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

O R D E R

Motion to Dismiss

Defendants move to dismiss[1] plaintiffs' second amended complaint, or in the alternative, to strike portions of plaintiffs' second amended complaint. This motion is opposed.[2] Oral argument was requested and has been heard.

Background

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

[1]Docket No. 42.

[2]Docket No. 43.

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."[3] The Infuse® device went through the FDA's Premarket Approval process and was approved for use on July 2, 2002, for anterior lumbar interbody spinal fusion surgeries.[4]

Plaintiffs allege that "[o]n 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."[5] Plaintiffs allege that "the Atlas vertebral cage was not designed for use with a biologic, like rhBMP-2[,]" but that Dr. Pannu "was induced by Medtronic's misrepresentations to perform this procedure, utilizing unapproved devices."[6] Specifically, plaintiffs allege that Dr. Pannu "recalled reading [a]

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[3]Second Amended Complaint for Damages at ¶ 99, Docket No. 39.

[4]Id. at ¶¶ 98 & 102.

[5]Id. at ¶ 23.

[6]Id. at ¶¶ 27-28.

2004 article by Dr. Haid, wherein the results of the 1999 PLIF study ... was published in a distorted, false, and misleading manner."[7] Plaintiffs also allege that in 2003 and 2004, Medtronic sales rep Kris Boetcher discussed the off-label use of Infuse with Dr. Pannu and "represented ... that Infuse was both safe and effective" for off-label uses and "that patients who underwent surgery with Infuse® achieved better fusions."[8] Plaintiffs allege that Boetcher was "frequently in the operating room with Dr. Pannu and ... he would assist Dr. Pannu and his nurses with the 'appropriate' doses for unapproved procedures," but plaintiffs do not specifically allege that Boetcher was in the operating room during Debra's surgery.[9]

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."[10] Plaintiffs further allege that Debra "continues to suffer daily, disabling pain that prevents her from performing many basic activities of daily living."[11]

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[7] Id. at ¶ 268.

[8] Id. at ¶¶ 270-271.

[9] Id. at ¶ 275.

[10] Id. at ¶ 29.

[11] Id. at ¶ 30.

On February 27, 2014, plaintiffs commenced this action. Plaintiffs' original complaint was 99 pages long and contained 420 paragraphs.[12] In the original complaint, Debra asserted seven state law causes of action against defendants: 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. 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."[13] Patrick asserted a loss of consortium claim.

Defendants moved to dismiss plaintiffs' original complaint, and on July 23, 2014, the court granted that motion, dismissing all of plaintiff's claims.[14] The majority of Debra's claims were dismissed because they were preempted by the Medical Device Amendments of 1976. The court 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

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[12]Docket No. 1.

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

[14]Order re Motion to Dismiss, Docket No. 25.

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.[15] Debra's remaining fraud claims (those based on defendants' off-label promotion) were dismissed because they had not been pled with the required particularity.[16] 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.[17] Patrick's loss of consortium claim was dismissed because all of Debra's claims were dismissed.[18] 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 events to the FDA, 4) Debra's breach of express warranty claim, and 5) Patrick's loss of consortium claim.[19]

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[15] Id. at 20, 25, 31 & 33.

[16] Id. at 29.

[17] Id. at 29 & 34.

[18] Id. at 36.

[19] Id. at 37.

On August 13, 2014, plaintiffs filed their first amended complaint.[20] Plaintiffs' first amended complaint was 146 pages long and contained 675 paragraphs. Attached to the complaint were seven exhibits, totaling 53 pages. In the first amended complaint, Debra again asserted 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 asserted a claim for loss of consortium. And, plaintiffs appeared to be also asserting a claim for punitive damages.

Defendants moved to dismiss plaintiffs' first amended complaint, and on November 21, 2014, the court granted that motion.[21] The court found that plaintiffs had improperly repled claims that had been dismissed because they were preempted.[22] The court dismissed with prejudice Debra's adverse events claims and her breach of express warranty claim for failure to state plausible claims.[23] The court found that Debra had adequately pled an off-label promotion fraud claim in connection with Dr. Pannu's reading of the Dr.

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[20]Docket No. 26.

[21]Docket No. 38.

[22]Id. at 10.

[23]Id. at 12 & 18.

Haid article, but that her other allegations as to how Dr. Pannu was impacted by defendants' off-label promotion were not sufficiently particular.[24] Finally, the court concluded that plaintiffs' first amended complaint should be dismissed in its entirety because plaintiffs had failed to comply with Rule 8(a)(2).[25] The court gave plaintiffs "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."[26] The court directed plaintiffs to limit their allegations "to those necessary to support" their few remaining claims, and the court warned plaintiffs that "[a]ny further failure to comply with Rule 8(a)(2) could result in the dismissal of this action with prejudice."[27]

On December 15, 2014, plaintiffs filed their second amended complaint.[28] Plaintiffs' second amended complaint is 74 pages long and contains 347 paragraphs. Attached to the second amended complaint are five exhibits, totaling 43 pages. The second amended complaint begins with four pages of definitions and introduction. It then has eight paragraphs which describe Debra's surgery. For the next 40-some paragraphs, plaintiffs allege that the Infuse device was not approved for the type of procedure Debra had.

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[24]Id. at 14.

[25]Id. at 19-20.

[26]Id. at 20.

[27]Id.

[28]Docket No. 39.

Plaintiffs then devote eighteen paragraphs to describing the FDA "regulatory landscape." At paragraph 90 on page 19, plaintiffs finally begin to allege what they contend are the "relevant facts." The "relevant facts" section of the second amended complaint is 44 pages long. Nowhere in the first 41 pages of this section are Debra's surgery or her surgeon mentioned. Finally, at paragraph 265 on page 61, plaintiffs begin to allege facts that relate to Debra's surgery and the misrepresentations defendants allegedly made to her surgeon, Dr. Pannu. These factual allegations span less than three pages of plaintiffs' second amended complaint. Based on these allegations, Debra asserts three causes of action against defendants: 1) fraudulent misrepresentation/fraud in the inducement, 2) strict products liability - misrepresentation, and 3) a violation of Arizona's Consumer Protection Statutes. And, Patrick again asserts a claim for loss of consortium.

Defendants now move to dismiss plaintiffs' second amended complaint on the grounds that Debra has again failed to plead her fraud claims with the particularity required by Rule 9 and because plaintiffs have again failed to comply with Rule 8(a).

Discussion

"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., 771 F.3d 638, 640 (9th Cir. 2014) (quoting Fed. R. Civ. P. 8(a)(2)). Although "to satisfy Rule 8(a)(2), a

complaint must contain sufficient factual content 'to state a claim to relief that is plausible on its face[,]" id. at 641 (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007)), that does not mean that a plaintiff can include irrelevant factual allegations, allegations that have no nexus to the claims being asserted. Plaintiffs' second amended complaint continues to say "too much." Knapp v. Hogan, 738 F.3d 1106, 1109 (9th Cir. 2013). Plaintiffs' second amended complaint has pages and pages of irrelevant factual allegations. Plaintiffs argue that all of these factual allegations are necessary to show that defendants were perpetrating a complex fraudulent scheme that spanned several years and involved a multitude of players, but the court directed plaintiffs to focus on the factual allegations that were pertinent to Debra's surgery, rather than attempting to allege a fraud on the market type claim. It was perhaps most telling that at oral argument, in arguing that Debra had pled her fraud claims with the required particularity, plaintiffs' counsel made reference to only a handful of paragraphs in the second amended complaint. The court is mindful that plaintiffs' second amended complaint is shorter than the two prior complaints and has over 300 fewer paragraphs than plaintiffs' first amended complaint, but that in and of itself does not mean that plaintiffs have complied with Rule 8(a). Rule 8(a) requires a short and plain statement of a claim. Plaintiffs' second amended complaint is neither short nor plain. There are times when a lengthy complaint is necessary, but this is not one of them.

Plaintiffs have again failed to comply with Rule 8(a)(2), and their second amended complaint is dismissed with prejudice.

Conclusion

Defendants' motion to dismiss[29] is granted. The clerk of court shall enter judgment dismissing plaintiffs' second amended complaint with prejudice.

DATED at Anchorage, Alaska, this 1st day of April, 2015.

/s/ H. Russel Holland
United States District Judge

[29]Docket No. 42.