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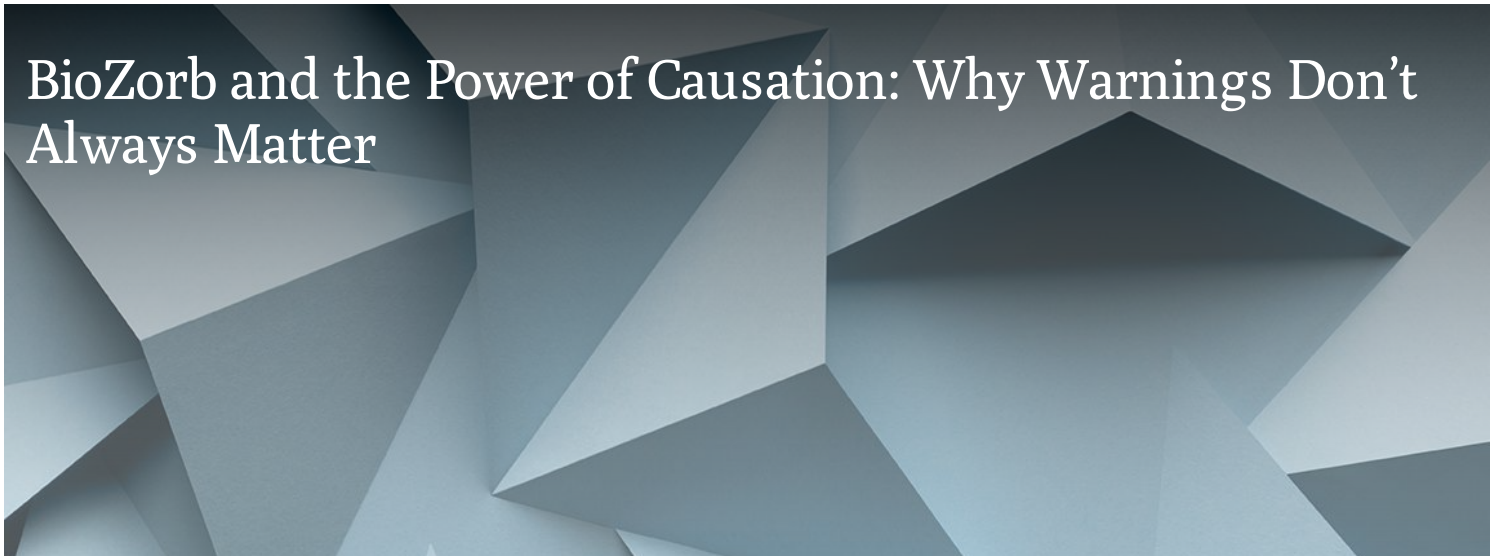
BLOG

BioZorb and the Power of Causation: Why Warnings Don't Always Matter



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In the ongoing litigation involving the BioZorb device, the U.S. District Court for the District of Massachusetts recently ruled on defendant-manufacturer Hologic's motion for summary judgment in the case of *In re BioZorb Device Products Liability Litigation*, No. 22-cv-11895-ADB, 2025 WL 509834, at *4 (D. Mass. Feb. 12, 2025). Plaintiff Pamela Gibson, one of four bellwether trial plaintiffs, alleged that Hologic's failure to adequately warn her breast cancer surgeon about the risks associated with the BioZorb device led to her injuries. *Id.* at *1. But the court granted partial summary judgment in Hologic's favor, dismissing Gibson's failure-to-warn claim but allowing other claims to proceed. *Id.* at *4.

FACTUAL BACKGROUND AND PROCEDURAL HISTORY

The BioZorb is an FDA-approved Class II medical device designed to mark excision sites for future medical procedures—particularly, for radiation therapy. *Id.* at *1. Made of a spiral-shaped bioabsorbable spacer with permanent titanium clips, the BioZorb is intended to dissolve into the body over time, leaving behind the titanium markers for radiographic targeting. *Id.* The device is implanted in breast cancer patients during procedures like mastectomies and lumpectomies. *Id.*

In this case, Gibson's surgeon, Dr. Laura Pomerenke, implanted the BioZorb in Gibson's right breast during a partial mastectomy to give the radiation doctor a smaller target and reduce the amount of radiation used after treatment. *Id.* at *1-2. Afterward, Gibson testified that she experienced pain and felt a lump in her breast. *Id.*

During post-operative follow-up months later, Dr. Pomerenke noticed that Gibson had begun to develop mild lymphedema (a buildup of lymph fluid between the skin and muscle) and radiation fibrosis (thickening and scarring of tissue caused by radiation) at the incision site. *Id.* at *2. Yet Dr. Pomerenke testified that she did not think the fibrosis was caused by the BioZorb, nor did the fibrosis make her reconsider her decision to use the BioZorb in Gibson's treatment. *Id.* Dr. Pomerenke also testified that she observed no evidence suggesting that the BioZorb had migrated or failed to resorb. *Id.*

Gibson and four co-plaintiffs sued Hologic, alleging four theories of negligence: failure to warn, negligence for design defect, breach of implied warranty of merchantability, and general negligence. *Id.* The court set up a phased discovery process, with the initial phase intended to allow summary judgment motions related to the learned

intermediary doctrine's application to the failure-to-warn claim. *Id.* As part of this process, Hologic moved for summary judgment on the learned intermediary doctrine. *Id.*

ANALYSIS

After considering each of Gibson's four claims, the court granted Hologic's motion in part and denied it in part. Under governing conflict of law principles, it applied Colorado law.

The court first considered the failure-to-warn claim, which required Gibson to prove "that the manufacturer gave an inadequate warning of the danger that caused the [plaintiff's] injury." *Id.* at *3 (alteration in original). For a medical device like the BioZorb, which "is available only to physicians and obtained by prescription," Colorado courts apply the learned intermediary doctrine. Under that defense to liability, Hologic's duty to warn was "limited to an obligation to advise the prescribing physician"—here, Dr. Pomerenke—"of any potential dangers that may result from the [BioZorb]'s use." *Id.* (alteration in original).

The core question for this claim was one of causation: "whether an adequate warning would have altered Dr. Pomerenke's decision to use the BioZorb," thereby preventing Gibson's injuries. *Id.* Noting that "Gibson's counsel never questioned Dr. Pomerenke at her deposition as to whether a stronger warning would have changed her decision use the BioZorb," the court found that Gibson failed to point to any evidence that could clear even this "modest" threshold. *Id.* at *4.

It wasn't enough that Gibson's attorney elicited testimony that Dr. Pomerenke was unaware of "variety of potential risks associated with the BioZorb." *Id.* The court made clear that such testimony failed to answer "the critical question" in the causation inquiry: "what Dr. Pomerenke would have done if she had known of those risks." *Id.* (emphasis in original) And that gap in the causation analysis was fatal to Gibson's failure-to-warn claim.

Dr. Pomerenke had otherwise testified that she believed Gibson's injuries were attributable to radiation fibrosis (an unrelated surgical complication), not the BioZorb, and that she stood by her decision to use the device. *Id.* And because Gibson failed to present sufficient evidence that an enhanced warning would have changed her decision to do so, the court granted summary judgment and dismissed the claim. *Id.*

The court allowed Gibson's second count (a design-defect claim) to proceed because it fell outside the narrow scope of the summary judgment phase, which was focused on the learned intermediary doctrine. *Id.* But it also partially granted summary judgment on Gibson's breach of warranty and negligence claims to the extent they relied on a failure-to-warn theory. *Id.*

KEY TAKEAWAYS

This case underscores the importance of demonstrating proximate causation in failure-to-warn claims, particularly in medical device product liability cases. To succeed, plaintiffs must provide evidence that an adequate warning would have directly influenced the physician's decision to use the product. In this case, the plaintiff failed to establish this link, which led to the dismissal of the failure-to-warn claim.

The ruling also highlights the protection afforded to manufacturers under the learned intermediary doctrine. The court emphasized that a manufacturer's duty to warn is directed only to the prescribing physician, not the patient, and since the prescribing physician did not believe a stronger warning would have changed her decision, the plaintiff's claim was dismissed.
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