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| 6 | IN THE UNITED STATES DISTRICT COURT | |
| 7 | FOR THE DISTRICT OF ARIZONA | |
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| 9 | Cristina Ramirez, | No. CV-13-00512-PHX-GMS |
| 10 | Plaintiff, | ORDER |
| 11 | V. | |
| 12 | Medtronic Incorporated, a Minnesota corporation; and Medtronic Sofamor Danek | |
| 13 | USA Incorporated, Defendants, | |
| 14 | Defendant. | |
| 15 | Pending before the Court is Defendant's Motion for Reconsideration (Doc. 56), | |
| 16 | for the reasons stated below, the motion is denied. Nevertheless, to the extent that the | |
| 17 | Court did not sufficiently distinguish Perez in its order on the motion to dismiss, the | |
| 18 | Court makes the following clarification. | |
| 19 | In bringing its motion for clarification, Medtronics essentially acknowledges that it | |
| 20 | is not raising a new matter, but nevertheless respectfully asserts that this Court | |
| 21 | misperceives the actual import of Perez v. Nidek Co., Ltd., 711 F.3d 1109 (9th Cir. 2013). | |
| 22 | With its motion for reconsideration, Medtronics provides the Court with the appellate | |
| 23 | briefs and the complaint in the lower court in Perez to assert that the Ninth Circuit Panel | |
| 24 | had before it the question of whether pre-emption covered of off-label uses of FDA | |
| 25 | approved products that were promoted by their manufacturers as well as on-label uses of | |
| 26 | medical devices approved by the FDA. Thus, Medtronics asserts that Perez should be | |
| 27 | read to stand for the proposition that federal law pre-empts any liability for medical | |
| 28 | product manufacturers who actively promote the off-label use of their approved FDA | |
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products. Because Infuse was approved by the FDA for some treatments, Medtronics asserts that it cannot be held liable for any off-label use of Infuse that it actively promoted. With all due respect, *Perez* cannot be read so broadly.

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As this Court determined in its order denying the motion to dismiss, the basis of the *Perez* Court's decision does not relate to whether the manufacturer or other parties of the medical product involved in *Perez* were promoting off-label uses. Rather, the basis of the Court's decision is that none of the Plaintiffs alleged that they suffered any injury as a result of the off-label use of the medical product at issue in that case—a surgical procedure involving a laser to treat farsightedness. Further, none of the Plaintiffs alleged that the laser surgery was ineffective in treating their farsightedness. ("[Plaintiff] does not allege any injury stemming from surgery. Nor does [Plaintiff] claim that his or any other surgery was ineffective.") Id. at 1112. Their claims resulted "solely because the Food and Drug Administration ("FDA") status of the device was not disclosed to them." *Id.* at 1111.

15 In affirming the District Court's dismissal of the California common law claims 16 based on both express and implied pre-emption, the Court re-affirmed that, in light of the 17 absence of any injury, or any claim that the surgery was ineffective, the putative class 18 claimants' common law causes of action, were at their core, merely a claim that would 19 have required the laser manufacturer, health care facilities, and physicians to issue 20 warnings not required by the FDA and the Medical Device Amendments. "The theory is 21 that the defendants misled the proposed class by failing to disclose that the Laser was not 22 FDA approved for hyperopic [farsightedness] surgeries even though Nidek and the 23 doctors knew or should have known that the proposed class members believed the Laser 24 was FDA approved for such surgeries." *Id.* at 1117.

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claim for violating a state-law duty that parallels a federal-law duty under the MDA."

Nevertheless, even in the case of such parallel claims, the MDA preempted any

requirement that "is different from, or in addition to, any requirement applicable under

In its analysis the *Perez* court noted that "the MDA does not preempt a state-law"

this chapter to the device." Because the gravamen of the claims was not one for injury or
even for the ineffectiveness of the surgery, the Defendants were merely seeking, through
the auspices of state law, to require a warning in circumstances in which the FDA and the
MDA did not require a warning. The claim was thus pre-empted by federal law.

5 Further, the *Perez* court held that a state law claim that merely sought to impose 6 additional warnings to those required by a federal regulatory scheme that was already 7 being enforced by the FDA was impliedly pre-empted because it was analogous to the 8 *Buckman* claim that the Defendants were committing fraud on the FDA. But, the Court 9 further noted:

> Although [Plaintiff] is not barred from bringing *any* fraud claim related to the surgeries, he cannot bring a claim that rests solely on the non-disclosure to patients of facts tied to the scope of PMA approval. While courts have acknowledged that some fraud and false advertising claims related to FDA status may go forward, Perez cites to no case where a court has allowed a plaintiff to bring suit solely for failure to disclose lack of FDA approval.

16 *Id.* at 1119-20.

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17 Unlike Perez, here Plaintiff is not seeking to use state law merely to have it impose a disclosure obligation on manufacturers that is not required by federal law in the 18 19 absence of other real damage to the Plaintiff. Ms. Ramirez alleges specific harm 20 attributable to the off-label use of the device which off-label uses were actively promoted by Medtronics in various ways. The complaint alleges that off-label uses of Infuse by 21 22 physicians made up close to 90% of the \$800 million dollars in revenue that Infuse 23 generated in 2011, that it had consulting agreements with physicians who promoted the 24 off-label uses of Infuse, including the surgeon that performed the unsuccessful surgery on 25 the Plaintiff. To read *Perez* as constituting a blanket pre-emption on all off-label uses of 26 an FDA approved product that has been actively promoted by a manufacturer for off-27 label uses, seems to run contrary to the specific language in *Perez*, that provides that 28 "although [Plaintiff] is not barred from bringing any fraud claim related to the surgeries,

he cannot bring a claim that rests solely on the non-disclosure to patients of facts tied to 2 the scope of PMA approval." Here Ramirez does not assert such a claim, but asserts a claim based on real physical injury to herself and the further assertion of an ineffective 3 4 surgical procedure.

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5 Further to read *Perez* to pre-empt all claims against manufacturers who actively promote the off-label use of products approved by the FDA for other uses would provide 6 7 manufacturers with not just a shield, but a sword through which they could, with 8 impunity, promote unapproved uses of approved products in ways that might be 9 profitable but extremely dangerous to the public, and this for product uses that are not subjected to the use-specific specifications mandated by the FDA and for which pre-10 11 emption should apply. While *Perez* does seem to stand for the proposition that when the 12 Plaintiff suffered no injury from the off-market use of an approved product promoted by 13 a manufacturer any claim against a manufacturer is pre-empted, nothing in Perez stands 14 for the proposition that so long as a manufacturer's product has been approved for any 15 use, the manufacturer may promote off-label uses with impunity.

16 Under Rule 59(e), a motion for reconsideration may be granted only on one of four grounds, "1) the motion is necessary to correct manifest errors of law or fact upon 17 18 which the judgment is based; 2) the moving party presents newly discovered or 19 previously unavailable evidence; 3) the motion is necessary to prevent manifest injustice 20 or 4) there is an intervening change in controlling law." Turner v. Burlington N. Santa Fe R.R. Co., 338 F.3d 1058, 1063 (9th Cir. 2003) (internal quotations and emphasis 21 22 omitted). Motions for reconsideration are disfavored and are not the place for parties to 23 make new arguments not raised in their original briefs and arguments. See Northwest 24 Acceptance Corp. v. Lynnwood Equip., Inc., 841 F.2d 918, 925-26 (9th Cir. 1988). Nor 25 should such motions ask the Court to "rethink what the court has already thought 26 through-rightly or wrongly." See United States v. Rezzonico, 32 F.Supp.2d 1112, 1116 27 (D. Ariz. 1998) (quoting Above the Belt, Inc. v. Mel Bohannon Roofing, Inc., 99 F.R.D. 28 99, 101 (E.D. Va. 1983)). The Court has already thought through the claim that Perez.

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prevents at least some of the claims asserted here. At the motion to dismiss stage, this
 Court rejected that contention. While this motion for reconsideration has allowed the
 Court to re-examine the issue and state its distinction with more clarity, the result is the
 same. The Motion for Reconsideration is denied.
 IT IS HEREBY ORDERED that the Motion for Reconsideration (Doc. 56) is

IT IS HEREBY ORDERED that the Motion for Reconsideration (Doc. 56) is denied.

Dated this 24th day of October, 2013.

A Munay Suon G. Murray Snow

G. Murray Snow United States District Judge