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6 **IN THE UNITED STATES DISTRICT COURT**
7 **FOR THE DISTRICT OF ARIZONA**
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9 Janine Dehart,

10 Plaintiff,

11 v.

12 Johnson & Johnson, et al.,

13 Defendants.
14

No. CV-20-02493-PHX-DWL

ORDER

15 On September 27, 2021, the Court issued a lengthy order addressing Defendants’
16 motion to dismiss the First Amended Complaint (“FAC”). (Doc. 25.) The Court concluded
17 that six counts of the FAC—the claims for negligence, strict liability-manufacturing defect,
18 breach of express warranty, strict liability-breach of implied warranty, constructive fraud,
19 and negligent infliction of emotional distress—were subject to dismissal and determined
20 that Plaintiff should be granted leave to amend as to five of the dismissed counts. (*Id.*)

21 Following the issuance of this order, Plaintiff filed the Second Amended Complaint
22 (“SAC”). (Doc. 26.) In the SAC, Plaintiff reasserts the five dismissed claims as to which
23 she was granted leave to amend and offers various new factual allegations intended to cure
24 the deficiencies identified in the previous order. (*Id.*) In response, Defendants moved to
25 dismiss the five reasserted counts. (Doc. 27.) The motion is now fully briefed. (Docs. 29,
26 30.)¹ For the following reasons, the motion is granted in part and denied in part.

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28 ¹ Defendants’ request for oral argument is denied because the issues are fully briefed and argument would not aid the decisional process. *See* LRCiv 7.2(f).

1 **DISCUSSION**

2 I. Legal Standard

3 “[T]o survive a motion to dismiss under Rule 12(b)(6), a party must allege
4 ‘sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its
5 face.’” *In re Fitness Holdings Int’l, Inc.*, 714 F.3d 1141, 1144 (9th Cir. 2013) (quoting
6 *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). “A claim has facial plausibility when the
7 plaintiff pleads factual content that allows the court to draw the reasonable inference that
8 the defendant is liable for the misconduct alleged.” *Id.* (quoting *Iqbal*, 556 U.S. at 678).
9 “[A]ll well-pleaded allegations of material fact in the complaint are accepted as true and
10 are construed in the light most favorable to the non-moving party.” *Id.* at 1444-45 (citation
11 omitted). However, the court need not accept legal conclusions couched as factual
12 allegations. *Iqbal*, 556 U.S. at 679-680. Moreover, “[t]hreadbare recitals of the elements
13 of a cause of action, supported by mere conclusory statements, do not suffice.” *Id.* at 679.
14 The court also may dismiss due to “a lack of a cognizable theory.” *Mollett v. Netflix, Inc.*,
15 795 F.3d 1062, 1065 (9th Cir. 2015) (citation omitted).

16 II. Analysis

17 A. **Strict Liability-Manufacturing Defect**

18 In the September 27, 2021 order, the Court dismissed Plaintiff’s claim for strict
19 liability-manufacturing because the factual allegations in the FAC were “too conclusory.”
20 (Doc. 25 at 7.) Specifically, the Court explained that although the FAC asserted that “[t]he
21 TVT-S product implanted in the Plaintiff . . . deviated materially from Defendants’ design
22 and manufacturing specifications in such a manner as to pose unreasonable risks of serious
23 bodily harm to the Plaintiff,” this allegation was “deficient because it doesn’t explain *why*
24 there was a deviation—it doesn’t, for example, identify the design and manufacturing
25 specifications that Defendants were supposed to follow and then identify a specific way in
26 which the device that was implanted in [Plaintiff] deviated from those standards.” (*Id.*)
27 The Court also rejected Plaintiff’s position that it is unnecessary for a plaintiff asserting a
28 manufacturing defect claim to provide non-conclusory allegations at the pleading stage,

1 concluding that such an approach was foreclosed by *Iqbal* and its progeny. (*Id.*)

2 In the SAC, Plaintiff reasserts a claim for strict liability-manufacturing defect.
3 (Doc. 26 ¶¶ 127-38.) In support of this claim, the SAC adds an allegation that “[t]he TVT-
4 S that was implanted in Plaintiff was manufactured in a manner that deviated materially
5 from Defendants’ design specifications. Specifically and upon information and belief, the
6 TVT-S that was implanted in Plaintiff was cut in such a manner creating unintended sharp
7 edges in this product which, in turn caused the mesh erosion Plaintiff experienced in March
8 of 2019.” (Doc. 26-1 at 54-55.)

9 Defendants argue that the manufacturing defect claim remains deficient because
10 Plaintiff still “does not identify how [her] TVT-S deviated from Defendants’ design and
11 manufacturing specifications.” (Doc. 27 at 2-6.) As for the new allegation regarding
12 “unintended sharp edges,” Defendants contend that (1) Plaintiff “does not allege what the
13 design specifications called for in terms of the cutting of the mesh and how, specifically,
14 [Defendants] deviated from those specifications when [they] cut the mesh in her TVT-S”;
15 and (2) any allegation of *unintended* sharp edges would be inconsistent with the allegation
16 elsewhere in the SAC that the design of the device was defective *because* it called for sharp
17 edges. (*Id.* at 4, citing Doc. 26 ¶¶ 88, 152.) Finally, Defendants note that, during oral
18 argument on a motion to dismiss in a similar case in the Eastern District of Michigan in
19 August 2021, Plaintiff’s counsel conceded that he is unaware of any facts that might
20 support a manufacturing defect claim. (*Id.* at 5.)

21 In response, Plaintiff begins by reiterating her position (which the Court rejected in
22 the previous order) that it is unnecessary for a plaintiff asserting a manufacturing defect
23 claim to provide non-conclusory allegations in support of that claim at the pleading stage.
24 (Doc. 29 at 3-5.) Next, Plaintiff asserts that her “allegation that the TVT’s design deviated
25 from its intended specifications by using non-medical grade material is sufficient to state a
26 manufacturing defect claim.” (*Id.* at 5.) Finally, Plaintiff argues that the case from the
27 Eastern District of Michigan actually supports her position because the court in that case
28 “would likely grant a motion for leave to amend that complaint at the close of discovery if

1 the facts warrant [a manufacturing defect] claim.” (*Id.* at 5-6.)

2 In reply, Defendants argue that Plaintiff’s legal arguments are based on “the exact
3 same out-of-Circuit authorities that she cited in response to the” previous motion to
4 dismiss; note that the allegation regarding “using non-medical grade material” was present
5 in the FAC and the sufficiency of that allegation was already rejected; identify a recent
6 decision, *Harju v. Johnson and Johnson*, 2021 WL 3929232 (W.D. Wash. 2021), in which
7 similar allegations were found insufficient to support a manufacturing defect claim; and
8 assert that the Eastern District of Michigan case supports dismissal of this claim at this
9 time. (Doc. 30 at 1-3.)

10 The new factual allegations in the SAC are sufficient to remedy the deficiencies
11 identified in the September 27, 2021 order. Unlike the previous iteration of the complaint,
12 the SAC now alleges, with particularity, how the TVT-S product implanted in Plaintiff
13 deviated from Defendants’ design and manufacturing specifications—because it was “cut
14 in such a manner” that it had “unintended” sharp edges. Although Plaintiff puzzlingly
15 makes no effort to discuss the sufficiency of this new allegation in her response to the
16 motion to dismiss—she instead focuses on other issues and allegations—the Court
17 concludes that it plausibly alleges the existence of a manufacturing defect. *See generally*
18 *Harduvel v. Gen. Dynamics Corp.*, 878 F.2d 1311, 1317 (11th Cir. 1989) (“Th[e]
19 distinction between ‘aberrational’ defects and defects occurring throughout an entire line
20 of products is frequently used in tort law to separate defects of manufacture from those of
21 design. Stated another way, the distinction is between an unintended configuration, and an
22 intended configuration that may produce unintended and unwanted results.”) (citation
23 omitted).²

24 ² The Court acknowledges that other courts have construed the allegation of
25 “unintended sharp edges” in similar products as an allegation of a design defect rather than
26 a manufacturing defect. *Wells v. Johnson & Johnson*, 2021 WL 3578191, *2 (W.D. Okla.
27 2021) (dismissing manufacturing defect claim in similar case because the allegation “that
28 cutting the products creates unintended sharp edges” is ultimately an allegation of “a defect
in Gynemesh’s *design*, not in the manufacturing of the specific Gynemesh causing
Plaintiff’s injury”). But here, the SAC does not merely allege that the sharp edges
themselves were “unintended”—an allegation that, on its own, is somewhat ambiguous as
to whether the unintended result flowed from the manufacturing process or the design
process—but goes further and alleges that this unintended result flowed from how the

1 Defendants' arguments to the contrary are unavailing. Although the SAC does not
2 offer a detailed technical discussion of Defendants' design and manufacturing
3 specifications, the Court is not persuaded that such a fine level of pleading detail is
4 necessary to survive a motion to dismiss. *Iqbal*, 556 U.S. at 677-78 (“[T]he pleading
5 standard Rule 8 announces does not require ‘detailed factual allegations,’ but it demands
6 more than an unadorned, the-defendant-unlawfully-harmed-me accusation.”) (citation
7 omitted). True, the September 27, 2021 order faulted Plaintiff for not identifying “the
8 design and manufacturing specifications that Defendants were supposed to follow” (Doc.
9 25 at 7), but Plaintiff has now adequately done so by alleging that her product had
10 unintended sharp edges and was the product of cutting errors. Such allegations identify, at
11 least implicitly, the aspects of Defendants' design and manufacturing specifications on
12 which Plaintiff's manufacturing defect claim is based.

13 As for Defendants' contention that Plaintiff's manufacturing defect theory is
14 inconsistent with her design defect theory, this may be true but Defendants do not explain
15 why such inconsistency requires dismissal at this stage of the case. *Lacey v. Maricopa*
16 *Cty.*, 693 F.3d 896, 918 n.10 (9th Cir. 2012) (en banc) (“We note that the
17 complaint pleads alternative facts This is permissible.”).

18 As for the proceedings in the Eastern District of Michigan, Defendants fail to
19 explain why Plaintiff should be bound by her counsel's statements in a different case in
20 which she was not a party. At any rate, although Plaintiff's counsel may not have been
21 able to articulate a plausible manufacturing defect theory at the time of that hearing in
22 August 2021, Plaintiff's counsel *was* able to articulate such a theory when filing the SAC
23 in this case in October 2021, and the sufficiency of the SAC is all that matters now.

24 Finally, *Harju* sheds no light on the current controversy because it only addresses
25 the sufficiency of the “use of non-medical grade material” allegation that appeared in the
26 FAC, not the new “unintended sharp edges” allegation that appears in the SAC.

27 Defendants' request to dismiss the manufacturing defect claim is denied.

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particular product was “cut.” This allegation bears directly on the manufacturing process.

1 **B. Negligence**

2 In the September 27, 2021 order, the Court dismissed Plaintiff’s negligence claim
3 because it was duplicative of her strict liability claims. (Doc. 25 at 10-15.) The Court
4 acknowledged “that a finding of redundancy may not be warranted” in one specific
5 circumstance—where a plaintiff seeks to assert both a negligence claim and a strict liability
6 claim based on a manufacturing defect theory—but concluded that Plaintiff couldn’t avail
7 herself of this potential exception because it had “already determined that [Plaintiff’s]
8 manufacturing defect claim is subject to dismissal.” (*Id.* at 13.)

9 In the SAC, Plaintiff reasserts a negligence claim. (Doc. 26 ¶¶ 77-116.) In support
10 of this claim, the SAC adds various new factual allegations, including allegations regarding
11 Defendants’ failure to engage in product testing. (Doc. 26-1 at 35-44.)

12 Defendants argue that Plaintiff’s negligence claim must be dismissed because it
13 remains “redundant of her strict liability claims.” (Doc. 27 at 6-9.) As for the new testing-
14 related allegations, Defendants argue they do nothing to cure the redundancy problem
15 because “if Plaintiff’s injuries were linked to a failure by Defendants to test the TVT-S,
16 then that testing would have revealed either a manufacturing defect, a design defect, or a
17 warnings/marketing defect—the three recognized product liability theories.” (*Id.* at 8.)
18 Alternatively, Defendants argue that the new testing-related allegations are conclusory
19 because “Plaintiff does not allege what the standard of care called for in terms of testing,
20 what level of testing that Defendants performed, how that level of testing deviated from
21 the standard of care, or how any alleged deviation caused her injuries.” (*Id.* at 9.)

22 In response, Plaintiff begins by reiterating the same arguments regarding
23 redundancy that she advanced (and the Court rejected) in her response to the previous
24 motion to dismiss. (Doc. 29 at 6-8.) Plaintiff then argues that her new testing-related
25 allegations should be deemed sufficient to avoid a finding of redundancy because
26 “[n]egligent testing is a viable theory under Arizona law” and “Plaintiff should not be
27 prohibited or limited in her evidence based on Defendants’ attempt by way of this Motion
28 to parse [her] negligence claim into minutia.” (*Id.* at 8-9.)

1 In reply, Defendants clarify that they aren't seeking to prevent Plaintiff from
2 presenting testing-related evidence and arguments at trial—they are simply arguing that
3 such allegations form “part of her design defect and failure to warn claims.” (Doc. 30 at
4 3-4.) Defendants also note that Plaintiff failed to respond to their “alternative argument
5 that she does not plead any facts that could plausibly support any [testing-related] theories.”
6 (*Id.* at 4-5.)

7 On the one hand, Defendants are correct that the presence of the new testing-related
8 allegations in the SAC does nothing to alter the redundancy analysis—Plaintiff appears to
9 be under the misimpression that such allegations may only be pursued as part of a
10 negligence claim, but the relevant authorities hold otherwise. Restatement (Third) of Torts
11 § 2, cmt. n (“[E]vidence that the defendant did or did not conduct adequately reasonable
12 research or testing before marketing the product may be admissible (but is not necessarily
13 required) regardless of whether the claim is based on negligence, strict liability, or implied
14 warranty of merchantability.”).

15 On the other hand, in the September 27, 2021 order, the Court recognized that
16 Plaintiff's negligence claim would cease being redundant of her strict liability claims if she
17 were able to articulate a plausible strict liability claim premised on a manufacturing defect
18 theory. (Doc. 25 at 13.) Because Plaintiff has now done so, it follows that her negligence
19 claim is no longer subject to dismissal on redundancy grounds.

20 Defendants' request to dismiss the manufacturing defect claim is denied.

21 C. **Negligent Infliction of Emotional Distress**

22 In the September 27, 2021 order, the Court dismissed Plaintiff's claim for negligent
23 infliction of emotional distress (“NIED”) because the factual allegations in the FAC failed
24 to “establish that [Plaintiff] sustained the sort of physical injury, long-term physical illness,
25 or mental disturbance required by Arizona NIED law.” (Doc. 25 at 15-16.)

26 In the SAC, Plaintiff reasserts an NIED claim. (Doc. 26 ¶¶ 274-89.) In support of
27 this claim, the SAC adds the following new factual allegations:

- 28 ▪ “After Plaintiff's TVT-S mesh eroded and was partially removed in 2019,

1 Plaintiff experienced constant fear, stress and anxiety since she knows mesh
2 from this device remains inside her body.” (Doc. 26-1 at 98.)

- 3 ▪ “The constant fear, stress and anxiety Plaintiff experiences with knowledge
4 that the TVT-S mesh could erode again, necessitating revision surgeries, has
5 caused her pain and suffering.” (*Id.*)
- 6 ▪ “Furthermore, since Defendants withdrew the TVT-S from the U.S.
7 marketplace allegedly because the complication rates were high and there
8 was no medical literature supporting the device’s safety and efficacy,
9 Plaintiff remains in constant fear since there is a problematic or unsafe and
10 ineffective device that remains inside her body that could cause chronic
11 injuries, some of which she already experienced.” (*Id.* at 99.)
- 12 ▪ “Plaintiff’s manifestations of fear, stress and anxiety have affected her to the
13 extent that she experiences constant pain and other injuries associated with
14 the TVT-S device.” (*Id.*)

15 Defendants argue that Plaintiff’s NIED claim remains subject to dismissal because
16 the “SAC does not contain any new facts that would show [Plaintiff] has sustained severe
17 emotional distress,” noting that although “Plaintiff alleges that she has experienced
18 ‘constant fear, stress, and anxiety’ which have manifested into ‘constant pain and other
19 injuries associated with the TVT-S device,’” the SAC fails to allege “that Plaintiff has
20 sought professional help for any alleged emotional injuries.” (Doc. 27 at 9-10.)

21 In response, Plaintiff argues that her claim should be deemed sufficient because she
22 has “alleged physical harm and long-standing emotional disturbance.” (Doc. 29 at 9-10.)
23 Plaintiff further contends that “[t]he Court is not bound to Defendants’ manufactured
24 pleading standard that they insist should be followed.” (*Id.*)

25 In reply, Defendants emphasize that “Plaintiff does not deny that her SAC does not
26 even allege that she has received any professional counseling or treatment for any alleged
27 emotional injuries” and characterize the SAC’s new factual allegations as “naked assertions
28 devoid of further factual enhancement.” (Doc. 30 at 4-5.)

1 The Court concludes, with the benefit of hindsight, that it should not have dismissed
2 the NIED claim from the previous iteration of Plaintiff’s complaint and further concludes
3 that the NIED claim in the SAC survives dismissal.

4 As discussed in the September 27, 2021 order, the rule in Arizona is that when an
5 NIED plaintiff seeks recovery for an emotional injury *unaccompanied by a physical injury*,
6 the plaintiff must show that the emotional injury eventually resulted in some form of
7 “bodily harm,” such as “a physical injury” or “a long-term physical illness or mental
8 disturbance.” *Monaco v. HealthPartners of S. Arizona*, 995 P.2d 735, 739 (Ariz. Ct. App.
9 1999).³ There are many Arizona decisions addressing the sort of evidence that is necessary
10 to sustain an NIED claim in this situation.

11 For example, in *Monaco*, the plaintiff alleged that his doctor erroneously
12 administered a medicine containing “a radioactive substance,” which in turn caused him to
13 “not stop thinking he might contract cancer.” *Id.* at 737. This anxiety was so severe that
14 the plaintiff was eventually diagnosed with post-traumatic stress disorder and had to
15 receive anger counseling from one doctor and anxiety counseling from a different doctor.
16 *Id.* at 739. Under those facts, the court rejected a sufficiency-of-the-evidence challenge
17 because the plaintiff had sustained “substantial, long-term emotional disturbances
18 sufficient to support the claim for negligent infliction of emotional distress.” *Id.*

19 In contrast, in *Burns v. Jaquays Min. Corp.*, 752 P.2d 28 (Ariz. Ct. App. 1987), and
20 *DeStories v. City of Phoenix*, 744 P.2d 705 (Ariz. Ct. App. 1987), courts sustained

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22 ³ This is also the scenario addressed in § 436A of the Restatement (Second) of Torts,
23 which explains that “[i]f the actor’s conduct is negligent as creating an unreasonable risk
24 of causing either bodily harm or emotional disturbance to another, *and it results in such*
25 *emotional disturbance alone, without bodily harm* or other compensable damage, the actor
26 is not liable for such emotional disturbance.” *Id.* (emphasis added). Similarly, the
27 illustration provided in § 436A involves a situation in which a defendant “negligently
28 manufactures” a food product containing broken glass; the plaintiff “upon eating it finds
her mouth full of glass” but “is not cut or otherwise physically injured, and she succeeds
in removing the glass without bodily harm”; and the plaintiff “is frightened at the
possibility that she may have swallowed some of the glass,” which “results in nausea and
nervousness lasting for one day, and in inability to sleep that night, but in no other harm.”
Id. Although the manufacturer “is not liable” to the plaintiff in that situation, *id.*, the
illustration in § 436A does not address the parameters of liability when (as in this case) the
plaintiff suffers direct physical injury from the product in addition to an alleged emotional
injury.

1 sufficiency-of-the-evidence challenges to similar claims. In *Burns*, the plaintiffs developed
2 a “fear of contracting asbestos-related diseases in the future” after being exposed to
3 asbestos fibers that were emitted from a mill on the defendant’s property. 752 P.2d at 30-
4 31. Although the plaintiffs submitted medical evidence that some of them “suffered severe
5 and clinically significant mental distress as a consequence of the asbestos situation” and
6 that this mental distress manifested itself in “psychosomatic injuries” such as “headaches,
7 acid indigestion, weeping, muscle spasms, depression and insomnia,” the court concluded
8 that such “transitory physical phenomena” were “not the type of bodily harm which would
9 sustain a cause of action for emotional distress.” *Id.* at 32. Similarly, in *DeStories*, the
10 plaintiffs “were exposed to airborne asbestos dust” while working at the Phoenix airport.
11 744 P.2d at 706. Although the plaintiffs asserted that they sustained “reasonably
12 foreseeable mental anguish” arising from “cancer-phobia,” the court rejected their claims
13 as a matter of law because they “adduced no evidence tending to establish the existence of
14 any physical harm or medically identifiable effect from their exposure to asbestos or their
15 associated emotional distress.” *Id.* at 709-11.⁴

16 In the September 27, 2021 order, the Court construed Plaintiff’s NIED claim as
17 resembling the sort of claim at issue in *Monaco*, *Burns*, and *DeStories*—that is, a claim
18 based solely on the fear of contracting a future illness—and concluded that the allegations
19 in the FAC were insufficient to support such a claim because Plaintiff failed to provide
20 non-conclusory allegations concerning the nature and substantiality of her emotional
21 distress and whether it ultimately manifested as bodily harm. Upon reflection, however,
22 the Court recognizes that Plaintiff is not merely alleging that she suffered emotional harm
23 as a result of Defendants’ conduct. In paragraph 4 of the SAC, Plaintiff alleges that she
24 has already suffered a direct physical injury as a result of Defendants’ conduct—
25 specifically, “mesh implant complications necessitating removal, pelvic and rectal pain,

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27 ⁴ See also *Gau v. Smitty’s Super Valu, Inc.*, 901 P.2d 455, 457 (Ariz. Ct. App. 1995)
28 (rejecting NIED claim, where a four-year-old child suffered “transitory nightmares and
sleep disturbance” after his mother was falsely accused of shoplifting and the mother and
child were detained and separated, because the child “suffered no physical injury” and the
emotional injuries “subsided without medical treatment”).

1 dyspareunia, vaginal discharge, difficulty voiding, [and] worsening stress urinary
2 incontinence.” (Doc. 26 ¶ 4.) Given the presence of these allegations, Plaintiff’s ability to
3 seek recovery for emotional injuries is not contingent on a showing that those injuries
4 separately caused her to suffer bodily harm. *See, e.g., Felder v. Physiotherapy Associates*,
5 158 P.3d 877, 888-89 (Ariz. Ct. App. 2007) (“[Defendant] argues that there was
6 insufficient evidence to support the anxiety claim. In support of its argument, [Defendant]
7 cites [*DeStories*], in which the plaintiff sought to recover damages for emotional harm
8 absent any physical injury, based on plaintiff’s increased risk of contracting asbestosis or
9 lung cancer. Because Felder has suffered physical injuries, including an orbital bone
10 fracture, ruptured retinal tissue, subretinal hemorrhaging, and other injuries to his eye, we
11 find *DeStories* inapposite. . . . Because Felder suffered serious physical harm, he is able to
12 recover for his anxiety over his less than 1% chance of neovascularization.”). *See generally*
13 Erica Goldberg, *Emotional Duties*, 47 Conn. L. Rev. 809, 822-23 (2015) (“If a plaintiff
14 demonstrates bodily injury or the invasion of certain other types of interests, he can be
15 awarded the full extent of his psychological injuries without being subject to any
16 heightened substantive standards, which are necessary when asserting purely emotional
17 claims. Examples of damages given for pain and suffering ‘parasitic’ to physical injury
18 include emotional damage awards based on . . . compensation for fear of developing cancer
19 when the plaintiff suffered a physical injury leading to that fear These parasitic
20 damages do not concern courts in the same way as stand-alone emotional claims, perhaps
21 because courts are less concerned that parasitic emotional claims are fraudulent”)
22 (citations omitted).

23 Put another way, the rule in Arizona is that “there can be no recovery for mental
24 disturbance *unless* physical injury, illness or other physical consequence accompany it, *or*
25 physical harm develops as a result of the plaintiff’s emotional distress.” 744 P.2d at 709
26 (emphases added). Here, there is no need to proceed to the second part of this test (which
27 was at issue in *Monaco*, *Burns*, and *DeStories*) because Plaintiff alleges that her mental
28 disturbance was accompanied by a direct physical invasion and resulting physical injury.

1 *Cf. Ball v. Prentice*, 781 P.2d 628, 630 (Ariz. Ct. App. 1989) (“[W]hile there was some
2 uncertainty about the right to recover damages for emotional distress without some
3 physical injury or ‘impact’ . . . there [is] little doubt that one [can] recover damages for
4 emotional distress and accompanying physical injury as a result of a tortfeasor’s negligence
5 when one was physically involved in an accident and suffered some impact triggering the
6 emotional responses. . . . [Because] Ball was a participant and victim, not a bystander . . .
7 [w]hether Ball’s emotional problems, nausea, sleeplessness, tension and headaches are
8 causally connected to the accident and the extent and duration of those injuries is a matter
9 for jury determination.”).

10 Defendants’ request to dismiss the NIED claim is denied.

11 **D. Breach Of Express Warranty**

12 In the September 27, 2021 order, the Court dismissed Plaintiff’s claim for breach of
13 express warranty based on the statute of limitations. (Doc. 25 at 21-23.) Specifically, the
14 Court noted that, under A.R.S. § 47-2725, express warranty claims are generally subject to
15 a four-year statute of limitations and generally accrue at the time of product delivery; that
16 the device was implanted in Plaintiff in June 2009 but she did not file suit until February
17 2017 (*i.e.*, more than four years later); that the FAC did not contain any non-conclusory
18 allegations that might support application of the discovery rule or equitable tolling; and
19 that Plaintiff could not take advantage of § 47-2725(B), which calls for the delayed accrual
20 of claims based on a warranty of “future performance,” because the FAC did not allege
21 when Plaintiff discovered the breach of the alleged future performance warranty. (*Id.*)

22 In the SAC, Plaintiff reasserts a claim for breach of express warranty. (Doc. 26
23 ¶¶ 188-218.) In support of this claim, the SAC adds an array of new factual allegations
24 intended to support application of the discovery rule, equitable tolling, and/or the future
25 performance exception. (Doc. 26-1 at 70-76).

26 Defendants argue the warranty claim remains subject to dismissal on statute-of-
27 limitations grounds because (1) the new factual allegations intended to trigger the
28 discovery rule “are immaterial because there is no discovery rule for breach of express

1 warranty claims under Arizona law”; (2) the new factual allegations intended to trigger
2 equitable tolling miss the mark because they pertain to conduct occurring between 2016
3 and December 2020, well after the statute of limitations expired in 2013; and (3) Plaintiff
4 can’t rely on the future performance exception in § 47-2725(B) because the SAC includes
5 only “vague allegations of future performance” and other courts have recognized that
6 “more specific allegations are required to toll the statute of limitations under the future
7 performance exception.” (Doc. 27 at 10-12.) Alternatively, Defendants argue that the
8 warranty claim fails because the SAC does not identify any “specific affirmation of fact
9 made to [Plaintiff] that became the basis of the bargain” and that the contents of the TVT-
10 S “Instructions for Use” package insert can’t form the basis of a warranty claim because
11 they “are not affirmations made by Defendants directly to the Plaintiff, a necessary
12 requirement for a breach of express warranty claim under Arizona law.” (*Id.* at 12-14.)
13 Finally, and further alternatively, Defendants argue the warranty claim fails due to a lack
14 of causation. (*Id.* at 14.)

15 In response, Plaintiff argues that the SAC’s new factual allegations are sufficient to
16 trigger the discovery rule, equitable tolling, the future performance exception, and the
17 fraudulent concealment doctrine. (Doc. 29 at 10-14.)

18 In reply, Defendants argue that Plaintiff’s reliance on Oregon cases construing the
19 discovery rule is misplaced because “the Oregon statute of limitations is materially
20 different than the Arizona statute of limitations”; that Plaintiff can’t rely on the “future
21 performance” exception in § 47-2725(B) because the “SAC does not identify any language
22 of the purported warranty that ‘explicitly extends to future performance’”; that Plaintiff
23 can’t rely on the fraudulent concealment doctrine because she has not alleged facts with
24 the degree of particularity required by Rule 9(b); and that Plaintiff failed to respond to their
25 arguments regarding the untimeliness of her equitable estoppel claim, the overall
26 vagueness of her warranty-related allegations, and the lack of allegations establishing
27 causation. (Doc. 30 at 5-8.)

28 The express warranty claim is no longer subject to dismissal on statute-of-

1 limitations grounds because the new factual allegations in the SAC plausibly establish that
2 the claim is timely pursuant to the “future performance” provision of § 47-2725(B). That
3 provision explains that “[a] breach of warranty occurs when tender of delivery is made,
4 except that where a warranty explicitly extends to future performance of the goods and
5 discovery of the breach must await the time of such performance,” in which case “the cause
6 of action accrues when the breach is or should have been discovered.” Here, the SAC
7 alleges that “Defendants warranted that the TVT-S product will permanently cure or
8 alleviate Plaintiff’s SUI and would not need to be partially removed” and also “warranted
9 that their TVT-S product is a permanent implant, i.e., it is safe and effective and will cure
10 or alleviate Plaintiff’s SUI for her entire life.” (Doc. 26 ¶ 196.) These allegations are
11 sufficient at the pleading stage to establish that Defendants did, in fact, provide a warranty
12 that explicitly extended to future performance. Although Defendants fault Plaintiff for not
13 attaching any actual warranty documents to the SAC, “[t]here is no requirement in the
14 Federal Rules of Civil Procedure that a party must attach a document described in a
15 complaint to the complaint.” *Travelers Cas. & Sur. Co. v. Smith*, 2007 WL 927964, *1
16 (W.D. Pa. 2007). Similarly, although Defendants dispute whether such a document exists
17 (they claim it “does not exist”), such factual disputes are not properly resolved at the
18 motion-to-dismiss stage. *Unique Lighting Sys., Inc. v. Alliance Outdoor Lighting, Inc.*,
19 2007 WL 9776729, *3 (S.D. Cal. 2007) (“In reviewing a motion to dismiss under Rule
20 12(b)(6), the court must assume the truth of all factual allegations and must construe them
21 in the light most favorable to the nonmoving party. . . . [T]here is no requirement that
22 documents must be attached to the complaint.”).

23 Defendants also cite a series of cases in which courts “found that . . . vague and
24 conclusory allegations are insufficient to invoke the future performance exception.” (Doc.
25 30 at 6.) Those cases are easily distinguishable because they involved complaints that
26 included few, if any, details about the alleged warranty of future performance. *Parcell v.*
27 *Wright Med. Tech., Inc.*, 2012 WL 2675258, *4 (D. Ariz. 2012) (“[T]he cited paragraphs
28 only vaguely reference Defendants’ general marketing strategies and ‘misrepresentations’

1 to the medical community. From these vague allegations, the Court is unable to draw a
2 reasonable inference that an express warranty that explicitly extended to future
3 performance existed.”); *Reiniger v. W.L. Gore & Associates, Inc.*, 2010 WL 1948588, *2
4 (D. Ariz. 2010) (“[I]n fact, the Court is not aware of any allegation in the complaint that
5 even refers to any warranty by Gore related to the future performance of the mesh device.”);
6 *Bergman v. Johnson & Johnson*, 2021 WL 3604305, *5 (D. Minn. 2021) (“Plaintiffs have
7 not alleged any specifics about Defendants’ express warranties such as the format, timing,
8 or language used.”). The SAC, in contrast, specifically alleges that Defendants warranted
9 their product as a “permanent” cure that “would not need to be partially removed” and
10 would continue performing “for [Plaintiff’s] entire life.” If such representations do not
11 qualify as an express warranty of future performance, it is difficult to understand what sort
12 of representation could qualify.

13 For these reasons, the allegations in the SAC are sufficient to establish that
14 Plaintiff’s claim for breach of express warranty did not accrue when the device was
15 originally delivered (*i.e.*, in 2009) but instead accrued when Defendants’ breach of the
16 warranty of future performance was (or should have been) discovered by Plaintiff. *See*
17 A.R.S. § 47-2725(B). The SAC alleges, for the first time, that Plaintiff actually made this
18 discovery in or around 2019. (Doc. 26-1 at 72 [“In March of 2019, Plaintiff experienced a
19 TVT-S mesh erosion and subsequently underwent an excision procedure on March 21,
20 2019. Sometime between February of 2019 and March 21, 2019, Plaintiff was scheduled
21 for a mesh excision/revision procedure. During this period, Plaintiff discovered that
22 Defendants breached their express warranties that the TVT-S was a permanent device
23”].) Accordingly, Plaintiff’s warranty claim is not subject to dismissal on statute-of-
24 limitations grounds.

25 Nor are Defendants entitled to relief based on their alternative dismissal arguments.
26 Although Defendants accuse Plaintiff of failing to “identify[] any specific affirmation of
27 fact made to her that became the basis of the bargain” (Doc. 27 at 13), specific affirmations
28 of fact appear in paragraph 196 of the SAC, which alleges that “Defendants warranted that

1 the TVT-S product will permanently cure or alleviate Plaintiff’s SUI and would not need
2 to be partially removed” and “warranted that their TVT-S product is a permanent implant,
3 i.e., it is safe and effective and will cure or alleviate Plaintiff’s SUI for her entire life.”
4 Defendants also contend that Plaintiff lacks standing because all of the challenged
5 representations were set forth in a package insert that Plaintiff did not directly receive (Doc.
6 27 at 13-14), but the Court does not construe the SAC as necessarily alleging that the
7 warranties of future performance were set forth in the package insert. To be sure,
8 paragraphs 209-11 of the SAC identify a series of specific representations that were set
9 forth in the package insert, but those representations appear to be different from the
10 warranties of future performance discussed in paragraph 196. Although the SAC is not a
11 model of clarity on how the representations in paragraph 196 were made, when they were
12 made, and how Plaintiff received them—indeed, paragraphs 213 and 214 suggest that
13 Defendants made statements about the challenged product through an array of different
14 channels, including “labeling, advertising, marketing materials, detail persons, seminar
15 representations, publications, notice letters, and regulatory submissions” as well as
16 “brochure(s) regarding the product”—the bottom line is that Defendants have not
17 established that the SAC fails on its face based on the absence of a direct representation to
18 Plaintiff. Although Defendants may very well end up prevailing on such a defense at a
19 later stage of this case, they are not entitled to relief on that ground now. Finally,
20 Defendants’ causation-related challenge fails for the same reasons that the Court rejected
21 their causation-related challenges to the FAC. (Doc. 25 at 5, 9.)

22 **E. Constructive Fraud**

23 In the September 27, 2021 order, the Court dismissed Plaintiff’s claim for
24 constructive fraud because, under Arizona law, such a claim must arise out of a fiduciary
25 or confidential relationship and the FAC failed to allege facts suggesting that Plaintiff had
26 such a relationship with either Defendant. (Doc. 25 at 19-21.)

27 In the SAC, Plaintiff reasserts a claim for constructive fraud. (Doc. 26 ¶¶ 219-39.)
28 In support of this claim, the SAC adds the following new factual allegations:

- 1 ▪ “On February 24, 2007, Plaintiff’s implanting physician, Dr. Lee Koon,
2 attended an Advanced Pelvic Floor Level 2 and Incontinence Course and
3 cadaver lab offered by Defendants related to the TVT-S device.” (Doc. 26-
4 1 at 84.)
- 5 ▪ “The February 24, 2007 above-referenced practical event was directed by
6 Defendants’ retained primary preceptor Dr. Robert Rogers and their sales
7 representative, Mike Moore.” (*Id.* at 85.)
- 8 ▪ “At the above-referenced practical event, Dr. Lee Koon was provided
9 information regarding the TVT-S device that was intended to be conveyed to
10 Plaintiff during the consent process for the TVT-S.” (*Id.*)
- 11 ▪ “The above-referenced information regarding the known risks, adverse
12 events, and contraindications associated with the TVT-S device was false.”
13 (*Id.*)
- 14 ▪ “The above-referenced false information regarding the known risks, adverse
15 events, and contraindications regarding the TVT-S device was intended to
16 induce Plaintiff’s reliance on that information in consenting to have the TVT-
17 S implanted in her body in 2009.” (*Id.*)

18 Defendants argue that the constructive fraud claim remains subject to dismissal
19 because the new factual allegations in the SAC do not “show[] that [Plaintiff] was in a
20 fiduciary or confidential relationship with Defendants” and because the SAC “continues to
21 conclusorily allege that the parties were in a special relationship but fails to plead any
22 particular facts invoking one of the enumerated ways that a quasi-fiduciary or confidential
23 relationship may be established under Arizona law.” (Doc. 27 at 14-17.) Defendants also
24 cite an array of district court decisions rejecting constructive fraud claims under analogous
25 circumstances. (*Id.* at 17-18.)

26 In response, Plaintiff does not provide any discussion of the new factual allegations
27 in the SAC or attempt to explain, with specificity, why those new allegations should be
28 deemed sufficient to allege the existence of a confidential or fiduciary relationship. (Doc.

1 29 at 14-15.) Instead, Plaintiff generically notes that the existence of a confidential or
2 fiduciary relationship typically presents a question of fact and argues that “the jury should
3 determine if such relationship exists.” (*Id.*)

4 In reply, Defendants note that “Plaintiff does not address any of the cases cited by
5 Defendants in their opening brief in which courts have found that Defendants do not have
6 a fiduciary relationship with patients implanted with their medical devices” and “does not
7 cite a single instance in which any court in this country has determined that a medical
8 device manufacturer has a confidential or fiduciary relationship with patients who use their
9 devices.” (Doc. 30 at 8-9.)

10 Plaintiff’s constructive fraud claim remains deficient. As discussed in the
11 September 27, 2021 order, the general rule in Arizona is that “commercial transactions do
12 not create a fiduciary relationship unless one party agrees to serve in a fiduciary capacity.”
13 *Cook v. Orkin Exterminating Co., Inc.*, 258 P.3d 149, 152 (Ariz. Ct. App. 2011). The new
14 factual allegations in the SAC simply provide more detail about what was fundamentally a
15 commercial transaction—the sale of a medical device. *RHN Inc. v. CNA Nat’l Warranty*
16 *Corp.*, 2019 WL 4345332, *5 (D. Ariz. 2019) (“To plausibly allege the existence of a
17 fiduciary duty, plaintiff must offer some allegation that renders the relationship something
18 more than an ‘arm’s length’ relationship. . . . Merely entering into a commercial contract
19 is not enough.”); *Andes Indus., Inc. v. Cheng Sun Lan*, 774 F. App’x 358, 360-61 (9th Cir.
20 2019) (upholding dismissal where plaintiff “did not plead any specific facts supporting its
21 conclusory allegation that [defendant] owed [plaintiff] a fiduciary duty”).

22 **F. Leave To Amend**

23 Plaintiff seeks leave to amend in the event of dismissal. (Doc. 29 at 15.) Plaintiff
24 clarifies that any amended complaint “will be based on the same facts and causes of action
25 in” the SAC. (*Id.*)

26 Plaintiff’s amendment request is denied. Although Rule 15(a)(2) provides that the
27 Court “should freely give leave [to amend] when justice so requires,” and although the
28 Ninth Circuit has emphasized that “[t]his policy is ‘to be applied with extreme liberality,’”

1 *Eminence Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1051 (9th Cir. 2003) (citation
2 omitted), an amendment request may be denied if it would produce an undue delay in the
3 litigation or be futile. *AmerisourceBergen Corp. v. Dialysist W., Inc.*, 465 F.3d 946, 951
4 (9th Cir. 2006). Additionally, “the district court’s discretion to deny leave to amend is
5 particularly broad where plaintiff has previously amended the complaint.” *Metzler Inv.*
6 *GMBH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1072 (9th Cir. 2008) (quotation omitted).
7 Here, Plaintiff has already been given several opportunities to amend her complaint, the
8 parties (and Court) have expended significant resources addressing the sufficiency of those
9 amendments, this case is now more than a year old, and Plaintiff suggests that any future
10 iteration of the complaint would be based on “the same facts” as the current iteration. The
11 Court thus concludes that further amendment would result in undue delay and be futile.

12 Accordingly,

13 **IT IS ORDERED** that Defendants’ motion to dismiss (Doc. 27) is **granted in part**
14 **and denied in part.**

15 Dated this 11th day of January, 2022.

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19 _____
20 Dominic W. Lanza
21 United States District Judge
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