

**UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA**

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BRETT SCOVIL,

Plaintiff,

v.

MEDTRONIC INCORPORATED,
MEDTRONIC SOFAMOR DANEK USA
INCORPORATED, and MEDTRONIC
VERTELINK INCORPORATED,

Defendants.

Case No. 2:14-CV-00213-APG-VCF

ORDER

(DKT. #51)

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Plaintiff Brett Scovil alleges he suffered when his physicians used the Infuse Bone Graft and LT-Cage (“Infuse”) device during his back surgery. Scovil contends his physicians used the device in a way not approved by the Food and Drug Administration (“FDA”), which he refers to as “off-label” use. Scovil alleges his physicians did so because defendants falsely promoted that physicians could safely and effectively use Infuse off-label. He therefore asserts various claims against defendants Medtronic Incorporated, Medtronic Sofamor Danek USA Incorporated, and Medtronic Vertelink Incorporated (together, “Medtronic”) for their conduct in promoting off-label use of the device as safe and effective.

Scovil initially brought suit in Arizona with his brother, Leigh Scovil, who also underwent back surgery with the Infuse device. (Dkt. #1.) The United States District Court for the District of Arizona dismissed the plaintiffs’ manufacturing defect, design defect, failure to warn, and strict liability claims as preempted by the Food, Drug, and Cosmetic Act (“FDCA”). (Dkt. #30 at 15-17, 20.) The court also found their negligence claim was preempted to the extent it was based on “researching, manufacturing, selling, labeling, testing, distributing, and analyzing” Infuse, but the court ruled their negligence, fraud, and intentional misrepresentation claims were not preempted to the extent they were based on defendants’ marketing of Infuse. (*Id.* at 17-19.) The court also found the fraud and intentional misrepresentations claims were pled with the requisite

1 particularity. (*Id.* at 18-19.) The court declined to find the unfair competition claim was
2 preempted, but the court noted the claim potentially lacked legal merit. (*Id.* at 19 & n.14.)
3 Finally, the court dismissed claims for breach of express and implied warranties because it found
4 Medtronic conspicuously disclaimed all warranties, and such disclaimers are valid under Arizona
5 law. (*Id.* at 20.) The court then granted Medtronic’s motion to sever the two plaintiffs’ claims
6 and transferred Brett Scovil’s case to this court. (*Id.* at 20-21.)

7 After the transfer, the parties agreed that Scovil would file an amended complaint. (Dkt.
8 #42.) Scovil’s amended complaint asserts claims against Medtronic for manufacturing defect,
9 failure to warn, negligence, fraud, intentional misrepresentation, Nevada unfair competition, and
10 breach of express and implied warranties. (Dkt. #43.) Medtronic again moves to dismiss each of
11 these claims on various grounds.

12 **I. Background**

13 Medtronic manufactures, promotes, and markets the Infuse device, which is used by
14 surgeons in back surgeries to cure back pain.¹ (Dkt. #43 at 2-4.) Infuse consists of two
15 components that are sold in separate packages but are meant to be used as a single device. (*Id.* at
16 2, 9.) The first component is a protein that stimulates bone growth, known as recombinant human
17 bone morphogenetic protein-2, that is placed on a collagen sponge. (*Id.* at 2, 8.) The second
18 component is a metal cage that acts as a scaffold to hold the sponge. (*Id.* at 2.)

19 Infuse was classified as a Class III device under the FDCA. (*Id.* at 5.) Class III devices
20 pose the greatest risk of death or injury and includes implantable surgical devices such as Infuse.
21 (*Id.*); *see also* 21 U.S.C. § 360c(a)(1)(C). Because Infuse is a Class III device, Medtronic was
22 required to obtain premarket approval from the FDA prior to selling it on the market. (Dkt. #43 at
23 5-6); *see also* 21 U.S.C. § 360c(a)(1)(C). The premarket approval process is designed to provide
24 the FDA with reasonable assurance that the device is safe and effective for its intended use. (Dkt.
25 #43 at 6); *see also* 21 U.S.C. § 360c(a)(1)(C). During this process, the FDA determines the

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27 ¹ The factual recitation is derived from the complaint’s allegations, which I take as true for
28 purposes of resolving Medtronic’s motion to dismiss. *See Williams v. Gerber Prods. Co.*, 552 F.3d 934,
937 (9th Cir. 2008).

1 proper labeling for the device's intended uses. (Dkt. #43 at 6); *see also* 21 U.S.C.
2 §§ 360c(a)(2)(B), 360e(d)(1)(A). A manufacturer is not permitted to market the device until it
3 has FDA approval and once approval is obtained, the manufacturer cannot promote the device for
4 uses that have not been approved by the FDA. (Dkt. #43 at 6); *see also* 21 U.S.C. § 360e; 21
5 C.F.R. § 814.80. Following approval, the manufacturer is under a continuing duty to report to the
6 FDA any information that reasonably suggests the device caused or contributed to death or
7 serious injury. (Dkt. #43 at 6); *see also* 21 C.F.R. § 803.50(a). The FDA granted premarket
8 approval to Infuse on July 2, 2002 for a limited use where both components must be used together
9 in an anterior lumbar interbody fusion procedure involving a single-level fusion in the L4-S1
10 region. (Dkt. #43 at 6, 9-10.)

11 According to Scovil, after approval, Medtronic failed to advise the FDA of dangers related
12 to Infuse. (*Id.* at 6.) Scovil contends the protein can lead to excessive bone growth and related
13 complications. (*Id.* at 11.) Scovil alleges Medtronic knowingly failed to report adverse events to
14 the FDA as required. (*Id.* at 18-19.)

15 Additionally, Scovil alleges Medtronic engaged in a concerted campaign to promote uses
16 of Infuse not approved by the FDA. He alleges this campaign included false representations
17 about the safety of off-label uses of the device or its components. (*Id.* at 6.) For example, Scovil
18 alleges Medtronic promoted Infuse as safe to use in back surgery procedures other than the
19 anterior lumbar interbody fusion procedure. (*Id.* at 10-11.) As evidence of this marketing
20 scheme, Scovil alleges Medtronic sales representatives and consultants received a booklet
21 containing information about the volume and dosage of the protein to be used in off-label
22 applications. (*Id.* at 17.) Additionally, Scovil asserts Medtronic developed a CD series that
23 included information on off-label procedures and sponsored a training program that showed
24 physicians how to perform these off-label uses. (*Id.*)

25 Scovil contends Medtronic made millions of dollars in undisclosed payments to certain
26 doctors, whom Scovil refers to as "Key Opinion Leaders," to publish articles in medical journals,
27 deliver presentations, and appear at consulting engagements to promote off-label uses of Infuse.
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1 (*Id.* at 15, 17-18.) Specifically, Scovil asserts Dr. Thomas A. Zbeblick co-authored preliminary
2 studies of Infuse without disclosing he received millions of dollars from Medtronic. (*Id.* at 15.)
3 Scovil identifies several other doctors by name who allegedly received millions of dollars from
4 Medtronic. (*Id.*) According to the amended complaint, sales of the protein greatly exceeded sales
5 of the separately-packaged metal cage even though the devices were supposed to be used
6 together, demonstrating substantial off-label use as a result of Medtronic’s marketing. (*Id.* at 13.)

7 Scovil underwent back surgery on October 24, 2006. (Dkt. #43 at 24.) Scovil’s surgeons
8 performed a two-level (L4-5 and L5-S1) anterior lumbar interbody fusion procedure using only
9 the Infuse Bone Graft component without the LT-Cage. (*Id.* at 24.) The surgeons’ use of the
10 device in this fashion was off-label because they used it at multiple vertebra levels and they did
11 not use the LT-Cage. (*Id.*) Following the surgery, Scovil suffered severe back pain. (*Id.*) In the
12 spring of 2013, Scovil’s doctor advised him that his back pain was the result of nerve
13 impingement from bony overgrowth caused by the Infuse Bone Graft. (*Id.*) According to Scovil,
14 his surgeons used Infuse off-label due to Medtronic’s promotion campaign and because they were
15 unaware of the risks associated with off-label use. (*Id.* at 23-24; *see also id.* at 17.)

16 In his Amended Complaint, Scovil asserts claims for manufacturing defect (count one),
17 failure to warn (count two), negligence (count four),² fraud (count five), intentional
18 misrepresentation (count six), Nevada Unfair Competition Law (count seven), and breach of
19 express and implied warranties (count eight). Medtronic moves to dismiss, arguing Scovil
20 inappropriately re-pleaded the manufacturing defect, failure to warn, and negligence claims even
21 though those claims previously were dismissed in whole or in part. Medtronic also argues I
22 should reconsider whether Scovil pleaded his fraud and intentional misrepresentation claims with
23 particularity. Medtronic contends I should dismiss the unfair competition claim because Nevada
24 does not have an “Unfair Competition Law.” Finally, Medtronic argues I should dismiss Scovil’s
25 breach of warranty claims because Nevada would give effect to Medtronic’s conspicuous
26 disclaimer of warranties.

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28 ² The Amended Complaint does not contain a cause of action labeled as count three.

1 Scovil responds that he has clarified his manufacturing defect and failure to warn claims
2 such that they no longer are preempted. Scovil contends his negligence, fraud, and intentional
3 misrepresentation claims are not preempted because they are based on Medtronic’s false
4 representations made during the promotion of off-label uses of Infuse. Scovil also argues the
5 District of Arizona already held he adequately pleaded his fraud-based claims with the requisite
6 particularity. Finally, Scovil asserts that his breach of express warranty claim survives because,
7 under Nevada law, Medtronic’s express warranties about Infuse’s safety in off-label uses override
8 a general disclaimer.

9 **II. Discussion**

10 In considering a motion to dismiss, “all well-pleaded allegations of material fact are taken
11 as true and construed in a light most favorable to the non-moving party.” *Wylar Summit P’ship v.*
12 *Turner Broad. Sys., Inc.*, 135 F.3d 658, 661 (9th Cir. 1998). However, I do not necessarily
13 assume the truth of legal conclusions merely because they are cast in the form of factual
14 allegations in the plaintiff’s complaint. *See Clegg v. Cult Awareness Network*, 18 F.3d 752, 754-
15 55 (9th Cir. 1994). A plaintiff must make sufficient factual allegations to establish a plausible
16 entitlement to relief. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007). Such allegations
17 must amount to “more than labels and conclusions, [or] a formulaic recitation of the elements of a
18 cause of action.” *Id.* at 555.

19 Portions of Medtronic’s motion seek reconsideration of the District of Arizona’s prior
20 order in this case. Unless the court expressly enters final judgment, the court’s orders are
21 “subject to reopening at the discretion of the district judge.” *Moses H. Cone Mem’l Hosp. v.*
22 *Mercury Constr. Corp.*, 460 U.S. 1, 12 (1983) (citing Fed. R. Civ. P. 54(b)). “Reconsideration is
23 appropriate if the district court (1) is presented with newly discovered evidence, (2) committed
24 clear error or the initial decision was manifestly unjust, or (3) if there is an intervening change in
25 controlling law.” *Sch. Dist. No. 1J, Multnomah Cnty., Or. v. ACandS, Inc.*, 5 F.3d 1255, 1263 (9th
26 Cir. 1993). A district court also may reconsider its decision if “other, highly unusual,
27 circumstances” warrant it. *Id.*

1 **A. Manufacturing Defect - Count One**

2 Scovil’s original complaint contained a manufacturing defect claim. (Dkt. #1 at 32.) The
3 District of Arizona ruled this claim was preempted by the FDCA because Medtronic “did not
4 violate any federal law concerning its manufacturing process, and finding that the process was
5 unsafe would necessarily undermine the FDA’s finding that the benefits of its manufacturing
6 process for on-label uses outweighed the risks presented by off-label uses.” (Dkt. #30 at 16.)
7 Count one of Scovil’s amended complaint alleges that the “Infuse drug implanted into [Scovil]
8 was defective as evidenced by its failure to comply with the manufacturing specifications
9 required” by the FDA through premarket approval. (Dkt. #43 at 25.) Additionally, Scovil alleges
10 Medtronic “failed to manufacture the specific Infuse Device [Scovil] received in accordance with
11 the FDA-approved manufacturing process and specifications.” (*Id.*) Scovil alleges the device he
12 received “differs from Infuse devices that were manufactured in accordance with the FDA’s pre-
13 market approval,” and “the specific Infuse [he] received contained a defect and was unreasonably
14 dangerous.” (*Id.*)

15 Medtronic moves to dismiss this claim, arguing Scovil improperly reasserted it.
16 Medtronic also argues that to the extent Scovil is now attempting to assert his particular Infuse
17 device was defective because it was not manufactured in accordance with the FDA-approved
18 manufacturing process, he has not adequately alleged what about the Infuse used in his procedure
19 was defective, how the defect resulted from a deviation from the approved manufacturing
20 process, or what federal requirement Medtronic failed to satisfy in manufacturing the device used
21 in Scovil’s procedure. Scovil responds that he is not reasserting the same claim the District of
22 Arizona found preempted. Rather, he is clarifying that his manufacturing defect claim is based on
23 a theory that Medtronic failed to manufacture the Infuse device he received in accordance with
24 the FDA-approved manufacturing process.

25 To allege a strict products liability claim, a plaintiff must allege that: “1) the product had a
26 defect which rendered it unreasonably dangerous, 2) the defect existed at the time the product left
27 the manufacturer, and 3) the defect caused the plaintiff’s injury.” *Fyssakis v. Knight Equip. Corp.*,

1 826 P.2d 570, 571 (Nev. 1992). The plaintiff must allege facts supporting each of these elements
2 to plead a plausible entitlement to relief. *Wilson v. Hewlett-Packard Co.*, 668 F.3d 1136, 1143-45
3 (9th Cir. 2012) (holding the plaintiff adequately alleged facts identifying the design defect and a
4 safety hazard but the plaintiff did not allege a causal connection between the alleged defect and
5 the safety hazard).

6 Scovil has not alleged facts plausibly showing a manufacturing defect. Scovil has not
7 alleged any facts regarding a defect in the Infuse device used in his procedure, how the
8 manufacturing process for his device differed from the FDA-approved process, or how any such
9 defect caused his injury. Scovil's factual allegations state it was the manner in which his
10 surgeons used the Infuse, not a manufacturing defect in the particular device, that led to his
11 injuries. Scovil's conclusory allegations tracking the elements of a manufacturing defect claim,
12 with no pertinent facts in support, are insufficient. In response to Medtronic's motion, Scovil has
13 not identified any additional facts he could or would allege to cure these pleading deficiencies,
14 nor does he request leave to amend this claim. I therefore dismiss Scovil's manufacturing defect
15 claim with prejudice.

16 **B. Failure to Warn - Count Two**

17 Scovil's original complaint contained a failure to warn claim. (Dkt. #1 at 33.) The District
18 of Arizona held the claim was preempted because it would require Medtronic to give additional
19 warnings not required by the FDA. (Dkt. #30 at 17.) Scovil has added new allegations that
20 Medtronic failed to report adverse events to the FDA as required. Count two of the amended
21 complaint alleges Medtronic was under a continuing duty to report adverse events to the FDA.
22 (Dkt. #43 at 26.) Scovil alleges Medtronic failed to report adverse events to the FDA as required,
23 thereby preventing his surgeons from learning of the dangers associated with off-label use. (*Id.*)

24 Medtronic moves to dismiss this claim for two reasons. First, Medtronic argues Scovil
25 has not alleged sufficient supporting facts. Second, Medtronic also argues that even if this claim
26 is sufficiently pleaded, it is impliedly preempted because it attempts to enforce the Medical
27 Devices Amendments ("MDA") to the FDCA through private litigation. Scovil responds that this
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1 claim is adequately pleaded, and that the claim is not preempted because he alleges Medtronic
2 violated federal law and he bases his claim on a parallel duty to report defects under state law.
3 Scovil contends the Ninth Circuit previously held a similar claim was not preempted.

4 *1. Adequate Allegations*

5 Scovil alleges Medtronic had a duty to warn about the dangers associated with off-label
6 use of Infuse, including a continuing duty to report adverse events to the FDA. (Dkt. #43 at 26.)
7 Scovil alleges that before his surgery, Medtronic “failed to provide medical device reports to the
8 FDA . . . concerning problems with off-label Infuse use.” (*Id.*) He further alleges Medtronic’s
9 failure to do so prevented Scovil and his surgeons, who allegedly were unaware of the risks
10 associated with off-label use of Infuse, “from learning of the dangers of using Infuse in off-label
11 procedures.” (*Id.*; *see also id.* at 13-14, 24.) The amended complaint also alleges that once the
12 FDA learned of adverse outcomes, it took regulatory action, including issuing a public health
13 notification and declining to approve a higher strength version of Infuse. (*Id.* at 13.) Scovil
14 alleges Medtronic’s failures “proximately caused” his injuries. (*Id.* at 26.)

15 Viewing these allegations and all reasonable inferences in Scovil’s favor, he has alleged
16 a plausible claim for relief. Scovil has alleged non-conclusory allegations that Medtronic had a
17 duty to report adverse events to the FDA; that it failed to do so before Scovil’s surgery; that had it
18 done so, the FDA would have taken action to warn the public about additional adverse events;
19 and that once Scovil’s physicians received further information, they would not have conducted
20 the off-label procedure. Whether Scovil will be able to prove his claim is not before me at the
21 dismissal stage, nor is Medtronic’s factual quarrel with whether it actually failed to report adverse
22 events to the FDA or whether the FDA would have issued warnings had the FDA been aware of
23 additional adverse events. I therefore deny Medtronic’s motion to dismiss on this ground.

24 *2. Preemption*

25 A state law tort claim may be expressly or impliedly preempted by the MDA. *See Riegel*
26 *v. Medtronic, Inc.*, 552 U.S. 312, 321-22 (2008); *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531
27 U.S. 341, 348 (2001). The MDA contains an express preemption clause:
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1 Except as provided in subsection (b)³ of this section, no State or political
2 subdivision of a State may establish or continue in effect with respect to a device
intended for human use any requirement--

3 (1) which is different from, or in addition to, any requirement applicable under this
chapter to the device, and

4 (2) which relates to the safety or effectiveness of the device or to any other matter
5 included in a requirement applicable to the device under this chapter.

6 21 U.S.C. § 360k(a); *see also* 21 C.F.R. § 808.1(d)(2). By its plain language, the MDA expressly
7 preempts “only state requirements ‘different from, or in addition to, any requirement applicable . .
8 . to the device’ under federal law.” *Riegel*, 552 U.S. at 321. Thus, to determine if a claim is
9 expressly preempted, I first determine whether the federal government “has established
10 requirements applicable to” the device in question. *Id.* at 321. The premarket approval process
11 constitutes federal requirements applicable to Infuse, and thus the first element of the express
12 preemption test is satisfied. *See id.* at 322-23. I thus must determine whether the asserted state
13 law claims are based on Nevada requirements that are different from or in addition to those
14 federal requirements. *See id.* at 321-22.

15 Implied preemption, on the other hand, occurs when Congress occupies the field of a
16 regulated area (field preemption) or when state requirements conflict with federal requirements
17 (conflict preemption). *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1230 (9th Cir. 2013) (en banc).
18 The FDA and MDA do not field preempt state law tort claims. *Id.* at 1231. However, the FDA
19 and the MDA may conflict preempt state tort claims if the state law “actually conflicts with a
20 federal requirement, making impossible compliance with both requirements . . . or when a state
21 requirement stands as an obstacle to the accomplishment and execution of the full purposes and
22 objectives of Congress.” *Id.* (quotation and internal citations omitted). For example, the FDCA
23 provides the FDA “a variety of enforcement options that allow it to make a measured response to
24 suspected fraud upon the Administration.” *Id.* at 353. Thus, allowing a state law tort claim based
25 on fraud on the FDA during the premarket approval process would “inevitably conflict with the
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28 ³ Subsection (b) does not apply.

1 FDA’s responsibility to police fraud consistently with the Administration’s judgment and
2 objectives,” and thus was impliedly preempted. *Id.* at 350, 353. Additionally, because Congress
3 intended the MDA to be enforced only by the federal government, to avoid implied preemption,
4 the plaintiff’s state law claims must arise from independent state law duties that do not “exist
5 solely by virtue of the FDCA . . . requirements.” *Id.* at 352-53.

6 In sum, there is a “narrow gap through which a state-law claim must fit to escape
7 preemption by the FDCA.” *Perez v. Nidek Co., Ltd.*, 711 F.3d 1109, 1120 (9th Cir. 2013)
8 (quotation omitted). “The plaintiff must be suing for conduct that *violates* the FDCA (or else his
9 claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the
10 conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*.)” *Id.*
11 (quotation omitted, emphasis in original).

12 The Ninth Circuit has held that a state law tort claim alleging the defendant failed to
13 report adverse events to the FDA as required was not preempted where that same conduct
14 violated state law imposing a duty on manufacturers to use reasonable care to warn about an
15 unsafe product. In *Stengel*, the plaintiff made the same failure to warn argument Scovil makes
16 here, but in relation to a different Medtronic medical device. 704 F.3d at 1226, 1232-33. The
17 Ninth Circuit held this claim was not expressly preempted because Arizona law imposed on
18 manufacturers a duty to warn about known risks associated with a product, and this duty
19 paralleled the federal duty imposed by the MDA to report known adverse events to the FDA. *Id.*
20 at 1233. The state law tort claim was not impliedly preempted because it depended on the
21 independent state law duty rather than on the federal statutory reporting requirements. *Id.* The
22 Ninth Circuit relied on Arizona law that imposed on manufacturers a general continuing duty to
23 warn of dangers. *Id.* The Ninth Circuit also stated that “[i]f a more precise parallel were
24 necessary,” Arizona law provides that a manufacturer may satisfy its duty if it warns a third party
25 and “given the nature of the warning and the relationship of the third party, there is reasonable
26 assurance that the information will reach those whose safety depends on their having it.” *Id.*
27 (quotation omitted).

1 Medtronic’s argument that Scovil’s failure to warn claim is impliedly preempted is
2 foreclosed by *Stengel*. Scovil has asserted the same claim as the *Stengel* plaintiff based on
3 Medtronic’s alleged failure to report adverse events to the FDA as required by federal law. Like
4 Arizona, Nevada law contains a parallel requirement because it imposes a continuing duty on
5 manufacturers to warn of defects in their products. *See Wyeth v. Rowatt*, 244 P.3d 765, 780 (Nev.
6 2010) (en banc) (stating that “if a drug manufacturer knows, or has reason to know, of increased
7 dangers that are not already identified in its drug’s label, compliance with the FDA’s minimal
8 standard may not satisfy its duty to warn,” and the manufacturer’s campaign of misinformation
9 regarding the drug’s safety supported punitive damages); *Lewis v. Sea Ray Boats, Inc.*, 65 P.3d
10 245, 249 (Nev. 2003) (en banc) (stating a manufacturer has a duty to warn about the dangers that
11 may result from a product’s “use or foreseeable misuse” (quotation omitted)).⁴ Thus, under
12 *Stengel*, Scovil’s claim is not preempted.

13 An analysis of the “narrow gap” through which Scovil’s claim must fit to avoid
14 preemption confirms *Stengel*’s conclusion. Scovil’s claim alleges a violation of federal law based
15 on Medtronic’s alleged failure to report adverse events to the FDA (and his claim therefore is not
16 expressly preempted) but he is suing Medtronic because that conduct violates parallel state law
17 duties to warn (and his claim therefore is not impliedly preempted).

18 Medtronic relies on out-of-circuit authority to argue I nevertheless should find this claim
19 preempted, but I am bound to apply Ninth Circuit law. *Hart v. Massanari*, 266 F.3d 1155, 1170
20 (9th Cir. 2001). Accordingly, I will not dismiss Scovil’s failure to warn claim as preempted.

21 **C. Negligence - Count Four**

22 Scovil’s original complaint contained a negligence claim. (Dkt. #1 at 34-37.) The District
23 of Arizona held that the allegations in the original complaint relating to “researching,
24 manufacturing, selling, labeling, testing, distributing, and analyzing” Infuse were preempted
25 because the FDA premarket approval process expressly covers these areas and by granting

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27 ⁴ *Cf. Klasch v. Walgreen Co.*, 264 P.3d 1155, 1160 (Nev. 2011) (en banc) (holding that when a
28 pharmacist knows of a customer-specific risk, the pharmacist “has a duty to warn the customer or to notify
the prescribing doctor of the customer-specific risk”).

1 premarket approval, the FDA necessarily determined Medtronic was not negligent in carrying out
2 these functions. (Dkt. #30 at 17-18.) However, the District of Arizona found the allegations that
3 Medtronic negligently merchandised, advertised, and promoted Infuse were not preempted
4 because off-label promotion violates federal law (and thus is not expressly preempted) but
5 Scovil's claim is based on state negligence law (and thus not impliedly preempted). (*Id.* at 18.)
6 Count four of the amended complaint contains similar allegations that Medtronic was negligent in
7 "researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing,
8 testing, distributing, and marketing" Infuse. (Dkt. #43 at 27.)

9 Medtronic moves to dismiss this claim, arguing Scovil improperly re-pleaded the claim in
10 its entirety even though the District of Arizona found certain aspects of the claim were
11 preempted. Medtronic also argues I should reconsider the District of Arizona's decision that the
12 marketing aspects of this claim are not impliedly preempted based on other cases post-dating the
13 District of Arizona's order. Those cases have held that a duty to refrain from off-label promotion
14 arises solely from federal law, with no state law corollary. Scovil responds by arguing his
15 negligent marketing claim is not preempted because he seeks to enforce a parallel state law duty
16 of a manufacturer to not market its product for uses it knows or should know are not safe.

17 Scovil does not defend his negligence claim to the extent it is based on "researching,
18 manufacturing, selling, labeling, testing, distributing, and analyzing" Infuse. I agree with the
19 District of Arizona's reasoning and decision that Scovil's negligence claim based on these
20 allegations is preempted. Scovil's negligence claim is therefore dismissed with prejudice to the
21 extent it is based on "researching, manufacturing, selling, labeling, testing, distributing, and
22 analyzing" Infuse.

23 However, reconsideration of the District of Arizona's preemption decision with respect to
24 Scovil's negligent marketing claim is not warranted. Medtronic has not identified any newly
25 discovered evidence nor an intervening change in controlling law that would support
26 reconsideration. The District of Arizona's decision was not clearly erroneous or manifestly
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1 unjust. Even if I reconsidered the District of Arizona’s preemption decision, Scovil’s negligent
2 marketing claim is not preempted.

3 Pursuant to FDA regulations, “[a] device may not be . . . advertised in a manner that is
4 inconsistent with any conditions to approval specified in the PMA approval order for the device.”
5 21 C.F.R. § 814.80; *see also Carson v. Depuy Spine, Inc.*, 365 Fed. Appx. 812, 815, 2010 WL
6 547506, at *2 (9th Cir. 2010) (“[W]hile doctors may use a drug or device off-label, the marketing
7 and promotion of a Class III device for an unapproved use violates Section 331 of the FDCA.”
8 (citing 21 U.S.C. § 331)). Federal law thus prohibits marketing of a Class III device that
9 negligently promotes an off-label use as safe and effective when in fact it is not. Consequently,
10 Scovil’s negligence claim is not expressly preempted because it does not impose a requirement
11 different from or in addition to the federal requirement. Scovil’s claim is not impliedly
12 preempted because he bases his claim on state negligence law, not on the violation of federal law.
13 *See Eidson v. Medtronic*, --- F. Supp. 2d ----, 2014 WL 1996024, *17 (N.D. Cal. 2014); *Houston*
14 *v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1179 (C.D. Cal. 2013); *Schouest v. Medtronic, Inc.*, 13
15 F. Supp. 3d 692, 705 (S.D. Tex. 2014). I therefore will not dismiss Scovil’s negligence claim to
16 the extent it is based on negligently marketing off-label uses of Infuse as safe and effective.

17 **D. Fraudulent and Intentional Misrepresentation - Counts Five & Six**

18 The original complaint alleged fraudulent and intentional misrepresentations. (Dkt. #1 at
19 38-42.) The District of Arizona ruled these claims were not expressly preempted because they
20 paralleled the federal prohibition of misleading off-label promotion and they were not impliedly
21 preempted because they are based on traditional state common law. (Dkt. #30 at 18.) The District
22 of Arizona also found the claims were pleaded with sufficient particularity. (*Id.* at 19.) Counts
23 five and six allege Medtronic knowingly concealed adverse information and knowingly provided
24 inaccurate or misleading information regarding the safety and effectiveness of Infuse’s off-label
25 uses. (Dkt. #43 at 29-32.) According to the amended complaint, Medtronic knew off-label use of
26 Infuse could lead to serious adverse events but continued to promote off-label use as safe and
27 effective through its sales representatives and Key Opinion Leaders. (*Id.*) Scovil alleges his
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1 medical providers relied on these representations and omissions and had they known of the risks,
2 they would not have used Infuse off-label. (*Id.* at 31.)

3 Medtronic requests I reconsider whether these claims are impliedly preempted. Medtronic
4 argues that the concept of off-label use derives from the FDCA and has no independent meaning
5 in Nevada law. Medtronic also contends I should reconsider whether these claims are adequately
6 pleaded.

7 Reconsideration of the District of Arizona’s rulings with respect to these claims is not
8 warranted. Medtronic has not identified any newly discovered evidence or an intervening change
9 in controlling law that would support reconsideration of either the preemption decision or whether
10 the claim was alleged with the requisite particularity. Additionally, the District of Arizona’s
11 decision was not clearly erroneous or manifestly unjust. Even if I reconsidered the District of
12 Arizona’s preemption decision, dismissal on this basis is not warranted for the same reasons that
13 the negligent marketing claim is not preempted. The fraudulent and intentional misrepresentation
14 claims are not expressly preempted because federal law prohibits false promotion of a device’s
15 off-label uses and Nevada law imposes a parallel requirement not to engage in fraudulent
16 misrepresentations that is not different from, or in addition to, the federal requirement. Further,
17 the claims are not impliedly preempted because they find their source in state common law
18 regarding misrepresentations and fraud and are not based on the mere fact that Medtronic
19 engaged in off-label promotion. I therefore will deny the motion to dismiss as to these claims.

20 **E. Nevada Unfair Competition Law - Count Seven**

21 Count seven of the amended complaint alleges Medtronic violated the “Nevada Unfair
22 Competition Law” by marketing Infuse in a misleading manner. (Dkt. #43 at 33-34.) The original
23 complaint contained a similar claim under Arizona unfair competition law. (Dkt. #1 at 43-44.)
24 The District of Arizona declined to dismiss this claim because it found Medtronic had
25 mischaracterized the plaintiffs’ claim and thus the argument Medtronic made in support of
26 dismissal was flawed. (Dkt. #30 at 19-20.) However, the District of Arizona noted that it was
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1 “doubtful” the plaintiffs could succeed on this claim because it required proof of interference with
2 the plaintiffs’ ability to conduct business. (*Id.* at 20 n.14.)

3 Medtronic moves to dismiss this claim because it is invalid under Arizona law for the
4 reasons stated in the prior order. Medtronic also argues there is no “Unfair Competition Law” in
5 Nevada and thus I should dismiss this claim with prejudice. Scovil has not responded to this
6 portion of Medtronic’s motion and he therefore consents to dismissal of this claim. LR 7-2(d).
7 He has not clarified the basis for this claim nor has he requested leave to amend it. I dismiss this
8 claim with prejudice.

9 **F. Breach of Express and Implied Warranties - Count Eight**

10 Count eight alleges Medtronic’s marketing campaign expressly and impliedly warranted
11 to physicians, the medical community, and the general public that off-label use of Infuse was safe
12 and effective. (Dkt. #43 at 35-36.) According to the amended complaint, Scovil’s doctors relied
13 on these express and implied warranties. (*Id.* at 35.) Scovil alleges Medtronic’s marketing
14 campaign to promote Infuse’s off-label uses as safe and effective overrides the warranty
15 disclaimer on the Infuse label. (*Id.* at 35-36.) The original complaint contained a similar claim
16 but did not allege that the express and implied representations should override the warranty
17 disclaimer on the label. (Dkt. #1 at 44-45.) The District of Arizona dismissed this claim because
18 Arizona law enforces conspicuous warranty disclaimers. (Dkt. #30 at 20.)

19 Medtronic moves to dismiss this claim, arguing Nevada gives effect to conspicuous
20 warranty disclaimers and Nevada does not override those disclaimers in favor of expressions of
21 warranties outside the parties’ contract. Medtronic contends its disclaimer was conspicuous and
22 cannot be undone by the nonspecific warranties alleged in the amended complaint. Medtronic
23 also argues this claim is preempted because for Scovil to prevail, a jury would have to find that
24 Infuse was not safe and effective and that finding would conflict with the FDA’s premarket
25 approval decision.

26 Scovil responds that under Nevada law, a warranty disclaimer in a form contract cannot
27 disclaim express warranties that form part of the basis of the parties’ bargain. Scovil also argues
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1 Nevada has adopted the Uniform Commercial Code (“UCC”) and pursuant to certain relevant
2 UCC provisions, Medtronic cannot induce the purchase of its device with express warranties and
3 then attempt to disclaim those warranties. Scovil contends he avoids express preemption because
4 he alleges Medtronic violated federal law through its promotion of off-label use and Nevada
5 imposes a parallel duty. He argues his claim is not impliedly preempted because it rests on state
6 law regarding breach of a warranty.

7 Under Nevada’s UCC, “there is an implied warranty that a good is merchantable and
8 suitable for the particular purpose for which it is sold.” *Vacation Vill., Inc. v. Hitachi Am., Ltd.*,
9 874 P.2d 744, 747 (Nev. 1994) (citing Nev. Rev. Stat. §§ 104.2314-.2315). A manufacturer may
10 disclaim these implied warranties only through specific and conspicuous written language. Nev.
11 Rev. Stat. §§ 104.2316(2), (3)(a). A conspicuous disclaimer “exclude[s] warranties, if any,
12 outside the contract.” *Sierra Creek Ranch, Inc. v. J.I. Case*, 634 P.2d 458, 460 (Nev. 1981); *see*
13 *also Bill Stremmel Motors, Inc. v. IDS Leasing Corp.*, 514 P.2d 654, 656 (Nev. 1973); Nev. Rev.
14 Stat. § 104.2316 cmt. 2 (“The seller is protected under this Article against false allegations of oral
15 warranties by its provisions on parol and extrinsic evidence . . .”).

16 However, a form disclaimer will not be effective to exclude express written warranties.
17 *Sierra Diesel Injection Serv., Inc. v. Burroughs Corp., Inc.*, 890 F.2d 108, 113 (9th Cir. 1989)
18 (applying Nevada law and stating that “when an express warranty is read together with a warranty
19 disclaimer, the express warranty is given effect over the disclaimer”); Nev. Rev. Stat.
20 § 104.2316(1) & cmt. 1 (stating the UCC “protect[s] a buyer from unexpected and unbargained
21 language of disclaimer by denying effect to such language when inconsistent with language of
22 express warranty and permitting the exclusion of implied warranties only by conspicuous
23 language or other circumstances which protect the buyer from surprise”); Nev. Rev. Stat.
24 § 104.2313 cmt. 1 (“‘Express’ warranties rest on ‘dickered’ aspects of the individual bargain, and
25 go so clearly to the essence of that bargain that words of disclaimer in a form are repugnant to the
26 basic dickered terms.”). An express warranty may be created through “[a]ny affirmation of fact
27 or promise made by the seller to the buyer which relates to the goods and becomes part of the
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1 basis of the bargain.” *Id.* § 104.2313(1)(a). Such an affirmation or promise “creates an express
2 warranty that the goods shall conform to the affirmation or promise.” *Id.* The seller need not use
3 the words “warrant” or “guarantee” and the seller need not specifically intend to make a warranty.
4 *Id.* § 104.2313(2). However, “an affirmation merely of the value of the goods or a statement
5 purporting to be merely the seller’s opinion or commendation of the goods does not create a
6 warranty.” *Id.*

7 Here, Scovil does not dispute that Medtronic disclaimed implied warranties relating to
8 Infuse nor does he contend those disclaimers were inconspicuous. In his response to Medtronic’s
9 motion, he abandons his implied warranty claim, arguing only that his breach of express warranty
10 claim should survive dismissal. (Dkt. #56 at 15-18.) I therefore dismiss Scovil’s claim for breach
11 of implied warranties with prejudice.

12 As to Scovil’s breach of express warranty claim, an express warranty overrides a warranty
13 disclaimer under Nevada law. Consequently, Medtronic cannot disclaim any express warranty it
14 may have made relating to the safety and effectiveness of off-label uses of Infuse. The claim is
15 not expressly or impliedly preempted for the same reasons as the negligence, fraud, and
16 intentional misrepresentation claims. Federal law prohibits false or misleading off-label
17 promotion, and “to the extent that [p]laintiff seeks to impose liability on [d]efendants for
18 voluntarily making misleading warranties outside the label, [p]laintiff is not imposing any
19 requirement different from or additional to what federal law already requires.” *Houston*, 957 F.
20 Supp. 2d at 1181. “In other words, to avoid state law liability on this claim, [d]efendants need
21 only to refrain from making misleading warranties, which adds no burden beyond what federal
22 law already imposes.” *Id.* For this same reason, a jury would not have to disagree with the FDA’s
23 findings regarding Infuse’s safety and effectiveness to find in Scovil’s favor on this claim.
24 Rather, through the premarket approval process and the prohibition on marketing off-label uses
25 for Class III devices, the FDA already concluded that warranting off-label use of Infuse as safe
26 and effective through off-label promotion was prohibited. The claim is not impliedly preempted
27 because it is based on traditional state law regarding breach of warranty. *See id.*

1 To state a breach of warranty claim under Nevada law, a plaintiff must allege “that a
2 warranty existed, the defendant breached the warranty, and the defendant’s breach was the
3 proximate cause of the loss sustained.” *Nevada Contract Servs., Inc. v. Squirrel Cos., Inc.*, 68
4 P.3d 896, 899 (Nev. 2003). Scovil alleges Medtronic expressly warranted in journal articles and
5 advertising, and through sales representatives and Key Opinion Leaders, that off-label use of
6 Infuse was safe and effective. (Dkt. #43 at 35.) However, he does not allege facts regarding what
7 specific affirmations of fact or promises Medtronic made to him or to his physicians or that those
8 specific affirmations or promises became part of the basis of the bargain. *See, e.g., Houston*, 957
9 F. Supp. 2d at 1181; *Arthur v. Medtronic, Inc.*, No. 4:14-CV-52 (CEJ), 2014 WL 3894365, at *8
10 (E.D. Mo. Aug. 11, 2014) (slip copy) (same and collecting cases). I therefore dismiss without
11 prejudice Scovil’s breach of express warranty claim.

12 **III. Conclusion**

13 IT IS THEREFORE ORDERED that defendants’ motion to dismiss (Dkt. #51) is
14 GRANTED in part and DENIED in part. Plaintiff Brett Scovil’s claims for manufacturing defect
15 (count one), negligence based on allegations other than marketing (part of count four), unfair
16 competition (count seven), and breach of implied warranty (part of count eight) are dismissed
17 with prejudice. Scovil’s claim for breach of express warranty (part of count eight) is dismissed
18 without prejudice. Defendants’ motion is denied in all other respects.

19 DATED this 2nd day of March, 2015.

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22 ANDREW P. GORDON
23 UNITED STATES DISTRICT JUDGE
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