

United States District Court
For the Northern District of California

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

RICHARD EIDSON,)
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Plaintiff,)
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v.)
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MEDTRONIC, INC.; MEDTRONIC)
SOFAMOR DANEK USA,INC.,)
)
Defendants.)
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SCOTT BELL AND APRIL BELL,)
)
Plaintiffs,)
)
v.)
)
MEDTRONIC, INC.; MEDTRONIC)
SOFAMOR DANEK USA,INC.,)
)
Defendants.)
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Case Nos.: 13-CV-02049
13-CV-01502

ORDER GRANTING IN PART AND
DENYING IN PART DEFENDANTS'
MOTIONS TO DISMISS RICHARD
EIDSON'S COMPLAINT AND SCOTT
AND APRIL BELL'S COMPLAINT

Plaintiffs Scott and April Bell ("the Bells") commenced this action on April 3, 2013, alleging that Scott Bell suffered harmful side effects following a spinal fusion operation in which his surgeon used a spinal fusion device produced by Medtronic, Inc. and Medtronic Sofamor Danek USA, Inc. (collectively, "Defendants"). ECF Bell No. 37, 13-CV-01502, Bell First

1 Amended Complaint (hereinafter “Bell complaint”).¹ Plaintiff Richard Eidson (“Eidson”) brought
2 this action on May 6, 2013, also based on harmful effects he suffered after undergoing spinal
3 surgery in which his surgeon used the same medical device produced by Defendants. ECF Eidson
4 No. 38, 13-CV-02049, Eidson First Amended Complaint (hereinafter “Eidson complaint”). The
5 two cases have been related because they involve the same product and similar questions of law.
6 ECF Bell No. 23. On October 3, 2013, the Court granted Defendants’ motion to dismiss the Bells’
7 complaint and granted in part and denied in part Defendants’ motion to dismiss Eidson’s
8 complaint. *Eidson v. Medtronic, Inc.*, 2013 WL 5533081 (N.D. Cal. Oct. 3, 2013) (“October 3,
9 2013 Order”). The Court held that all of the Bells’ claims were barred by the statute of limitations,
10 and that all of Eidson’s non-fraud claims were either preempted or failed to show a causal nexus
11 between Eidson’s injuries and Defendants’ conduct. *Id.* at *14, *16-18. The Court also held that
12 Eidson’s fraud-based claims were not preempted and were pled with sufficient particularity under
13 Federal Rule of Civil Procedure 9(b). *Id.* at *11. Both the Bells and Eidson were granted leave to
14 amend.

15 Defendants now move to dismiss both amended complaints pursuant to Federal Rule of
16 Civil Procedure 12(b)(6) for failure to state a claim upon which relief may be granted. ECF Bell
17 No. 42; ECF Eidson No. 39. This Order addresses both motions to dismiss.

18 The Court vacated the hearing on Defendants’ motion to dismiss the Eidson complaint.
19 ECF No. 57. The Court held a hearing on Defendants’ motion to dismiss the Bell complaint on
20 May 8, 2014 concerning only the statute of limitations issue. Having considered the submissions
21 and oral arguments of the parties, the relevant law, and the record in this case, the Court GRANTS
22 IN PART with prejudice and DENIES IN PART Defendants’ motion to dismiss the Eidson
23 complaint, and GRANTS IN PART with prejudice and DENIES IN PART Defendants’ motion to
24 dismiss the Bell complaint.

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26 _____
27 ¹ As this Order addresses two related cases brought by different plaintiffs, this Order will continue
28 to follow the convention established by this Court’s October 3, 2013 Order by using the following
nomenclature for docket numbers in the Bell case: “ECF Bell No. X,” and the following
nomenclature for docket numbers in the Eidson case: “ECF Eidson No. X.”

1 **I. BACKGROUND**

2 **A. Factual Allegations**

3 **1. Infuse Device and Premarket Approval**

4 The Court reviewed the factual background of these cases in its October 3, 2013 Order. *See*
5 *Eidson*, 2013 WL 5533081, at *1-3. Here, the Court briefly notes the relevant facts.

6 Medtronic Sofamor Danek, USA, Inc. manufactures a medical device known as the Infuse
7 Device (“Infuse”) which stimulates bone growth in spinal fusion surgeries. Bell Complaint ¶ 2;
8 *Eidson* Complaint ¶ 2. Infuse consists of three components: (1) the active ingredient, a liquid form
9 of the protein rhBMP–2 which stimulates bone growth, (2) a metallic spinal fusion cage (the “LT
10 Cage”) to stabilize and hold in place the liquid protein, and (3) a spongy carrier for the protein. *Id.*
11 ¶ 34; *Id.* ¶ 33. The FDA in July 2002 granted Infuse premarket approval (“PMA”) as a medical
12 device under the Federal Food, Drug, and Cosmetic Act of 1938 (“FDCA”), as amended by the
13 Medical Device Amendments of 1976 (“MDA”). *Id.* ¶¶ 58, 63; *Id.* ¶¶ 45, 60. Following this
14 approval, Defendants were permitted to sell the Infuse Device. *Id.* ¶ 44; *Id.* ¶ 43.

15 The FDA’s approval letter stated that the Device may be implanted (1) from the anterior
16 (front) abdomen, (2) for purposes of a single-level fusion, (3) within lumbar spine levels L4
17 through S1, and that Infuse must not be used without the LT Cage. *Id.* ¶¶ 65, 66; *Id.* ¶ 64. Any
18 operation that uses the Device in a manner other than that approved by the FDA is called an “off-
19 label” use. *Id.* ¶ 67; *Id.* ¶ 66. This includes operations in which the spine is approached from the
20 back and operations without the LT Cage. *Id.* ¶¶ 4, 69; *Id.* ¶¶ 4, 68. During approval hearings, FDA
21 officials expressed concern about potential side effects stemming from off-label use and advised
22 Defendants to take steps to prevent such use. *Id.* ¶¶ 70, 73, 75-77; *Id.* ¶¶ 72-76.

23 Plaintiffs allege that beginning in 1999, Defendants were aware that medical studies had
24 found evidence of severe side effects associated with the off-label use of Infuse, particularly
25 excessive bone growth. *Id.* ¶¶ 103-105; *Id.* ¶¶ 104-105, 123. Despite this knowledge, Defendants
26 embarked on a vigorous campaign to promote off-label uses of Infuse by establishing
27 consulting/royalty agreements with physicians who advocated off-label uses. *Id.* ¶¶ 120-121, 179-
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1 184; *Id.* ¶¶ 119-120, 178-183. Defendants also funded studies and articles by opinion leaders that
2 omitted mentions of the risks of off-label use or understated the incidence of adverse effects. *Id.* ¶¶
3 105, 127; *Id.* ¶¶ 71, 104, 126. In addition, Defendants failed to report adverse events suffered by
4 patients who used Infuse off-label to the FDA, and by April 2008 Defendants had reported only
5 262 of an estimated 50,000-250,000 adverse events. *Id.* ¶ 319; *Id.* ¶ 309. This failure to report led
6 to the omission of these events from the FDA’s publicly accessible MAUDE database. *Id.* ¶¶ 113,
7 280; *Id.* ¶¶ 111-112, 279. These activities led to investigations by the Department of Justice
8 resulting in a \$40 million settlement and Corporate Integrity Agreement on July 18, 2006. *Id.* ¶¶
9 146-150; *Id.* ¶¶ 145-149. Defendant’s promotion of off-label use also led to significant
10 controversial media coverage in the *Wall Street Journal* and the *New York Times*. *Id.* ¶¶ 96, 185,
11 191; *Id.* ¶¶ 95, 184, 190-191.

12 2. Scott Bell’s surgery

13 In February 2005, Scott Bell underwent a spinal fusion operation in which his surgeon, Dr.
14 Seago, used Infuse in an off-label manner by implanting it by posterior approach and by failing to
15 use an LT Cage. Bell Complaint ¶ 286. The Bells allege that Defendants directly and indirectly
16 encouraged his surgeon to use an off-label procedure. *Id.* ¶ 287. Dr. Seago did not inform the Bells
17 that the operation would involve rhBMP-2, and the surgical consent form Mr. Bell signed
18 inaccurately implied that the surgery would instead involve a natural iliac crest bone graft. *Id.* ¶
19 290, 292. Only the hospital’s “sticker page” of equipment used in the procedure notes the use of an
20 artificial protein graft. *Id.* ¶ 293. After his surgery, Scott Bell experienced increased pain and was
21 told by Dr. Seago that this was due to a “biological phenomenon.” *Id.* ¶ 291. On March 2, 2007,
22 Scott Bell was diagnosed with advanced bony overgrowth in the area of his spine targeted by the
23 surgery. *Id.* ¶ 288. Scott Bell underwent corrective surgery for this overgrowth on May 3, 2007. *Id.*
24 Neither Dr. Seago nor any of Scott Bell’s other physicians ever informed him that Infuse was used
25 in his surgery and may have contributed to his side effects. *Id.* ¶¶ 294-296.

26 As a result, Plaintiffs Scott and April Bell bring five causes of action against Defendants in
27 connection with Infuse: (1) fraudulent misrepresentation/fraud in the inducement (*id.* ¶¶ 299–311);
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1 (2) strict products liability—failure to warn (*id.* ¶¶ 312–327); (3) negligent misrepresentation (*id.*
2 ¶¶ 328–338); (4) negligent failure to warn (*id.* ¶¶ 329–353); and (5) loss of consortium on behalf of
3 April Bell (*id.* ¶¶ 354–356).

4 **3. Richard Eidson’s surgery**

5 On November 11, 2008, Plaintiff Richard Eidson underwent a spinal fusion operation that
6 utilized Infuse in an off-label manner by implanting the device from the back, by using a multi-
7 level fusion, and by failing to use an LT Cage. Eidson Complaint ¶ 285. Eidson alleges Defendants
8 directly and indirectly encouraged his surgeon, Dr. Smith, to use an off-label procedure. *Id.* ¶ 285-
9 286. After the surgery, Eidson began experiencing pain, weakness, decreased sensation, and
10 decreased reflexes in his legs and back pain. *Id.* ¶ 287. On May 14, 2012, he was diagnosed with
11 fluid-filled cysts within the vertebral bodies where the surgery had taken place, and now has severe
12 pain, reduced sensation, strength, and reflexes in his lower extremities. *Id.* ¶ 288. He has also
13 suffered bone resorption and bone overgrowth. *Id.* ¶ 12.

14 As a result, Eidson brings four causes of action against Defendants in connection with
15 Infuse: (1) fraudulent misrepresentation/fraud in the inducement (*id.* ¶¶ 290–302); (2) strict
16 products liability—failure to warn (*id.* ¶¶ 303–317); (3) negligent misrepresentation (*id.* ¶¶ 318–
17 328); and (4) negligent failure to warn (*id.* ¶¶ 329–342).²

18 _____
19 ² Both Plaintiffs’ First Amended Complaints include two causes of action (negligent
20 misrepresentation and negligent failure to warn) not included in their original complaints. Plaintiffs
21 justify the inclusion of these new causes of action by insisting that they allege the same misconduct
22 set forth in the “Strict Liability – Misrepresentation” claims in their original complaints and that
23 Plaintiffs have merely “re-labeled” that claim. Bell MTD Opp’n at 10-11; Eidson Opp’n at 7-8. The
24 Court’s October 3, 2013 Order advised Plaintiffs that they would not be permitted to “add new
25 parties or causes of action without a stipulation or order of the Court.” *Eidson*, 2013 WL 5533081
26 at *18. Although Plaintiffs have violated the Court’s Order, the Court will not require Plaintiffs to
27 formally move for leave to amend their complaints before the Court rules on Defendants’ pending
28 motions to dismiss. In order to avoid delay on Defendants’ motion to dismiss, the Court simply
construes the Plaintiffs’ alteration of their complaints as a motion to amend under Federal Rule of
Civil Procedure 15. Under Rule 15(a), leave to amend “should be freely granted when justice so
requires.” *Lopez v. Smith*, 203 F.3d 1122, 1127 (9th Cir. 2000) (en banc) (internal quotation marks
omitted). Because Defendants, in their oppositions, have not objected to the fact that Plaintiffs have
included new causes of action, the Court grants Plaintiffs’ motion for leave to amend. The Court
warns Plaintiffs, however, that should they include new causes of action in the future without a
stipulation or Court order, those causes of action will be dismissed with prejudice.

1 **B. Procedural History**

2 Plaintiffs Scott and April Bell filed their original complaint on April 3, 2013. ECF Bell No.
3 1. Defendants filed a Motion to Dismiss the Complaint on May 14, 2013. ECF Bell No. 10.
4 Plaintiffs filed an opposition to the Motion to Dismiss on July 1, 2013. ECF Bell No. 20.
5 Defendants filed a reply on July 22, 2013. ECF Bell No. 24.

6 Plaintiff Richard Eidson filed his complaint on May 6, 2013. ECF Eidson No. 1.
7 Defendants filed a Motion to Dismiss the Complaint on May 28, 2013. ECF Eidson No. 9. Plaintiff
8 filed an opposition to the Motion to Dismiss on July 1, 2013. ECF Edison No. 18. Defendants filed
9 a reply on July 22, 2013. ECF Eidson No. 21.

10 On October 3, 2013, the Court granted Defendants’ motion to dismiss as to the Bells’
11 claims and granted in part and denied in part Defendants’ motion to dismiss as to Eidson, giving
12 both plaintiffs leave to amend.

13 Plaintiffs Scott and April Bell filed a First Amended Complaint on November 15, 2013.
14 ECF Bell No. 37. Defendants filed a Motion to Dismiss the First Amended Complaint on January
15 8, 2014. ECF Bell No. 42 (“Bell MTD”). Plaintiffs filed an opposition on February 7, 2014. ECF
16 Bell No. 46 (“Bell MTD Opp’n”). Defendants filed a reply on February 21, 2014. ECF Bell No. 47.

17 Plaintiff Richard Eidson filed a First Amended Complaint on November 15, 2013. ECF
18 Eidson No. 38. Defendants filed a Motion to Dismiss the First Amended Complaint on January 8,
19 2014. ECF Eidson No. 39 (“Eidson MTD”). Plaintiff filed an opposition on February 7, 2014. ECF
20 Edison No. 46 (“Eidson Opp’n”). Defendants filed a reply on February 21, 2014. ECF Eidson No.
21 47 (“Eidson Reply”).³

22 **II. LEGAL STANDARDS**

23 **A. Motion to Dismiss Under Rule 12(b)(6)**

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26 ³ Defendants filed notices of supplemental authorities on March 7, 2014, March 13, 2014, March
27 20, 2014, March 27, 2014, April 8, 2014, April 16, 2014, and April 30, 2014. ECF Bell Nos. 48,
28 49, 50, 51, 53, 54, 55; ECF Eidson Nos. 48, 49, 50, 51, 52, 53, 54. The Court has considered these
supplemental authorities.

1 Federal Rule of Civil Procedure 12(b)(6) permits a party to move to dismiss a complaint for
2 failure to state a claim upon which relief can be granted. To survive a motion to dismiss, a
3 complaint must plead “enough facts to state a claim to relief that is plausible on its face.” *Bell Atl.*
4 *Corp. v. Twombly*, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). A claim is
5 plausible when the plaintiff pleads “factual content that allows the court to draw the reasonable
6 inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662,
7 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009). For purposes of ruling on a Rule 12(b)(6) motion, a
8 court “accept[s] factual allegations in the complaint as true and construe[s] the pleadings in the
9 light most favorable to the nonmoving party.” *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519
10 F.3d 1025, 1031 (9th Cir.2008). Moreover, the court “presume[s] that general allegations embrace
11 those specific facts that are necessary to support the claim.” *Nat’l Org. for Women v. Scheidler*, 510
12 U.S. 249, 256, 114 S.Ct. 798, 127 L.Ed.2d 99 (1994), *quoting Lujan v. Defenders of Wildlife*, 504
13 U.S. 555, 561, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992). A complaint’s non-conclusory factual
14 allegations and reasonable inferences drawn from them, “must be plausibly suggestive of a claim
15 entitling the plaintiff to relief.” *Moss v. United States Secret Serv.*, 572 F.3d 962, 970 (9th
16 Cir.2009), *citing Iqbal*, 129 S.Ct. at 1949.

17 A court is not required, however, to “ ‘assume the truth of legal conclusions merely because
18 they are cast in the form of factual allegations.’ ” *Fayer v. Vaughn*, 649 F.3d 1061, 1064 (9th
19 Cir.2011) (per curiam) (quoting *W. Mining Council v. Watt*, 643 F.2d 618, 624 (9th Cir. 1981)). A
20 court also need not accept as true allegations contradicted by judicially noticeable facts, *Shwarz v.*
21 *United States*, 234 F.3d 428, 435 (9th Cir. 2000). Mere “conclusory allegations of law and
22 unwarranted inferences are insufficient to defeat a motion to dismiss.” *Adams v. Johnson*, 355 F.3d
23 1179, 1183 (9th Cir. 2004); *accord Iqbal*, 556 U.S. at 678, 129 S.Ct. 1937.

24 **B. Federal Rule of Civil Procedure 9(b)**

25 When sitting in diversity, a court applies Federal Rule of Civil Procedure 9(b)’s heightened
26 pleading standard to any state law causes of action sounding in fraud or deceit. *See Vess v. Ciba-*
27 *Geigy Corp. USA*, 317 F.3d 1097, 1103 (9th Cir. 2003). Rule 9(b) provides that “[i]n alleging fraud
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1 or mistake, a party must state with particularity the circumstances constituting fraud or mistake.” A
2 complaint must “be ‘specific enough to give defendants notice of the particular misconduct . . . so
3 that they can defend against the charge and not just deny that they have done anything wrong.’ ”
4 *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1124 (9th Cir. 2009) (citation omitted). The complaint
5 must include facts regarding the “time, place, and specific content of the false representations as
6 well as the identities of the parties to the misrepresentations.” *Edwards v. Marin Park, Inc.*, 356
7 F.3d 1058, 1066 (9th Cir. 2004) (citation omitted). In addition, “[t]he plaintiff must set forth what
8 is false or misleading about a statement, and why it is false.” *In re GlenFed, Inc. Sec. Litig.*, 42
9 F.3d 1541, 1548 (9th Cir. 1994) (en banc), *superseded by statute on other grounds*.

10 **C. Leave to Amend**

11 If the Court determines that the complaint should be dismissed, it must then decide whether
12 to grant leave to amend. Under Rule 15(a) of the Federal Rules of Civil Procedure, leave to amend
13 “should be freely granted when justice so requires,” bearing in mind that “the underlying purpose
14 of Rule 15 . . . [is] to facilitate decision on the merits, rather than on the pleadings or
15 technicalities.” *Lopez v. Smith*, 203 F.3d 1122, 1127 (9th Cir. 2000) (en banc) (internal quotation
16 marks omitted). Nonetheless, a court “may exercise its discretion to deny leave to amend due to
17 ‘undue delay, bad faith or dilatory motive on part of the movant, repeated failure to cure
18 deficiencies by amendments previously allowed, undue prejudice to the opposing party. . . , [and]
19 futility of amendment.’” *Carvalho v. Equifax Info. Servs., LLC*, 629 F.3d 876, 892-93 (9th Cir.
20 2010) (alterations in original) (quoting *Foman v. Davis*, 371 U.S. 178, 182 (1962)).

21 **D. Requests for Judicial Notice**

22 While a court generally may not consider evidence or documents beyond the complaint in
23 the context of a Rule 12(b)(6) motion to dismiss, Federal Rule of Evidence 201(d) provides that
24 “[a] court shall take judicial notice [of an adjudicative fact] if requested by a party and supplied
25 with the necessary information.” A court may take judicial notice of any fact that is “not subject to
26 reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the
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1 trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy
2 cannot be reasonably questioned.” *Id.*

3 A court may consider documents “whose contents are alleged in a complaint and whose
4 authenticity no party questions,” despite such documents not being physically attached to the
5 pleadings. *Knieval v. ESPN*, 393 F.3d 1068, 1076 (9th Cir. 2005). A court may also take judicial
6 notice of “matters of public record outside the pleadings.” *Mack v. S. Bay Beer Distribs., Inc.*, 798
7 F.2d 1279, 1282 (9th Cir.1986), *overruled on other grounds by Astoria Fed. Sav. & Loan Ass'n v.*
8 *Solimino*, 501 U.S. 104, 111 S.Ct. 2166, 115 L.Ed.2d 96 (1991). While matters of public record are
9 proper subjects of judicial notice, a court may take notice only of the authenticity and existence of
10 the documents, not the veracity or validity of their contents. *See Lee v. City of Los Angeles*, 250
11 F.3d (9th Cir. 2001).

12 Defendants have filed Requests for Judicial Notice in support of their motions to dismiss
13 both Plaintiffs’ complaints. ECF Bell No. 44; ECF Eidson No. 41. With regard to Defendants’
14 motion to dismiss the Bell complaint, the documents as to which Defendants request notice are
15 precisely the same as those contained in the Request for Judicial Notice accompanying their motion
16 to dismiss the original complaint. *See* ECF Bell No. 11; ECF Bell No. 44. Because Plaintiffs have
17 not filed an opposition to these requests and for the reasons set forth in this Court’s October 3,
18 2103 Order, the Court grants all of Defendants’ requests.⁴

19 With regard to Defendant’s motion to dismiss the Eidson complaint, Exhibits A-H, for
20 which Defendants request notice, are the same as those contained in the Request for Judicial Notice
21 accompanying Defendants’ motion to dismiss the original complaint. *See* ECF Eidson No. 10; ECF
22 Eidson No. 41. Plaintiffs have not filed an opposition to these requests, and for the reasons set forth
23 in this Court’s October 3, 2103 Order, the Court grants Defendants’ request for judicial notice with
24 regard to those exhibits.

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27 ⁴ For a full discussion of the Court’s reasoning in granting all these judicial notice requests, *see*
28 *Eidson*, 2013 WL 5533081, at *5-6.

1 However, Defendants also request judicial notice of one document not contained in the
2 Request for Judicial Notice accompanying their motion to dismiss the original complaint. The
3 newly included document, Exhibit I, consists of a Medtronic “Important Medical Information”
4 label regarding the use of Infuse. ECF Eidson No. 41, at 2. Defendants assert that Exhibit I is the
5 warning label in effect at the time of Eidson’s surgery. *Id.* at 3-4. The Court based its grant of all
6 Defendants’ previous requests on the fact that “all of the documents at issue appear on the FDA’s
7 public website,” and were matters of the public record. *Eidson*, 2013 WL 5533081, at *5-6. With
8 regard to Exhibit I, however, Defendants provide no citation to any FDA website or publication,
9 and the label itself is a creation of Medtronic rather than the FDA. Exhibit I thus does not qualify
10 as a matter of public record. Nonetheless, the Court grants the request for judicial notice.
11 Defendants invoke the doctrine of incorporation by reference, claiming that the Eidson complaint
12 challenges the sufficiency of the Infuse warning label and thus incorporates that label by reference.
13 ECF Eidson No. 41, at 3-4. The Court agrees. Eidson’s complaint asserts that any warnings issued
14 by Defendants regarding the dangers of off-label use were “insufficient in light of” Defendant’s
15 promotional activities. Eidson Complaint ¶ 309(iii). Accordingly, Eidson directly challenges the
16 sufficiency of the FDA-approved warnings and the contents of those warnings are thus
17 incorporated in his complaint. Moreover, Eidson has not opposed Defendants’ Request for Judicial
18 Notice of Exhibit I nor questioned its authenticity. Thus, because a court may consider documents
19 “whose contents are alleged in a complaint and whose authenticity no party questions,”
20 *Knievel*, 393 F.3d at 1076, the Court takes judicial notice of Exhibit I.

21 **III. REGULATORY BACKGROUND AND PREEMPTION LAW**

22 Before addressing Defendants’ arguments, the Court sets forth the regulatory background
23 and legal framework for preemption.

24 **A. Federal Regulation of Medical Devices**

25 In 1976, Congress enacted the MDA, which “imposed a regime of detailed federal
26 oversight” over the entry of medical devices. *Riegel v. Medtronic*, 552 U.S. 312, 316 (2008).
27 Notably, a process of premarket approval was established for new Class III devices. *Id.* at 316–17.
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1 Premarket approval is a “rigorous” process in which the manufacturer submits to the FDA
2 extensive reports, design specifications and descriptions, samples of the device, and proposed
3 labeling, and the FDA spends an average of 1,200 hours per application reviewing and evaluating
4 these materials. *Id.* at 317-18. The FDA then “weigh[s] any probable benefit to health from the use
5 of the device against any probable risk of injury or illness from such use,” and “grants premarket
6 approval only if it finds there is a ‘reasonable assurance’ of the device’s ‘safety and
7 effectiveness.’” *Id.* (internal quotation marks omitted).

8 **B. Federal Preemption**

9 **1. Express Preemption**

10 Defendants move to dismiss Eidson’s complaint on the ground that all of his state law
11 claims are expressly preempted by the MDA. The MDA contains an express preemption provision:

12 [N]o State or political subdivision of a State may establish or continue in effect with respect
13 to a device intended for human use any requirement—

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

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

18 21 U.S.C. § 360k(a). The Supreme Court established a two-step framework for analyzing express
19 preemption under the MDA in *Riegel*, 552 U.S. at 322. The court must first determine whether the
20 FDA has established requirements applicable to the device at issue. If so, the court must then
21 determine whether the plaintiff’s claims are based on state requirements regarding the device that
22 are “different from, or in addition to” the federal requirements, and that relate to the safety or
23 effectiveness of the device. *Id.* at 321-22. If so, the plaintiff’s claims are expressly preempted by
24 the MDA. *Id.* at 316.

25 State law claims can escape preemption only if they are based on state duties “parallel” to
26 federal duties stemming from the FDA regulations. *See Stengel v. Medtronic Inc.*, 704 F.3d 1224,
27 1228 (9th Cir. 2013) (en banc). If state law liability could be found notwithstanding compliance
28 with the federal requirements, those state law duties are not parallel to the federal requirements and
will be preempted. *See Riegel*, 552 U.S. at 328. “To properly plead parallel claims that survive

1 preemption, a plaintiff must allege facts (1) showing an alleged violation of FDA regulations or
2 requirements related to [the device], and (2) establishing a causal nexus between the alleged injury
3 and the violation.” *Erickson v. Boston Scientific Corp.*, 846 F.Supp.2d 1085, 1092 (C.D. Cal. 2011)
4 (internal quotation marks omitted).

5 **2. Implied Preemption**

6 The MDA also prohibits suits by private litigants to enforce the provisions of the Act,
7 requiring that all such actions “shall be by and in the name of the United States.” 21 U.S.C. §
8 337(a). The Supreme Court, in *Buckman Co. v. Plaintiffs’ Legal Committee*, 531 U.S. 341 (2001),
9 interpreted this provision as impliedly preempting claims seeking to enforce an exclusively federal
10 requirement not grounded in traditional state tort law. *See id.* at 352-53.

11 The Supreme Court in *Buckman* impliedly preempted a plaintiff’s claims alleging that a
12 device manufacturer made misrepresentations to the FDA during the PMA process. *Id.* at 348
13 (“[T]he plaintiffs’ state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly
14 pre-empted by, federal law”). However, courts have made clear that *Buckman* should not be read to
15 foreclose claims based on any conduct that violates the FDCA. Rather, state law claims may avoid
16 preemption if they rely on traditional state tort law duties which predate the FDCA requirements.
17 *See, e.g., Riley v. Cordis Corp.*, 625 F.Supp.2d 769, 776–77 (D. Minn. 2009) (to escape
18 preemption, conduct forming the basis of claims “must be the type of conduct that would
19 traditionally give rise to liability under state law—and that would give rise to liability under state
20 law even if the FDCA had never been enacted.”). In sum, a claim is impliedly preempted under
21 *Buckman* if it is cognizable only by virtue of the provisions of the FDCA itself, and would not be
22 independently viable under state law; conversely, a state law cause of action escapes implied
23 preemption if it would state a claim under state law even in the absence of the FDCA. *See*
24 *Buckman*, 531 U.S. at 348.

25 Together, express preemption and implied preemption provide only a “narrow gap” through
26 which a plaintiff’s claims must fit in order to survive. *Perez v. Nidek Co., Ltd.*, 711 F.3d 1109,
27 1120 (9th Cir. 2013) (“The plaintiff must be suing for conduct that *violates* the FDCA (or else his
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1 claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct
2 violates the FDCA (such a claim would be impliedly preempted under *Buckman*.)” (emphasis in
3 original) (citation omitted).

4 **IV. ANALYSIS**

5 **A. Analysis of Defendant’s Argument that the Bells’ Claims are Time-Barred**

6 The Court first addresses Defendants’ argument that all of the Bells’ claims are time-barred.
7 Bell MTD at 4-8. In its October 3, 2013 Order, this Court dismissed the Bells’ claims with leave to
8 amend, finding that the claims were barred by the statute of limitations because the Bells’
9 complaint did not allege sufficient facts regarding the discovery rule. *Eidson*, 2013 WL 5533081,
10 at *16-18. The Court finds that the Bells have now alleged sufficient facts to plead the discovery
11 rule, and thus rejects Defendants’ argument that all of the Bells’ claims are time-barred.

12 In their amended complaint, the Bells have included the following assertions regarding their
13 delay in discovering Defendants’ wrongdoing and filing their suit:

14 (1) “At the time of his surgery on February 24, 2005, Dr. Randall Seago did not inform
15 plaintiff Scott Bell that he was using rhBMP-2 by any name (INFUSE®, BMP), and did not
16 obtain his consent to use rhBMP-2.” Bell Complaint ¶ 290.

17 (2) “Mr. Bell’s consent form does not mentioned [sic] rhBMP, BMP, or INFUSE®. Instead,
18 ... the consent implies that bone was to be taken from Mr. Bell’s iliac crest, not that
19 INFUSE® would be used.” *Id.* at ¶ 292.

20 (3) “The operative report itself does not mentioned [sic] the use of rhBMP-2. Only the
21 separate ‘sticker page,’ which is the hospital’s record of devices and equipment used during
22 the procedure, mentions the use of rhBMP-2.” *Id.* at ¶ 293.

23 (4) “When plaintiff Scott Bell experienced increased pain after his surgery, Dr. Randall
24 Seago told him that his pain was due to a ‘biological phenomenon’ in terms of the way Mr.
25 Bell’s body uniquely reacted to surgery. Dr. Seago did not state, or imply in any way, that
26 Mr. Bell’s pain and other symptoms were potentially the result of any product used during
27 the surgery.” *Id.* at ¶ 291.

1 (5) “At no time did any of Scott Bell’s treating physicians inform him that rhBMP-2 had
2 been used in his surgery.” *Id.* at ¶ 294.

3 (6) “At no time did any of Scott Bell’s treating physicians inform him that any product
4 defect of failure might have caused or contributed to his new symptoms.” *Id.* at ¶ 295.

5 (7) “Until April 2012, Scott Bell had no reason to suspect, and did not suspect, that any
6 product defect or failure might have caused his symptoms.” *Id.* at ¶ 296.

7 (8) “In April 2012, Scott Bell’s mother saw a lawyer commercial regarding lawsuits
8 involving MEDTRONIC’S INFUSE® device. She mentioned this to Scott Bell, asking
9 whether that device might have been used in his surgery. Within two weeks, in April 2012,
10 Scott Bell contacted a lawyer in order to find out whether this device had been used in his
11 surgery and might have contributed to his injuries.” *Id.* at ¶ 297.

12 (9) “Despite diligent investigation by Plaintiff into the cause of his injuries, including
13 numerous consultations with Mr. Bell’s medical providers, the nature of Plaintiff’s injuries
14 and damages, and their relationship to INFUSE® was not discovered, and through
15 reasonable care and diligence could not have been discovered, until a date within the
16 applicable statute of limitations for filing Plaintiff’s claims.” *Id.* at ¶ 298.

17 Defendants argue that the Bells have failed to plausibly allege facts regarding why their failure to
18 file a timely claim should be excused. Bell MTD at 4-8. The Court disagrees.

19 A federal court sitting in diversity on a state law claim must apply the state statute of
20 limitations. *Bancorp Leasing & Fin. Corp. v. Agusta Aviation Corp.*, 813 F.2d 272, 274 (9th Cir.
21 1987). Because the statute of limitations is an affirmative defense, the “defendant has the burden of
22 proving the action is time-barred.” *Grisham v. Philip Morris, Inc.*, 670 F.Supp.2d 1014, 1020 (C.D.
23 Cal. 2009) (citation omitted). Under California Civil Procedure Code § 335.1, personal injury
24 claims based on defective products are subject to a two-year limitations period. *Soliman v. Philip*
25 *Morris Inc.*, 311 F.3d 966, 971 (9th Cir. 2002). “In ordinary ... actions, the statute of limitations ...
26 begins to run upon the occurrence of the last element essential to the cause of action.” *Gutierrez v.*
27 *Mofid*, 39 Cal.3d 892, 899 (1985) (citation omitted). Therefore, for personal injury claims, the date
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1 of accrual of the cause of action is generally the date of physical injury. *See Jolly v. Eli Lilly & Co.*,
2 44 Cal.3d 1103, 1109 (1988). Although the general rule provides that the statute of limitations
3 begins to run “when the cause of action is complete with all of its elements,” *Norgart v. Upjohn*
4 *Co.*, 21 Cal.4th 383, 389 (1999), the discovery rule delays the commencement of the running of the
5 statute until the plaintiff “is aware of her injury and its negligent cause.” *Jolly*, 44 Cal.3d at 1109.
6 More specifically, under the discovery rule, the statute of limitations begins to run not when the
7 plaintiff sustains her injury, but rather “when the plaintiff suspects or should suspect that her injury
8 was caused by wrongdoing, that someone has done something wrong to her.” *Id.* at 1110. Thus, the
9 discovery rule “delays accrual until the plaintiff has, or should have, inquiry notice of the cause of
10 action.” *Fox v. Ethicon Endo-Surgery, Inc.*, 35 Cal.4th 797, 807 (2005). However, a “plaintiff
11 whose complaint shows on its face that [her] claim would be barred without the benefit of the
12 discovery rule must specifically plead facts to show (1) the time and manner of discovery *and* (2)
13 the inability to have made earlier discovery despite reasonable diligence.” *Id.* at 808 (citation
14 omitted). Here, the Bells did not file their lawsuit until six years after Scott Bell sustained his
15 injuries and underwent corrective surgery in May 2007. *Eidson*, 2013 WL 5533081, at *18.
16 Nonetheless, the Bells argue that their claims are not barred by the statute of limitations because
17 the discovery rule delayed the accrual of their claims. Below, the Court explains why the Bells
18 have now pled sufficient facts to allege the delayed discovery rule. First, the Court explains why it
19 is plausible that, as the Bells argue, the Bells were not on inquiry notice concerning the role Infuse
20 played in causing Scott Bell’s injuries until April 2012 when Scott Bell’s mother saw a commercial
21 about lawsuits concerning Infuse. Second, the Court explains why the Bells have pled sufficient
22 facts showing (1) the time and manner of discovery and (2) the inability to have made earlier
23 discovery despite reasonable diligence.

24 First, the Court concludes that it is plausible that the Bells were not on inquiry notice until
25 April 2012. The discovery rule “delays accrual until the plaintiff has, or should have, inquiry notice
26 of the cause of action.” *Fox*, 35 Cal.4th at 807. Inquiry notice occurs “when the plaintiff suspects
27 or should suspect that her injury was caused by wrongdoing, that someone has done something
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1 wrong to her.” *Jolly*, 44 Cal.3d at 1110. “The question when a plaintiff actually discovered or
2 reasonably should have discovered the facts for purposes of the delayed discovery rule is a
3 question of fact unless the evidence can support only one reasonable conclusion.” *Ovando v.*
4 *County of Los Angeles*, 159 Cal. App. 4th 42, 61 (2008) (citing *Jolly*, 44 Cal.3d at 1112); *see also*
5 *Ward v. Westinghouse Canada, Inc.*, 32 F.3d 1405, 1408 (9th Cir. 1994) (“Under California law,
6 the question of when [the plaintiff] was on inquiry notice of potential wrongdoing is a factual
7 question.”). *See also E-Fab, Inc. v. Accountants, Inc. Services*, 64 Cal. Rptr. 3d 9, 17 (Cal. App.
8 6th Dist. 2007) (“Resolution of the statute of limitations issue is normally a question of fact. More
9 specifically, as to accrual, once properly pleaded, belated discovery is a question of fact. As our
10 state’s high court has observed: ‘There are no hard and fast rules for determining what facts or
11 circumstances will compel inquiry by the injured party and render him chargeable with knowledge.
12 It is a question for the trier of fact.’ However, whenever reasonable minds can draw only one
13 conclusion from the evidence, the question becomes one of law.”) (internal citations and quotation
14 marks omitted).

15 Here, in light of the Bells’ allegations, the Court finds that the question of when the Bells
16 were on inquiry notice of Defendants’ alleged wrongdoing is a question of fact, and cannot be
17 decided as a matter of law at this stage of the proceedings, because the Bells’ allegations do not
18 support only one reasonable conclusion. While Defendants argue that the only reasonable
19 conclusion is that the Bells were on inquiry notice by May 2007 when Scott Bell underwent
20 corrective surgery for his bony overgrowth or at the latest by 2008, Bell MTD at 8, it is plausible
21 that the Bells were not on inquiry notice that Scott Bell’s injury was caused by Infuse until April
22 2012. This is because the Bells allege that Scott Bell’s surgeon never told him that Infuse was to be
23 used in the 2005 surgery nor obtained Scott Bell’s consent to use it. *Id.* at ¶ 290. Nor did any
24 physician ever tell Scott Bell that Infuse had been used in his surgery. *Id.* at ¶ 294. Further, Scott
25 Bell’s surgery consent form, which did not mention Infuse, implied that the bone to be used in the
26 surgery was to be taken from Scott Bell’s iliac crest. *Id.* at ¶ 292. The Bells further allege that no
27 physician told Scott Bell that a product defect might have contributed to his new pain or symptoms.
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1 *Id.* at ¶ 295. To the contrary, when he began experiencing pain, his surgeon told him his pain was
2 due to a “ ‘biological phenomenon’ in terms of the way [his] body uniquely reacted to surgery.” *Id.*
3 at ¶ 291. Accepting these facts as true and construing them in Plaintiffs’ favor as the Court must at
4 this stage, the Court finds it is plausible that the Bells did not have reason to know or suspect that
5 wrongdoing caused Scott Bell’s injuries until April 2012 when Scott Bell’s mother saw a
6 commercial regarding Infuse. *Id.* at ¶ 296. This is because given Scott Bell’s doctors’ failure to
7 disclose the use of Infuse in Scott Bell’s surgery and representations about the cause of his pain,
8 Scott Bell may reasonably have relied on his doctor’s representations rather than trying to figure
9 out on his own that Infuse was used during his surgery and that Infuse caused his injuries.

10 Defendants’ arguments to the contrary are unavailing. Defendants argue that the Bells
11 should have been on inquiry notice by May 2007 because the reasonable person would have
12 requested his surgical records from his initial surgery after having to go through corrective surgery
13 in May 2007. Bell MTD at 6. Defendants claim those records would have revealed the alleged
14 wrongdoing because the Bells’ own complaint concedes that the separate sticker page to the
15 operative report, which is the hospital’s “record of devices and equipment used during the
16 procedure,” mentioned the use of rhBMP-2, the protein used in Infuse. *Id.* (citing Bell Complaint at
17 ¶ 293).⁵ The Bells have also conceded that the operative report indicated the use of “Infuse,” *see*
18 ECF No. 60 (Letter from Plaintiffs’ Counsel to the Court). Defendants further note how Scott
19 Bell’s pre-surgery consent form indicated that an “intervertebral fusion device” was to be used in
20 the surgery, Bell MTD at 6 (citing Bell Complaint at ¶ 292). However, Defendants’ argument is
21 unpersuasive because it is plausible that the reasonable person would not see a need to request or
22 inspect his surgical records if his physician failed to disclose the use of Infuse during surgery and
23 led him to believe that a “biological phenomenon” caused his injuries. *See, e.g., Unjian v. Berman*,
24 208 Cal. App. 3d 881, 885 (1989) (finding triable issue of fact as to delayed discovery because an
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26 _____
27 ⁵ In the Bells’ Opposition, they also concede that the sticker page listed “the make, manufacture,
28 model, and identifier for the devices and equipment used during [the] procedure,” which means they concede that the name “Infuse” and the name of the manufacturer of Infuse, i.e., Medtronic, appeared on the sticker page. Bell Opp’n at 4.

1 operation’s failure to produce expected result would not necessarily suggest to the ordinary person
2 that operation had been performed negligently and a jury could reasonably conclude plaintiff was
3 justified in accepting doctor’s explanations); *Lamb v. Scripp Clinic*, 2006 WL 172070, *5 (Cal.
4 App. 4th Dist. 2006) (reversing grant of summary judgment to defendant on statute of limitations
5 grounds where plaintiff’s doctor “responded in a manner that could lead a reasonable person to
6 believe there was no negligence” by himself and the other doctors who participated in plaintiff’s
7 surgery); *Lucas v. Somberg*, 2006 WL 2270928, *1 (Cal. App. 2d Dist. 2006) (finding triable issue
8 of fact as to delayed discovery, reasoning that because plaintiff “was given an explanation [by
9 doctor] that there would be no resulting scars [from his burns], the question of his reasonable
10 diligence in discovering his permanent scarring is one of fact”). On this point, the California court
11 of appeal’s decision in *Unjian* is illustrative. There, a plaintiff sued his plastic surgeon after
12 unsuccessful face-lift surgery. *Id.* at 883-884. Although the plaintiff noticed shortly after the
13 operation that his face looked “ ‘worse’ ” after the operation, he remained in the surgeon’s care for
14 ten more months and the defendant surgeon told him the problem could have been caused by a
15 preexisting condition. *Id.* at 883. Reversing a summary judgment in favor of the plastic surgeon,
16 the court of appeal found triable issues of fact existed as to whether California Code of Civil
17 Procedure ¶ 340.5 was tolled by the plaintiff’s delayed discovery. *Id.* at 888. The court of appeal
18 reasoned that the fact that the operation did not produce the expected result did not necessarily
19 connect the injury to the defendant’s negligence. *Id.* at 885. The court of appeal found the plaintiff
20 could have reasonably accepted the doctor’s alternative explanation of the injury and therefore
21 there was a triable issue as to when the plaintiff knew or should have known of the injury and its
22 negligent cause. *Id.* at 884-888. Like in *Unjian*, it is plausible that Scott Bell reasonably accepted
23 his doctor’s explanation that a “biological phenomenon” caused his injuries and thus found no
24 reason to inquire further.

25 Second, Defendants argue that even assuming the Bells were not placed on inquiry notice
26 by May 2007, they should have been placed on notice by 2008 because their complaint alleges that
27 the off-label use of Infuse was the subject of widespread media attention as early as July 1, 2008,
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1 including articles that stated that off-label use could lead to bony overgrowth of the type which
2 Scott Bell was experiencing. *See* Bell MTD at 6-7; Bell Complaint ¶ 96 (discussing September 4,
3 2008 Wall Street Journal article linking off-label use of Infuse to “unwanted bone growth near
4 nerves” and stating that 75 percent of adverse events reported to the FDA involved off-label
5 use); *id.* ¶ 201 (noting a May 19, 2009 New York Times article regarding Defendants coming
6 under investigation by the Department of Justice for off-label promotion of Infuse); *id.* ¶ 94 (citing
7 how FDA issued on July 1, 2008 a “Public Health Notification” warning about the “serious
8 complications” that may arise from off-label use). Defendants’ argument fails because it has been
9 rejected by California courts. In *Unruh–Haxton v. Regents of University of California*, 162
10 Cal.App.4th 343, 364 (Cal. App. 4th Dist. 2008), the California court of appeal held that “public
11 awareness of a problem through media coverage alone [cannot] create [] constructive suspicion for
12 purposes of [the delayed] discovery [rule].” This is because “[t]he statute of limitations does not
13 begin to run when some members of the public have a suspicion of wrongdoing, but only ‘once the
14 plaintiff has a suspicion of wrongdoing.’ ” *Id.* at 361 (citing *Nelson v. Indevus Pharmaceuticals,*
15 *Inc.*, 142 Cal. App. 4th 1202, 1206 (Cal. App. 2d Dist. 2006) (emphasis in original)).

16 Similarly, in *Nelson*, the plaintiff’s cause of action arose from her use of a diet drug sold as
17 Redux. *Id.* at 1204. The defendant argued that the plaintiff’s action was barred by the statute of
18 limitations, because the limitations period began to run when the dangers of a similar drug, known
19 as “Fen-phen,” were widely publicized. *Id.* The court of appeal disagreed, finding that the plaintiff
20 had no obligation to read newspapers and watch television news or otherwise seek out information
21 not disclosed by her prescribing doctor. *Id.* at 1208. The court of appeal’s conclusion was bolstered
22 by Code of Civil Procedure section 340.8, the statute of limitations for claims involving toxic torts
23 or hazardous materials, which specifically provides that “[m]edia reports regarding the hazardous
24 material or toxic substance contamination do not, in and of themselves, constitute sufficient facts to
25 put a reasonable person on inquiry notice that the injury or death was caused or contributed to by
26 the wrongful act of another.” *Id.* (citing Cal. Code. Civ. P. ¶ 340.8). In sum, the court of appeal
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1 held there is no rule of “constructive suspicion” that triggers the statute of limitations simply when
2 the dangers of a product are publicized.

3 Federal courts applying California law have come to similar conclusions. *See, e.g., Yumul v.*
4 *Smart Balance, Inc.*, 733 F. Supp. 2d 1134, 1143 n.17 (C.D. Cal. 2010) (rejecting defendant’s
5 argument that media reports would suffice to show that plaintiff was on inquiry notice as a matter
6 of law); *Migliori v. Boeing N. Am., Inc.*, 97 F.Supp.2d 1001, 1011 (C.D. Cal. 2000) (holding at
7 motion to dismiss stage that “[t]he mere fact of publicity ... does not conclusively show that a
8 plaintiff must be imputed with knowledge” and does not establish that plaintiffs’ claims are time-
9 barred as a matter of law). Here, the Bells’ complaint nowhere alleges that the Bells were aware of
10 these articles, saw them, or read them, and thus it is plausible that they were not in fact aware of
11 such articles or information. *See Unruh-Haxton*, 162 Cal.App.4th at 363-364 (rejecting defendant’s
12 claim that publicity gave rise to plaintiffs’ constructive knowledge of the media coverage); *McGill*
13 *v. M.J. Brock & Sons, Inc.*, 91 Cal. Rptr. 2d 135, 142-143 (Cal. App. 4th Dist. 1999) (denying
14 summary judgment to defendants on statute of limitations grounds and rejecting argument that
15 media reports sufficed to put plaintiffs on notice because “there is no evidence that any of the
16 plaintiffs read any of those articles or even received any of those newspapers.”).

17 The Court further notes that even assuming the Bells saw these media articles, it is plausible
18 that the articles would not have put the Bells on notice because the Bells allege they had no idea
19 that Infuse was used in Scott Bell’s surgery. This point distinguishes this case from *Soliman v.*
20 *Philip Morris Inc.*, 311 F.3d 966 (9th Cir. 2002). There, a California plaintiff brought suit against a
21 tobacco company claiming that smoking had injured him. *Id.* at 969. The company moved for
22 dismissal on statute of limitations grounds because the plaintiff had smoked for thirty-some years
23 before filing his claim and did not qualify for the delayed discovery rule because he should have
24 been on notice of the health hazards of smoking long before filing his claim. *Id.* at 970. The district
25 court granted the motion to dismiss, and the Ninth Circuit affirmed, holding that a “smoker who is
26 injured by a product he believed to be safe has reason at least to suspect that its manufacturer or
27 seller has done something wrong.” *Id.* at 972. The court held the limitations period began when the
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1 plaintiff should have known he was addicted. *Id.* at 973. Despite the fact that the plaintiff claimed
2 he didn't realize he was addicted until the year 2000, "a reasonable person would have discovered
3 it sooner" given that "the dangers of nicotine addiction have been in the public spotlight for many
4 years." *Id.* at 973, 975. *Soliman* is inapposite here because Soliman obviously knew he was
5 smoking. In contrast, Scott Bell had no idea that Infuse had been used in his surgery because his
6 doctors never told him it was and actually indicated to him in 2007, before the media coverage of
7 Infuse in 2008, that his injuries were caused by a biological phenomenon. Thus, it is plausible that
8 Scott Bell would not have known that media reports on Infuse, to the extent he saw them, applied
9 to him.

10 In sum, the Court cannot conclude that the only reasonable inference to be drawn from the
11 Bells' allegations is that a reasonable person in Scott Bell's position would have been on inquiry
12 notice at the latest by 2008. Thus, Defendants have not met their burden of showing that the Bells
13 suspected or should have suspected the wrongful cause of Scott Bell's injuries by 2008.

14 Second, the Court explains why the Bells have pled sufficient facts showing (1) the time
15 and manner of discovery and (2) the inability to have made earlier discovery despite reasonable
16 diligence. "Once the plaintiff has a suspicion of wrongdoing, and therefore an incentive to sue, she
17 must decide whether to file suit or sit on her rights. So long as a suspicion exists, it is clear that the
18 plaintiff must go find the facts; she cannot wait for the facts to find her." *Jolly*, 44 Cal.3d at 1111.
19 Thus, in California, a "plaintiff whose complaint shows on its face that [her] claim would be barred
20 without the benefit of the discovery rule must specifically plead facts to show (1) the time and
21 manner of discovery and (2) the inability to have made earlier discovery despite reasonable
22 diligence." *Fox*, 35 Cal.4th at 808 (citation omitted). The burden is "on the plaintiff to show
23 diligence; conclusory allegations will not withstand demurrer." *Id.* (internal quotations omitted).

24 The Bells have met their burden with respect to the first prong of the *Fox* test by alleging
25 the time and manner of discovery, i.e., when they were on inquiry notice of Defendants' alleged
26 wrongdoing. Their complaint makes clear how and when Scott Bell discovered facts sufficient to
27 put the Bells on notice. The complaint alleges Scott Bell was alerted in April 2012 by his mother
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1 based on a television commercial she saw, after which time Scott Bell contacted a lawyer to
2 investigate. Bell Complaint ¶ 297. The Bells have also pled sufficient facts with respect to the
3 second prong of the *Fox* test by alleging that they acted with reasonable diligence to discover the
4 cause of his injuries and were unable to have made earlier discovery despite such diligence. Bell
5 Complaint ¶ 298. Standing alone, such allegations would be deemed conclusory and would fail to
6 withstand dismissal. However, the Bells allege additional facts that support their allegations, as
7 elaborated above. For example, they allege that they made “numerous consultations with Mr. Bell’s
8 medical providers,” *id.*, that his doctor never informed him Infuse was to be used in the surgery,
9 that Scott Bell’s consent form never mentioned Infuse but implied that the bone was to be taken
10 from his iliac crest instead, that his doctor told him his pain was due to a “biological phenomenon”
11 and did not mention it could be caused by any product used during his surgery. *Id.* at ¶¶ 290-296.
12 These allegations could support the inference that a reasonably diligent person would not have
13 made an earlier discovery by investigating further, given that Scott Bell may have reasonably relied
14 on his doctor’s statement that the cause of his injuries was just a “biological phenomenon.”
15 Accordingly, the Court finds that the Bells have pled sufficient facts showing their inability to have
16 made earlier discovery despite reasonable diligence.

17 Finally, the Court notes that four of the cases cited by Defendants, namely *Jolly*, *Norgart*,
18 *Fox*, and *Gutierrez*, are readily distinguishable from the instant case. “In both *Jolly* and *Norgart*,
19 the court emphasized that the plaintiffs had ample reason to suspect the basis of their claims.” *Fox*,
20 35 Cal.4th at 814. In fact, in those cases, as well as in *Gutierrez*, the plaintiffs actually admitted
21 that they suspected the defendant’s wrongful conduct at a time that rendered their claims time-
22 barred. *See Jolly*, 44 Cal.3d at 1112; *Norgart*, 21 Cal.4th at 405–6; *Gutierrez*, 39 Cal.3d at 895-97
23 (noting that plaintiff conceded in her deposition that “she felt [as early as 1978] that the surgeons
24 had ‘done something wrong’ to her.”). In this case, on the other hand, Scott Bell’s medical
25 providers did not inform him that Infuse was used in his surgery and instead implied the bone was
26 to be taken from his iliac crest, and also told him that his post-surgery pain was the result of a
27 “biological phenomenon” and his unique reaction to the surgery. Additionally, *Jolly* and *Norgart*
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1 were decided at the summary judgment stage, meaning the court was “presented with a more fully
2 developed factual basis for determining when and how the plaintiff discovered an injury, whether
3 the plaintiff conducted a reasonable investigation, when such an investigation would have brought
4 to light the factual basis for the cause of action ... and whether the plaintiff could have discovered
5 the factual basis for a cause of action earlier by exercising reasonable diligence.” *Fox*, 35 Cal.4th at
6 810. On the other hand, this motion has been brought at the pleading stage, so the Court must take
7 all of the Bells’ factual allegations as true. Finally, unlike the plaintiff in *Fox*, the Bells did not fail
8 to “allege facts explaining why [they] did not have reason to discover earlier the factual basis of”
9 their claims. *Id.* at 806.

10 Because the Court finds that the Bell complaint alleges sufficient facts to satisfy the
11 pleading requirements of the discovery rule, the Court rejects Defendants’ argument that the Bell
12 complaint must be dismissed as time-barred.

13 **B. Analysis of both Richard Eidson and the Bells’ Fraudulent**
14 **Misrepresentation/Fraud in the Inducement Claims, Negligent Misrepresentation**
15 **Claims, Strict Liability Failure to Warn Claims, and Negligent Failure to Warn**
16 **Claims**

17 Both Eidson and the Bells bring the same four causes of action: (1) fraudulent
18 misrepresentation/fraud in the inducement; (2) negligent misrepresentation; (3) strict products
19 liability failure to warn; and (4) negligent failure to warn. The Bells also bring a fifth cause of
20 action: loss of consortium on behalf of April Bell. The Court addresses April Bell’s consortium
21 claim in Part IV.C below. In this section, the Court addresses both Eidson and the Bells’ fraudulent
22 misrepresentation/fraud in the inducement claims, negligent misrepresentation claims, strict
23 liability failure to warn claims, and negligent failure to warn claims. Defendants raise the exact
24 same arguments against each of these four claims in their motion to dismiss the Eidson complaint
25 and their motion to dismiss the Bell complaint. Thus, the Court addresses Defendants’ arguments
26 together with respect to both Eidson and the Bells’ claims below.⁶ The Court refers collectively to
27 Eidson and the Bells as “Plaintiffs” below.

28 ⁶ For purposes of citations, the Court refers only to the Eidson complaint and the Eidson MTD,
Eidson Opp’n, and Eidson Reply throughout the rest of this section, although the reader should

1 Defendants argue that all of Plaintiffs' claims are expressly and impliedly preempted,
2 Eidson MTD at 4-18, and that their fraud claims are not pled with the requisite particularity and fail
3 to state a claim under California law. Eidson MTD at 19-21. Plaintiffs respond that their claims are
4 not preempted, are pled with the requisite particularity, and state valid claims under state law. *See*
5 *generally* Eidson Opp'n. The Court discusses each of Defendants' three arguments in turn below.

6 **1. Preemption of Plaintiffs' Claims**

7 The Court first addresses whether each of Plaintiffs' claims are expressly or impliedly
8 preempted under federal law.⁷

9 **a. Fraud-based claims: fraudulent misrepresentation/fraud in the** 10 **inducement claim and negligent misrepresentation**

11 The Court will consider Plaintiffs' two fraud-based claims together: Plaintiffs' fraudulent
12 misrepresentation/fraud in the inducement claim and negligent misrepresentation claim. The Court
13 concludes that neither claim is expressly or impliedly preempted.

14 In its October 3, 2013 Order, the Court noted that Eidson's original complaint was unclear
15 as to precisely what conduct by Defendants formed the basis of Eidson's fraud-based claims. The
16 two fraud-based claims evaluated in the October 3, 2013 Order were the fraudulent
17 misrepresentation/fraud in the inducement claim and strict products liability misrepresentation
18 claim. The Court held that to the extent Eidson's fraud-based claims alleged misrepresentations or

19 bear in mind that the Court intends to refer as well to the identical sections in the Bell MTD, Bell
20 Opp'n, Bell Reply, and Bell complaint. The briefing by both parties in both cases is substantively
21 identical except with respect to the arguments concerning the statute of limitations issue and loss of
22 consortium claim in the Bells' case, which do not appear in the parties' briefing for the Eidson
23 case. The Bell complaint and Eidson complaint are also substantively identical except for the fact
24 sections regarding Scott Bell and Eidson's surgeries and the additional allegations in the Bell
25 complaint regarding the Bells' delayed discovery of Defendants' alleged wrongdoing and April
26 Bell's loss of consortium claim.

27 ⁷ In its October 3, 2013 Order, the Court held that the first prong of the *Riegel* express preemption
28 test was "clearly met" because the PMA process subjected Infuse to FDA "requirements" within
the meaning of *Riegel*. *See Eidson*, 2013 WL 5533081 at *8 ("the Infuse Device was approved by
the FDA, and such PMA imposes federal 'requirements' that are specific to the device").
Defendants do not challenge this holding. Thus, the Court adheres to its previous conclusion and
considers *Riegel*'s threshold prong met. The second prong of *Riegel*'s express preemption test –
whether Plaintiffs' claims are "different from, or in addition to" or "parallel to" federal
requirements – will be addressed separately for each of Plaintiffs' claims.

1 omissions in the FDA-approved warning labels accompanying Infuse, such claims were expressly
2 preempted because “requiring Defendants to alter the Infuse Device’s warnings and label in order
3 to provide extra warnings beyond those already approved during the PMA process would impose
4 labeling and warning requirements ‘different from, or in addition to’ federal requirements.” *Eidson*,
5 2013 WL 5533081 at *9. The Court held that if, on the other hand, Eidson’s fraud-based claims
6 alleged Defendants made misrepresentations or omissions in the course of promoting Infuse for
7 off-label use, such claims were not expressly or impliedly preempted. *See id.* at *10-11. As a result,
8 the Court denied Defendants’ motion to dismiss Eidson’s fraud-based claims.

9 After the October 3, 2013 Order, Eidson amended his complaint to allege two fraud-based
10 claims: fraudulent misrepresentation/fraud in the inducement, and negligent misrepresentation. The
11 first, his fraudulent misrepresentation/fraud in the inducement claim, is the same as in his original
12 complaint because he left it unaltered. The second, negligent misrepresentation, is a new claim
13 because Eidson changed his original strict products liability misrepresentation claim to a negligent
14 misrepresentation claim. The Bells also have amended their complaint to allege two fraud-based
15 claims: fraudulent misrepresentation/fraud in the inducement, and negligent misrepresentation. The
16 Bells’ fraudulent misrepresentation/fraud in the inducement claim is substantively identical to the
17 fraudulent misrepresentation/fraud in the inducement claim in Eidson’s amended complaint, and
18 the Bells’ negligent misrepresentation claim is substantively identical to the negligent
19 misrepresentation claim in Eidson’s amended complaint.

20 As to the Plaintiffs’ first fraud claim, fraudulent misrepresentation/fraud in the inducement,
21 Defendants urge dismissal on the grounds that this claim “still appears to challenge the sufficiency
22 of the Infuse Device FDA-approved labeling.” Eidson MTD at 7. Plaintiffs’ oppositions suggest
23 rather that this claim is based on fraudulent conduct in the course of off-label promotion. Eidson
24 MTD at 4. As to the second fraud claim, negligent misrepresentation, that claim alleges that
25 Defendants negligently made misrepresentations or omissions in the course of promoting Infuse for
26 off-label use. Eidson Complaint ¶¶ 318-328. Defendants urge dismissal of this claim on the
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1 grounds that *any* cause of action based on off-label promotion is expressly and impliedly
2 preempted. *Eidson* MTD at 15, 17.

3 The Court analyzes Defendants’ challenge to the Plaintiffs’ two fraud-based claims together
4 below and concludes that Defendants have not provided any persuasive reason for the Court to
5 change its original conclusion in its October 3, 2013 Order that the fraud-based claims are not
6 expressly or impliedly preempted to the extent they are based on fraudulent conduct in the course
7 of off-label promotion.

8 **i. Express preemption**

9 Plaintiffs’ fraudulent misrepresentation/fraudulent inducement and negligent
10 misrepresentation claims are not expressly preempted because they impose state tort law duties that
11 parallel federal requirements. Defendants argue that because off-label promotion is not necessarily
12 a violation of federal law, state claims based on such promotion cannot be parallel to federal
13 requirements. *Eidson* MTD at 13-14. However, as the Court noted in its October 3, 2013 Order,
14 courts in the Ninth Circuit have generally held that device manufacturers are prohibited by federal
15 law from promoting or advertising off-label use because such promotion is deemed to be false or
16 misleading. *See Eidson*, 2013 WL 5533081 at *10; *Carson v. Depuy Spine, Inc.*, 365 Fed. Appx.
17 812, 815 (9th Cir. 2010) (“[W]hile doctors may use a drug or device off-label, the marketing and
18 promotion of a Class III device for an unapproved use violates Section 331 of the FDCA.”); *In re*
19 *Epogen & Aranesp Off-Label Marketing & Sales Practices Litigation*, 590 F.Supp.2d 1282, 1287
20 (C.D. Cal. 2008) (“Under FDA regulations, drug manufacturers are prohibited from promoting off-
21 label uses of prescription drugs.”). Thus, as this Court previously explained, the duties underlying
22 these two fraud claims are not “different from, or in addition to” the federal requirement banning
23 off-label promotion because there is “no likelihood that Defendants could be held liable under [the]
24 state law without having violated [] federal law.” *Eidson*, 2013 WL 5533081 at *10 (citation
25 omitted).

1 Even assuming off-label promotion per se does not constitute a violation of federal law as
2 Defendants argue, *see* Eidson MTD at 13-14,⁸ Defendants have advanced no authority suggesting
3 that federal law permits false and misleading off-label marketing, and there is in fact law to the
4 contrary. In holding that fraud claims based on Medtronic’s promotion of Infuse escaped express
5 preemption, the court in *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166 (C.D. Cal. 2013), held
6 that federal law requires that advertising beyond the subject device’s label not be false or
7 misleading. *Id.* at 1179-80.⁹ Thus, here, even assuming truthful off-label promotion does not
8 violate federal law, Plaintiffs’ claims still escape express preemption because they allege that
9 specific aspects of Defendants’ promotion activities were false or misleading. For example,
10 Plaintiffs allege Defendants knowingly marketed Infuse in misleading ways, such as by paying
11 kickbacks to “opinion leaders” to directly advocate off-label use of Infuse to other spine surgeons
12 without disclosing their financial relationship with Defendants and bankrolling falsified medical
13 studies and articles. Eidson Complaint ¶¶ 104, 119-122. Accordingly, the Court concludes that the
14 state tort law duties underlying Plaintiffs’ claims are not “different from, or in addition to” federal
15 requirements, which unquestionably ban fraudulent marketing.

16 Other courts that have confronted these very same issues in cases involving these very same
17 Defendants have similarly held that fraud-based claims alleging deceptive off-label promotion
18 escape express preemption. *See, e.g., Alton v. Medtronic, Inc.*, 3:13-CV-409-PK, 2013 WL
19 4786381 (D. Or. Sept. 6, 2013); *Kashani-Matts v. Medtronic, Inc.*, 2013 WL 6147032 (C.D. Cal.
20 Nov. 22, 2013) (“To the extent that Plaintiff’s fraud claims are based on alleged misrepresentations
21 and omissions Medtronic made while promoting and marketing the Infuse Device, such claims

22
23 ⁸ Courts have reached different conclusions as to whether *truthful* off-label marketing violates
24 federal law. *Compare Dawson v. Medtronic, Inc.*, 3:13-CV-663-JFA, 2013 WL 4048850 (D.S.C.
25 Aug. 9, 2013) (“This court is not convinced that off-label promotion violates the FDCA”), *with In*
re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig., 590 F. Supp. 2d 1282, 1290 (C.D.

26 Cal. 2008) (“Differently put, (truthful) off-label promotion of a drug . . . violates the FDCA.”).
27 ⁹ A device under the MDA is defined as “misbranded” if its advertising is false or misleading in
28 any particular way. 21 U.S.C. § 352(q). The FDCA prohibits the introduction into interstate
commerce of any misbranded device. 21 U.S.C. § 331(a). Accordingly, any false or misleading
promotion of a device that is used in interstate commerce violates federal law.

1 could survive preemption”); *Scovil v. Medtronic, Inc.*, 2014 WL 502923 (D. Ariz. Feb. 7, 2014)
2 (holding that claim based on false statements made to doctors in promoting Infuse for off-label use
3 escapes express preemption); *Hawkins v. Medtronic, Inc.*, 2014 WL 346622 (E.D. Cal. Jan. 30,
4 2014) (same). Accordingly, the Court finds Plaintiffs’ fraudulent misrepresentation/fraud in the
5 inducement and negligent misrepresentation claims to be parallel to federal requirements, and thus
6 not expressly preempted.

7 **ii. Implied Preemption**

8 The Court also finds that Plaintiffs’ fraudulent misrepresentation/fraudulent inducement
9 claim and negligent misrepresentation claims based on misleading off-label promotion are not
10 impliedly preempted, because, as held in this Court’s October 3, 2013 Order, such claims are
11 “based on state common law tort duties that exist independently from the FDCA and not solely by
12 virtue of the FDCA.” *Eidson*, 2013 WL 5533081 at *11 (citing *Buckman*, 521 U.S. at 353, which
13 holds that so long as a state law claim exists independently of federal requirements and does not
14 exist “solely by virtue” of those federal requirements, there is no implied preemption).

15 Defendants ask the Court to reconsider this holding, arguing that *Perez v. Nidek Co., Ltd*,
16 711 F.3d 1109 (9th Cir. 2013), controls and suggests that Plaintiffs’ “claims based on off-label
17 promotion are impliedly preempted[.]” *Eidson* MTD at 18. The Court disagrees. In *Perez*, the
18 Ninth Circuit held that a fraud claim against a medical device manufacturer was impliedly
19 preempted pursuant to *Buckman*. The plaintiff alleged that the manufacturer of a laser approved by
20 the FDA for use in nearsightedness surgery had modified the laser to allow it to be used in
21 farsightedness surgery as well, despite the fact that the FDA had not yet approved it for that use.
22 *Perez*, 711 F.3d at 1112. The plaintiff also alleged that the manufacturer knew doctors were using
23 the laser off-label to treat farsightedness, *id.*, and that the manufacturer failed to disclose to patients
24 that the device was not approved for such use despite knowing that patients would believe the
25 device was FDA-approved for their surgeries. *Id* at 1117. The Ninth Circuit reasoned that the
26 plaintiff’s claims were not grounded in preexisting state law, and thus were impliedly preempted,
27
28

1 because “[l]ike the fraud-on-the-FDA claims in *Buckman*,¹⁰ Perez’s fraud by omission claim
2 exist[s] solely by virtue of the FDCA.” *Perez*, 711 F.3d at 1119. The court reasoned that because
3 the plaintiff had challenged *only* the failure of the manufacturer to warn patients that a particular
4 use was not FDA-approved, his claim did not implicate an independent state law duty. *Id.* The
5 omission at issue – the “scope of PMA approval” as to off-label use – could only give rise to
6 liability because of the existence of the FDCA approval process. *Id.* The court held that as in
7 *Buckman*, the existence of the federal enactment was a critical element of plaintiff’s case. *Id.*

8 *Perez* is easily distinguishable. *Perez*’s claim was based solely on the device manufacturer’s
9 fraud by omission – failure to notify patients that the device was not approved by the FDA for
10 certain off-label uses. *Id.* at 1112-13. Unlike *Perez*, Plaintiffs are not accusing Defendants simply
11 of creating a product capable of off-label use and selling it to hospitals knowing it would be used
12 unsafely without warning patients that off-label use was not FDA-approved. Rather, Plaintiffs
13 allege that Defendants engaged in affirmatively fraudulent conduct when promoting Infuse for off-
14 label use. Defendants are accused not of simply selling a device they know will be used off-label as
15 in *Perez*, but of falsifying medical research and making statements via sales representatives and
16 opinion leaders that knowingly understate the dangers of off-label use of Infuse. The omissions of
17 which Plaintiffs complain are not simply the failure to warn patients of the fact of non-approval by
18 the FDA, but failure to warn patients of known dangers associated with off-label Infuse usage. The
19 main point here is that California common law unquestionably prohibits commercial
20

21 ¹⁰ In *Buckman*, plaintiffs who suffered injuries from the use of bone screws in spinal surgery
22 brought state law fraud actions against a consultant who secured FDA approval for the screws. The
23 plaintiffs claimed that the defendant secured FDA approval only by fraudulently misrepresenting
24 the intended use of the screws during the application process, thereby causing the FDA to wrongly
25 grant approval and leading to plaintiffs’ injuries. *Buckman*, 531 U.S. at 347. The Supreme Court
26 held such state law fraud claims were impliedly preempted under the MDA, as they amounted to
27 nothing more than attempted private enforcement of the FDCA and thus “inevitably conflict with
28 the FDA’s responsibility to police fraud consistently with the Administration’s judgment and
objectives.” *Id.* at 350. The Supreme Court suggested that the only types of state law claims that
could survive implied preemption under the MDA were those that relied “on traditional state tort
law which had predated the federal enactments in questions [sic].” *Id.* at 353. Claims based solely
on an applicant’s misstatements or omissions to the FDA during the approval process fail to meet
that requirement, as they “exist solely by virtue of the FDCA disclosure requirements.” *Id.*

1 WL 5533081 at *12. To the extent it was instead based on Defendants’ failure to report to the FDA
2 adverse events regarding the dangers of off-label use, the Court found it was not expressly or
3 impliedly preempted but nonetheless dismissed the claim for failure to establish a causal nexus
4 between Eidson’s injury and Defendants’ conduct. *Id.* Subsequent to the Court’s October 3, 2013
5 Order, both Eidson and the Bells amended their complaints to make clear that both their strict
6 liability *and* negligent failure to warn claims are now each based on the same “three theories.”
7 Eidson Complaint ¶¶ 309, 336. In its analysis below, the Court concludes that Plaintiffs’ failure to
8 warn claims based on their first two theories – “overpromotion” and deceptive off-label promotion
9 – are expressly preempted. The Court concludes that Plaintiffs’ third theory premised on
10 Defendants’ failure to report adverse events to the FDA, however, escapes preemption.

11 **i. “Overpromotion”**

12 Plaintiffs’ first theory underlying their failure to warn claims alleges that “MEDTRONIC
13 breached its duty by overpromoting INFUSE® to Plaintiff and Plaintiff’s physicians for use in off-
14 label procedures.” Eidson Complaint ¶¶ 309(a), 336(a). The Court concludes that because these
15 claims challenge the sufficiency of the FDA-mandated warnings issued by Defendants, Plaintiffs’
16 failure to warn claims based on an overpromotion theory are expressly preempted.¹¹

17 Plaintiffs allege that “[a]ny warnings MEDTRONIC may have issued concerning the
18 dangers of off-label use [...] were insufficient *in light of* MEDTRONIC’S contradictory prior,
19 contemporaneous, and continuing illegal promotional efforts and overpromotion.” Eidson
20 Complaint ¶ 309a (emphasis added). The California Supreme Court has interpreted state law failure
21 to warn claims sounding in “overpromotion” as one way to attack a warning that is facially
22 sufficient to satisfy a manufacturer’s duty to warn, but the efficacy of which is undermined by
23 aggressive promotion by the manufacturer. *See Stevens v. Parke, Davis & Co.*, 9 Cal. 3d 51, 65,
24 507 P.2d 653, 661 (1973) (“Although the manufacturer or supplier of a prescription drug has a duty
25 to adequately warn the medical profession of its dangerous properties or of facts which make it
26 likely to be dangerous, an adequate warning to the profession may be eroded or even nullified by

27 ¹¹ The Court does not reach the question whether Plaintiffs’ failure to warn claims based on
28 overpromotion are also impliedly preempted.

1 overpromotion of the drug through a vigorous sales program which may have the effect of
2 persuading the prescribing doctor to disregard the warnings given.”). Here, Plaintiffs’ claims
3 embrace such a theory by arguing that the FDA-mandated warnings were rendered insufficient by
4 Defendants’ excessive promotional activities. The Court concludes this renders these claims
5 expressly preempted because they impose greater warning requirements on Defendants than the
6 FDA requires. To state it differently, if Plaintiffs’ state law claims were allowed to proceed to trial,
7 a jury could hold Defendants liable for warnings they issue regarding Infuse that fully comply with
8 FDA requirements simply because they are rendered “insufficient” as a result of Defendants’
9 excessive promotion activities. Imposing such a state law duty, then, would establish requirements
10 “different from, or in addition to” the federal law governing medical devices, and the state law duty
11 is preempted.¹²

12 **ii. Deceptive Off-label Promotion**

13 Plaintiffs’ second theory alleges that “MEDTRONIC breached its duty in that, in the course
14 of promoting INFUSE® for off-label use (a use which the FDA had not reviewed or approved and
15 for which the FDA had not reviewed or approved any written warnings), MEDTRONIC both
16 affirmatively misrepresented and omitted information regarding the risks of the very off-label use
17 MEDTRONIC was promoting.” Eidson Complaint ¶¶ 309(b), 336(b). This Court held in its
18 October 3, 2013 Order that a failure to warn claim based on Defendants’ failure to issue
19 appropriate warnings regarding the dangers of off-label use beyond those required by the FDA is
20 expressly preempted because a “failure to warn claim that imposes obligations on Defendants
21 beyond those imposed during the PMA process ... imposes warning requirements ‘in addition to’
22 federal requirements.” *Eidson*, 2013 WL 5533081 at *12 (citation omitted). Plaintiffs have
23

24 ¹² Plaintiffs’ oppositions do not provide any argument with respect to Plaintiffs’ overpromotion
25 theory. Defendants argue that Plaintiffs’ failure to warn claims premised on an overpromotion
26 theory must be dismissed because overpromotion “is not a cause of action in California.” Eidson
27 MTD at 10 n.4. Defendants are incorrect. California courts have approved jury verdicts on failure
28 to warn claims based on an overpromotion theory such as the one Plaintiffs raise here. *See, e.g.,*
Stevens v. Parke, Davis & Co., 9 Cal. 3d 51, 507 P.2d 653 (1973) (manufacturer of prescription
drug could be held liable where excessive promotion undermined the efficacy of its otherwise
adequate warning labels).

1 presented no persuasive reason for the Court to revisit that holding. Plaintiffs’ argument is
2 essentially that this Court’s prior Order held that the “strict liability – misrepresentation” claim
3 escaped preemption to the extent it was based on misrepresentations made during Defendants’ off-
4 label promotion activities. *Eidson* Opp’n at 7-9. Plaintiffs insist that they have merely
5 “reorganized” the “strict liability – misrepresentation” cause of action as “failure to warn” claims,
6 and that these “failure to warn” claims should thus benefit from the Court’s prior holding that
7 misrepresentation claims can escape preemption. *Id* at 8. Plaintiffs’ argument fails, as explained
8 below.¹³

9 Preemption analysis hinges on the extent to which state law liability can be imposed on a
10 Defendant who has complied fully with the FDA requirements. *See Riegel*, 552 U.S. at 322. In
11 other words, the MDA’s preemption provision invalidates only state law duties that would impose
12 requirements “different from, or in addition to” the requirements imposed on a medical device by
13 the FDA. 21 U.S.C. § 360(c). Only if violation of a state law duty necessarily violates the federal
14 requirements as well can the state law claim escape express preemption, because such a state law
15 would not impose any requirements different from or in addition to what federal law already
16 mandates. *See Riegel*, 552 U.S. at 321-22. Accordingly, this Court’s prior reasoning in holding that
17 the “strict liability – misrepresentation” claim was not preempted hinged on the fact that because
18 FDA requirements prohibit false or misleading promotion of medical devices, any conduct giving
19 rise to state law liability for fraud would by necessity constitute a violation of federal law. *See*
20 *Eidson*, 2013 WL 5533081 at *10-11. California’s cause of action for failure to warn, in contrast,
21 requires *no showing* that a defendant engaged in any misleading or deceptive misrepresentation or
22 omission. *See* California Civil Jury Instructions 1205 & 1222 (setting out elements of strict liability
23 and negligent failure to warn, none of which include fraudulent conduct). As such, Plaintiffs’
24 “reorganizing” does not save their failure to warn claims from express preemption because
25 Defendants could be held liable under California law for conduct – i.e. for failure to warn – that
26 does not violate the FDCA. In other words, if Plaintiffs’ claims were to survive preemption, a jury

27 ¹³ The Court does not reach the question whether Plaintiffs’ failure to warn claims based on
28 deceptive off-label promotion are also impliedly preempted.

1 could find that Defendants’ promotional activities did not contain material misrepresentations or
2 omissions, yet still impose liability for failure to warn about the dangers of Infuse.

3 Moreover, every district court to apply California law to analogous facts has held that
4 California’s failure to warn cause of action is preempted. *See Houston*, 957 F. Supp. 2d at 1177
5 (“For Plaintiff to prevail, a jury would have to find either that Defendants were required to include
6 warnings beyond those in the FDA-approved label for the Infuse Device, or that Defendants were
7 obligated to issue post-sale warnings ... In either case, Plaintiff aims to foist upon Defendants
8 labeling or warning requirements ‘in addition to’ what federal law requires”); *Hawkins*, 2014 WL
9 346622, at *14-15 (holding California state law failure to warn claims for off-label promotion of
10 Infuse expressly preempted); *Kashani-Matts*, 2013 WL 6147032, at *4 (same). California state
11 courts have followed suit. In *Coleman v. Medtronic*, for example, the California court of appeal
12 affirmed a lower court’s dismissal of failure to warn claims based on precisely the same off-label
13 promotion of Infuse at issue in this case. 223 Cal. App. 4th 413, 430-31 (Cal. App. 2d. Dist. 2014),
14 *cert. granted*, 2014 WL 1714946 (Apr. 30, 2014). Accordingly, the Court concludes that Plaintiffs’
15 failure to warn claims based on off-label promotion of Infuse are expressly preempted.

16 **iii. Failure to Report Adverse Events to FDA**

17 **a. Express and Implied Preemption**

18 Plaintiffs’ third theory underlying their failure to warn claims is that “MEDTRONIC
19 breached its duty in that it failed to warn Physicians by failing to communicate the growing number
20 of adverse events [regarding off-label use] to the FDA from 2002 to 2011, as it was required to do
21 by federal law.” Eidson Complaint ¶¶ 309(c); 336(c). The Court’s October 3, 2013 Order held that
22 Eidson’s strict liability failure to warn claim based on failure to report adverse events to the FDA
23 escaped both express and implied preemption. *Eidson*, 2013 WL 5533081 at *12-13. As the Court
24 observed, federal law – 21 C.F.R. § 803.50(a) – requires that manufacturers report any information
25 “reasonably suggest[ing]” that one of their devices “[m]ay have caused or contributed to a death or
26 serious injury.” As such, this Court reasoned that a state law duty requiring that Defendants warn
27 the FDA of adverse events was “parallel to” the existing federal requirements. *Eidson*, 2013 WL
28

1 5533081 at *12. The Court also found no implied preemption, based on Ninth Circuit precedent,
2 *see Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1228 (9th Cir. 2013) (en banc). *Eidson*, 2013 WL
3 5533081 at *12-13. Defendants argue that Plaintiffs’ failure to warn claims based on this third
4 theory are expressly and impliedly preempted. *Eidson* MTD at 15, 18. The Court disagrees because
5 Defendants present no compelling reason for the Court to reconsider its holdings in the October 3,
6 2013 Order.

7 As this Court previously held, *Stengel* is apposite and controlling as to both express and
8 implied preemption because it involved highly analogous claims to those at issue here. In *Stengel*,
9 the Ninth Circuit held that an Arizona state law negligence claim based on failure to report adverse
10 events to the FDA regarding Defendants’ device was not expressly preempted because the “state-
11 law duty parallel[ed][the] federal-law duty” to report events to the FDA. *See Stengel*, 704 F.3d at
12 1223. Under Arizona law, a manufacturer’s duty to warn consumers about known product dangers
13 may be satisfied by a warning to third parties, if the nature of the warning and of the relationship
14 between the third party and consumer means that a warning given to the third party could be
15 expected to reach the ultimate user of the product. *Id.* (“Arizona law contemplates a warning to a
16 third party such as the FDA.”). Therefore, the court reasoned that Arizona state law paralleled
17 federal requirements because it demanded the same conduct of manufacturers that federal law did –
18 notifying the FDA of adverse events, where such notification could be expected to put doctors and
19 patients on notice of the product’s dangers.

20 *Stengel* also held that the state law claim escaped implied preemption, as the “state-law
21 claim [was] independent of the FDA’s pre-market approval process that was at issue in *Buckman*.”
22 *Id.* at 1233. Unlike the claim at issue in *Buckman*, the plaintiffs in *Stengel* were not suing simply to
23 enforce FDA requirements; they were suing under the theory that the defendants’ failure to report
24 to the FDA directly violated their duty to warn consumers. The state law cause of action could thus
25 exist independently of any federal requirement to report adverse events to the FDA. *See Stengel*,
26 704 F.3d at 1235 (Watford, J., concurring) (“[I]n contrast to *Buckman*, the *Stengels*’ claim is
27 grounded in a traditional category of state law failure-to-warn claims that predated the federal
28

1 enactments in question” and therefore their claim “does not exist solely by virtue of those
2 enactments”) (citing *Buckman*, 531 U.S. at 353).

3 Defendants ask the Court to reconsider its previous finding that Plaintiffs’ claims are not
4 expressly preempted, claiming *Stengel* is distinguishable because its reasoning was based on
5 Arizona’s state law duty to warn third parties while California state law does not require a similar
6 duty to warn third parties rather than direct consumers. Eidson MTD at 15, 17. However,
7 Defendants are wrong to make this distinction because California law – like the Arizona law at
8 issue in *Stengel* – requires a manufacturer to discharge its duty to warn consumers by
9 communicating warnings to a third party in circumstances where such a warning is necessary to put
10 consumers on notice of the danger. *See Persons v. Salomon N. Am., Inc.*, 217 Cal.App.3d 168, 178
11 (1990) (duty to warn can be satisfied by warning a third party “[w]hen a manufacturer or
12 distributor has no effective way to convey a product warning to the ultimate consumer.”).
13 Therefore, like the claims in *Stengel*, Plaintiffs’ failure to warn claims parallel federal requirements
14 because they demand the same conduct of manufacturers that federal law does – notifying the third
15 party FDA of adverse events, where such notification could suffice to put doctors and patients on
16 notice of the product’s dangers. Thus, Plaintiffs’ claims are not expressly preempted.

17 Defendants also argue that Plaintiffs’ claims based on a failure to report adverse events to
18 the FDA are impliedly preempted because the duty to report such events exists solely by virtue of
19 the FDCA. Eidson MTD, at 18-19. The Court rejects this argument, as the Ninth Circuit confronted
20 and rejected this argument in *Stengel*. California’s duty to warn of product dangers – including its
21 duty to warn third parties, if appropriate and necessary – exists independently of any federal law.
22 Just as in *Stengel*, Plaintiffs are not attempting to act as a private enforcer of the FDCA. Rather,
23 they are seeking to hold Defendants liable for violating their state law duty to warn them of known
24 dangers, on the theory that reporting to the FDA would ultimately have put them on notice of the
25 danger because adverse events are published in the MAUDE database.

26 Most lower courts – both federal and state – that have analyzed and applied *Stengel* to
27 California state law failure to warn claims premised on a failure to report to the FDA have held that
28

1 the claims escape both express and implied preemption. *See, e.g., Ramirez*, 961 F. Supp. 2d at 1002
2 (following *Stengel* and declining to dismiss a “failure to warn” claim premised on defendants’
3 failure to report adverse events involving Infuse to the FDA); *Houston*, 2014 WL 1364455 (same);
4 *Coleman*, 223 Cal. App. 4th at 429-30. In sum, the Court continues to follow *Stengel* and thus
5 holds Plaintiffs’ failure to warn claims premised on Defendants’ failure to report adverse events to
6 the FDA are not expressly or impliedly preempted.

7 **b. Causal Nexus**

8 While the Court’s October 3, 2013 Order held that Eidson’s failure to warn claims escaped
9 preemption to the extent they were based on a failure to report adverse events to the FDA, the
10 Court nonetheless dismissed those claims because Eidson had failed to show how the failure to
11 report caused his injuries. *Eidson*, 2013 WL 5533081 at *13. To properly plead claims that escape
12 preemption, “a plaintiff must allege facts (1) showing an alleged violation of FDA regulations or
13 requirements related to [the device], and (2) establishing a causal nexus between the alleged injury
14 and the violation.” *Erickson v. Boston Scientific Corp.*, 846 F.Supp.2d 1085, 1092 (C.D. Cal.
15 2011). This Court noted that Eidson had only alleged a single adverse incident that Defendants had
16 failed to report, and that Eidson’s failure to specify the date of this event left the Court with “no
17 basis to evaluate whether the failure to report may have had a causal effect on Eidson’s injuries.”
18 *Id.* Subsequent to that Order, the Bells and Eidson both changed their complaints to address this
19 deficiency. Defendants now argue Plaintiffs have failed to cure this deficiency regarding causation.
20 Eidson MTD at 2. The Court disagrees.

21 Plaintiffs have sought to cure this defect by referencing a study by a Dr. Carragee which
22 finds that by April 2008, Defendants had reported only 262 of an estimated 50,000-250,000
23 adverse events involving the off-label use of Infuse. Eidson Complaint at ¶¶ 255, 309 (c)(iii)-(v).
24 Plaintiffs also claim that “[t]he FDA maintains a MAUDE database on reported adverse events,
25 which is a public database known to, and discussed in, the medical community, including
26 Plaintiff’s physicians” and that “[i]f MEDTRONIC had communicated adverse events to the FDA
27 as required by law, this would have effectively warned plaintiff’s surgeon of those adverse events –
28

1 both directly and through the discussion of those adverse events that would have followed in the
2 literature and at meetings plaintiff's surgeon attended." *Id.* at ¶¶ 309(c)(iii)-(x), ¶¶ 336(c)(viii)-(x).
3 Defendants cite to *Hawkins*, 2014 WL 346622, for the proposition that general allegations that a
4 device manufacturer failed to report to the FDA are not sufficient to establish a causal nexus to a
5 plaintiff's injuries stemming from off-label use. Eidson Reply at 4-5. In *Hawkins*, much like in
6 Plaintiffs' original complaints, the court dismissed the plaintiff's claims because he had failed to
7 provide specific dates of adverse events or show how the failure to report them caused his injuries.
8 *See Hawkins*, 2014 WL 346622 at *8 ("Plaintiff generally alleges that Defendants failed to report
9 adverse events to the FDA. He also generally alleges that these failures caused or contributed to his
10 injuries. What is not alleged is any factual content that would support the causal nexus.").

11 In the instant case, Plaintiffs have amended their claims to include additional facts about the
12 specific nature of Defendants' failure to report. As such, the reasoning in *Hawkins* no longer
13 applies. By including facts relating to Dr. Carragee's study, Plaintiffs have shown that (1)
14 Defendants underreported adverse events on a large scale, and (2) plaintiffs' surgeons would have
15 had access to adverse reports if they were properly submitted. Eidson Complaint ¶¶ 249-254,
16 309(c)(iii)-(x), 336(c)(viii)-(x). At the pleading stage, these allegations are sufficient to support a
17 reasonable inference that had Defendants made the required reports, Plaintiffs' physicians would
18 have been put on notice of the danger of off-label use of Infuse and may have elected to conduct
19 the surgeries differently. *Id.* at ¶ 314 ("Plaintiff's physician would not have [] used INFUSE® off-
20 label by utilizing a posterior approach, using INFUSE for an off-label indication, and by using
21 INFUSE® without an LT Cage and in a manner otherwise not approved by the FDA had they
22 known of the true safety risks"). Other courts have allowed claims against these same Defendants
23 to proceed based on Dr. Carragee's study. *See Houston*, 2014 WL 1364455 at *7-8 (finding that
24 Dr. Carragee's study supported an inference of causation sufficient to survive a motion to
25 dismiss).¹⁴ In sum, the Court declines to dismiss Plaintiffs' failure to warn claims for failure to
26 allege causation.¹⁵

27 ¹⁴ Defendants also question the validity of Dr. Carragee's study by claiming that Dr. Carragee is
28 not impartial, Eidson Reply at 4 n.1, and attack the plausibility of Plaintiffs' assertion that accurate

1 dismissed because they are not pled with the necessary particularity under Federal Rule of Civil
2 Procedure 9(b). Eidson MTD at 3, 19-20. Federal Rule of Civil Procedure 9(b) provides that “[i]n
3 alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud
4 or mistake.” Fed. R. Civ. P. 9(b). The Court already held in its October 3, 2013 Order that Eidson’s
5 fraud-based claims – fraudulent misrepresentation/fraud in the inducement and strict products
6 liability misrepresentation – satisfied Rule 9(b). *Eidson*, 2013 WL 5533081, at *11. Defendants ask
7 the Court to reconsider this holding based on *Houston v. Medtronic*, 957 F. Supp. 2d at 1180.
8 *Eidson* MTD at 20. That case similarly involved Medtronic defending against claims based on off-
9 label marketing of the Infuse product, and was dismissed for insufficient particularity because the
10 court found that the complaint failed to “allege the specific contents of those representations, when
11 and where Defendants allegedly made them, and to whom they were made. Nor has Plaintiff
12 alleged which parts of the misrepresentations were misleading, and *why* they are false.” *Houston*,
13 957 F. Supp. 2d at 1180. The Court declines to change its conclusion because Defendants have
14 advanced no persuasive reason to reconsider its prior conclusion that Eidson’s fraud claims were
15 pled with “voluminous particularity.” *Eidson*, 2013 WL 5533081, at *11. The same goes for
16 Defendants’ challenge to the Bells’ fraud claims because the Bells’ allegations are identical to
17 Eidson’s allegations. Plaintiffs have not simply made general allegations of malfeasance; they have
18 alleged facts relating to: (1) specific scientific articles funded by Medtronic, including their
19 authors, dates of publication, and what information was misstated or omitted in them; (2)
20 misleading statements and omissions made by named “opinion leaders” in the course of
21 promotional activities,” and (3) allegedly deceptive activities undertaken by Defendants’ sales
22 representatives. *See, e.g.*, *Eidson* Complaint ¶ 86 (noting 2004 study which falsely claimed that
23 patients suffered no ill effects from bony overgrowth complications); *id.* at ¶ 185 (noting 2006
24 conference call in which “opinion leader” Rick Sasso understated esophageal complications from
25 the use of Infuse in off-label procedures); *id.* at ¶ 167 (noting that Defendants instructed their sales
26 representatives in how to “get around” restrictions in off-label promotion). The Court continues to
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28

1 find that these allegations put Defendants on sufficient notice of the particular misconduct alleged
2 to permit Medtronic to prepare a defense to Plaintiffs' claims.

3 Similar claims have withstood Rule 9(b) challenges in this Circuit. *See Alton*, 2013 WL
4 4786381 (holding, in nearly identical case regarding state law fraud claims regarding off-label
5 promotion of Infuse, that fraud claims satisfied Rule 9(b)). In fact, *Houston*, cited by Defendants,
6 now supports a denial of Rule 9(b) dismissal because after the court's dismissal, the plaintiff in that
7 case amended her complaint by adding additional facts. *See Houston v. Medtronic, Inc.*, 2014 WL
8 1364455, at *8 (C.D. Cal. Apr. 2, 2014). That court very recently rejected Medtronic's renewed
9 motion to dismiss, holding that Houston's amended complaint now satisfies Rule 9(b) because the
10 plaintiff had added facts about specific studies and presentations. *See id.* at *9.¹⁶ In sum, the Court
11 holds that Plaintiffs have pled their fraud-based claims with sufficient particularity to survive a
12 motion to dismiss.

13 3. Failure to State a Claim under California Law

14 Finally, the Court addresses Defendants' argument that Plaintiffs' fraud-based causes of
15 action fail to state a claim under California law. Eidson MTD at 8, 21. Defendants assert that
16 Plaintiffs' fraud claims are tantamount to a general "fraud-on-the-market" complaint in which a
17 plaintiff seeks to hold a defendant liable for misrepresentations that mislead consumers generally
18 rather than the plaintiff or the plaintiff's agent specifically. *Id.* The California Supreme Court has
19 held that such "fraud-on-the-market" claims are not cognizable under California law; plaintiffs
20

21 ¹⁶ Defendants also argue that fraud claims similar to those Plaintiffs make here were dismissed for
22 failure to satisfy Rule 9(b) in *Hawkins v. Medtronic, Inc.*, 1:13-CV-00499 AWI SK, 2014 WL
23 346622 (E.D. Cal. Jan. 30, 2014). Eidson Reply at 10. *Hawkins*, however, is distinguishable. There,
24 the court relied on the fact that the plaintiff had alleged defendants engaged in off-label promotion
25 via opinion leaders and Medtronic-funded articles, but noted that "nothing in the complaint points
26 to specific content in those articles or statements made by the named opinion leaders that were
27 allegedly false, or why the representations were untrue." *Hawkins*, 2014 WL 346622 at *12. In the
28 instant cases, by contrast, Plaintiffs have adequately alleged specifics regarding the way in which
such journal articles and opinion leader statements were false or misleading. With regard to Dr.
Kuklo's 2008 article in the *Journal of Bone and Joint Surgery*, for example, Plaintiffs allege that
the article falsely identified uninvolved surgeons as co-authors, suggested an inflated efficacy rate
for Infuse, and reported positive results for a "ghost population" of patients that never existed.
Eidson Complaint ¶¶ 192, 196, 197.

1 must plead that they or their agent relied on the misrepresentations in order to maintain an action
2 sounding in fraud. *See Mirkin v. Wasserman*, 5 Cal. 4th 1082, 1091-1096 (1993).¹⁷ Defendants’
3 argument fails because Plaintiffs’ complaints do plead reliance by their agents – i.e., their surgeons.
4 Although Plaintiffs acknowledge that they do not allege specifically upon which articles,
5 presentations, and promotional activities their surgeons relied in deciding to use Infuse in an off-
6 label manner, Eidson Opp’n at 5, they explicitly allege their doctors relied upon Defendants’
7 representations regarding the safety risks of Infuse when deciding to use Infuse in an off-label way.
8 Eidson Complaint at ¶ 300. Further, the Court has not found any case holding that in order to
9 survive a challenge that a plaintiff’s claim is simply a generalized fraud-on-the-market claim, a
10 plaintiff must identify the *specific* statements upon which the plaintiff or his agent relied from
11 among a large number of fraudulent statements alleged in the complaint. To the contrary,
12 California courts have generally held that where a plaintiff’s fraud claim is based on a long-term
13 promotional campaign involving a large number of false statements, the plaintiff is *not* required to
14 identify in the pleadings precisely when each false statement was made and on which the plaintiff
15 or his agent relied. *See Comm. On Children’s Television, Inc. v. Gen. Foods Corp.*, 35 Cal. 3d 197,
16 218-19, 673 P.2d 660, 674 (1983) (reasoning that a long-term promotional campaign may persuade
17 by “cumulative impact” rather than specific discrete false statements, and therefore plaintiffs
18 “should be able to base their cause of action upon an allegation that they acted in response to an
19 advertising campaign even if they cannot recall the specific advertisements.”); *Morgan v. AT & T*
20 *Wireless Servs., Inc.*, 177 Cal. App. 4th 1235, 1262, 99 Cal. Rptr. 3d 768, 790-91 (2009) (“[W]here
21 a fraud claim is based upon numerous misrepresentations, such as an advertising campaign that is
22 alleged to be misleading, plaintiffs need not allege the specific advertisements the individual
23 plaintiffs relied upon.”); *Whiteley v. Philip Morris Inc.*, 117 Cal. App. 4th 635, 680-81, 11 Cal.

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25 ¹⁷ *Mirkin* recognized that “misrepresentations to the plaintiff may be communicated indirectly
26 through an agent or third party,” but the plaintiff must show that the third party relied on the
27 misrepresentations. *Id.* at 1096. *See, e.g., Grinnell v. Charles Pfizer & Co.*, 274 Cal.App.2d 424,
28 441 (1969) (plaintiffs, who had not heard or read misrepresentations of pharmaceutical
manufacturer, were allowed to sue manufacturer for breach of express warranty because the
doctors who administered the drugs had relied on the manufacturer’s representation and acted as
the plaintiffs’ agent);

1 Rptr. 3d 807, 844-45 (2004) (affirming verdict for plaintiff who successfully sued tobacco
2 company for misleading advertising campaign, on grounds that plaintiff “did not have to prove that
3 she saw or heard any *specific* misrepresentations of fact or false promises that defendants made.”)
4 (emphasis added). Thus, the Court rejects Defendants’ argument that Plaintiffs’ claims are simply
5 generalized fraud-on-the-market claims.¹⁸

6 **C. Analysis of April Bells’ Loss of Consortium Claim**

7 April Bell’s loss of consortium claim alleges that as a result of Defendants’ actions, her
8 marital relationship with her husband has suffered. Bell Complaint at ¶ 356. In California, the
9 spouse of an individual injured by a third party has a cause of action for loss of consortium: the
10 loss of conjugal fellowship and sexual relations. *Rodriguez v. Bethlehem Steel Corp.*, 525 P.2d 669,
11 670 (Cal. 1974). A loss of consortium claim is derivative of and dependent on the spouse’s
12 negligence action. *Calatayud v. State of California*, 18 Cal.4th 1057 n.4 (1998).

13 Defendants argue that April Bell’s loss of consortium claim fails as a matter of law because
14 it is a derivative claim and “all of the claims upon which April Bell brings her claim are preempted
15 and/or otherwise barred under California law.” Bell MTD at 25. Thus, Defendants argue her claim
16 is preempted as well. *Id.* The Court grants in part and denies in part Defendants’ motion to dismiss
17 April Bell’s claim. To the extent April Bell’s claim derives from those of Scott Bell’s claims which
18 this Court has found preempted in this Order, April Bell’s claim is also preempted, and the motion
19 to dismiss is GRANTED. However, to the extent that April Bell’s claim derives from those of Scott
20 Bell’s claims which this Court has found not preempted, April Bell’s claim is not preempted, and
21 the motion to dismiss is DENIED.

22 **V. CONCLUSION**

23 With respect to the Eidson complaint, the Court DENIES Defendants’ motion to dismiss
24 Eidson’s fraudulent misrepresentation/fraud in the inducement and negligent misrepresentation
25

26 ¹⁸ The Court also notes that it declines to dismiss this action at this stage for failure to adequately
27 plead reliance in light of how Plaintiffs have not yet had the benefit of discovery and the
28 opportunity to depose their physicians to determine which precise meetings they attended, articles
they read, and promotions they received and relied upon.

1 claims based on fraudulent conduct in the course of off-label promotion because such claims are
2 not expressly or impliedly preempted. The Court DENIES Defendants' motion to dismiss Eidson's
3 failure to warn claims based on Defendants' failure to report adverse events to the FDA because
4 such claims are not expressly or impliedly preempted. The Court GRANTS with prejudice
5 Defendants' motion to dismiss Eidson's failure to warn claims based on Defendants'
6 overpromotion of off-label use of Infuse and based on Defendants' deceptive off-label promotion
7 because those claims are expressly preempted.

8 With respect to the Bell complaint, the Court DENIES Defendants' motion to dismiss the
9 Bells' fraudulent misrepresentation/fraud in the inducement and negligent misrepresentation claims
10 based on fraudulent conduct in the course of off-label promotion because such claims are not
11 expressly or impliedly preempted. The Court DENIES Defendants' motion to dismiss the Bells'
12 failure to warn claims based on Defendants' failure to report adverse events to the FDA because
13 such claims are not expressly or impliedly preempted. The Court GRANTS with prejudice
14 Defendants' motion to dismiss the Bells' failure to warn claims based on Defendants'
15 overpromotion of off-label use of Infuse and based on Defendants' deceptive off-label promotion
16 because those claims are expressly preempted. The Court GRANTS IN PART AND DENIES IN
17 PART Defendants' motion to dismiss April Bell's loss of consortium claim.

18
19 **IT IS SO ORDERED.**

20 Dated: May 13, 2014

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22 _____
23 LUCY H. KOH
24 United States District Judge
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