WO IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

DEBRA and PATRICK MARTIN, Plaintiffs, vs. MEDTRONIC, INC., and MEDTRONIC SOFAMOR DANEK USA, INC., Defendants.	)	No. 2:14-cv-0385-HRH

ORDER

Motion to Strike;
Motion to Dismiss

Defendants move to dismiss[1] plaintiffs' first amended complaint. This motion is opposed.[2] In the alternative, defendants move to strike portions of plaintiffs' first amended complaint.[3] The motion to strike is opposed.[4] Oral argument was requested and has been heard on both motions.

[1]Docket No. 28.

[2]Docket No. 29.

[3]Docket No. 27.

[4]Docket No. 30.

Background

Plaintiffs are Debra and Patrick Martin. Defendants are Medtronic, Inc. and Medtronic Sofamor Danek USA, Inc.

Defendants manufacture and sell a Class III medical devise known as Infuse® Bone Graft/LT-Cage Lumbar Tapered Fusion Device. The "Infuse® product consists of (1) a metallic spinal fusion cage (the LT-Cage™); (2) Infuse® Bone Graft kit which comes with a vial of liquid rhBMP-2 and absorbable collagen sponges (ACS), which serve as carriers for the rhBMP-2 when the two are placed inside the LT-Cage."[5] The Infuse® device went through the FDA's Premarket Approval process and was approved for use on July 2, 2002, for anterior lumbar interbody (ALIF) spinal fusion surgeries.[6]

"On or about July 14, 2010, the [p]laintiff Debra Martin underwent a posterolateral lumbar fusion at L4-5 and L5-1. To achieve fusion, [Debra's] surgeon, Dr. Yadship Pannu, performed an unapproved procedure by utilizing a posterolateral approach and by packing Atlas vertebral cages with Infuse® Bone Graft and placing the cages into multiple levels of [Debra's] spine."[7] Plaintiffs allege that "the Atlas vertebral cage was not designed

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[5]First Amended Complaint for Damages at 44, ¶ 197, Docket No. 26.

[6]Id. at 44, ¶ 196 & 45, ¶ 200.

[7]Id. at 8, ¶ 23.

for use with a biologic, like rhBMP-2 [,]" but that Dr. Pannu "was induced by Medtronic's misrepresentations to perform this procedure[.][8] Plaintiffs allege that

> a. [defendants] fraudulently concealed and misrepresented the health and safety hazards, symptoms, constellation of symptoms, diseases and/or health problems associated with the unapproved uses of Infuse®;
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> b. [defendants] fraudulently concealed and misrepresented their practice of promoting and marketing to physicians, including Plaintiff's physicians, the practice of using Infuse® without an LT-Cage™ and/or the practice of using unapproved cages instead, like the cage used in [Debra's] surgery, and placing it via a posterolateral approach; [and]
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> c. [defendants] fraudulently concealed and misrepresented information about the known comparative risks and benefits of the use of Infuse® and the relative benefits and availability of alternate products, treatments and/or therapies.[9]

More specifically, plaintiffs allege that

> a. Dr. Pannu completed his residency at Loyola University in Baltimore, Maryland from 1997 through 2003, when Infuse® Bone Graft was just being introduced to physicians. At that time, Loyola was what Dr. Pannu termed a "Medtronic facility," meaning that the hospital received various educational grants from Medtronic.
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> b. Dr. Pannu's professors at Loyola first taught him how to use Infuse® Bone Graft. Dr. Pannu was told that Infuse® was safer and more effective than ICBG or donor bone (allograft). It was

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[8] Id. at ¶¶ 27-28.

[9] Id. at 125-126, ¶ 550.

at this time that Dr. Pannu said he learned about the safety and efficacy profile of Infuse.

c. In addition to his training that he received from Loyola, Dr. Pannu relied heavily upon the medical literature that he read on Infuse® Bone Graft. Specifically, Dr. Pannu recalls reading a number of articles through the "journal club" he was a part of, where he and other physicians read and reviewed articles on Infuse® Bone Graft, none of which disclosed any adverse events. Dr. Pannu recalled reading the 2004 article by Dr. Haid,[10] wherein the results of the 1999 PLIF study ... were published in a distorted, false, and misleading manner.

d. Dr. Pannu relied upon this and other articles to ascertain how safe Infuse® Bone Graft was for his patients like Debra Martin.

e. After completing his residency, Dr. Pannu began working at Midwest Neurosciences in 2003, where he continues to work today. While there, Dr. Pannu continued to educate himself on Infuse®. Specifically, Dr. Pannu relied upon information he received from his colleagues, particularly Dr. Arvind Ahuja. Dr. Ahuja, according to a published article in The Milwaukee Journal Sentinel,[11] similarly relied upon the medical literature on Infuse® Bone Graft to ascertain the safety and efficacy profile of the product and was likewise misled by the false statements contained therein.

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[10]Plaintiffs allege that Dr. Haid "was a co-author of one of the principal studies published on Infuse®" and that he failed to report "the true findings of" the 1999 PLIF study, the results of which were "disastrous", reporting instead that the use of Infuse® in a posterior lumbar interbody fusion (PLIF) were "encouraging." Id. at 94-95, ¶ 396. Plaintiffs allege that Haid was defendants' agent and that in his article he "downplayed the bone overgrowth complications, claiming that while bony overgrowth showed up on CT scans, patients did not suffer ill effects." Id. at 55, ¶¶ 245-246.

[11]Plaintiffs have attached this article to their complaint as Exhibit 7.

> f. Dr. Pannu's Medtronic sales representative was Kris Boetcher. Mr. Boetcher was frequently in the operating room with Dr. Pannu, and during these procedures, he would assist Dr. Pannu and his nurses with the appropriate doses for unapproved procedures, such as Debra Martin's. Dr. Pannu believed that the unapproved procedures he was performing were safe, because Mr. Boetcher was helping to ensure patients received a proper dose of rhBMP-2.
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> g. Ultimately, Dr. Pannu decided to use Infuse® on Debra Martin, because he believed that it was safer and more effective than ICBG, based upon the misrepresentations outlined herein.[12]

Plaintiffs allege that "on or around August 2013, [Debra] was diagnosed with bony overgrowth at L5-S1. A CT-scan also revealed the formation of a cyst near the cage, which had become displaced. As a result, [Debra] has required extensive medical treatment."[13] Plaintiffs further allege that Debra "continues to suffer daily, disabling pain that prevents her from performing many basic activities of daily living."[14] In short, plaintiffs allege that defendants' misrepresentations led to Dr. Pannu's off-label use of the Infuse® device, which led to bony overgrowth in Debra's spine, which has caused her debilitating pain.

On February 27, 2014, plaintiffs commenced this action. In their original complaint, Debra asserted seven state law causes of action against defendants: 1) fraudulent

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[12]First Amended Complaint for Damages at 126-127, ¶ 551, Docket No. 26.

[13]Id. at 9, ¶ 29.

[14]Id. at ¶ 30.

misrepresentation/fraud in the inducement, 2) strict products liability - failure to warn, 3) strict products liability - design defect, 4) strict products liability - misrepresentation, 5) product liability - negligence, 6) breach of express warranty, and 7) violation of Arizona's Consumer Protection statutes. Debra's claims were based on her contention that defendants "should not have violated federal law by falsely and misleadingly promoting and marketing new designs and uses for a product that were never considered or approved by the FDA."[15] Patrick asserted a loss of consortium claim.

Defendants moved to dismiss plaintiffs' original complaint, and on July 23, 2014, the court granted that motion and all of plaintiff's claims were dismissed.[16] The majority of Debra's claims were dismissed because they were preempted by the Medical Device Amendments of 1976. "A state law claim will be expressly preempted ... when 1) there are federal requirements applicable to the medical device and 2) the state law claim seeks to impose requirements that relate to safety and effectiveness of the device that are 'different from, or in addition to' those federal requirements." Hawkins v. Medtronic, Inc., Case No. 1:13–CV–00499 AWI SKO, 2014 WL 346622, at *3 (E.D. Cal. Jan. 30, 2014) (quoting Riegel v. Medtronic, Inc., 552 U.S. 312, 321-22 (2008)). "A state law claim will be impliedly preempted when it is not based on a violation of state law tort duties." Id. at *4. The court

[15]Memorandum in Opposition to Defendants' Motion to Dismiss at 3, Docket No. 15 (emphasis omitted).

[16]Order re Motion to Dismiss at 37, Docket No. 25.

held that the following claims were preempted: 1) Debra's fraud claims based on allegations that defendants made misrepresentations and omissions in the labeling of the Infuse device; 2) Debra's product liability failure to warn claim based on defendants' off-label promotion, 3) Debra's design defect claim, 4) Debra's negligence claim based on a failure to provide warnings on the labeling of the Infuse Device, 5) Debra's negligence claim based on the design and manufacture of the Infuse Device, and 6) Debra's negligence claim based on defendant's off-label promotion of the Infuse Device.[17] Debra's remaining fraud claims (those based on defendants' off-label promotion) were dismissed because they had not been pled with the required particularity.[18] Debra's breach of express warranty claim and her products liability and negligence claims based on a failure to report adverse events to the FDA were dismissed because she had failed to state plausible claims.[19] Patrick's loss of consortium claim was dismissed because all of Debra's claims were dismissed.[20] Plaintiffs were given leave to amend

> 1) Debra's fraud claims based on defendants' misrepresentations in off-label promotion, 2) Debra's failure to warn claim based on a failure to report adverse events to the FDA, 3) Debra's negligence claim based on a failure to report adverse

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[17] Id. at 20, 25, 31, & 32-33.

[18] Id. at 29.

[19] Id. at 29, 34 & 36.

[20] Id. at 36.

> events to the FDA, 4) Debra's breach of express warranty claim, and 5) Patrick's loss of consortium claim.[21]

On August 13, 2014, plaintiffs filed their first amended complaint. In the amended complaint, Debra again asserts seven state law causes of action: 1) fraudulent misrepresentation/fraud in the inducement, 2) strict products liability - failure to warn, 3) strict products liability - design defect, 4) strict products liability - misrepresentation, 5) product liability - negligence, 6) breach of express warranty, and 7) violation of Arizona's Consumer Protection statutes. Patrick again asserts a claim for loss of consortium. Plaintiffs also appear to be asserting a claim for punitive damages.

Pursuant to Rules 9(b) and 12(b)(6), Federal Rules of Civil Procedure, defendants now move to dismiss plaintiffs' amended complaint. Should the court not dismiss all of plaintiffs' claims, defendants move to strike certain portions of plaintiffs' amended complaint.

Discussion

"Rule 12(b)(6) authorizes courts to dismiss a complaint for 'failure to state a claim upon which relief can be granted.'" In re Rigel Pharmaceuticals, Inc. Securities Litig., 697 F.3d 869, 875 (9th Cir. 2012) (quoting Fed. R. Civ. P. 12(b)(6)). "To avoid dismissal, the complaint must provide 'more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.'" Id. (quoting Bell Atl. Corp. v. Twombly, 550

[21]Id. at 37.

U.S. 544, 555 (2007)). "'[A] plaintiff must 'allege sufficient factual matter ... to state a claim to relief that is plausible on its face.'" OSU Student Alliance v. Ray, 699 F.3d 1053, 1061 (9th Cir. 2012) (quoting Pinnacle Armor, Inc. v. United States, 648 F.3d 708, 721 (9th Cir. 2011)). "In evaluating a Rule 12(b)(6) motion, the court accepts the complaint's well-pleaded factual allegations as true and draws all reasonable inferences in the light most favorable to the plaintiff." Adams v. U.S. Forest Srvc., 671 F.3d 1138, 1142-43 (9th Cir. 2012). "Rule 9(b) provides that '[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.'" United States ex rel. Cafasso v. General Dynamics C4 Systems, Inc., 637 F.3d 1047, 1054-55 (9th Cir. 2011) (quoting Fed. R. Civ. P. 9(b)). "To satisfy Rule 9(b), a pleading must identify 'the who, what, when, where, and how of the misconduct charged,'" as well as "'what is false or misleading about [the purportedly fraudulent] statement, and why it is false.'" Id. at 1055 (quoting Ebeid ex rel. United States v. Lungwitz, 616 F.3d 993, 998 (9th Cir. 2010)).

Defendants first move to dismiss the claims that this court found were preempted but which Debra has again asserted in the amended complaint. Although they were not given leave to amend as to these claims, plaintiffs have repleaded 1) Debra's fraud claims in Counts 1, 4, and 7 which are based on allegations that defendants made misrepresentations and omissions in the labeling of the Infuse device; 2) Debra's strict products liability claim in Count 2 that is based on the off-label promotion of the Infuse device; 3) Debra's

strict products liability - design defect claim in Count 3; and 4) Debra's negligence claims in Count 5 which were based on allegations that defendants failed to provide warnings on the labeling of the Infuse device, were negligent during the manufacture or design of the Infuse device, and were negligent in promoting the Infuse device for off-label use. Plaintiffs noted that they were repleading these claims for purposes of an appeal, but there was no reason to do so. See Lacey v. Maricopa County, 693 F.3d 896, 928 (9th Cir. 2012) ("For claims dismissed with prejudice and without leave to amend, [the court] will not require that they be repleaded in a subsequent amended complaint to preserve them for appeal"). These claims are again dismissed and to the extent it was not clear in the court's order on defendants' first motion to dismiss, these claims are dismissed with prejudice.

Defendants next argue that Debra's strict products liability failure to warn claim (Count 2) and negligence claim (Count 5) which are based on allegations that defendants failed to warn the FDA about adverse events should be dismissed. Defendants argue that plaintiffs have again failed to allege how the failure to warn the FDA about adverse events caused or contributed to their damages or injuries. "Manufacturers are required by the FDCA to report to the FDA adverse events where an approved device may have caused or contributed to a death or serious injury, or where a recurring malfunction would likely cause or contribute to a death or serious injury." Hawkins, 2014 WL 346622, at *8. In order

for an adverse events claim to be plausible, there must be "a causal connection between [plaintiffs'] injuries and the alleged failure to report...." Id. at *8.

Plaintiffs allege that "Medtronic ... failed to report adverse events to the FDA" and thus Debra's "surgeon was unable to access this information via the FDA's adverse event database."[22] Plaintiffs allege that the adverse

> reports would have been available to [Debra's] surgeon via the FDA's online database, and they would have been available to researchers publishing independent studies on the safety and efficacy of Infuse®. Because Medtronic negligently failed to adequately report adverse events to the FDA, [p]laintiff's surgeon relied upon false and misleading information when he decided to use Infuse® in an unapproved procedure on Debra Martin.[23]

Plaintiffs also allege that Dr. Pannu "relied on the Medtronic Defendants' inadequate warnings in deciding to use Infuse® in an off-label manner. Plaintiff and Plaintiff's physician would not have used Infuse® off-label without an LT-Cage™ and with an Atlas vertebral cage via a posterolateral approach, had they known of the true safety risks related to Infuse®."[24] Plaintiffs further allege that "researchers who conducted independent studies and who relied upon adverse event data submitted to the FDA to determine the safety profile of Infuse® could not gain access to this information" and thus "even those

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[22]First Amended Complaint for Damages at 130, ¶¶ 575-76, Docket No. 26.

[23]Id. at 137, ¶ 622.

[24]Id. at 131, ¶ 581.

attempting to conduct or read non-industry sponsored information concerning the safety of Infuse® were unable to do so."[25] Plaintiffs argue that these allegations are sufficient to state a plausible claim. Plaintiffs insist that their allegations suggest that if defendants had properly reported adverse events, that information would have reached Dr. Pannu before he did Debra's surgery in 2010.

Plaintiffs' allegations are insufficient to state a plausible claim. Plaintiffs still have not alleged how defendants' alleged failure to warn the FDA about adverse events contributed to their injuries. What is missing from Debra's adverse events claims is any connection between defendants' alleged failure to report adverse events and her surgery. Plaintiffs also have not alleged any factual support for these claims, such as any details (the date, nature of injuries, or method of implant) about any adverse events that should have been reported. Without such factual detail, it is not possible to tell if timely reporting would have affected the off-label use of the Infuse device during Debra's surgery. Debra's adverse events claims in Count 2 and Count 5 are dismissed. These claims are dismissed with prejudice. Plaintiffs are not given leave to amend because they have already had one opportunity to amend these claims and they still failed to state a plausible claim. See Cafasso, 637 F.3d at 1058 (quoting Ascon Props., Inc. v. Mobil Oil Co., 866 F.2d 1149, 1160

[25]Id. at 130, ¶¶ 577-578.

(9th Cir. 1989)) ("'[t]he district court's discretion to deny leave to amend is particularly broad where plaintiff has previously amended the complaint'").

Defendants next argue that plaintiffs have again failed to plead Debra's off-label promotion fraud claims with the required particularity. Defendants argue that plaintiffs still have not pled with particularity any false promises or misrepresentations allegedly made by defendants to Debra or her physician. Although plaintiffs have alleged that "Dr. Pannu relied heavily upon the medical literature that he read on Infuse® Bone Graft ... none of which disclosed any adverse events[,]"[26] defendants argue that plaintiffs have not identified any of these articles by title, date, or author, much less identified any misrepresentations that were contained in these articles. Defendants argue that plaintiffs' fraud claims suffer from the same problems that the Minnesota state court has found in the Infuse cases before it. In Anderson v. Medtronic, the court explained that the plaintiffs alleged that their doctors "relied on the available medical literature on Infuse®, which specifically portrayed the off-label use of Infuse® ... as a safe and effective use of the product."[27] "None of these allegations specifies which articles the individual treating physicians allegedly read or relied upon in making their treating decisions. None of these allegations specifies any authors, journals, or date ranges for the articles allegedly read. None of these allegations

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[26]Id. at 126, ¶ 551c.

[27]Anderson v. Medtronic, slip. op. at 5, Exhibit A, Notice of Supplemental Authority [etc.], Docket No. 33.

specifies which statements in the articles read by the treating physicians are claimed to be misstatements."[28] Defendants insist that the same is true here, that plaintiffs have failed to allege any specifics about any of the medical literature that Dr. Pannu allegedly read.

As plaintiffs are quick to point out, however, they have alleged that Dr. Pannu read a particular article (the Haid article) that addressed using the Infuse device off-label and that Dr. Pannu relied on the medical literature he was reading in deciding whether to use the Infuse device off-label. They have alleged which particular statements in the Haid article were false and they have alleged why they were false.[29] As for defendants' contention that plaintiffs have not adequately alleged that Haid was defendants' agent, plaintiffs support their conclusory allegation that Haid was defendants' agent with an allegation that "[b]etween 1996 and 2010, Dr. Haid received $25,549,813.96 in royalties and consulting fees from Medtronic. Of that amount, Dr. Haid received $2,484,450.94 in 2004."[30] These allegations are sufficiently particular. In connection with the Haid article, Debra has alleged the who, what, when, where, and how.

Plaintiffs' other allegations as to how Dr. Pannu was impacted by defendants' off-label promotion are not, however, sufficiently particular. Plaintiffs argue that they have

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[28]Id. at 5-6.

[29]First Amended Complaint for Damages at 55-56, ¶¶ 246-250, Docket No. 26.

[30]Id. at 95, ¶ 400.

also alleged that the medical literature influenced Dr. Pannu indirectly, as Dr. Pannu discussed the safety and efficacy of the Infuse device with Dr. Ahuja.[31] But, it is not sufficient for plaintiffs to allege that Dr. Ahuja read some unidentified "medical literature" and then shared this information with Dr. Pannu. Similarly, plaintiffs' allegations regarding Dr. Pannu's training lack particularity because plaintiffs have not alleged that anyone at Loyola had the authority to speak on defendants' behalf nor have they alleged what specific misrepresentations were made by any of the professors or hospital staff. Plaintiffs' allegations that Dr. Pannu relied on misrepresentations from his Medtronic sales rep, Kris Boetcher, come closer but still lack particularity because plaintiffs do not allege any specific misrepresentations that Boetcher made regarding Debra's off-label procedure or explain how any alleged misrepresentation made by Boetcher specifically caused plaintiffs' injuries.

Plaintiffs also make a general argument that their amended complaint is replete with allegations that the representations that defendants made that the Infuse device was safe for off-label use were false[32] and that defendants made these representations in order to

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[31] Id. at 126, ¶ 551e.

[32] Id. at 17, ¶ 79 ("Defendants continued to represent that Infuse® Bone Graft was/is safer, more effective and the best alternative for spinal fusion, all the while knowing that this was absolutely false, even after the United States Senate report and the YODA study were released"); 55, ¶ 245 (alleging that the Haid article "inaccurately maintained that" patients in the 1999 PILF study "were not harmed by Infuse® Bone Graft"; 64-67, ¶¶ 282-
(continued...)

induce physicians, such as Dr. Pannu, to use the Infuse device off-label.[33] Plaintiffs insist that these allegations support their contention that Dr. Pannu would not have used the Infuse device for Debra's surgery had he known about the significant risk of complications associated with doing so.

But these allegations are not tied specifically to Dr. Pannu or to Debra. Rather, these allegations suggest that what plaintiffs are attempting to do here is advance a "fraud-on-

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[32](...continued)
290 (allegations related to the June 2011 issue of The Spine Journal which was "a special edition dedicated to addressing serious patient safety and ethical concerns related to the use of RhBMP-2 ... in the spine"); 91, ¶ 376 ("In a published interview with SpineUniverse.com ..., Dr. Burkus said that he was 'using rhBMP-2 in anterior and posterior lumbar spinal fusion surgeries' and falsely stated that 'no adverse events have been linked to the use of rhBMP-2'"); 92, ¶ 381 ("Dr. Zdeblick was an author or co-author of ... articles [that] were either edited or heavily drafted by Medtronic employees and exaggerated the benefits of Infuse® Bone Graft, while deliberately omitting adverse events and playing up any side effects associated with using ICBG"); 99, ¶ 418 ("Dr. Kuklo's Medtronic-sponsored study was false, the falsity only uncovered when one of the study's supposed, 'co-authors,' Lt. Col. Romney C. Andersen, was congratulated on its publication by a colleague. After his discovery, Lt. Col. Anderson alerted Army investigators to the false claims"); 103, ¶ 439 ("[i]n all of the principal studies cited in the Baucus-Grassley report released by the Senate Committee on Finance (as well as in many others), Medtronic officials inserted language into studies that promoted Infuse® as a better technique than harvesting bone from the patient's iliac crest by emphasizing the pain associated with using autograft, actively concealing adverse events and/or manipulating success criteria to falsely inflate the benefits of Infuse®"; 112, ¶ 463 ("The Medtronics Defendants, through their website, www.Medtronic.com, falsely claim that '[b]one formation remote from the site of the implantation was not seen in the clinic trials'")" 117, ¶ 497 ("the Medtronic Defendants promoted not only the use of its Infuse® Bone Graft into markets unapproved for Infuse® but also falsely reassured physicians and patients that Class II surgical cages, such as the Atlas verterbral cage, could safely and effectively be used with a biologic").

[33]Id. at 127, ¶¶ 553-554.

the-market" theory, with the "market" being the medical community at large. But courts have generally found such theories inapplicable to product liability cases. See, e.g., Chudasama v. Mazda Motor Corp., 123 F.3d 1353, 1369 n.39 (11th Cir. 1997) ("The fraud on the market theory of securities law, however, is based on concepts and policies that simply do not apply in a products liability case"). Plaintiffs cannot pursue a "fraud of the market" theory.

Defendants next argue that Debra's breach of express warranty claim should be dismissed because it is not adequately pled and it is barred by the Infuse warranty disclaimer. "Under Arizona law, '[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.'" Arvizu v. Medtronic Inc., --- F. Supp. 2d ---, 2014 WL 4204933, at *9 (D. Ariz. 2014) (quoting Dillon v. Zeneca Corp., 42 P.3d 598, 602 (Ariz. Ct. App. 2002)). "'[A]ny affirmation that forms the basis of an express warranty must be between the seller and the buyer.'" Id. (quoting Ramirez v. Medtronic Inc., 961 F. Supp. 2d 977, 1001 (D. Ariz. 2013)).

Plaintiffs allege that defendants "utilized journal articles, advertising media, sales representatives/consultants, and paid Key Opinion Leaders to urge the use, purchase, and utilization of unapproved uses of Infuse® Bone Graft" to "expressly warrant[] to physicians, including [Debra's] physician and other members of the general public and

medical community, that such off-label uses, including uses in lumbar fusion procedures, were safe and effective."[34] Plaintiffs also allege that Debra's "treating surgeon relied on Defendants' express warranty representations regarding the safety and efficacy of unapproved uses of Infuse®, but such off-label uses, including uses in lumbar fusion procedures, were not effective, safe, and proper for the use as warranted in that Infuse® was dangerous when put to these promoted uses."[35]

Debra has still failed to state a plausible breach of express warranty claim. Debra's vague allegations that there were affirmations made by defendants and defendants' agents that the Infuse device was safe and effective when used off-label are insufficient. In order to state a plausible claim, plaintiffs needed to allege that defendants made affirmations directly to Debra, which they have not done. Thus, Debra's breach of express warranty claim is dismissed. This claim is dismissed with prejudice. Plaintiffs are not given leave to amend as they have had an opportunity to amend this claim and still failed to state a plausible claim.

Defendants next argue that Patrick's loss of consortium claim should be dismissed. But, Patrick's loss of consortium claim survives defendants' motion to dismiss because Debra's fraud claims based on defendants' off-label promotion survive.

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[34]First Amended Complaint for Damages at 139, ¶ 635, Docket No. 26.

[35]Id. at ¶ 637.

Lastly, defendants argue that plaintiffs' punitive damages claim should be dismissed because punitive damages are a remedy, not a claim. See Allen v. Quest Online, LLC, Case No. CV–11–138–PHX–GMS, 2011 WL 4403674, at *11 (D. Ariz. Sept. 22, 2011) ("Damages cannot stand alone as a separate claim"). Plaintiffs may seek punitive damages as a remedy, but it is not a substantive claim for relief. To the extent that plaintiffs have asserted a separate claim for punitive damages, that claim is dismissed.

Although the court has determined that Debra's fraud claims based on defendants' off-label promotion survive defendants' Rule 12(b)(6) motion and that Patrick's loss of consortium claim also survives, plaintiffs' amended complaint is nonetheless dismissed in its entirety for failure to comply with Rule 8(a)(2). "When a complaint fails to comply with" Rule 8(a)(2), "the district court has the power, on motion or sua sponte, to dismiss the complaint...." Simmons v. Abruzzo, 49 F.3d 83, 86 (2d Cir. 1995). "Rule 8(a)(2) of the Federal Rules of Civil Procedure requires that each claim in a pleading be supported by 'a short and plain statement of the claim showing that the pleader is entitled to relief....'" Landers v. Quality Communications, Inc., --- F.3d ---, 2014 WL 5840039, at *2 (9th Cir. 2014). Plaintiffs' amended complaint is 146 pages long and contains 675 numbered paragraphs and has seven exhibits attached. Quite simply, it "says too much." Knapp v. Hogan, 738 F.3d 1106, 1109 (9th Cir. 2013). It is "prolix, replete with redundancy, and largely irrelevant...." McHenry v. Renne, 84 F.3d 1172, 1177 (9th Cir. 1996). Even with the majority

of Debra's claims dismissed, it would be unfair to require defendants to answer the amended complaint. See Cafasso, 637 F.3d at 1059 (quoting Mendez v. Draham, 182 F. Supp. 2d 430, 433 (D.N.J. 2002) ("'Only through superhuman patience, effort, and insight, could any attorney review the allegations of the Complaint and make paragraph-by-paragraph responses.'").

However, plaintiffs are given leave to file a second amended complaint but only as to Debra's fraud claims which are based on defendants' off-label promotion and as to Patrick's loss of consortium claim. Plaintiffs' allegations in their second amended complaint must be limited to those necessary to support these few remaining claims. Although the court is denying defendants' motion to strike as moot, plaintiffs would do well to consider the objections raised in that motion when drafting their second amended complaint as most of defendants' objections were well taken. Any further failure to comply with Rule 8(a)(2) could result in the dismissal of this action with prejudice.

Conclusion

Defendants' Rule 12(b)(6) motion to dismiss[36] is granted in part and denied in part. Defendants' motion to strike[37] is denied as moot. The court sua sponte dismisses plaintiffs' first amended complaint in its entirety. Plaintiffs are given leave to amend only as to

[36]Docket No. 28.

[37]Docket No. 27.

Debra's fraud claims that are based on defendants' off-label promotion and as to Patrick's loss of consortium claim. Plaintiffs' second amended complaint, should they elect to file one, shall be filed on or before December 15, 2014.

DATED at Anchorage, Alaska, this 21st day of November, 2014.

/s/ H. Russel Holland
United States District Judge