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UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF CALIFORNIA

MICHAEL COLBATH,  
  
Plaintiff,  
  
v.  
  
MERCK & CO., INC., AND MERCK  
SHARP & DOHME CORP.,  
  
Defendants.

Case No.: 3:21-cv-120-W (DEB)

**ORDER GRANTING IN PART AND  
DENYING IN PART DEFENDANTS’  
MOTION TO DISMISS  
PLAINTIFF’S COMPLAINT [DOC.  
6]**

Pending before the Court is Defendants Merck & Co., Inc., and Merck Sharp & Dohme Corp.’s (collectively “Defendants”) Motion to Dismiss Plaintiff Michael Colbath’s Complaint for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). (*Mot. to Dismiss (“MTD”)* [Doc. 6].) Plaintiff opposes the Motion. (*Opp’n* [Doc. 12].) The Court decides the matter on the papers submitted and without oral argument. See Civ. L.R. 7.1(d)(1). For the reasons stated below, the Court **GRANTS IN PART AND DENIES IN PART** Defendants’ Motion to Dismiss. [Doc. 6].

**I. BACKGROUND**

On May 6, 2014, Plaintiff Michael Colbath, who was 14 years old at the time,

1 received his first dose of Gardasil—a vaccine for Human Papillomavirus (“HPV”).  
2 (*Compl.* [Doc. 1] ¶ 346.) He received his second dose two months later on July 9, 2014.  
3 (*Id.*) Prior to receiving the vaccine, Plaintiff was physically active, athletic, and did well  
4 in school. (*Id.* ¶ 348.) He allegedly had no autoimmune diseases, no autonomic issues,  
5 and no orthostasis. (*Id.*) After receiving his first Gardasil dose, however, Plaintiff  
6 experienced a burning sensation over his arm and developed extreme fatigue. (*Id.* ¶¶  
7 350-51.) After his second dose, Plaintiff experienced that same burning pain in his arm,  
8 developed severe foot pain, forcing him to use crutches, started to have memory  
9 problems, and developed “terrible” headaches. (*Id.* ¶ 352.)

10 When the time for his third dose came, Plaintiff’s pediatrician, Dr. Krak, decided  
11 not to administer the third injection, fearing that the Gardasil may have caused Plaintiff’s  
12 foot pain. (*Id.* ¶ 353.) Plaintiff’s injuries allegedly got worse over time, and he was  
13 eventually diagnosed with Postural Orthostatic Tachycardia (“POTS”), Idiopathic  
14 Hypersomnia (“IH”), Myalgic Encephalomyelitis/ Chronic Fatigue Syndrome (“ME/  
15 CFS”), Chronic Fatigue and Immune Dysfunction Syndrome (“CFIDS”), Immune-  
16 mediated Encephalitis (“IE”), Complex Regional Pain Syndrome (“CRPS”), and  
17 Gastroparesis. (*Id.* ¶ 358.)

18 As a result, Plaintiff brings this action against Defendants Merck & Co., Inc., and  
19 Merck Sharp & Dohme Corp. He alleges that Defendants’ Gardasil vaccine—which they  
20 designed, manufactured, and marketed—caused him to suffer severe autonomic,  
21 neurological, and heterogeneous autoimmune injuries. (*Id.* ¶ 1.) He asserts claims for:  
22 (1) negligence; (2) strict liability failure to warn; (3) strict liability manufacturing defect;  
23 (4) breach of express warranty; (5) common law fraud; and (6) violation of California’s  
24 unfair competition law. (*Id.* ¶¶ 365-481.)

## 25 26 **II. LEGAL STANDARD**

27 The Court must dismiss a cause of action for failure to state a claim upon which  
28 relief can be granted. Fed. R. Civ. P. 12(b)(6). A motion to dismiss under Rule 12(b)(6)

1 tests the legal sufficiency of the complaint. Parks Sch. of Bus., Inc. v. Symington, 51  
2 F.3d 1480, 1484 (9th Cir. 1995). A complaint may be dismissed as a matter of law either  
3 for lack of a cognizable legal theory or for insufficient facts under a cognizable theory.  
4 Balistreri v. Pacifica Police Dep’t., 901 F.2d 696, 699 (9th Cir. 1988). In ruling on the  
5 motion, a court must “accept all material allegations of fact as true and construe the  
6 complaint in a light most favorable to the non-moving party.” Vasquez v. L.A. Cnty.,  
7 487 F.3d 1246, 1249 (9th Cir. 2007).

8 Complaints must contain “a short and plain statement of the claim showing that the  
9 pleader is entitled to relief.” Fed. R. Civ. P. 8(a)(2). The Supreme Court has interpreted  
10 this rule to mean that “[f]actual allegations must be enough to rise above the speculative  
11 level.” Bell Atl. Corp. v. Twombly, 550 U.S. 554, 555 (2007). The allegations in the  
12 complaint must “contain sufficient factual matter, accepted as true, to ‘state a claim to  
13 relief that is plausible on its face.’” Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (citing  
14 Twombly, 550 U.S. at 570).

15 Well-pleaded allegations in the complaint are assumed true, but a court is not  
16 required to accept legal conclusions couched as facts, unwarranted deductions, or  
17 unreasonable inferences. Papasan v. Allain, 478 U.S. 265, 286 (1986); Sprewell v.  
18 Golden State Warriors, 266 F.3d 979, 988 (9th Cir. 2001). Leave to amend should be  
19 freely granted when justice so requires. See Fed. R. Civ. P. 15(a). However, denial of  
20 leave to amend is appropriate when such leave would be futile. See Cahill v. Liberty  
21 Mut. Ins. Co., 80 F.3d 336, 339 (9th Cir. 1996); Plumeau v. Sch. Dist. No. 40 Cnty. of  
22 Yamhill, 130 F.3d 432, 439 (9th Cir. 1997).

### 23 24 **III. DISCUSSION**

25 Plaintiff asserts the following six claims against Defendants: (1) negligence; (2)  
26 strict liability failure to warn; (3) strict liability manufacturing defect; (4) breach of  
27 express warranty; (5) fraud; and (6) unfair competition. Defendants move to dismiss all  
28 of Plaintiff’s claims under Rule 12(b)(6) for failure to state claim. Defendants also

1 request judicial notice of 31 exhibits, which include publications and releases from the  
2 FDA, CDC, WHO, and European Medicine Agency, Gardasil patient information and  
3 prescribing information, and medical definitions of Plaintiff’s alleged injuries. [Doc. 7].  
4 Plaintiff opposes Defendants’ request for judicial notice because the exhibits allegedly  
5 contain disputed facts. [Doc. 12]. The Court elects to take notice of the exhibits for their  
6 existence, not for the truth of the disputed facts. See, e.g., Sciortino v. Pepsico, Inc., 108  
7 F.Supp.3d 780, 791 n.2 (N.D. Cal. 2015).

8  
9 **A. FAILURE TO WARN UNDER THEORIES OF NEGLIGENCE AND STRICT**  
10 **LIABILITY (COUNTS I-II)**

11 Plaintiff alleges that Defendants failed to adequately warn him, his parents, his  
12 medical providers, and the “general public” of serious side effects of Gardasil. (*Compl.*  
13 ¶¶ 370, 377). He asserts claims for “failure to warn” under theories of negligence (Count  
14 I) and strict liability (Count II). (*Id.* ¶¶ 381, 393; *Opp’n* at 5-6.) Defendants argue that  
15 Plaintiff’s failure to warn claims are barred by the Vaccine Act and the Learned  
16 Intermediary Doctrine and are deficient for inadequate causation. (*MTD* at 12-14.)

17 To maintain a negligence action under California law, a plaintiff must allege that a  
18 defendant owed him a legal duty, breached that duty, and that the breach proximately  
19 caused injury to him. Garcia v. W & W Cmty. Dev., Inc., 186 Cal. App. 4th 1038, 1044  
20 (2010). In the negligence failure to warn context, plaintiffs must prove “that a  
21 manufacturer or distributor did not warn of a particular risk for reasons which fell below  
22 the acceptable standard of care, i.e., what a reasonably prudent manufacturer would have  
23 known and warned about.” Carlin v. Super. Ct., 13 Cal. 4th 1104, 1112 (1996) (citation  
24 omitted).

25 To maintain a strict liability failure to warn claim, a plaintiff must prove that:

26 (1) the defendant manufactured, distributed, or sold the product; (2) the  
27 product had potential risks that were known or knowable at the time of  
28 manufacture or distribution, or sale; (3) that the potential risks presented a  
substantial danger to users of the product; (4) that ordinary consumers would

1 not have recognized the potential risks; (5) that the defendant failed to  
2 adequately warn of the potential risks; (6) that the plaintiff was harmed  
3 while using the product in a reasonably foreseeable way; (7) and that the  
4 lack of sufficient warnings was a substantial factor in causing the plaintiff's  
harm.

5 Rosa v. City of Seaside, 675 F.Supp.2d 1006, 1011 (N.D. Cal. 2009) (citing Jud. Council  
6 of Cal. Civ. Jury Instruction No. 1205). Regarding the second factor—whether the risks  
7 were known or knowable at the time of manufacture—plaintiff must prove “only that the  
8 defendant did not adequately warn of a particular risk that was known or knowable in  
9 light of the generally recognized and prevailing best scientific and medical knowledge  
10 available at the time of manufacture and distribution.” Rosa, 675 F.Supp.2d at 1012  
11 (quoting Anderson v. Owens–Corning Fiberglas Corp., 53 Cal. 3d 987, 1002 (1991)).

12 In 1986, Congress passed the National Childhood Vaccine Injury Act (the  
13 “Vaccine Act”) “in an attempt to balance the need for widespread childhood vaccinations  
14 with the need for ‘optimal prevention against adverse reactions to vaccines.’” Holmes v.  
15 Merck & Co., Inc., 697 F.3d 1080, 1082 (9th Cir. 2012) (quoting 42 U.S.C. § 300aa–1).  
16 “Congress passed the law after hearing testimony that, although vaccines inevitably  
17 harmed only a very small number of people, litigation arising from these injuries was  
18 threatening the stability of the nation’s vaccine program.” Holmes, 697 F.3d at 1082.

19 Section 22 of the Vaccine Act states: “No vaccine manufacturer shall be liable ...  
20 solely due to the manufacturer’s failure to provide direct warnings to the injured party (or  
21 the injured party’s legal representative) of the potential dangers resulting from the  
22 administration of the vaccine manufactured by the manufacturer.” 42 U.S.C. § 300aa-  
23 22(c). In other words, the Vaccine Act “eliminat[es] liability for not providing direct  
24 warnings to a claimant.” Holmes, 697 F.3d at 1083. Similarly, California’s Learned  
25 Intermediary Doctrine provides that “in the case of prescription drugs, the duty to warn  
26 runs *to the physician*, not to the patient.” Carlin, 13 Cal. 4th at 1116.<sup>1</sup>

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27  
28 <sup>1</sup> The rationale for the Learned Intermediary Doctrine is as follows:

1 The first issue to decide is whether Plaintiff's failure to warn claims are barred by  
2 the Vaccine Act and the Learned Intermediary Doctrine. Plaintiff alleges that Defendants  
3 failed to warn him, his parents, *his medical providers*, and the general public. (*Compl.* ¶¶  
4 370, 377.) While Defendants do not have a duty to warn Plaintiff, his mother, or the  
5 public in general, they do have a duty to warn Plaintiff's medical providers. Because  
6 Plaintiff alleges that Defendants failed to warn his medical providers, the Vaccine Act  
7 and the Learned Intermediary Doctrine do not bar his failure to warn claims.

8 The second issue is whether Plaintiff pled sufficient causation at this early stage of  
9 the litigation. Defendants argue that Plaintiff's failure to warn claims are legally  
10 deficient because he does not adequately plead that his injuries were *caused* by  
11 Defendants' failure to warn his medical providers. (*MTD* at 13). According to  
12 Defendants, Plaintiff "fails to allege that his prescribing doctor read, much less relied  
13 upon, any particular information provided by [Defendants]." (*Id.*)

14 Defendants rely on Renteria v. Ethicon, Inc., 2020 WL 7414744, at \*7 (C.D. Cal.  
15 Nov. 18, 2020), and Motus v. Pfizer Inc. (Roerig Div.), 358 F.3d 659, 661 (9th Cir. 2004)  
16 in support of their lack of causation argument. These cases, however, are inapposite  
17 because both were in the summary judgment phase, and both had the luxury of hearing  
18 testimony from the prescribing doctor. Motus, 358 F.3d at 661 ("Because the doctor  
19 testified that he did not read the warning label that accompanied Zolofit or rely on  
20 information provided by Pfizer's detail men before prescribing the drug to Mr. Motus, the  
21 adequacy of Pfizer's warnings is irrelevant to the disposition of this case."); Renteria,

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22  
23 (1) The doctor is intended to be an intervening party in the full sense of the word.  
24 Medical ethics as well as medical practice dictate independent judgment, unaffected by  
25 the manufacturer's control, on the part of the doctor. (2) Were the patient to be given the  
26 complete and highly technical information on the adverse possibility associated with the  
27 use of the drug, he would have no way to evaluate it, and in his limited understanding he  
28 might actually object to the use of the drug, thereby jeopardizing his life. (3) It would be  
virtually impossible for a manufacturer to comply with the duty of direct warning, as  
there is no sure way to reach the patient.

Carmichael v. Reitz, 17 Cal. App. 3d 958, 989 (1971) (citation and quotation omitted).

1 2020 WL 7414744, at \* 7 (“Dr. Chew testified that she did not rely on the manufacturer’s  
2 product warnings ... Therefore, Plaintiff’s failure to warn and fraud-based claims fail as a  
3 matter of law.”).

4 In contrast, this action is still in the pleading stage where the Court must accept all  
5 material allegations of fact as true and construe the complaint in a light most favorable to  
6 the non-moving party. Vasquez, 487 F.3d at 1249. Moreover, “basic causation-related  
7 issues involve questions of fact, unless reasonable [persons] will not dispute the absence  
8 of causality.” Vickers v. United States, 228 F.3d 944, 953 (9th Cir. 2000) (citations and  
9 quotations omitted).

10 Plaintiff alleges that had Defendants adequately warned his medical providers, then  
11 “upon information and belief, Plaintiff’s medical providers would not have offered or  
12 recommended Gardasil to Plaintiff.” (*Compl.* ¶ 381.) At this stage, without access to  
13 testimony from Plaintiff’s prescribing physician, the Court cannot say for certain that  
14 reasonable persons will not dispute the absence of causality. Therefore, Plaintiff’s failure  
15 to warn claims under theories of strict liability and negligence<sup>2</sup> may proceed beyond the  
16 pleading stage and can be addressed again, if appropriate, at summary judgment.

17 Accordingly, Defendants’ Motion to Dismiss Plaintiff’s claims for negligence  
18 (Count I) and strict liability failure to warn (Count II) is **DENIED**.

19  
20 **B. STRICT LIABILITY – MANUFACTURING DEFECT (COUNT III)**

21 Defendants argue that Plaintiff’s manufacturing defect claim (Count III) fails  
22 because (1) Plaintiff “alleges no facts showing that the manufacture of his particular dose  
23

24  
25 <sup>2</sup> Defendants also argue that Plaintiff’s negligence claim is an improper “shotgun pleading.” (*MTD* at  
26 21.) “Shotgun pleadings are pleadings that overwhelm defendants with an unclear mass of allegations  
27 and make it difficult or impossible for defendants to make informed responses to the plaintiff’s  
28 allegations.” Sollberger v. Wachovia Sec., LLC, 2010 WL 2674456, at \*4 (C.D. Cal. June 30, 2010).  
Here, Defendants have sufficient notice and detail to make informed responses to Plaintiff’s allegations.  
Thus, Plaintiff’s negligence claim is not an improper shotgun pleading.

1 of Gardasil was defective,” and (2) Plaintiff’s manufacturing defect claim is just a thinly  
2 veiled “design defect” claim, artfully pled to avoid preemption under the Vaccine Act.  
3 (*Id.* at 8-10.) Indeed, Section 22 of the Vaccine Act “expressly preempts design-defect  
4 claims seeking compensation for injury or death caused by a vaccine’s unavoidable side  
5 effects.” Holmes, 697 F.3d at 1084; 42 U.S.C. § 300aa-22(b)(1).

6 Plaintiff counters that his Gardasil doses were defective because they contained  
7 “dangerous” ingredients that were not disclosed and approved by the FDA, and that  
8 Plaintiff was injured as a result of this defect. (*Compl.* ¶¶ 412-414, 419; *Opp’n* at 12.)  
9 For example, Plaintiff alleges on information and belief that the Gardasil he was injected  
10 with contained HPV L1-DNA fragments, which make the vaccine more potent and  
11 dangerous than intended, and that it contained neurotoxins like phenylmethylsulfonyl  
12 fluoride, which is not intended for human consumption or injection. (*Id.*)

13 Under a strict liability manufacturing defect theory, “a defective product is one that  
14 differs from the manufacturer’s intended result or from other ostensibly identical units of  
15 the same product line.” Barker v. Lull Eng’g Co., 20 Cal. 3d 413, 429 (1978). This  
16 theory assumes that “a suitable design is in place, but that the manufacturing process has  
17 in some way deviated from that design.” In re Coordinated Latex Glove Litig., 99 Cal.  
18 App. 4th 594, 613 (2002). To survive a motion to dismiss, “plaintiffs should  
19 *identify/explain how* the [product] either deviated from [defendant’s] intended  
20 result/design or *how* the [product] deviated from other seemingly identical [product]  
21 models.” In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Pracs. &  
22 Prods. Liab. Litig., 754 F.Supp.2d 1208, 1222 (C.D. Cal. 2010) (quotations and citation  
23 omitted.) “[A] bare allegation that the product had “a manufacturing defect” is an  
24 insufficient legal conclusion.” Marroquin v. Pfizer, Inc., 367 F.Supp.3d 1152, 1160 (E.D.  
25 Cal. 2019) (citation omitted).

26 In contrast, in design defect claims, which are preempted by the Vaccine Act, “the  
27 injury producing agent is common to all products of a certain line, and the defect lies in  
28 the original design or model.” Morris v. Parke, Davis & Co., 667 F.Supp. 1332, 1335



1 (C.D. Cal. 1987) (citation omitted); Barker, 20 Cal. 3d at 429 (“A design defect ... cannot  
2 be identified simply by comparing the injury-producing product with the manufacturer’s  
3 plans or with other units of the same product line, since by definition the plans and all  
4 such units will reflect the same design.”).

5 Here, Plaintiff does not explain how the two Gardasil doses *he* received deviated  
6 from Defendants’ intended design. Instead, Plaintiff suggests that *every* Gardasil dose  
7 contains unapproved and undisclosed DNA fragments and “dangerous toxins.” Indeed,  
8 Plaintiff alleges that the Gardasil doses reached him “without substantial change in their  
9 condition as designed, manufactured, sold, distributed, labeled, and marketed by  
10 [Defendants].” (*Compl.* ¶ 415.) Because Plaintiff alleges that all Gardasil doses contain  
11 undisclosed DNA fragments and dangerous toxins, it appears he is actually alleging that  
12 the *design* of Gardasil is defective. Thus, having failed to explain how the Gardasil he  
13 received deviated from Defendants’ intended design or how the Gardasil deviated from  
14 other seemingly identical product models, Plaintiff’s strict liability manufacturing defect  
15 claim (Count III) is **DISMISSED WITH LEAVE TO AMEND**.

### 16 17 C. EXPRESS WARRANTY (COUNT IV)

18 An express warranty “is a contractual promise from the seller that the goods  
19 conform to the promise.” Daugherty v. American Honda Motor Co., Inc., 144 Cal. App.  
20 4th 824, 830 (2006). Breach of express warranty requires the exact terms of the  
21 warranty, plaintiff’s reasonable reliance, and a breach, which proximately causes injury  
22 to plaintiff. Williams v. Beechnut Nutrition Corp., 185 Cal. App. 3d 135, 142 (1986).

23 Defendants argue that Plaintiff’s breach of express warranty claim (Count IV) fails  
24 because (1) it is barred by the Vaccine Act and the Learned Intermediary Doctrine, (2)  
25 Plaintiff failed to provide pre-suit notice to Defendants on his warranty claim, and (3)  
26 Plaintiff failed to plead privity of contract with Defendants. (*MTD* at 15.)

27 Plaintiff counters that the Vaccine Act and Learned Intermediary Doctrine do not  
28 apply to express warranty claims, that his mother relied on Defendants’ representations

1 concerning Gardasil’s safety and efficacy, that Plaintiff was injured as a proximate result  
2 of the breach, and that California law does not require pre-suit notice or privity of  
3 contract for breach of warranty claims rooted in products liability. (*Opp’n* at 13-14.)

4 Contrary to Plaintiff’s assertion, the Learned Intermediary Doctrine “applies to a  
5 breach of express warranty claim predicated on a failure to warn claim.” See Tapia v.  
6 Davol, Inc., 116 F.Supp.3d 1149, 1162 (S.D. Cal. 2015); Carlin, 13 Cal. 4th at 1118.  
7 Under the Learned Intermediary Doctrine, “the express warranties run to the physician,  
8 and not to the Plaintiff.” Tapia, 116 F.Supp.3d at 1162 (citation omitted). Plaintiff does  
9 not allege that his physician relied on the express warranties contained in Gardasil’s  
10 packaging and promotional materials. Plaintiff only alleges that his mother relied on  
11 Defendants’ written advertisements for Gardasil. (*Compl.* ¶ 432.) Therefore, because  
12 Plaintiff fails to adequately allege reliance on the express warranties, his claim for breach  
13 of express warranty (Count IV) is **DISMISSED WITH LEAVE TO AMEND**.

#### 14 15 **D. COMMON LAW FRAUD (COUNT V)**

16 Plaintiff’s fifth claim is for “common law fraud.” Although not identified  
17 explicitly in the Complaint, Plaintiff argues in his Opposition to the Motion to Dismiss  
18 that this claim includes three categories of fraud: fraudulent concealment, negligent  
19 misrepresentation, and intentional misrepresentation. (*Opp’n* at 15; Cal. Civ. Code §§  
20 1710(1)-(3)).

21 Defendants argue that Plaintiff’s fraud claim should be dismissed because it is  
22 barred by the Vaccine Act and because he failed to plead it with sufficient particularity  
23 under Federal Rule of Civil Procedure 9(b). (*MTD* at 16.) Defendants also argue that  
24 Plaintiff may not add claims for fraudulent concealment and negligent misrepresentation  
25 in his Opposition when they were not explicitly mentioned in his Complaint. (*Reply*  
26 [Doc. 14] at 7.) But alleging specific legal theories is not required as long as plaintiff  
27 alleges sufficient facts to put defendant on notice of the claim. See Johnson v. City of  
28 Shelby, Miss., 574 U.S. 10, 11-12 (2014) (“[N]o heightened pleading rule requires

1 plaintiffs seeking damages for violations of constitutional rights to invoke § 1983  
2 expressly in order to state a claim.”); Kirkpatrick v. Cnty of Washoe, 843 F.3d 784, 790  
3 (9th Cir. 2016) (claim factually asserting constitutional rights violation not inadequate  
4 because it failed to specifically refer to the Fourth Amendment).

5 “To establish a claim for fraudulent misrepresentation, the plaintiff must prove: (1)  
6 the defendant represented to the plaintiff that an important fact was true; (2) that  
7 representation was false; (3) the defendant knew that the representation was false when  
8 the defendant made it, or the defendant made the representation recklessly and without  
9 regard for its truth; (4) the defendant intended that the plaintiff rely on the representation;  
10 (5) the plaintiff reasonably relied on the representation; (6) the plaintiff was harmed; and  
11 (7) the plaintiff's reliance on the defendant's representation was a substantial factor in  
12 causing that harm to the plaintiff.” Graham v. Bank of America, N.A., 226 Cal. App. 4th  
13 594, 605-606 (2014) (citation and quotations omitted).

14 “The elements of negligent misrepresentation are: (1) a misrepresentation of a past  
15 or existing material fact, (2) without reasonable grounds for believing it to be true, (3)  
16 with intent to induce another's reliance on the fact misrepresented, (4) ignorance of the  
17 truth and justifiable reliance thereon by the party to whom the misrepresentation was  
18 directed, and (5) damages.” Zetz v. Boston Scientific Corp., 398 F.Supp.3d 700, 712-13  
19 (E.D. Cal. 2019) (quotations and citation omitted).

20 “The required elements for fraudulent concealment are: (1) concealment or  
21 suppression of a material fact; (2) by a defendant with a duty to disclose the fact to the  
22 plaintiff; (3) the defendant intended to defraud the plaintiff by intentionally concealing or  
23 suppressing the fact; (4) the plaintiff was unaware of the fact and would not have acted as  
24 he or she did if he or she had known of the concealed or suppressed fact; and (5) plaintiff  
25 sustained damage as a result of the concealment or suppression of the fact.” Graham, 226  
26 Cal. App. 4th at 606 (citation omitted).

27 Because each of these claims sound in fraud, Plaintiff must satisfy the pleading  
28 requirements of Rule 9(b). See Ibarra v. Trimark Funding, Inc., 2010 WL 3076291, at \*2

1 (S.D. Cal. Aug. 6, 2010) (noting that “claim[s] for fraud and negligent misrepresentation  
2 must meet Rule 9(b)’s particularity requirements.”); see also Zetz, 398 F.Supp.3d at 713,  
3 n.3 (finding same). Under Rule 9(b), a party alleging fraud “must state with particularity  
4 the circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b). A complaint  
5 “must identify the who, what, when, where, and how of the misconduct charged, as well  
6 as what is false or misleading about the purportedly fraudulent statement, and why it is  
7 false.” Davidson v. Kimberly-Clark Corp., 889 F.3d 956, 964 (9th Cir. 2018).  
8 “[A]llegations of fraud must be specific enough to give defendants notice of the  
9 particular misconduct which is alleged to constitute the fraud charged so that they can  
10 defend against the charge and not just deny that they have done anything wrong.” United  
11 States v. United Healthcare Ins. Co., 848 F.3d 1161, 1180 (9th Cir. 2016) (quotations and  
12 citations omitted). But in cases alleging fraudulent concealment, some courts relax the  
13 specificity requirements of Rule 9(b). See UMG Recordings, Inc. v. Global Eagle  
14 Entertainment, Inc., 117 F.Supp.3d 1092, 1107 (C.D. Cal. 2015); In re Apple & AT &  
15 TM Antitrust Litig., 596 F.Supp.2d 1288, 1310 (N.D. Cal. 2008) (“Where the claim is  
16 one of fraud by omission ..., the pleading standard is lowered on account of the reduced  
17 ability in an omission suit to specify the time, place, and specific content relative to a  
18 claim involving affirmative misrepresentations”) (citation and quotation omitted).

19 As discussed above, Plaintiff alleges that Defendants failed to warn his medical  
20 providers about potential severe side-effects of Gardasil. (*Compl.* ¶ 463.) Because this  
21 allegation concerns fraudulent concealment, Plaintiff’s failure to specify the time and  
22 place of the omissions will not bar his claim. See In re Apple, 596 F.Supp.2d at 1310.  
23 Plaintiff has plead the content of the omission and the injuries resulting from the  
24 omissions with sufficient particularity under Rule 9(b). Therefore, Defendants’ Motion  
25 to Dismiss Plaintiff’s fraudulent concealment claim is **DENIED**.

26 Further, in support of his claims for intentional/fraudulent misrepresentation and  
27 negligent misrepresentation, Plaintiff alleges that Defendants made the following “false  
28 representations”: (1) “Gardasil is effective in preventing cervical and anal cancer”; (2)

1 “Gardasil is safe”; and (3) “cervical and anal cancer were far more prevalent than they  
2 really are.” (*Compl.* ¶ 454; *Opp’n* at 16.) Plaintiff alleges that his mother was exposed to  
3 these false representations in Defendants’ “One Less” advertising campaign. (*Compl.* ¶  
4 445; *Opp’n* at 16.)

5 Plaintiff also alleges that Defendants committed the following “fraudulent acts” in  
6 order to mislead Plaintiff, the public, and the medical community: (1) failing to test  
7 Gardasil against a true inert placebo and lying to the public that Gardasil was tested  
8 against a placebo; (2) failing to conduct a sufficient number of studies for the targeted  
9 patient population; (3) not using the commercial dosage in one of the key clinical trials,  
10 which was used to obtain licensing for the commercial dosage of Gardasil; (4) using very  
11 restrictive exclusionary criteria in the clinical study patient population but then not  
12 revealing or warning about these exclusionary criteria in the label; and (5) failing to  
13 disclose all of the ingredients in Gardasil. (*Compl.* ¶ 458; *Opp’n* at 16-17.)

14 However, it is not sufficient that Plaintiff’s mother, the public, or the “medical  
15 community” in general were exposed to these alleged false representations. Under the  
16 Vaccine Act and the Learned Intermediary Doctrine, the duty to warn runs to the  
17 *physician*, not to the patient. See Conte v. Wyeth, Inc., 168 Cal. App. 4th 89, 98-99  
18 (2008) (applying the learned intermediary doctrine to claims of fraud against a drug  
19 manufacturer); see also Saavedra v. Eli Lilly and Co., 2013 WL 6345442, at \*5 (C.D. Cal.  
20 Feb. 26, 2013). Because Plaintiff fails to allege that his medical providers saw, let alone  
21 relied on Defendants’ affirmative misrepresentations, Plaintiff’s claims for intentional  
22 misrepresentation and negligent misrepresentation are legally deficient. Therefore,  
23 Plaintiff’s claims for intentional misrepresentation and negligent misrepresentation are  
24 **DISMISSED WITH LEAVE TO AMEND.**

25  
26 **E. UNFAIR COMPETITION UNDER CALIFORNIA LAW (COUNT VI)**

27 Plaintiff alleges that Defendants’ failure to warn about the allegedly dangerous  
28 side-effects of Gardasil constitutes an unlawful, unfair, or fraudulent business practice

1 under California’s Unfair Competition Law (“UCL”)—California Business and  
2 Professions Code Section 17200. (*Compl.* ¶ 466.) As a result of this unfair practice,  
3 Plaintiff and his mother were allegedly misled into purchasing and consenting to the  
4 Gardasil injections. (*Id.* ¶ 468.) Plaintiff seeks restitution, restitutionary disgorgement of  
5 Defendants’ profits, attorneys’ fees, costs, punitive damages, and an injunction  
6 prohibiting Defendants from “continuing its false advertising and unlawful acts and  
7 practices concerning Gardasil.” (*Id.* ¶¶ 479-481.)

8 Defendants argue that Plaintiff’s UCL claim fails because it is barred by the  
9 Vaccine Act and Learned Intermediary Doctrine and because he is not entitled to any  
10 damages under the UCL. (*MTD* at 19-20.)

11 First, Plaintiff alleges that Defendants failed to warn his medical providers.  
12 (*Compl.* ¶ 404.) Although this allegation is not pled explicitly in the UCL section in  
13 Plaintiff’s Complaint, he incorporates all previous Complaint allegations into his UCL  
14 claim. (*Id.* ¶ 465.) Therefore, because Plaintiff alleges that Defendants failed to warn his  
15 medical providers, the Vaccine Act and the Learned Intermediary Doctrine do not bar  
16 Plaintiff’s UCL claim.

17 Second, Plaintiff alleges that he is entitled to restitution under the UCL because he  
18 and his mother “were misled into purchasing and consenting to the Gardasil injections,”  
19 which on information and belief cost more than \$100 per vile. (*Id.* ¶¶ 468, 479-480.)  
20 “The object of restitution is to restore the status quo by returning to the plaintiff funds in  
21 which he or she has an ownership interest.” Korea Supply Co. v. Lockheed Martin Corp.,  
22 29 Cal. 4th 1134, 1149 (2003). “[R]estitution, amounting to a full refund would be an  
23 appropriate remedy under the law.” Krueger v. Wyeth, Inc., 396 F.Supp.3d 931, 953-54  
24 (S.D. Cal. 2019). Accordingly, if Plaintiff’s UCL claim has merit, he would potentially  
25 be entitled to restitution under the UCL. See id.

26 Therefore, Defendants’ Motion to Dismiss Plaintiff’s California unfair competition  
27 claim (Count VI) is **DENIED**.

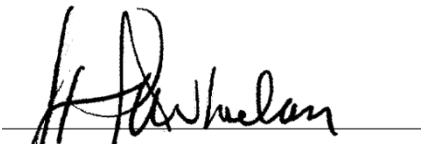
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1           **IV. CONCLUSION AND ORDER**

2           For the foregoing reasons, the Court **GRANTS IN PART AND DENIES IN**  
3 **PART** Defendants’ Motion to Dismiss. [Doc. 6]. Specifically, Defendants’ Motion to  
4 Dismiss as to Counts I, II, and VI is **DENIED**. Defendants’ Motion to Dismiss as to  
5 Counts III and IV is **GRANTED WITH LEAVE TO AMEND**. Regarding Plaintiff’s  
6 claims for “common law fraud”—Count V—Defendants’ Motion to Dismiss Plaintiff’s  
7 claims for intentional misrepresentation and negligent misrepresentation is **GRANTED**  
8 **WITH LEAVE TO AMEND**, and Defendant’s Motion to Dismiss Plaintiff’s claim for  
9 fraudulent concealment is **DENIED**. Plaintiff has until **April 19, 2022**, to file a first  
10 amended complaint addressing the deficiencies noted above. See Civ. L.R. 15.1.

11           **IT IS SO ORDERED.**

12 Dated: March 29, 2022

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15 Hon. Thomas J. Whelan  
16 United States District Judge  
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