UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

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| NICOLE FRANKS,<br><br>Plaintiff,<br><br>v.<br><br>COOPERSURGICAL, INC.; THE COOPER COMPANIES, INC.; FEMCARE, LTD. – UK SUBSIDIARY OF UTAH MEDICAL PRODUCTS, INC.; and UTAH MEDICAL PRODUCTS, INC.,<br><br>Defendants. | ) | C.A. No. 22-046 WES |

**MEMORANDUM AND ORDER**

WILLIAM E. SMITH, District Judge.

This is a products liability suit brought by Plaintiff Nicole Franks alleging injuries caused by Filshie Clips, which are small clamps placed on the fallopian tubes during tubal ligation surgery. See Compl. ¶¶ 19-22, 55-68, ECF No. 1. The manufacturers and distributors of Filshie Clips - Defendants Utah Medical Products, Inc. ("UMP"), Femcare, Ltd. ("Femcare"), The Cooper Companies, Inc. ("TCC"), and Coopersurgical, Inc. ("CSI") - move to dismiss the Complaint.[1] Defendants argue that the Court does not have

[1] UMP's Renewed Mot. Dismiss, ECF No. 66; UMP's Mem. Law Supp. Renewed Mot. Dismiss ("UMP Mem."), ECF No. 66-1; Femcare's Renewed Mot. Dismiss, ECF No. 67; Femcare's Mem. Law Supp. Renewed Mot. Dismiss ("Femcare Mem."), ECF No. 67-1; TCC's Renewed Mot. Dismiss, ECF No. 68; TCC's Mem. Law Supp. Renewed Mot. Dismiss ("TCC Mem."),

personal jurisdiction over them, that Rhode Island is not the proper venue for Franks's claims, and that the Complaint fails to state a claim upon which relief can be granted.[2] For the reasons below, the Court GRANTS UMP's Motion, GRANTS IN PART and DENIES IN PART Femcare's Motion, GRANTS TCC's Motion, and GRANTS IN PART and DENIES IN PART CSI's Motion.

**I. ALLEGATIONS**

As touched upon briefly above, Filshie Clips ("clips" for short) are part of the "Filshie Clip system" for laparoscopic tubal ligation surgery. Compl. ¶ 19. Inserting the device involves snapping a titanium clip with silicone rubber lining around each fallopian tube. Id. ¶¶ 19-21. The clips serve as a form of long-term birth control by exerting continued pressure on the fallopian tube. Id. ¶¶ 18, 20, 22, 40. Filshie Clips are a Class III medical device. Id. ¶¶ 24-25. Femcare, the manufacturer of Filshie Clips, obtained Conditional Premarket Approval ("PMA") for

ECF No. 68-1; CSI's Renewed Mot. Dismiss, ECF No. 69; CSI's Mem. Law Supp. Renewed Mot. Dismiss ("CSI Mem."), ECF No. 69-1.

[2] Franks opposes each motion. See Pl.'s Opp'n Mem. Law UMP's Renewed Mot. Dismiss ("Pl.'s UMP Mem."), ECF No. 71; Pl.'s Opp'n Mem. Law Femcare's Renewed Mot. Dismiss ("Pl.'s Femcare Mem."), ECF No. 72; Pl.'s Opp'n Mem. Law TCC's Renewed Mot. Dismiss ("Pl.'s TCC Mem."), ECF No. 73; Pl.'s Opp'n Mem. Law CSI's Renewed Mot. Dismiss ("Pl.'s CSI Mem."), ECF No. 70. Each Defendant filed a reply. See Ump Reply, ECF No. 77; Femcare Reply, ECF No. 78; TCC Reply, ECF No. 75; CSI Reply, ECF No. 76.

the device by the Food and Drug Administration ("FDA") in 1996 for manufacturing and commercial distribution. Id. ¶¶ 23, 25, 41.

In the PMA application for Filshie Clips, Femcare reported that several adverse effects of the device could occur, including device migration at a rate of 0.13%. Id. ¶ 49. Migration happens when a clip detaches from where it was originally placed on the fallopian tube and moves to a different location in a woman's body, resulting in severe and permanent injuries. Id. ¶¶ 44-45.

Franks underwent tubal ligation surgery that utilized Filshie Clips in August 2014. Id. ¶¶ 55-56. Franks alleges she received disclosure and consent information prior to the surgery related to the generic risks and hazards associated with the ligation procedure itself, but her doctors did not mention any risk of Filshie Clips migrating. Id. ¶¶ 57-58.

Soon after her surgery, Franks experienced several adverse symptoms related to clip migration including heavier periods, extreme menstrual cramps, pain in her lower abdominal/pelvic region, and weight gain. Id. ¶¶ 59, 61. Franks and her physician investigated her symptoms with a biopsy – which came back negative – and a hysterectomy. Id. ¶ 61. She and her physician explored various potential diagnoses including endometriosis. Id. An August 2021 CT scan revealed that the clips displaced and migrated from their original location. Id. ¶ 62. As of the filing of this

action, Franks is actively seeking surgery to have the clips removed. Id. ¶ 63.

According to Franks, Filshie Clips have a migration rate of 25%, well over what was originally reported to the FDA. Id. ¶¶ 44, 81. Despite knowing that this adverse event occurs at a higher rate than reported, Defendants neither warned nor adequately informed Franks or her healthcare provider of the higher migration rate or of the severity and permanency of the resulting injuries. Id. ¶¶ 102-04, 117, 126, 139. Moreover, because Filshie Clips are PMA, Defendants, as manufacturers and distributors of the clips, had a continuing duty to report these adverse events to the FDA but failed do so. Id. ¶¶ 47-49, 53, 81. Defendants' failure to report the adverse effects contributed to Franks's injuries. Id. ¶¶ 50, 70-71, 160.

Based on the allegations above, Franks brings state law claims against the Defendants for: Design Defect (Count I); Manufacturing Defect (Count II); Failure to Warn (Count III); Strict Liability (Count IV); Negligence (Count V); "Violation of Consumer Protection Laws" (Count VI); Gross Negligence (Count VII); and Punitive Damages (Count VIII).

**II. LEGAL STANDARDS**

When challenged, the plaintiff bears the burden of demonstrating that the court can exercise personal jurisdiction

over an out-of-state defendant. Chen v. U.S. Sports Acad., Inc., 956 F.3d 45, 51 (1st Cir. 2020). When, like here, personal jurisdiction is challenged early in a case through a Rule 12(b)(2) motion to dismiss and the court has not held an evidentiary hearing, the court applies the prima facie standard. Motus, LLC v. CarData Consultants, Inc., 23 F.4th 115, 121 (1st Cir. 2022); see Adelson v. Hananel, 510 F.3d 43, 48 (1st Cir. 2007) (referring to this method as the "prima facie evidentiary standard"). Under this standard, a court "acts not as a factfinder, but as a data collector" in determining "whether the plaintiff has proffered facts that, if credited, would support all findings 'essential to personal jurisdiction.'" Chen, 956 F.3d at 51 (quoting Foster-Miller, Inc. v. Babcock & Wilcox Can., 46 F.3d 138, 145 (1st Cir. 1995)).

Accordingly, the plaintiff's burden requires that she "proffer evidence which, taken at face value, suffices to show all facts essential to personal jurisdiction." Baskin-Robbins Franchising LLC v. Alpenrose Dairy, Inc., 825 F.3d 28, 34 (1st Cir. 2016). A plaintiff cannot meet her burden on mere "conclusory averments;" she must "adduce evidence of specific facts." Chen, 956 F.3d at 51 (quoting Foster-Miller, 46 F.3d at 145). This includes "facts from the pleadings and whatever supplemental filings (such as affidavits) are contained in the record, giving

credence to the plaintiff's version of genuinely contested facts." Baskin-Robbins, 825 F.3d at 34. The court may also "add to the mix facts put forward by the defendants, to the extent that they are uncontradicted." Mass. Sch. of L. at Andover, Inc. v. Am. Bar Ass'n, 142 F.3d 26, 34 (1st Cir. 1998).

To survive a motion to dismiss under Rule 12(b)(6), the complaint must state a claim that is "plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). In other words, the "[f]actual allegations must be enough 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. at 555 (citations and footnote omitted). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Twombly, 550 U.S. at 556). When determining whether a complaint satisfies that standard, a court must assume the truth of all well-pleaded facts and "give the plaintiff the benefit of all reasonable inferences therefrom." Ruiz v. Bally Total Fitness Holding Corp., 496 F.3d 1, 5 (1st Cir. 2007). Dismissal is appropriate if the complaint fails to set forth "factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable legal theory." Gagliardi

v. Sullivan, 513 F.3d 301, 305 (1st Cir. 2008) (internal quotation marks omitted) (quoting Centro Médico del Turabo, Inc. v. Feliciano de Melecio, 406 F.3d 1, 6 (1st Cir. 2005)).

## III. DISCUSSION

### A. Rule 12(b)(2): Lack of Personal Jurisdiction[3]

In cases like this one, where subject matter jurisdiction is premised on diversity, to establish personal jurisdiction over a defendant, the court "must determine whether the defendant's contacts with the state satisfy both the state's long-arm statute as well as the Due Process Clause of the Fourteenth Amendment." Vapotherm, Inc. v. Santiago, 38 F.4th 252, 258 (1st Cir. 2022). Rhode Island's long-arm statute, R.I. Gen. Laws § 9-5-33, is "coextensive" with the Due Process Clause, meaning the Due Process analysis controls. Astro-Med, Inc. v. Nihon Kohden Am., Inc., 591 F.3d 1, 8-9 (1st Cir. 2009).

To satisfy Due Process, the defendant must "have certain minimum contacts with [the forum] such that the maintenance of the suit does not offend 'traditional notions of fair play and substantial justice.'" Int'l Shoe Co. v. Washington, 326 U.S. 310, 316 (1945) (quoting Milliken v. Meyer, 311 U.S. 457, 463 (1940)); see Burger King Corp. v. Rudzewicz, 471 U.S. 462, 474

[3] CSI does not challenge the Court's exercise of personal jurisdiction over it.

(1985); World-Wide Volkswagen Corp. v. Woodson, 444 U.S. 286, 297 (1980). "As long as due process concerns are satisfied, a federal court 'may exercise either general[4] or specific jurisdiction over a defendant.'" Chen, 956 F.3d at 55 (quoting Baskin-Robbins, 825 F.3d at 35).

Franks alleges that the Court has specific jurisdiction over all Defendants. Compl. ¶¶ 13-15. To assert specific personal jurisdiction over a defendant, the defendant must "purposefully avail[] itself" of the forum state and the plaintiff's claims "'must arise out of or relate to the defendant's contacts' with the forum." Ford Motor Co. v. Mont. Eighth Jud. Dist. Ct., 141 S. Ct. 1017, 1024-25 (2021) (first quoting Hanson v. Denckla, 357 U.S. 235, 253 (1958), and then quoting Bristol-Myers Squibb Co. v. Super. Ct. of Cal., 582 U.S. 255, 262 (2017) (emphasis omitted) ("BMS")). The standard requires "a demonstrable nexus between the complaint's claims and the activities in the forum." PREP Tours, Inc. v. Am. Youth Soccer Org., 913 F.3d 11, 18 (1st Cir. 2019) (quotation marks omitted). Courts in the First Circuit are guided by a three-part test:

> First, the claim underlying the litigation must directly arise out of, or relate to, the defendant's forum-state

[4] General jurisdiction exists in forums where a defendant is incorporated, has its "principal place of business," or in which the defendant consented to do business. See Mallory v. Norfolk S. R.R. Co., 600 U.S. 122, 134-37 (2023).

> activities. Second, the defendant's in-state contacts must represent a purposeful availment of the privilege of conducting activities in the forum state, thereby invoking the benefits and protections of that state's laws and making the defendant's involuntary presence before the state's courts foreseeable. Third, the exercise of jurisdiction must . . . be reasonable.

Id. at 17 (emphasis added) (quoting United Elec., Radio & Mach. Workers of Am. v. 163 Pleasant St. Corp., 960 F.2d 1080, 1089 (1st Cir. 1992)). Said succinctly, the standard lays out three touchstones for establishing specific jurisdiction: "relatedness, purposeful availment, and reasonableness." Motus, 23 F.4th at 122.

1. Whether the Court has Specific Jurisdiction Over Femcare

i. Relatedness

There is no real dispute that Franks's claims against Femcare "arise out of or relate to" Femcare's contacts in Rhode Island. See Ford Motor Co., 141 S. Ct. at 1024-25 (quoting BMS, 582 U.S. at 262). Filshie Clips, which are manufactured by Femcare, have been distributed into Rhode Island long before Franks's surgery, and are used by medical professionals in treating patients in Rhode Island. Compl. ¶¶ 14-15, 42. This provides a "demonstrable nexus" between Femcare's contacts in Rhode Island and Franks's injury. See PREP Tours, 913 F.3d at 18.

ii. Purposeful Availment

Femcare argues that it has not purposefully availed itself of

the privilege of conducting business in Rhode Island. Femcare Mem. 8-14. Principally, Femcare points its finger at its distributors, Avalon Medical Corporation ("Avalon") and CSI, because they are the entities that marketed and sold Filshie Clips in the United States. Id. at 10-11. Femcare only delivered the product to the distributors. Id. Moreover, Femcare designed the product for global use, not just for U.S. distribution. Id. at 11. Relying on Supreme Court precedent, Femcare argues its mere awareness that its product could reach Rhode Island does not meet the "stream of commerce" standard. Id. at 11-12 (relying on J. McIntyre Mach., Ltd. v. Nicastro, 564 U.S. 873, 889 (2011) (Breyer, J., concurring)).

The purposeful availment requirement ensures "the exercise of jurisdiction is essentially voluntary and foreseeable," Knox v. MetalForming, Inc., 914 F.3d 685, 691 (1st Cir. 2019), and not based on a defendant's "random, fortuitous, or attenuated contacts," Burger King, 471 U.S. at 475 (citation and quotation marks omitted). Nor can jurisdiction be based on "unilateral activity of another party or a third person." Id. (quoting Helicopteros Nacionales de Colombia, S.A. v. Hall, 466 U.S. 408, 417 (1984)). In other words, defendants, including those that are foreign, must "reasonably anticipate being haled into [the forum] court." Id. at 474 (quoting World-Wide Volkswagen Corp., 444 U.S.

at 297); Plixer Int'l, Inc. v. Scrutinizer GmbH, 905 F.3d 1, 7 (1st Cir. 2018) (noting that the purposeful availment requirement applies to foreign defendants).

Placing "a product into the stream of commerce, without more," is not sufficient to show purposeful availment. Asahi Metal Indus. Co., Ltd. v. Super. Ct. of Cal., 480 U.S. 102, 113 (1987) (plurality op.); see J. McIntyre, 564 U.S. at 888 (Breyer, J., concurring) (describing how "a single isolated sale" into a forum cannot create jurisdiction). A defendant reaps the benefits of a forum by, for example, "designing the product for the market in the forum State, advertising in the forum State, establishing channels for providing regular advice to customers in the forum State, or marketing the product through a distributor who has agreed to serve as the sales agent in the forum State." Asahi Metal, 480 U.S. at 112 (plurality op.).

Both parties attempt to hang their hat on the holding of J. McIntyre. There, the plaintiff was injured by a machine that was manufactured in England and distributed to New Jersey through an independent distributor. J. McIntyre, 564 U.S. at 878 (plurality op.). The manufacturer neither marketed its product nor shipped it. Id. The plurality of the Supreme Court held that a court may exercise jurisdiction "only where the defendant can be said to have targeted the forum; as a general rule, it is not enough that

the defendant might have predicted that its goods will reach the forum State." Id. at 882. From this, the plurality instructed that a personal jurisdiction analysis must focus on a defendant's conduct towards a particular state, and not to the United States generally. Id. at 884. Because the manufacturer did not purposefully direct its conduct to New Jersey, according to the plurality, the trial court could not exercise personal jurisdiction. Id. at 886.

In a concurrence, Justice Breyer resolved the matter on a narrower basis. He concluded the trial court could not exercise jurisdiction because only one of the manufacturer's goods were sold in New Jersey. Id. at 888 (Breyer, J., concurring). Relying on Asahi, he found there was "no 'something more,'" such as "special state-related design, advertising, advice, and marketing" to show purposeful availment. Id. at 889 (quoting Asahi, 480 U.S. at 112 (plurality op.)). As the decision that resolved the case on the narrowest ground, the Court must adhere to Justice Breyer's concurrence. Plixer, 905 F.3d at 10 (citing Marks v. United States, 430 U.S. 188, 193 (1977) (declining the defendant's invitation to adopt the J. McIntyre plurality opinion; finding Justice Breyer's opinion as the "narrowest and so controls here"). This means that "establish[ing] specific targeting of a forum" is not "the only means of showing . . . purposeful availment." Id.

at 9. In fact, there is jurisdiction if there is "'regular flow or regular course of sale' in the forum." Knox, 914 F.3d at 691 (quoting Plixer, 905 F.3d at 10).

Franks argues that Femcare availed itself of the benefits of doing business in Rhode Island. It points out that, over the past thirty years, Femcare has sold four million Filshie Clips in the United States, of which 3,480 were distributed in Rhode Island between 2008 and 2018. Pl.'s Femcare Mem. 40-41. This is not surprising given that Filshie Clips went through a rigorous PMA process so Femcare could broadly distribute Filshie Clips across the United States. Id. at 34. Avalon served as Femcare's first distributor before CSI acquired it.[5] Femcare Mem. 10 n.3; Pl.'s Femcare Mem. 42-43.

As part of its agreement with Avalon, and then CSI,[6] Femcare was responsible for ensuring the clips were FDA compliant. Pl.'s Femcare Mem. 33, 35, 37, 43. The agreements with both distributors obligated Femcare to provide marketing materials and product samples; provide its own employees to assist the distributors with

[5] See PXG, Coopersurgical Acquisition Corp. Purchase of the Stock of Avalon Medical Corp. (Oct. 27, 2003), ECF No. 72-6; PXK, Cooper Unit Acquires Avalon Medical Corporation, Distributor of Female Sterilization System (Oct. 28, 2003), ECF No. 72-10.

[6] CSI became Femcare's distributor in 2003. Pl.'s Femcare Mem. 32-33; Femcare Mem. 10 n.3.

marketing and training; and consult with the distributors as part of its market review for Filshie Clips in the United States. Id. at 33, 43. Femcare was responsible for tracking the device's distribution in the United States, including those in Rhode Island. Id. at 35-36, 43. In fact, Femcare utilized traceable software to track the distribution of Filshie Clips. Id. at 35-36 (quoting PXQ, Rule 30(b)(6) Dep. (Dec. 13, 2022), ECF No. 72-16)). Even more, Femcare processes all U.S.-based complaints for Filshie Clips. Id. at 37, 43.

These facts convince the Court that it may exercise jurisdiction over Femcare based on its "regular flow or regular course of sales" in Rhode Island. First Circuit precedent confirms this. In Knox, the First Circuit upheld the exercise of personal jurisdiction over a company that sold forty-five machines and 234 parts in Massachusetts over a sixteen-year period. 914 F.3d at 692; see also Plixer, 905 F.3d at 4-5 (finding jurisdiction where a company "sold its services to 156 U.S. customers" during a three-and-a-half month period). Here, by contrast, over a ten-year period, Femcare's distributors sent around 3,500 Filshie Clips into Rhode Island. PXS, Femcare Sales Records 2004-2020 (CSI000343), ECF No. 72-18.

But that is not all; Femcare did "something more" to avail itself of the Rhode Island market. The distribution agreement

between Femcare and its distributors allowed Femcare to have its hand in how Filshie Clips were marketed and promoted throughout the United States, including Rhode Island. Its role included monitoring and tracing the distribution of Filshie Clips, as required by FDA regulations. Avalon and CSI were not "independent distributor[s]" that Femcare used and had no control over. See J. McIntyre, 564 U.S. at 878, 887-88 (Breyer, J., concurring) (noting that the use of an independent distributor to sell machines into the United States was not sufficient to assert jurisdiction). Nor was Femcare merely "aware[]" that Filshie Clips may enter Rhode Island through the stream of commerce. See Asahi Metal, 480 U.S. at 112 (plurality op.). Rather, Femcare had control over the sale, distribution, marketing, and safety monitoring of its device. See id. (finding an intent to serve a market can be deduced from "marketing the product through a distributor who has agreed to serve as the sales agent in the forum State").

In the end, Femcare's contacts with Rhode Island make the Court's exercise of jurisdiction "voluntary and foreseeable." See Plixer, 905 F.3d at 7. This is not a case where Filshie Clips were sold in Rhode Island in an isolated manner. See J. McIntyre, 564 U.S. at 888-89 (Breyer, J., concurring). Rather, this is an instance where a manufacturer had its product distributed across the United States without any attempts to limit the territory to

which Filshie Clips would be sold. See id. at 878 (plurality op.) (noting that there was "no allegation that the distributor was under [the defendant's] control"); see also Pl.'s Femcare Mem. 38. Thus, Femcare's activities demonstrate that it purposefully availed itself of the benefit of doing business in Rhode Island.[7]

[7] Femcare objects to some of the exhibits that Franks uses in support of her jurisdiction argument on the basis that they are unauthenticated and contain hearsay statements. See Femcare Reply 2-6. In particular, it challenges the Court's consideration of Plaintiff Exhibits F, G, K, L, and S.

In response, Franks asserts that many of those documents are authentic because CSI produced them. Pl.'s Sur-reply 3-4, ECF No. 82. Though Femcare is not the party that produced the above documents, their authenticity is hard to challenge given there is little question on their origin. Moreover, Femcare is using its authenticity argument both as a sword and a shield – counsel asserts that they cannot authenticate the documents from CSI, but Femcare and CSI share the same counsel and CSI does not challenge the Court's exercise of personal jurisdiction. Accordingly, the Court will consider these documents over Femcare's objection.

Femcare also argues Exhibits F and K cannot be considered because they contain hearsay statements. Femcare Reply 3-4. It is an open question whether the rule against hearsay applies on a motion to dismiss for personal jurisdiction. CRG Fin., LLC v. Two Diamond Cap. Corp., No. 19-cv-10182-DJC, 2020 WL 1308193, at *5 n.2 (D. Mass. Mar. 19, 2020). Authority suggests that the rule does not apply, and therefore, the Court may rely on documents containing hearsay so long as it "bears circumstantial indicia of reliability." Presby Pat. Tr. v. Infiltrator Sys., Inc., No. 14-cv-542-JL, 2015 WL 3506517, at *1 n.2 (D.N.H, Jun. 3, 2015) (quoting Akro Corp. v. Luker, 45 F.3d 1541, 1546-47 (Fed. Cir. 1995)). Accordingly, the Court will refer to these documents to the extent they are reliable.

iii. Reasonableness

Femcare does not challenge the reasonableness of the Court's exercise of jurisdiction. To assess reasonableness, we consider the "gestalt" factors: (1) Femcare's burden of appearing in Rhode Island; (2) Rhode Island's interest in adjudicating the dispute; (3) Franks's interest in obtaining convenient and effective relief; (4) the judicial system's interest in obtaining the most effective resolution of the controversy; and (5) the common interests of all sovereigns in promoting substantive social policies. Rodriguez-Rivera v. Allscripts Healthcare Sols., Inc., 43 F.4th 150, 166 (1st Cir. 2022). These factors aid the court in "achieving substantial justice" when exercising personal jurisdiction. Nowak v. Tak How Invs., Ltd., 94 F.3d 708, 717 (1st Cir. 1996). If minimum contacts exist, however, the gestalt factors "rarely" preclude the court from exercising jurisdiction. Cambridge Literary Props., Ltd. v. W. Goebel Porzellanfabrik G.m.b.H & Co. Kg., 295 F.3d 59, 66 (1st Cir. 2002).

Here, the Court has no information to consider as to the first factor. As to the second factor, Rhode Island has a strong interest in having cases involving in-state injuries caused by out-of-state actors litigated in the forum. See Burger King, 471 U.S. at 473; Ticketmaster-N.Y., Inc. v. Alioto, 26 F.3d 201, 211 (1st Cir. 1994) ("The forum state has a demonstrable interest in

exercising jurisdiction over one who causes tortious injury within its borders."). Franks's choice of the forum, as a Rhode Island resident, is afforded deference as required by the third factor. Neither party submitted evidence in support of the fourth factor, so the Court cannot make a judgment either way. Finally, the fifth factor also weighs in favor of jurisdiction because Rhode Island "has a legitimate stake in providing its citizens with a convenient forum for adjudicating disputes." Baskin-Robbins, 825 F.3d at 41.

Taken together, exercising jurisdiction over Femcare would be reasonable. Because Femcare's contacts relate to Franks's claims and Femcare purposefully availed itself of the benefit of doing business in Rhode Island, this Court's exercise of jurisdiction over Femcare does not offend notions of fair play and substantial justice.[8]

[8] Femcare also argues that Rhode Island is not the proper venue for this action. See Femcare's Mem. 14-16. Venue is proper in "(1) a judicial district in which any defendant resides, if all defendants are residents of the State in which the district is located; (2) a judicial district in which a substantial part of the events or omissions giving rise to the claim occurred . . . ; or (3) if there is no district in which an action may otherwise be brought as provided in this section, any judicial district in which any defendant is subject to the court's personal jurisdiction with respect to such action." 28 U.S.C. 1391(b). Here, a substantial part of the events took place in Rhode Island, see Compl. ¶¶ 55-68, and the Court has personal jurisdiction over Femcare. Therefore, Rhode Island is the proper venue for this action. CSI does not challenge venue.

2. Whether the Court has Personal Jurisdiction Over UMP and TCC

In her Complaint, Franks alleges that UMP "conduct[ed] substantial business" in Rhode Island and sold its products in the state with the intent "that they be used by medical professionals treating patients." Compl. ¶¶ 14-16. In her brief, Franks focuses on UMP's conduct after UMP purchased the remaining exclusive U.S. distribution rights of CSI in February 2019.[9] See Pl.'s UMP Mem. 32-33.

UMP's contacts with Rhode Island are insufficient to establish specific jurisdiction. Franks alleges that, in August 2014, Filshie Clips were implanted in her during tubal litigation surgery and that she began experiencing pain thereafter. Compl. ¶¶ 55-56, 61. Because the clips – the alleged cause of Franks's injuries – were implanted before UMP became actively involved in selling, marketing, and distributing Filshie Clips, Franks's claims do not "arise out of or relate to" UMP's contacts in Rhode Island. See Ford Motor Co., 141 S. Ct. at 1024-25 (quoting BMS, 582 U.S. at 262). In other words, there is no causal relationship between UMP's conduct and Franks's injuries. See Harlow v. Children's Hosp., 432 F.3d 50, 61-62 (1st Cir. 2005) ("Because causation is central to the relatedness inquiry, in most cases,

[9] Franks does not argue that the Court has specific jurisdiction over TCC based on its contacts with Rhode Island.

contacts coming into existence after the cause of action arose will not be relevant."). Accordingly, UMP's after-the-injury conduct cannot establish specific jurisdiction. See Ford Motor Co., 592 U.S. at 373-74 (Alito, J., concurring) (rejecting a strict "but for" causation standard for specific jurisdiction but noting that some "causal link . . . is needed"); BMS, 582 U.S. at 262 (holding that contacts not creating "the very controversy that establishes jurisdiction" are insufficient in establishing personal jurisdiction).

Alternatively, Franks argues that the Court can exercise specific jurisdiction over UMP and TCC because the Court has personal jurisdiction over them as "alter egos" of Femcare and CSI, respectively. See Pl.'s UMP Mem. 35-43; Pl.'s TCC Mem. 32-43.

Under the alter ego rule, a court can exercise personal jurisdiction "if the parent company exerts so much control over the subsidiary that the two do not exist as separate entities but are one and the same for purposes of jurisdiction." Russell v. Enterprise Rent-A-Car Co. of R.I., 160 F. Supp. 2d 239, 252 (D.R.I. 2001). Thus, finding personal jurisdiction over one corporate entity allows the court to exercise jurisdiction over the other. Id. The inquiry is the same as a veil-piercing analysis where the court reviews "whether the parent corporation and its subsidiary

were separately incorporated, had separate boards of directors, maintained separate financial records, and had separate facilities and operating personnel." Id.

There is a presumption of corporate separateness between parent companies and their subsidiaries. Id. at 250. As a result, Rhode Island courts are reluctant to pierce the corporate veil and will only do so to prevent injustice. Doe v. Gelineau, 732 A.2d 43, 48-49, 51 (R.I. 1999); R & B Elec. Co., Inc. v. Amco Const. Co., Inc., 471 A.2d 1351, 1354 (R.I. 1984). A plaintiff must present "clear evidence" to overcome the presumption of corporate separateness. Russell, 160 F. Supp. 2d at 250. Indeed, piercing the corporate veil requires a showing that the two corporate entities are "de facto nonexistent." Text Order (Aug. 1, 2022).

Evidence must demonstrate that the parent company "dominated" the subsidiary's "finances, policies, and practices" to such an extent that it "suggest[s] that the subsidiary is organized, controlled, and operated as merely an instrumentality, agency, conduit, or adjunct of the parent." Id.; see UST Corp. v. Gen. Rd. Trucking Corp., 783 A.2d 931, 940-41 (R.I. 2001); Gelineau, 732 A.2d at 49. Clear evidence must show that the parent company is using the subsidiary "to defeat public conveniences, justify wrong, protect fraud, or defend crime." R & B Elec., 471 A.2d at 1354 (quoting Vennerbeck & Clase Co. v. Juergens Jewelry Co., 164

A. 509, 510 (R.I. 1933)). This does not include the mere "ownership of local corporate entities" and the sharing of officers. Russell, 160 F. Supp. 2d at 251.

Franks argues that the line of separation between UMP and Femcare is blurred, making the two indistinguishable. Pl.'s UMP Mem. 35-43. According to Franks, this is supported by the fact that the two entities share leadership – Kevin Cornwell, for example, is both UMP's CEO and a director on Femcare's board. Id. at 36. There also appears to be confusion concerning when an employee acts on behalf of one company over another; employees sometimes wear hats for both companies simultaneously. Id. at 36-37. Financially, UMP absorbed Femcare's debt in 2011 and the two companies submit consolidated regulatory filings. Id. at 38-39. With respect to Filshie Clips, UMP apparently had a prominent role in conducting a risk assessment for Filshie Clips and has worked closely with Femcare in processing complaints about the product. Id. at 40-43. UMP submits evidence to the contrary reflecting how UMP shares only two officers and directors, has separate finances, has separate assets and operations, and observes corporate formalities. UMP Mem. 15-17.

TCC is in a unique situation because TCC is the parent company of Cooper Medical, Inc. ("CMI") which is the parent company of CSI. TCCXB, TCC's Resps. Pl.'s First Req. Prod. Docs., ECF No.

52-1. In essence, for there to be personal jurisdiction over TCC under an alter ego theory, the Court would not only have to pierce the veil between TCC and CMI but also between CMI and CSI.

In support of her theory, Franks heavily relies on the fact that TCC and CSI share several employees. One member of TCC's Executive Management Team is a current president of CSI; several TCC executives held leadership roles at CSI; and several employees serve as officers both at TCC and CSI. Pl.'s TCC Mem. 33-36. There also appears to have been collaboration between TCC and CSI in issuing press releases. Id. at 36-38. Franks uses a 2003 press release to infer that TCC was the one who actually paid for the U.S. distribution rights for Filshie Clips, not CSI. Id. at 40-41. Franks also references TCC's 2004 10-K filing where TCC referred to it and CSI collectively, indicating they are one in the same. Id. at 39. Finally, Franks notes TCC was involved in processing complaints from women who were injured by Filshie Clips. Id. at 41-42. Franks, however, does not address the relationships between TCC and CMI, and CMI and CSI, except to surmise that CMI has "no other role than acting as a holding company for [CSI]." Id. at 33 n.30.

The Court cannot pierce any corporate veil based on Franks's evidence. Despite the evidence showing crossover between UMP and Femcare, and TCC and CSI, there is no indicia of fraud, wrongdoing,

domination, misuse, or subversion of corporate formalities. See R & B Elec., 471 A.2d at 1354. The evidence Franks puts forward – the sharing of directors, officers, and employees; shared press releases; collective references in regulatory filings – does not warrant the piercing of any corporate veil.[10] See Russell, 160 F. Supp. 2d at 251-52; see also Madison Cnty. Commc'ns Dist. v. CenturyLink, Inc., CV 12-J-1768-NE, 2012 WL 13180839, *8 (N.D. Ala. Dec. 20, 2012) (describing how parent companies "may from time to time collectively refer to all of its subsidiaries, either on the [parent]'s website or in press releases, [which] is nothing more than expected and typical brand marketing"). In other words, the evidence does not convince the Court that piercing the corporate veils would remedy any "unjust" or "inequitable" behavior. See R & B Elec., 471 A.2d at 1354. Moreover, much of the evidence Franks relies on to support her alter ego theory came after Filshie Clips were implanted in Franks, limiting its relevancy to the Court's jurisdictional inquiry. See BMS, 137 S. Ct. at 1780; Harlow, 432 F.3d at 61-62.

[10] Significantly, Franks's analysis fails to grapple with the issue of piercing the two corporate veils between TCC and CSI. Her argument that the Court should ignore the entity separating TCC and CSI because CMI is, "to the best of Plaintiff's knowledge," a holding company for CSI, lacks a legal and factual basis. Pl.'s TCC Mem. 33 n.30.

Plaintiff has failed to meet her burden of showing that the Court can exercise personal jurisdiction over UMP and TCC. Thus, the Court grants UMP's and TCC's Motions under Rule 12(b)(2) for lack of personal jurisdiction.

**B. Rule 12(b)(6): Failure to State a Claim Upon Which Relief Can be Granted**

Defendants CSI and Femcare (hereinafter "Defendants") argue that Franks failed to state a claim upon which relief can be granted because her claims are preempted by federal law, precluded by the statute of limitations, and fail as a matter of law under the Learned Intermediary Doctrine. The Court will address each argument in turn.

1. Whether Franks's Claims are Preempted by Federal Law

To be sold and distributed, Filshie Clips had to be approved by the FDA through the PMA process. The process is governed by the Medical Device Amendments of 1976 ("MDA") to the Federal Drug and Cosmetic Act ("FDCA"). See 21 U.S.C. § 360c et seq. The FDCA divides medical devices into three categories depending on how much a device needs to be regulated to ensure safety and effectiveness. Id. § 360c(a)(1); Plourde v. Sorin Grp. USA, Inc., 23 F.4th 29, 32 (1st Cir. 2022). The Filshie Clip is a Class III device. Compl. ¶ 25. Such devices either "present[] a potential unreasonable risk of illness or injury" or are "purported or represented to be for a use in supporting or sustaining human life

or for a use which is of substantial importance in preventing impairment of human health." 21 U.S.C. § 360c(a)(1)(C). The level of risk associated with these devices requires the manufacturer to "prove their safety and efficacy" before the FDA by going through the "complex and costly" PMA process. Plourde, 23 F.4th at 32; see 21 U.S.C. § 360e(a); Medtronic, Inc. v. Lohr, 518 U.S. 470, 476-77 (1996) (summarizing the MDA and the PMA process).

As part of the "rigorous" PMA process, an applicant must submit detailed reports of studies and investigations regarding the device's safety and efficacy; full descriptions of the device's components, methods, packaging, and more; and proposed labeling, among other things. Riegel v. Medtronics, Inc., 552 U.S. 312, 317-18 (2008) (citing 21 U.S.C. § 360e(c)(1)). As part of the process, the FDA consults outside experts, requests and reviews additional data, and conducts other reviews in weighing the health benefits against the risks of injury and illness presented by the device. Id.; see 21 U.S.C. § 360c(a)(2)(C).

The FDA will grant PMA if it determines there is "a reasonable assurance" of the device's "safety and effectiveness." 21 U.S.C. § 360e(d). This is found if the device's "probable benefit[s] to health from the use of the device" outweigh "any probable risk of injury or illness from such use." Id. § 360c(a)(2)(C).

A manufacturer's duty to the FDA does not end once it gets

the green light on its medical device. See id. § 360i; 21 C.F.R. § 814.84. The manufacturer must still, inter alia, inform the FDA of incidents in which a device "[m]ay have caused or contributed to a death or serious injury." See 21 C.F.R. § 803.50(a)(1); see also id. § 814.84(b)(2) (obligating manufacturers to inform the FDA of new clinical investigations or scientific studies concerning a device). A manufacturer's failure to comply with its post-approval requirements may result in the FDA's withdrawal of approval of the device. Id. § 814.82(c).

The above scheme balances three primary policy concerns. Plourde, 23 F.4th at 32. It considers the need for proposed medical devices to be "carefully scrutinized for safety," "the freedom of patients and doctors to use potentially life-saving technology as they see fit without undue delay," and the extent to which states should regulate the same sphere. Id. (quoting Caplinger v. Medtronic, Inc., 784 F.3d 1335, 1336 (10th Cir. 2015) (Gorsuch, J.)).

Congress, when it passed the MDA, exercised its power under the Supremacy Clause,[11] see U.S. Const. art. VI, cl. 2, through the

[11] The Supremacy Clause gives Congress the power to invalidate state laws that "interfere with, or are contrary to," federal law. Gibbons v. Ogden, 22 U.S. 1, 211 (1824); see Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 372 (2000). This can be done expressly, see Chamber of Com. of U.S.A v. Whiting, 563 U.S. 582,

following proviso:

> Except as [authorized by the FDA], no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement —
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the FDCA].

21 U.S.C. § 360k(a). In interpreting § 360k, the Supreme Court concluded the section "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements."[12] Riegel, 552 U.S. at 330

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594 (2011), or if there is a conflict between state and federal law, Crosby, 530 U.S. at 372.

[12] Riegel v. Medtronics, Inc. concerned an implanted catheter, which was approved as a Class III medical device. 552 U.S. 312, 320 (2008). The plaintiff-petitioner sued the manufacturer after the catheter allegedly caused complications following surgery. Id. The plaintiff-petitioner alleged that the catheter was designed, labeled, and manufactured in a way that violated New York common law. Id. at 320-21. At no point did the plaintiff-petitioner argue that the duties under New York common law were parallel to FDA requirements. Id. at 330. Thus, the Court concluded that the lower court properly dismissed the complaint because the manufacturer could have violated state law while being fully compliant with FDA regulations. Id. The Court did not address whether the plaintiff-petitioner's claims were parallel to FDA requirements.

(quoting Lohr, 518 U.S. at 495). Said differently, if state-law requirements are "different from, or in addition to" the requirements under the MDA, then the state law is preempted. Id. at 321-22, 330 (quoting 21 U.S.C. § 360k(a)(1)).

Based on § 360k, the Court in Riegel came up with a two-part test. The Court must first determine if the FDA requirements apply to the device. If so, it must then examine whether a plaintiff's state law claim relates to the device's safety and effectiveness and rests on requirements that are "different from, or in addition to," the federal requirements. Id. at 321-22 (quoting 21 U.S.C. § 360k(a)(1)); see Plourde, 23 F.4th at 33.

State laws may also be impliedly preempted by the MDA. Under Section 337, "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). The Supreme Court concluded that the statutory language reflects Congress's intent of having the federal government exclusively enforce the FDCA. Buckman Co. v. Pl.'s Legal Comm., 531 U.S. 341, 352 (2001).[13] Thus,

[13] Buckman Co. v. Plaintiffs' Legal Committee involved state-law negligence suits premised on alleged injuries caused by orthopedic bone screws, a Class III medical device. 531 U.S. 341, 343-44 (2001). The plaintiff-respondent alleged the consulting company made fraudulent misrepresentations to the FDA during the PMA process. Id. at 343. The Court characterized the plaintiff-

state law claims that exist "solely by virtue" of an FDCA violation are preempted. Id. at 352-53; Plourde, 23 F.4th at 33. In Buckman, the Supreme Court emphasized that when manufacturers make fraudulent misrepresentations during the PMA process, the FDA is empowered to punish and deter such violations under the MDA. Id. at 343, 348, 350-51. And it further distinguished between claims based on a "fraud-on-the-agency" theory and claims based on state common law. Id. at 351-52 (relying on Silkwood v. Kerr-McGee Corp., 464 U.S. 238 (1984)). Claims like the former are preempted while the latter are not.

Taking § 360k(a) and § 337(a) together, plaintiffs are left with a

> narrow gap through which [their] state-law claim must fit if it is to escape express or implied preemption: [t]he plaintiff[s] must be suing for conduct that violates the FDCA (or else [their] claim is expressly preempted by [§ 360k(a)], but [they] must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted [by § 337(a)])).

Dumont v. Reilly Foods Co., 934 F.3d 35, 42 (1st Cir. 2019) (quoting In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig., 623 F.3d 1200, 1204 (8th Cir. 2010) (quotations omitted and emphases in original)).

Turning to Defendants' motions, there is no disagreement that

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respondents' state-law claims against the defendant as "fraud-on-the-FDA claims." Id. at 348.

the test laid out in Riegel applies. Moreover, there is no disagreement that the FDA imposes Class III device requirements on Filshie Clips. Unsurprisingly, the parties disagree whether the second part of the Riegel test is satisfied. The parties, however, do not properly apply part two of the Riegel test.

Defendants argue that Plaintiff's state-law product liability claims – design defect, manufacturing defect, failure to warn, and strict liability[14] – are expressly preempted by § 360k. CSI Mem. 11-14; Femcare Mem. 23-27. The claims are preempted, according to Defendants, because the common law standards under Rhode Island law "differ from or add to" – and thus do not parallel – "the federal requirements." CSI Mem. 11; Femcare Mem. 24.

For product liability claims, the Rhode Island Supreme Court adopted Section 402A of the Restatement (Second) of Torts. Ritter v. Narragansett Elec. Co., 283 A.2d 255, 263 (1971); see Castrigano v. E.R. Squibb & Sons, Inc., 546 A.2d 775, 779 (R.I. 1988). Section 402A reads:

> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm

[14] Under Rhode Island law, a plaintiff may pursue a strict product liability claim under failure to warn, design defect, and manufacturing defect theories. Costa v. Johnson & Johnson, C.A. No. 17-452 WES, 2023 WL 2662903, at *2 (D.R.I. Mar. 28, 2023) (citing Castrignano v. E.R. Squibb & Sons, Inc., 546 A.2d 775, 779 (R.I. 1988)).

> thereby caused to the ultimate user or consumer, or to his property, if
>
> (a) the seller is engaged in the business of selling such a product, and
>
> (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

Restatement (Second) of Torts, § 402A (1965). The Rhode Island Supreme Court went on to explain that "unreasonably dangerous" means that "the defect in the product establishes a strong likelihood of injury to the user or consumer thereof." Ritter, 283 A.2d at 263.

Defendants argue that Franks's claims are preempted because they require Filshie Clips to be evaluated under a standard that is different from the standard used by the FDA during the PMA process. CSI Mem. 13, 16; Femcare Mem. 25-26. In particular, the common law "unreasonably dangerous" standard does not appear in the FDA standard under § 360c and, therefore, the common law duty adds to or is different from the standard. CSI Mem. 12-13; Femcare Mem. 25-26. Fair enough, but, to grant PMA under the MDA, the manufacturer must provide "reasonable assurance" of the device's "safety and effectiveness." 21 U.S.C. §§ 360c(a)(2)(C); 360e(d). The Court is strained to find much daylight between the two standards. Both the Rhode Island common law duty and the FDA standard for PMA approval focus on a device's reasonableness in

proportion to the device's risk to safety.[15] In essence, the Rhode Island common law standard is effectively the same as the FDA requirements outlined in the MDA. In any event, no state common law duty matches the MDA standard language. Cf. Riegel, 552 U.S. at 325 (noting the differing considerations taken into account by a jury and the FDA). Defendants' method for determining whether a state law claim is parallel to federal requirements would virtually eliminate any common law claim against a manufacturer of a Class III medical device, a result explicitly rejected by the Supreme Court. See Lohr, 518 U.S. at 487-88 (rejecting the petitioner's argument that Congress preempted all state law causes of action against manufacturers of medical devices under FDA jurisdiction).

Franks, on the other hand, argues that the Rhode Island common law duty parallels the FDA requirements because a Class III medical device is one that supports or sustains human life or is of substantial importance in preventing impairment of human health;"

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[15] Compare Dangerous, Black's Law Dictionary (11th ed. 2019) ("likely to cause serious bodily harm"), and Dangerous, Merriam-Webster's Dictionary 292 (10th ed. 2002) ("able or likely to inflict injury or harm"), with Safe, Black's Law Dictionary (11th ed. 2019) ("Not exposed to danger; not causing danger), and Safety, Merriam-Webster's Dictionary 1027 (10th ed. 2002) ("the condition of being safe from undergoing or causing hurt, injury, or loss"), and Safe, Merriam-Webster's Dictionary 1027 (10th ed. 2002) ("free from harm or risk; secure from threat of danger, harm, or loss").

or "presents a potential unreasonable risk of illness or injury." Pl.'s Femcare Mem. 12 (quoting 21 U.S.C. § 360c(a)(1)(C)(ii)) (emphasis added); Pl.'s CSI Mem. 12. But, as Defendants point out, the language in section 360c is not the federal requirement for FDA approval; it is the very definition of what is a Class III medical device. CSI Reply 2-3. The purpose of the PMA process is to mitigate the unreasonable risk of illness or injury by requiring manufacturers to "provid[e] reasonable assurance[s]" of the device's "safety and effectiveness." 21 U.S.C. §§ 360c(a)(2)(C); 360e(d).

To be sure, both parties misunderstand step two of the Riegel test. The question of whether a state law claim is different from or in addition to the FDA requirements is a factual one. The court inquires whether the plaintiff's allegations, if true, would impose liability on a manufacturer defendant even though it complied with the FDA requirements. If so, the plaintiff's claims are expressly preempted. See Wolicki-Gables v. Arrow Int'l, Inc., 634 F.3d 1296, 1301-02 (11th Cir. 2011); Funk v. Stryker Corp., 631 F.3d 777, 782 (5th Cir. 2011); In re Medtronic, 623 F.3d at 1205-07. If the defendant violated FDA standards, the question then becomes whether the alleged conduct independently and plausibly states a state law claim. Stengel v. Medtronic, Inc., 704 F.3d 1224, 1232-34 (9th Cir. 2013); Bausch v. Stryker Corp.,

630 F.3d 546, 558-61 (7th Cir. 2010). The Court will address each of Franks's claims in turn.

**Design Defect (Count I).** Franks brings a products liability claim alleging that the design of the Filshie Clips used on her was defective.[16] See Compl. ¶¶ 79-87. In particular, she alleges that the design allows for the clips to migrate from where they were originally implanted at a higher rate than what the manufacturer reported to the FDA and that Defendants failed to report such information. Id. ¶¶ 80-81. Claims for design defect are expressly preempted by the MDA unless the plaintiff alleges that the design of the medical device used on the plaintiff deviated from the design approved by the FDA. See Cunningham v. Abbott Vascular, Inc., C.A. No. 21-10241-MLW, 2022 WL 2387903, at *5 (D. Mass. Mar.

[16] A design defect claim under Rhode Island law requires the plaintiff to prove five elements:

> (1) that there was a defect in the design or construction of the product in question; (2) that the defect existed at the time the product left the hands of the defendant; (3) that the defect rendered the product unreasonably dangerous, and by unreasonably dangerous it is meant that there was a strong likelihood of injury to a user who was unaware of the danger in utilizing the product in a normal manner; (4) that the product was being used in a way in which it was intended at the time of the accident; and (5) that the defect was the proximate cause of the accident and plaintiff's injuries.

Crawford v. Cooper/T. Smith Stevedoring Co., 14 F. Supp. 2d 202, 211 (D.R.I. 1998).

1, 2022), report and recommendation adopted, 2023 WL 6397839, at *2 (Sept. 29, 2023) (dismissing design defect claims premised on medical device design approved by the FDA); Raab v. Smith & Nephew, Inc., 150 F. Supp. 3d 671, 690-91, 695 (S.D. W. Va. 2015) (same); Simon v. Smith & Nephew, Inc., 990 F. Supp. 2d 395, 405-06 (S.D.N.Y. 2013) (same). Franks does not allege that the design of the Filshie Clips implanted in her deviated from the design approved by the FDA. Thus, Franks's design defect claim is expressly preempted.

**Manufacturing Defect (Count II).** Similar to her design defect claim, Franks alleges that the Filshie Clips implanted in her were improperly manufactured.[17] Compl. ¶¶ 88-97. The alleged manufacturing defect stems from Defendants' failure to report the higher migration rates to the FDA. Id. ¶ 94. Claims for alleged manufacturing defects can only survive preemption if the plaintiff sufficiently alleges that the defendant failed to manufacture the device used by the plaintiff in accordance with the specifications approved by the FDA. See Cunningham, 2022 WL 2387903, at *5 (dismissing manufacturing defect claim due to lack of allegations

[17] A claim for manufacturing defect requires the plaintiff to show that the defect was "caused by a mistake or accident in the manufacturing process." Guilbeault v. R.J. Reynolds Tobacco Co., 84 F. Supp. 2d 263, 281 (D.R.I. 2000) (quoting Swajian v. Gen. Motors Corp., 916 F.2d 31, 35 (1st Cir. 1990)).

that the device implanted in the plaintiff did not comply with FDA-approved specifications); Warstler v. Medtronic, Inc., 238 F. Supp. 3d 978, 987-88 (N.D. Oh. 2017) (same); Cooley v. Medtronic, Inc., Civil No. 09-30-ART, 2012 WL 1380265, at *4 (E.D. Ky. Apr. 20, 2012) (same); see also Bausch, 630 F.3d at 549, 552-53, 559 (reversing dismissal of state law claims premised on allegations that that the device was adulterated and that defendant's manufacturing process did not comply with federal standards). Here, there are no factual allegations that the Filshie Clips implanted in Franks were manufactured in a way that was not approved by the FDA. Because of this deficiency, Franks's manufacturing defect claim is expressly preempted.

**Failure to Warn (Count III).** Franks alleges that Defendants failed to warn of the higher-than-reported migration rates.[18] Compl. ¶¶ 98-110. She alleges that Defendants had a parallel duty to warn of the higher migration rates by reporting the adverse events to the FDA. Id. ¶¶ 102-04; see 21 C.F.R. § 803.50 (outlining duty of manufacturers to report adverse events to the FDA). Courts have

[18] Under Rhode Island law, a plaintiff can establish a failure to warn claim by establishing that the defendant failed to warn of the product's dangers "that are reasonably foreseeable and knowable at the time of marketing[,]" "render[ing] the product unreasonably dangerous in spite of all reasonable care exercised by the manufacturer." Castrignano, 546 A.2d at 782.

concluded that state law failure-to-warn claims run parallel to a manufacturer's duty to report adverse events. See, e.g., Stengel, 704 F.3d at 1232-33 ("[Plaintiff's] failure to warn claim is neither expressly nor impliedly preempted by the MDA to the extent that this claim is premised on [defendant's] violation of FDA regulations with respect to reporting [adverse events] caused by the [device]." (quoting Hughes v. Bos. Sci. Corp., 631 F.3d 762, 776 (5th Cir. 2011))); A.F. ex rel. Fogel v. Sorin Grp. USA, Inc., 346 F. Supp. 3d 534, 542–45 (S.D.N.Y. 2018) (denying motion to dismiss claim premised on the defendant's alleged failure to report adverse events); Laverty v. Smith & Nephew, Inc., 197 F. Supp. 3d 1026, 1035 (N.D. Ill. 2016) (describing how "[t]he MDA sets standards for what, when, how, and to whom a manufacturer must report" but it does not preempt a state-imposed duty to warn); Garross v. Medtronic, Inc., 77 F. Supp. 3d 809, 815-16 (E.D. Wis. 2015) (finding that claims premised on the defendant's alleged failure to report adverse events to the FDA, including claims for failure to warn, run parallel to the defendant's duty to warn patients of risks); see also Lohr, 518 U.S. at 501-02 (finding that the plaintiff's state-law failure to warn claim was not preempted by the MDA).

The question then turns on whether a manufacturer's failure to report requisite information to the FDA can support a failure

to warn claim under Rhode Island law. The Court concludes that the answer is yes. In Hodges v. Brannon, the plaintiff, the wife of a decedent, sued a doctor and a drug manufacturer because the high blood pressure medication that they prescribed and manufactured, respectively, caused the decedent's death. 707 A.2d 1225, 1226 (R.I. 1998). During trial, the lower court instructed the jury to only consider the manufacturer's FDA report with respect to whether the manufacturer had a duty to warn but not with respect to whether the drug was the decedent's cause of death. Id. at 1228. The Rhode Island Supreme Court upheld the lower court's instruction. Id. The court's decision demonstrates that, under Rhode Island law, a duty to warn claim can be premised on the manufacturer's inadequate reporting to the FDA. See In re Allergan Biocell Textured Breast Implant Prods. Liab. Litig., 537 F. Supp. 3d 679, 729,731 (D.N.J. 2021) (relying on Hodges in identifying Rhode Island as a state that "allow[s] a failure to warn claim based on a device manufacturer's inadequate reporting to the FDA under state law tort principles"). Thus, given that Defendants' alleged failure to warn of adverse events violates both their requirements under the MDA and their duties under Rhode Island law, Franks's failure to warn claim is not expressly preempted by the MDA.

Nor is her claim impliedly preempted under Buckman. This

claim does not "exist solely by virtue of the FDCA disclosure requirements" – like a fraud-on-the-FDA theory - but rather "rel[ies] on traditional state tort law." See Buckman, 531 U.S. at 352–53. Franks's claim is "based on the underlying state duty to warn about the dangers or risks of [the] product." See Hughes, 631 F.3d at 775; see also Bausch, 630 F.3d at 557. Unlike Buckman, where the defendant was alleged to have made fraudulent representations to the FDA during the PMA process – a process that is "wholly federal," Stengel, 704 F.3d at 1230, because it "originates from, is governed by, and terminates according to federal law," Buckman, 518 U.S. at 347-48 – Franks's claims relate to violations of FDA regulations outside of the PMA process.[19] See Stengel, 704 F.3d at 1231; Hughes, 631 F.3d at 765. In sum, Franks's failure to warn claim is not preempted by the MDA.[20]

[19] To dispel any ambiguity, to the extent that Franks's failure to warn claim is premised on Defendants' failure to report higher migration rates during the PMA process, such allegations are preempted. See Compl. ¶¶ 81, 102.

[20] The Court's conclusion is confirmed by the implication of the First Circuit's decision in Plourde v. Sorin Grp. USA, Inc., 23 F.4th 29, 32 (1st Cir. 2022). The plaintiff there was injured by a medical device and brought negligence and failure-to-warn claims premised on the defendant not reporting adverse events to the FDA. Id. at 34. The lower court found that the plaintiff's claims were preempted because the plaintiff failed to identify a parallel duty under Massachusetts law to report adverse events. Plourde v. Sorin Grp. USA, Inc., 517 F. Supp. 3d 76, 88-91 (D. Mass. 2021). In the end, the First Circuit certified a question

**Strict Liability (Count IV).** Under Rhode Island law, a plaintiff can pursue a strict liability claim where she alleges that the manufacturer failed to warn of a product's dangerousness. Castrignano, 546 A.2d at 779 (citing Thomas v. Amway Corp., 488 A.2d 716, 722 (R.I. 1985)). If a product is found to be

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to the Massachusetts Supreme Judicial Court ("SJC") asking whether a manufacturer's failure to report adverse events to the FDA gives rise to liability under Massachusetts law. Plourde, 23 F.4th at 37. The SJC never answered the question, however, because the appeal was voluntarily dismissed before it could do so. Stewart-Mackey v. Corcym, Inc., C.A. No. 23-cv-10155-ADB, 2023 WL 7091041, at *4 (D. Mass. Oct. 26, 2023). Nevertheless, by certifying the question to the SJC, the court in Plourde impliedly determined that such a claim is not preempted under Buckman. See Cupek v. Medtronic, Inc., 405 F.3d 421, 444-45 & n.2 (6th Cir. 2005) (dispensing with the question of whether there was a state law duty to warn post-PMA because the court found that the claim was impliedly preempted). The court of appeals could have concluded that the claim is impliedly preempted without having to find if such a duty exists under Massachusetts law. The First Circuit would likely not have certified the question to the SJC – a direction the court was reluctant to take, see Plourde, 23 F.4th at 36-37 – just to dismiss the action as impliedly preempted if the SJC answered the certified question in the affirmative. Contra Mink v. Smith & Nephew, Inc., 860 F.3d 1319, 1330 (11th Cir. 2018) (concluding failure to warn claim was impliedly preempted); see also Dumont v. Reily Foods Co., 934 F.3d 35, 41-43 (1st Cir. 2019) (finding that the plaintiff's unfair and deceptive practice claim under Massachusetts law was not impliedly preempted even though the alleged conduct would implicate federal false-labeling standards); id. at 43 ("[The FDCA] will restrict the factfinder to determining whether conduct that does violate the federal regulations is also deceptive under Massachusetts law by virtue of its nature rather than its federal illegality.").

unreasonably dangerous under a failure to warn theory, "then the manufacturer is liable for that defect." Id. (citing Ritter, 283 A.2d at 262). Because Franks's failure to warn claim is not preempted, neither is her claim for strict liability. See Compl. ¶¶ 111-21.

**Negligence (Count V).** Franks's negligence claim is premised on the same allegations as her other claims – Defendants were negligent in not reporting Filshie Clips's adverse events to the FDA, Franks, and her physician. See Compl. ¶¶ 122-36. Rhode Island's failure to warn claim "is equivalent to the standard for negligence." Castrignano, 546 A.2d at 782; accord DiPalma v. Westinghouse Elec. Corp., 938 F.2d 1463, 1466 (1st Cir. 1991) ("It is clear under Rhode Island law that the duty to warn . . . is measured, in all respects material to this case, by the same standard as the duty to warn that is enforceable in a negligence cause of action."). Accordingly, Franks's negligence claim under a failure to warn theory is also not preempted.[21]

* * * * *

On a final note on the issue of preemption, Defendants argue that the MDA preempts Rhode Island state law product liability

[21] Defendants do not argue that Plaintiff's claim under the state's Consumer Protection Laws (Count VI) is preempted by federal law.

claims because such a determination is made by a jury rather than the FDA. CSI Mem. 13, 16; Femcare Mem. 25-26, 29. Having a jury determine whether a product is "unreasonably dangerous," according to Defendants, would "substitute[] a trier of fact for the FDA's regulatory authority and expertise." CSI Mem. 13; Femcare Mem. 25-26. As a result, because the FDA is not involved in a jury's determination, such claims would be preempted. This maximalist position, however, has no basis in Supreme Court or First Circuit precedent and would grant carte blanche immunity to all manufacturers of medical devices. Again, the Supreme Court rejected the very notion that Congress, when it passed the MDA, intended to preempt all state law claims against medical device manufacturers that engaged in wrongdoing. Lohr, 518 U.S. at 487-88. In fact, the Court explicitly held that "[n]othing in § 360k denies [states] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." Id. at 495; see Plourde, 23 F.4th at 33. Even more, the Court in Riegel considered the fact that the FDA is in a better position to consider both the risks and benefits of a medical device than a jury but did not conclude that Congress intended on precluding juries from having any role in reviewing claims involving medical devices. See 552 U.S. at 324-25.

Defendants' proposition undermines the Supreme Court's

pronouncements concerning the delicate regime Congress created in passing the MDA. Indeed, Lohr, Reigel, and Buckman are consistent in holding that state law claims, which are ordinarily decided by a jury, are not preempted so long as the duties under those claims are parallel to federal requirements. Thus, the fact that a jury reviews state law claims, rather than the FDA, does not serve as a basis for preemption.

3. Whether Plaintiff's Remaining Claims are Untimely

Defendants argue that Franks's remaining claims are barred by the statute of limitations. CSI Mem. 24-26; Femcare Mem. 37-39. Under Rhode Island law, the statute of limitations for personal injury claims based on product liability is three years from the date of injury. R.I. Gen. Laws § 9-1-14; see Houllahan v. Gelineau, 296 A.3d 710, 718 (R.I. 2023). But, "when the fact of the injury is unknown to the plaintiff when it occurs, the applicable statute of limitations will be tolled and will not begin to run until, in the exercise of reasonable diligence, the plaintiff should have discovered the injury or some injury-causing wrongful conduct." Martin v. Howard, 784 A.2d 291, 299 (R.I. 2001); see Anthony v. Abbott Labs., 490 A.2d 43, 45-46 (R.I. 1985) (applying rule in drug product-liability case).

Here, Franks alleges that Filshie Clips were placed on her fallopian tubes in August 2014 during her tubal ligation surgery.

Compl. ¶¶ 55-56. Though she started feeling pain after her surgery, Franks alleges she was not aware that the clips migrated from their original location until August 2021 while undergoing radiology. Id. ¶¶ 59-62. Franks filed her claim on January 27, 2022. See generally id.

Defendants argue that Franks has not alleged plausible facts to gain the benefit of the discovery rule and that she should have discovered her alleged injury before the statute of limitations lapsed in August 2017. CSI Mem. 25-26; Femcare Mem. 38. Franks alleges that, soon after her August 2014 surgery, she, and her physician, "explored a number of potential diagnoses including endometriosis" and she underwent a hysterectomy and a biopsy. Compl. ¶ 61. During this time, Franks alleges that Defendants failed to report the higher migration rates, preventing her and her physician from exploring whether a detached clip was the cause of Franks's pain. See id. ¶¶ 64-68. Considering Franks's alleged efforts to identify her pain and her allegations that Defendants failed to disclose the higher migration rates, the Court finds that the discovery rule applies.[22] Accordingly, the Court finds that Franks filed her Complaint within the statute of limitations

[22] Discovery in this case may reveal more information concerning when and how soon Franks should have discovered her injury.

and the Court will not dismiss it on this basis.

4. Whether the Learned Intermediary Doctrine Serves as a Bar to Franks's Remaining Claims

Finally, Defendants argue that Franks's remaining claims should be dismissed under the learned intermediary doctrine. CSI Mem. 26-29; Femcare Mem. 39-41. Under the doctrine, a manufacturer can "absolve" itself from liability for its failure to warn a consumer of the risks associated with a medical device "by providing an adequate warning . . . to 'prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings.'" Costa v. Johnson & Johnson, C.A. No. 17-452 WES, 2023 WL 2662903, at *3 (D.R.I. Mar. 28, 2023) (quoting Restatement (Third) of Torts: Products Liability § 6(d)(1)). The theory puts the onus on a patient's physician to inform her of the risks associated with a particular medical device because the physician is in a better position to understand the risks, and inform the patient of those risks by virtue of their doctor-patient relationship. Id. A manufacturer can benefit from the doctrine only if its warnings are "adequate[]." In re Fresenius Granuflo/Naturalyte Dialysate Prods. Liab. Litig., MDL No. 13-2428, 2023 WL 5807340, at *16 (D. Mass. Sept. 7, 2023); Monroe v. Medtronic, Inc., 511 F. Supp. 3d 26, 35-36 (D. Mass. 2021).

Both parties recognize that the Rhode Island Supreme Court

has yet to adopt the learned intermediary doctrine. Pl.'s CSI Mem. 18; CSI Mem. 27; Femcare Mem. 39. As this Court has previously explained, the Rhode Island Supreme Court would likely adopt the doctrine, if given the opportunity, considering its reliance on the Second and Third Restatements of Torts as the basis for the state's product liability law. See Costa, 2023 WL 2662903, at *3.

Defendants argue that Franks's Complaint does not adequately allege that her physician did not receive adequate warnings for Filshie Clips. CSI Mem. 28-29; Femcare Mem. 40-41. Franks alleges that Defendants had a duty to warn Franks and her physician of the migration risks associated with the clips and failed to do so. Compl. ¶¶ 45, 66, 102-04, 117, 126, 139. Franks also alleges that the warnings it did give were inadequate given the disparity between the migration rates Defendants reported to the FDA and the rate Franks alleges. Id. ¶¶ 41, 44-46, 104, 106, 132. In fact, at the time of filing her Complaint, Defendants still had not adequately warned the FDA of the higher migration rates. Id. ¶ 67. Thus, at this stage of the case, assuming Franks's allegations to be true, the learned intermediary doctrine does not serve as a bar to Franks's remaining claims.

**IV. CONCLUSION**

For the reasons stated above, the Court:

- GRANTS UMP's Renewed Motion to Dismiss, ECF No. 66, under Rule 12(b)(2). UMP is dismissed from the case;
- GRANTS IN PART and DENIES IN PART Femcare's Renewed Motion to Dismiss, ECF No. 67, under Rule 12(b)(6). Femcare's Motion is granted with respect to Counts I and II but denied with respect to Counts III-VIII;
- GRANTS TCC's Renewed Motion to Dismiss, ECF No. 68, under Rule 12(b)(2). TCC is dismissed from the case; and
- GRANTS IN PART and DENIES IN PART CSI's Renewed Motion to Dismiss, ECF No. 69, under Rule 12(b)(6). CSI's Motion is granted with respect to Counts I and II but denied with respect to Counts III-VIII.

IT IS SO ORDERED.

William E. Smith
District Judge
Date: March 14, 2024