IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF HAWAII

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| KARLA BEAVERS-GABRIEL,<br><br>Plaintiff,<br><br>vs.<br><br>MEDTRONIC, INC. and MEDTRONIC SOFAMOR DANEK USA, INC.,<br><br>Defendants. | ) | CIV. NO. 13-00686 JMS-RLP<br><br>ORDER DENYING DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S SECOND AMENDED COMPLAINT FOR DAMAGES FILED 10/6/14, DOC. NO. 69 |

**ORDER DENYING DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S SECOND AMENDED COMPLAINT FOR DAMAGES FILED 10/6/14, DOC. NO. 69**

## I. INTRODUCTION

On December 16, 2013, Plaintiff Karla Beavers-Gabriel ("Plaintiff") filed this diversity action against Medtronic, Inc. and Medtronic Sofamor Danek USA, Inc. (collectively, "Medtronic" or "Defendants"), asserting state law claims based on injuries she sustained after undergoing spinal surgery in which her surgeon used Defendants' Infuse® Bone Graft (the "Infuse Device"), a Class III prescription medical device, in an off-label manner not approved by the Food and Drug Administration ("FDA").

On April 10, 2014, the court granted Defendants' Motion to Dismiss the Complaint, with leave to amend as to certain claims (the "April 10, 2014 Order"). *See Beavers-Gabriel v. Medtronic, Inc.*, 15 F. Supp. 3d 1021 (D. Haw. 2014). The April 10, 2014 Order determined that several of Plaintiff's claims were preempted by the Medical Device Amendments ("MDA") of the Food, Drug, and Cosmetic Act ("FDCA"), and that the remaining claims were insufficiently pled to allege a plausible claim for relief. Plaintiff ultimately filed a Second Amended Complaint ("SAC")[1] attempting to correct the deficiencies outlined in the April 10, 2014 Order.

Currently before the court is Defendants' Motion to Dismiss the SAC pursuant to Rule 12(b)(6), Doc. No. 69, arguing that the new claims are still preempted by the MDA and/or include insufficient allegations to assert a plausible claim for relief. Based on the following, the court DENIES Defendants' Motion.

## II. BACKGROUND

### A. Factual Background

The SAC includes 203 pages, 539 paragraphs, and ten exhibits, including one exhibit consisting of a 190-page deposition transcript. Much of the

[1] Plaintiff initially filed an Amended Complaint, which the court struck for including claims which were dismissed without leave to amend. *See* Doc. No. 62.

SAC rehashes what was alleged in the original Complaint containing 141 pages and 414 paragraphs, with the additional material directed to addressing deficiencies in the Complaint outlined by the April 10, 2014 Order.

Similar to the Complaint, the SAC includes various allegations regarding (1) the general regulatory landscape for medical devices, Doc. No. 62, SAC at 18-50; (2) Medtronic's promotion of the Infuse Device for off-label purposes, *id.* at 51-100; and (3) Medtronic's knowledge and/or notice that the Infuse Device was not safe for unapproved purposes. *Id.* at 101-146. Because the April 10, 2014 Order outlined these background facts in detail, the court does not detail them again here, and instead discusses Plaintiff's specific allegations in more detail below as they relate to each claim.

Rather, suffice to say that the SAC alleges that (1) the FDA approved the Infuse Device to be used in anterior lumbar interbody fusion ("ALIF") surgeries at L4-S1, using all components of the device (the two components being the Infuse Bone Graft Component and the LT-Cage); (2) Medtronic promoted the Infuse Device for off-label purposes while at the same time hiding known side effects; (3) Plaintiff underwent a transforaminal lumbar interbody fusion ("TLIF") and posterolateral fusion at L5-S1 in which the Infuse Device was used in an off-label manner by using a transforaminal and posterolateral approach as well as by

placing the active ingredient, rhBMP-2, both inside and outside of non-LT-Cages; (4) Plaintiff's surgeon, Dr. Jon Graham, was induced to use the Infuse Device in an off-label manner by Medtronic's false representations and omissions; and (5) Plaintiff developed heterotopic bone growth, secondary to the Infuse Device, causing her injury. With regard to Dr. Graham's decision to use the Infuse Device in an off-label manner, the SAC attaches his deposition transcript, which was taken after Plaintiff filed this action. *See* Doc. No. 67, SAC Ex. 10.

**B. Procedural History**

On December 16, 2013, Plaintiff filed this action alleging eight causes of action titled (1) Fraudulent Misrepresentation and Fraud in the Inducement; (2) Strict Products Liability -- Failure to Warn; (3) Strict Products Liability -- Design Defect; (4) Strict Products Liability -- Misrepresentation; (5) Products Liability -- Negligence; (6) Breach of Express Warranty; (7) Breach of Hawaii's Consumer Protection Statutes; and (8) Punitive Damages.

The parties subsequently stipulated to dismissal of the claim for Breach of Hawaii's Consumer Protection Statutes, Doc. No. 21, and Plaintiff conceded to dismissal of the Strict Products Liability -- Misrepresentation claim. The April 10, 2014 Order dismissed the remaining claims as preempted by the MDA and/or insufficiently pled, with leave for Plaintiff to amend as to specific

theories of relief as to Plaintiff's claims for Fraudulent Misrepresentation and Fraud in the Inducement, Strict Products Liability -- Failure to Warn, Products Liability -- Negligence, and Breach of Warranty.

Plaintiff's counsel subsequently took the deposition of Dr. Graham to obtain evidence in support of an amended complaint and in particular, to determine whether Plaintiff could establish the connection between Defendants' alleged misrepresentations and omissions, and Dr. Graham's decision to use the Infuse Device in an off-label manner for Plaintiff's surgery. *See* Doc. No. 44. On September 2, 2014, Plaintiff filed her Amended Complaint, Doc. No. 50, which the court struck for failure to follow the April 10, 2014 Order -- Plaintiff had included claims and theories of relief that were dismissed without leave to amend. *See* Doc. No. 62.

On October 6, 2014, Plaintiff filed her SAC. Doc. No. 63. The SAC alleges claims titled (1) Fraudulent Misrepresentation and Fraud by Omission (Count I); (2) Negligent Misrepresentation (Count II); (3) Strict Products Liability -- Failure to Warn the FDA (Count III); (4) Negligent Failure-to-Warn the FDA (Count IV); and (5) Breach of Express Warranty (Count V). Plaintiff seeks general, consequential, and punitive damages, as well as attorneys' fees and costs.

On October 20, 2014, Defendants filed their Motion to Dismiss the SAC.[2] Doc. No. 69. Plaintiff filed her Opposition on November 17, 2014, Doc. No. 72, and Defendants filed a Reply on November 24, 2014. Doc. No. 75. A hearing was held on December 8, 2014.

After the December 8, 2014 hearing, the court directed the parties to submit supplemental briefing regarding the plausibility of the failure-to-warn claims, Doc. No. 77, and Plaintiff submitted her supplemental brief on December 16, 2014, Doc. No. 79, and Defendants submitted their supplemental reply on December 23, 2014. Doc. No. 82.

## III. STANDARDS OF REVIEW

### A. Rule 12(b)(6): Failure to State a Claim

Federal Rule of Civil Procedure 12(b)(6) permits a motion to dismiss a claim for "failure to state a claim upon which relief can be granted[.]"

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)); *see also Weber v. Dep't of Veterans Affairs*,

[2] Defendants also filed a Motion to Strike Portions of the SAC, Doc. No. 68, which the court denied as premature at the December 8, 2014 hearing.

521 F.3d 1061, 1065 (9th Cir. 2008). This tenet -- that the court must accept as true all of the allegations contained in the complaint -- "is inapplicable to legal conclusions." *Iqbal*, 556 U.S. at 678. Accordingly, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* (citing *Twombly*, 550 U.S. at 555); *see also Starr v. Baca*, 652 F.3d 1202, 1216 (9th Cir. 2011) ("[A]llegations in a complaint or counterclaim may not simply recite the elements of a cause of action, but must contain sufficient allegations of underlying facts to give fair notice and to enable the opposing party to defend itself effectively.").

Rather, "[a] claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 556). In other words, "the factual allegations that are taken as true must plausibly suggest an entitlement to relief, such that it is not unfair to require the opposing party to be subjected to the expense of discovery and continued litigation." *Starr*, 652 F.3d at 1216. Factual allegations that only permit the court to infer "the mere possibility of misconduct" do not show that the pleader is entitled to relief as required by Rule 8. *Iqbal*, 556 U.S. at 679.

## B. Federal Rule of Civil Procedure 9(b)

Federal Rule of Civil Procedure 9(b) requires that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." "Rule 9(b) requires particularized allegations of the circumstances *constituting* fraud." *In re GlenFed, Inc. Sec. Litig.,* 42 F.3d 1541, 1547 (9th Cir. 1994) (en banc), *superseded on other grounds by* 15 U.S.C. § 78u-4.

In their pleadings, Plaintiff must include the time, place, and nature of the alleged fraud; "mere conclusory allegations of fraud are insufficient" to satisfy this requirement. *Id*. at 1548 (citation and quotation signals omitted). However, "[m]alice, intent, knowledge, and other condition of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b); *see also In re GlenFed, Inc. Sec. Litig*, 42 F.3d at 1547 ("We conclude that plaintiffs may aver scienter . . . simply by saying that scienter existed."); *Walling v. Beverly Enter.*, 476 F.2d 393, 397 (9th Cir. 1973) (Rule 9(b) "only requires the identification of the circumstances constituting fraud so that the defendant can prepare an adequate answer from the allegations." (citations omitted)).

A motion to dismiss for failure to plead with particularity is the functional equivalent of a motion to dismiss under Rule 12(b)(6). *Vess v. Ciba-*

*Geigy Corp. USA*, 317 F.3d 1097, 1107 (9th Cir. 2003). In considering a motion to dismiss, the court is not deciding the issue of "whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *Jackson v. Carey*, 353 F.3d 750, 755 (9th Cir. 2003) (*quoting Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974)).

## IV. ANALYSIS

Due to the sheer number of the allegations in the SAC -- 539 paragraphs in total -- both Defendants and this court are faced with the daunting task of determining the precise basis for each of Plaintiff's claims and whether each claim alleges a plausible basis for relief. This task is further compounded by the facts that (1) the SAC includes a significant number of allegations that simply provide background information as opposed to a basis for a claim for relief, and (2) each claim incorporates by reference every paragraph alleged in the SAC without regard to which allegations actually make up the basis of each claim. To assist in wading through this sea of allegations, the court finds that the April 10, 2014 Order is a natural starting point to focus the parties' arguments on the claims now alleged in the SAC -- the April 10, 2014 Order detailed the legal framework for express preemption and implied preemption, and applied this framework in determining what claims and theories of relief Plaintiff was permitted to amend.

Further, in striking Plaintiff's First Amended Complaint, the court made clear that the claims in the SAC are limited to what the April 10, 2014 Order allowed and no more. The court therefore proceeds to address Defendants' arguments as to each claim, in light of the theories of relief allowed by the April 10, 2014 Order.

### A. Fraudulent Misrepresentation and Fraud by Omission (Count I), and Negligent Misrepresentation (Count II)

The SAC's claims for Fraudulent Misrepresentation and Fraud by Omission (Count I), and Negligent Misrepresentation (Count II) allege that Defendants misrepresented and/or concealed health and safety problems associated with off-label use of the Infuse Device in promoting the device to surgeons, and in particular to Dr. Graham. *See* Doc. No. 63, SAC ¶¶ 469, 482. Plaintiff's Complaint previously alleged a similar claim titled "Fraudulent Misrepresentation and Fraud in the Inducement," which the April 10, 2014 Order explained "appears to be based on misrepresentations and omissions (1) contained in the labeling of the Infuse Device, and/or (2) made in promoting off-label use of the Infuse Device." 15 F. Supp. 3d at 1036. The April 10, 2014 Order dismissed this claim without leave to amend as preempted to the extent it was based on fraud in the labeling of the Infuse Device. *Id.* The August 10, 2014 Order further

determined that a claim based on promoting off-label uses was not preempted, but that Plaintiff failed to allege sufficient facts supporting this theory.

Defendants argue that Plaintiff's new claims fail to correct the deficiencies of the Complaint -- that portions of these claims are preempted, and that Plaintiff has failed to allege with sufficient particularity any claim based on off-label promotion.[3] The court addresses these arguments in turn.

### *1. Preemption of Fraudulent Concealment Claims*

The April 10, 2014 Order outlined in detail the preemption framework, and the court does not detail its contours again here. In summary:

> Together, express preemption and implied preemption identify a "'narrow gap' through which a state-law claim must fit to escape preemption." [*Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013)]. "The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under [*Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001)])." *Id.* (citing *In re Medtronic, Inc., Sprint Fidelis Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010)) (emphasis in both). Thus, to avoid

[3] Defendants also argue that the court should strike the Negligent Misrepresentation claim because the April 10, 2014 Order did not grant Plaintiff leave to allege new claims. The court agrees that Plaintiff violated the April 10, 2014 Order by including this claim. As discussed at the December 8, 2014 hearing, however, the court declines to strike this claim given that leave to amend is freely granted, *see* Fed. R. Civ. P. 15(a), and Defendants presented substantive arguments seeking dismissal of this claim. Striking this claim would only further delay this action, especially where the court finds that Plaintiff has adequately alleged this claim.

> preemption, a plaintiff must assert a state-law claim that is premised on a violation of law, but that is not based solely on such violation.

*Id.* at 1032. Applying this framework, the April 10, 2014 Order determined that a fraud claim based on alleged misrepresentations and omissions in the labeling of the Infuse Device is "expressly preempted because it seeks to impose different and/or additional written warnings and labeling beyond those approved by the FDA through the PMA process." *Id.* at 1036. The April 10, 2014 Order further rejected Defendants' arguments that a fraud claim based on Defendants' alleged false and misleading off-label promotion of the Infuse Device was preempted, or that a fraud claim based on an omission theory was preempted. *Id.* at 1037.

Defendants once again argue that Plaintiff's claims, to the extent based on a fraud-by-omission theory, are preempted. In particular, Defendants argue that the FDA-approved label for the Infuse Device warned against off-label surgical procedures and ectopic bone growth such that Plaintiff's assertions that Defendants were required to disclose any additional information impermissibly challenges the sufficiency of the FDA labeling. Doc. No. 69-1, Def.'s Mot. at 11-12. The court rejects this argument.

As an initial matter, to the extent Plaintiff's claims suggest that Defendants were required to include any additional and/or different labeling, the

court agrees that such claim is not only preempted, but prohibited by the April 10, 2014 Order, which did not grant leave to assert such claims. But Plaintiff's allegations are not directed to the Infuse Device's *labeling* -- rather, Plaintiff asserts that Defendants failed to disclose relevant information regarding off-label uses of the Infuse Device to both the FDA and Dr. Graham. Indeed, the misrepresentations and omissions Plaintiff has identified are not directed to labeling, but rather directed to the statements and omissions Medtronic has made outside of the labeling and in promoting the Infuse Device for off-label purposes (and after the labeling was approved).

In particular, Plaintiff asserts that the relevant omissions include that Defendants failed to disclose to Dr. Graham that (1) there was no approved dose of the active ingredient that would make the Infuse Device safe for Plaintiff's TLIF procedure, (2) the Infuse Device has a 5.57 times greater risk of heterotopic bone grown than a patient undergoing a TLIF with local bone; and (3) the medical literature relied upon by Dr. Graham was largely ghost-written by Defendants.[4] *See* Doc. No. 72, Pl.'s Opp'n at 12-13 (citing Doc. No. 63, SAC ¶¶ 258, 412, 414-

[4] In reply, Defendants argue that preemption applies to any claim asserting that Defendants concealed that medical literature was ghost-written and edited by Medtronic employees. *See* Doc. No. 75, Def.'s Reply at 9. Because Defendants' argument is wholly conclusory and Plaintiff has not had the opportunity to respond, the court does not address this argument.

15, 430-32). In other words, Plaintiff asserts that Defendants should have disclosed this information when they promoted the Infuse Device for off-label purposes, and that these omissions induced Dr. Graham to use the Infuse Device for Plaintiff's surgery. The court therefore rejects that Plaintiff's fraud by omission claims are preempted.

***2. Whether the SAC Alleges a Plausible Basis for Relief***

In determining that the Complaint failed to sufficiently allege the basis of a fraud claim, the August 10, 2014 Order outlined that the Complaint detailed numerous alleged misrepresentations and omissions including, for example, that Defendants (1) funded studies which failed to accurately describe the adverse side effects of off-label uses, (2) ensured that adverse side effects were under-reported by writing and editing the published medical literature, and (3) used "opinion leaders" and other paid physician consultants to promote off-label uses of the Infuse Device at conferences, VIP meetings, demonstrations, and to serve as resources for other physicians seeking information on off-label uses. 15 F. Supp. 3d at 1038. The August 10, 2014 Order nonetheless dismissed the claim for failure to include allegations making "the connection between Defendants' alleged misdeeds and Plaintiff and Plaintiff's physicians -- *i.e.*, that

Plaintiff and Plaintiff's physicians relied on these misrepresentations." *Id.* at 1038.

Like the Complaint, the SAC once again alleges that Defendants engaged in numerous alleged misrepresentations and omissions. *See* Doc. No. 63, SAC at pp. 51-100 (outlining "Medtronic's Fraudulent Scheme to Promote Unapproved Use of Infuse Bone Graft to Surgeons like Plaintiff's Surgeon"); *see also id.* ¶ 469 (asserting various misrepresentations and omissions). The SAC also includes a new section, however, outlining the "False Representations and Omissions Made by Medtronic to [Dr. Graham]," *id.* at pp. 157-169, which attempts to tie Defendants' alleged misrepresentations to Dr. Graham's decision to use the Infuse Device for Plaintiff's surgery. In particular, the SAC alleges that Dr. Graham relied on a variety of tainted information regarding off-label uses of the Infuse Device which Medtronic provided to Dr. Graham through sales representatives, medical literature, and at medical conferences.

Defendants argue that Plaintiff's allegations as to each of these particular sources of information still fail to establish the requisite connection between any bad act by Medtronic and Dr. Graham's decision to use the Infuse Device for Plaintiff's surgery. The court agrees in part.

Plaintiff's allegations regarding several of these sources are still too vague to support the inference that Dr. Graham relied upon them in deciding to use the Infuse Device for Plaintiff's surgery. For example, the SAC alleges that Dr. Graham received medical journal articles from a Medtronic sales representative, Eric Hanson, as well as from Medtronic's Office of Medical Affairs. *See* Doc. No. 63, SAC ¶¶ 403-05. But the SAC never identifies (1) the specific journal articles that were provided to Dr. Graham, (2) the misrepresentations and/or omissions contained in these articles, (3) whether these articles discuss the Infuse Device for the specific off-label use for Plaintiff's surgery, and (4) the dates Dr. Graham received such information in relation to Plaintiff's surgery.

As another example, the SAC alleges that Medtronic exaggerated the drawbacks to using alternatives to the Infuse Device, such as using another bone harvested from the patient (called an "autograft"). *Id.* ¶ 406. The SAC infers that Dr. Graham relied on this information because he testified that he stopped using autografts due to the pain associated with harvesting bone from a patient's hip, which he asserted he knew based on his personal experience and the literature.[5]

[5] The SAC similarly alleges that Dr. Graham read literature by Dr. Charles Branch, who authored an article regarding a PLIF study which reported "astonishingly low and false number of adverse events." Doc. No. 63, SAC ¶ 410. The SAC never asserts, however, that Dr. Graham (continued...)

Doc. No. 63, SAC ¶¶ 408-09. But the SAC does not allege that Dr. Graham's belief is based on any literature written and/or influenced by Medtronic (as opposed to another source), leaving the court to speculate what literature Dr. Graham read, whether it was drafted and/or edited by Medtronic, and whether such literature included any false or misleading statements.

The SAC also alleges that Medtronic paid Dr. Graham to attend a medical conference in Memphis where Dr. Kevin Foley, one of Medtronic's "Key Opinion Leaders," ("KOL"),[6] may have made "some passing mention" of the Infuse Device for TLIF procedures while discussing a different Medtronic product. *Id.* ¶¶ 419-24. But the SAC fails to identify what Dr. Graham was told, or explain how only a "passing mention" of the procedure could influence Dr. Graham's decision to use the Infuse Device for Plaintiff's surgery.

Despite these conclusory allegations requiring speculation to connect Defendants' alleged misdeeds to Dr. Graham's decision to use the Infuse Device

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[5](...continued)
read this particular article by Dr. Branch (as opposed to any other articles Dr. Branch may have authored or edited), and the SAC fails to explain how this article (if Dr. Graham did in fact read it) affected his decision to use the Infuse Device for Plaintiff's surgery, which was a TLIF, not PLIF surgery. Indeed, Dr. Graham testified that he could not recall which of Dr. Branch's articles he read and that he may have been referring to a different "Dr. Branch." *See* Doc. No. 67, SAC Ex. 10 at 174-75.

[6] According to the SAC, a "KOL" is a surgeon who uses the Infuse Device in a high number of surgeries, whose opinion is well-regarded in the medical field, and who is paid by Medtronic to advocate off-label use of the Infuse Device. Doc. No. 63, SAC ¶¶ 162-65.

for Plaintiff's surgery, the SAC includes other allegations that make this connection plausible and that satisfy Rule 9(b). For example, the SAC alleges that Dr. Graham attended a conference at the Honolulu Spine Center prior to Plaintiff's surgery where Dr. Lanman, a KOL paid by Medtronic, spoke about using the Infuse Device for minimally invasive procedures such as TLIFs, and that this talk confirmed for Dr. Graham that the Infuse Device was appropriate for his patients such as Plaintiff. *Id.* ¶¶ 425-27. In other words, the SAC alleges that Dr. Lanman, on behalf of Medtronic, promoted the Infuse Device for the TLIF procedure, and that this talk gave Dr. Graham assurance that the TLIF procedure was a proper off-label use of the Infuse Device.[7]

The SAC also alleges that Dr. Graham received information regarding the Infuse Device from Medtronic sales representative Geoff Cloward, who was present for nearly every surgery Dr. Graham performed using the Infuse Device. *Id.* ¶¶ 398-400. Although Dr. Graham cannot recall which particular articles Cloward provided him, the SAC asserts that (1) Dr. Graham requested that

[7] Defendants argue that the SAC fails to allege with particularity an agency relationship between Dr. Lanman and Medtronic. *See* Doc. No. 69-1, Defs.' Mot. at 26. The court disagrees -- the SAC identifies him as a KOL receiving tens of thousands of dollars in consulting fees from Defendants, and that he actively promoted the Infuse Device for off-label purposes. Doc. No. 63, SAC ¶¶ 246-48, 428. These allegations support the inference that Defendants were paying Dr. Lanman to promote the Infuse Device for off-label purposes, and that he was Medtronic's agent. *See also Martin v. Medtronic, Inc.*, --- F. Supp. 3d ----, 2014 WL 6633540, at *6 (D. Ariz. Nov. 21, 2014) (determining that similar allegations were sufficient to establish agency).

Cloward provide literature demonstrating that the Infuse Device was efficacious for the procedures in which he intended to use the product, (2) the literature was likely directed to off-label uses because Dr. Graham does not perform ALIF procedures, and (3) none of the articles provided by Cloward contained alarming levels of adverse events which are now contained in more current literature. *Id.* ¶¶ 401-04. The SAC further asserts that Dr. Graham obtained dosing information from Medtronic sales representatives when using the Infuse Device off-label because they have "up-to-date information as far as the optimal dose to put in there," and that Dr. Graham relied on Cloward to determine the proper dose for Plaintiff's procedure. *Id.* ¶ 411. Cloward apparently provided Dr. Graham this information even though "[t]here is insufficient scientific evidence concerning the proper dosages of rhBMP-2 for use in unapproved procedures" such as Plaintiff's surgery. *Id.* ¶ 55. Thus, these allegations raise the reasonable inference that Cloward provided Dr. Graham information indicating that the Infuse Device was safe and effective for Plaintiff's TLIF procedure, including specific dosage information even though there is no safe and effective dosage when used off-label, and that Dr. Graham relied on this information.

In opposition, Defendants attempt to discredit these allegations. In particular, as to the allegations regarding Dr. Lanman, Defendants assert that

elsewhere in Dr. Graham's deposition testimony he asserted that Dr. Lanman did not discuss off-label uses of the Infuse Device. *See* Doc. No. 69-1, Def.'s Mot. at 25. Defendants ignore, however, that the deposition testimony also supports the allegations in the SAC, and conflicts in the testimony cannot be resolved on a motion to dismiss. Specifically, in support of the allegations in the SAC, Dr. Graham testified, in part:

> Q. Do you remember talking with any other people on that list that we had on Exhibit 7 about Infuse or rhBMP?
> A. Well, part of Dr. Lanman's lecture that he gave was, you know, his technique for -- I think he talked about mostly TLIF; but he did mention the use of Infuse for interbody fusion using TLIF technique.
> Q. Sure. And do you remember him telling you that it was safe and effective for that procedure?
> MR. BROWN: Objection, calls for speculation.
> A. I don't remember that; but, I mean, he presented his data. He showed us cases. He gave a lecture about it. You know, he talked about his -- talked about mostly surgical technique; but he did discuss the use of it.
> Q. Okay. And I think you said earlier that it confirmed your belief earlier that it was -- it was appropriate for use in your patients, correct?
> A. That's correct.

Doc. No. 67, SAC Ex. 10 at 173.

As to the allegations regarding Cloward, Defendants argue that the SAC fails to identify any specific misrepresentations and/or omissions that Cloward made. The allegations nonetheless raise the reasonable inference that he

provided Dr. Graham information regarding the Infuse Device for use in a TLIF procedure -- the SAC alleges that Dr. Graham requested that Cloward provide literature demonstrating that the Infuse Device was efficacious for the procedures in which he intended to use the product (*e.g.*, the TLIF procedure for Plaintiff's surgery), Dr. Graham decided to use the Infuse Device for Plaintiff's surgery, and Cloward provided Dr. Graham dosing information for this use. These allegations are "specific enough to give [D]efendants notice of the particular misconduct so that [they] can defend against the charge and not just deny that [they have] done anything wrong." *Vess*, 317 F.3d at 1108.

Finally, Defendants argue that the court should disregard Plaintiff's allegations that Cloward provided dosing information for Plaintiff's surgery because he is not listed on the hospital record identifying all individuals present in the operating room.[8] *See* Doc. No. 69-1, Def.'s Mot. at 26-27. Defendants ignore

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[8] Defendants also argue that the court should follow a handful of Minnesota state court cases which have rejected that allegations regarding dosing are sufficient to support a fraud claim. These cases are not persuasive authority on Hawaii law and are in any event distinguishable because they did not include similar allegations that a Medtronic representative provided dosing information for the plaintiff. *See, e.g.*, *Anderson v. Medtronic, Inc*., 2014 WL 5528664, at *5 (Minn. Dist. Ct. Oct. 16, 2014) (finding insufficient allegation that "Dr. Jensen met with a MEDTRONIC sales representative, who told Dr. Jensen that many other physicians were using Infuse® off-label suuessfully [sic] in the same manner that Dr. Jensen implanted Infuse® in JAMIE ANDERSON" where "Plaintiffs do not identify the sales representatives in question, or state when or where the alleged communications occurred[, or ]allege that the information communicated by the sales representatives was false"); *Davenport v. Medtronic, Inc.*, 2014 WL 1102736, at *2 (Minn. Dist. Ct. Mar. 19, 2014) ("Plaintiffs did not identify any (continued...)

that even if Cloward was not physically present for Plaintiff's surgery, such fact does not negate Plaintiff's allegations -- Cloward could still have provided this information without being in the room.

In sum, the court finds that Plaintiff has alleged sufficient facts making the connection between Defendants' alleged misdeeds and Plaintiff and Dr. Graham -- *i.e.*, that in determining to use the Infuse Device for Plaintiff's TLIF procedure, Dr. Graham relied on misrepresentations and/or omissions made by Medtronic or its agents. The court therefore DENIES Defendants' Motion to Dismiss Counts I and II of the SAC.

**B. Breach of Express Warranty (Count V)**

The April 10, 2014 Order determined that the Complaint's claim for breach of express warranty survived both express preemption and implied preemption, but that Plaintiff failed to allege sufficient facts to assert a plausible claim. 15 F. Supp. 3d at 1042-43. The April 10, 2014 Order explained that although the Complaint detailed Medtronic's alleged representations regarding off-label use of the Infuse Device, it failed "to include any facts suggesting that

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[8](...continued)
particular statement by Mr. Johnson, failing even to allege that he instructed Dr. Ray that his recommendations were safe and effective. Moreover, Plaintiffs have not alleged that Mr. Johnson played any particular role in Dr. Ray's medical decision to perform an off-label procedure on Mr. Davenport.").

those representations became the 'basis of the bargain' for Plaintiff and her physicians[, and] fail[ed] to describe what specific warranties Medtronic made to Plaintiff and/or her physicians." *Id.*; *see also Stoebner Motors, Inc. v. Automobili Lamborghini S.P.A.*, 459 F. Supp. 2d 1028, 1035 (D. Haw. 2006) (explaining that a breach of warranty claim requires a plaintiff to establish "that (1) Defendants made an affirmation of fact or promise regarding the product, (2) that statement became part of the basis of the bargain, and (3) the product failed to perform according to the statement") (quoting *Neilsen v. Am. Honda Motor Co.*, 92 Haw. 180, 190-91, 989 P.2d 264, 274-75 (Haw. App. 1999)).

Plaintiff bases her breach of warranty claims on the same allegations as her fraud claim -- that Defendants made warranties in the medical literature, during medical conferences, and by sales representatives who encouraged off-label uses of the Infuse Device. *See* Doc. No. 63, SAC ¶¶ 531-33. Defendants argue (as they did as to Plaintiff's fraud claims) that these allegations fail to allege the content of any specific misrepresentations, what was misleading about such warranties, and/or how Plaintiff and Dr. Graham relied on such warranties to cause

Plaintiff injury.[9] *See* Doc. No. 69-1, Defs.' Mot. at 29. The court rejects this argument.

As explained above for Plaintiff's fraud claims, some of the SAC's allegations regarding medical literature and other representations by individuals paid by Defendants are too vague and conclusory because they fail to identify the particular representation made and/or tie that representation to Dr. Graham's decision to use the Infuse Device for Plaintiff's TLIF procedure. Other allegations -- in particular, the SAC's allegations regarding Cloward's and Dr. Lanman's representations to Dr. Graham -- are sufficiently detailed to raise the reasonable inference that (1) Defendants, through Cloward and Dr. Lanman, made an affirmation of fact or promise that the Infuse Device was safe and effective for off-

[9] Defendants also argue, in conclusory fashion, that Plaintiff cannot allege a plausible breach of warranty claim because the labeling for the Infuse Device expressly disclaims the existence of any warranties. *See* Doc. No. 69-1. Defs.' Mot. at 30 (citing Doc. No. 63-6, SAC Ex. 8 at 3 ("No warranties, express or implied, are made."). Although Defendants cite two cases rejecting breach of warranty claims on this basis under Arizona and Delaware law respectively, *see Scovil v. Medtronic, Inc*., 995 F. Supp. 2d 1082, 1098 (D. Ariz. 2014), and *Scanlon v. Medtronic Sofamor Danek USA Inc*., --- F. Supp. 2d ----, 2014 WL 3737501, at *7 (D. Del. July 28, 2014), Defendants fail to address whether Hawaii law permits such disclaimers. Further, Defendants' argument fails to take into account that this claim is based on post-marketing statements. For example, *Alton v. Medtronic, Inc*., 970 F. Supp. 2d 1069 (D. Or. 2013), allowed a breach of warranty claim to stand, reasoning that this claim "is not premised on any warranty set forth in the Infuse labeling or in connection with any FDA-approved application of the Infuse device, but rather on alleged express warranties made to the medical community regarding the safety of non-approved applications of the protein component of the Infuse device." *Id.* at 1104-05. *Alton* therefore held that "any express warranty offered by Medtronic in the course of its voluntary statements to the public and to the medical community regarding off-label applications of the device would not be within the scope of the disclaimer contained in the FDA-mandated labeling." *Id.* at 1105.

label use such as in Plaintiff's surgery, (2) those statements became part of the basis of the bargain for Dr. Graham in deciding to use the Infuse Device for Plaintiff's surgery, and (3) the Infuse Device failed to perform according to Cloward's and Dr. Lanman's representations. These allegations therefore plausibly allege a breach of warranty claim.

The court therefore DENIES Defendants' Motion to Dismiss as to Plaintiff's breach of warranty claim.

### C. Strict Products Liability - Failure to Warn the FDA (Count III); and Negligent Failure-to-Warn the FDA (Count IV)

The Complaint alleged claims for strict liability and negligence based on the theory that Defendants failed to warn Plaintiff and Plaintiff's doctors regarding the adverse effects of using the Infuse Device in an off-label manner. The April 10, 2014 Order dismissed these claims as expressly preempted because they sought to impose a duty to provide warnings beyond those already outlined by the FDA, which is prohibited by *Riegel v. Medtronic, Inc*., 552 U.S. 312 (2008). 15 F. Supp. 3d at 1039-40. The April 10, 2014 Order nonetheless granted Plaintiff leave to amend to base these claims on the theory that Defendants failed to report to the FDA adverse events related to the Infuse Device's off-label use. *Id.* at 1040. The April 10, 2014 Order further did not address whether such a claim would be preempted or whether Plaintiff would be able to allege sufficient

facts to tie the failure to submit reports of adverse events to the FDA to a failure to warn Plaintiff and Plaintiff's physicians. *Id.*

The SAC now alleges these claims based on the theory that Medtronic failed to report adverse events to the FDA.[10] In particular, for the strict liability claims, the SAC alleges that (1) Defendants breached their duty to report to the FDA adverse events and all studies known to it regarding the Infuse Device's off-label use, Doc. No. 63, SAC ¶¶ 491-92; *see also id.* ¶¶ 109-19, 145; (2) as a result of this breach, the warnings provided by Medtronic failed to provide information an ordinary physician or consumer would expect when using the product in a reasonably foreseeable manner, *id.* ¶ 495; (3) Plaintiff and her physicians would have been able to make an informed decision regarding the Infuse Device had Defendants complied with their obligation to truthfully report adverse events, *id.* ¶ 498; and (4) Dr. Graham relied upon Defendants' inadequate warnings, causing harm to Plaintiff. *Id.* ¶¶ 501-02. Plaintiff's negligence claim similarly alleges that

[10] The SAC also includes some allegations suggesting that Defendants had a duty to warn Plaintiff and her physicians directly. *See* Doc. No. 63, SAC ¶ 490 (stating that Defendants had a duty to warn Plaintiff and her physicians); *id.* ¶¶ 510-11 (similar). Defendants point to these allegations as establishing that Plaintiff's claims are predicated on a failure to warn doctors directly, and are therefore preempted by the FDCA. *See* Doc. No. 69-1, Def.'s Mot. at 5. The court agrees that to the extent these allegations could be construed as alleging a stand-alone claim based on Defendants' duty to directly warn Plaintiff and her doctors, the April 10, 2014 Order already dismissed such claims as preempted without leave to amend. The allegations in the SAC, however, are broader than merely asserting a claim based on a failure to warn Plaintiff and her physicians -- they assert that Defendants failed to warn the FDA. The court therefore focuses on only those allegations relevant to this latter theory.

Defendants had a duty to Plaintiff and her physicians to exercise reasonable care in light of their superior knowledge of the Infuse Device, *id.* ¶¶ 509-511; (2) Defendants breached this duty by failing to report adverse events to the FDA; *id.* ¶¶ 513-514; and (3) due to this breach, Dr. Graham relied upon false and/or misleading information in deciding to use the Infuse Device on Plaintiff, causing Plaintiff injury. *Id.* ¶¶ 515-19.

Defendants argue that these claims are preempted by the FDCA and otherwise fail to allege a plausible claim for relief. The court addresses each of these arguments.

***1. Preemption***

Plaintiff's claims are based on a violation of federal law requirements -- that Defendants failed to report adverse events to the FDA. *See, e.g.*, 21 C.F.R. § 803.50(a). As a result, express preemption does not apply. *See Beavers-Gabriel*, 15 F. Supp. 3d at 1031 (explaining that a claim is "expressly preempted by the MDA where (1) the FDA has established requirements applicable to the particular medical device at issue; and (2) the state common law claims seek to impose requirements that are 'different from, or in addition to' the federal requirements, and that relate to safety and effectiveness" (quoting *Riegel*, 552 U.S. at 321-22)). Rather, Defendants appear to argue that Plaintiff's claims are

impliedly preempted, *i.e.*, that the claims are based solely on a violation of federal law, and not based on traditional state tort law. *See id.* at 1032. In particular, Defendants argue that their duty to report adverse events to the FDA is wholly separate from Defendants' duty to warn physicians under Hawaii law. So, the argument goes, this allegation is based solely on a violation of federal law, not a traditional state tort law such that preemption applies. *See* Doc. No. 69-1, Defs.' Mot. at 5-7. Based on *Stengel v. Medtronic Inc.*, 704 F.3d 1224 (9th Cir. 2013) (en banc), the court rejects this argument.

*Stengel* held that a negligence claim was not preempted where it alleged that Medtronic violated a state-law duty of care by failing to report known risks associated with a medical device to the FDA. Specifically, a proposed amended complaint alleged that:

> under federal law, Medtronic had a "continuing duty to monitor the product after pre-market approval and to discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product." It further alleges that Medtronic failed to perform its duty under federal law to warn the FDA. Finally, the complaint alleges that, because Medtronic failed to comply with its duty under federal law, it breached its "duty to use reasonable care" under Arizona negligence law.

*Id.* at 1232.

*Stengel* determined that this claim is not preempted "insofar as the state-law duty parallels a federal-law duty under the MDA." *Id.* at 1233. *Stengel* cited several state-law duties that run parallel to the federal-law duty to report to the FDA, including that Arizona law (1) "protects the safety and health of Arizona citizens by imposing a general duty of reasonable care on product manufacturers;" (2) "includes a cause of action for failure to warn," and (3) "contemplates a warning to a third party such as the FDA." *Id.* at 1233. As a result, *Stengel* held that this negligence claim "is a state-law claim that is independent of the FDA's pre-market approval process," and "rests on a state-law duty that parallels a federal-law duty under the MDA . . . ." *Id.*

Like Arizona law, Hawaii law imposes a general duty of reasonable care on product manufacturers, and recognizes a cause of action for failure to warn. *See, e.g.*, *Tabieros v. Clark Equip. Co.*, 85 Haw. 336, 354-55, 944 P.2d 1279, 1297-98 (1997) (recognizing "[t]he legal duty of manufacturers . . . to exercise reasonable care in the design and incorporation of safety features to protect against foreseeable dangers" and that "a manufacturer must give appropriate warning of any known dangers which the user of its product would not ordinarily discover" (quoting *Ontai v. Straub Clinic & Hosp., Inc*., 66 Haw. 237, 247-48, 659 P.2d 734, 742-43 (1983)) (footnotes omitted, alterations in original).

Further, this duty extends to warnings to third parties -- Hawaii law "impose[s] liability through the entire chain of distribution and manufacture under strict liability law," *Kealoha v. E.I. Du Pont de Nemours & Co.*, 844 F. Supp. 590, 595 (D. Haw. 1994), *aff'd sub nom*., *Kealoha v. E.I. du Pont de Nemours & Co.*, 82 F.3d 894 (9th Cir. 1996); and Hawaii courts have a "recognized public policy of providing 'the maximum possible protection that the law can muster against dangerous defects in products." *In re Haw. Fed. Asbestos Cases*, 960 F.2d 806, 817-18 (9th Cir. 1992) (quoting *Stewart v. Budget Rent-A-Car Corp*., 52 Haw. 71, 470 P.2d 240, 243 (1970)). Thus, this duty of care supplies a basis for Plaintiff's strict liability and negligence claims that arises independently of Plaintiff's duty to warn the FDA under federal law.

Defendants largely ignore *Stengel* and instead attempt to recast Plaintiff's failure-to-warn claims as boiling down to a challenge of the FDA labeling.[11] Doc. No. 69-1, Defs.' Mot. at 5-7. According to Defendants, doctors

[11] Defendants cite to a number of cases which are: (1) decided by courts not bound by *Stengel*; (2) otherwise unpersuasive; and/or (3) do not address similar claims to those alleged here. *See, e.g.*, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (determining that claim challenging labeling for generic drug was preempted); *Dunbar v. Medtronic, Inc*., 2014 WL 3056026, at *4 (C.D. Cal. June 25, 2014) (dismissing as preempted claim based on "a theory that either (1) Medtronic was required to include warnings beyond those in the FDA-approved label of INFUSE, or (2) Medtronic was obligated to issue post-sale warnings about potential adverse effects from off-label use of INFUSE"); *Pinsonneault v. St. Jude Med., Inc*., 953 F. Supp. 2d 1006, 1017 (D. Minn. 2013) (applying *In re Medtronic, Inc*., 623 F.3d 1200, 1205-06 (8th Cir. 2010), to find that claim based on failure to warn the FDA was preempted where the plaintiff (continued...)

such as Dr. Graham do not review adverse events reports and instead rely on the FDA labeling, and reporting adverse events rarely results in changes to labeling. Thus, Defendants assert that this claim attempts to hold Defendants liable for failure to change their labeling, a claim which would be expressly preempted. *Id.*

Contrary to Defendants' argument, Plaintiff is not challenging the labeling of the Infuse Device (a claim the court dismissed without leave to amend), but rather is asserting a straightforward *Stengel* claim -- that Defendants failed to provide required information to the FDA, which, if Dr. Graham was aware of, would have affected his decision to use the Infuse Device for Plaintiff's surgery.

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[11](...continued)
acknowledged that the "duty to report to the FDA arises only under federal law"); *Dawson v. Medtronic, Inc*., 2013 WL 4048850, at *7 (D.S.C. Aug. 9, 2013) (finding state-law claim preempted because "all of these regulations relate to information that manufacturers are required to provide to the FDA, and Plaintiff cannot usurp the FDA's regulatory oversight role for policing purported violations of the agency's regulations").

Needless to say, Defendants' caselaw is not persuasive. Rather, the vast majority of cases within this Circuit have applied *Stengel* to find that claims based on a failure to warn the FDA regarding off-label uses of the Infuse Device survive preemption. *See, e.g.*, *Arvizu v. Medtronic Inc*., --- F. Supp. 2d ----, 2014 WL 4204933, at *8 (D. Ariz. Aug. 25, 2014); *Martin v. Medtronic, Inc*., --- F. Supp. 2d ----, 2014 WL 3635292, at *12 (D. Ariz. July 23, 2014); *Eidson v. Medtronic, Inc*., --- F. Supp. 2d ----, 2014 WL 1996024, at *19 (N.D. Cal. May 13, 2014); *Houston v. Medtronic, Inc*., 2014 WL 1364455, at *7-8 (C.D. Cal. Apr. 2, 2014); *Hawkins v. Medtronic, Inc*., 2014 WL 346622, at *8 (E.D. Cal. Jan. 30, 2014); *Ramirez v. Medtronic Inc*., 961 F. Supp. 2d 977, 1002 (D. Ariz. 2013), *clarified on denial of reconsideration* (Oct. 24, 2013).

The court therefore finds that Plaintiff's strict liability and negligence claims based on a failure to warn the FDA theory are not preempted.

***2. Whether the Failure to Warn Claims Are Sufficiently Pled***

Defendants argue that Plaintiff has failed to allege any facts tying their alleged failure to submit reports of adverse events to the FDA to a failure to warn Dr. Graham, especially where Dr. Graham testified that he had no knowledge whether Medtronic reported adverse events to the FDA, and he was already aware at the time of Plaintiff's surgery of the potential for unwanted, ectopic bone growth, the complication which Plaintiff experienced. Doc. No. 69-1, Defs.' Mot. at 8-9. The court rejects this argument.

To establish this claim, Plaintiff must plead facts suggesting "that if Medtronic had properly reported the adverse events to the FDA as required under federal law, that information would have reached [Dr. Graham] in time to prevent [Plaintiff's] injuries." *Stengel*, 704 F.3d at 1234 (Watford, J., concurring) (citing *Hughes v. Boston Scientific Corp*., 631 F.3d 762, 770 n.5, 776 (5th Cir. 2011)). Plaintiff bases this claim on the theory that had Defendants properly reported adverse events to the FDA, "this would have effectively warned [Dr. Graham] of those adverse events -- both directly and through the discussion of those adverse events that would have followed in the literature and at meetings [Dr. Graham]

attended." Doc. No. 79, Pl.'s Suppl. Memo. at 3 (quoting *Eidson*, 2014 WL 1996024, at *20). The court finds that the SAC includes allegations supporting such conclusion.

After premarket approval, a device manufacturer has on-going reporting duties to the FDA. These include, for example, reporting specific adverse consequences to patients (*i.e.*, where the device causes or contributes to death or serious injury), as well as broader reporting requirements, including submitting periodic reports which include (1) a summary of "[u]npublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant;" and (2) a summary of "[r]eports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant." 21 C.F.R. § 814.84(b); *see also* Doc. No. 63, SAC ¶¶ 109-114, 117 (outlining reporting requirements to the FDA). Thus, a device manufacturer must report information regarding the device -- whether that information is known to the manufacturer or should reasonably be known it -- and which is found in not only published scientific literature, but also in unpublished data. The court refers to these reporting requirements simply as "the duty to report adverse events to the FDA."

The SAC asserts that Medtronic breached the duty to report adverse events to the FDA caused in off-label use of the Infuse Device. In particular, the SAC alleges that Medtronic was involved in drafting, editing, and shaping the content of medical journal articles authored by its KOLS, and that these articles falsely reported a lack of adverse events for off-label uses of the Infuse Device and/or mis-classified them as "anticipated" instead of "unanticipated," which prevented proper recognition of these events. *Id.* ¶¶ 256-58. Later independent reviews determined that there were 315 adverse events in studies where their published results stated there were "no unanticipated device-related adverse events," and that "[e]arlier disclosure of all relevant data would have better informed clinicians and the public than the initial published trial reports did." *Id.* ¶¶ 349-50. Another study "concluded that 'Level I and Level II evidence from original FDA summaries, original published data, and subsequent studies suggest possible study design bias in the original trials, as well as a clear increased risk of complications and adverse events to patients receiving rhBMP -2 in spinal fusion,'" and that "the 'risk of adverse events associated with rhBMP-2 is 10 to 50 times the original estimates reported in the industry-sponsored peer reviewed publications.'" *Id.* ¶ 371.

The SAC further includes allegations supporting a plausible inference that full disclosure of this information to the FDA would have affected Dr. Graham's decision to use the Infuse Device for Plaintiff's surgery. The SAC asserts that Dr. Graham relies on a number of sources of information when learning about a new product, including reading available articles and information provided by Medtronic sales representatives, attending conferences, and having discussions with others in the medical field. *Id.* ¶¶ 395-96. Dr. Graham also testified that he reads and relies on peer-reviewed literature in his field on a regular basis. Doc. No. 67, SAC Ex. 10. at 89. The literature available to Dr. Graham (whether provided directly to him or relied upon by others with whom he spoke), however, was allegedly infected with Medtronic's under-reporting of adverse events -- according to the SAC, Medtronic's alleged under-reporting of adverse events to the FDA was found not only in the articles it assisted in drafting and/or editing, but also in non-industry-sponsored studies which relied upon the information submitted to the FDA. *Id.* ¶ 497. Thus, these allegations suggest that Medtronic's alleged widespread failure to report adverse events to the FDA contributed to Dr. Graham's decision to use the Infuse Device for Plaintiff's surgery.

In opposition, Defendants argue that these allegations fail to sufficiently connect any failure to report adverse events to Dr. Graham's decision to use the Infuse Device for Plaintiff's surgery where (1) the SAC fails to identify what specific information Medtronic failed to report and how such information would be relevant to Plaintiff's surgery; (2) the SAC fails to identify any particular articles Dr. Graham relied upon in deciding to use the Infuse Device; and (3) Dr. Graham conceded that he never read any adverse reports submitted to the FDA. Doc. No. 82, Defs.' Suppl. Reply at 4-6.

The court rejects that Plaintiff must outline each and every adverse event that Medtronic failed to report. Rather, the SAC suggests that Medtronic's failure to report adverse events and/or mischaracterize them to avoid proper reporting was systemic, and resulted in an overall lack of disclosure of relevant data. *See* Doc. No. 53, SAC ¶¶ 256-58, 349-50, 371. Given these allegations, the court finds that Plaintiff need not identify any particular article Dr. Graham relied upon or allege that Dr. Graham read the information provided to the FDA to state a plausible claim under *Twombly*. Rather, these allegations plausibly support that this misinformation affected the medical field's dialog regarding the Infuse Device, and Dr. Graham was certainly part of that dialog through reading the literature, attending conferences, and in his discussions with others. Whether this

misinformation in fact affected Dr. Graham's decision to use the Infuse Device for Plaintiff's surgery is not an issue the court can resolve on a Rule 12(b)(6) Motion.

In further opposition, Defendant argues that the SAC cannot make the connection between any failure to report adverse events and Dr. Graham's decision to use the Infuse Device for Plaintiff's surgery where Dr. Graham testified that he knew of the risk of ectopic bone growth, the complication Plaintiff suffered from her surgery. Doc. No. 82, Defs.' Suppl. Reply at 7. Although Dr. Graham knew of the possible complications of using the Infuse Device, such fact does not discredit the SAC's assertions that full disclosure of all adverse events would have affected the information before Dr. Graham and his decision to use the Infuse Device. *See also Houston*, 2014 WL 1364455, at *8 n.3 (rejecting same argument because "[a]t issue is not Medtronic's failure to warn of a particular side effect, but rather Medtrnoic's alleged failure to warn of the incidence rate of certain serious side effects"); *Eidson*, 2014 WL 1996024, at *21 n.14 (rejecting similar argument and noting that "Defendants' arguments are best resolved by a jury").

The court therefore DENIES Defendants' Motion to Dismiss Counts III and IV of the SAC.

### D. Punitive Damages

Defendants argue that Plaintiff's claim for punitive damages fails where all of her other claims should be dismissed. Doc. No. 69-1, Defs.' Mot. at 31. To be clear, Plaintiff has not asserted a stand-alone claim for punitive damages -- the April 10, 2014 Order explained that punitive damages is a remedy, not a substantive claim for relief. 15 F. Supp. 3d at 1043. And to the extent Defendants argue that Plaintiff is not entitled to this relief, the court rejects such argument where the SAC asserts plausible claims. The court therefore DENIES Defendants' Motion to Dismiss as to Plaintiff's request for punitive damages.

## V. CONCLUSION

For the foregoing reasons, the court DENIES Defendants' Motion to Dismiss the Second Amended Complaint. Remaining in this action are Plaintiff's claims for:

(1) Fraudulent Misrepresentation and Fraud by Omission (Count I), and Negligent Misrepresentation (Count II), to the extent based on Defendants' alleged misrepresentations and/or concealments regarding health and safety problems associated with off-label use of the Infuse Device;

(2) Breach of Express Warranty (Count V), to the extent based on Defendants' alleged representations regarding off-label use of the Infuse Device; and

(3) Strict Products Liability - Failure to Warn the FDA (Count III); and Negligent Failure-to-Warn the FDA (Count IV), to the extent based on Defendants' alleged failure to warn Dr. Graham regarding the adverse effects of using the Infuse Device in an off-label manner.

IT IS SO ORDERED.

DATED: Honolulu, Hawaii, January 9, 2015.

/s/ J. Michael Seabright
J. Michael Seabright
United States District Judge