UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

DOE, et al,	)	3:18-CV-000352 (KAD)
Plaintiffs,	)	
	)	
v.	)	
	)	
BAUSCH & LOMB, INC., et al,	)	
Defendants.	)	March 11, 2020

MEMORANDUM OF DECISION ON THE DEFENDANTS' MOTION TO DISMISS (ECF NO. 95) AND PLAINTIFFS' MOTION FOR LEAVE TO AMEND THE COMPLAINT (ECF NO. 126)

Kari A. Dooley, United States District Judge:

This is a products liability action involving the Trulign Toric intraocular lens ("Trulign Lens" or "Trulign Lenses"). The Trulign Lenses, manufactured by Defendant Bausch & Lomb, Incorporated ("B&L") for the treatment of cataracts, are Class III medical devices approved for sale by the United States Food & Drug Administration ("FDA"). In the Second Amended Complaint ("SAC"), Marjorie Glover and her husband, Charles Glover, (individually, "Mrs. Glover" and "Mr. Glover," and, collectively, the "Plaintiffs") assert ten causes of action against Defendants,[1] each arising out of alleged complications resulting from the implantation of a Trulign Lens in each of Mrs. Glover's eyes. Defendants filed a motion to dismiss this action on a variety of bases pursuant to Rule 12(b)(2), Rule 12(b)(6), and Rule 9(b). Following the filing of the motion to dismiss, the Plaintiffs sought leave to amend the complaint to add an additional cause of action under the Connecticut Unfair Trade Practices Act ("CUTPA"), to which the Defendants objected. This memorandum of decision addresses both motions.

[1] Bausch & Lomb, Incorporated ("B&L"), Bausch Health Companies, Inc. ("Bausch Health") f/k/a Valeant Pharmaceuticals International, Inc. ("VPII"), Bausch & Lomb Holdings Inc. ("B&L Holdings"), Valeant Pharmaceuticals International ("VPI"), and Valeant Pharmaceuticals North America ("VPNA").

For the reasons set forth in this decision, the Defendants' Motion to Dismiss is GRANTED and the Plaintiffs' Motion for Leave to Amend is DENIED.

Allegations and Background

The following is alleged in the SAC. The Trulign Lens is the latest in a line of "accommodating" lenses that are surgically implanted in the eyes to replace one's natural lens after the natural lens is removed during cataract surgery. It is a Class III medical device that was required to pass the FDA's rigorous premarket approval process before it could be sold to the public.

Mrs. Glover underwent two successive cataract surgeries in 2014 during which her physician surgically implanted a Trulign Lens in each eye. Mrs. Glover was diagnosed ultimately with Z-Syndrome in both of her eyes. This asymmetric vaulting, known as "Z-Syndrome," is a post-operative complication unique to the Trulign Lens and its predecessor, the Crystalens lenses, and occurs when one haptic of the Lens pulls forward, while the other remains either in the normal position or is pushed backward, resembling the letter "Z" with the tilted optic in the middle. As a result, Mrs. Glover has had additional surgeries and other extensive treatment over the course of the years following the implant surgery. She has suffered significant vision impairment, including the loss of visual acuity in both eyes, complete loss of depth perception, extreme photosensitivity, limited ability to see at night and double vision. She also suffers continuously from the loss of balance, vertigo, headaches, extreme eye pain, eye fatigue and tearing. Plaintiffs allege that Mrs. Glover's injuries are caused by the Trulign Lenses.

Plaintiffs further allege that Defendants knew of the unique risk of Z-Syndrome posed by the Trulign Lenses while developing, seeking approval for and marketing the product. However, Plaintiffs allege, Defendants made misrepresentations to the FDA, including that Z-Syndrome could be successfully treated, while the FDA considered approval of the lenses. Post-approval,

Plaintiffs claim that Defendants failed to conduct post-market surveillance and to file adverse event reports with the FDA regarding known incidents of Z-Syndrome. Ultimately, Defendants failures caused the FDA-approved labeling on the Trulign Lenses to mislead ophthalmologists and their patients regarding Z-Syndrome. If Defendants had not failed in their obligations to the FDA, Mrs. Glover would not have suffered the injuries described above because she and her physician would not have selected the Trulign Lenses.

On July 5, 2018, Defendants filed a Motion to Dismiss pursuant to Rule 12(b)(2), Rule 12(b)(6), and Rule 9(b).[2] The Court held oral argument on the Motion to Dismiss on January 17, 2019. After oral argument, the parties filed multiple submissions supplementing their arguments. On July 16, 2019, Plaintiffs moved to amend their complaint pursuant to Rule 15(a)(2) to add a claim under CUTPA, to which the Defendants objected. The issues raised in the parties' motions are addressed as is necessary below.

Personal Jurisdiction

Defendants B&L Holdings, VPNA, VPI, and Bausch Health ("Jurisdictional Defendants") move to dismiss all claims against them for lack of personal jurisdiction. To survive a motion to dismiss filed pursuant to Rule 12(b)(2), "plaintiff must make a prima facie showing that jurisdiction exists." *SPV Osus Ltd. v. UBS AG*, 882 F.3d 333, 342 (2d Cir. 2018) (internal quotation marks omitted). "Prior to discovery, a plaintiff may defeat a motion to dismiss based on legally sufficient allegations of jurisdiction." *Metro. Life Ins. Co. v. Robertson-Ceco Corp.*, 84 F.3d 560, 566 (2d Cir. 1996). However, "[v]ague and conclusory allegations . . . are not enough to establish personal jurisdiction." *Rivera v. Armstrong*, 2007 WL 683948, at *1 (D. Conn. Mar. 2, 2007) (internal quotation marks and citations omitted).

[2] This matter was transferred to the undersigned on September 21, 2018.

In order to establish personal jurisdiction over the Jurisdictional Defendants, Plaintiffs must show that the Jurisdictional Defendants (1) are subject to personal jurisdiction under Connecticut's long-arm statute and (2) that exercising personal jurisdiction over them is consistent with the Due Process Clause of the Fourteenth Amendment. *See, e.g.*, *Sonera Holding B.V. v. Cukurova Holding A.S.*, 750 F.3d 221, 224 (2d Cir. 2014). For the Court's exercise of personal jurisdiction to satisfy due process, a non-resident must have sufficient "minimum contacts" with the forum state "such that maintenance of the suit 'does not offend traditional notions of fair play and substantial justice.'" *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 291–92 (1980) (quoting *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)) (internal quotation marks omitted). To avoid offending traditional notions of fair play and substantial justice, the non-resident's contacts with the forum must establish either general or specific jurisdiction.[3] *See Bristol-Myers Squibb Co. v. Superior Court of California, San Francisco Cty.*, 137 S. Ct. 1773, 1779–80 (2017). The non-resident's contacts with the forum establish specific jurisdiction when the non-resident "has purposefully directed his activities at residents of the forum, and the litigation results from alleged injuries that arise out of or relate to those activities." *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 (1985) (internal citations and quotation marks omitted). "'It is essential in each case that there be some act by which the defendant purposefully avails itself of the privilege of conducting activities within the forum State, thus invoking the benefits and protections of its laws.'" *MacDermid, Inc. v. Deiter*, 702 F.3d 725, 730 (2d Cir. 2012) (quoting *Burger King Corp.*, 471 U.S. at 475) (brackets omitted).

[3] Plaintiffs concede that the Jurisdictional Defendants are not subject to general jurisdiction in Connecticut. (*See* ECF No. 96 at p. 36 n.27). Accordingly, the Court addresses only specific jurisdiction as to the Jurisdictional Defendants.

Plaintiffs' allegations regarding the Jurisdictional Defendants' contacts with Connecticut are, at best, vague. In their SAC, Plaintiffs state:

> This Court has personal jurisdiction over Defendants because they transact business in the United States, including in the District of Connecticut; have substantial aggregate contacts with the United States, including within this District; engaged and are engaging in conduct that has and had a direct, substantial, reasonably foreseeable, and intended effect of causing injury to persons throughout the United States, and specifically in this District where the devices were sold to Plaintiff's doctor; and, Defendants purposely availed themselves of the laws of the United States.

(ECF No. 93 ¶ 36). Similarly, throughout the SAC, Plaintiffs make factual allegations regarding the Defendants collectively or only with respect to "Bausch & Lomb." For example, Plaintiffs allege, "Although Defendants have recently acknowledged some of the risks and dangers of Z Syndrome and some related complications resulting from the Lenses in the 2016 Instructions for Use, Defendants did not disclose and still have not fully disclosed the seriousness of the issue," (*Id*. ¶ 135), and, "Bausch & Lomb knew, and/or had reason to know, that its representations and suggestions to ophthalmologists that Trulign Lenses were safe and effective for use in the eyes were materially false and misleading." (*Id*. ¶ 152). Such vague allegations levied against the Jurisdictional Defendants do not satisfy Plaintiffs' burden.

However, Plaintiffs argue that personal jurisdiction is established as to the Jurisdictional Defendants because B&L's contacts with Connecticut may be imputed to the Jurisdictional Defendants insofar as B&L is their "alter ego." Plaintiffs summarily assert that "there existed a unity of interest in ownership between certain Defendants and other certain Defendants such that any individuality and separateness between the certain Defendants has ceased and these Defendants are the alter ego of the other certain Defendants and exerted control over those Defendants." (*Id*. ¶ 158). To support their allegation that B&L is VPNA's alter ego, Plaintiffs rely on the declaration of Chuck Hess, Vice President and General Manager of B&L's surgical division

in the United States, in which Mr. Hess states that "the B&L business in the U.S. is operated, in part, through the B&L subsidiary and, in part, as a division of [VPNA] . . . ." (ECF No. 18-2 ¶ 5). On the other hand, Defendants point to the declaration of Kristen O'Donnell, Director, Legal and Corporate Secretary of VPNA, which lays out how each of the Defendants is a legally separate entity. (ECF No. 95-1).

In Connecticut, "a court will disregard the corporate structure and pierce the corporate veil only under exceptional circumstances, for example, where the corporation is a mere shell, serving no legitimate purpose, and used primarily as an intermediary to perpetuate fraud or promote injustice." *SFA Folio Collections, Inc. v. Bannon*, 217 Conn. 220, 230 (1991) (internal quotation marks omitted). Plaintiffs' conclusory allegations, even coupled with Mr. Hess' statement, provide no basis for the Court to disregard the corporate structure of any Defendant. Accordingly, all claims against B&L Holdings, VPNA and VPI are dismissed for lack of personal jurisdiction.[4]

The analysis is different for Bausch Health. Plaintiffs argue that the Order granting Defendants B&L and Bausch Health's Motion to Transfer pursuant to 28 U.S.C. § 1404(a) ("Transfer Order"), (ECF No. 39), establishes personal jurisdiction as to Defendant Bausch Health under the law-of-the-case doctrine.[5] Cases may be transferred pursuant to § 1404(a) "to any other district . . . where it *might have been brought* . . . ." 28 U.S.C. § 1404(a) (emphasis added). A case "might have been brought" in a district if the defendants are subject to personal jurisdiction in that district. *See generally*, *Hoffman v. Blaski*, 363 U.S. 335 (1960); *Wilson v. DirectBuy, Inc.*, 821 F. Supp. 2d 510, 515 (D. Conn. 2011) (noting "[t]o decide whether an action

[4] The Plaintiffs also request the opportunity to conduct jurisdictional discovery if the Court determines that the record is insufficient to establish personal jurisdiction over these Defendants. The Court denies this request in light of the Court's decision dismissing the complaint with prejudice.

[5] Plaintiffs' argument that the law-of-the-case establishes jurisdiction over the Defendants is applicable only to Defendant Bausch Health and not to all Jurisdictional Defendants because the other Jurisdictional Defendants were added to the case through Plaintiffs' First Amended Complaint (ECF No. 69), which was filed after the Order transferring the case to this Court was entered. (ECF No. 39).

'might have been brought' in the proposed transferee forum, the court must first determine whether the defendants are subject to personal jurisdiction in that forum . . . .").

This case was transferred to the District of Connecticut pursuant to § 1404(a). (ECF No. 39). Even though, as Defendants argue, there was no explicit finding in the Transfer Order as to whether Defendants B&L and Bausch Health were subject to personal jurisdiction in the District of Connecticut, it is necessary, as discussed above, for the transferor court to find that defendants are subject to personal jurisdiction in the transferee district for a case to be transferred there pursuant to § 1404(a). And a fair reading of the district court's decision transferring the case makes clear that the court held the view that the case could have been (and perhaps should have been) brought in Connecticut. Therefore, it is law-of-the-case that Defendant Bausch Health is subject to personal jurisdiction in the District of Connecticut. *See Bank of Am. v. Pastorelli-Cuseo*, 2017 WL 4678184, at *2 (D. Conn. Oct. 17, 2017) (citing *DeWeerth v. Baldinger*, 38 F.3d 1266, 1271 (2d Cir. 1994)) ("The [law-of-the-case] doctrine 'applies to issues that have been decided either expressly or by necessary implication' . . . ."). And although the determination is not binding on this Court, *see Rezzonico v. H&R Block*, 182 F.3d 144, 149 (2d Cir. 1999), the fact that the transfer was, in part, at the urging of Bausch Health, *see* ECF No. 36, counsels against revisiting the issue. *See, e.g., Intellivision v. Microsoft Corp.*, 484 F. App'x 616, 618–19 (2d Cir. 2012) (summary order) (discussing the scope and application of judicial estoppel).

Common Law Claims—Counts One, Five and Six

Pursuant to Rule 12(b)(6), the Defendants seek to dismiss the claims purportedly brought pursuant to Connecticut common law at Counts One—fraudulent omission; Five—negligent misrepresentation; and Six—fraud, because those claims are barred by the Connecticut Product Liability Act ("CPLA").

A defendant may seek dismissal of claims if those claims fail to state a claim for which any relief might be granted. FED. R. CIV. P. 12(b)(6). To survive a motion to dismiss filed pursuant to Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. "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." *Id*. (quoting *Twombly*, 550 U.S. at 556). Legal conclusions and "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements," are not entitled to a presumption of truth. *Iqbal*, 556 U.S. at 678. Nevertheless, when reviewing a motion to dismiss, the court must accept well-pleaded factual allegations as true and draw "all reasonable inferences in the non-movant's favor." *Interworks Sys. Inc. v. Merch. Fin. Corp.*, 604 F.3d 692, 699 (2d Cir. 2010). Where, as here, a party alleges that a particular count is barred by the CPLA, a court will dismiss that count pursuant to Rule 12(b)(6) if, "drawing inferences in favor of the plaintiff, [it] falls within the scope of the CPLA *as a matter of law*." *Acadia Ins. Co. v. Connecticut Light & Power Co.*, No. 3:12-cv-1467 (MPS), 2013 WL 467817, at *2 (D. Conn. Feb. 7, 2013) (emphasis in original).

The CPLA is the "exclusive remedy for claims falling within its scope." *Winslow v. Lewis-Shepard, Inc.*, 212 Conn. 462, 471 (1989). A plaintiff cannot assert common law causes of action for product liability. *Id*.; *see also Densberger v. United Techs. Corp.*, 297 F.3d 66, 70 (2d Cir. 2002) (The CPLA "bars separate common law *causes of action* in product liability cases.") (emphasis in original). "In addition, a product liability claim is defined broadly to include, but not

be limited to, all actions based on '[s]trict liability in tort; negligence; breach of warranty, express or implied; breach of or failure to discharge a duty to warn or instruct, whether negligent or innocent; misrepresentation or nondisclosure, whether negligent or innocent.'" *Gerrity v. R.J. Reynolds Tobacco Company*, 263 Conn. 120, 127 (2003) (quoting CONN. GEN. STAT. § 52-572m(b)). And "the CPLA excludes all claims for personal injury caused by the warnings, instructions, marketing, packaging or labeling of any product." *Johannsen v. Zimmer, Inc.*, 2005 WL 756509, at *10 (D. Conn. Mar. 31, 2005) (internal quotation marks and citations omitted) (excluding Plaintiff's fraud claim because it arose "out of his personal injuries as allegedly caused by inaccurate or fraudulent marketing, packaging or labeling.").

Here, Plaintiffs concede that "[t]he core set of operative facts supporting [their] cause of action, and all of the legal theories flowing therefrom, is the Defendants' failure to report adverse events [and] their dissemination of false and misleading marketing materials [regarding their product]." (ECF No. 96 at p. 31–32). Because Counts One, Five and Six are all common law causes of action falling within the scope of the CPLA they are barred by the CPLA.

Counts One, Five and Six are dismissed with prejudice. *See Cuoco v. Moritsugu*, 222 F.3d 99, 112 (2d Cir. 2000) ("The problem with [the Plaintiffs'] causes of action is substantive; better pleading will not cure it. Repleading would thus be futile. Such a futile request to replead should be denied.").

Preemption

The Defendants also seek dismissal of all claims on the ground that they are preempted by the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"). By way of background:

> Congress enacted the MDA to extend the coverage of the [FDCA] to medical devices. The MDA divides medical devices into three classes according to user risk.

> Class I devices pose the least risk; Class III devices pose the most. Class I devices are subject to general controls such as labeling requirements. Class II devices are subject not only to general controls, but also to special controls such as performance standards, postmarket surveillance, and patient registries. If a device cannot be determined to provide a reasonable assurance of safety and effectiveness under Class I or II controls and is either marketed as a life-supporting device or may cause an unreasonable risk of illness or injury, it is a Class III device. A Class III device is subject to a pre-market approval process of the FDA. . . .
>
> The FDA's pre-market approval process of a Class III device is rigorous. The FDA performs a risk-benefit assessment of the device and determines the adequacy of the manufacturer's proposed label. The FDA then denies, approves, or approves with conditions on distribution, marketing, or sale. Once the FDA approves a device, the manufacturer is required to report any information that reasonably suggests that the device (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that any recurring malfunction would be likely to cause or contribute to a death or serious injury.

Stengel v. Medtronic Inc., 704 F.3d 1224, 1226–27 (9th Cir. 2013) (internal quotation marks, brackets and citations omitted).

Causes of action brought pursuant to state law involving Class III medical devices, such as the Trulign Lens, may be expressly or impliedly preempted by federal law. First, the MDA contains an express preemption provision:

> [N]o 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 this chapter.

21 U.S.C. § 360k(a).[6] In *Riegel v. Medtronic, Inc.*, the Supreme Court held that the MDA expressly preempts state law claims where: (1) the FDA has established requirements applicable to the

[6] Preemption under § 360k(a) is an affirmative defense. *See Riegel v. Medtronic, Inc.*, 451 F.3d 104, 107 (2d Cir. 2006), *aff'd*, 552 U.S. 312, 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008). While parties should file an answer asserting an affirmative defense and then file a motion for judgment on the pleadings pursuant to Rule 12(c) to seek judgment on that affirmative defense, *see, e.g.*, *Richards v. Mitcheff*, 696 F.3d 635, 637–38 (7th Cir. 2012), "[a]n affirmative defense may be raised by a pre-answer motion to dismiss under Rule 12(b)(6) . . . if the defense appears on the face

particular medical device; and (2) the state law claims would impose "requirements with respect to the device that are 'different from, or in addition to'" the federal requirements that relate to either: (i) "safety or effectiveness"; or (ii) "any other matter included in a requirement applicable to the device." 552 U.S. 312, 321–23 (2008) (quoting 21 U.S.C. § 360k(a)).

In addition, federal law impliedly preempts state law claims if those claims are based solely on violations of FDCA requirements. *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 353 (2001); *see also Norman v. Bayer Corp*., No. 3:16-cv-00253(JAM), 2016 WL 4007547, at *2 (D. Conn. July 26, 2016) ("[A] state claim is impliedly preempted under the FDCA if the conclusion that the state law has been violated is based solely on a violation of the FDCA."). In other words, "a litigant's [state law] claim may be *impliedly* preempted when the state-law claim is in substance (even if not in form) a claim for violating the FDCA—that is, when the state claim would not exist if the FDCA did not exist." *McConologue v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 93, 101 (D. Conn. 2014) (emphasis in original; internal quotation marks and citation omitted).

Between those claims that are expressly preempted and those that are impliedly preempted is an extremely narrow class of claims that are not preempted. "The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such claim would be impliedly preempted under *Buckman*)." *In re Medtronic, Inc., Sprint Fidelis Leads Products Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010) (emphasis in original; internal citation omitted). Plaintiffs must advance a state law claim that parallels federal law "but which . . . is not wholly derivative of

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of the complaint." *Pani v. Empire Blue Cross Blue Shield*, 152 F.3d 67, 74 (2d Cir. 1998). The parties do not address whether the Defendants' preemption defense appears on the face of Plaintiffs' complaint. And Plaintiffs have not challenged the Defendants' use of a motion pursuant to 12(b)(6). Because FDA regulation of the Trulign Lenses is at the heart of Plaintiffs' complaint the Court concludes that Defendants' preemption argument is apparent on its "face." *See, e.g., Iowa Pub. Employees' Ret. Sys. v. MF Glob., Ltd.*, 620 F.3d 137, 145 (2d Cir. 2010) (finding that defendants' affirmative defense was apparent from the plaintiffs' allegations in their complaint).

federal law." *Nagel v. Smith & Nephew, Inc.*, No. 3:15-cv-00927 (JAM), 2016 WL 4098715, at *4 (D. Conn. July 28, 2016) (citing *In re Medtronic, Inc.*, 623 F.3d at 1204).

Of course, in the event a claim is not preempted by federal law, the claim must otherwise satisfy the pleading requirements discussed above.

Failure to Warn under the CPLA (Count Two)

Under the CPLA, "[a] product seller may be subject to liability for harm caused to a claimant who proves . . . that the product was defective in that adequate warnings or instructions were not provided." CONN. GEN. STAT. § 52-572q(a). Plaintiffs predicate their failure-to-warn claim, at least in part, on a purported duty to warn owed to Mrs. Glover or her doctors. But Plaintiffs fail to identify any FDCA requirement directing Defendants to provide warnings to consumers or physicians separate and distinct from their disclosure obligations to the FDA or the use of FDA approved labels. Accordingly, to impose such a duty under the CPLA would be to impose requirements "different from, or in addition to" FDCA requirements and this claim is therefore expressly preempted by § 360k(a). *See Norman*, 2016 WL 4007547 at *3 ("[I]t is clear that plaintiff cannot bring a claim because defendants failed to warn plaintiff personally . . . because such a claim would be expressly preempted as imposing obligations beyond those of the FDCA."); *McConologue*, 8 F. Supp. 3d at 108 (dismissing failure-to-warn claim because, among other reasons, plaintiff "failed to allege the existence of any FDA requirements applicable to consumer warnings such that the Court may determine whether a state failure to warn claim is 'different from, or in addition to' FDA requirements . . . ."); *Stengel*, 704 F.3d at 1234 (Watford, J., concurring) (noting that claims based on a state law duty to warn doctors are expressly preempted by § 360k(a)).

Plaintiffs also allege Defendants failed to abide by their FDA reporting obligations. (*See, e.g.*, ECF No. 93 ¶ 113 (Defendants "ignored and neglected [their] responsibilities to the FDA and the conditional approval [they] had received to market the Trulign Lenses when [they] failed to timely file adverse event reports . . . .")). This claim is impliedly preempted because it is wholly derivative of the FDCA. Plaintiffs have not identified any duty under Connecticut law that required the Defendants to warn or communicate adverse event reports to the FDA so as to give rise to a parallel claim under Connecticut law. *Norman*, 2016 WL 4007547 at *4 ("To avoid preemption, a claim must be premised on the type of conduct that would traditionally give rise to liability under state law—and that would give rise to liability under state law even if the FDCA had never been enacted.") (quotation marks and citation omitted).

Count Two is dismissed with prejudice. *See Cuoco*, 222 F.3d at 112.

Negligence under the CPLA (Count Four)

Under the CPLA, product liability claims include actions based on theories of negligence. CONN. GEN. STAT. § 52-572m(b). Here, again, Plaintiffs allege that Defendants were negligent insofar as they failed to report adverse events to the FDA, and that such failures deprived Mrs. Glover or her doctors of information that would have stopped their use of the Trulign Lenses. Because the FDCA, and its accompanying regulations, requires adverse event reporting to the FDA, *see, e.g.*, 21 C.F.R. § 803.50(a), Plaintiffs' negligence claim is likely not expressly preempted. However, as discussed above, under Connecticut law, manufacturers do not have a duty to report adverse events to regulatory entities such as the FDA. *Norman*, 2016 WL 4007547 at *4 ("There is no general or background duty under Connecticut law to report risks *to a regulatory body*.") (emphasis in original). Therefore, Plaintiffs' negligence claim predicated on

essentially the same facts as their failure to warn claim, is wholly derivative of the FDCA and is impliedly preempted. *See Buckman Co.*, 531 U.S. at 353; *McConologue*, 8 F. Supp. 3d at 101.

Count Four is dismissed with prejudice. *See Cuoco*, 222 F.3d at 112.

Manufacturing Defect Under the CPLA (Count Three)

Under the CPLA, in order to prove a strict liability claim, Plaintiffs must show that the device was "in a defective condition unreasonably dangerous to her and that this defect caused the injury for which she seeks damages." *Simoneau v. Stryker Corp.*, 2014 WL 1289426, at *5 (D. Conn. 2014). Such defective condition may be "due to a flaw in the manufacturing process, a design defect or because of inadequate warnings or instructions." *Id*. (internal quotation marks and citation omitted). "In order to avoid preemption on a manufacturing defect claim, [Plaintiffs] must allege that [the] device was not manufactured in conformance with the specifications approved by the FDA." *Norman*, 2016 WL 4007547 at *3.

While the Plaintiffs do indeed allege that "[t]he Lenses were not manufactured in conformity with the manufacturer's design or in conformity with the FDA approved design that Defendants had submitted to FDA," (ECF No. 93 ¶ 188), the Defendants' argument that this allegation, and the others surrounding it, are conclusory, is persuasive. The Plaintiffs allege that asymmetric vaulting, known as "Z-Syndrome," is a post-operative complication unique to the Trulign and Crystalens lenses, that Mrs. Glover was diagnosed with Z-Syndrome, and that the Z-Syndrome caused her pain and suffering. Plaintiffs do not, however, allege that Mrs. Glover's device suffered from any specific manufacturing defect. Nor do they identify which FDA approved specification was allegedly not met. *See Burrell v. Bayer Corp.*, 260 F. Supp. 3d 485, 493 (W.D.N.C. 2017) ("[P]laintiff has not linked any manufacturing deficiency to the device that the plaintiff received and how it caused the alleged injuries, which federal courts have found to be a

necessary component of a negligent manufacturing defect claim."). Indeed, the thrust of the Plaintiffs' complaint is that **even as designed and approved by the FDA**, the lens is "defective" as unreasonably dangerous due to inadequate labelling and warnings. Thus, while Plaintiffs' manufacturing defect claim is not preempted, Plaintiffs do not plausibly allege such a claim so as to avoid dismissal pursuant to Rule 12(b)(6).

Count Three is dismissed. Further, the dismissal is with prejudice. This case has already been pending for approximately two and a half years. The SAC is Plaintiffs' third attempt to adequately plead their claims and it appears to the Court, given the nature and thrust of Plaintiffs' allegations, that further amendment would be futile. *See Ruotolo v. City of New York*, 514 F.3d 184, 191 (2d Cir. 2008) ("Leave to amend, though liberally granted, may properly be denied for: 'undue delay . . . on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc.'" (quoting *Foman v. Davis*, 371 U.S. 178, 182 (1962)).

Plaintiffs' Claims Under California Law

Plaintiffs bring three counts alleging violations of California statutes: Deceit by Concealment, California Civil Code §§ 1709, 1710 (Count Seven); a violation of Cal. Bus. & Prof. Code §§ 17200, et seq. (Count Eight), and a violation of Cal. Bus. & Prof. Code §§ 17500, et seq. (Count Nine). Plaintiffs' brief in opposition to the motion to dismiss devotes exactly six sentences to these causes of action. They cite no authority, provide no analysis and summarily assert that the claims are adequately pled. They do not address the Defendants' preemption argument in the context of these statutes at all.[7] Accordingly, insofar as these claims derive from

[7] Nor do Plaintiffs meaningfully address the additional bases upon which the Defendants sought dismissal of these claims. Plaintiffs' failure to make any substantive effort to defend these claims, either with respect to the question of preemption or the other asserted deficiencies, renders them abandoned. *Packer v. SN Servicing Corp.*, 250 F.R.D.

the same nucleus of factual allegations—the failure to warn either Mrs. Glover or her doctors or the failure to advise the FDA of adverse outcomes—Plaintiffs have failed to establish that these statutes create independent requirements under California law which also parallel the obligations imposed by the FDCA so as to avoid preemption. Accordingly, Counts Seven, Eight and Nine are dismissed with prejudice. *See Cuoco*, 222 F.3d at 112.

Loss of Consortium (Count Ten)

Under Connecticut law, a claim for loss of consortium is derivative of claims for personal injury brought by the injured plaintiff. *See Bye v. Cianbro Corp.*, 951 F. Supp. 2d 322, 330 (D. Conn. 2013). Indeed, the consortium claim fails if the injured plaintiff's claims fail. *Id.* Here, as discussed above, all of Mrs. Glover's claims seeking relief for her alleged injuries fail. As a result, Plaintiffs' consortium claim must also fail and is dismissed.

Leave to Amend

Under Rule 15(a)(2), Plaintiffs may amend their complaint if given leave to do so by the Court and the Court "should freely give leave when justice so requires." FED. R. CIV. P. 15(a)(2). "It is within the sound discretion of the district court to grant or deny leave to amend." *WC Capital Mgmt., LLC v. UBS Sec., LLC*, 711 F.3d 322, 334 (2d Cir. 2013) (internal quotation marks and citation omitted). And, "[a] court may deny leave to amend as futile if 'a proposed claim could not withstand a motion to dismiss pursuant to Rule 12(b)(6).'" *Nagel*, 2016 WL 4098715 at *8 (quoting *Dougherty v. Town of N. Hempstead Bd. Of Zoning Appeals*, 282 F. 3d 83, 88 (2d. Cir. 2013)).

Plaintiffs seek leave to add a CUTPA claim to their complaint. Plaintiffs argue that this Court should give them leave due to an intervening decision of the Connecticut Supreme Court,

108, 115 (D. Conn. 2008); *Massaro v. Allingtown Fire Dist.*, 2006 WL 1668008, at *5 (D. Conn. June 16, 2006). They are dismissed on this basis as well.

Soto v. Bushmaster Firearms Int'l, LLC, 331 Conn. 53 (2019), *cert. denied sub nom. Remington Arms Co., LLC, et al. v. Soto*, No. 19-168, 2019 WL 5875142 (U.S. Nov. 12, 2019). Plaintiffs suggest that this decision stands for the proposition that the exclusivity provision of the CPLA does not bar CUTPA claims "as long as the CUTPA claims stand on their own, as they do here, and relate back to the original filing . . . ." (ECF No. 127 at p. 9).

Regardless as to whether the exclusivity provision of the CPLA bars CUTPA claims, a review of the CUTPA claim in Plaintiffs' proposed Third Amended Complaint, ECF No. 127-1 ¶¶ 260–71, reveals that it would be dismissed as expressly preempted by § 360k(a). The primary allegation of the CUTPA claim appears to be that Defendants inadequately warned of the Trulign Lens' dangers. However, the Plaintiffs do not allege that the Trulign Lens' warnings deviated from those that were approved by the FDA, only that the warnings were deficient and thus, because such a claim attacks the FDA approved labeling, it is expressly preempted. *See*, *e.g.*, *In re Medtronic*, 623 F.3d at 1205 (state law claims that would require warnings or information in addition to the FDA-mandated labeling are "precisely the type[s] of state requirement[s] that [are] 'different from or in addition to' the federal requirement[s] and therefore [are] preempted"). Because Plaintiffs' CUTPA claim would not survive dismissal pursuant to Rule 12(b)(6), Plaintiffs' Motion for Leave to Amend is denied.

Conclusion

For the foregoing reasons, the Defendants' Motion to Dismiss is GRANTED[8] and the Plaintiffs' Motion for Leave to Amend is DENIED.

SO ORDERED at Bridgeport, Connecticut, this 11th day of March 2020.

/s/ Kari A. Dooley
KARI A. DOOLEY
UNITED STATES DISTRICT JUDGE

[8] The Defendants also sought dismissal on res judicata grounds, asserting that the stipulation of dismissal "with prejudice" of a largely identical lawsuit brought in New York was a determination on the merits. *See Van Hof v. Town of Warwick*, 249 A.D.2d 382 (1998) ("The general rule is that a stipulation of discontinuance 'with prejudice' is afforded res judicata effect and will bar litigation of the discontinued causes of action."). Plaintiffs argue that the stipulation of dismissal should not be given preclusive effect because it was the intent of the parties that the dismissal be without prejudice and that it was an error that the stipulation of dismissal was drafted to include the "with prejudice" language. "[T]he language 'with prejudice' is narrowly interpreted when the interests of justice, or the particular equities involved, warrant such an approach." *Pawling Lake Prop. Owners Ass'n, Inc. v. Greiner*, 72 A.D.3d 665, 667 (2010) (quoting *Dolitsky's Dry Cleaners v. YL Jericho Dry Cleaners*, 203 A.D.2d 322, 323 (1994)). For example, in *D'Angelo v. City of New York*, the court determined that the stipulated dismissal "with prejudice" of a New York state court action did not have res judicata effect because the parties were "fully aware" of related claims being prosecuted in federal court. 929 F. Supp. 129, 135 (S.D.N.Y. 1996). The court found that giving the stipulated dismissal res judicata effect "would [have] frustrate[d] the intent of the parties as well as the purpose of the rules of preclusion as defined under New York law." *Id*.

"Generally res judicata is an affirmative defense to be pleaded in the defendant's answer. However, when all relevant facts are shown by the court's own records, of which the court takes notice, the defense may be upheld on a Rule 12(b)(6) motion without requiring an answer." *Day v. Moscow*, 955 F.2d 807, 811 (2d Cir. 1992) (internal citations omitted). Thus, "[a] court may consider a *res judicata* defense on a Rule 12(b)(6) motion to dismiss when the court's inquiry is limited to the plaintiff's complaint, documents attached or incorporated therein, and materials appropriate for judicial notice." *TechnoMarine SA v. Giftports, Inc.*, 758 F.3d 493, 498 (2d Cir. 2014). Here, in their opposition to Defendants' motion to dismiss, Plaintiffs submit documents relevant to a determination of Defendants' res judicata defense, but outside the record the Court may consider in the context of a 12(b)(6) motion. Specifically, Plaintiffs submitted email communications between counsel on the issue of the parties' intent. The Defendants object to the Court's consideration of those materials. Accordingly, it is not appropriate for the Court to decide whether the stipulation "with prejudice" should be afforded res judicata effect at this stage of the proceedings.