UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

EDWARD R. KARAZIN and IRENE M. KARAZIN, *Plaintiffs*, *v.* WRIGHT MEDICAL TECHNOLOGY, INC., *Defendant*.	Civil No. 3:17cv823 (JBA) September 14, 2018

RULING ON DEFENDANT'S MOTION TO DISMISS

Plaintiffs Edward R. Karazin and his wife Irene M. Karazin bring this action against Defendant Wright Medical Technology, Inc. ("Wright") to recover damages allegedly suffered in connection with the malfunction of a Profemur Z device implanted in Mr. Karazin. Plaintiffs assert one product liability claim with multiple theories pursuant to the Connecticut Product Liability Act ("CPLA") (Count One) and one loss of consortium claim (Count Two). Defendant now moves to dismiss both counts pursuant to Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief can be granted. (Def.'s Mot. to Dismiss [Doc # 39] at 1.) For the reasons that follow, Defendant's Motion is granted in part and denied in part.

I. Facts Alleged

On March 30, 2005, Mr. Karazin underwent total hip replacement surgery. (Am. Compl. [Doc. # 35] ¶ 13.) As part of that total hip replacement, Mr. Karazin's doctor implanted an artificial hip stem and neck known as the "Profemur Z," designed, manufactured, marketed, sold, and

distributed by Defendant. (*Id.*) The hip stem and neck—together constituting the Profemur Z—are two of five separate components which comprise a total hip replacement. (*Id.* ¶¶ 10, 13).

More than ten years later, on October 28, 2015, the Profemur Z device implanted in Mr. Karazin suffered a "catastrophic failure and fracture" requiring removal of the fractured Profemur Z and replacement with another hip prosthesis. (*Id.* ¶¶ 20-23.) As a result, Mr. Karazin suffered "serious injuries, some [or] all of which may be permanent." (*Id.* ¶ 47.)

Plaintiffs allege that the Profemur Z device is "more prone to component fracture . . . than hip devices manufactured by other companies" and that Defendant "knew or had reason to know" of that increased likelihood of fracture "at a time before the implantation and/or failure of" Mr. Karazin's Profemur Z device. (*Id.* ¶¶ 14, 17.) Plaintiffs further allege that, before the implantation of the Profemur Z device in Mr. Karazin, Defendant had "regular and frequent communications from and/or to surgeons who had implanted the Profemur Z, including plaintiff's surgeon, regarding failures, fractures, and complications" with the device. (*Id.* ¶ 19.) Plaintiffs also allege that on October 12, 2015, approximately two weeks before Plaintiff's surgery to remove the fractured Profemur Z, Defendant recalled "a version" of its Profemur Z due to an "unexpected rate of fractures after surgery." (*Id.* ¶ 16.)

Plaintiffs also allege that Defendant failed to comply with Federal Drug Administration regulations regarding timely reporting of issues with medical devices, including failures to timely "report adverse events; . . . conduct failure investigations and analyses; . . . report any and all information concerning product failures and corrections; . . . fully inform FDA of unanticipated adverse effects, increases in the incidence of adverse effects, or device failures necessitating a labeling, manufacturing, or device modification; … [and] conduct necessary design validation." (*Id.* ¶¶ 26-33.)

With regard to the specific Profemur Z device implanted in Mr. Karazin, Plaintiffs generally allege that the device was sold by Defendant in a "defective condition unreasonably dangerous to the user or consumer," that "said defective condition existed at the time of sale," and that the device reached Mr. Karazin and his implanting physician "without substantial change in condition." (*Id.* ¶¶ 41-42.) Plaintiffs additionally allege that the Profemur Z device implanted in Mr. Karazin "was not reasonably safe as intended to be used; . . . was not reasonably safe for users or consumers; . . . had an inadequate design for the purposes of hip replacement; . . . had manufacturing errors or defects that made it prone to premature failure or fracture; . . . contained unreasonably dangerous design defects; . . . was insufficiently tested" and included a warning about dangers posed to consumers which was "inadequate." (*Id.* ¶ 48.)

More specifically, Plaintiffs allege manufacturing defects resulting from "size tolerances out of specification and not within industry acceptable standards, or manufacturing processes that modified the components in a manner which increased the likelihood of component failure or fracture." (*Id.* ¶ 48(e).) Plaintiffs' alleged design defect is "an inherently unstable and defective design, which resulted in an unreasonably high probability of early failure." (*Id.* ¶ 48(f).)

Plaintiffs also allege that Defendant provided insufficient warnings and labeling for the Profemur Z. These alleged labeling problems include warnings that were "insufficient to alert . . . as to the risk of adverse events and/or reactions"; "misleading warnings emphasizing the efficacy of the Profemur Z while downplaying the risks associated with it"; "insufficient and/or incorrect warnings to alert consumers . . . regarding the risk, scope, duration, and severity of the adverse reactions associated with the Profemur Z"; "fail[ure] to provide the requisite information to a surgeon of standard competence and experience for the safe and effective use of the Profemur Z"; failure to "disclose that [the Profemur Z] was inadequately tested"; "fail[ure] to convey adequate

post-marketing warnings regarding the risk, severity, scope, and/or duration of the dangers posed by the Profemur Z"; and failure to give consumers the instructions and "information necessary to avoid or mitigate" the dangers posed by the Profemur Z. (*Id.* ¶ 48.)

Finally, Plaintiffs allege that Defendant "negligently misrepresented material facts regarding the Profemur Z's safety, efficacy, and fitness for human use by claiming" that the device (1) "was fit for its intended purpose when, in fact, it was not;" (2) "had been adequately and reliably tested when, in fact, it was not;" (3) had a risk of "serious events and/or effects . . . comparable to that of other hip replacement systems, when in fact it was not;" and (4) "had not caused or contributed to serious adverse events and/or effects requiring the premature explants of the device when, in fact, it had." (*Id.* ¶ 50.)

II. Discussion

A. Legal Standard

"To survive a motion to dismiss, 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)). Plaintiff must "plead[] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* Mere "labels and conclusions" or a "formulaic recitation of the elements of a cause of action" are insufficient. *Twombly*, 550 U.S. at 555; *see also* Fed. R. Civ. P. 12(b)(6). However, to plead a plausible claim "a complaint does not need to contain detailed or elaborate factual allegations." *Keiler v. Harlequin Enterprises Ltd.*, 751 F.3d 64, 70 (2d Cir. 2014).

For some claims, the facts necessary to prove the plaintiff's allegations are likely to be primarily or entirely within the control of the defendant until the discovery phase of litigation. Where, as here, "'much of the critical information . . . is kept confidential as a matter of federal

law'" due to medical device regulations and "will, therefore, be unavailable to a plaintiff without discovery," courts may consider that lack of access in assessing the sufficiency of a plaintiff's complaint. *Simoneau v. Stryker Corp.*, 2014 WL 1289426 at *6 (D. Conn. 2014) (quoting *Bausch v. Stryker Corp.*, 630 F.3d 546, 560 (7th Cir. 2010)) (finding plaintiff's complaint for medical device malfunction under the CPLA sufficiently stated a claim for relief).

B. Count One: Product Liability under CPLA

All Connecticut state law product liability claims must be asserted under the CPLA, which displaces related common law causes of action and provides for several theories of liability, including both strict liability and negligence theories. CONN. GEN. STAT § 52-572(m)-(n). Strict liability claims under the CPLA can include theories of manufacturing defect, design defect, or state law "malfunction theory." Plaintiffs' complaint offers myriad theories as to the nature of Defendant's liability, and the Court will address each in turn.[1]

1. Manufacturing Defect

A manufacturing defect is "a flaw in the manufacturing process which causes the product to deviate from the design standards and intended specifications." *McConologue v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 93, 109 (D. Conn. 2014) (citing *Miller v. United Technologies Corp*, 233 Conn. 732, 779 (1995)). Therefore, to plausibly state a claim of manufacturing defect, Plaintiffs

[1] Plaintiffs' complaint alludes heavily to claims of failure to comply with regulations of the Food and Drug Administration. (*See* Am. Compl. ¶¶ 24-33.) However, while these allegations are incorporated by reference into Counts One and Two of the Amended Complaint, (*id.* ¶¶ 34-60,) Plaintiffs' Opposition to Defendant's Motion to Dismiss focuses solely on the CPLA-based claims and makes no reference to violations of FDA regulations. (*See* Pl.'s Opp'n to Def.'s Mot. Dismiss [Doc. # 40] at 3-10.) Therefore the Court will treat Count One of the Amended Complaint as asserting only CPLA-based claims and will not address issues of FDA compliance.

must plead factual content showing the plausibility that Mr. Karazin's Profemur Z deviated from Defendant's intended design and specifications in some way.

Plaintiffs contend that the allegation that Defendant "committed manufacturing errors, including but not limited to, size tolerances out of specification and not within industry acceptable standards, or manufacturing processes that modified the components in a manner which increased the likelihood of component failure or fracture" is sufficient to satisfy the pleading standard on this theory.[2] (Am. Compl. ¶ 48(e); Pl.'s Opp'n to Def.'s Motion [Doc. # 40] at 5.) Defendant argues that the reference to "size tolerances out of specification" is insufficient because the complaint "does not even identify the manufacturing specifications at issue, let alone plead facts plausibly explaining how the 'size tolerances' were noncompliant and how such noncompliance affected the device." (Def.'s Reply [Doc. # 41] at 5.) Defendant also cites *McConologue*, *Simoneau*, and *Bausch* as examples of complaints which included more factual detail than does Plaintiffs' Amended Complaint. (Def.'s Reply at 5-6.) Plaintiffs note correctly that *McConologue* "does not establish a pleadings floor." (Pl.'s Opp'n at 5.) Nor do *Simoneau* or *Bausch* establish the minimum factual allegations necessary to state a claim.

Though Plaintiffs' complaint undoubtedly would benefit from inclusion of additional facts, the facts Defendant identifies as fatally omitted are precisely the type of facts which are largely within Defendant's control prior to the initiation of discovery and therefore cannot reasonably be expected to be included in the complaint. *See Simoneau*, 2014 WL 1289426 at *6. Plaintiffs have

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[2] In their Opposition, Plaintiffs also reference "other manufacturing errors" which made the Profemur Z prone to premature fracture. (Pl.'s Opp'n at 5.) However, Plaintiffs' opposition to the Defendant's Motion to Dismiss must be grounded in the complaint itself. Factual allegations contained in Plaintiffs' opposition brief which are not present in the Amended Complaint will not be considered.

clearly alleged a fact—that the size tolerances were out of specification—which, if true, could support their claim that Mr. Karazin's Profemur Z deviated from manufacturing specifications. The additional facts Defendant requests are the "detailed or elaborate factual allegations" which *Twombly* and *Iqbal* do not require. *See Keiler,* 751 F.3d at 70. Plaintiffs have met their pleading burden as to their manufacturing defect claim.

2. Design Defect

A design defect claim is predicated on a product which is "otherwise properly manufactured, but is nonetheless unreasonably dangerous because its attributes can cause an unexpected injury." *Moss v. Wyeth*, 872 F. Supp. 2d 162, 166 (D. Conn. 2012). There are two possible tests for identifying design defects. First, under the "consumer expectations test," a product is designed defectively if it "failed to perform as safely as an ordinary consumer would expect when used in a reasonably foreseeable manner." *Id.* Second, under the "risk-utility" test, a product is designed defectively if, "in the case of complex products, the risk of danger inherent in the design of the product outweighs its utility." *Id.* (citing *Potter v. Chicago Pneumatic Tool Co.*, 241 Conn. 199, 211 (1997)). The parties here disagree as to which test applies to Plaintiffs' claim of design defect. (Def.'s Mem. at 5-6, n.3; Pl.'s Opp'n at 6-7.)

Regardless of which test applies here, Plaintiffs have not plead facts sufficient to render their design defect claim facially plausible. Plaintiffs do not identify in any way which aspect of the Profemur Z was allegedly defectively designed, how the design was unreasonably or unexpectedly unsafe in light of the many benefits of hip replacements, or any specifics at all about reasonable alternative design. Plaintiffs support their claim of sufficient specificity only by referencing in their briefing the "modularity of the two piece neck and hip stem" coupled with recitation of the conclusory statements of the complaint. (Pl.'s Mem. at 6.)

Plaintiffs' argument here fails on several grounds. First, the Amended Complaint makes absolutely no mention of "modularity." (*See generally* Am. Compl.) Plaintiffs' counsel's reference to "modularity" in their Opposition to Defendant's Motion to Dismiss does not suffice to state a claim absent any reference to such a flaw in the complaint itself. *See Nechis v. Oxford Health Plans, Inc.*, 421 F.3d 96, 100 (2d Cir. 2005) ("we limit our consideration" of dismissal for failure to state a claim "to facts stated in the complaint or documents attached to the complaint as exhibits or incorporated by reference"); *Wright v. Ernst & Young LLP*, 152 F.3d 169, 178 (2d Cir. 1998) (refusing to consider an allegation first mentioned in plaintiff's opposition to a motion to dismiss).

Second, by Plaintiffs' own explanation, the "two piece neck and hip stem" is the entirety of the Profemur Z. (*See* Am. Compl. ¶ 13 ("an artificial hip stem and neck known as the PROFEMUR Z . . . hereinafter, the neck and stem components together will be referred to as the PROFEMUR Z").) Pointing to the entirety of the device in question, without more, is not sufficient to state a claim of design defect.

Finally, while Plaintiffs asserted a series of legal conclusions as to the inadequacy of the Profemur Z's design, (*See* Am. Compl. ¶ 48[3]; Pl.'s Opp'n at 6-7,) they merely recite legal components of the two design defect tests—precisely the type of assertions which the Supreme

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[3] For example, the Amended Complaint alleges that the Profemur Z was "not reasonably safe as intended to be used" or "for users or consumers," had a "defective" and "inadequate design" which was "inherently unstable" and an "unreasonably high probability of early failure." (Am. Compl. ¶ 48(a)-(c), (f).) It also alleges that the Profemur Z's design "was defective and/or unstable in light of reasonable alternative designs," "was manifestly unreasonable in that its risk of harm so clearly exceeded its utility that a reasonable consumer would not purchase the product," was "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchased it," "failed to perform in a manner reasonably expected in light of its nature and intended function," "had risks which exceeded the benefits of the medical device," and "was more dangerous than the ordinary consumer would expect." (*Id.* ¶ 48(h)-(n).)

Court has deemed insufficient to state a claim and not entitled to the presumption of truth afforded by courts to the facts alleged in a complaint when considering a motion to dismiss. *See Twombly*, 550 U.S. at 555.

As the Court may neither consider assertions first made in Plaintiffs' Opposition nor credit the bare legal conclusions of the Amended Complaint, Plaintiffs' only remaining factual allegation in support of their design defect claim is the assertion that the Profemur Z's design was "inherently unstable." (Am. Compl. ¶ 48(f).) That assertion alone is not sufficient to "raise [Plaintiffs'] entitlement to relief above the speculative level." *Keiler*, 751 F.3d at 70. Plaintiffs have not met their pleading burden as to their design defect claim.

3. Failure to Warn

Strict liability applies to failure to warn claims where adequate warnings or instructions were not provided and where the harm suffered would not have occurred had adequate warnings been given. *See McConologue*, 8 F. Supp. 3d at 100 (citing CONN. GEN. STAT § 52-572(q)).

Defendant argues that Plaintiffs' series of allegations regarding the warnings provided about the Profemur Z is insufficient to state a claim because they do not address "how the applicable warnings and/or instructions were allegedly inadequate, what warnings and/or instructions should have been provided, or that had such warnings and/or instructions been provided, Plaintiffs would not have suffered the injuries alleged." (Def.'s Mem. at 10-11.) Defendant claims that Plaintiffs failed to plead "any allegations regarding which specific risks were missing, which warnings were misleading, and which warnings were incorrect," (*Id.* at 11,) and failed to "identify what Wright Medical supposedly knew, when Wright Medical supposedly knew it, or what associated warning was necessary," (Def.'s Reply at 7.).

To the extent that Defendant requests detailed factual allegations regarding exactly what instructions should have been provided, its argument is unavailing as that information is both the type of "detailed or elaborate factual allegations" not required at this stage of litigation, *Keiler*, 751 F.3d at 70, and some of it likely the type of information that could not be available to Plaintiffs prior to discovery.

Moreover, Defendant's claims about the inadequacy of Plaintiffs' allegations are contradicted by the text of the Amended Complaint. Plaintiffs allege that specific risks were within Defendant's knowledge, including "failures, fractures, and complications" of the Profemur Z device—i.e., "what Wright Medical supposedly knew." (Am. Compl. ¶ 19.) Plaintiffs allege a specific source of that information: "surgeons who had implanted the [Profemur Z], including plaintiff's surgeon." (*Id.*) Plaintiffs allege that Defendant knew that information "before the implantation" of a Profemur Z device in Mr. Karazin—i.e., "when Wright Medical supposedly knew it." (*Id.*) Plaintiffs specifically cite "surgical protocol and surgical technique literature" among the allegedly inadequate warnings—i.e. "which warnings were incorrect."

Plaintiffs have minimally pleaded enough facts to "nudge[] their claims across the line from conceivable to plausible" as *Twombly* requires, 550 U.S. at 547, and have therefore met their pleading burden on the failure to warn claim.

4. Malfunction Theory

Connecticut recognizes a "malfunction theory," which allows plaintiffs to use circumstantial evidence to make a prima facie claim of product liability. *See Metro. Prop. & Cas. Ins. Co. v. Deere & Co.*, 302 Conn. 123, 132 (2011). However, Plaintiffs may use that alternative theory only where evidence of a product defect is "unavailable . . . such that the plaintiff is unable to produce direct evidence of a defect because of the loss of essential components of the product."

Id. Also, in order to successfully invoke the malfunction theory, "[i]f a product is not new or nearly new when it allegedly malfunctioned, and the product functioned without problems indicative of a defect before the malfunction, the plaintiff must present some evidence to explain how the product could have operated without incident for a time and then have failed on this particular occasion." *Id.* at 147. Without such explanation, "any link between the product failure and a defect attributable to the manufacturer is simply too attenuated to serve to establish liability on the part of the manufacturer." *Id.*

In support of their argument that the Amended Complaint states a claim on this theory, Plaintiffs cite only the Complaint's allegation that the fracture of Mr. Karazin's Profemur Z "was of a kind that does not ordinarily occur in the absence of a product defect and any defect most likely existed at the time the product left the defendants' control and was not the result of any reasonably possible causes not attributable to the defendants." (Am. Compl. ¶ 53; Pl.'s Opp'n at 9.) Absent any supporting fact-based allegations, Plaintiff has offered only conclusory legal statements and a recitation of the elements of malfunction theory, which are insufficient to state a claim for relief. *See Twombly*, 550 U.S. at 555.

Importantly, Plaintiffs offer no allegations whatsoever to explain the ten year period between the implantation of Mr. Karazin's Profemur Z in 2005 and its malfunction in 2015. (Am. Compl. ¶¶ 13, 20.) Without any such factual claims, the link between the alleged failure of the Profemur Z and a defect attributable to Defendant via the malfunction theory is "simply too attenuated." *See Metro Prop. & Cas.*, 302 Conn. at 147. Plaintiffs have not met their pleading burden on the malfunction theory claim.

5. Negligence

The CPLA also encompasses product defect claims which would traditionally be common law negligence claims. CONN. GEN. STAT § 52-572(m). Plaintiffs assert theories of negligent design, negligent manufacture, and negligent failure to warn. (Pl.'s Opp'n at 9-10; Am. Compl. ¶¶ 49-50.)

In addition to reiterating the bulk of its allegations made with regard to strict liability theories of manufacturing defect, design defect, and failure to warn, the Amended Complaint alleges that the Profemur Z was "negligently designed and manufactured" and that Defendant "negligently misrepresented material facts" about the device's "safety, efficacy, and fitness for human use" in its publications about the Profemur Z. (Am. Compl. ¶ 50.) In support of their argument that these allegations are sufficient to state a claim, Plaintiffs assert that Defendant "had a duty to exercise due care in designing, testing, manufacturing, distributing, marketing, promoting, and selling" the Profemur Z and that "[i]n breach of this duty, [Defendant] was negligent in [its] design, manufacture, and marketing of the device." (Pl.'s Opp'n at 9.)

Defendant argues, (Def.'s Mem. at 13,) and Plaintiff does not dispute, that Plaintiffs' negligent misrepresentation claims are subject to the heightened pleading standard for fraud claims under Fed. R. Civ. P. 9(b). Though the Second Circuit has not explicitly ruled on whether negligent misrepresentation claims must satisfy Rule 9(b), many district courts in this Circuit have so required. *See, e.g., McCullough v. World Wrestling Enter., Inc.*, 172 F. Supp. 3d 528, 561 (D. Conn. 2016) ("The requirements of Rule 9(b) are also applicable to negligent misrepresentation claims."); *Pearsall Holdings, LP v. Mountain High Funding, LLC*, 2014 WL 7270334 at *3 (D. Conn. 2014) ("As th[e] contention" that Rule 9(b) applies to fraudulent and negligent misrepresentation claims "appears to be undisputed and is in accord with the caselaw in this Circuit, the Court will apply Rule 9(b) to those counts."); *Pilarczyk v. Morrison Knudsen Corp.*, 965 F. Supp. 311, 323

(N.D.N.Y. 1997) ("The particularity requirements of Rule 9(b) apply to claims of negligent misrepresentation as well."). Because the application of Rule 9(b) "is cast in terms of the conduct alleged, and is not limited to allegations styled or denominated as fraud or expressed in terms of the constituent elements of a fraud cause of action," *Rombach v. Chang*, 355 F.3d 164, 171 (2d Cir. 2004), some district courts have conducted case-specific analyses to determine the applicability of Rule 9(b)'s particularity requirement to the conduct underlying claims of negligent misrepresentation. *See, e.g., Silvercreek Management, Inc. v. Citigroup, Inc.*, 248 F. Supp. 3d 428, 452-453 (S.D.N.Y. 2017) (applying case-by-case approach and declining to apply Rule 9(b) to negligent misrepresentation claim where the complaint "expressly disclaims 'any allegation of scienter or recklessness'").

Though Plaintiffs' Amended Complaint does not articulate a fraud cause of action, its negligent misrepresentation is couched in fraud-like terms of known falsity:[4] Defendant "knew that the [Profemur Z] was prone to fracture," knew that it was "defective and harmful to consumers," regularly communicated with surgeons "regarding failures, fractures and complications" of the device, and misrepresented that the Profemur Z "had not caused or contributed to serious adverse events and/or effects requiring the premature explants of the device when, in fact, it had." (Am. Compl. at ¶¶ 17-19, 50(v).) Because the Amended Complaint alleges

[4] In Connecticut, a plaintiff alleging fraudulent misrepresentation must demonstrate: "(1) [t]hat a false representation was made as a statement of fact; (2) that it was untrue and known to be untrue by the party making it; (3) that it was made to induce the other party to act on it; and (4) that the latter did so act on it to his injury." *Miller v. Appleby*, 183 Conn. 51, 54–55 (1981). An action for negligent misrepresentation requires: (1) a false representation made as a statement of fact and for the guidance of the other party; (2) failure to exercise due care on the part of the party making the statement; (3) justifiable reliance to its detriment by the harmed party. *Craine v. Trinity College*, 259 Conn. 625, 661 (2002).

that Defendant knew its claims were false—not simply that it failed to exercise due care in making the alleged misrepresentations—its misrepresentation claims are subject to the heightened pleading standard of Rule 9(b).

Under Rule 9(b), Plaintiff must "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Rombach*, 355 F.3d at 170 (quoting *Mills v. Polar Molecular Corp.*, 12 F.3d 1170, 1175 (2d Cir. 1993)). Plaintiffs here fail to specify any particular statements, identify a particular speaker, or state the particular time and place of the alleged misrepresentations, (*see* Am. Compl. ¶ 50,) thus Plaintiffs' negligent misrepresentation claims are not supported by sufficient factual allegations. *See, e.g., McCullough*, 172 F. Supp. 3d at 561 (finding a lengthy complaint "replete with allegations" that defendant had "misrepresented material facts," including various health risks, did not meet Rule 9(b)'s pleading standard due to lack of factual support).

That leaves only Plaintiffs' claims of negligent manufacture and negligent design, subject to the standard pleading requirements of Rule 8, *Twombly*, and *Iqbal*. Defendant notes correctly that these assertions of negligence lack any factual support and consist only of bare legal conclusions and recitations of the elements of negligence. (Def.'s Mem. at 12.) Plaintiffs argue that their negligence claims are sufficient "for the same reasons that the allegations of strict liability are sufficient to state a claim." (Pl.'s Opp'n at 9.) As the Court finds that Plaintiffs' strict liability design defect claim lacks sufficient factual support, their negligent design claim lacks sufficient support as well. And although the Court finds that Plaintiffs' strict liability manufacturing defect claim is pled with sufficient detail, those allegations include no factual support for an inference that negligence caused that manufacturing defect. In the absence of any specific factual allegations whatsoever as

to the nature of Defendant's breach of its duty of care, Plaintiffs have not met their pleading burden on their negligence claims.

C. Count Two: Loss of Consortium

Count Two of the Amended Complaint asserts that Mrs. Karazin has "been deprived of the companionship and society of her husband" "as a result of" Mr. Karazin's injury. (Am. Compl. ¶ 60.) Defendant argues, and Plaintiffs do not dispute, that Mrs. Karazin's loss of consortium claim is derivative of Mr. Karazin's CPLA claims. (Def.'s Mem. at 14-15; Pl.'s Opp'n at 10.) Defendant makes no argument that Mrs. Karazin's loss of consortium claim must be dismissed where Mr. Karazin's claims survive Defendant's Motion to Dismiss. (*See generally* Def.'s Mem.; Def.'s Reply.)

Therefore, Mrs. Karazin's loss of consortium claim will not be dismissed insofar as it is derivative of those of Mr. Karazin's claims in Count One which the Court finds above have met the pleading requirements.

III. Conclusion

For the foregoing reasons, Defendant's Motion to Dismiss [Doc. # 39] is DENIED as to Plaintiffs' manufacturing defect and failure to warn claims in Count One, GRANTED as to Plaintiffs' design defect, malfunction theory, and negligence claims in Count One, and DENIED as to Count Two insofar as Count Two alleges claims which are derivative to the claims in Count One not dismissed herein.

IT IS SO ORDERED.

/s/

Janet Bond Arterton, U.S.D.J.

Dated at New Haven, Connecticut this 14th day of September 2018.