

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF IDAHO

KRISTA GREEN,

Plaintiff,

v.

W. L. GORE & ASSOCIATES, INC.,
A Delaware Corporation, registered to
do business in Idaho, and JOHN DOES
1-100,

Defendants.

Case No. 4:19-cv-00022-DCN

**MEMORANDUM DECISION AND
ORDER**

I. INTRODUCTION

This matter comes before the Court on Defendant W.L. Gore & Associates, Inc.’s (“Gore”) Motion to Dismiss. Dkt. 17. The Court held oral argument on March 2, 2020 and took the motion under advisement.¹ Having reviewed the record and briefs, the Court finds the facts and legal arguments are adequately presented. Dist. Idaho Loc. Civ. R. 7.1(d). Upon review, and for the reasons set forth below, the Court GRANTS Gore’s Motion to Dismiss, but will allow Green the opportunity to amend her Complaint.

¹ Neither Green nor any person representing Green was present at the scheduled time for oral argument. Though the Court’s docket indicates that Green received notice of the hearing (Dkt. 26), there is a possibility that Green did not receive any notice. The Court treated Green’s absence as a waiver of her oral argument and allowed her to move forward on her briefing alone. This does not prejudice Green because, as will be discussed, the Court is granting Green the opportunity to amend her Complaint.

II. BACKGROUND²

On or around September 11, 2006, Krista Green had an appendectomy. As a part of that surgery, doctors implanted GORE-TEX DualMesh EMERGE PLUS Biomaterial (“Mesh”) into Green.

Since that date, Green has “experienced excessive pain, burning, pulling and swelling from the surgery.” Dkt. 2, at 3. In 2012, Green gave birth to her third child, but despite a normal delivery, the child died nine weeks later. Further, in 2014, Green was diagnosed with uterine cancer and received a hysterectomy.

On November 30, 2017, Green received a CT scan of her abdomen and pelvis. In addition to the Mesh, the CT scan showed some irregularities, such as a “ventral bulg[e]” and a “lobulated right renal lesion.” *Id.* On January 30, 2018, Green was diagnosed with a “recurrent right lower quadrant incisional hernia with mesh and partial small bowel obstruction symptoms,” and the Mesh was surgically removed from Green. *Id.* at 4.

On January 22, 2019, Green filed her Complaint against Gore. Green alleges three separate causes of action: (1) “strict liability;” (2) “strict products liability: failure to warn;” and (3) “negligence.” *Id.* at 4–7. Green seeks at least ten million dollars in damages for each cause of action. After the Court granted some extensions, on September 3, 2019, Gore filed the instant Motion to Dismiss pursuant to Federal Rules of Civil Procedure 8 and 12(b)(6).

² The facts in this section come from Plaintiffs’ Complaint, Dkt. 1, and are accepted as true. *Wilson v. Lynch*, 835 F.3d 1083, 1092 (9th Cir. 2016).

III. LEGAL STANDARD

Federal Rule of Civil Procedure 12(b)(6) permits a court to dismiss a claim if the plaintiff has “fail[ed] to state a claim upon which relief can be granted.” “A Rule 12(b)(6) dismissal may be based on either a ‘lack of a cognizable legal theory’ or ‘the absence of sufficient facts alleged under a cognizable legal theory.’” *Johnson v. Riverside Healthcare Sys., LP*, 534 F.3d 1116, 1121 (9th Cir. 2008) (citation omitted). Federal Rule of Civil Procedure 8(a)(2) requires a complaint to contain “a short and plain statement of the claim showing that the pleader is entitled to relief,” in order to “give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.” *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 554 (2007). “This is not an onerous burden.” *Johnson*, 534 F.3d at 1121.

A complaint “does not need detailed factual allegations,” but it must set forth “more than labels and conclusions, and a formulaic recitation of the elements.” *Twombly*, 550 U.S. at 555. The complaint must also contain sufficient factual matter to “state a claim to relief that is plausible on its face.” *Id.* at 570. A claim is plausible “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

In considering a Rule 12(b)(6) motion, the Court must view the complaint in the light most favorable to the claimant and “accept[] all well-pleaded factual allegations as true, as well as any reasonable inference drawn from them.” *Johnson*, 534 F.3d at 1122.

In cases decided after *Iqbal* and *Twombly*, the Ninth Circuit has continued to adhere to the rule that a dismissal of a complaint without leave to amend is inappropriate unless it is beyond doubt that the complaint could not be saved by an amendment. *See Harris v.*

Amgen, Inc., 573 F.3d 728, 737 (9th Cir. 2009).

IV. ANALYSIS

Gore presents three arguments for dismissal. First, Gore argues that the statute of limitations bars Green’s lawsuit. Second, Gore similarly contends that Idaho’s statute of repose prevents Green from suing. Lastly, Gore believes that Green’s Complaint is insufficient under the heightened *Iqbal* and *Twombly* standards for pleading under Rule 8. The Court will address each argument in turn.

A. Statute of Limitations

“A claim may be dismissed under Rule 12(b)(6) on the ground that it is barred by the applicable statute of limitations only when ‘the running of the statute is apparent on the face of the complaint.’” *Von Saher v. Norton Simon Museum of Art at Pasadena*, 592 F.3d 954, 969 (9th Cir.2010) (quoting *Huynh v. Chase Manhattan Bank*, 465 F.3d 992, 997 (9th Cir.2006)). “[I]t is well-settled that statutes of limitations are affirmative defenses, not pleading requirements.” *Wyatt v. Terhune*, 315 F.3d 1108, 1117–18 (9th Cir. 2003). Put differently, “Rule 8 does not require plaintiffs to plead around affirmative defenses.” *U.S. Commodity Futures Trading Comm’n v. Monex Credit Co.*, 931 F.3d 966, 972 (9th Cir. 2019); *see also Lusnak v. Bank of Am., N.A.*, 883 F.3d 1185, 1194 n.6 (9th Cir. 2018) (“Ordinarily, affirmative defenses . . . may not be raised on a motion to dismiss except when the defense raises no disputed issues of fact.”). A court may “consider an affirmative defense on a motion to dismiss when there is some obvious bar to securing relief on the face of the complaint. In other words, dismissal based on an affirmative defense is permitted when *the complaint* establishes the defense.” *U.S. Commodity*, 931 F.3d at 973

(emphasis in original) (internal quotations and citations omitted).

Here, Gore contends that Idaho's statute of limitations for product liability bars Green's Complaint. As the statute of limitations is an affirmative defense, the Court may consider it only if it is obvious from the face of the Complaint that the statute of limitations applies.

Idaho Code sections 6-1403 and 5-219 contain Idaho's statute of limitations for product liability.³ In product liability cases, a plaintiff must bring an action "no more than two (2) years from the time the cause of action accrued." Idaho Code § 6-1403. Generally, accrual occurs at "the time of the occurrence, act or omission complained of." Idaho Code § 5-219(4). However, there is an exception to this general rule. If the action arises out of "the placement and inadvertent, accidental or unintentional leaving of any foreign object in the body," or if the alleged wrongdoer has "fraudulently and knowingly concealed from the injured party" the fact of damage, then a discovery rule of one year also applies. In other words, under either of these two circumstances, accrual occurs "when the injured party knows or in the exercise of reasonable care should have been put on inquiry regarding the condition or matter complained of." *Id.* A plaintiff then must commence an action within two years of the time of occurrence, act or omission complained of (the general rule) or within one year of the discovery of the matter complained of (discovery rule), whichever is later. *Id.*

³ Idaho Code section 6-1403 governs product liability and sets a two (2) year statute of limitations for any such claims. Idaho Code § 6-1403(3). However, section 6-1403 directly refers to section 5-219's explanation of when the cause of action accrues. *Id.*

Here, neither exception applies. First, there are no allegations in the Complaint that Gore—or anybody else for that matter—fraudulently concealed Green’s injuries. Second, this is not the case where a foreign object has been placed *and* inadvertently, accidentally, or unintentionally left in the body. Though the Mesh was implanted and left in Green’s body, this was an intended action. *Stuard v. Jorgenson*, 249 P.3d 1156, 1163 (Idaho 2011) (“[A] medical device which is placed in the body intentionally for the purpose of medical treatment is not a ‘foreign object’ under the statute.”). Thus, there is no exception to the two-year general rule and the one-year discovery rule under the statute of limitations does not apply.

As the one-year discovery rule does not apply, Green must show that she brought her claims within two years of “the time of the occurrence, act or omission complained of.” Idaho Code § 5-291(4). However, the Court’s analysis here is not as cut and dry as it would seem. The Idaho Supreme Court has interpreted this language “flexibly” in an attempt to “avoid absurd results.” *Davis v. Moran*, 735 P.2d 1014, 1019 (Idaho 1987). According to *Davis* and its progeny, despite the plain language of the statute, Idaho’s statute of limitations under section 5-219 does not begin to run until there is “some damage” to the plaintiff which is “objectively ascertainable.” *Stuard*, 249 P.3d at 1160. Though it is tempting to refer to this interpretation as a discovery rule, the Idaho Supreme Court has explicitly rejected this line of thinking. *See id.* (“[T]his Court has made very clear that whether there was some damage, or whether that damage was objectively ascertainable, does not depend upon the knowledge of the injured party because such dependence would effectively create a discovery rule, which the legislature has expressly rejected.”) (internal

quotations omitted).

In clarifying this position, the Idaho Supreme Court emphasized the difference between when a plaintiff should have ascertained the damage based on her subjective symptoms—which would typically trigger the statute of limitations under a discovery rule—and objectively ascertainable damage. *Id.* at 1160–61. (“Stuard seems to equate ‘symptoms’ with ‘damage.’ However, symptoms are by nature subjective, and therefore are not determinative in an ‘objective’ analysis such as the one this Court has stated is the standard for evaluating the accrual of a [Idaho Code section 5-219] claim. . . . To allow for accrual to begin only once the parties have been put on notice of the damage, or in other words, once the damage is actually “ascertained” would effectively create a discovery rule, which the legislature has rejected.”).

This fiat from the Idaho Supreme Court essentially creates a third, middle-ground standard, located somewhere between a strict interpretation of the general rule and the subjective discovery rule. In other words, for purposes of this case, the accrual of Green’s claims does not necessarily begin at the time of the occurrence, act, or omission complained of—September 11, 2006—nor does it accrue when Green knew or should have been put on inquiry of the injury.⁴ Rather, the accrual of Green’s claims began when “some damage” was “objectively ascertainable.” *Id.* at 1160.

The District of Idaho has handled a case with nearly identical facts as are present in

⁴ The caveat, of course, is that if some damage was objectively ascertainable at the time of the occurrence, act, or omission complained of, then the statute of limitations would begin at that time. *Stuard*, 249 P.3d at 1162 (finding the claims accrued—and therefore the statute of limitations began to run—at the time of the plaintiff’s surgery because there was also objectively ascertainable damage at the same time).

this case. *See Chariton v. Ethicon, Inc.*, 2014 WL 7689738 (D. Idaho April 29, 2014). In *Chariton*, a doctor implanted mesh inside the plaintiff during a repair of her hernia in 2007. *Chariton*, 2014 WL 7689738 at *1.⁵ For nearly four years, the plaintiff experienced “abdominal pain, swelling, difficulty walking, and other discomfort.” *Id.* The plaintiff eventually underwent an exploratory laparoscopy on June 11, 2011, during which a doctor removed some of the old mesh from the 2007 surgery and implanted new mesh. *Id.* Some months later, in September 2011, a doctor told her the 2007 mesh was defective and caused her injuries. *Id.* The plaintiff filed suit on August 19, 2013. *Id.* The defendants subsequently filed a motion to dismiss, alleging the plaintiff filed suit after the statute of limitations had run. *Id.*

After discussing Idaho Code section 5-219(4) alongside *Davis*, the *Chariton* court determined the damage was objectively ascertained on June 11, 2011, the date of plaintiff’s exploratory laparoscopy surgery, and thus her complaint was time-barred. *Id.* at *3. In so holding, the *Chariton* court did not rely on the date the plaintiff discovered that the mesh was the likely cause of her injuries, nor did it determine that the nearly four years of pain and suffering the plaintiff experienced was evidence that some damage was objectively ascertainable before June 11, 2011. The Court finds this approach helpful in determining the question before it today.

Here, the Mesh was implanted on September 11, 2006. However, there is no indication in the Complaint that any damage was objectively ascertainable at this time.

⁵ The mesh used in *Chariton* was a different mesh than the one used in this case.

Following the implantation, Green experienced over eleven years of pain, burning, pulling, and swelling. However, just as in *Chariton*, this evidence is subjective in nature, “and therefore . . . not determinative in an objective analysis . . . for evaluating the accrual” of Green’s claims. *Stuard*, 249 P.3d at 1160. Further, as neither of the exceptions of Idaho Code section 5-219(4)—accidentally leaving a foreign object in a body or fraudulently concealing a plaintiff’s damage—apply, the Court cannot utilize the discovery rule, *i.e.* the Court cannot base the accrual of Green’s claims on “when [Green knew] or in the exercise of reasonable care should have been put on inquiry regarding the condition or matter complained of.” *See* Idaho Code § 5-219(4).

Based solely on Green’s Complaint, the date that some damage became objectively reasonable was November 10, 2017, when a CT scan showed damage on or near the internal site of where the Mesh was implanted. There is simply not enough evidence in the Complaint to show that such damage could have been objectively ascertained at an earlier date. As such, because Green filed her Complaint within two years of November 10, 2017, the statute of limitations does not bar her claims.⁶ Thus, the Court will deny the portion of Gore’s Motion to Dismiss regarding the statute of limitations.

That said, the Court will not foreclose the statute of limitations defense entirely. During discovery, should Gore uncover additional facts which show that Green’s injuries could have been objectively ascertained at an earlier date, Gore may again raise the affirmative defense of the statute of limitations. *See Chariton*, 2014 WL 1689738 at *3

⁶ Gore argues that Green was required to bring her claims within one year of the date of the CT scan. However, this argument applies the one-year discovery rule which is not applicable to this case.

(“The establishment of this date is a factual matter under *Davis* that typically cannot be resolved on a motion to dismiss but must await summary judgment proceedings or trial.”).

B. Statute of Repose

In Idaho, similar to a statute of limitations, a statute of repose is “an affirmative defense to liability.” *Oats v. Nissan Motor Corp. in the U.S.A.*, 879 P.2d 1095, 1098 (Idaho 1994). Again, this means the Court should not consider this argument at this stage of the litigation unless it is obvious from the Complaint that Green’s claims are barred. *See U.S. Commodity*, 931 F.3d at 973.

A statute of repose is a cousin to a statute of limitations. Typically, both prevent a suit that is brought after a specified time. As has been discussed, a statute of limitations begins to run upon accrual of the claim, whether that accrual begins at the time of the occurrence complained of or when a reasonable person should have discovered an injury. *See, e.g.*, Idaho Code § 5-219. A statute of repose, however, “is not related to the accrual of any cause of action; the injury need not have occurred, much less have been discovered,” but “begins when a specific event occurs.” 54 C.J.S. Limitations of Actions § 4, at 20–21 (1987).

Idaho’s statute of repose is found in its product liability statute. The statute states that:

Except [when the product seller has expressly warranted the product for a longer period], a product seller shall not be subject to liability to a claimant for harm under this chapter if the product seller proves by a preponderance of the evidence that the harm was caused after the product's “useful safe life” had expired.

“Useful safe life” begins at the time of delivery of the product and extends for the time during which the product would normally be likely to perform or be stored in a safe manner. For the purposes of this chapter, “time of delivery” means the time of delivery of a product to its first purchaser or lessee who was not engaged in the business of either selling such products or using them as component parts of another product to be sold.

.....

(2) Statute of repose.

(a) Generally. In claims that involve harm caused more than ten (10) years after time of delivery, a presumption arises that the harm was caused after the useful safe life had expired. This presumption may only be rebutted by clear and convincing evidence.

Idaho Code § 6-1403.

The language in subsection (2)(a) setting a rebuttable presumption differentiates Idaho’s statute of repose from others. Normally, a statute of response bars a suit completely. *See Fields v. Legacy Health Sys.*, 413 F.3d 943, 952 (9th Cir. 2005) (stating that Oregon’s medical malpractice statute of repose “extinguishes all actions . . . that are not brought within five years”); *Behurst v. Crown Cork & Seal USA, Inc.*, 2007 WL 987452 (D. Oregon Mar. 30, 2007) (stating that under Oregon’s product liability statute of repose, a claim “must be commenced not later than . . . ten years after the date on which the product was first purchased for use or consumption”); *Papasan v. Dometic Corp.*, 2017 WL 4865602 (N.D. Cal. Oct. 27, 2017) (recognizing that Ohio’s statute of repose states “no cause of action based on a product liability claim shall accrue against the manufacturer or supplier of a product later than ten years from the date that the product was delivered to its first purchaser or first lessee”); *Statute of Repose*, Black’s Law Dictionary (11th ed. 2019) (defining “statute of repose” as “[a] statute barring any suit that is brought after a specific

time since the defendant acted”). Idaho’s statute of repose, though, does not bar a suit if not brought within ten years, but creates “a presumption . . . that the harm was caused after the useful safe life had expired.” Idaho Code § 6-1403. Further, a plaintiff may rebut this presumption with clear and convincing evidence. *Id.*

In this case, Idaho’s statute of repose requires evidence beyond the pleadings. Because it is not obvious from the face of Green’s Complaint that Idaho’s statute of repose bars her claims, the Court declines to affirmatively rule on Gore’s affirmative defense of the statute of repose at this time. *See U.S. Commodity*, 931 F.3d at 973.

Further, Idaho’s statute of repose contains an exception clause which might apply. “The ten (10) year period of repose . . . shall not apply if the harm was caused by prolonged exposure to a defective product” Idaho Code § 6-1403(b)(4). Without ruling on whether this exception applies in this case, the Court notes that according to Green’s Complaint, the Mesh was defective, and it caused her harm by virtue of it being in constant contact with her innards for over eleven years. Based on the limited facts in the Complaint, which the court must accept as true, it is plausible that this exception applies in this case. Thus, the Court will deny the portion of Gore’s Motion to Dismiss regarding the statute of repose.

However, just as with Gore’s statute of limitations affirmative defense, the Court will not preclude Gore from utilizing its statute of repose affirmative defense at the summary judgment stage. Should the facts show that the exception to the ten-year period of repose is inapplicable and should Green fail to rebut the presumption that the useful safe life of the Mesh had expired, Gore may raise its arguments again at summary judgment.

C. Sufficiency of Green's Complaint Under *Iqbal*, *Twombly*, and Rule 8

Gore suggests that Green's Complaint "offers nothing more than stock phrases and threadbare conclusions instead of well-pleaded factual allegations" for each of her three causes of action. Dkt. 17-1, at 9. Green disagrees and contends that Federal Rule of Civil Procedure 8(a)(2) requires only notice pleading.

The new pleading standard announced in *Iqbal* and *Twombly* has replaced notice pleading. See *In re Century Aluminum Co. Securities Litigation*, 729 F.3d 1104, 1107 (9th Cir. 2013) ("*Iqbal* and *Twombly* moved us away from a system of pure notice pleading."). "In addition to providing fair notice, the complaint's allegations must now suggest that the claim has at least a plausible chance of success." *Id.* As the Court has already detailed the current pleading standard in Section III of this decision, it will now turn to Green's Complaint.

As an initial matter, Green's complaint is largely composed of very conclusory statements and provides little factual support. Green begins her Complaint with general allegations, wherein she describes the Mesh in medical terms, then states that Gore received "a special 510(k) premarket notification" for the Mesh and was granted "market clearance . . . by the Department of Health & Human Services, Food and Drug Administration ("FDA"), Office of Device Evaluation." Dkt. 2, at 2. Green next alleges that "the FDA later recalled [the Mesh] and suggested removal of the implanted [Mesh] from patients," due to "complaints and complications caused by the [Mesh]," such as "physical pain and suffering; adhesion; intestinal fistulas," and others. *Id.*

Green alleges that she received the Mesh on September 11, 2006, due to an

appendectomy. *Id.* at 3. Green then alleges that “since the time of the [Mesh] implant, Plaintiff experienced excessive pain, burning, pulling and selling from the surgery.” *Id.* Green also states that in 2012 she delivered a baby “normally,” but the baby “mysteriously died nine weeks later,” and that in 2014 she was diagnosed with uterine cancer and received a hysterectomy.” *Id.* Green ends her general allegations by mentioning the CT scan received on November 30, 2017, and the subsequent removal of the mesh on January 30, 2018. *Id.*

Gore denies that the FDA ever recalled the Mesh or that it suggested its removal from patients. For support, Gore submits “a list of all recalled hernia mesh products from 2004 to current showing that Gore has never recalled its MESH or other hernia mesh devices” as an exhibit. Dkt. 17-1, at 4. Gore urges the Court to take judicial notice of the exhibit, arguing that it is a public record, and suggests the Court may do so without converting its Motion to Dismiss into a motion for summary judgment.

Typically, Rule 12(b)(6) limits a courts review to the contents of the complaint; otherwise, the 12(b)(6) motion must be treated as one for summary judgment. *See Keams v. Tempe Tech. Inst., Inc.*, 110 F.3d 44, 46 (9th Cir. 1997). However, courts may “consider certain materials—documents attached to the complaint, documents incorporated by reference in the complaint, or matters of judicial notice—without converting the motion to dismiss into a motion for summary judgment.” *United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003).

Federal Rule of Evidence 201 “permits a court to take judicial notice of undisputed “matters of public record.” *Lee v. City of Los Angeles*, 250 F.3d 668, 688–89 (9th Cir.

2001). However, a court may not take judicial notice of a public record for the truth of the facts it contains, but simply for the existence of the document. *Id.* at 690. “Indeed, factual challenges to a plaintiff’s complaint have no bearing on the legal sufficiency of the allegations under Rule 12(b)(6).” *Id.* at 688. Accordingly, judicial notice is appropriate only when the matter is established “beyond reasonable controversy.” *Id.* at 690.

In reviewing Gore’s exhibit, the Court is unable to identify any information that establishes Gore’s allegation that it never recalled its Mesh beyond reasonable controversy. The exhibit contains numerous pages of screen printouts, purportedly taken from the FDA’s website. Dkt. 17-3, at 2–6. Gore provides no authority suggesting that a screen print-out from a website qualifies as a public record. Additionally, Green clearly disputes that the Mesh was recalled. As such, the Court declines to take judicial notice of Gore’s exhibit. *See Lee*, 250 F.3d at 690 (finding the district court erred “by taking judicial notice of disputed matters of fact to support its ruling”).

The Court now turns to each of Green’s causes of action.

1. Strict Liability

Green’s first cause of action is for “strict liability.” Dkt. 2, at 4. “Generally speaking, there are three general categories of strict liability in product liability cases—manufacturing flaws, design defects, or failure to warn.” *Wilson v. Amneal Pharm., L.L.C.*, 2013 WL 6909930, at *7 (D. Idaho Dec. 31, 2013) (citing *Toner v. Lederle Labs.*, 732 P.2d 297, 306 (Idaho 1987)). To establish a case for strict liability based on any of the three available theories, “a plaintiff must establish that (1) the product in question was defective, (2) the defect existed at the time the product left the manufacturer’s control, and (3) that

the defective product was the proximate cause of the plaintiff's injuries." *Puckett v. Oakfabco, Inc.*, 979 P.2d 1174, 1179 (Idaho 1998). "Regardless of the theory under which recovery is sought in a products liability action, a plaintiff must establish that the injury is causally related to defendant's act or omission." *Watson v. Navistar Int'l Transp. Corp.*, 827 P.2d 656, 674 (Idaho 1992).

Green has not specified whether she is bringing her first cause of action under a manufacturing flaw theory or a design defect theory.⁷ Nevertheless, the Court will proceed with analysis on this claim.⁸ Although Idaho courts recognize both "manufacturing flaws" and "design defects" as product liability theories, Idaho courts have also clarified that "[t]here is no rational distinction between [the] design and manufacture" theories. *Rindlisbaker v. Wilson*, 519 P.2d 421 (Idaho 1974).

In addition to arguing that Green has insufficiently pled this claim, Gore suggests that Green's operating physician altered the Mesh, thus breaking "the chain of causation between any alleged defect and her alleged injury." Dkt. 17-1, at 10.

"'Alteration or modification' occurs when a person or entity other than the product seller changes the design, construction, or formula of the product" Idaho Code § 6-1405(4). Whether there was an alteration is "a jury question, unless the court is able to rule

⁷ As Green's second cause of action is for "Strict Products Liability: Failure to Warn," the Court does not consider failure to warn as one of the potential theories for Green's first cause of action.

⁸ Though there is precedent for dismissing a claim for "strict product liability" because it "is not considered a separate cause of action," *Wilson*, 2013 WL 6909930, at *8 (citing *Toner*, 732 P.2d at 306), the Court must construe the pleadings liberally and afford Green the benefit of any doubt. *Bretz v. Kelman*, 773 F.2d 1026, 1027 n.1 (9th Cir 1985) (en banc).

as a matter of law that the facts are undisputed and lead to but one reasonable conclusion.” *Tuttle v. Sudenga Industries, Inc.*, 868 P.2d 473, 477 (Idaho 1994). The Court here is unable to do so. Green’s Complaint contains an operative note, on which is written “[w]e customized tailored a gortex dual mesh truss to overlap [the hernia] by 3cm circumferentially.” Dkt. 2, at 10. In a light most favorable to Green, this is not conclusive evidence of the surgeon or hospital staff changing the design, construction, or formula of the Mesh. Instead, it appears that somebody on the medical team simply cut the Mesh so it would properly fit in its desired location.

Even if this were considered an alteration, though, such an act would not break the chain of causation as Gore suggests. In its briefing, Gore cites to *Tuttle*, stating “A third party who substantially alters a product breaks the chain of causation.” Dkt. 17-1, at 10. This statement cherry picks language from *Tuttle* while ignoring its holding. The language in *Tuttle* that Gore cites to actually states “[p]resuming that strict product liability does not attach if the product is substantially altered because such alteration breaks the chain of causation, the district court ruled that the alteration of the auger covers was substantial and therefore constituted the proximate cause of Tuttle’s injury.” *Tuttle*, 868 P.2d at 476. However, two sentences later, the *Tuttle* court goes on to say that this “analysis conducted by the district court and its summary disposition of this case was incorrect” *Id.* The court continues by explaining that an alteration does not break the chain of causation, but instead “reduce[s] the claimant’s damages.” *Id.* at 477. Thus, that somebody “custom tailored a gortex dual mesh,” even if considered an alteration, does not bar Green’s Complaint at this stage of the litigation.

Returning to the sufficiency of Green’s first cause of action, Green fails to allege any additional facts to support her claims and instead relies completely on conclusory statements. For example, Green states Gore placed the Mesh “into the stream of commerce in a defective and unreasonably dangerous condition.” Dkt. 2, at 4. Noticeably absent, though, are facts to support Green’s conclusions. Specifically, there is no identification or description in the Complaint of the alleged defect. Green alleges that the Mesh was recalled because it caused physical pain, scarring, and other unpleasantries, yet fails to tie these symptoms to any defect in the Mesh itself. Additionally, and perhaps more importantly, Green does not allege how the supposed defect caused any of the pain or other damages *she* suffered.

It appears Green concludes that, because the Mesh and the pain were present at the same spot, and because the Mesh had been previously recalled,⁹ the Mesh was defective and caused her injuries. This is not enough to “allow[] the court to draw the reasonable inference that [Gore] is liable for the misconduct alleged.” *Iqbal*, 556 U.S. at 678. As it currently reads, the Complaint suggest that the Mesh is a potential cause of the injuries but stops short of the plausibility line. Though Green might have a colorable claim, her Complaint needs more factual support to clear the hurdle set by Rule 8.

2. Strict Product Liability: Failure to Warn

Here, Green’s second cause of action is starkly similar to her first one. Again, Green fails to allege how the Mesh was defective or dangerous. Green also fails to identify exactly

⁹ Again, Gore disputes that the Mesh was ever recalled.

how Gore failed to warn consumers, or how Gore's failure to warn caused her injuries. Instead, Green simply states that there were "inadequate warning and/or [in]adequate clinical trials, *in vivo* and *in vitro* testing and study, and inadequate reporting regarding the results" without identifying any information concerning the warnings, trials, testing, studies, and reports, either concerning what was done or what should have been done. *See* Dkt. 2, at 6. Just as with her first cause of action, these conclusory allegations, without any factual support suggesting defect or causation, are likewise insufficient.

3. *Negligence*

Under her negligence claim, Green sets forth the elements of a common negligence claim, to wit: (1) duty; (2) breach of that duty; (3) causation; and (4) damage. Dkt. 2, at 7. However, Green fails to cite any case applying the elements of common negligence to a negligence claim involving product liability. This is important as a negligence claim involving product liability requires a plaintiff to meet the same elements as a strict product liability claim; that is "1) . . . she was injured by the product, 2) the injury was the result of a defective or unsafe product, and 3) that a defect existed when the product left the control of the manufacturer." *Watson*, 827 P.2d at 674.

The language in Green's negligence cause of action suggests that Green is relying on product liability as a theory for Gore's negligence. Specifically, she states that Gore breached its duty by "producing a substandard, defective and unsafe [Mesh] with design or manufacturing defects." Dkt. 2, at 7. Thus, the Court will treat Green's claim for negligence as a product liability action based on negligence and not a common negligence claim. *See Hepburn*, 2018 WL 2275219, at *7 (D. Idaho May 17, 2018) (finding a claim for common

negligence must be treated as a product liability action based on negligence when the plaintiff based the claim off a defective product).

Regardless, Green has not provided adequate facts to support a claim for product liability based on negligence.¹⁰ The entirety of Green's negligence cause of action states:

Plaintiff reaffirms and realleges all proceeding paragraphs, as if fully set forth herein. Defendants owed a duty to Plaintiff to provide a Hernia Mesh in accordance with applicable industry and manufacturing standards. Defendants breached this duty to Plaintiff by producing a substandard, defective and unsafe Hernia Mesh with design or manufacturing defects. As a direct and proximate result of the negligence of Defendants, the Plaintiff was physically and emotionally damaged. Plaintiff prays for judgment against Defendants, jointly and severally, for Ten Million Dollars (\$10,000,000) compensatory damages, plus interest, costs and attorneys' fees.

Dkt. 2, at 7. In short, Green again relies solely on the fact that the Mesh and the injury occurred at the same site during the relevant timeframe to support her claim. Green still fails to allege how or why the Mesh was defective or how the Mesh caused her injuries. This pleading does not meet the standards set by Rule 8, *Iqbal*, and *Twombly*.

To summarize, Green's Complaint does not meet the current pleading standards. Specifically, Green does not allege any facts showing in what manner the Mesh was defective or how the Mesh caused her injuries. Thus, the Court will GRANT Gore's Motion to Dismiss.

D. Leave to Amend

Leave to amend pleadings shall be freely given when justice so requires. Fed. R.

¹⁰ Even if the Court were to treat Green's claim as one for common negligence, the Court still finds it lacking the necessary factual support.

Civ. P. 15(a). Courts apply Rule 15 with extreme liberality. *Eminence Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1051 (9th Cir. 2003) (citations omitted). In determining whether to grant leave to amend, the court generally considers five factors: (1) undue delay; (2) bad faith; (3) futility of amendment; (4) prejudice to the opposing party; and (5) whether the plaintiff has previously amended the complaint. *United States v. Corinthian Colls.*, 655 F.3d 984, 995 (9th Cir. 2011) (citation omitted). These factors are not weighted equally: futility of amendment alone can justify the denial of a motion to amend. *Ahlmeyer v. Nev. Sys. of Higher Educ.*, 555 F.3d 1051, 1055 (9th Cir. 2009).

Here, Green may have a colorable case against Gore if she can provide more factual support. Thus, the Court will dismiss Green's claims without prejudice and grant her leave to amend her Complaint. Green must submit an amended complaint within 30 days of the date of this decision.

V. CONCLUSION

Gore's statute of limitations and statute of repose affirmative defenses are not appropriate on a motion to dismiss because they require the Court to consider only Green's Complaint, and Green's Complaint does not provide sufficient information that would allow the Court to grant them at this time. These arguments are more suited for summary judgment. However, Green fails to meet the pleading standards under Rule 8, *Iqbal*, and *Twombly* due to the lack of factual support for her overly conclusory Complaint. Thus, the Court will GRANT Gore's Motion to Dismiss and DISMISS Green's Complaint WITHOUT PREJUDICE.

VI. ORDER

IT IS HEREBY ORDERED THAT:

1. Gore's Motion to Dismiss (Dkt. 17) is GRANTED. Green's claims are DISMISSED WITHOUT PREJUDICE. Green may file an amended complaint within thirty (30) days of the date of this order. Failure to do so could result in the Court dismissing this case with prejudice.



DATED: April 3, 2020



David C. Nye
Chief U.S. District Court Judge