast, [and] could be expelled from the breast which can lead to drainage and infection."

[SAC ¶ 51]. Counts II, III and IV, respectively, assert claims for design defect, breach of implied warranty, and negligence. [Id. ¶¶ 55–89].

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) (citing Celotex Corp. v. Catrett, 477 U.S. 317, 331 (1986)).

"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) (alteration in original) (quoting Cában Hernandez v. Philip Morris USA, Inc., 486 F.3d 1, 8 (1st Cir. 2007)). 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." Pleasantdale, 37 F.4th at 733 (quoting Mesnick v. Gen. Elec. Co., 950 F.2d 816, 822 (1st Cir. 1991)).

B. Conflict of Law

Federal courts sitting in diversity jurisdiction generally apply the forum state's conflict of law rules — here, Massachusetts. 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))). Under Massachusetts conflict of law rules, Pennsylvania law governs plaintiff's claims because the events giving rise to those claims took place in Pennsylvania. See Burleigh v. Alfa Laval, Inc., 313 F. Supp. 3d 343, 353–59 (D. Mass. 2018) (describing factors considered under Massachusetts conflict-of-law analysis for products liability claims). Rishell resides in Pennsylvania, was treated for breast cancer and implanted with BioZorb there, [ECF 86-1 ¶ 6], and suffered her alleged injuries there. Thus, for reasons similar to those expressed in this Court's earlier ruling on Hologic's alleged failure to warn concerning risks associated with BioZorb, the Court will apply the law of the place of injury (here, Pennsylvania) to Rishell's

claims. See Evers v. Hologic, Nos. 22-cv-11895, 22-cv-12194, 2024 WL 4309413, at *7–9 (D. Mass. Sept. 26, 2024).

C. Learned Intermediary Doctrine

In failure-to-warn cases, the plaintiff must prove that the defendant's conduct was the proximate cause of her injuries. See Simon v. Wyeth Pharms., Inc., 989 A.2d 356, 368 (Pa. Super. Ct. 2009). If a plaintiff's alleged injuries relate to a pharmaceutical product or medical device, Pennsylvania law requires the application of the learned intermediary doctrine. See id.; Lineberger v. Wyeth, 894 A.2d 141, 144 (Pa. Super. Ct. 2006). The doctrine provides that a defendant-seller's common-law duty to warn of reasonably foreseeable risks runs to the physician and not to the patient herself. See, e.g., Cohen v. Johnson & Johnson, 634 F. Supp. 3d 216, 237 (W.D. Pa. 2022).

"Thus, in an action against a [medical device] manufacturer based upon inadequate warnings, the issue to be determined is whether the warning, if any, that was given to the prescribing physicians was proper and adequate." Simon, 989 A.2d at 369 (quoting Taurino v. Ellen, 579 A.2d 925, 927 (Pa. Super. Ct. 1990)). The physician relies on their "independent medical judgment, taking into account the data supplied to [them] from the manufacturer, other medical literature, and any other source available to [them], and weighing that knowledge against the personal medical history of the patient" in order to help the patient make an informed decision as to therapy. Makripodis v. Merrell-Dow Pharms., Inc., 523 A.2d 374, 378 (Pa. Super. Ct. 1987) (quoting Leibowitz v. Ortho Pharm. Corp., 307 A.2d 449, 457 (Pa. Super. Ct. 1973)). Therefore, once "the manufacturer [has] provide[d] proper warning to a consumer's physician, it will have discharged its duty to the consumer." Bergstresser v. Bristol-Myers Squibb Co., No. 12-cv-01464, 2013 WL 1760525, at *5 (M.D. Pa. Apr. 24, 2013). Then, to prevail on the

element of causation, the "plaintiff must establish that if defendant 'had issued a proper warning to the [plaintiff's physician], [the physician] would have altered [their] behavior and the injury would have been avoided.'" Daniel v. Wyeth Pharms., Inc., 15 A.3d 909, 923–24 (Pa. Super. Ct. 2011) (quoting Demmler v. SmithKline Beecham Corp., 671 A.2d 1151, 1155 (Pa. Super. Ct. 1996)); see also Simon, 989 A.2d at 368.

Courts applying Pennsylvania law have declined to apply a heeding presumption in pharmaceutical cases based on negligence.[5] See Kline v. Zimmer Holdings, Inc., No. 13-cv-00513, 2015 WL 4077495, at *26 (W.D. Pa. July 6, 2015) (finding that, in Pennsylvania, "the 'heeding presumption' has been applied only to strict liability causes of action"); see also Viguers v. Philip Morris USA, Inc., 837 A.2d 534, 537 (Pa. Super. Ct. 2003) (noting that the use of a heeding presumption "has been authorized in Pennsylvania only in cases involving workplace exposure to asbestos" (citing Coward v. Owens-Corning Fiberglas Corp., 729 A.2d 614, 621 (Pa. Super. 1999)); Lineberger v. Wyeth, 72 Pa. D. & C.4th 35 (Phila. Ct. Com. Pl. 2005) ("In Pennsylvania the heeding presumption has never been applied to a negligence case."); Bergstresser, 2013 WL 1760525 at *5 ("[I]n a negligence claim based upon failure to warn, the plaintiff must prove that the manufacturer was at fault.").

Therefore, in the absence of a heeding presumption, at summary judgment, the burden of production falls to the plaintiff to identify a genuine dispute of material fact concerning whether

[5] A heeding presumption, when applied, is 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). It is used as "a burden-shifting device that makes it easier for a plaintiff to prove causation." Id. Hence, within this framework, when a warning is determined to be inadequate, "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.

an adequate warning to her prescribing physician could have staved off her injuries. Stange v. Janssen Pharms., Inc., 179 A.3d 45, 57 (Pa. Super. Ct. 2018) ("A plaintiff who has established both a duty and a failure to warn must also establish causation by showing that, if properly warned, he or she would have altered behavior and avoided injury" (quoting Kurer v. Park, Davis & Co., 679 N.W.2d 867, 876 (Wis. Ct. App. 2004))); cf. Motus v. Pfizer, Inc., 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001) (applying California law). "Where the record on summary judgment lacks support for a plaintiff's argument that a different warning would have altered the prescribing physician's choice of medication for the plaintiff, summary judgment for the defendant on the ground of lack of causation is appropriate." In re Zyprexa Prod. Liab. Litig., Nos. 04-md-01596, 06-cv-01600, 2009 WL 1514427, at *14 (E.D.N.Y. May 29, 2009) (applying Pennsylvania law).

D. Analysis

1. Failure to Warn (Count I)

Hologic argues that based on the summary judgment record, Rishell will be unable to prove at trial that an adequate warning about the BioZorb's risks could have deterred Dr. Turner from using the device. [ECF No. 66 at 1]. In particular, Hologic relies on Dr. Turner's deposition testimony that using the BioZorb was the right treatment choice for Rishell "based on the information he had at the time." [Id. at 7]; see [Turner Dep. at 162:21–22]. Hologic also contends that the summary judgment record lacks any definitive evidence that Dr. Turner would have changed his decision if an adequate warning had been given. See [ECF No. 66 at 7–8].

The facts of this case present a triable dispute as to causation. Dr. Turner's stated at his deposition that, if he had known (or put differently, had been warned) of the risks associated with the BioZorb device, he would have re-evaluated "the risk-benefit ratio" taking into account the

additional information, including by "inform[ing] Ms. Rishell of that risk." [Turner Dep. at 70:5–20]. Dr. Turner testified that knowledge of such risks "could have" led him "not [to] implant the BioZorb device in Ms. Rishell." [Id. at 71:8–12]. Drawing all reasonable inferences in favor of Rishell as the non-moving party, a jury could also conclude that if advised of the risks by her physician, a reasonable person in Rishell's position would not have agreed to a course of treatment that included the BioZorb, even if her physician had recommended it. Cf. Himes v. Somatics, LLC, 549 P.3d 916, 926 (Cal. 2024) (applying California law). Furthermore, Dr. Turner no longer uses the device in his practice following his experiences with Rishell and other patients who experienced similar side effects. See [Turner Dep. at 20:8–15]. Based on this testimony, a jury drawing reasonable inferences in Rishell's favor could conclude that an advance warning about the risks would have led Dr. Turner to decline to use the BioZorb in treating Rishell.

The Court's conclusion is unchanged by Hologic's suggestion that Dr. Turner did not rely on the IFU to make his decision regarding Rishell. [ECF No. 66 at 12]. This argument is belied by the summary judgment record. While Dr. Turner may not recall how many times he reviewed the IFU or if he read it more than once, [Turner Dep. at 131:20–24], when asked if he had in fact read it, he said that "in the process of the initial use of the Biozorb," the IFU at least "came across [his] desk," [id. at 130:4–8]. It is Dr. Turner's practice and "starting point" to review "product labeling or product instructions for use." [Id. at 111:24–12:8]. Drawing all reasonable inferences for the plaintiff at the summary judgment stage, the Court concludes that this discrepancy leaves a triable issue of fact for a jury to determine.

Thus, because the Court concludes that a genuine dispute of material fact remains on the issue of causation, the motion for summary judgment as to Count I is **DENIED**.

2. Breach of Implied Warranty of Merchantability (Count III)

Rishell's opposition to Defendant's motion relies on Massachusetts law, rather than Pennsylvania law, to support her breach of warranty claim. See [ECF No. 86 at 19]. It is a "settled conclusion" under Pennsylvania law that there is no "implied warranty of merchantability in the sale of prescription drugs," and that federal courts have "predicted that the Pennsylvania Supreme Court would extend that holding to embrace medical devices." Runner v. C.R. Bard, 108 F. Supp. 3d 261, 267, 268 (E.D. Pa. 2015). Therefore, Plaintiff's claim for breach of implied warranty of merchantability fails under Pennsylvania law. See Makripodis, 523 A.2d at 377 (affirming a trial court's decision to dismiss the "portion of appellant's complaint which alleged a cause of action against [Defendant] for breach of a warranty of merchant[a]bility). Accordingly, the motion for summary judgment as to Count III is **GRANTED**.

3. Negligence (Count IV)

Hologic argues that the court should grant summary judgment on Plaintiff's negligence claim. Negligence "is the failure to use the ordinary care a reasonably prudent person would use under the same or similar circumstances." Taylor, 1998 WL 962062 at *11. As set forth in the SAC, Plaintiff's allegations of general negligence mirror aspects of her failure to warn and design defect allegations. [SAC ¶¶ 73–89]. Because the Court has concluded that the summary judgment record gives rise to a genuine dispute of material fact as to the failure to warn claim, and that the design defect allegations are not properly before the Court at this stage, summary judgment as to Count IV is **DENIED**. See Murray v. Synthes (U.S.A.), Inc., No. 95-cv-07796, 1999 WL 672937, at *9 (E.D. Pa. Aug. 23, 1999) (ruling that negligence claims for "producing a device that was poorly designed; failing to conduct adequate tests and studies; failing to provide

appropriate warnings; and failing to obtain proper regulatory clearances" were "viable and not futile").

III. CONCLUSION

Summary judgment is **DENIED** as to Counts I, II, and IV and **GRANTED** as to Count III.

SO ORDERED.

January 3, 2025

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