IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

Abigail Stratton, Plaintiff, v. Merck & Co., Inc., a New Jersey Corporation; and Merck Sharp & Dohme Corp., a new Jersey Corporation, Defendants.	C/A No.: 2:21-02211-RMG **ORDER AND OPINION**

Before the Court is Defendants' motion to dismiss Plaintiff's complaint. (Dkt. No. 6). For the reasons set forth below, the Court grants in part and denies in part Defendants' motion to dismiss.

I. Background

On November 6, 2017, Dr. Vanessa A. Hajzus administered the first dose of Defendants' Gardasil vaccine to Plaintiff. (Dkt. No. 1. ¶ 347). As a result, Plaintiff allegedly developed various health problems including but not limited to postural orthostatic tachycardia syndrome ("POTS"). Plaintiff declined to receive a second dose of Gardasil. (*Id.* ¶¶ 351-56).

In accordance with the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10 *et seq.*, Plaintiff brought a petition in the United States Court of Federal Claims seeking compensation for her alleged vaccine-related injuries. The Order Concluding Proceedings was filed on July 8, 2021. Defendants do not dispute that Plaintiff's claims are properly exhausted.

Plaintiff now brings this complaint asserting claims for (1) negligence; (2) strict liability (failure to warn); (3) strict liability (manufacturing defect); (4) breach of warranty; and (5) common law fraud. (Dkt. No. 1).

On October 10, 2021, Defendants moved to dismiss Plaintiff's complaint in its entirety. Plaintiff opposes Defendants' motion. (Dkt. No. 9). Defendants have filed a reply. (Dkt. No. 10).

Defendants' motion is fully briefed and ripe for disposition.[1]

II. Legal Standard

Rule 12(b)(6) of the Federal Rules of Civil Procedure permits the dismissal of an action if the complaint fails "to state a claim upon which relief can be granted." A claim survives the motion if the complaint provides enough facts to "'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). This is a test of the legal sufficiency of the complaint and, therefore, Rule 12(b)(6) "does not resolve contests surrounding the facts, the merits of the claim, or the applicability of defenses." *Republican Party of N.C. v. Martin*, 980 F.2d 943, 952 (4th Cir. 1992). Instead, the district court's "inquiry then is limited to whether the allegations constitute a short and plain statement of the claim showing that the pleader is entitled to relief." *Id*. (internal quotation marks and citation omitted). For that analysis, the district court "need not accept as true unwarranted inferences, unreasonable conclusions, or arguments"; however, it must "assume the truth of all facts alleged in the complaint and the existence of any fact that can be proved, consistent with the complaint's allegations." *E. Shore Mkts., Inc. v. J.D. Assocs. Ltd. P'ship*, 213 F.3d 175, 180 (4th Cir. 2000).

III. Discussion

[1] The day after Defendants filed the instant motion to dismiss, the Court issued an order granting Plaintiff leave to file an amended complaint to correct the purported pleading defects in her complaint. (Dkt. No. 8). Plaintiff was informed that if she filed an amended complaint on or before November 1, 2021, the Court would deny Defendants' motion to dismiss without prejudice. Plaintiff did not file an amended complaint, however, and opposed Defendants' motion on the merits.

As noted above, Plaintiff brings six causes of action against Defendants: (1) negligence; (2) strict liability (failure to warn); (3) strict liability (manufacturing defect); (4) breach of warranty; and (5) common law fraud. Defendants argue the entirety of Plaintiff's claims are subject to dismissal. The Court addresses each of Defendants' arguments in turn.

A. Plaintiff's Negligence Claim Is Preempted in Part by the Vaccine Act.

Defendants argue that Plaintiff's negligence claim is, at least partially, a veiled design defect claim that the National Childhood Vaccine Injury Act (the "Vaccine Act") preempts. *See* 42 U.S.C. § 300aa-1 *et seq.* Plaintiff agrees that the Vaccine Act preempts design defect claims but denies that her negligence claim challenges Gardasil's design.

In *Bruesewitz v. Wyeth LLC*, 562 U.S. 223 (2011) the Supreme Court held that § 300aa-22(b)(1) of the Vaccine Act bars state-law design defect claims against vaccine manufacturers. Section 300aa-22(b)(1) reads, "No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." The *Bruesewitz* court reasoned:

> The "even though" clause clarifies the word that precedes it. It delineates the preventative measures that a vaccine manufacturer *must* have taken for a side effect to be considered "unavoidable" under the statute. Provided that there was proper manufacture and warning, any remaining side effects, including those resulting from design defects, are deemed to have been unavoidable. State-law design-defect claims are therefore pre-empted.
>
> If a manufacturer could be held liable for failure to use a different design, the word "unavoidable" would do no work. A side effect of a vaccine could *always* have been avoidable by use of a differently designed vaccine not containing the harmful element. The language of the provision thus suggests that the *design* of the vaccine is a given, not subject to question in the tort action. What the statute establishes as a complete defense must be unavoidability (given safe manufacture and warning)

> *with respect to the particular design*. Which plainly implies that the design itself is not open to question.

562 U.S. at 231-32 (footnotes omitted). The Vaccine Act also affords immunity from liability for, *inter alia*, failure to warn if a manufacturer has complied with regulatory requirements and has given the warning to the healthcare professional, the vaccine recipient or the vaccine recipient's legal representative. § 300aa-22(c); *Bruesewitz*, 562 U.S. at 229 & n.25 ("The immunity does not apply if the plaintiff establishes by clear and convincing evidence that the manufacturer was negligent, or was guilty of fraud, intentional and wrongful withholding of information, or other unlawful activity.") (citing §§ 300aa-22(b)(2), 30aa-23(d)(2)); *Holmes v. Merck & Co, Inc.*, 697 F.3d 1080, 1085 (9th Cir. 2012).

The Court finds that portions of Plaintiff's negligence claim are barred by the Vaccine Act. Plaintiff alleges that Defendants "lied" to the FDA about Gardasil containing HPV L1-DNA fragments. (Dkt. No. 1 ¶ 137). Plaintiff also takes issue with Gardasil containing amorphous aluminum hydroxyphosphate sulfate, borax, polysorbate, and yeast. (*Id.* ¶¶ 129, 148, 154, 159). Publicly available documents show, however, that the FDA is aware of the presence of such substances. "FDA Information on Gardasil – Presence of DNA Fragments Expected, No Safety Risk," (Dkt. No. 6-33); Gardasil 9 Label (Dkt. No 6-34 at 11) (listing other ingredients).[2] Given

[2] The Court may properly consider such information in ruling on Defendants' motion without converting it into a motion for summary judgment. *Zak v. Chelsea Therapeutics Int'l, Ltd.*, 780 F.3d 597, 607 (4th Cir. 2015) (noting courts may consider relevant facts from the public record and documents "integral to and explicitly relief on in the complaint" at the pleading stage); (Dkt. No. 1 ¶ 242) (referring to Gardasil's label); *see, e.g.*, *Proffitt v. Bristol-Myers Squibb Co.*, No. 1:17-cv-04391, 2018 WL 3318893, at *4 & n.1 (S.D.W. Va. July 5, 2018) (considering alleged defective medication's label on motion for judgment on the pleadings); *In re Coloplast Corp. Pelvic Support Sys. Prod. Liab. Litig.*, 219 F. Supp. 3d 577, 579 (S.D.W. Va. 2016) (considering "package insert offer[ing] a product description and a warranty statement" in ruling on motion for judgment on the pleadings and finding it was "integral" to plaintiff's claim for relief); *Mills v. Bristol-Myers Squibb Co.*, No. CV 11-968-PHX-FJM, 2011 WL 3566131, *3 n.2 (D. Ariz. Aug.

the FDA is aware of the components Plaintiff attacks in its complaint, the Court finds that, to the extent Plaintiff's negligence claim challenges these components, the claim is a veiled design defect claim preempted by the Vaccine Act.

In sum, the Court grants Defendants' motion to the extent that Plaintiff's negligence claim challenges the presence of HPV L1-DNA fragments, amorphous aluminum hydroxyphosphate sulfate, borax, polysorbate, or yeast in Gardasil.

B. Plaintiff's Manufacturing Defect Claim Is Inadequately Pled and Otherwise Barred by the Vaccine Act.

Defendants argue that Plaintiff's manufacturing defect claim must be dismissed because it is a veiled design-defect claim. Plaintiff disputes the contention and argues her claim is properly pled.

A manufacturing defect claim is an allegation "that a particular product was defectively manufactured." *Watson v. Ford Motor Co.*, 699 S.E.2d 169, 174 (S.C. 2010). "There is not an abundance of case law in South Carolina about how a manufacturing defect differs from other defects." *Fisher v. Pelstring*, 817 F. Supp. 2d 791, 818 (D.S.C. 2011), *on reconsideration in part* (Jan. 11, 2012). Other courts have defined a manufacturing defect as existing "when a product does not conform to the design standards and blueprints of the manufacturer and the flaw makes the product more dangerous and therefore unfit for its intended or foreseeable uses." *See Gerber v. Hoffmann-La Roche, Inc.*, 392 F. Supp. 2d 907, 922 (S.D. Tex. 2005) (internal quotation marks and citation omitted) (applying Texas law) (granting summary judgment to a manufacturer on a plaintiff's manufacturing defect claim in a products liability action involving prescription drug

12, 2011) ("We may consider the Plavix label attached as an exhibit to defendants' motion to dismiss ... because it is a matter of public record."); *Adamson v. Ortho–McNeil Pharm., Inc.,* 463 F.Supp.2d 496, 500–01 (D.N.J. 2006) (considering a drug packaging insert on a motion to dismiss).

Accutane); *see also Wheeler v. HO Sports, Inc.,* 232 F.3d 754, 757 (10th Cir. 2000) (applying Oklahoma law) ("A product is defective in manufacture if it deviates in some material way from its design or performance standards. The issue is whether the product was rendered unsafe by an error in the manufacturing process," which is "often established by showing that a product, as produced, failed to conform with the manufacturer's specifications." (internal quotation marks and citations omitted)); *Wankier v. Crown Equip. Corp.,* 353 F.3d 862, 867 (10th Cir.2003) (applying Utah law) (holding that "a manufacturing defect claim, by its nature, involves a deviation from the product's design specifications, to the injury or potential injury of a user" and that "[t]he gravamen of the tort is not defective design but defective execution of the design").

Plaintiff alleges that Gardasil is defectively manufactured because it includes HPV L1-DNA fragments. (Dkt. No. 1 ¶¶ 137, 412) ("Merck lied both to the FDA and the public about including a secret and potentially hazardous ingredient, HPV L1-DNA fragments in Gardasil."). Plaintiff alleges that Gardasil is also defectively manufactured because it contains "dangerous and undisclosed increments and neurotoxins, including . . . phenylmethylsulfonyl fluoride (PMSF), a toxic nerve agent." (*Id.* ¶ 413). Plaintiff alleges that "Gardasil products reached the intended consumers, handlers, and users or other persons . . . including Plaintiff, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Merck." (*Id.* ¶ 414).

The Court finds that Plaintiff fails to state a manufacturing defect claim. Plaintiff has not plausibly alleged that the Gardasil dose Plaintiff received failed to comply with the Defendants' specifications. Plaintiff alleges the opposite—namely that the vaccine Plaintiff received reached her "without substantial change in [its] condition as designed [and] manufactured" by Defendants. Again, Plaintiff challenges only the design of Gardasil, something the Vaccine Act prohibits. *See*

Silver v. Bayer Healthcare Pharms., Inc., No. 2:19-CV-3495-DCN-MHC, 2021 WL 4596918, at *13 (D.S.C. June 10, 2021) (dismissing manufacturing defect claim where plaintiff did not allege how her dose deviated from defendant's manufacturing standards), *adopted in part, rejected in part by* 2021 WL 4472857 (Sept. 30, 2021).

Accordingly, the Court grants Defendants' motion as to Plaintiff's manufacturing defect claim.

C. Plaintiff's Direct Failure-To-Warn Claim is Barred by the Vaccine Act but Her Failure-To-Warn Claim as to Doctors or Medical Intermediaries Is Not.

Defendants argue that Plaintiff's failure to warn claim, as it applies to her directly or other consumers, fails because it is barred by the Vaccine Act. Defendants also argue that the learned intermediary doctrine bars Plaintiff's claim as it applies to Defendants' alleged failure to warn Plaintiff's health care professionals.

"Under South Carolina law, a 'products liability case may be brought under several theories, including negligence, strict liability, and warranty.'" *Sauls v. Wyeth Pharms., Inc.,* 846 F. Supp. 2d 499, 502 (D.S.C. 2012) (quoting *Rife v. Hitachi Constr. Mach. Co.,* 363 S.C. 209, 609 S.E.2d 565, 568 (S.C. Ct. App. 2005)). Proximate causation is critical to any theory under which a products liability case proceeds, and requires a showing that "'the injury occurred because the product was in a defective condition unreasonably dangerous to the user.'" *Id.* (quoting *Holst v. KCI Konecranes Int'l Corp.,* 390 S.C. 29, 699 S.E.2d 715, 719 (S.C. Ct. App. 2010)). Prescription drugs are neither defective nor unreasonably dangerous if accompanied by proper directions and warnings. *See Brooks v. Medtronic, Inc.,* 750 F.2d 1227, 1229–30 (4th Cir.1984) (explaining that prescription drugs often cause unwanted side effects and are deemed "unavoidably unsafe," but are not defective or unreasonably dangerous if adequate warnings of potential side effects are

included). "Failure to give such a warning constitutes a 'defect' in the product and renders the manufacturer liable for selling a product in an unreasonably dangerous manner." *Id.* at 1230.

In South Carolina, the learned intermediary doctrine applies to prescription drug manufacturers. *Odom v. G.D. Searle & Co.,* 979 F.2d 1001, 1003 (4th Cir. 1992). Under the learned intermediary doctrine, "the manufacturer's duty to warn extends only to the prescribing physician, who then assumes responsibility for advising the individual patient of risks associated with the drug or device." *Id.* In a prescription drug case, a plaintiff must not only show that the drug manufacturer's warning was inadequate, but "also establish that the inadequacy of the warning was the proximate cause of the plaintiff's injury." *Sauls,* 846 F. Supp. 2d at 502 (citing *Stanback v. Parke, Davis, & Co.,* 657 F.2d 642, 645 (4th Cir.1981)). The rationale behind this doctrine is the doctor is in a better position to warn the patient than the manufacturer. *Bean v. Upsher-Smith Pharms., Inc.*, No. 4:16-CV-01696-RBH, 2017 WL 4348330, at *8 (D.S.C. Sept. 29, 2017), *aff'd*, 765 F. App'x 934 (4th Cir. 2019). Considering the learned intermediary doctrine, "the burden remains on the plaintiff to demonstrate that the additional non-disclosed risk was sufficiently high that it would have changed the treating physician's decision to prescribe the product for the plaintiff." *Odom,* 979 F.2d at 1003.

Plaintiff alleges that Defendants failed to adequately warn of "the full and complete risks of Gardasil" because Defendants "failed to properly investigate, study, research, test, manufacture, label or promote Gardasil." (Dkt. No. 1 ¶¶ 390-91). Defendants allegedly failed to "adequately and accurately warn of the true risks of Plaintiff's injuries, including but not limited to, POTS, and autoimmune diseases." (*Id.* ¶ 399). Plaintiff alleges that Defendants failed to disclose to Plaintiff's medical providers that, *inter alia*, Gardasil presents "severe risks of triggering and increasing the risk of various autoimmune diseases, including but not limited to POTS." (*Id.* ¶¶ 376(m), 403).

The Court finds that, as to Defendants alleged failure to warn Plaintiff *directly*, the Vaccine Act bars Plaintiff's claim. The Vaccine Act places the following limitation on warning claims, "No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, 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) (emphasis added). Accordingly, the Court dismisses Plaintiff's failure to warn claim to the extent it concerns Defendants' "failure to provide warnings to the public or to consumers." *See, e.g.*, *Blackmon v. American Home Prods. Corp.*, 328 F. Supp. 2d 659, 666 (S.D. Tex. 2004) (Vaccine Act preempts claims for failure to provide warnings directly to public or plaintiff); *Sykes v. Glaxo–SmithKline*, 484 F.Supp.2d 289, 304 (E.D. Pa. 2007) (same); *G.M. v. Sanofi Pasteur Inc.*, No. CV 14-9549 FMO (ASX), 2016 WL 7638186, at *4 (C.D. Cal. Mar. 22, 2016) ("To the extent plaintiff alleges that defendant failed to warn her or the public of the risks that the Fluzone vaccine could cause transverse myelitis, such claims are expressly preempted by the Vaccine Act."). As it concerns Plaintiff's claim that Defendants failed to adequately warn Plaintiff's *doctor or medical intermediaries*, however, the Court finds the claim adequately pled and allows it to proceed. *See* 42 U.S.C. § 300aa-22(b)(2) ("[A] vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act and section 262 of this title ... applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought ...."); (Dkt. No. 1 ¶¶ 376(m), 403); *Sanofi*, 2016 WL 7638186, at *4 (noting that the Vaccine Act "imposes a burden of production on the manufacturer to show material compliance with FDA regulations"

and declining to dismiss a failure to warn medical professional claims at the pleading stage) (citing *Sykes*, 484 F. Supp. 2d at 305)); *Blackmon*, 328 F. Supp. 2d at 666-67 ("Defendants are not entitled to the presumption until they produce evidence of compliance with the FDA regulations. The Court cannot accept the fact that the FDA licensed the vaccines as *prima facie* evidence that Defendants complied with all regulations and are therefore entitled to the statutory presumption of proper warnings.") (internal citation omitted).

D. Plaintiff's Claim for Breach of Express Warranty Is Adequately Pled.

Next, Defendants argue that Plaintiff's claim for breach of express warranty is either barred by the Vaccine Act or inadequately pled because it does not allege, *inter alia*, that Dr. Hajzus relied on a specific warranty issued by Defendants.

To establish a cause of action for breach of express warranty, a plaintiff must prove (1) the existence of an express warranty, (2) breach of an express warranty, and (3) damages proximately caused by the breach. *See Cox House Moving, Inc. v. Ford Motor Co.,* No. 7:06–1218–HMH, 2006 WL 2303182, *4 (D.S.C. Aug. 8, 2006) (citing *Besse v. Gen. Motors Corp.,* 317 F. Supp. 2d 646, 654 n. 7 (D.S.C. 2004)). Under South Carolina law, an express warranty is created in the following ways:

> (a) Any affirmation of fact or promise, including those on containers or labels, made by the seller to the buyer, whether directly or indirectly, which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods conform to the affirmation or promise.
>
> (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
>
> (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

S.C. Code Ann. § 36-2-313(1). "When goods do not conform to a promise or an affirmation of fact made by a seller, or the goods do not conform to a description, sample, or model, then a seller has breached an express warranty." *Herring v. Home Depot, Inc.*, 565 S.E.2d 773, 776 (S.C. Ct. App. 2002) (internal quotation marks omitted).

In her complaint, Plaintiff alleges that Defendants marketed to both patients and medical providers that Gardasil was "safe" and "effective" in preventing cancer but failed to "include the complete array of risks associated with Gardasil." (Dkt. No. 1 ¶¶ 425-26). Plaintiff alleges Defendants' representations as to Gardasil's safety, representations made through a variety of media including "the Gardasil label, publications, television advertisements, billboards, print advertisements, online advertisements and websites, and other written materials," were not true, (*Id.* ¶¶ 425, 431), and that, "[a]s a proximate result of [Defendants'] wrongful acts," Plaintiff was injured, (*Id.* ¶ 432).

The Court finds that Plaintiff has adequately pled an express warranty claim. Plaintiff alleges that Defendants represented to Plaintiff's medical providers that Gardasil was safe without fully disclosing the "completely array of risks associated with Gardasil," (*Id.* ¶¶ 425, 428), and that Plaintiff's physician likely relied on those representations, (*Id.* ¶ 350).

Accordingly, Defendants' motion is denied on this point.

E. Plaintiff Fails to Properly Plead a Claim for Common Law Fraud.

Defendants argue that Plaintiff's common law claim for fraud is subject to dismissal for various reasons. First, Defendants argue that Plaintiff merely recycles her failure-to-warn claim—a claim barred by the Vaccine Act. Second, Defendants argue that Plaintiff fails to plead fraud with the requisite specificity because the complaint does not state "when" Plaintiff was exposed the supposedly fraudulent marketing materials. Third, Defendants argue that Plaintiff fails to

adequately plead that Plaintiff's treating physician, Dr. Hajzus, was exposed personally to the supposedly fraudulent marketing materials. Last, Defendants argue that much of Defendants' alleged conduct is not actionable under South Carolina law because South Carolina law does not have a "failure-to-test" claim in products liability actions. In opposition, Plaintiff argues she plausibly states a common law fraud claim because her complaint alleges Defendants made the "following 'false representations': (1) 'Gardasil is effective in preventing cervical and anal cancer,'; (2) 'Gardasil is safe'; and (3) cervical cancer was far more prevalent than it really was.'" (Dkt. No. 9 at 20); (Dkt. No. 1 ¶ 452). Plaintiff does not address Defendants' remaining arguments.

In order to prove fraud, the following elements must be shown by clear and convincing evidence: (1) a representation; (2) its falsity; (3) its materiality; (4) either knowledge of its falsity or a reckless disregard of its truth or falsity; (5) intent that the representation be acted upon; (6) the hearer's ignorance of its falsity; (7) the hearer's reliance on its truth; (8) the hearer's right to rely thereon; and (9) the hearer's consequent and proximate injury. *Ardis v. Cox,* 314 S.C. 512, 431 S.E. 2d 267, 269 (S.C. Ct. App. 1993).

When a plaintiff alleges fraud, Rule 9(b) of the Federal Rules of Civil Procedure requires courts to apply a heightened pleading standard. *See* Fed. R. Civ. P. 9(b). Rule 9(b) "creates an exception to Rule 8's relaxed standard." *Pub. Employees' Ret. Ass'n of Colo. v. Deloitte & Touche, L.L.P.,* 551 F.3d 305, 311 (4th Cir. 2009). Rule 9(b) requires that when "alleging fraud ..., a party must state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). The United States Court of Appeals for the Fourth Circuit has acknowledged four purposes behind the heightened pleading requirement for fraud. *U.S. ex rel. Harrison v. Westinghouse Savannah River Co.,* 352 F.3d 908, 921 (4th Cir.2003) (citing *Harrison v. Westinghouse Savannah River Co.,* 176 F.3d 776, 784 (4th Cir.1999)). First, it provides defendants with "sufficient information to

formulate a defense by putting [them] on notice of the conduct complained of." *Id.* Second, it "protect[s] defendants from frivolous suits," *id.,* recognizing that "allegations of fraud ... frequently are advanced only for their nuisance or settlement value," *Teachers' Ret. Sys. of La. v. Hunter,* 477 F.3d 162, 171 (4th Cir.2007) (citing 5A Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1296 (3d ed.2004)). Third, it "eliminate[s] fraud actions in which all the facts are learned after discovery," *U.S. ex rel. Harrison v. Westinghouse Savannah River Co.,* 352 F.3d at 921 (citing *Harrison v. Westinghouse Savannah River Co.,* 176 F.3d at 784), and "discourag[es] fishing expeditions brought in the dim hope of discovering a fraud," *Pub. Employees Ret. Ass'n of Colo.,* 551 F.3d at 311. And fourth, it "protects defendants from harm to their goodwill and reputation." *U.S. ex rel. Harrison v. Westinghouse Savannah River Co.,* 352 F.3d at 921 (citing *Harrison v. Westinghouse Savannah River Co.,* 176 F.3d at 784).

The heightened pleading standard in Rule 9(b) requires plaintiffs to plead with particularity "'the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby.'" *Harrison v. Westinghouse Savannah River Co.,* 176 F.3d at 784 (quoting 5 Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure: Civil* § 1297 (2d ed.1990)). Thus, plaintiffs must demonstrate "the 'who, what, when, where, and how' of the alleged fraud." *U.S. ex rel. Wilson v. Kellogg Brown & Root, Inc.,* 525 F.3d 370, 379 (4th Cir.2008) (quoting *U.S. ex rel. Willard v. Humana Health Plan of Tex., Inc.,* 336 F.3d 375, 384 (5th Cir.2003)). Also, "[m]ere allegations of 'fraud by hindsight' will not satisfy the requirements of Rule 9(b)." *Harrison v. Westinghouse Savannah River Co.,* 176 F.3d at 784 (citing *Hillson Partners Ltd. P'ship v. Adage, Inc.,* 42 F.3d 204, 209 (4th Cir.1994)). However, "Rule 9(b) allows conclusory allegations of defendant's knowledge as to the true facts and of defendant's intent to deceive." *Id.*

In her complaint, Plaintiff alleges that despite knowing of the hazards and dangers associated with Gardasil, dangers which Defendants knew or should have known about due to poorly designed clinical trials and studies, Defendants represented through "statements . . . made in its publications, ubiquitous television advertisements, billboards, print advertisements, online advertisements and website, and other written materials" that Gardasil was safe and effective at preventing cancer when it was not. (Dkt. No. 1 ¶¶ 441-43). Plaintiff alleges she was "exposed" to these materials and that these materials induced into her consenting to take Gardasil. Specifically, Plaintiff alleges she was exposed to Defendants' "One Less" advertisement campaign. (*Id.* ¶ 444). Plaintiff alleges that the advertisement did not include safety warnings about POTS and that the "ubiquitous nature of these Gardasil commercials . . . gave the impression that cervical cancer was on the rise and more prevalent than it actually was." (*Id.* ¶ 444-45). As it concerns the doctor that administered Plaintiff Gardasil, Plaintiff alleges only that "Merck's advertisements assert that the HPV vaccine prevents cervical cancer. For example, in a presentation to medical doctors, Merck proclaimed: 'Every year that increases in coverage [of the vaccine] are delayed, another 4,400 women will go on to develop cervical cancer.'" (*Id.* ¶ 116).

The Court finds that Plaintiff's claim for common law fraud is inadequately pled. As to Plaintiff, the complaint fails to allege with particularity when Defendants made the allegedly false statements to her. *U.S. ex rel. Conrad v. GRIFOLS Biologicals Inc.*, No. CIV.A-RDB 07-3176, 2010 WL 2733321, at *4 (D. Md. July 9, 2010) (dismissing fraud claims where plaintiff alleged that "Novartis submitted false information to CMS sometime after November 12, 1999" but gave "no specific times during which this alleged fraudulent activity occurred"); *Heavener v. Quicken Loans, Inc.*, No. 3:12-CV-68, 2013 WL 2444596, at *7 (N.D.W. Va. June 5, 2013) (dismissing fraud claim where plaintiff failed, inter alia, to "allege an approximate date or time period that the

[allegedly fraudulent] appraisal was performed"). Further, to the extent Plaintiff has alleged fraud on Plaintiff's treating physician Dr. Hajzus, the Court finds that claim fails to allege with specificity the who, what, when, where, or how of the supposedly fraudulent communications—a fact Plaintiff in-effect concedes by failing to contest Defendants' argument to this effect in her opposition. *See Luberda v. Purdue Frederick Corp.*, 4:13-cv-00897, 2014 WL 1315558, at *6 & n.3 (D.S.C. Mar. 28, 2014) (noting that, in addition to pleading the elements of fraud, when it concerns prescription drugs, "the plaintiff must plead facts in accordance with the learned intermediary doctrine regarding the misrepresentation or failure to disclose to [the plaintiff's] physician and the other elements of fraud including reliance by the physician on the misrepresentation").

For the above reasons, Defendants' motion is granted on this point.

IV. Conclusion

For the foregoing reasons, Defendants' motion to dismiss (Dkt. No. 6) is **GRANTED IN PART AND DENIED IN PART**. The motion is granted to the extent that: (1) Plaintiff's negligence claim is dismissed to the extent it challenges the presence of HPV L1-DNA fragments, amorphous aluminum hydroxyphosphate sulfate, borax, polysorbate, or yeast in Gardasil; (2) Plaintiff's manufacturing defect claim is dismissed; (3) Plaintiff's direct failure-to-warn claim is dismissed; and (4) Plaintiff's common law fraud claim is dismissed. Defendants' motion is otherwise **DENIED.** In sum, except as limited above, Plaintiff's claims for negligence, breach of express warranty, and failure to warn shall proceed.

AND IT IS SO ORDERED.

s/ Richard Mark Gergel
Richard Mark Gergel
United States District Judge

November 17, 2021
Charleston, South Carolina