UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: BIOZORB DEVICE PRODUCTS LIABILITY LITIGATION	*	
This Order Relates to the Following Cases:	*	
	*	Civil Action No. 22-cv-11895-ADB
No. 1:22-cv-11895-ADB	*	
No. 1:22-cv-12194-ADB	*	
No. 1:23-cv-10260-ADB	*	
No. 1:23-cv-10579-ADB	*	
No. 1:23-cv-10599-ADB	*	

MEMORANDUM AND ORDER

BURROUGHS, D.J.

Before the Court is Defendant Hologic's Motion to Dismiss the design defect claims alleged by the plaintiffs in the above-captioned cases ("Plaintiffs"). [ECF No. 190 ("Motion" or "Mot.")][1]; see also [ECF No. 191 ("Memorandum in Support of Motion" or "Mem.")]. For the reasons set forth below, the motion is **DENIED**.

I. BACKGROUND

A. Relevant Facts

The following facts are drawn from the well-pleaded allegations in the Plaintiffs' operative complaints, which the Court construes in the light most favorable to them as the non-moving party. See Monroe v. Medtronic, Inc., 511 F. Supp. 3d 26, 33 (D. Mass. 2021).

[1] All record citations in this order refer to the consolidated docket, Case No. 22-cv-11895, unless otherwise specified.

1. Background on the BioZorb

Plaintiffs received surgical treatment for breast cancer, during which they were implanted with BioZorb markers. [ECF No. 178 ¶ 1 ("Fourth Amended Complaint" or "FAC")].[2] The BioZorb is a class II medical device cleared by the U.S. Food and Drug Administration ("FDA") in February 2012. [Id. ¶ 9]. The device is a "three-dimensional implantable radiographic marker" consisting of "a bioabsorbable spacer that holds six radiopaque titanium clips." [Id. ¶ 10]. It is "indicated for use in radiographic marking." [Id. ¶ 11]. The spacer material, made of polylactic acid, "is intended to be resorbed by the body through hydrolysis, leaving the radiopaque clips as permanent indicators of the soft tissue site" for "future medical procedures," including CT imaging, mammography, MRI, and ultrasound. [Id. ¶¶ 10–11].

According to the BioZorb's instructions and Hologic's marketing, the BioZorb should completely resorb within "one or more years." [FAC Ex. A]. Plaintiffs allege that Hologic knew or should have known that the device may fail to resorb, and that clinical evidence indicated that the device could cause "infection, fluid buildup (seroma), [the] device [to] mov[e] out of position (migration)" or "break[] through the skin (erosion)," as well as "pain, discomfort from feeling the device in the breast, [and] rash[es]," potentially requiring "medical treatment to remove the device." [FAC ¶ 20]. Further, Hologic knew or should have known of clinical evidence showing that the BioZorb could require "an increase [in] a patient's radiation dose, contributing

[2] This order cites primarily to the version of the Fourth Amended Complaint filed on the master docket, which pertains to plaintiffs Shelley Evers, Kathleen Lyons, Rita Melkonian, Christina Patras, and Tricia Willard. Amended Complaints identical to the FAC in all respects except for the plaintiff-specific injury allegations were filed on the same date on the dockets of each of the Track A and B cases. See [Case No. 22-cv-12194, ECF No. 153]; [Case No. 23-cv-10260, ECF No. 120]; [Case No. 23-cv-10599, ECF No. 138]; [Case No. 23-cv-10579, ECF No. 111] (collectively, the "Amended Complaints").

to further complications." [Id. ¶ 16]. Plaintiffs also allege that Hologic "attempted to obtain FDA approval of the BioZorb [m]arkers as 'designed to improve cosmetic outcomes for patients using it.'" [Id. ¶ 26]. The FDA, however, determined that Hologic "had not provided any data to support its claim that the device improved cosmetic outcomes," [id.], and the device never received FDA approval for cosmetic outcomes, see [id. ¶ 22].

Plaintiffs allege that Hologic was responsible for the design, research, development, testing, packaging, labeling, and supplying of the BioZorb, [FAC ¶ 91], and that its design is "defective because of design aspects, including, but not limited to, its shape, surface, texture, material, and integration of parts." [Id. ¶ 71]. These features "could all have been feasibly changed to make the device less harmful," [id. ¶ 72], as "[t]here are technologically feasible and practical alternative designs that would have reduced or prevented the Plaintiffs' harm," [id. ¶ 73]. Specifically:

> In the oncological surgical market, alternative designs exist that are mechanically feasible, safer, and cost significantly less than BioZorb. For example, titanium clips that have been on the market for years carry less clinical risk to the patient. In fact, as one recent clinical study found: "the use of clips to mark the tumor bed is more cost-effective than the use of the BioZorb Marker which does not provide value given its relative high cost and lack of clinical advantage scientifically shown over the use of surgical clips."

[Id. ¶ 74 (quoting Ramy Rashad, Katheryn Huber & Abhishek Chatterjee, Cost-Effectiveness of the Biozorb Device for Radiation Planning in Oncoplastic Surgery, 7 Cancer & Clinical Oncology 23, 28 (2018))]. By contrast, Plaintiffs assert that Hologic's design of the BioZorb "poses a high gravity of danger" because, for example, "the Marker does not fully absorb in the body, migrates or is expelled from the body, or causes an infection, [and] a patient may be required to undergo an additional surgery to remove the device." [Id. ¶ 75]. Plaintiffs further allege that they "were harmed because of the defective design of the BioZorb marker." [Id.

¶ 70]; see also, e.g., [id. ¶¶ 27–56, 76 (describing plaintiff-specific injuries for Shelley Evers, Christina Patras, Rita Melkonian, and Tricia Willard)].

B. Procedural History

The Court assumes the parties' general familiarity with the procedural facts related to this case. The operative Amended Complaints for purposes of this motion were filed, with leave, on October 18, 2024. See supra note 2. Hologic filed the instant motion on November 11, 2024. [ECF Nos. 190, 191]. Plaintiffs opposed on December 2, 2024, [ECF No. 193 ("Opposition" or "Opp.")], and Hologic replied on December 16, 2024, [ECF No. 200 ("Reply")].

II. DISCUSSION

A. Legal Standard

1. Failure to State a Claim

"Dismissal of a complaint pursuant to Rule 12(b)(6) is inappropriate if the complaint satisfies Rule 8(a)(2)'s requirement of a 'short and plain statement of the claim showing that the pleader is entitled to relief.'" Ocasio-Hernández v. Fortuño-Burset, 640 F.3d 1, 11–12 (1st Cir. 2011) (quoting Fed. R. Civ. P. 8(a)(2)). "A short and plain statement needs only enough detail to provide a defendant with fair notice of what the . . . claim is and the grounds upon which it rests." Id. at 12 (internal quotation marks omitted) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)). Still, "to 'show' an entitlement to relief a complaint must contain enough factual material 'to raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true (even if doubtful in fact).'" Id. (quoting Twombly, 550 U.S. at 555). "Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." Id. (internal quotation marks omitted) (quoting Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)).

To apply these standards, courts "employ a two-pronged approach." Ocasio-Hernández, 640 F.3d at 12. To begin, a court must "identify[] and disregard[] statements in the complaint that merely offer "legal conclusions couched as fact" or "[t]hreadbare recitals of the elements of a cause of action." Id. (cleaned up) (quoting Iqbal, 556 U.S. at 678). "Non-conclusory factual allegations in the complaint must then be treated as true, even if seemingly incredible." Id. "If that factual content, so taken, 'allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged,' the claim has facial plausibility." Id. (quoting Iqbal, 556 U.S. at 678). The resulting inquiry demands a "context-specific" approach, asking courts "to draw on . . . judicial experience and common sense." Iqbal, 556 U.S. at 679.

2. Negligent Design Defect

The parties agree that the law of the place of injury applies to these claims. Because Plaintiffs were injured in different states, different state negligence laws govern their respective design defect claims.[3] Hologic's motion objects on four grounds that cut across the applicable state laws: specifically that the Amended Complaints (1) fail to plead a specific defect, (2) do not allege that the defect was a consequence of Hologic's negligence, (3) where required under state law, fail to identify a reasonable alternative design, and (4) where required under state law, do not allege the contours of a risk-utility analysis. The Court rejects each argument for the reasons that follow.

[3] This motion is governed by the following states' laws in connection with the referenced plaintiffs: California (Rita Melkonian, Anne Thalman, and Denice Chambers); Colorado (Pamela Gibson); Florida (Nerissa Burke); Illinois (Pamela Mazzanti); Indiana (Tricia Willard); Michigan (Beth Deuel and Diane Lyon); New York (Christina Patras, Julie Block, and Kimberly Taylor); North Carolina (Karen Ensley); Ohio (Rebecca Shirkey); Pennsylvania (Tina Stine, Joye Rishell, and Joanna Perez); South Carolina (Cynthia Kresch); Texas (Della Debbas and Katy Wharton); Washington (Diane Anderson); and Wisconsin (Shelley Evers).

B. Analysis

1. Pleading of Defects

Hologic contends that Plaintiffs' allegation that "[t]he design of the BioZorb Marker is defective because of design aspects, including but not limited to, its shape, surface, texture, material, and integration of parts" fails to "identify any particular aspect of the BioZorb's design that constitutes a defect," as required under all relevant states' laws. [Mem. at 6 (emphasis omitted)]. Hologic posits that "this 'laundry list' allegation is entirely conclusory, as it does not specify which component or aspect of the device is allegedly defective or how such an element (or combination of them) is defective." [Id.]. Although Plaintiffs do not dispute that they must plead a defect to state a claim under the law of every state applicable here, they maintain that the allegations are adequate. [Opp. at 3–4].

There is no question that "a bare assertion that a defendant . . . has knowingly manufactured and sold a product that is 'defective,' or suffers from 'safety-related defects,' does not suffice to state a viable claim." See Cunningham v. Abbott Vascular, Inc., No. 21-cv-10241, 2022 WL 2387903, at *8 (D. Mass. Mar. 1, 2022) (quoting Iannacchino v. Ford Motor Co., 888 N.E.2d 879, 888 (Mass. 2008)) report and recommendation adopted, 2023 WL 6397839 (D. Mass. Sept. 29, 2023). Likewise, allegations that a medical device "was manufactured in violation of the Federal Food, Drug and Cosmetic Act . . . and regulations promulgated pursuant to said Act" or that the manufacturer engaged in negligence by "designing, manufacturing, and/or distributing a product in a defective condition," in the absence of further factual context, also do not suffice. Zeman v. Williams, No. 11-cv-10204, 2014 WL 3058298, at *4 (D. Mass. July 7, 2014) (cited in Reply at 1 n.1); see also Wilkins v. Genzyme Corp., No. 21-cv-10023,

2022 WL 4237528, at *23 (D. Mass. Sept. 14, 2022) (dismissing claim where defect was so "unclear" that it offered no more than a "bare allegation").

That said, Plaintiffs both identify defective components and explain the nature of the underlying defects, and, contrary to Hologic's view that Plaintiffs must identify a more specific defective aspect of the BioZorb, these allegations are adequate. On its face, the Amended Complaints allege that the defective aspects of the BioZorb are its "shape, surface, texture, material, and integration of parts," [FAC ¶ 71], and, more to the point, that such aspects are defective because their design may lead the device "not [to] fully absorb in the body," to "migrate[]," to be "expelled from the body," or to "cause[] an infection," [id. ¶ 75]. It is also readily apparent and easily inferred that Plaintiffs' allegation is that the defect derives, at least in part, from the bioabsorbable scaffolding. As Plaintiffs allege, and the Court discusses further below, titanium clips implanted without the BioZorb scaffolding existed on the market prior to the introduction of the BioZorb, [Id. ¶ 71], and, according to the Amended Complaints, would not have led to the injuries Plaintiffs suffered, [id. ¶ 70].

Taking these allegations as true, it is plausible (and not merely speculative or possible) that the BioZorb contains a defect.[4] These allegations are consistent with pleadings readily accepted in other courts that characterize a plausible defect based on the product's operational failure, rather than (at least at the pleading stage) a concrete engineering deficiency that led to

[4] Although neither Plaintiffs nor Hologic hones in on a particular definition of defect under any applicable state's law, these allegations comport with broadly understood categories of design defects. Allegedly harmful "products may be defective in character" for a variety of reasons, including if they "[a]re unsafe, though perfectly manufactured, because they produce unacceptable consequences" or "[a]re incapable of meeting their implied or express claims of performance or safety." See, e.g., Thomas Parker Redick, Products Liability: Design and Manufacturing Defects § 4:2 (2d ed. 2024).

the failure. See, e.g., Guariglia v. Proctor & Gamble Co., No. 15-cv-04307, 2018 WL 1335356, at *4 (E.D.N.Y. Mar. 14, 2018) (holding that "Plaintiffs[']claim that the stains were caused by the Tide Pods' failure to dissolve . . . plausibly allege[d] that the product posed a substantial likelihood of harm and that the defective design was a substantial factor in causing the Plaintiffs' injuries" (emphasis added)); Clark v. Am. Honda Motor Co., 528 F. Supp. 3d 1108, 1115 (C.D. Cal. 2021) ("[A] complaint provides fair notice of the defect if it (1) identifies the particular part or system affected by the defect, and (2) describes the problems allegedly caused by the defect."); City of High Point, N.C. v. Suez Treatment Sols. Inc., 485 F. Supp. 3d 608, 630 (M.D.N.C. 2020) (allowing defect claim to proceed based on similar allegations because "a product defect may be inferred from evidence the product was put to its ordinary use and the product malfunctioned" (quoting DeWitt v. Eveready Battery Co., 550 S.E.2d 511, 516 (N.C. Ct. App. 2001))). To demand more at the pleading stage would, as Plaintiffs point out, require them "to possess technical or scientific knowledge about the inner workings of the product" and "contravene the notice pleading requirement" of Rule 8. Sullivan v. Aventis, Inc., No. 14-cv-2939, 2015 WL 4879112, at *7 (S.D.N.Y. Aug. 13, 2015); accord Manning v. Bos. Med. Ctr. Corp., 725 F.3d 34, 45 (1st Cir. 2013) ("In connection with a threshold plausibility inquiry, a high degree of factual specificity is not required." (quoting Grajales v. P.R. Ports Auth., 682 F.3d 40, 47 (1st Cir. 2012))); Hoak v. Spineology, Inc., No. 22-cv-06049, 2023 WL 6290495, at *6 (N.D. Ill. Sept. 27, 2023) (construing the Rule 8 standard as not requiring "specific facts as to the precise nature of" a defect).[5]

[5] Hologic cites a decision from another session of this Court that granted a motion to dismiss where the complaint failed to "define with specific detail what aspect of the product's design left it unreasonably dangerous." Moon v. Instant Brands LLC, No. 22-cv-11814, 2023 WL 3126078,

2. Causation

Hologic also argues that Plaintiffs have "not allege[d] that any defect in the BioZorb resulted from any negligent conduct" on its part. [Mem. at 7]. Plaintiffs respond that their allegations concerning Hologic's knowledge about the defects coupled with the allegation that Hologic "failed to take reasonable measures to mitigate or eliminate the risks posed by the defective design" are sufficient at this stage. [Opp. at 4–5 & n.1]. Plaintiffs contend that it is enough to have alleged that Hologic "knew or should have known" of the BioZorb's tendency not to resorb or to migrate and "fail[ed] to exercise due care under the circumstances." [Id. at 5 (quoting Witt v. Howmedica Osteonics Corp., No. 13-cv-20742, 2014 WL 1330840, at *2 (S.D. Fla. Mar. 28, 2014))]. Hologic insists that Witt is more permissive than the approach prescribed by Twombly and Iqbal. [Reply at 2].

The Plaintiffs' broader allegations describe "a factual context that supports an inference of liability as one plausible explanation for what has been alleged." 5B A. Benjamin Spencer, Arthur R. Miller & Charles Alan Wright, Federal Practice & Procedure § 1357 (4th ed. 2024). Plaintiffs allege that Hologic was or should have been aware of clinical evidence and incident reports concerning the alleged defects, analysis of which is cited in the Amended Complaints. [FAC ¶¶ 14–17 & n.2]. The allegations also describe an FDA Safety Communication issued in February 2024 that reported adverse events consistent with the alleged defects. [Id. ¶¶ 18–26 &

---

at *4 (D. Mass. Apr. 27, 2023); [Reply at 5–6]. Even if the Court were to assume that specificity is required, the design defect allegations in Moon fell far short of what Plaintiffs allege here, offering the bare assertion that the defendant, who made Pyrex baking dishes, "had a duty to manufacture a product that would not spontaneously break apart under normal handling and use." Moon, 2023 WL 3126078, at *4. Nor did the plaintiff in that case propose an alternative design, as required under Massachusetts law, that might have elucidated the alleged defect. See id. As discussed throughout this order, Plaintiffs here have done both.

nn.4–5]. Perhaps most notably, the Amended Complaints allege that Hologic sought to obtain FDA approval for the BioZorb as "designed to improve cosmetic outcomes," but the FDA concluded that Hologic lacked clinical data to support that the device in fact improved such outcomes. [Id. ¶ 26]. Hologic nevertheless continued to understand the device as being designed in a manner appropriate for that purpose. See, e.g., [id. ¶ 23]. The design defect claim incorporates these allegations by reference. [Id. ¶ 68]. Construing these well-pleaded allegations in the light most favorable to plaintiffs, the design defect allegations set forth a narrative wherein Hologic failed to avoid reasonably foreseeable defects in the product. [Id. ¶ 71].

The question then becomes whether, taking these facts as true and construing reasonable inferences in favor of Plaintiffs, these allegations offer enough factual content to state a plausible claim. The Court holds that they do. Whether or not the Court agrees with Hologic's characterization of Witt as out of step with Rule 8, Plaintiffs here have pleaded more. To wit, the pleadings here go beyond an allegation that Hologic "fail[ed] to exercise due care" concerning the alleged defects. Witt, 2014 WL 1330840, at *2. Plaintiffs set forth an array of allegations describing the manner in which Hologic (allegedly) breached its duty to exercise reasonable care to avoid foreseeable risks: by failing to account for clinical data and other information about the advantages, risks, and efficacy of the BioZorb in the course of designing the device. See, e.g., McGrain v. C.R. Bard, Inc., 551 F. Supp. 3d 529, 541 (E.D. Pa. 2021). These allegations place Hologic on sufficient notice of the nature of Plaintiffs' theory of causation. See Hochendoner v. Genzyme Corp., 95 F. Supp. 3d 15, 24 (D. Mass. 2015), aff'd in part and rev'd in part for lack of standing, 823 F.3d 724 (1st Cir. 2016) ("The [R]ule 8 pleading standard requires notice, not details.").

3. Feasible Alternative Design

As previewed above, the parties identify New York, North Carolina, Ohio, Pennsylvania, South Carolina, and Texas law as requiring Plaintiffs to identify a feasible alternative design in order to state a claim for design defect liability. See [Mem. at 13–18]. Here, Plaintiffs allege that "[t]here are technologically feasible and practical alternative designs that would have reduced or prevented Plaintiffs' harm" and that such designs "are mechanically feasible, safer, and cost . . . less than BioZorb." [FAC ¶¶ 73–74]. Hologic contends that, for purposes of the state laws that require such a showing, these allegations are inadequate because they "do[] not identify any particular alternative design." [Mem. at 8]. Plaintiffs say the Court should infer from their allegations that an alternative design would involve embodiments where the scaffolding would not lead to migration or a failure to resorb. [Opp. at 6]. They also argue the Plaintiffs' reference to non-scaffolded titanium clips satisfies the reasonable-alternative-design requirement. [Opp. at 7]. Hologic responds that titanium clips are a "different product," not an alternative design of the BioZorb. [Id. (quoting Sisk v. Abbott Lab'ys, No. 11-cv-0159, 2012 WL 3155586, at *5 (W.D.N.C. June 19, 2012))]; see also Tersigni v. Wyeth, 817 F.3d 364, 368 (1st Cir. 2016) (assuming, without deciding, on an appeal from grant of summary judgment to defendant, that Massachusetts law would require a plaintiff "to show that the product in question could have been more safely designed, not that a different product was somehow safer")].

Hologic's suggestion that, by removing the scaffolding while retaining the titanium clips, its product would "no longer" be a radiographic marker, is unavailing. Tersigni, 817 F.3d at 369 (quoting Caterpillar, Inc. v. Shears, 911 S.W.2d 379, 385 (Tex. 1995)). As Plaintiffs plead their case, which the Court must credit at this stage, titanium clips and the BioZorb are variations of radiographic markers. The Amended Complaints describe the BioZorb as a "radiographic

marker" comprised of a dissolvable scaffold "that holds six . . . titanium clips." [FAC ¶ 10]. After the scaffold dissolves, the only component of the BioZorb that remains is the "clips," which are "permanent." [Id.]. The FDA Safety Communication similarly describes the BioZorb as having "two parts: a plastic component that is intended to be dissolved completely in the patient's body in one year or longer, and a titanium metal component that is permanent." See [FAC ¶ 18 n.4]. The allegations cite clinical studies explaining that titanium clips used without the scaffolding aspect of the BioZorb are likewise used "to mark the tumor bed" in breast cancer treatment. [FAC ¶ 74 (quoting Ramy Rashad, Katheryn Huber & Abhishek Chatterjee, Cost-Effectiveness of the Biozorb Device for Radiation Planning in Oncoplastic Surgery, 7 Cancer & Clinical Oncology 23, 28 (2018))]. In other words, as alleged, titanium clips are a key component of the BioZorb — and indeed, the component that provides the radiographical utility for the BioZorb's FDA-approved purpose. See Izzy v. Procter & Gamble Co., No. 23-cv-02125, 2024 WL 3970856, at *9 (D.S.C. Mar. 22, 2024) (allowing design defect claim to survive dismissal because plaintiff "ha[d] 'identif[ied] a specific design approach that has been implemented elsewhere in the industry' and provided some evidence that it can be implemented by Defendant" (citing Wickersham v. Ford Motor Co., 194 F. Supp. 3d 434, 440 (D.S.C. 2016))).

Additionally, Plaintiffs cite medical studies indicating that using titanium clips "to mark the tumor bed is more cost-effective than the use of the BioZorb Marker which does not provide value given its relative high cost and lack of clinical advantage scientifically shown over the use of surgical clips." [FAC ¶ 74]. The allegation that the BioZorb does not provide a therapeutic advantage over ordinary titanium clips satisfies the requirement that a proposed alternative not undermine the utility of the product. See, e.g., Huffman v. Electrolux Home Prods., Inc., 129 F. Supp. 3d 529, 541 (N.D. Ohio 2015) (citation omitted).

Moreover, Plaintiffs' allegations are wholly different from those rejected by the First Circuit in Tersigni, cited by Hologic as an archetypically deficient design defect pleading, where plaintiffs only alleged that "there were other, safer methods of weight loss available." Tersigni, 817 F.3d at 368. Tersigni might supply a useful analog if Plaintiffs sought to meet the alternative-design requirement by pointing to other surgical or radiology techniques that would obviate the need for use of a BioZorb. Those, obviously, would not be a variation on the design of a radiographic marker. But that is not Plaintiffs' argument. Plaintiffs propose that Hologic's product could have been "more safely designed" by manufacturing titanium clips without the allegedly defective scaffolding material, not, as in Tersigni, that a "different product was somehow safer." Id.; cf., e.g., Hilaire v. DeWalt Indus. Tool Co., 54 F. Supp. 3d 223, 248 (E.D.N.Y. 2014) (concluding proposed alternative, a "trap saw," was "an entirely different device from a table saw"); Bell v. Boehringer Ingelheim Pharms., Inc., No. 17-cv-01153, 2018 WL 2447788, at *5 (W.D. Pa. May 31, 2018) (same, where plaintiff only identified "completely different drugs that he could have taken"). That is enough to survive Hologic's motion at this stage.[6]

[6] In any case, Tersigni was an appeal from a grant of summary judgment. The Court agrees with Plaintiffs that, because titanium clips and the BioZorb are both alleged to be radiographic markers, any further dispute concerning the adequacy of titanium clips as a reasonable alternative design involves questions of fact that the Court cannot resolve on this motion. See also Baksic v. Ethicon Inc., 659 F. Supp. 3d 763, 773–74 (W.D. Tex. 2023); cf. Barnes v. Medtronic, PLC, No. 17-cv-14194, 2019 WL 1353880, at *4 (E.D. Mich. Mar. 26, 2019) (rejecting a proposed alternative design on a motion to dismiss where "Plaintiff's theory allege[d] that all polyester hernia meshes [we]re unacceptable" and "[h]er proposed alternatives are alternative treatment methods or alternative types of mesh, not alternative production practices or designs for polyester hernia mesh").

4. Risk-Benefit/Consumer Expectations

Finally, Hologic contends that Plaintiffs have failed to state a claim under the laws of states that require a risk-benefit or consumer expectation analysis, which are Colorado, Michigan, and Washington.[7] [Mem. at 8–9, 12–13]. A risk-benefit analysis requires "proponents of a design defect claim" to "demonstrat[e] that, on balance, the risk of danger inherent in a challenged design outweighs the benefits of such a design." Barton v. Adams Rental, Inc., 938 P.2d 532, 537 (Colo. 1997); see also Prentis v. Yale Mfg. Co., 365 N.W.2d 176, 184 (Mich. 1984) ("When a jury decides that the risk of harm outweighs the utility of a particular design (that the product is not as safe as it *should* be) it is saying that in choosing the particular design and cost trade-offs, the manufacturer exposed the consumer to greater risk of danger than he should have.").

The parties dispute whether and to what extent Colorado, Michigan, and Washington[8] law require parties to plead that "the risks of the device outweigh its benefits." [Mem. at 8]. The parties' briefing of these issues was very thin. Still, based on the Court's examination of the cited precedent, the risk-utility analysis in Colorado applies only to claims alleging strict products liability, not design defects claims based on negligence. See, e.g., Bartholic v. Scripto-Tokai Corp., 140 F. Supp. 2d 1098, 1106, 1111 (D. Colo. 2000) (describing elements of strict

---

[7] At least some "South Carolina courts [have also] appl[ied] the 'risk-utility' test," but Hologic does not argue for dismissal under South Carolina law on that ground. Jolly v. Gen. Elec. Co., 869 S.E.2d 819, 842 (S.C. Ct. App. 2021); see also [Mem. at 17]; [Reply at 8].

[8] Hologic also asserts that the Amended Complaints needed to include allegations about either a risk-utility or consumer-expectation analysis in order to state a claim under Washington law. [Mem. at 8–9, 18–19]. Hologic's cited cases make clear, however, that the "risk utility and consumer expectations tests are used to determine whether a manufacturer is strictly liable and do not apply to a negligence design defect claim." Payne v. Paugh, 360 P.3d 39, 54 (Wash. Ct. App. 2015). Plaintiffs allege negligence, not strict liability.

liability claim based on design defect, cited in Mem. at 8); Watson v. Vista Outdoor, Inc., No. 16-cv-00514, 2016 WL 11523306, at *2–3 (D. Colo. June 29, 2016) (discussing risk-utility analysis under subheading "[w]hether Plaintiffs state a claim under Strict Product Liability," cited in Mem. at 10).

As to Michigan law, Hologic cites only to a summary judgment ruling in support of its argument that a risk-utility analysis is required on a negligence claim, which does not illuminate the standard this Court should apply here. See McClarty v. C.R. Bard Inc., No. 14-cv-13627, 2020 WL 6075520, at *4 (E.D. Mich. Oct. 15, 2020). Even assuming that Plaintiffs' pleadings needed to satisfy each factor the McClarty court demanded at summary judgment, Plaintiffs clear that hurdle. As the court there explained, those requirements boiled down to a "demonstrat[ion] [of] the magnitude of risks involved," that such risks were "foreseeable," and a "reasonable alternative design." See id. at *4. Plaintiffs have alleged that the "BioZorb's design poses a high gravity of danger," [FAC ¶ 75], including by exposing patients to an unreasonable risk of "infection, fluid buildup," movement or erosion of the device, "discomfort, [and] rash[es]," requiring "additional medical treatment to remove the device," [id. ¶ 20]. They further allege that Hologic knew or should have known about these risks, i.e., that such risks were foreseeable. [id. ¶¶ 15–17]. Finally, as set forth above, they have pleaded an alternative design. The Court's analysis need go no further.

III. CONCLUSION

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

SO ORDERED.

March 14, 2024

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