UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE BIOZORB DEVICE PRODUCTS LIABILITY LITIGATION	*	
	*	Civil Action No. 1:22-cv-11895-ADB
This Order Relates To:	*	
Case No. 1:23-cv-10260-ADB	*	

MEMORANDUM AND ORDER

BURROUGHS, D.J.

Before the Court is Defendant Hologic's motion for summary judgment on Plaintiff Cynthia Kresch's claim that Hologic's alleged failure to warn her breast-cancer surgeon about the risks associated with a radiographic marking device called BioZorb caused her to suffer a variety of injuries. [ECF No. 78 ("Motion" or "Mot.")].[1] Kresch is one of more than eighty plaintiffs spread across twenty-two cases before this Court who are alleging negligence by Hologic in connection with the design and marketing of BioZorb. Kresch has been designated as one of four bellwether trial pool plaintiffs.[2] In support of the pending summary judgment motion, Hologic contends that the undisputed facts foreclose a finding that Hologic's failure to warn her physician about the risks associated with BioZorb proximately caused Kresch's injuries. See [ECF No. 79 ("Memorandum" or "Mem.")]. For the reasons that follow, Hologic's motion is **DENIED**.

[1] Unless otherwise specified, all citations to the record refer to Case No. 1:23-cv-10260-ADB.
[2] See [Case No. 1:22-cv-11895-ADB, ECF No. 201 at 1–2].

I. BACKGROUND

A. Factual Background

The BioZorb is an implantable medical device approved by the Food and Drug Administration ("FDA") as a Class II medical device indicated for situations where an excision site needs to be marked for future medical procedures, such as radiation treatment. See [ECF No. 98-1 ("Responsive Statement of Undisputed Facts" or "RSUF") ¶¶ 1–3]. The device consists of a spiral-shaped bioabsorbable spacer that holds permanent titanium clips. [Id. ¶ 2]. Although BioZorb markers come in a range of sizes, the parties agree that the image below depicts an accurate visual representation of the device.

[Id. ¶ 2]. The device is claimed to dissolve into the body during a process that Hologic calls "resorption," leaving behind titanium clips that are visible on radiographic imaging. [Id. ¶ 4].

According to the BioZorb's Instructions for Use ("IFU") in effect at the time of Kresch's operation, the resorption process may take "up to one or more years." [ECF No. 120-1 ("IFU")]. Specifically, the IFU advised that "[t]he 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.

[Id.].

Cynthia Kresch, a citizen of South Carolina, was diagnosed with a cancerous tumor in her right breast in September 2020. [RSUF ¶¶ 5–6]. On October 30, 2020, Kresch underwent a partial mastectomy and sentinel lymph node excision at a Prisma Health outpatient surgical clinic in Greenville, South Carolina, performed by Dr. John Rinkliff. [Id. ¶ 7]. Dr. Rinkliff implanted a BioZorb device in Kresch's right breast to flag her excision site for radiology and to improve Kresch's cosmetic outcome, or cosmesis. [Id.]; see [ECF No. 81-1 ("Rinkliff Dep.") at 93:3–10]. Because pathologic analysis could not confirm that the first procedure had removed the entire tumor, Dr. Rinkliff performed a second surgery at Prisma Health Greenville Memorial Hospital on November 10, 2020. [RSUF ¶ 8]. During the second operation, done to remove additional potentially cancerous tissue, Dr. Rinkliff removed and then re-implanted the BioZorb. [Id.]

In June 2021, Kresch began experiencing pain and swelling in her right breast, [ECF No. 107 ("Response to Statement of Additional Facts" or "RSAF") ¶ 1], and the following month underwent an incisional drainage procedure to treat an abscess in that breast. [Id. ¶ 3]. Kresch then continued to receive bi-weekly wound care over the following ten months. [Id. ¶ 5]. A clinical note from Prisma Health dated June 10, 2022, noted a "[w]hite hard tip . . . protruding from breast wound" and that "[a]pprox[imately] 2 cm of broken BioZorb [was] removed from [her] wound." [ECF No. 98-30 at 5]; [RSAF ¶¶ 6, 8]. Two weeks later, on June 27, 2022 Kresch underwent further surgery to "remove multiple portions of the BioZorb." [RSAF ¶ 11].

Dr. Rinkliff sat for a deposition in connection with this case on May 22, 2024. Dr. Rinkliff testified that he had implanted fewer than fifty BioZorb devices between approximately 2019 and 2021, when he stopped using the device. [Rinkliff Dep. at 29:2–6, 91:23–92:2]. Prior to treating Kresch, Dr. Rinkliff had communicated with a Hologic sales representative about the BioZorb and other surgical devices sold by the company. [Id. at 88:17–90:10]. The representative was sometimes present in or around Prima Health operating rooms during procedures and would provide information about the BioZorb. [Id. at 90:22–24].

Initially, the Hologic representative told Dr. Rinkliff that the dissolvable material in the BioZorb would resorb within either six to ten or six to twelve months, leaving behind only the titanium clips. [Id. at 36:15–17, 37:5–8, 91:1–3, 91:7–11]. As Dr. Rinkliff became experienced with the BioZorb, however, he realized that the resorption time in his patients was taking much longer. [Id. at 37:9–16]. According to his testimony, he and his colleagues saw that "the longer we used [the BioZorb], the more we were realizing that this thing [was] not going away as fast as we thought it was." [Id. at 37:13–16].

During his deposition, Dr. Rinkliff was questioned about an FDA advisory communication published on February 27, 2024 (the "FDA Safety Communication"), see [ECF No. 98-8], concerning "adverse event reports" linked to use of the BioZorb. [Rinkliff Dep. at 115:10–116:19]. The FDA Safety Communication described complications including infection, fluid buildup, migration, erosion, pain, palpability, and "other complications possibly associated with extended resorption time." [ECF No. 98-8 at 2]. Dr. Rinkliff testified that he "was not aware when [he] did Mrs. Kresch's surgery that there were problems with BioZorb implants." See [Rinkliff Dep. at 116:22–117:7]. Kresch's counsel then asked whether such knowledge would have changed his decision to use the device and engaged in the following dialogue:

> Q. If you had known about these issues with the BioZorb device listed in the FDA safety communication [at the time of Kresch's surgery] in 2020, would you have still implanted the BioZorb device into Ms. Kresch?
> . . .
> A. I don't know that I can answer that question. It would be what type of problems they're reporting. I guess I would use an example. There are warnings with mesh for hernia repair, and we still use mesh today, understanding that the benefits outweigh the risks. So I don't know that – it's a hypothetical question, and it would be based on very specific things that I could say yes or no, I would implant or not implant at that time.

[Id. at 117:8–22].

B. Relevant Procedural History

Kresch and four co-plaintiffs filed this lawsuit on January 31, 2023, [ECF No. 1], and have since amended their complaint twice, [ECF Nos. 113, 120]. The operative complaint asserts four causes of action: Negligence for Failure to Warn (Count I), Negligence for Design Defect (Count II), Breach of Implied Warranty of Merchantability (Count III), and Negligence (Count IV). [ECF No. 120 ("Second Amended Complaint" or "SAC")].

The Court's case management orders allowed phased discovery and early summary judgment motions. [ECF Nos. 13–14]. The first phase of discovery is limited to core document discovery and depositions of plaintiffs and their implanting physicians to allow for summary judgment motions limited in scope to the application of the learned-intermediary doctrine to the causation analysis for each plaintiff's failure-to-warn claims. See [ECF No. 13]. Accordingly, Hologic filed the instant motion for summary judgment on the basis of the learned-intermediary doctrine on June 28, 2024. [Mot.; Mem.]. Kresch opposed on August 5, 2024, [ECF No. 98 ("Opposition" or "Opp.")], and Hologic replied on August 23, 2024, [ECF No. 106 ("Reply")].

II. DISCUSSION

A. Conflict of Laws

Federal courts sitting in diversity jurisdiction apply the forum state's choice of substantive 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))). As this Court has previously explained, the balancing test under Massachusetts conflict-of-laws rules for products-liability cases favors applying the law of the place of injury based on the facts of these cases. 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); In re BioZorb Device Prod. Liab. Litig., Nos. 22-cv-11895-ADB, 22-cv-12194-ADB, 2024 WL 4309413, at *7–9 (D. Mass. Sept. 26, 2024) (concluding that Burleigh factors weighed in favor of the law of the place of injury). As Kresch's deposition testimony establishes, she has been a citizen of South Carolina for most of her life, [ECF No. 81-2 ("Kresch Dep.") at 16:22–18:16], was implanted with the BioZorb device there, and suffered her resulting injuries there, [RSUF ¶¶ 5–7]. Thus, the Court will apply South Carolina law to Kresch's claims.

B. Analysis

1. Legal Standard

A movant may obtain summary judgment only by showing "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). The moving party 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. 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 cases go 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) (citation and alteration omitted). 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)).

2. Count I: Failure to Warn

While the South Carolina Supreme Court has not spoken directly on the issue, it is likely that the court would apply the learned-intermediary doctrine in failure-to-warn cases involving prescription drugs and medical devices. For instance, the court has held that pharmacists are not strictly liable for side effects of complications of the drugs they supply because the duty to warn runs to the doctors as "learned intermediar[ies]." Madison v. Am. Home Prods. Corp., 595 S.E.2d 493, 496 (S.C. 2004). The Fourth Circuit has inferred from this dicta that the court would

apply the learned-intermediary doctrine in failure-to-warn cases. See Bean v. Upsher-Smith Pharms., Inc., 765 Fed. App'x 934, 936 (4th Cir. 2019) (interpreting Madison as "extend[ing]" drug manufacturers' duty to warn "only to physicians" (citation omitted)); see also Brooks v. Medtronic, Inc., 750 F.2d 1227, 1231 (4th Cir. 1984) (predicting that S.C. Supreme Court would apply the learned-intermediary doctrine in accordance with the "substantial majority of jurisdictions."). Similarly, the South Carolina Court of Appeals has held that the doctrine would apply in failure-to-warn cases. See Jolly v. Gen. Elec. Co., 869 S.E.2d 819, 838 (S.C. Ct. App. 2021). Finding no precedent to the contrary, the Court concludes that under South Carolina law, a medical-device manufacturer's duty to warn runs only to the prescribing physician. Cf. Violette v. Smith & Nephew Dyonics, Inc., 62 F.3d 8, 13 (1st Cir. 1995) (describing the learned-intermediary doctrine as "the general rule" among states regarding "medical devices," collecting cases, and citing Brooks).

Under the learned-intermediary doctrine, "the manufacturer's duty to warn extends only to the prescribing physician, who then assumes responsibility for advising the individual patient of risks associated with the drug or device." Odom v. G.D. Searle & Co., 979 F.2d 1001, 1003 (4th Cir. 1992) (applying South Carolina law). The Fourth Circuit has predicted that South Carolina would not apply a heeding presumption in such cases. Id. (explaining that "[t]here is no . . . presumption under South Carolina law" that an adequate warning would have been heeded if provided); accord Sauls v. Wyeth Pharms., Inc., 846 F. Supp. 2d 499, 504 (D.S.C. 2012) ("[T]he burden rests with Sauls to prove proximate causation by demonstrating that an adequate warning would have altered Dr. Bennett's prescription decision."). Consequently, courts applying South Carolina law grant summary judgment when the plaintiff cannot point to record evidence creating a triable issue as to whether their physician would have acted differently in the face of a

stronger warning. See, e.g., Odom, 979 F.2d at 1003; Sauls, 846 F. Supp. 2d at 504; Carnes v. Eli Lilly & Co., No. 13-cv-00591-CMC, 2013 WL 6622915, at *1 (D.S.C. Dec. 16, 2013).

Here, however, Kresch has identified ample evidence in the summary-judgment record to create a genuine dispute of material fact as to whether Dr. Rinkliff, as the learned-intermediary between Kresch and Hologic, would have declined to use the BioZorb in Kresch's treatment in had he received a stronger warning concerning the risk of prolonged resorption. Hologic "[a]ssum[es] for purposes of [its] Motion that the BioZorb's warnings [were] inadequate," and contends that even so, the court should grant summary judgment here because the record lacks evidence that a stronger warning would have led Dr. Rinkliff not to use the device. [Mem. at 14]. Specifically, Hologic points to testimony by Dr. Rinkliff that it contends equivocates over whether the adverse-event reports contained in the FDA Safety Communication would have led him to change his prescribing decision. [Id.] This testimony, Hologic contends, is too evasive to defeat summary judgment. [Id.]

Kresch convincingly responds that Hologic's argument overlooks other testimony provided by Dr. Rinkliff that would allow "a reasonable jury [to] find that he would not have implanted the device in Ms. Kresch had he known in advance of her surgery that," for example, "the device could fail to absorb." [Opp. at 12 n.9]. Dr. Rinkliff testified that although Hologic warned that the dissolvable material in the BioZorb could take more than twelve months to resorb, "the longer [he and his colleagues] used [BioZorb], the more [they] were realizing [the BioZorb was] not going away as fast as [they] thought." [Rinkliff Dep. at 37:9–16]; see also [id. at 38:5–9]. Dr. Rinkliff reached this understanding based not on information provided by Hologic, but rather through his own clinical experience. [Id. at 37:9–11]. Dr. Rinkliff's eventual decision to stop using the device after discovering the risk of extended resorption would allow a

reasonable jury to infer that Dr. Rinkliff believed that the potential risks associated with extended resorption outweighed the BioZorb's benefits.[3] Because the "non-disclosed risk" of prolonged resorption ultimately led Dr. Rinkliff to "change[] [his] decision to prescribe the product" to later patients, Sauls, 846 F. Supp. 2d at 502 (quoting Odom, 979 F.2d at 1003), a reasonable jury could conclude, by a preponderance of the evidence,[4] that an earlier warning about such a risk may have hastened his decision to stop using the BioZorb such that he would no longer have used it by the time of Kresch's treatment, which would have interrupted "the chain of events resulting in [Kresch]'s injuries."[5] Fisher v. Pelstring, 817 F. Supp. 2d 791, 812 (D.S.C. 2011). This is hardly a case where Kresch "has failed to proffer any evidence that could establish proximate causation." Sauls, 846 F. Supp. 2d at 504. Kresch has, to the contrary,

[3] Other warnings that Hologic omitted may have had a similar effect. For example, Rinkliff testified that "the BioZorb was presented" as having "a twofold purpose" of "aiding a[] good cosmetic outcome," or cosmesis, "as well as marking the cavity for potential radiation." [Rinkliff Dep. at 27:9–13]. Because there are other available radiographic markers, Dr. Rinkliff explained that he used the BioZorb specifically because of its purported cosmetic benefits; he "would have not used a BioZorb device if it was solely a marking device." [Id. at 93:3–10]. That said, he also testified that he could not recall Hologic warning him that the BioZorb lacked FDA approval for improved cosmesis. [Id. at 122:15–19].

[4] When determining whether "there is a genuine issue for trial," the Court must take into account the substantive evidentiary burden Kresch would have to carry before a jury—here, a preponderance of the evidence. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250 (1986).

[5] The Court further notes that a jury could reach this conclusion notwithstanding Dr. Rinkliff's testimony concerning the adverse-event reports contained in the FDA Safety Communication. Although Dr. Rinkliff testified that the reason he "stopped using BioZorb was not because of adverse events" reported by the FDA, he also testified unequivocally that he stopped using the device because his own experience led him to believe he "could get a better result not using it," [Rinkliff Dep. at 121:10–15, 19–23], and specifically, that the BioZorb was not dissolving as quickly as Hologic had told him it would or as quickly as other dissolvable suture material, [id. at 38:5–9]. Thus, a reasonable jury could conclude that a warning from Hologic about this risk could have caused Dr. Rinkliff not to use the device at all—including on Kresch—even if he could not say unequivocally that knowledge of the adverse events reported in the FDA Safety Communication, without any further warning from Hologic, would have changed his decision to use the BioZorb in Kresch's case.

"identif[ied] 'significantly probative' evidence favoring [her] position." Irobe v. U.S. Dep't of Agric., 890 F.3d 371, 377 (1st Cir. 2018) (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249–50 (1986)).

For the foregoing reasons, summary judgment as to Count I of Cynthia Kresch's complaint is **DENIED**.

3. Counts II, III, and IV

In the pending motion, Hologic further contends that Plaintiff has inadequately pleaded the design defect claim contained in Count II by, among other things, not identifying any "specific defects in the design of BioZorb." See [Mem. at 1–2]. Because these arguments are unrelated to the learned-intermediary doctrine, they fall outside the limited scope of the summary judgment filings permitted at this stage under the Court's bellwether order. In any event, as the Court allowed the plaintiffs in these cases to amend their design defect claims and Hologic to file a separate motion to dismiss, which is now fully briefed, see [Case No. 22-cv-11895-ADB, ECF Nos. 190–91, 193, 200], the Court **DENIES** Hologic's motion for summary judgment as to the design defect claims without prejudice.

To the extent Hologic seeks summary judgment on Counts III and IV based on the learned-intermediary doctrine, summary judgment is **DENIED** for the same reasons as for Count I. See In re BioZorb, 2024 WL 4309413, at *13.

III. CONCLUSION

For the foregoing reasons, the motion is **DENIED**.

SO ORDERED.

January 15, 2025

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