UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

MARJORIE and CHARLES GLOVER, *Plaintiffs*, v. BAUSCH & LOMB, INCORPORATED, VALEANT PHARMACEUTICALS INTERNATIONAL, INC. N/K/A BAUSCH HEALTH COMPANIES INC., and DOES 1 THROUGH 50, INCLUSIVE, *Defendants*.	)	CASE NO. 3:18-cv-352 (KAD) JULY 25, 2023

MEMORANDUM OF DECISION
RE: DEFENDANTS' MOTION TO DISMISS AND/OR STRIKE THE THIRD AMENDED COMPLAINT (ECF NO. 164)

Kari A. Dooley, United States District Judge:

The parties' familiarity with the allegations and procedural history of this case is presumed. Briefly, Marjorie Glover underwent two cataract surgeries in 2014, during which Trulign Lenses manufactured by Defendants were implanted into each eye. Plaintiffs allege that following Mrs. Glover's second surgery, she began to experience severe complications, including significant vision loss and eye pain, and has since underwent many painful and ultimately unsuccessful surgeries to restore her vision. Mrs. Glover has since been diagnosed with Z Syndrome, or vaulting, in both eyes, which causes the lens to twist or tilt. This Court granted Defendants' motion to dismiss the Second Amended Complaint as preempted by federal law and denied Plaintiffs leave to amend the complaint. Plaintiffs appealed to the Second Circuit Court of Appeals, which certified two questions of law to the Connecticut Supreme Court. Following remand of this matter from the Second Circuit, Plaintiffs' claims had narrowed to a single claim under the Connecticut Product Liability Act ("CPLA") for failure to warn arising out of the alleged post-approval failure of

Defendants to report adverse events to the Food and Drug Administration ("FDA") or to conduct the mandated post-approval study, and a loss of consortium claim. In an effort to streamline the litigation going forward, the Court directed Plaintiffs to file a Third Amended Complaint ("TAC") containing only the remaining claims. Plaintiffs filed the TAC on October 17, 2022. *See* ECF No. 162. Pending before the Court is Defendants' motion to dismiss the TAC, or, alternatively, a motion to strike portions of the TAC. *See* ECF No. 164. As set forth below, the motion to dismiss is DENIED. The motion to strike paragraph 52 of the TAC is GRANTED. The motion to strike in all other respects is DENIED.

Standard of Review

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 557). 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).

Under Rule 12(f), "[t]he court may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." "[T]he party moving to strike 'bears a heavy burden' and must show that '(1) no evidence in support of the allegations would be admissible; (2) the allegations have no bearing on the issues in the case; and (3) permitting

allegations to stand would result in prejudice to the movant.'" *Walczak v. Pratt & Whitney*, No. 3:18-cv-00563 (VAB), 2019 WL 145526, at *2 (D. Conn. Jan. 9, 2019) (quoting *Tucker v. Am. Int'l Grp.*, 936 F. Supp. 2d 1, 16 (D. Conn. 2013)). "Motions to strike under Rule 12(f) are generally disfavored and will not be granted unless the matter asserted clearly has no bearing on the issue in dispute. Furthermore, [t]o the extent that Defendants' aim is to avoid unduly inflaming and prejudicing the jury, the court may take into account that the Complaint will not be submitted to the jury." *Walczak*, 2019 WL 145526, at *2 (citations and internal quotation marks omitted); *see also Gierlinger v. Town of Brant*, No. 13-cv-00370 (AM), 2015 WL 3441125, at *1 (W.D.N.Y. May 28, 2015) ("[B]ecause striking a [part] of a pleading is a drastic remedy . . . motions under Rule 12(f) are viewed with disfavor by the federal courts and are infrequently granted.").

Discussion

Motion to Dismiss

Defendants argue that the TAC lacks sufficient specificity regarding particular adverse events attributable to Trulign Lenses which Defendants failed to report to the FDA. The Court disagrees.[1]

Plaintiffs allege that the FDA's premarket approval of Crystalens, the predecessor version of Trulign Lenses, required Defendants to report all adverse reactions within ten days of learning

[1] Plaintiffs rely upon the Connecticut Supreme Court's decision wherein the court concluded that Plaintiffs' allegations adequately alleged a violation of the CPLA. Although Connecticut pleading requirements are very similar to the requirements set forth in *Iqbal* and *Twombly*, *compare Coppola Const. Co., Inc. v. Hoffman Enterprises Ltd. Partnership*, 309 Conn. 342, 350 (2013) ("[W]e construe the complaint in the manner most favorable to sustaining its legal sufficiency. . . . Thus, [i]f facts provable in the complaint would support a cause of action, the motion to [dismiss] must be denied. . . . Moreover, we note that [w]hat is necessarily implied [in an allegation] need not be expressly alleged. . . . It is fundamental that in determining the sufficiency of a complaint challenge by a defendant's motion to [dismiss], all well-pleaded facts and those facts necessarily implied from the allegations are taken as admitted. . . . Indeed, pleadings must be construed broadly and realistically, rather than narrowly and technically."), with *Iqbal*, 556 U.S. at 678, they are not identical, and thus, the Connecticut Supreme Court's assessment, which relied upon state court pleading requirements, does not resolve this question. However, given the similarities between the two pleading standards, the Connecticut Supreme Court's assessment is certainly instructive.

of any injury "that is attributable to the device" and "has not been addressed by the product's labeling" or "has been addressed by the device's labelling but is occurring with unexpected severity or frequency." TAC at 28 ¶ 101. Defendants' supplemental premarket approval for Trulign Lenses likewise required that they submit adverse event reports to the FDA within thirty days of receiving or becoming aware of information that suggests that their product "may have caused or contributed to a death or serious injury" or "has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur." TAC at 28 ¶ 102. Plaintiffs allege that Defendants failed to timely file adverse event reports with the FDA with known incidents of Z Syndrome. TAC at 28 ¶ 103. Indeed, Plaintiffs allege that Defendants failed to timely file adverse event reports regarding Mrs. Glover even though Bausch & Lomb was informed of her adverse results numerous times. TAC at 28 ¶ 104.

A medical article published in 2008 regarding Crystalens reported at least four incidents of Z Syndrome; Defendants only filed one adverse event report with the FDA in 2009. TAC at 20–21 ¶¶ 64–67. At the time the FDA was considering approval of Trulign Lenses, the FDA knew of three incidents of Z Syndrome during clinical testing. TAC at 23 ¶ 76. However, there were approximately 270 reports related to vaulting and five cases reported in medical literature. TAC at 23 ¶ 77. Vaulting or Z Syndrome were not reported in the adverse events section in the physician labeling available at the time of Mrs. Glover's surgeries in 2014. TAC at 29 ¶ 106. In fact, there are more than five hundred adverse event reports to the FDA from 2013 to 2016 linking vaulting to Trulign Lenses. TAC at 33 ¶ 126.

Plaintiffs allege that Defendants' failure to conduct post-market surveillance and to file adverse event reports with the FDA with known incidents of Z Syndrome resulted in "misleading,

inaccurate, erroneous and incomplete" information provided to physicians. TAC at 25 ¶ 85. Had Defendants timely filed and reported adverse events for Crystalens and Trulign Lenses, Mrs. Glover and her physician would not have selected Trulign Lenses. TAC at 31 ¶ 113. Furthermore, had Plaintiffs been aware of the adverse events reports that showed that Trulign Lenses were more dangerous than Crystalens, that the available treatment options (including removal of the lenses) may not be successful, or that Defendants delayed an FDA-ordered safety study, Mrs. Glover would not have had Trulign Lenses implanted. TAC at 31 ¶ 114.

These allegations and the inferences to be drawn therefrom are sufficient to survive a motion to dismiss. Although conclusory and speculative allegations are insufficient to state a causal connection in a failure to warn claim, *see Vieira v. Mentor Worldwide, LLC*, 845 F. Appx. 503, 505–06 (9th Cir. 2021) (dismissal appropriate where plaintiff failed to allege actual adverse events manufacturer did not report and instead only alleged that had manufacturer conducted its post-approval studies differently, manufacturer would have identified additional adverse events it would have reported to the FDA), the TAC alleges relevant date ranges in which adverse events occurred but were not reported to the FDA and identifies at least four instances of Z Syndrome occurring but only one adverse event report filed by Defendants to the FDA. Such allegations are adequate to state a plausible failure to warn claim. *See, e.g.*, *Michajlun v. Bausch & Lomb, Inc.*, No. 14-cv-1365 (JMA), 2015 WL 1119733, at *8 (S.D. Cal. Mar. 11, 2015); *Eidson v. Medtronic, Inc.*, 40 F. Supp. 3d 1202, 1233–34 (N.D. Cal. 2014); *Comella v. Smith & Nephew, Inc.*, No. 13-cv-1850 (JBZ), 2013 WL 6504427, at *4 (N.D. Ill. Dec. 11, 2013). While the limited number of unreported adverse events "provides a thin causal connection," it is "a plausible connection nonetheless." *Michajlun*, 2015 WL 1119733, at *8.

Defendants next argue that Plaintiffs have not adequately alleged that Mrs. Glover's injuries were proximately caused by Defendants' conduct, and specifically, that causation is too speculative to be inferred from the allegations. Defendants' argument goes to the merits of Plaintiffs' claim. Plaintiffs have alleged that had Defendants reported adverse events post-approval, and had Defendants conducted the requisite study in a timely fashion, Plaintiffs and Mrs. Glover's physicians were likely to have had better and more accurate information regarding the risk of Trulign Lenses. Plaintiffs allege that with such information, Mrs. Glover would have elected not to implant the Trulign Lenses. Proving by a preponderance of the evidence each inferential step in this layered causal chain may turn out to be very difficult, but at this juncture in the litigation, with all inferences drawn in Plaintiffs' favor, causation is adequately pled. The motion to dismiss is therefore DENIED.[2]

Motion to Strike

Plaintiffs were instructed to file a Third Amended Complaint that comported with the Second Circuit's decision and which contained only the remaining claims. Plaintiffs did not file a motion to amend the complaint to add different legal or factual theories of liability, and no such opportunity would have been granted at this stage of the litigation, given the age of the case and the lengthy procedural path it has already traveled. Notwithstanding, at paragraph 52, Plaintiffs assert a never-before-seen allegation that Defendants failed to train ophthalmologic surgeons with "special procedures and safe techniques to implant, and if necessary, explant these very special Lenses." TAC at 18 ¶ 52. Defendants seek to strike this allegation as outside the scope of this Court's directive and as an unauthorized amendment to the operative complaint. Plaintiffs do not meaningfully address this argument in their opposition, an implicit acknowledgment that

[2] Because the Court has denied the motion to dismiss as to the CPLA claim, there is no basis upon which to dismiss the derivative loss of consortium claim.

Defendants are correct in their assessment. The Court agrees with Defendants. The contours of the remaining claims in this case have been forged through five years of litigation before this Court, the Second Circuit Court of Appeals, and the Connecticut Supreme Court. Those claims do not include a theory of liability arising out of Defendants' failure to train surgeons regarding the implant or explant of Trulign Lenses. Paragraph 52 is accordingly stricken.

Defendants next argue that Plaintiffs should have removed whole swaths of allegations insofar as they are now irrelevant to the narrow remaining CPLA claim. Plaintiffs object on the grounds that the allegations are relevant and material to the remaining claim. The Court need not dissect the TAC and each such allegation to resolve this dispute. First, it is not the Court's practice to provide the operative complaint to the jury, and thus, any arguably unnecessary allegations will not find their way to the finder of fact. *Walczak*, 2019 WL 145526, at *2. Second, discovery in this case will be defined by the claims themselves and will not be dictated by Plaintiffs' decision to include specific factual allegation which may or may not be probative of those claims.[3] *Norwalk Cove Marina, Inc. v. S/V Odysseus*, 90 F. Supp. 2d 190, 194 (D. Conn. 2000) ("In considering a motion to strike, the court does not examine the merits of the action, but merely determines whether any matter contained in the pleading itself was improperly included."). Finally, whether or to what extent the allegations are probative of the remaining claims cannot and should not be determined on a motion to strike. *See Lynch v. Southampton Animal Shelter Foundation, Inc.*, 278 F.R.D. 55, 66 (E.D.N.Y. 2011) (Defendants "will have ample opportunity after discovery to show that these allegations are baseless or irrelevant to Plaintiffs' claims."). The motion to strike allegations other than paragraph 52 is therefore DENIED.

Conclusion

[3] The Court observes that the parties have not identified any discovery disputes arising from the inclusion of these allegations in the TAC.

The motion to dismiss is DENIED. The motion to strike paragraph 52 of the TAC is GRANTED. The motion to strike in all other respects is DENIED.

SO ORDERED at Bridgeport, Connecticut, this 25th day of July 2023.

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