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,

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

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

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

II. LEGAL STANDARD

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

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

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

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

III. DISCUSSION

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

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

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

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

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

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

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

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

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

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

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

[1] The rationale for the Learned Intermediary Doctrine is as follows:

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

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

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

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> (1) The doctor is intended to be an intervening party in the full sense of the word. Medical ethics as well as medical practice dictate independent judgment, unaffected by the manufacturer's control, on the part of the doctor. (2) Were the patient to be given the complete and highly technical information on the adverse possibility associated with the use of the drug, he would have no way to evaluate it, and in his limited understanding he 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).

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

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

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

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

B. STRICT LIABILITY – MANUFACTURING DEFECT (COUNT III)

Defendants argue that Plaintiff's manufacturing defect claim (Count III) fails because (1) Plaintiff "alleges no facts showing that the manufacture of his particular dose

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[2] Defendants also argue that Plaintiff's negligence claim is an improper "shotgun pleading." (*MTD* at 21.) "Shotgun pleadings are pleadings that overwhelm defendants with an unclear mass of allegations and make it difficult or impossible for defendants to make informed responses to the plaintiff's 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.

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

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

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

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

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

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

C. EXPRESS WARRANTY (COUNT IV)

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

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

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

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

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

D. COMMON LAW FRAUD (COUNT V)

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

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

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

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

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

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

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

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

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

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

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

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

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

E. UNFAIR COMPETITION UNDER CALIFORNIA LAW (COUNT VI)

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

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

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

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

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

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

IV. CONCLUSION AND ORDER

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

IT IS SO ORDERED.

Dated: March 29, 2022

Hon. Thomas J. Whelan
United States District Judge