UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION
3:22-MD-3036-RJC-DCK

IN RE: GARDASIL PRODUCTS LIABILITY LITIGATION	)	**MDL No. 3036**
	)	**THIS DOCUMENT RELATES TO ALL CASES**

PLAINTIFFS' POSITION STATEMENT

In these consolidated actions, the administration of Gardasil, a vaccine manufactured and promoted by Merck & Co., Inc. and Merck Sharpe & Dohme Corp. (collectively "Merck"), caused Plaintiffs to suffer certain autoimmune injuries, as described more fully below. Gardasil purports to prevent infection from a small handful of the many Human Papillomavirus Virus ("HPV") strains. Plaintiffs seek to recover under theories of negligence, strict products liability (failure to warn and manufacturing defect), breach of warranty, common law fraud and violation of certain state consumer laws. Generally, Plaintiffs allege Merck failed to warn of Gardasil's risks of inducing certain autoimmune and neurological injuries; Merck took steps to mask and downplay these risks; and Merck was also negligent in the way it conducted its clinical trials and post-marketing pharmacovigilance. Plaintiffs further allege that, in its direct-to-consumer advertising to patients and parents, Merck misrepresented and overemphasized Gardasil's efficacy while concealing Gardasil's serious risks.

A. Brief Factual Background Concerning Gardasil and Autoimmune Injury

In June 2006, after a "fast-tracked" review by the Food and Drug Administration ("FDA"), Merck marketed Gardasil for use in girls ages 9 through 12, teenage girls 13 through

19, and young women ages 20 through 26. The vaccine was promoted as being capable of preventing infection from four strains of the Human Papillomavirus ("HPV"). HPV is primarily a sexually transmitted virus that may be contracted when someone becomes sexually active. There are over 100 strains of the virus for which the vaccine is not efficacious. The stated purpose of the vaccine was to prevent cervical cancer, although there were and are no clinical trials that even attempted to establish this alleged downstream benefit.

In 2014, Merck sought and obtained approval for a new version of the vaccine, Gardasil 9, which contains the same basic ingredients as Gardasil.[1] It was approved for use in girls and now boys to prevent infection from nine strains of HPV, some of which are associated with certain cancers, including cervical and anal cancer. Presently, Gardasil 9 has been approved for and is being promoted by Merck with an emphasis on pre-teen boys and girls, and their parents, as well as to women and men up to age 45.

In a best-case scenario, Gardasil causes an immune response and production of anti-HPV antibodies to fend off a limited number of HPV virus strains. In a worst-case scenario, it causes the immune system to overreact and fail to differentiate human proteins from foreign proteins, causing the immune system to attack the body's own proteins and organs.

To stimulate an enhanced immune response, Merck added adjuvants to Gardasil. Among those adjuvants was Merck's proprietary form of aluminum known as amorphous aluminum hydroxyphosphate sulfate (AAHS). While Gardasil's adjuvants on their own can cause adverse effects, because of the peptide commonality between HPV and human proteins, the boosted

[1] After the approval of the Gardasil 9 vaccine, the original Gardasil vaccine was phased out of the U.S. Market and the original Gardasil vaccine is no longer available for sale in the United States. Both Gardasil and Gardasil 9 will be collectively referred to as "Gardasil" in this position statement.

immune response triggered by Gardasil's adjuvants to Gardasil's HPV virus-like particles can cause cross-reactions and dangerous attacks against human proteins. This process, which is referred to as "molecular mimicry," can cause various autoimmune disorders, including most prominently, neurological, autonomic and autoimmune injuries, such as Postural Orthostatic Tachycardia Syndrome (POTS) or Orthostatic Intolerance (OI).[2]

Autoimmunity arises when a person's immune system makes a mistake and begins to attack healthy tissue instead of a foreign invader. Such a mistake arises from the similarity (mimicry) between the amino acid sequences of "self" and the "foreign" invader. In other words, the body's immune system attacks the host tissue as well as the vaccine's antigen due to similarity between some amino acid sequences of both.

Gardasil produces an antibody response that is as much as 50 times greater than what would follow natural infection. When a human host's cells are confronted with an adjuvant-induced 50 times greater immune attack than a natural infection, some hosts' systems are not able to resolve the autoimmune attack leading to longer term autoimmune diseases related to where the cell mimicry occurred. In these cases, neurological cells with common amino acid sequences to the virus epitopes get an overwhelming, adjuvant-boosted immune attack that may

[2] When a person is lying down, approximately one-quarter of their blood volume resides in the chest area. When the person stands up, a significant amount of that blood shifts to the lower extremities. This causes impaired return of blood flow to the heart which also reduces blood pressure. In healthy individuals, the autonomic nervous system adjusts the heartrate to counteract this effect and the hemodynamic changes are negligible. However, in individuals such as many of the Plaintiffs who are now suffering from dysautonomia or autonomic ailments, such as POTS or Orthostatic Intolerance ("OI"), the body's ability to adjust the heartrate and compensate for the blood flow is corrupted resulting in a host of symptoms, including but not limited to, dizziness, lightheadedness, vertigo, nausea, chronic headaches, vision issues due to the loss of blood flow to the brain, light and sound sensitivity, loss of consciousness, shortness of breath, chest pain, gastrointestinal issues, body pains, insomnia, and confusion and/or difficulty sleeping. In certain cases of POTS, patients will also be diagnosed with other medical conditions, including but not limited to, chronic fatigue syndrome and fibromyalgia.

persist, leading to prolonged autoimmune neurological conditions.

The overlap between the human proteins and the viral proteins can be substantial. To date, at least 82 sequences of seven amino acids (heptapeptides) that overlap perfectly with the HPV16 proteins contained in Gardasil have been identified. A key study concludes: "Based on the need for five or six amino acids to induce a monoclonal antibody response, the 82 heptapeptide overlaps can clearly induce autoimmune reactions." Darja Kanduc, *Quantifying the Possible Cross-Reactivity Risk of an HPV16 Vaccine*, 8 JOURNAL OF EXPERIMENTAL THERAPEUTICS AND ONCOLOGY 66 (2009). In every case, the mechanism of injury is essentially the same. The only variation is the site where the molecular mimicry loses immune tolerance in a particular patient.[3] Presently, a majority of the plaintiffs whose cases are pending before the MDL sustained autoimmune-induced autonomic injuries, including POTS or Orthostatic

[3] Several published medical journal articles have discussed the link between Gardasil and autoimmune and neurological injuries. *See e.g.*, Svetlana Blitshetyn, *Postural Tachycardia Syndrome After Vaccination with Gardasil*, 17 EUROPEAN J. OF NEUROLOGY e52 (2010); Deirdre Little et al., *Premature ovarian failure 3 years after menarche in a 16-year-old girl following human papillomavirus vaccination*, BRIT. MED. J. CASE REPORTS (2012); Serena Colafrancesco et al., *Human Papilloma Virus Vaccine and Primary Ovarian Failure: Another Facet of the Autoimmune Inflammatory Syndrome Induced by Adjuvants*, 70 AM. J. REPRODUCTIVE IMMUNOLOGY 309 (2013); Svetlana Blitshetyn, *Postural Tachycardia Syndrome Following Human Papillomavirus Vaccination*, 21 EUROPEAN J. OF NEUROLOGY 135 (2014); Tomomi Kinoshita et al., *Peripheral Sympathetic Nerve Dysfunction in Adolescent Japanese Girls Following Immunization With Human Papillomavirus Vaccine,* 53 INTERNAL MEDICINE 2185 (2014); Louise S. Brinth et al., *Orthostatic Intolerance and Postural Tachycardia Syndrome As Suspected Adverse Effects of Vaccination Against Human Papilloma Virus*, 33 VACCINE 2602 (2015); Louise S. Brinth et al., *Is Chronic Fatigue Syndrome/Myalgic Encephalomyelitis a Relevant Diagnosis in Patients with Suspected Side Effects to Human Papilloma Virus Vaccine*, 1 INT. J. OF VACCINE & VACCINATION 3 (2015); Jill R. Schofield et al., *Autoimmunity, Autonomic Neuropathy, and HPV Vaccination, A Vulnerable Subpopulation*, CLINICAL PEDIATRICS (2017); Shu-Ichi Ikeda et al., *Suspected Adverse Effects After Human Papillomavirus Vaccination: A Temporal Relationship*, 66 IMMUNOLOGIC RESEARCH 723 (2018); Svetlana Blitshetyn, *Human Papilloma Virus (HPV) Vaccine Safety Concerning POTS, CRPS and Related Conditions*, CLINICAL AUTONOMIC RESEARCH (2019); Lars Jørgensen et al., *Benefits and Harms of the Human Papillomavirus (HPV) Vaccines: Systemic Review with Meta-Analyses of Trial Data from Clinical Study Reports*, 9 SYSTEMATIC REVIEWS 43 (February 2020).

Intolerance and similar neurological injuries and symptomology.

B. Status Concerning the Number of Known Cases and Pending (and Adjudicated) Motions

To the best of undersigned counsel's knowledge, to date, there are approximately 50 federal Gardasil personal injury tort cases pending against Merck. Of the pending federal cases, Merck Answered the Complaints in 12 of the cases without any motion practice. Merck filed "Rule 12" motions in approximately 22 of the pending cases and has not yet responded to the other pending federal Complaints.[4] In addition to the above 50 filed cases, there are approximately 51 additional Gardasil cases that have gone through the Vaccine Court[5] and are in

[4] Attached hereto as **Appendix A** is a Chart that contains the state and federal pending cases known to undersigned counsel and their current posture, including the information required to be provided concerning each case by the First Pre-Trial Order.

[5] For certain vaccines, including Gardasil, federal law, pursuant to Section 300aa-11 of the National Childhood Vaccine Injury Act of 1986 ("the Vaccine Act"), generally does not permit a person to bring a civil action against a vaccine manufacturer until the injured person has first filed a petition in the Vaccine Court (i.e., United States Court of Federal Claims) and has obtained a judgment from the Vaccine Court. 42 U.S.C.A. § 300aa-11. After the Vaccine Court issues its judgment, the petitioner has the option of rejecting the judgment and electing to file a civil action against the manufacturer. 42 U.S.C.A. §§ 300aa-11(a)(2) & § 300aa-21(a). The Vaccine Court program is a no-fault system brought against the federal government (the vaccine manufacturer is not a party to the Vaccine Court proceedings), discovery is generally not permitted (other than obtaining plaintiff's medical records) and monetary caps are placed on damages awarded through the vaccine court program. 42 U.S.C.A. §§ 12(d)(2)(E) (limits on discovery in Vaccine Court); 300aa-15 (damages limitations in Vaccine Court); *see also Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 228 (2011) (discussing the vaccine court). Generally, the petitioner is required to participate in the program for at least 240 days and if no decision on the substantive merits has been reached by that time, she can decide to opt out of the program to pursue civil remedies against the vaccine manufacturer in either state or federal court. 42 U.S.C.A. § 300aa-21(b)(1) & § 300aa-12(d)(3) & 12(g); *Bruesewitz*, 562 U.S. at 228. Even if a judgment on the merits is issued by the vaccine court, the petitioner has the option to reject the judgment (whether favorable or adverse) and pursue traditional tort remedies under state common law against the vaccine manufacturer. 42 U.S.C.A. § 300aa-21; *Bruesewitz*, 562 U.S. at 228. Should a petitioner elect to pursue tort damages under state common law, neither the

the process of being filed in this MDL; and counsel is also aware of at least 74 additional cases that are still in Vaccine Court, which will be filed in the MDL following conclusion of the Vaccine Court proceedings. Thus, within the next few months, counsel anticipates there will be at least 174 confirmed cases in the MDL, and of course various law firms also continue to review new cases which may be filed in the vaccine court and eventually the MDL.

Plaintiffs' view is that the case has passed the Rule 12 stage and should not be further delayed for such motion practice. Rather, the case should proceed with discovery. In the cases wherein Merck already filed "Rule 12" motions, seven Courts have issued rulings. In ***Colbath***, the Southern District of California denied Merck's motion to dismiss as to negligence, failure to warn, unfair competition, and fraudulent concealment, but granted it with leave to amend as to manufacturing defect, breach of express warranty, and misrepresentation – Merck subsequently Answered the Complaint. In ***Gramza***, the District of Arizona granted Merck's motion to strike references to Vioxx from the Complaint, and Merck subsequently Answered. In ***Balasco***, the District of Rhode Island denied Merck's motion to strike references to Vioxx from the Complaint but granted its motion to dismiss Plaintiff's Rhode Island Deceptive Trade Practices Act ("DTPA") claim, and Merck subsequently Answered the Complaint. In ***Walker***, the Western District of Wisconsin denied Merck's motion to strike Vioxx allegations from the Complaint, and Merck subsequently Answered. In ***Stratton***, the District of South Carolina granted and denied in part Merck's motion to dismiss (Stratton was allowed to proceed on her negligence, failure to warn, and breach of express warranty claims), and Merck subsequently Answered the Complaint. Stratton, however, subsequently voluntarily dismissed her Complaint for personal

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judgment nor the findings from the vaccine court are admissible in any future civil action. 42 U.S.C.A. § 300aa-23(e).

reasons. In ***Herlth***, the District of Connecticut granted Merck's motion to dismiss largely on broad federal preemption grounds, with leave to reopen the case and amend the Complaint.[6] Herlth filed a motion to reopen which was granted, and the Complaint was amended. Merck brought a second motion to dismiss, which was never adjudicated. In ***Flores***, the District of Nevada granted Merck's motion to dismiss with leave to amend. Flores amended her Complaint and Merck filed a second motion to dismiss, which was never adjudicated.[7]

In addition to *Flores* and *Herlth* (discussed *supra*), in *Atjian, Bergin, Butler, Dalton, Derr, Fetters, Hendrix, Hilton, Hoddick, Landers, Levy, Malloy, Pennell, Prudden, Soileau,* and *Wingerter*, Merck's motions to dismiss were pending and then administratively terminated after this Honorable Court entered its Order (ECF No. 38), terminating all pending motions in individual cases. Merck filed Answers (without any motion practice) in *Humphries*, *Landers* (*Krista*), *Lipscomb*, *McElerney*, *Muller*, *Raymer*, *Rizvi*, *Silver*, *Sullivan*, *Thomas*, and *Wagner*. Finally, in *Eshelman, Graves, Hartle, Hinojosa, Horton, Ivey, Lukas, Merino, Neves, Nyboer,*

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[6] While Merck Answered and/or filed motions to dismiss in other Gardasil cases, *Herlth* was the first case that Merck sought dismissal of failure to warn claims on preemption grounds premised on the Second Circuit's holding in *Gibbons v. Bristol-Myers Squibb Co*., 919 F.3d 699, 708 (2d Cir. 2019). However, the Second Circuit's ruling runs afoul of Supreme Court precedent, including the Supreme Court's subsequent decision in *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019). Although *Gibbons* placed the burden of pleading around preemption on the plaintiff, the Supreme Court in *Albrecht* subsequently held the reverse (i.e., holding that preemption is a defense upon which the defendant holds the burden of proof) thus confirming that *Gibbons* is flawed. *Albrecht*, 139 S. Ct. at 1678 ("The underlying question for this type of impossibility pre-emption defense is whether federal law (including appropriate FDA actions) prohibited the drug manufacturer from adding any and all warnings to the drug label that would satisfy state law. And, of course in order to succeed with that defense *the manufacturer must* show that the answer to this question is yes.") (emphasis added). Other Circuits agree. *See, e.g., Bennett v. Southwest Airlines Co*., 493 F.3d 762, 763 (7th Cir. 2007); *Cohen v. ConAgra Brands, Inc*., 16 F.4th 1283, 1289 (9th Cir. 2021); *In re Zofran (Ondansetron) Prod. Liab. Litig*., 541 F. Supp. 3d 164, 197 (D. Mass. 2021) (preemption is an affirmative defense which the defendant has burden to establish).

[7] For the benefit of the Court, appended hereto as **Appendix B** are copies of the above referenced rulings obtained to date on Merck's Rule 12 Motions.

O'Brien, Reddicks, Roeder, Rolf, and *Vela,* Merck has not yet responded to the Complaints.

C. Brief Status of Discovery

Discovery to date has in a large part been limited to written discovery and document production. The first Gardasil case that proceeded to discovery was a case pending in California state court, *Robi v. Merck et al*. No. BC628589. Merck initially produced only 700 pages of documents, however, after multiple discovery briefs and more than a dozen hearings over several months, Merck was ordered to produce various internal documents including various custodial files pursuant to court-ordered search terms. Additional custodians were added and the scope of discovery was broadened once the first federal case was filed, *Gramza v. Merck* (D.Ariz). As a result of the Orders obtained in *Robi* and the broadening of the custodians in *Gramza*, to date, Merck has produced approximately 8 million pages from custodial and regulatory files and 16 million pages of clinical trial data (i.e., some of the individual patient Case Report Forms ("CRFs") from some of the clinical trials of Gardasil).

Notwithstanding what would appear to be voluminous, Merck's productions remain inadequate. As way of example, despite relying upon FDA approval of Gardasil as a purported defense in the cases, Merck has refused to produce the complete regulatory file for Gardasil. Likewise, Merck has refused to produce the regulatory file in an easily accessible and reviewable electronic format which is known as the eCDT format that manufacturers routinely use to submit documents to the FDA. As to clinical trials, Merck has refused to produce the complete raw data from its Gardasil clinical trials, including the Case Report Forms, which are the documents used by clinical investigators to report adverse events experienced by clinical trial participants and which constitute an important part of the raw data from studies. Similarly, Merck has refused to produce its Clinical Trials Database, a database used by Merck to house data from its clinical

trials. Merck has likewise refused to produce or provide complete access to its Gardasil adverse events database, and it does not appear Merck has produced all causality assessments (where clinical trial investigators and/or Merck itself assess whether an adverse event is related to the vaccine or not), studies, and internal communications regarding Gardasil adverse events. These and other discovery issues will need to be resolved by the parties or adjudicated once discovery gets underway in the MDL.[8] Moreover, productions from many key individuals who were responsible for these vaccines remain necessary, as does, of course, depositions including needed 30(b)(6) depositions. Finally, it should be noted that this prior discovery, including negotiation of an ESI protocol and Protective Order, which led to the production of the current documents, was done almost exclusively by the undersigned firm, at a time when there were only one or a small handful of cases pending. Now, with substantially more cases, and more importantly, nearly a dozen different plaintiffs' law firms involved who have never had access to the previously-produced Merck discovery, have not had an opportunity to weigh in on the prior negotiated ESI protocols, protective orders, and discovery issues, and who understandably would like to be involved and provide input on any final discovery protocols that are ultimately agreed

[8] Some of the other discovery issues include, for example, the potential need for Merck to utilize technology assisted review (TAR) to produce documents as an adjunct to search terms; the need to broaden the custodians; the need for Merck to identify all employees involved in Gardasil, including all employees involved in regulatory, labeling, clinical trials, marketing, foreign and domestic studies (safety analyses), and pharmacovigilance so as to ensure the custodial files of the relevant employees are being obtained. In addition, a substantial number of documents have been either redacted or withheld under what appears to be spurious grounds, which likewise will need to be resolved or adjudicated. Of course, these are just a sampling of some of the shortcomings with the discovery produced to date.

As to depositions, no Merck employees or custodians have been deposed to date in any of the state or federal cases. Merck has taken the deposition of plaintiffs (and plaintiffs' mothers) in three federal cases: *Gramza*, *Walker* and *Humphreys*; and has deposed a treater in *Gramza* and a treater in *Walker*. Appendix A, attached hereto, also includes additional information concerning the general types of known discovery that has occurred in each known case.

upon or ordered in this MDL.

Plaintiffs' counsel looks forward to the upcoming Initial Conference and to address any questions the Court may have concerning the facts and legal issues in these consolidated actions.

Dated: September 20, 2022

Respectfully submitted,

/s/ Bijan Esfandiari

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Appendix A

Federal and State Court Case Lists

Federal Court Cases

	Plaintiff	Court	Answer/ Rule 12	Discovery
1	Atjian, Eduardo, II	U.S. District Court for the Central District of California	Rule 12 Not Adjudicated	No Discovery
2	Balasco, Julia	U.S. District Court for the District of Rhode Island	Rule 12 Adjudicated and Answered	Rule 26 and Written Discovery
3	Bergin, Payton	U.S. District Court for the Western District of North Carolina	Rule 12 Not Adjudicated	No Discovery
4	Butler, Skylee	U.S. District Court for the District of Massachusetts	Rule 12 Not Adjudicated	No Discovery
5	Canitz, Shannon N.	U.S. District Court for the District of Arizona	None	No Discovery
6	Colbath, Michael A.	U.S. District Court for the Southern District of California	Rule 12 Adjudicated and Answered	Rule 26 Initial Disclosure Exchanged
7	Counts, Madeline A.	U.S. District Court for the Northern District of Texas	None	No Discovery
8	Dalton, Ashley	U.S. District Court for the Eastern District of Michigan	Rule 12 Not Adjudicated	No Discovery
9	Derr, Maeson	U.S. District Court for the Middle District of North Carolina	Rule 12 Not Adjudicated	No Discovery
10	Eshelman, Avery	U.S. District Court for the Western District of Oklahoma	None	No Discovery
11	Fetters, Sydney M.	U.S. District Court for the Central District of California	Rule 12 Not Adjudicated	No Discovery
12	Flores, Savannah	U.S. District Court for the District of Nevada	Rule 12 Not Adjudicated	Rule 26 and Written Discovery
13	Gramza, Jasmyne	U.S. District Court for the District of Arizona	Answered	Rule 26 and Written Discovery. Plaintiff and mother deposed
14	Graves, Danielle T.	U.S. District Court for the Northern District of Texas	None	No Discovery
15	Hartle, Ethan C.	U.S. District Court for the Southern District of Iowa	None	No Discovery
16	Hendrix, Darby	U.S. District Court for the Northern District of Georgia	Rule 12 Not Adjudicated	No Discovery
17	Herlth, Korrine A.	U.S. District Court for the District of Connecticut	Rule 12 Not Adjudicated	Rule 26 and Written Discovery

Federal Court Cases

	Plaintiff	Court	Answer/ Rule 12	Discovery
18	Hilton, Kameron	U.S. District Court for the Western District of North Carolina	Rule 12 Not Adjudicated	No Discovery
19	Hinojosa Hernandez Sarni, Audrey E.	U.S. District Court for the District of Arizona	None	No Discovery
20	Hoddick, Jeffrey K.	U.S. District Court for the District of Hawaii	Rule 12 Not Adjudicated	No Discovery
21	Horton, Tristen J.	U.S. District Court for the Northern District of Florida	None	No Discovery
22	Humphries, Cooper	U.S. District Court for the Central District of Illinois	Answered	Rule 26 and Written Discovery. Plaintiff and mother deposed
23	Ivey, Madison C.	U.S. District Court for the Western District of Texas	None	No Discovery
24	Landers, Isabella	U.S. District Court for the Southern District of West Virginia	Rule 12 Not Adjudicated	No Discovery
25	Landers, Krista L.	U.S. District Court for the Northern District of Illinois, Eastern Division	Answered	No Discovery
26	Levy, Jacob D.	U.S. District Court for the Central District of California	Rule 12 Not Adjudicated	No Discovery
27	Lipscomb, Madelyn R.	U.S. District Court for the Northern District of Indiana, Fort Wayne Division	Answered	No Discovery
28	Lukas, Sarah F.	U.S. District Court for the Northern District of Ohio, Eastern Division	None	No Discovery
29	Malloy, Madelyn	U.S. District Court for the Eastern District of Texas	Rule 12 Not Adjudicated	No Discovery
30	McElerney, Corinn	U.S. District Court for the Middle District of Florida	Answered	Rule 26 and Written Discovery
31	Merino, Adriana	U.S. District Court for the District of Arizona	None	No Discovery
32	Muller, Ashley	U.S. District Court for the Northern District of Florida	Answered	Rule 26 and Written Discovery
33	Neves, Isabella	U.S. District Court for the District of New Jersey	None	No Discovery
34	Nyboer, Camille	U.S. District Court for the District of New Jersey	None	No Discovery

Federal Court Cases

	Plaintiff	Court	Answer/ Rule 12	Discovery
35	O'Brien, Madeleine	U.S. District Court for the Southern District of Texas	None	No Discovery
36	Pennell, Mackenzie	U.S. District Court for the Northern District of Ohio, Eastern Division	Rule 12 Not Adjudicated	No Discovery
37	Prudden, Christina L.	U.S. District Court for the Western District of Missouri	Rule 12 Not Adjudicated	No Discovery
38	Raymer, Jessica	U.S. District Court for the Northern District of Illinois, Eastern Division	Answered	No Discovery
39	Reddicks, Arianna	U.S. District Court for the District of Oregon	None	No Discovery
40	Rizvi, Aina	U.S. District Court for the District of New Jersey	Answered	No Discovery
41	Roeder, Megan	U.S. District Court for the Central District of California	None	No Discovery
42	Rolf, Michael B.	U.S. District Court for the District of Arizona	None	No Discovery
43	Silver, Ruby	U.S. District Court for the Middle District of Florida	Answered	Rule 26 and Written Discovery
44	Soileau, Nalon A.	U.S. District Court for the Middle District of Louisiana	Rule 12 Not Adjudicated	No Discovery
45	Sullivan, Emma	U.S. District Court for the District of New Jersey	Answered	No Discovery
46	Thomas, Mark on behalf of ZT	U.S. District Court for the Southern District of Florida	Answered	No Discovery
47	Vela, Joselyn	U.S. District Court for the District of Arizona	None	No Discovery
48	Wagner, Sonja	U.S. District Court for the Northern District of Illinois, Eastern Division	Answered	No Discovery
49	Walker, Sahara K.	U.S. District Court for the Western District of Wisconsin	Rule 12 Adjudicated and Answered	Rule 26 and Written Discovery. Plaintiff and mother deposed
50	Wingerter, Hannah R.	U.S. District Court for the Northern District of Georgia	Rule 12 Not Adjudicated	No Discovery

State Court Cases

	Victim/ Plaintiff	Court	Merck Responded?	Discovery
1	Robi, Jennifer	California Superior Court - Los Angeles County - Spring Street Courthouse	Answered	Written Discovery. Plaintiff and parents deposed.
2	Otto, Zachariah C.	California Superior Court - Orange County	Motion to Strike Adjudicated and Answered	Written Discovery
3	Carrillo, Kayla M.	California Superior Court - Orange County	Demurrer Pending	Written Discovery
4	Shain, Hayden M.	California Superior Court - Los Angeles County - Santa Monica Courthouse	Motion to Strike and Demurrer Adjudicated and Answered	Written Discovery
5	Brunker, Merrick	California Superior Court - Ventura County	Motion to Strike and Demurrer Not Adjudicated	Written Discovery
6	Rizi, Rameen Y.	California Superior Court - Los Angeles County - Spring Street Courthouse	Motion to Strike and Demurrer Not Adjudicated	Written Discovery
7	Trevisan, Victoria	California Superior Court - Los Angeles County - Spring Street Courthouse	Complaint not served	No Discovery

Appendix B

Federal and State Court Opinions

Julia Balasco v. Merck, et al.

1:20-cv-00364-MSM-PAS

U.S. District Court for the District of Rhode Island

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION

IN RE: GARDASIL PRODUCTS LIABILITY LITIGATION	**MDL DOCKET NO. 3036 3:22-md-03036-RJC-DCK**

THIS DOCUMENT RELATES TO ALL CASES

APPENDIX B
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Federal Court Case Opinions re Merck's Rule 12 Motions:

Most Recent California state court Opinion re Merck's Motion to Dismiss:

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

JULIA BALASCO, Plaintiff, v. MERCK & CO., INC. and MERCK SHARP & DOHME CORP., Defendants.	C.A. No. 1:20-CV-0364-MSM-PAS

ORDER

Mary S. McElroy, United States District Judge.

The plaintiff, Julia Balasco, filed this action seeking damages for personal injuries that she attributes to the Gardasil vaccine, manufactured and distributed by the defendants, Merck & Co., Inc. and Merck Sharp & Dohme Corp. (collectively "Merck"). The intended purpose of Gardasil was to protect against strains of Human Papillomavirus, commonly known as HPV. The plaintiff was inoculated with Gardasil in 2014 and alleges to have since developed fibromyalgia and autonomic dysfunction. Her Complaint asserts causes of action against Merck for negligence, strict product liability, manufacturing defect, express warranty, common-law fraud, and violation of Rhode Island's Deceptive Trade Practices Act.

Merck has filed a Motion to Dismiss Count VI of the Complaint (ECF No. 9) and a Motion to Strike certain factual allegations from the Complaint (ECF No. 10). The Court now proceeds to decide both Motions.

I. Merck's Motion to Dismiss Count VI

Merck moves pursuant to Fed. R. Civ. P. 12(b)(6) to dismiss Count VI of the plaintiff's Complaint wherein she alleges violations of the Rhode Island Deceptive Trade Practices Act ("DTPA"), R.I.G.L. § 6-13.1-1 *et seq.* Merck correctly asserts, and the plaintiff does not dispute, that the DTPA exempts from coverage activities that are subject to the control of state or federal regulatory bodies. R.I.G.L. § 6-13.1-4. The plaintiff recognizes in her Complaint that the U.S. Food and Drug Administration regulated the Gardasil vaccine. *See* ECF No. 1 ¶¶ 407.

The Court therefore dismisses Count VI.

II. Merck's Motion to Strike Certain Allegations in the Complaint

Pursuant to Fed. R. Civ. P. 12(f), Merck seeks to strike from the plaintiff's Complaint several allegations regarding the arthritis medication Vioxx, a drug previously sold by Merck. In 2004, Merck removed Vioxx from the market due to a connection with cardiovascular complications. Injuries caused by Vioxx resulted in substantial financial losses and litigation for Merck. Merck asserts that references to Vioxx have no relevance in this litigation because the damages the plaintiff claims are not from Vioxx (a drug she never alleges to have ingested) but from Gardasil. Moreover, Merck argues, the allegations concerning Vioxx are intended only to prejudice Merck, shock the reader, and sensationalize the plaintiff's lawsuit through an illusory connection to the Vioxx problems.

The plaintiff argues, however, that the factual background of Vioxx is necessary to demonstrate why Merck allegedly rushed Gardasil to the market with

insufficient safety studies—to earn money to offset the losses from Vioxx. To the plaintiff, Vioxx and Gardasil are two parts of one story.

Rule 12(f) permits a court to "order stricken from any pleading any . . . redundant, immaterial, impertinent, or scandalous matter." *Alvarado-Morales v. Digital Equipment Corp.*, 843 F.2d 613, 618 (1st Cir. 1988). A motion to strike under Rule 12(f) serves "'to avoid the needless expenditures of time and money,' in litigating issues which can be foreseen to have no bearing on the outcome." *Narragansett Tribe of Indians v. So. R.I. Land Development Corp.*, 418 F. Supp. 798, 801 (D.R.I. 1976). Ruling on a motion to strike is committed to the sound discretion of the court; however, "such motions are narrow in scope, disfavored in practice, and not calculated readily to invoke the court's discretion." *Boreri v. Fiat*, 763 F.2d 17, 23 (1st Cir. 1985).

Merck cites several products liability cases from other federal district courts, many of them involving pharmaceutical products, where the courts granted seemingly similar motions to strike.[1] In these cases, the courts struck the plaintiffs' allegations about a defendants' other products or prior bad behavior that was unrelated to the product that gave rise to the lawsuit. A review of those cases, however, reveals no attempt by the plaintiffs to connect the other products or acts to the deficiencies in the product that allegedly caused the plaintiffs' harm. Indeed, the

[1] Merck cites the following: *Simien v. C.R. Bard, Inc.*, 2020 WL 4922331 (E.D. Tex. Aug. 20, 2020); *Fraser v. Wright Med. Tech. Inc.*, 2018 WL 9986673 (S.D. Ill. Dec. 19, 2018); *McKinney v. Bayer Corp.*, 2010 WL 2756915 (N.D. Ohio July 12, 2020); *Johns v. Bayer Corp.*, 2010 WL 2573493 (S.D. Cal. June 24, 2010); *Perez v. ZTE (USA), Inc.*, 2019 WL 1471011 (N.D. Tex. Apr. 2, 2019); *Wood v. Ford Motor Co.*, 2015 WL 5965202 (M.D. Fla. Oct. 13, 2015).

allegations of unrelated matters in those cases were truly "immaterial, impertinent, or scandalous."

This Court cannot make a similar determination here. The plaintiff has alleged a connection between the impact of Vioxx's failure on Merck with the alleged dangers posed by Gardasil. It cannot be held that these allegations are "immaterial, impertinent, or scandalous" under the Rule 12(f) standard. *See Alvarado-Morales*, 843 F.2d at 618.

Merck also cites cases where allegations of prior wrongful behavior, even when used to demonstrate motive or intent, were stricken under Rule 12(f). Yet the allegations in those cases involved matters that, while perhaps similar to the facts giving rise to the litigation, were unconnected to the claims at issue. *See Strassman v. Fresh Choice, Inc.*, 1995 WL 743728, *17 (N.D. Cal. Dec. 7, 1995) (striking allegations that the defendant "participated in similar, yet unrelated, schemes to defraud investors"); *In re Valence Tech. Sec. Litig.*, 1995 WL 274343, *18-19 (N.D. Cal. 1995) (striking "statements insinuating improper conduct by [defendant] in connection with other offerings"). Again, the plaintiff draws a connection between the problems with Vioxx and the alleged dangers of Gardasil. These allegations therefore may stand, at least at this early pleading stage.

Finally, because the Vioxx allegations are not unrelated to the plaintiff's claims, these allegations of otherwise publicly available litigation information are not—for the purposes of pleading—unduly prejudicial to Merck. *See Ross-Simmons*

of Warwick, Inc. v. Baccarat, Inc., 182 F.R.D. 386, 398 (D.R.I. 1998) (recognizing prejudice as a factor on a motion to strike).

III. Conclusion

For the foregoing reasons, Merck's Motion to Dismiss Count VI (ECF No. 9) is GRANTED. Merck's Motion to Strike (ECF No. 10) is DENIED.

IT IS SO ORDERED.

Mary S. McElroy
United States District Judge
April 22, 2021

Michael Colbath v. Merck, et al.

3:21-cv-120-TJW-DEB

U.S. District Court for the Southern District of California

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]

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[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

Savannah Flores v. Merck, et al.

3:21-cv-00166-ART-CLB

U.S. District Court for the District of Nevada

UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

* * *

SAVANNAH FLORES,

Plaintiff,

v.

MERCK & CO., INC., *et al*.,

Defendants.

Case No. 3:21-cv-00166-MMD-CLB

ORDER

I. SUMMARY

Plaintiff Savannah Flores sued Defendants Merck & Company, Inc. and Merck Sharp & Dohme, Corporation (collectively "Merck") for injuries she allegedly suffered after receiving Merck's Gardasil vaccine. (ECF No. 1 at 5.) Before the Court is Merck's motion to dismiss (ECF No. 23 ("Motion"))[1] under Federal Rule of Civil Procedure 12(b)(6).[2] Because Flores failed to plead facially plausible claims and because some of her claims are preempted by the National Childhood Vaccine Injury Act ("Vaccine Act"), and as further explained below, the Court will grant the Motion and will grant Flores leave to amend some of her claims.

II. BACKGROUND

The following allegations are adapted from the Complaint unless noted otherwise. (ECF No. 1.)

[1]Flores filed an opposition to the Motion (ECF No. 27), and Merck filed a reply (ECF No. 29). Flores requested an oral argument but fails to elaborate or provide any reasoning as to why such a hearing is warranted. (ECF Nos. 27, 28.) After reviewing the briefs, the Court finds that an oral argument is unnecessary and declines Flores' request.

[2]The Court declines to take judicial notice of Merck's exhibits in support of its Motion because the Court does not rely on the exhibits, and consideration of the documents is not appropriate at the motion to dismiss stage without converting the Motion to one for summary judgment under Rule 12(d). (ECF No. 24.)

Merck is the "designer, manufacturer, labeler, and promoter" of the Gardasil vaccine. (*Id*. at 6.) Merck represents that the Gardasil vaccine, first approved by the United States Food and Drug Administration ("FDA") in 2006, helps protect against certain strains of the Human Papillomavirus ("HPV") that cause HPV-related cancers, including cervical, vulvar, vaginal, and anal cancer, and also genital warts. (ECF Nos. 1 at 12-13, 23 at 3-4.)

Flores allegedly received her first shot of Gardasil at the age of 14 and her second shot at the age of 15. (ECF No. 1 at 51.) Her mother allegedly consented to Flores receiving the vaccine because Flores' pediatrician, Dr. Stewart Tatum, told them Gardasil was "a safe and effective vaccine for preventing cervical cancer." (*Id*. at 52.) Flores' mother also saw marketing and advertising by Merck that the vaccine was safe. (*Id*. at 51-52.) After receiving the vaccine, Flores began experiencing symptoms, such as fatigue, dizziness, nausea, and increased hair growth on her body. (*Id*. at 52.) Flores has subsequently been diagnosed with "postural orthostatic tachycardia syndrome ("POTS"); orthostatic intolerance ("OI"); autonomic dysfunction; hypoaldosteronism; hirsutism; and chronic migraines," which she attributes to the vaccine. (*Id*. at 53.)

Flores allegedly filed a petition with the United States Court of Federal Claims to receive compensation for her vaccine-related injuries, as required by the National Vaccine Injury Compensation Program. (*Id*. at 54.) *See* 42 U.S.C. § 300aa–11(a)(2)(A). After judgment was rendered around April 10, 2019, Flores filed this lawsuit against Merck. (*Id*.)

In her Complaint, Flores asserts the following claims against Merck: (1) negligence, (2) strict liability failure to warn, (3) strict liability manufacturing defect, (4) breach of express warranty, and (5) common law fraud. (*Id*. at 55-72.) Merck now seeks dismissal of the claims. (ECF No. 23.)

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III. LEGAL STANDARD

A court may dismiss a plaintiff's complaint for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). A properly pleaded complaint must provide "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). While Rule 8 does not require detailed factual allegations, it demands more than "labels and conclusions" or a "formulaic recitation of the elements of a cause of action." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 555). "Factual allegations must be enough to rise above the speculative level." *Twombly*, 550 U.S. at 555. Thus, to survive a motion to dismiss, a complaint must contain sufficient factual matter to "state a claim to relief that is plausible on its face." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570).

In *Iqbal*, the Supreme Court of the United States clarified the two-step approach district courts are to apply when considering motions to dismiss. First, a district court must accept as true all well-pleaded factual allegations in the complaint; however, legal conclusions are not entitled to the assumption of truth. *See Iqbal*, 556 U.S. at 678. Mere recitals of the elements of a cause of action, supported only by conclusory statements, do not suffice. *See id.* Second, a district court must consider whether the factual allegations in the complaint allege a plausible claim for relief. *See id.* at 679. A claim is facially plausible when the plaintiff's complaint alleges facts that allow a court to draw a reasonable inference that the defendant is liable for the alleged misconduct. *See id.* at 678.

Where the complaint does not permit the Court to infer more than the mere possibility of misconduct, the complaint has "alleged—but it has not show[n]—that the pleader is entitled to relief." *Id*. at 679 (alteration in original) (quotation marks and citation omitted). That is insufficient. When the claims in a complaint have not crossed the line from conceivable to plausible, the complaint must be dismissed. *See Twombly*, 550 U.S. at 570. Dismissal of a complaint without leave to amend is only proper when it

is clear the complaint could not be saved by any amendment. *Ariz. Students' Ass'n v. Ariz. Bd. of Regents*, 824 F.3d 858, 871 (9th Cir. 2016); *see also* Fed. R. Civ. P. 15(a)(2) (instructing district courts to "freely give leave" to amend).

IV. DISCUSSION

Merck argues that the Court should dismiss all of Flores' claims because they are either insufficiently pled, preempted and barred by the Vaccine Act, and/or barred by the learned intermediary doctrine. (ECF No. 23 at 2.) The Court agrees, but finds that some of Flores' claims may be cured by amendment. The Court first addresses Flores' negligence, failure to warn, and breach of express warranty claims, which it finds are partially preempted by the Vaccine Act and/or barred by the learned intermediary doctrine. The Court then examines Flores' manufacturing defect and fraud claims, which it finds are insufficiently pled. For the reasons stated below, the Court will grant Merck's Motion.

A. Preemption for Negligence Claim

To start, part of Flores' negligence claim is preempted and barred by the Vaccine Act. Merck argues, in part, that dismissal is proper because Flores' negligence is a "poorly disguised" design-defect claim, which is preempted by the Vaccine Act. (*Id*. at 6.) Flores counters, in part, that none of her five claims have a design defect title, and her allegations merely "support traditional claims" for negligence. (ECF No. 27 at 8-9.) The Court agrees with Merck.

The Vaccine Act expressly provides that "[n]o 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." *See* 42 U.S.C. § 300aa–22(b)(1). In interpreting this statutory text, the United States Supreme Court held that the Vaccine Act "pre-empts all design-defect claims against vaccine

manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects." *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 243 (2011).

Accepting Flores' allegations as true, she appears to allege, in parts of her negligence claim, that the design of Gardasil is defective or inherently flawed, which is essentially a design defect claim. (ECF No. 1 at 23-26, 55-61.) For instance, Flores contends that Merck was negligent because it "had a duty to exercise reasonable care in the design" of Gardasil, and Merck breached its duty by failing to exercise ordinary care in the "development" of Gardasil. (*Id*. at 55-56.) She also suggests that existing ingredients in Gardasil were toxic or unsafe. (*Id*. at 57.) To the extent Flores' negligence claim[3] is premised on Gardasil's design defects, it is preempted by the Vaccine Act and barred. *See* 42 U.S.C. § 300aa–22(b)(1); *Bruesewitz*, 562 U.S. at 243. The Court therefore dismisses with prejudice, the part of Flores' negligence claim that is predicated on Gardasil's design defects.

Next, the remaining parts of Flores' negligence claim do not comply with Federal Rule of Civil Procedure 8(a) because they are unclear and appear to aggregate several distinct theories of liability. Rule 8(a) requires that pleadings contain "a short and plain statement of the claim showing that the pleader is entitled to relief[.]" Rule 8(a)'s pleading requirements can be violated not only "when a pleading says too little," but also "when a pleading says too much." *Knapp v. Hogan*, 738 F.3d 1106, 1109 (9th Cir. 2013), *cert. denied*, 574 U.S. 815 (2014); *see also McHenry v. Renne*, 84 F.3d 1172, 1179-80 (9th Cir.1996) (affirming a dismissal under Rule 8, and recognizing that "[p]rolix, confusing complaints such as the ones plaintiffs filed in this case impose unfair burdens on litigants and judges").

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[3]While the design-defect allegations are most prevalent in Flores' negligence claim, the Court notes similar language in her failure to warn claim and other parts of the Complaint. For instance, in her failure to warn claim, Flores contends that Merck had a duty to properly "design" its vaccine to ensure that Gardasil "did not cause users and consumers to suffer from unreasonable and dangerous risks." (ECF No. 1 at 62.) To the extent her failure to warn claim or any other claims are predicated on Gardasil's design defects, those parts are dismissed with prejudice for the reasons stated above. The Court cautions Flores against the inclusion of design-defect allegations in future pleadings.

Here, Flores' negligence claim is lengthy, difficult to follow, and replete with run-on sentences. (ECF No. 1 at 55-61.) Flores includes a superfluous number of allegations, including but not limited to, Merck's purported failure to exercise reasonable care in the "design, research, manufacture, marketing, advertisement, supply, promotion, packaging, sale, and distribution of Gardasil," flaws in Merck's clinical trials, Merk's failure to warn parents of Gardasil's defects, failure to adequately test the efficacy and safety of Gardasil, concealment of information, false advertising and "disease mongering," and failure to disclose ingredients. (*Id*.) The section's unnecessary lengthiness and Flores' aggregation of claims, some of which are unrelated to her specific injuries in this case, clearly ignore Rule 8(a)'s requirement of a "short and plain statement." *See Knapp*, 738 F.3d at 1109; *McHenry*, 84 F.3d at 1179-80. The Court therefore dismisses the remaining parts of Flores' negligence claim without prejudice, and with leave to amend.[4]

B. Preemption for Failure to Warn Claims

The Court first addresses the partial preemption of Flores' strict liability failure to warn claim by the Vaccine Act, and then examines the partial preemption of Flores' breach of express warranty claim. The Court will also address the partial barring of both claims by the learned intermediary doctrine under Nevada law.

1. Strict Liability Failure to Warn

Flores' strict liability failure to warn claim is partially preempted and barred. Merck argues that the Vaccine Act and the learned intermediary doctrine foreclose "any theory of liability premised on Merck's alleged failure to warn" Flores and her mother. (ECF No. 23 at 10.) Flores counters that Merck still "had a duty to provide accurate information in [its] advertisements" because Merck "engaged in direct-to-consumer advertising." (ECF No. 27 at 13.) The Court agrees with Merck.

[4]Although Rule 8(a) violations were most pervasive in Flores' negligence claim, the Court notes similar issues throughout Flores' 79-page Complaint. (ECF No. 1.) The Court cautions Flores to abide by Rule 8's requirements in future pleadings or her claims may be subject to dismissal.

Flores' failure to warn claim is premised on Merck's failure to disclose Gardasil's risks and "lack of efficacy" to Flores, Flores' mother, *and* Flores' medical providers. (ECF No. 1 at 62-66.) First, Merck's alleged failure to warn Flores and her mother is preempted by the Vaccine Act, which explicitly provides that "[n]o 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) . . ." *See* 42 U.S.C. § 300aa–22(c). The Ninth Circuit also emphasized that the Vaccine Act "eliminat[es] [manufacturer] liability for not providing direct warnings to a claimant," and explicitly held that the Act preempts all "failure to warn claims arising out of a vaccine-related injury or death, not just those that could have first been brought in the Vaccine Court." *Holmes v. Merck & Co., Inc.*, 697 F.3d 1080, 1083, 1087 (9th Cir. 2012) (emphasis added). In light of the aforementioned statutory language and the Ninth Circuit's clear holding in *Holmes*, the Court will dismiss with prejudice the part of Flores' claim that is premised on Merck's failure to warn Flores and her mother.[5] *See id*.

Second, even if the Vaccine Act did not partially preempt Flores' failure to warn claim, the claim would still be partially barred by the learned intermediary doctrine under Nevada law. The learned intermediary doctrine traditionally immunizes drug manufacturers from liability "to a patient taking the manufacturer's drug so long as the manufacturer has provided the patient's doctor with all relevant safety information for that drug" and shifts the responsibility to the patient's doctor to "convey to the patient any information that the doctor deems relevant." *Klasch v. Walgreen Co.*, 264 P.3d 1155, 1158 (Nev. 2011) (en banc) (citation omitted).

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[5]In her response, Flores appears to argue that Merck still had a duty to warn her and her mother because the company engaged in direct-to-consumer advertising. (ECF No. 27 at 13.) However, the Court is unpersuaded because the express statutory language of the Vaccine Act and prior holdings by the Ninth Circuit and the Nevada Supreme Court do not support this exception under the Vaccine Act and/or Nevada's learned intermediary doctrine. *See* 42 U.S.C. § 300aa–22(c); *Holmes*, 697 F.3d at 1083, 1087; *Klasch*, 264 P.3d at 1158.

The Nevada Supreme Court previously adopted the learned intermediary doctrine in the context of a pharmacist and customers, where it held that pharmacists do not have a "duty to warn of a prescribed medication's generalized risks." *Id*. at 1157-58. Since *Klasch*, judges in this district have extended the doctrine to drug and medical device manufacturers. *See Phillips v. C.R. Bard, Inc*., Case No. 3:12-cv-00344-RCJ-WGC, 2014 WL 7177256, at *9 (D. Nev. Dec. 16, 2014); *Flowers v. Eli Lilly & Co*., Case No. 3:14-cv-00094-LRH-VPC, 2015 WL 12622058, at *2-*3 (D. Nev. July 10, 2015); *Heinrich v. Ethicon, Inc.*, 455 F. Supp. 3d 968, 974 (D. Nev. 2020). Consistent with the reasoning in *Klasch*, where "the doctor is in the best position to warn the customer of a given medication's generalized risks," this Court predicts that the Nevada Supreme Court would likewise extend the learned intermediary doctrine to vaccine manufacturers. *See* 264 P.3d at 1159. Merck therefore does not have a duty to warn Flores and her mother of the generalized risks associated with Gardasil, and this part of Flores' claim is dismissed with prejudice.

Finally, Flores' remaining allegation that Merck failed to warn her medical providers is insufficiently pled. (ECF Nos. 1 at 62-66, 27 at 13.) To prevail on a strict liability claim, the plaintiff must demonstrate "(1) the product had a defect which rendered it unreasonably dangerous, (2) the defect existed at the time the product left the manufacturer, and (3) the defect caused the plaintiff's injury." *Fyssakis v. Knight Equip. Corp.*, 826 P.2d 570, 571 (Nev. 1992) (citation omitted). Product warnings must "adequately communicate any dangers that may flow from the use or foreseeable misuse of a product." *Yamaha Motor Co., U.S.A. v. Arnoult*, 955 P.2d 661, 665 (Nev. 1998) (citation omitted). "Strict liability may be imposed even where the product is faultlessly made, if it was unreasonably dangerous to place the product in the hands of the consumer without adequate warnings concerning its safe and proper use." *Id.* (citation omitted).

Here, Flores broadly alleges that Merck failed to warn "medical providers" of Gardasil's "dangerous propensities" and true risks. (ECF Nos. 1 at 62-63, 27 at 13.) To

start, it is unclear from the Complaint which medical provider Merck failed to warn—whether it was Dr. Tatum, the physician who recommended Gardasil to Flores, or another medical professional.[6] (ECF No. 1 at 62-66.) Next, Flores' allegations are conclusory and do not yield a facially plausible claim. *See Iqbal*, 556 U.S. at 678. She suggests that Merck knew about Gardasil's "dangerous propensities" and its "carcinogenic characteristics and autoimmune-inducing characteristics," but failed to warn medical providers. (ECF No. 1 at 63.) However, Flores fails to clarify what these characteristics were, and which risks were and were not conveyed to Flores' doctor, specifically. (*Id*.) Finally, Flores' failure to warn claim is excessively long, difficult to follow, and fails to comply with Rule 8(a) requirements. (*Id*.) *See Knapp*, 738 F.3d at 1109; *McHenry*, 84 F.3d at 1179-80. The Court therefore dismisses without prejudice, the part of Flores' claim that is premised on Merck's failure to warn her medical providers, and grants Flores leave to amend.

2. Breach of Express Warranty

Because Flores' breach of express warranty claim is a veiled failure to warn claim, the Court will also dismiss it. Flores alleges that Merck's express representations about Gardasil "included incomplete warnings and instructions," and Merck failed to warn of all the risks associated with Gardasil. (ECF No. 1 at 68-71.) The core allegations and language in Flores' breach of warranty and failure to warn claims are almost identical. (*Id*. at 62-71.) Because Flores' warranty claim is a veiled failure to warn claim, Merck's representations and statements to Flores' mother would be preempted by the Vaccine Act. *See Holmes*, 697 F.3d at 1083, 1087. Even if preemption did not apply, this part of her claim would still be barred by the learned intermediary doctrine. *See Klasch*, 264 P.3d at 1158.

Notably, Flores does not deny that part of her warranty claim may be foreclosed by the learned intermediary doctrine. (ECF No. 27 at 16.) She, instead, argues that her

[6]In her response, Flores alleges that Merck failed to warn her doctor, but fails to clarify who this doctor was. (ECF No. 27 at 13.)

claim is "not predicated solely on Merck's warranties to [her] mother" but also on Merck's warranties to the medical community. (*Id*.) The Court therefore dismisses with prejudice the part of her breach of warranty claim that is predicated on Merck's representations to her mother because it is barred by the Vaccine Act and the learned intermediary doctrine. *See Carter v. Ethicon, Inc.*, Case No. 2:20-cv-1232-KJD-VCF, 2021 WL 1226531, at *4 (D. Nev. Mar. 31, 2021) (granting summary judgment because the plaintiffs' "fraud-based claims and warranty claims are simply repackaged failure-to-warn claims").

Next, Flores fails to state a facially plausible claim for Merck's alleged breach of express warranty to her medical providers. First, Flores vaguely alleges that Merck made misrepresentations to her medical providers and the medical community, but fails to specify which providers Merck made the warranties to. (ECF No. 1 at 68-71.) Such bare allegations and lack of information violate Rule 8's notice requirements. *See Iqbal*, 556 U.S. at 678.

Second, Flores fails to substantiate how Merck's representations became part of the basis of the bargain—an element of breach of express warranty claims. *See* NRS § 104.2313(1) (providing that express warranties are created by "(a) [a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain . . . [or] (b) [a]ny description of the goods which is made part of the basis of the bargain . . ."); *see also Radcliff v. Amiraslanov*, 381 P.3d 653 (Nev. 2012). Instead, Flores makes conclusory allegations and refers to the fact that her mother would not have consented had she been adequately informed. (ECF No. 1 at 70-71.) But Flores fails to provide any facts that elucidate the agreement between Merck and her doctor. (*Id*. at 68-71.) Dismissal of this part of Flores' claim is therefore warranted because she fails to plead facts to support all elements of the claim.

Moreover, Nevada statutes suggest that, prior to bringing a breach of warranty claim, the plaintiff must first provide the defendant with some type of pre-suit notice. *See* NRS § 104.2607(3)(a) (providing that "[t]he buyer must within a reasonable time after

the buyer discovers or should have discovered any breach notify the seller of breach or be barred from any remedy"); *see also Banh v. Am. Honda Motor Co., Inc.*, Case No. 2:19-cv-05984-RGK-AS, 2019 WL 8683361, at *11 (C.D. Cal. Dec. 17, 2019); *Heath v. Tristar Prods., Inc.*, Case No. 2:17-cv-2869-GMN-BNW, 2019 WL 4738004, at *8 (D. Nev. Sept. 27, 2019). Flores has not alleged that she provided Merck with pre-suit notice, and the plain language of the statute does not provide for an exception where there is a lack of privity between the parties. (ECF Nos. 1 at 68-71, 27 at 17, 29 at 8.) *See* NRS § 104.2607(3)(a). The Court therefore dismisses Flores' breach of express warranty claim, as to her medical providers, without prejudice and with leave to amend.

C. Strict Liability Manufacturing Defect

Flores has not sufficiently pled her strict liability manufacturing defect claim. Merck argues that dismissal is proper because Flores fails to allege that the vaccine dosage she received deviated from manufacturing standards. (ECF No. 23 at 8-9.) The Court agrees with Merck.

In Nevada, the consumer-expectation test is used to determine liability for a manufacturing defect claim.[7] *See Ford Motor Co. v. Trejo*, 402 P.3d 649, 653 (Nev. 2017) (citations omitted). Under this test, the plaintiff must show the product "failed to perform in the manner reasonably to be expected in light of its nature and intended function and was more dangerous than would be contemplated by the ordinary user having the ordinary knowledge available in the community." *Id*. at 652 (citing *Ginnis v. Mapes Hotel Corp*., 470 P.2d 135, 138 (Nev. 1970)). However, "proof of an unexpected, dangerous malfunction may suffice to establish a prima facie case for the plaintiff of the existence of a product defect." *Stackiewicz v. Nissan Motor Corp. in U.S.A*., 686 P.2d 925, 928 (Nev. 1984).

Flores alleges that the Gardasil vaccine she received was "defective and unreasonably dangerous" because it contained undisclosed toxins like phenylmethylsulfonyl fluoride (PMSF) and HPV L1-DNA fragments, which does not

[7]The Court incorporates by reference the strict liability legal standard described in Section B.1.

comply with governing manufacturing protocol. (ECF No. 1 at 66-67.) However, Flores also suggests in her Complaint that certain "toxins" were already present in Gardasil, as approved by the FDA. (*Id*. at 23-26.) To the extent Flores' claim takes issue with Gardasil's intended design or *approved* vaccine components, her claim would be preempted and barred by the Vaccine Act, as explained above. *See* 42 U.S.C. § 300aa–22(b)(1); *Bruesewitz*, 562 U.S. at 243.

To the extent Flores is alleging that her Gardasil shots *deviated* from the approved or intended vaccine design, she has failed to allege a plausible claim. (ECF No. 1 at 66-68.) Flores contends that her Gardasil shots violated manufacturing specifications, but then puzzlingly states that the Gardasil products she received did not have a "substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Merck." (ECF Nos. 1 at 67, 23 at 8.) This significant contradiction does not yield a facially plausible manufacturing defect claim. *See Iqbal*, 556 U.S. at 678. Because Flores fails to allege the vaccine that she received was more dangerous than contemplated by an ordinary user, or that her specific shots deviated from Gardasil's approved design, the Court dismisses her claim without prejudice and with leave to amend. *See Ford Motor Co.*, 402 P.3d at 653; *Stackiewicz*, 686 P.2d at 928.

D. Fraud

Finally, Flores fails to meet the heightened pleading standard for fraud claims under Rule 9(b). Merck argues, in part, that dismissal is appropriate because Flores' fraud allegations are too vague, and she fails to plead with particularity. (ECF No. 23 at 15-16.) Flores counters, in part, that her allegations satisfied the elements for fraud under Nevada law and she "identif[ied] the circumstances constituting fraud so that Merck can prepare an adequate answer." (ECF No. 27 at 18-20.) The Court agrees with Merck.

Rule 9(b) provides that when a party alleges fraud, the party must "state with particularity the circumstances constituting fraud." The party must include the "the who,

what, when, where, and how of the misconduct charged." *Becerra v. Dr. Pepper/Seven Up, Inc.*, 945 F.3d 1225, 1228 (9th Cir. 2019) (citation omitted); *see also Depot, Inc. v. Caring for Montanans, Inc*., 915 F.3d 643, 668 (9th Cir. 2019) (noting that "the complaint must include an account of the time, place, and specific content of the false representations as well as the identities of the parties to the misrepresentations") (citations and quotation marks omitted).

Accepting Flores' allegations as true, she first contends that Merck "duped" her mother into believing Gardasil was safe and effective. (ECF No. 1 at 75.) She alleges that Merck misrepresented to her mother, through advertisements like the "One Less" campaign, that Gardasil can prevent cancer, and only had minor risks—while failing to disclose Gardasil's chronic and debilitating effects. (*Id*. at 73.) However, Flores fails to provide specific details[8] regarding exactly *when* her mother saw those advertisements and was exposed to Merck's alleged misrepresentations, as required by Rule 9(b). (*Id*. at 72-77.) *See Becerra*, 945 F.3d at 1228; *Depot*, 915 F.3d at 668.

Flores also makes broader allegations that Merck engaged in other fraudulent conduct that caused medical providers, regulators, and the general public to believe that Gardasil was safe and effective. (ECF No. 1 at 75.) These allegations stray even further from Rule 9(b)'s specificity requirements. Flores fails to clarify *who* these parties were, *when* and *where* these fraudulent activities occurred, and *what* was specifically misrepresented to these parties. (*Id*. at 75-76.) *See Becerra*, 945 F.3d at 1228; *Depot*, 915 F.3d at 668. Instead, Flores vaguely lists a series of allegations from the first 50 pages of her Complaint regarding general issues with Merck's clinical trials, the placebo used, and vaccine ingredients. (*Id*.) Flores therefore fails to meet the heightened

[8]In her response, Flores seems to suggest that dismissal is improper because she provided sufficient facts to support the elements for fraud under Nevada law. (ECF No. 27 at 18-19.) Even if this was true, dismissal is still warranted because Flores must follow federal procedural law when pleading her fraud claim under diversity jurisdiction. *See Sonner v. Premier Nutrition Corp.*, 971 F.3d 834, 839 (9th Cir. 2020) (noting that "[u]nder the doctrine first prescribed in *Erie* . . . federal courts exercising diversity jurisdiction must follow state substantive law and federal procedural law when adjudicating state law claims") (citation omitted).

pleading standard under Rule 9(b), and the Court dismisses her fraud claim without prejudice and with leave to amend.[9]

V. CONCLUSION

The Court notes that the parties made several arguments and cited to several cases not discussed above. The Court has reviewed these arguments and cases and determines that they do not warrant discussion as they do not affect the outcome of the issues before the Court.

It is therefore ordered that Merck's motion to dismiss (ECF No. 23) is granted.

Flores' negligence claim, to the extent it is predicated on any design defects of the Gardasil vaccine, is dismissed with prejudice; the remainder of her negligence claim is dismissed without prejudice and with leave to amend.

Flores' strict liability failure to warn claim, to the extent it is predicated on Merck's failure to warn her and her mother, is dismissed with prejudice; and to the extent it is predicated on Merck's failure to warn her physician, is dismissed without prejudice and with leave to amend.

Flores' breach of express warranty claim, to the extent it is predicated on Merck's warranties to her mother, is dismissed with prejudice; and to the extent it is predicated on Merck's warranties to her physician, is dismissed without prejudice and with leave to amend.

Flores' strict liability manufacturing defect claim and fraud claim are dismissed without prejudice and with leave to amend.

It is further ordered that, if Flores decides to file an amended Complaint—to the extent she is able to cure the deficiencies discussed herein—she must do so within 30

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[9]As stated above, the Court notes that Flores' fraud claim is excessively lengthy. (ECF No. 1 at 72-77.) The Court cautions Flores to comply with Rule 8(a) requirements and exclude unnecessary details in future pleadings to avoid dismissal.

days of the date of entry of this order. Flores' failure to file an amended Complaint within 30 days will result in dismissal of the remaining part of her claims with prejudice.

DATED THIS 16th Day of March 2022.

MIRANDA M. DU
CHIEF UNITED STATES DISTRICT JUDGE

Jasmyne Gramza v. Merck, et al.

2:20-cv-01425-DLR

U.S. District Court for the District of Arizona

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

Jasmyne Gramza,

Plaintiff,

v.

Merck & Company Incorporated, et al.,

Defendants.

No. CV-20-01425-PHX-DLR

ORDER

This is a products liability personal injury case in which Plaintiff Jazmyne Gramza alleges she sustained injuries from the Gardasil vaccine, manufactured by Defendant Merck. Although this case is about Gardasil, Gramza's complaint includes a number of allegations about a different Merck product—a pain medication called Vioxx—that Gramza never consumed, and which Merck removed from the market in 2004. Merck moves to strike the allegations in the complaint related to Vioxx. (Doc. 13.)

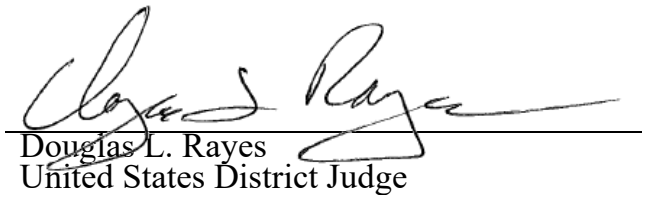
The Court "may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). "The rationale behind granting motions to strike is to 'avoid . . . prejudice to a party by preventing a jury from seeing the offensive matter or giving the allegation any unnecessary notoriety.'" *In re Valence Tech. Sec. Litig.*, No. C 94-1542-SC, 1995 WL 274343, at *18 (N.D. Cal. May 8, 1995) (quoting 5A Charles A. Wright and Arthur R. Miller, Federal Practice and Procedure § 1382, at 715 (2d ed. 1990)). "A matter is immaterial or impertinent when it is not relevant to the resolution of the issue at hand," and "[a] pleading or portion thereof

qualifies as 'scandalous' for the purposes of Rule 12(f) when it generally refers to any allegation that unnecessarily reflects on the moral character of an individual or states anything in repulsive language that detracts from the dignity of the court." *Judicial Watch, Inc. v. U.S. Dept. of Commerce*, 224 F.R.D. 261, 263 (D.D.C. 2004) (quotations and citations omitted).

Gramza contends that the Vioxx allegations provide historical context and describe prior bad acts that are probative of Merck's motive or intent for rushing Gardasil through the approval process. (Doc. 18.) Under the Federal Rules of Civil Procedure, however, a complaint need only contain a "short and plain statement of the claim showing that the pleader is entitled to relief," Fed. R. Civ. P. 8(a)(2), and pleading specific evidence generally is disfavored, especially when prejudicial, *see In re Valence*, 1995 WL 274343, at *19. Indeed, the Federal Rules explicitly permit "[m]alice, intent, knowledge, and other conditions of a person's mind" to be "alleged generally." Fed. R. Civ. P. 9(b). It therefore is unnecessary to include detailed allegations of prior bad acts in order to plausibly allege a defendant's motive or intent, which at the pleading stage "serve only to inflame the passions of the reader and prejudice the defendant." *See Strassman v. Fresh Choice*, Inc., No. C-95-20017 RPA, 1995 WL 743728, at *17 (N.D. Cal. Dec. 7, 1995). Absent a meritorious evidentiary objection, Gramza may, of course, "bring forth specific evidence of motive and intent at the summary judgment stage," but there is "no reason why such prejudicial evidence should be inserted at the pleading stage." *In re Valence*, 1995 WL 274343, at *19. This is especially true when Gramza's claims have nothing to do with injuries from consuming Vioxx.

IT IS ORDERED that Merck's motion to strike (Doc. 13) is **GRANTED**. Paragraphs 15-26, 53, H, and 358 concerning Vioxx are stricken from the complaint.

Dated this 22nd day of November, 2021.



Douglas L. Rayes
United States District Judge

Korrine Herlth v. Merck, et al.

3:21-cv-000438-JAM

U.S. District Court for the District of Connecticut

UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

KORRINE HERLTH,
Plaintiff,

v.

MERCK & CO., INC. *et al.*,
Defendants.

No. 3:21-cv-438 (JAM)

ORDER GRANTING MOTION TO DISMISS

Plaintiff Korrine Herlth alleges that she was injured after receiving two doses of the Gardasil vaccine. Herlth now brings a variety of product liability claims against the vaccine's manufacturers, Merck & Co., Inc., and Merck Sharp & Dohme Corp. (collectively, "Merck"). Merck has moved to dismiss her amended complaint. For the reasons set forth below, I will grant the motion to dismiss without prejudice.

BACKGROUND

I accept the following facts as true for purposes of considering Merck's motion to dismiss. After first receiving approval by the Food and Drug Administration ("FDA") in 2006, Merck has marketed versions of its Gardasil vaccine as a safe and effective means of preventing infection by the Human Papillomavirus ("HPV").[1] HPV is a viral infection and sexually transmitted disease that is believed to be associated with cervical and other cancers.[2] Since around that same time, the Centers for Disease Control and Prevention ("CDC") has recommended that nearly all children and young adults receive the Gardasil vaccine.[3] Gardasil is

[1] Doc. #18 at 12–13 (¶¶ 46–47, 49).
[2] *Id.* at 10 (¶¶ 31–32, 34).
[3] *Id.* at 12 (¶ 46).

currently approved for men and women between the ages of 9 and 45 years old, although Merck markets the vaccine primarily to pre-teen children and their parents.[4]

Herlth was 15 years old when her pediatrician, Dr. Allison Whitaker, recommended that she receive the Gardasil vaccine.[5] With the consent of Herlth's mother, Dr. Whitaker administered Herlth's first dose of Gardasil on October 2, 2013, during a routine visit to the pediatrician's office.[6]

Before the doctor's visit, Herlth's mother had seen television ads and other marketing regarding the safety and efficacy of the Gardasil vaccine.[7] Herlth alleges that her mother relied upon those marketing materials in choosing to have her vaccinated with Gardasil.[8]

Before receiving the vaccine, Herlth was in overall good health.[9] She was a vocational agriculture student and excelled in her studies.[10] She traveled with the school choir for performances, and she enjoyed being outdoors and taking care of farm animals.[11]

But after receiving her second dose of Gardasil in December 2013, Herlth began experiencing dizziness, shakiness, headaches, and nausea. She also experienced faintness, an elevated heartrate, and unsteadiness upon standing.[12] Based on her daughter's developing symptoms, Herlth's mother withdrew her consent, and Herlth did not receive her third dose of Gardasil.[13]

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[4] *Id.* at 13 (¶ 49).
[5] *Id.* at 51 (¶¶ 348, 350).
[6] *Id.* at 51–52 (¶ 350).
[7] *Id.* at 51–52, 71–72, 74–75 (¶¶ 349–50, 429, 442, 446, 449).
[8] *Id.* at 17, 51, 76, 78 (¶¶ 83, 349, 453–54, 457).
[9] *Id.* at 52 (¶ 351).
[10] *Ibid.*
[11] *Ibid.*
[12] *Ibid.* (¶ 352).
[13] *Ibid.* (¶ 353).

Over the following months, Herlth's health worsened. She was seen by multiple physicians for a variety of severe symptoms, including: daily seizures; vision, hearing, and balance problems; fatigue; anxiety and panic attacks; convulsions; sleep problems; depression; cognitive difficulties; numbness and tingling in her lower extremities; involuntary movements and tics; weakened connective tissue and chronic joint pain; and vaginismus and endometriosis.[14] Due to her health, Herlth opted out of normal teenage activities. She pulled back from participation in school and choir, and eventually, she was forced to finish high school from home and put off attending college altogether.[15]

Based upon her post-Gardasil symptoms and the results of several tests, Herlth has been diagnosed with a variety of severe medical conditions, including Postural Orthostatic Tachycardia Syndrome ("POTS") and chronic fatigue syndrome ("CFS").[16] POTS is a condition that affects the autonomic nervous system, which is responsible for automatically regulating vital bodily functions. POTS affects the body's ability to adjust the heartrate and compensate for blood flow, especially when the individual moves from a lying to standing position.[17] Individuals with POTS frequently experience dizziness, lightheadedness, vertigo, chronic headaches, vision issues due to the loss of blood flow to the brain, light and sound sensitivity, loss of consciousness, shortness of breath, chest pain, gastrointestinal issues, body pains, insomnia, and confusion and/or difficulty sleeping.[18] Researchers have allegedly linked POTS, CFS, and a variety of other autoimmune diseases to the Gardasil vaccine.[19]

[14] *Ibid.* (¶ 354).
[15] *Ibid.* (¶ 355).
[16] *Id.* at 53 (¶ 357).
[17] *Id.* at 40 (¶ 274).
[18] *Ibid.*
[19] *Id.* at 38, 40, 53 (¶¶ 262–64, 276, 357).

On January 13, 2016, Herlth filed a petition for compensation in the Office of the Special Masters of the U.S. Court of Federal Claims (sometimes called "Vaccine Court").[20] Under the National Childhood Vaccine Injury Act ("Vaccine Act"), 42 U.S.C. § 300aa-10 *et seq.*, an individual seeking compensation for an alleged vaccine-related injury must begin by filing a petition in Vaccine Court. *Id.* at § 300aa-11. If the injured party receives an unfavorable outcome, only then may she file a civil action against the vaccine manufacturer. *Id.* at § 300aa-21. On July 2, 2020, the Vaccine Court dismissed Herlth's claim for "insufficient proof." *Herlth v. Sec'y of Health & Hum. Servs.*, 2020 WL 4280698, at *2 (Fed. Cl. 2020).

On March 30, 2021, Herlth filed this federal lawsuit. Count One of her amended complaint alleges violations of the Connecticut Product Liability Act ("CPLA"), Conn. Gen. Stat. § 52-572m *et seq*. Gathered under her CPLA claim are a variety subclaims, including for failure to warn, manufacturing defect, and negligence.[21] Count Two is a claim for common law fraud. Merck now moves to dismiss the amended complaint for failure to state a claim under Rule 12(b)(6) of the Federal Rules of Civil Procedure.[22]

DISCUSSION

The standard that governs a motion to dismiss under Rule 12(b)(6) is well established. A complaint may not survive unless it alleges facts that, taken as true, give rise to plausible grounds to sustain a plaintiff's claims for relief. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Kim v. Kimm*, 884 F.3d 98, 103 (2d Cir. 2018). As the Supreme Court has explained, this "plausibility" requirement is "not akin to a probability requirement," but it "asks for more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 556 U.S. at 678. In other words, a valid

[20] *Id.* at 55 (¶ 361); *see also Herlth v. Sec'y of Health & Hum. Servs.*, 2020 WL 4280698 (Fed Cl. 2020).
[21] In her opposition to Merck's motion to dismiss, Herlth agreed to dismiss her CPLA subclaim for breach of express warranty. *See* Doc. #24 at 24 n.5.
[22] Doc. #20.

claim for relief must cross "the line between possibility and plausibility." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 557 (2007). A court must "accept as true all factual allegations and draw from them all reasonable inferences; but [it is] not required to credit conclusory allegations or legal conclusions couched as factual allegations." *Hernandez v. United States*, 939 F.3d 191, 198 (2d Cir. 2019).[23]

Count One – Connecticut Product Liability Act (CPLA)

Count One of the amended complaint alleges three subclaims for liability under the CPLA: (1) failure to warn, (2) manufacturing defect, and (3) negligence. I will address each subclaim in turn.

Failure to warn

Merck argues that Herlth's failure-to-warn claim as presently pleaded in the amended complaint is preempted by the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. § 301 *et seq*. I agree.

Under Connecticut law, manufacturers of products have a duty to ensure that their products are accompanied by adequate warnings or instructions. *See* Conn. Gen. Stat. § 52-572q(a); *LaMontagne v. E.I. DuPont De Nemours & Co., Inc.*, 41 F.3d 846, 859 (2d Cir. 1994). At the same time, the FDCA strictly regulates the labeling of all pharmaceuticals. *See* 21 U.S.C. § 301 *et seq.*; *Wyeth v. Levine*, 555 U.S. 555, 566–68 (2009). Before the FDA will approve the marketing of a new vaccine or other drug, the manufacturer must submit and the FDA must approve the exact text of the proposed label. *See* 21 U.S.C. § 355(b)(1)(A)(vi); *Wyeth*, 555 U.S. at 568; *Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699, 707 (2d Cir. 2019).

[23] Unless otherwise indicated, this opinion omits internal quotation marks, alterations, citations, and footnotes in text quoted from court decisions.

Generally speaking, a manufacturer may only change a vaccine label after the FDA approves a supplemental application. *See* 21 C.F.R. § 601.12(f)(1); *Wyeth*, 555 U.S. at 568. The exception to this rule is when a manufacturer may unilaterally modify its label through compliance with the "changes being effected" ("CBE") regulation. *See Gibbons*, 919 F.3d at 707. The CBE regulation allows a manufacturer to change its label without the FDA's preapproval if the changes "reflect newly acquired information" concerning contraindications, warnings, precautions, possible adverse reactions, or proper dosage and administration. *See* 21 C.F.R. § 601.12(f)(2)(i).[24]

A state law failure-to-warn claim against a drug manufacturer is preempted unless the drug manufacturer can simultaneously comply with its state law duty to warn *and* with federal labeling requirements under the FDCA. *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618–19 (2011). Because Merck secured FDA approval of its label in the first instance, Herlth's failure-to-warn claim is therefore preempted by federal law unless she has pleaded a labeling deficiency that Merck could have unilaterally corrected in accordance with the requirements of the CBE regulation. *See Gibbons*, 919 F.3d at 708; *Ignacuinos v. Boehringer Ingelheim Pharms. Inc.*, 490 F. Supp. 3d 533, 541 (D. Conn. 2020), *aff'd*, 8 F.4th 98 (2d Cir. 2021).

Under the terms of the CBE regulation, a manufacturer may unilaterally change its label only if it has "newly acquired information." 21 C.F.R. § 601.12(f)(2)(i). Any "information will be considered newly acquired if it consists of data, analyses, or other information not previously submitted to the agency." *Id.* at § 601.12(f)(6). Such information "may include (but [is] not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of

[24] A similar CBE regulation applies for non-vaccine drugs. *See Gibbons*, 919 F.3d at 707 (citing C.F.R. §§ 314.70(c)(6)(iii) & 314.3(b)). Because Herlth does not identify any material difference between the CBE regulation governing vaccines and the CBE regulation governing other drugs, this ruling relies in part on precedent like *Gibbons* that applies the CBE regulation governing non-vaccine drugs.

previously submitted data . . . if the studies, events or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA." *Ibid.*

Moreover, the regulations include a causation requirement between the newly acquired information and an adverse reaction to the drug: "newly acquired information 'must provide reasonable evidence of a causal association of a clinically significant adverse reaction linked to a drug.'" *McGrath v. Bayer HealthCare Pharms. Inc.*, 393 F. Supp. 3d 161, 167 (E.D.N.Y. 2019) (quoting 21 C.F.R. § 201.57(c)(6)(i)); *Gayle v. Pfizer Inc.*, 452 F. Supp. 3d 78, 85 (S.D.N.Y. 2020) (same), *aff'd*, 847 F. App'x 79 (2d Cir. 2021).

How does all this apply here? Because of the requirement that the information be "newly acquired," Herlth must allege that there was significant adverse risk information revealed to Merck at some point *after* the FDA's approval of Gardasil in June 2006. And because of the requirement under state law that a failure to warn have caused a plaintiff's injury, *see Sharp v. Wyatt, Inc.*, 31 Conn. App. 824, 835 (1993) *aff'd*, 230 Conn. 12 (1994), Herlth must plead facts to plausibly show that the newly acquired information was available to Merck *before* Herlth's second dose of Gardasil in December 2013 and that the information related to the same category of injuries alleged by Herlth.

Herlth has not plausibly pleaded these necessary facts. To be sure, her amended and lengthy complaint is replete with allegations about the potential risks of Gardasil, but most of those risks bear no relation to Herlth's alleged injuries. For example, Herlth cites studies purportedly showing that Gardasil increases the risks of fertility problems and perhaps even cancer itself.[25] But fertility problems and cancer are not among her alleged injuries.

[25] Doc. #18 at 43–44, 36 (¶¶ 285–86, 243–44).

More relevant to Herlth's own injuries is an allegation that "Gardasil has been linked to a myriad of autoimmune disorders, including . . . POTS."[26] But apart from that conclusory allegation, she does not allege newly acquired information containing "reasonable evidence" as required under 21 C.F.R. § 201.57(c)(6)(i) of a causal association between Gardasil and POTS. Herlth's allegations linking Gardasil to POTS primarily consist of citations to scientific journal and news articles. In addition to several articles published in the late 2010s—that is, well after Merck could have acted upon them to prevent Herlth's alleged injuries—she cites nine articles that were published between 2006 and 2013.[27] Aside from listing them, Herlth does not explain how these sources support her allegations. Upon review, some describe no more than a theoretical relationship between Gardasil and POTS, while others consist of case reports from individual patients. Several do not specifically relate to POTS or her other injuries, and others do not appear to specifically relate to the Gardasil vaccine.

To the extent that the Second Circuit's decision in *Gibbons* requires a plaintiff to allege newly acquired information at the pleading stage, Herlth argues that this requirement is no longer good law in light of the Supreme Court's later decision in *Merck Sharp & Dohme Corp. v.*

[26] *Id.* at 38 (¶ 263).

[27] *Id.* at 41, 53–54 (¶¶ 276, 357) (citing Darja Kanduc, *Peptide Cross-reactivity: The Original Sin of Vaccines*, 4 FRONTIERS IN BIOSCIENCE 1393 (June 2012); Nancy B. Miller, *Clinical Review of Biologics License Application for Human Papillomavirus 6, 11, 16, 18 L1 Virus Like Particle Vaccine* (S. cerevisiae) (STN 125126 GARDASIL), manufactured by Merck, Inc. at 393-394 (Table 302) (June 8, 2006); Svetlana, Blitshetyn, *Postural Tachycardia Syndrome After Vaccination with Gardasil*, 17 EUROPEAN J. OF NEUROLOGY e52 (2010); D.T. Little and H.R. Ward, *Premature ovarian failure 3 years after menarche in a 16-year-old-girl following human papillomavirus vaccination*, BMJ CASE REPORTS (Sept. 30, 2012); 72nd Report on the Alleged Irregularities in the Conduct of Studies Using Human Papilloma Virus (HPV) Vaccine by Programme for Appropriate Technology in Health (PATH) in India (August 2013); E. Israeli et al., *Adjuvants and Autoimmunity*, 18 LUPUS 1217 (2009); Darja Kanduc, *Quantifying the Possible Cross-Reactivity Risk of an HPV16 Vaccine*, 8 JOURNAL OF EXPERIMENTAL THERAPEUTICS AND ONCOLOGY 65 (2009); Darja Kanduc, *Potential Cross-Reactivity Between HPV16L1 Protein and Sudden Death Associated Antigens*, 9 JOURNAL OF EXPERIMENTAL THERAPEUTICS AND ONCOLOGY 159 (2011); Serena Colafrancesco et al., *Human Papilloma Virus Vaccine and Primary Ovarian Failure: Another Facet of the Autoimmune Inflammatory Syndrome Induced by Adjuvants*, 70 AM. J. REPRODUCTIVE IMMUNOLOGY 209 (2013); Murizo Rinaldi et al., *Anti-Saccharomyces Cerevisiae Autoantibodies in Autoimmune Diseases: From Bread Baking to Autoimmunity*, 45 CLINICAL REVIEWS IN ALLERGY AND IMMUNOLOGY 152 (October 2013)).

Albrecht, 139 S. Ct. 1668, 1684 (2019). According to Herlth, *Albrecht* clarified that preemption is an affirmative defense and that the burden falls on the defendant to show the *non*-existence of newly acquired information. I do not agree.

In *Albrecht*, the defendant drug manufacturer had conceded that it could have amended its label pursuant to the CBE regulation, 139 S. Ct. at 1675, and the Supreme Court considered only whether the claims were nonetheless preempted due to a showing by the defendant of "clear evidence that the FDA would not have approved a change to the . . . label," *id.* at 1672. Thus, *Albrecht* clarified the standard for a showing of "clear evidence." *See id.* at 1678 (holding that clear evidence is evidence that the manufacturer fully informed the FDA of justifications for a new warning and that the FDA, in turn, declined to approve the new warning). But *Albrecht* said nothing of a plaintiff's pleading requirements in cases where the defendant has *not* conceded the existence of newly acquired information. *See also Gibbons*, 919 F.3d at 708 (clarifying a two-step analysis wherein a plaintiff must plead newly acquired information, and only then does the burden shift to the defendant to show "clear evidence" that FDA would reject proposed label change); *see McGrath*, 393 F. Supp. 3d at 170–71 (distinguishing *Albrecht* on similar grounds).

Herlth further argues that the drug labeling preemption principles applied by the Second Circuit in *Gibbons* do not apply to vaccines like Gardasil. According to Herlth, because the Vaccine Act expressly preempts state law design-defect claims against vaccine manufacturers, *see Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 231–32 (2011), it follows that Congress impliedly decided against preemption of failure-to-warn claims for vaccines. But it makes no sense to infer from the fact that Congress decided to make it harder to sue a vaccine maker for a design defect that it must have intended to open the floodgates to suing vaccine makers for a failure to warn. In general, "neither an express pre-emption provision nor a saving clause bars the ordinary working

of conflict pre-emption principles." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001) (conflict preemption defense still available under FDCA despite express preemption provision in Medical Device Amendments).

In sum, because the amended complaint does not plead facts to plausibly establish that there was newly acquired information about the risks of Gardasil that caused Herlth's injuries, it does not allege facts sufficient to avoid preemption. Accordingly, I will dismiss the amended complaint's CPLA claim to the extent that it relies on a failure-to-warn theory of liability.

Manufacturing defect

Merck next argues that Herlth has failed to allege a plausible *manufacturing*-defect claim, as distinct from a *design*-defect claim that—as noted above—is expressly preempted by the Vaccine Act. I agree.

"Generally speaking, a manufacturing defect is a mistake in the assembly process, which results in a product that differs from the manufacturer's intended result." *Moss v. Wyeth Inc.*, 872 F. Supp. 2d 162, 166 (D. Conn. 2012) (citing *Miller v. United Techs. Corp.*, 233 Conn. 732, 779 (1995)). By contrast, "[a] design defect . . . exists when the product is otherwise properly manufactured, but is nonetheless unreasonably dangerous because its attributes can cause unexpected injury." *Ibid.* For complex products like vaccines, the product is defectively designed if "the risk of danger inherent in the design of the product outweighs its utility." *Ibid.*

Here, the amended complaint alleges various ways in which Gardasil is unreasonably dangerous, but it does not allege that the Gardasil doses that Herlth received deviated either from their manufacturer's intended result or from run-of-the-mill dosages of Gardasil vaccine. Aside from a conclusory allegation that the Gardasil manufacturing process "failed to comply with manufacturing specifications required by the governing manufacturing protocols and . . .

regulatory agencies," the crux of Herlth's claim is that Gardasil generally "contain[s] ingredients and toxins that were not disclosed in the FDA-approved specifications and/or otherwise not disclosed in the package insert."[28]

The amended complaint goes on to allege that Gardasil contains "dangerous and undisclosed HPV L1-DNA fragments" and the "toxic nerve agent" phenylmethylsulfonyl fluoride ("PMSF").[29] But it is not alleged that either ingredient was present in Gardasil due to a mistake or flaw in the manufacturing process.

In short, the complaint alleges a design-defect claim dressed up as a manufacturing-defect claim; it does not allege a plausible manufacturing-defect claim. *See Stratton v. Merck & Co., Inc.*, 2021 WL 5416705, at *3 (D.S.C. 2021) (dismissing similar manufacturing defect claim as to Gardasil). Accordingly, I will dismiss the amended complaint's CPLA claim to the extent that it relies on a manufacturing-defect theory of liability.

Negligence

In blunderbuss fashion, the amended complaint lumps a number of disparate theories of product liability under the general header of "negligence." According to Herlth, Merck breached its duty of reasonable care in "design, research, manufacture, advertisement, supply, promotion, packaging, sale, and distribution of Gardasil."[30] I have difficulty discerning from Herlth's sprawling and conclusory allegations and subsequent briefing the precise nature of her negligence claim. However, to the extent that she alleges negligent design, negligent manufacture, or negligent failure to warn, her claims fail for all of the reasons discussed above.

[28] Doc. #18 at 68 (¶ 411).
[29] *Ibid.* (¶¶ 412–13).
[30] Doc. #18 at 56–57 (¶ 368); *see also* Doc. #24 at 31–32.

Many of the allegations that Herlth tosses in under the general heading of "Negligence" discordantly allege fraud and intentional misrepresentation.[31] As an initial matter, the CPLA defines a "product liability claim" to "include[] all claims or actions brought for personal injury, death or property damage caused by the manufacture, construction, design, formula, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging or labeling of any product," and it states that such claims "shall include, *but [are] not limited to*, all actions based on the following theories: Strict liability in tort; negligence; breach of warranty, express or implied; breach of or failure to discharge a duty to warn or instruct, whether negligent or innocent; *misrepresentation or nondisclosure, whether negligent or innocent*." Conn. Gen. Stat. § 52-572m (emphasis added). In view that the CPLA does not exclude product-related fraud or *intentional* misrepresentation claims, I will assume for present purposes that the CPLA allows for claims of fraud or intentional misrepresentation. *See Hunte v. Abbott Lab'ys, Inc.*, 2021 WL 3679303, at *14 (D. Conn. 2021) (assuming without deciding issue).

For claims allowed under the CPLA that have a common law equivalent, a plaintiff must allege the facts necessary to allow for recovery under the common law. *See Ferry v. Mead Johnson & Co., LLC*, 514 F. Supp. 3d 418, 431 (D. Conn. 2021). To state a claim for intentional misrepresentation, a plaintiff must establish "(1) that a false representation was made as a statement of fact; (2) that it was untrue and known to be untrue by the party making it; (3) that it was made to induce the other party to act on it; and (4) that the latter did so act on it to his injury." *Id.* at 446 (quoting *Updike, Kelly, & Spellacy, P.C. v. Beckett*, 269 Conn. 613, 643 (2004)).

[31] The "Negligence" allegations of the amended complaint run for seven pages of the amended complaint. Doc. #18 at 56-63 (¶¶ 367-386). Several of the paragraphs expressly allege fraud or misrepresentation. *Id.* at 60-63 (¶¶ 377(q)-(u), 382, 385). The CPLA count of the complaint otherwise incorporates many of the other allegations elsewhere in the complaint that allege fraud. Doc. #18 at 56 (¶ 364).

Because intentional misrepresentation claims sound in fraud, a heightened pleading standard applies. *Ibid*. Specifically, Rule 9(b) of the Federal Rules of Civil Procedure provides that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Thus, to survive a motion to dismiss under Rule 9(b), the complaint must "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Ferry*, 514 F. Supp. 3d at 446 (quoting *U.S. ex rel. Chorches for Bankr. Est. of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 81 (2d Cir. 2017)). In other words, Rule 9(b) requires that the plaintiff identify "the who, what, when, where, and how" for each act of purported fraud. *Walters v. Performant Recovery, Inc.*, 124 F. Supp. 3d 75, 79 (D. Conn. 2015).

Relative to other elements of a claim sounding in fraud, "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). Nonetheless, the Second Circuit has made clear that plaintiffs in fraud cases must still "allege facts that give rise to a strong inference of fraudulent intent." *Lerner v. Fleet Bank, N.A.*, 459 F.3d 273, 290 (2d Cir. 2006). This strong inference can be shown "(a) by alleging facts to show that defendants had both motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness." *Id.* at 290–91. When pleading that a defendant had a motive and opportunity to commit fraud, a plaintiff cannot rely on "a general profit motive common to all corporations." *Landesbank Baden-Wurttemberg v. Goldman, Sachs & Co.*, 478 F. App'x. 679, 681 (2d Cir. 2012).

Herlth alleges that Merck intentionally misrepresented its Gardasil vaccine to both consumers—including Herlth and her mother—and also to medical providers. Beginning with

the alleged misrepresentations aimed at consumers, Herlth fails to allege any fraudulent statement with the particularity required by Rule 9(b). She alleges that Merck misrepresented the safety and efficacy of Gardasil through "incomplete warnings and instructions" and "statements it made in its publications, ubiquitous television advertisements, billboards, print advertisements, online advertisements and website, and other written materials intended for consumers, patients, parents of minor-aged patients, medical providers, and the general public, that Gardasil was safe and effective at preventing cancer."[32] To the extent that she claims to have been deceived by "incomplete warnings and instructions," Herlth's intentional misrepresentation subclaim is duplicative of her preempted failure to warn claim.

With respect to Merck's "ubiquitous" marketing and advertising materials, Herlth points to just two statements with any degree of particularity. The first is the "Mom, Dad, did you know?" ad campaign, which allegedly "said nothing about potential side effects."[33] But Herlth alleges that the ad aired in 2016—three years *after* she received the Gardasil vaccine. Thus, even if the ad contained known untruths intended to induce reliance, Herlth and her mother could not have plausibly "act[ed] on it to [their] injury." *See Updike, Kelly & Spellacy, P.C.*, 269 Conn. at 643.

The second set of statements—those conveyed by the "One Less" ad campaign—are also insufficient. According to the amended complaint, the ads "proclaimed that Gardasil was a 'cervical cancer vaccine' and that any young girl vaccinated with Gardasil would become 'one less' woman with cervical cancer."[34] Herlth also alleges that the ads "portrayed Gardasil as if there were no question as to the vaccine's efficacy in preventing cervical cancer, and [they]

[32] *Id.* at 73–4 (¶¶ 441–42).
[33] *Id.* at 17 (¶ 81).
[34] *Id.* at 17–18 (¶ 83).

disclosed none of Gardasil's side effects."[35] Herlth alleges that her mother was "exposed to" the ads,[36] and while it is not altogether clear that she is referring to the same "One Less" ads, she elsewhere alleges that her mother "saw and relied upon" certain Gardasil ads in advance of consenting to Herlth's vaccination.[37]

But setting aside the accuracy of her portrayal of the ads—elsewhere in the complaint Herlth alleges that the "One Less" ads *did* list side effects, including "pain, swelling or redness at injection site, fever, and/or nausea"[38]—Herlth does not "demonstrate with specificity why and how each statement [was] false or misleading." *Boca Raton Firefighters & Police Pension Fund v. Bahash*, 506 F. App'x 32, 38 (2d Cir. 2012). Indeed, aside from the ad's purportedly "false[] procla[mation] that Gardasil was a 'cervical cancer vaccine'"[39]—which Herlth contradicts elsewhere by admitting that cervical cancer was among the vaccine's approved indications[40]—she does not allege any *specific* statements in the ad that were made with knowing falsity. Instead, what she describes is a perfectly ordinary advertisement, highlighting a product's strengths while deemphasizing its weaknesses. Without more specificity, the complaint does not demonstrate with particularity or plausibility that the ad was either false or misleading.[41]

Nor does the complaint allege a strong inference of fraudulent intent, either "(a) by alleging facts to show that defendants had both motive and opportunity to commit fraud, or (b)

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[35] *Ibid.*
[36] *Id.* at 74 (¶ 442).
[37] *Id.* at 17 (¶ 83).
[38] *Id.* at 74 (¶ 442).
[39] *Id.* at 17 (¶ 83).
[40] *Id.* at 12 (¶ 46).
[41] While acknowledging the distinct elements of a claim for intentional misrepresentation, it is telling that breach of warranty claims in Connecticut require something more than a drugmaker's affirmance that its products are "safe and effective." *See, e.g.*, *Fraser v. Wyeth*, 857 F. Supp. 2d 244, 257–58 (D. Conn. 2012) ("a drug manufacturer's representation in advertising or a warning label that a product is safe or effective, or an advertisement or warning label that does not adequately highlight a particular known or knowable risk does not create an express warranty in the absence of a guarantee that the particular product is free from all harmful side effects"). Similarly here, it is not obviously false or misleading for a vaccine maker to represent a vaccine as effective or list its potential side effects in a non-exhaustive manner.

by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness." *Lerner*, 459 F.3d at 290–91. Aside from conclusory allegations of Merck's potential profit motive, the complaint does not suggest any motive or strong circumstantial evidence of recklessness. *See Chill v. Gen. Elec. Co.*, 101 F.3d 263, 268 (2d Cir. 1996) (motives that "could be imputed to any . . . for-profit endeavor[are] not sufficiently concrete for purposes of inferring scienter").

Herlth's claim of fraud against medical providers is alleged with even less particularity. In addition to the advertising campaigns discussed above, the complaint alleges that Gardasil was promoted to doctors through "door-to-door marketing" and in-person presentations.[42] But it does not specifically allege how any of these marketing efforts reached Herlth's pediatrician. As a result, the complaint does not plausibly allege that Herlth's pediatrician or anyone else acted upon Merck's alleged misrepresentations in a manner that resulted in Herlth's injuries. *See Ferry*, 514 F. Supp. 3d at 450–51 (dismissing fraud claim where complaint does not allege that plaintiffs or their doctor ever looked at purported fraudulent website).

In addition to her fraud-on-consumers and fraud-on-medical providers arguments, Herlth also makes a number of vague allegations pertaining to intentional misrepresentations aimed at the FDA. Among other "fraudulent activities that led regulators . . . to be duped into believing that Gardasil is safe and effective,"[43] the complaint alleges that Merck: evaluated Gardasil against an improper placebo in clinical trials, underrepresented pre-teen girls and boys among its trial participants, manipulated dosages in clinical trials, used overly exclusionary criteria in selecting the clinical study patient population, and failed to disclose to the FDA certain Gardasil ingredients.

[42] *See id.* at 14, 21 (¶¶ 63, 116).
[43] *Id.* at 76–77 (¶ 455).

But Herlth's fraud-on-the-FDA claims fail for two reasons. First, she fails to satisfy the heightened pleading standard under Rule 9(b), both because her allegations of "fraudulent activity" lack particularity—including where, when, and how the alleged misrepresentations were communicated to the FDA—and because her conclusory allegations do not permit a strong inference of fraudulent intent. She alleges no facts constituting strong circumstantial evidence of conscious misbehavior or recklessness, nor does she plausibly allege that Merck had any genuine opportunity to commit fraud—especially given the strictly regulated nature of pre-market drug approval.

Second, the Supreme Court has explicitly held that state law claims alleging "fraud on the FDA" are preempted under the FDCA. *See Buckman*, 531 U.S. at 348. In *Buckman*, the Supreme Court considered a state law fraud claim premised on the defendant's fraudulent misrepresentations to the FDA. *Id.* at 344. The plaintiffs, who were injured by a medical device, argued that the defendant's fraud was a "but for" cause of their injuries. *Ibid*. But the Supreme Court rejected their claims, holding that state law actions for fraud on the FDA "inevitably conflict with the FDA's responsibility to police fraud." *Id*. at 350.

Since *Buckman*, the Second Circuit has further clarified that state tort claims are preempted only when the cause of action assigns liability "*solely* on the basis" of fraud against the FDA. *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 98 (2d Cir. 2006) (emphasis in original).[44] Here, to the extent that she alleges "fraudulent activities" undertaken to deceive the FDA, Herlth seeks to assign liability solely on the basis of purported fraud against the FDA.

[44] That is not to say that allegations of fraud against the FDA can have no place in state product liability law. An allegation of fraud on the FDA may be used to overcome a vaccine manufacturer's presumption of immunity in failure-to-warn cases, for example. *See* 42 U.S.C. §§ 300aa-22(b)(2), 300aa-23(d)(2); *Bruesewitz*, 562 U.S. at 239 n.25; *see also Desiano*, 467 F.3d at 98 (allowing state law action requiring plaintiff to plead fraud-on-the-FDA merely as a means of overcoming drug manufacturer's presumption of immunity).

Thus, even if Herlth could satisfy Rule 9(b)'s heightened pleading standard, her intentional misrepresentation claim would nonetheless be preempted to the extent that it alleges fraud on the FDA.

That leaves a possible claim for negligent misrepresentation. To state a claim for negligent misrepresentation, a plaintiff must establish (1) that the defendant made a misrepresentation of fact (2) that the defendant knew or should have known was false, (3) that the plaintiff reasonably relied on the misrepresentation and thus (4) suffered pecuniary harm. *See Ferry*, 514 F. Supp. 3d at 446 (citing *Nazami v. Patrons Mut. Ins. Co.*, 280 Conn. 619, 626 (2006)). Courts disagree about whether the heightened pleading standard of Rule 9(b) applies to negligent misrepresentation claims. *See ARMOUR Capital Mgmt. LP v. SS&C Techs., Inc.*, 2018 WL 1368908, at *6 (D. Conn. 2018) (describing the disagreement). Nonetheless, courts agree that Rule 9(b) applies to negligent misrepresentation claims whenever they are "couched in fraud-like terms of known falsity." *See Ferry*, 514 F. Supp. 3d at 446; *ARMOUR Capital Mgmt. LP v. SS&C Techs., Inc.*, 2020 WL 64297, at *2 (D. Conn. 2020).

In my view, Herlth's negligent misrepresentation claims are indeed couched in fraud-like terms such that a heightened pleading standard applies. Her negligent misrepresentation claims are nearly indistinguishable from her claims of fraud, and indeed, the two claims are premised on many of the same alleged bad acts. Moreover, the negligence claim itself appears to assert that all of the same acts were both "negligent *and fraudulent*."[45] Thus, after evaluating her claims under the heightened pleading standard of Rule 9(b), I conclude that Herlth fails to state a claim for negligent misrepresentation for the same reasons as I have explained for her claims of fraud and intentional misrepresentation.

[45] Doc. #18 at 62 (¶ 382) (emphasis added).

Count Two – common law fraud

Count Two of the amended complaint alleges a claim for common law fraud. But it is well-established that the CPLA is the "exclusive remedy for—and the only cause of action available to—plaintiffs in Connecticut for product liability claims." *Ferry*, 514 F. Supp. 3d at 431. "The statute does not abolish common law claims in product liability actions, but instead incorporates them into a single count to simplify pleadings." *Collazo v. Nutribullet*, 473 F. Supp. 3d 49, 51 (D. Conn. 2020).

If a plaintiff wants to allege a claim for fraud arising from a product-related injury, she must do so under the umbrella of the CPLA rather than as a standalone common law claim. *See Fraser v. Wyeth, Inc.*, 857 F. Supp. 2d 244, 252 (D. Conn. 2012); *see also Doe v. Bausch & Lomb, Inc.*, 443 F. Supp. 3d 259, 270 (D. Conn. 2020) (dismissing standalone common law fraud and fraudulent omissions claims seeking recovery for product-caused injury). In addition, for the reasons that I have already explained above with respect to the allegations of fraud that Herlth has alleged under the rubric of her "Negligence" subclaim under the CPLA, Herlth has failed to adequately plead a claim for fraud. Accordingly, I will dismiss Count Two without prejudice to the extent that a claim for fraud may be properly re-alleged as a sub-claim under the CPLA.

CONCLUSION

For the reasons set forth above, the Court GRANTS the defendants' motion to dismiss the amended complaint (Doc. #18). This dismissal is without prejudice to the filing of a motion to re-open and an amended complaint within 30 days if the plaintiff has grounds to allege facts that would overcome the concerns stated in this ruling. The Clerk of the Court is directed to close the case without prejudice to re-opening in the event of the filing of a motion to re-open and an amended complaint.

It is so ordered.

Dated at New Haven this 15th day of March 2022.

/s/ ***Jeffrey Alker Meyer***
Jeffrey Alker Meyer
United States District Judge

Korrine Herlth v. Merck, et al.

3:21-cv-000438-JAM

U.S. District Court for the District of Connecticut

Order to Re-Open Case

Adlivankina, Valeriya

From: CMECF@ctd.uscourts.gov
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Subject: Activity in Case 3:21-cv-00438-JAM Herlth v. Merck & Co Inc et al Order on Motion to Reopen Case

Follow Up Flag: Flag for follow up
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U.S. District Court

District of Connecticut

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Case Name: Herlth v. Merck & Co Inc et al
Case Number: 3:21-cv-00438-JAM
Filer:
WARNING: CASE CLOSED on 03/16/2022
Document Number: 44(No document attached)

Docket Text:
**ORDER. In accordance with the Court's prior grant of leave to file a motion to re-open and amended complaint, the Court GRANTS the motion to re-open (Doc. #[42]). Defendants shall file any answer or other response to the Second Amended Complaint by May 16, 2022. It is so ordered.
Signed by Judge Jeffrey A. Meyer on 4/15/22. (Barry, Donna)**

3:21-cv-00438-JAM Notice has been electronically mailed to:

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3:21-cv-00438-JAM Notice has been delivered by other means to:

Abigail Stratton v. Merck, et al.

2:21-02211-RMG

U.S. District Court for the District of South Carolina, Charleston Division

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

Sahara Walker v. Merck, et al.

3:20-cv-01048-jdp

U.S. District Court for the Western District of Wisconsin

Adlivankina, Valeriya

From: wiwd_ecf@wiwd.uscourts.gov
Sent: Thursday, March 18, 2021 7:12 AM
To: wiwd_nef@wiwd.uscourts.gov
Subject: Activity in Case 3:20-cv-01048-jdp Walker, Sahara v. Merck & Co., Inc. et al Order on Motion to Strike

U.S. District Court

Western District of Wisconsin

Notice of Electronic Filing

The following transaction was entered on 3/18/2021 at 9:11 AM CDT and filed on 3/18/2021

Case Name: Walker, Sahara v. Merck & Co., Inc. et al
Case Number: 3:20-cv-01048-jdp
Filer:
Document Number: 19(No document attached)

Docket Text:

**** TEXT ONLY ORDER ****

Plaintiff is suing two related pharmaceutical companies for injuries she sustained from an HPV vaccine called Gardacil. Defendants move under Federal Rule of Civil Procedure 12(f) to strike allegations in the complaint related to problems with a drug called Vioxx, which is also manufactured by defendants but is not part of plaintiff's claims. Motions to strike are disfavored, and a court will only strike allegations in a complaint when "the challenged matter clearly has no bearing on the subject matter of the litigation and real prejudicial harm to the moving party is shown." *MBI Acquisition Partners, L.P. v. Chronicle Pub. Co.*, No. 01-cv-177, 2001 U.S. Dist. LEXIS 15387, 2001 WL 1478812, at *4 (W.D. Wis. Sept. 6, 2001). In this case, the parties debate whether evidence about Vioxx will be admissible under Federal Rule of Evidence 404(b), but that question is better left for summary judgment or trial. *See Chicago Printing Co. v. Heidelberg USA, Inc.*, No. 01 C 3251, 2001 WL 1646567 (N.D. Ill. Dec. 21, 2001). And the court isn't persuaded that the allegations are prejudicial. Defendants don't deny that all of the information in the complaint is public and already well publicized. Defendants' motion to strike, Dkt. [7], is DENIED. Signed by District Judge James D. Peterson on 3/18/2021. (kwf)

3:20-cv-01048-jdp Notice has been electronically mailed to:

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Hayden M. Shain v. Merck, et al.

21STCV35340

California Superior Court - Los Angeles County - Santa Monica Courthouse

SUPERIOR COURT OF CALIFORNIA, COUNTY OF LOS ANGELES

Civil Division

West District, Santa Monica Courthouse, Department O

21STCV35340 August 4, 2022
HAYDEN SHAIN vs MERCK & CO, INC., et al. 8:30 AM

Judge: Honorable H. Jay Ford III
Judicial Assistant: K. Neal
Courtroom Assistant: A. Khleif

CSR: Tammie Moore (Telephonic), #11525
ERM: None
Deputy Sheriff: None

APPEARANCES:

For Plaintiff(s): Bijan Esfandiari (Video); Stephanie Sherman (Video); Harrison James (Telephonic)

For Defendant(s): Kelly L. Kiseskey (Video); Holly Henrich (Video); Jeremy Esterkin (Video); Zachary Schwake (Telephonic)

NATURE OF PROCEEDINGS: Hearing on Demurrer - with Motion to Strike (CCP 430.10) (Merck & Co); Hearing on Demurrer - without Motion to Strike , Filed By Defendant Alisa A. Bromberg, MD; Case Management Conference

The Court issues the following tentative rulings:

DEMURRER TO COMPLAINT

MOVING PARTY: Defendant Alisa A. Bromberg, MD

TENTATIVE RULING

Defendant Alisa A. Bromberg, MD's Demurrer to the 7th, 8th and 9th causes of action is OVERRULED as to the 7th cause of action for medical malpractice and 9th cause of action for breach of fiduciary duty and SUSTAINED WITHOUT LEAVE TO AMEND as to the 8th cause of action for battery. Defendant to answer in 10 days.

I. Demurrer based on statute of limitations under CCP §340.5—OVERRULE

Defendant Bromberg demurs to the 7th through 9th causes of action for medical malpractice, battery and breach of fiduciary duty based on the one-year provision of CCP §340.5: "In an action for injury or death against a health care provider based upon such person's alleged

professional negligence, the time for the commencement of action shall be three years after the date of injury or one year after the plaintiff discovers, or through the use of reasonable diligence should have discovered, the injury, whichever occurs first." Code Civ. Proc., § 340.5.

Defendant Bromberg argues that, based on Plaintiff's complaint allegations, Plaintiff discovered or should have discovered his injury by February 2018, when he allegedly began to experience symptoms after receiving his first and only Gardasil shot. See Complaint, ¶353. Bromberg argues Plaintiff was therefore required to bring his claims by February 2019.

Bromberg's argument fails to take into account Plaintiff's status as a 15-year old minor when he received the Gardasil injection. See Complaint, ¶349. Under CCP §340.5, "[a]ctions by a minor shall be commenced within three years from the date of the alleged wrongful act…" Code Civ. Proc., § 340.5. A person who is a minor at the time of the wrongful act remains entitled to the 3-year limitations period for minors, regardless of when he or she reached the age of majority. See Steketee v. Lintz, Williams & Rothberg (1985) 38 CA.3d 46, 54-56; 3 Witkin, Cal. Proc. (6th ed. 2022), Actions, §640.

Based on this provision, Plaintiff argues in opposition that the applicable SOL is three years from January 2018, subject to tolling while his petition before the Vaccine Compensation Board was pending from October 2020 through July 2021. Bromberg does not address this argument on reply.

In addition, Plaintiff's allegations are not limited to Defendant Bromberg's recommendation of Gardasil and her failure to fully inform Plaintiff of its side effects prior to its administration in January 2018. Plaintiff also alleges that Defendant Bromberg was negligent, because she failed to "timely and properly diagnose that Plaintiff had sustained a Gardasil adverse reaction following his January 8, 2018 Gardasil injection." See Complaint, ¶484. The exact time frame of this post-injection negligence is unclear.

Bromberg fails to establish on demurrer that the 7th through 9th causes of action are clearly, affirmatively and necessarily barred by the SOL under CCP §340.5. See Roman v. County of Los Angeles (2000) 85 Cal.App.4th 316, 324-325 ("If the dates establishing the running of the statute of limitations do not clearly appear in the complaint, there is no ground for general demurrer"); CrossTalk Productions, Inc. v. Jacobson (1998) 65 Cal.App.4th 631, 635 ("demurrer based on an affirmative defense cannot properly be sustained where the action might be barred by the defense, but is not necessarily barred.") Bromberg's demurrer based on CCP §340.5 is OVERRULED.

II. 7th cause of action for medical malpractice—OVERRULED

The elements of a medical malpractice cause of action are (1) the duty of the professional to use such skill, prudence, and diligence as other members of his profession commonly possess and exercise; (2) a breach of that duty; (3) a proximate causal connection between the negligent conduct and the resulting injury; and (4) actual loss or damage resulting from the professional's negligence. See Avivi v. Centro Medico Urgente Medical Center (2008) 159 Cal.App.4th 463, 468 fn 2.

A lack of informed consent is a separate theory of liability from professional negligence or malpractice, and can generally be established by the patient–plaintiff's testimony. See Cobbs v. Grant (1972) 8 Cal.3d 229, 240–244; Arato v. Avedon (1993) 5 Cal.4th 1172, 1190–1191. As an "alternative negligence theor[y]," lack of informed consent can establish liability even when expert testimony has eliminated allegations of negligent performance. See Willard v. Hagemeister (1981) 121 Cal.App.3d 406, 417–418. The relevant question of fact is whether the treating professional gave the plaintiff sufficient information as to the nature of the procedure "so that she could intelligently decide whether to undergo the ... procedure. If [the treating professionals] did not make this minimal disclosure of material facts, they are liable for all injuries sustained by [the plaintiff] during the course of this ... treatment, whether the treatment was negligent or not." Id. at p. 418; Jambazian v. Borden (1994) 25 Cal.App.4th 836, 845.

Plaintiff's 7th cause of action for medical malpractice is based on multiple acts of negligence. Bromberg was allegedly negligent when she (1) negligently failed to timely and properly diagnose Plaintiff's adverse reaction to Gardasil; (2) negligently relied on "facts and information provided to them by Merck with respect to the effectiveness, safety, and the need for the administration of the Gardasil vaccine and in advising Plaintiff he be administered the Gardasil vaccine"; (3) informing Plaintiff that Gardasil was "safe" and only disclosing "nonspecific possible reactions listed on the Vaccine Information Statement"; and (4) failing to provide Plaintiff with "material facts and information as to the effectiveness, safety and need for the administration of the Gardasil vaccinations and in particular of the specific risk/benefit and quantitative risks, including but not limited to the serious autoimmune risks and lack of efficacy associated with the Gardasil vaccine." See Complaint, ¶¶482-491.

Plaintiff alleges that he was deprived of his right to informed consent, because Defendant's negligent failure to provide him with this information and providing incomplete information regarding the safety and effectiveness of Gardasil. See Complaint, ¶488. Plaintiff alleges neither

he nor his mother would have consented to Gardasil if they had known of the true risks associated with it and its lack of effectiveness. Id. at ¶489.

Defendant Bromberg argues Plaintiff failed to allege breach of any applicable standard of care. However, to the extent Plaintiff's 7th cause of action for medical malpractice is based on lack of informed consent, Plaintiff need not allege that Bromberg's disclosure breached a community standard of care. "[T]he patient's right of self-decision is the measure of the physician's duty to reveal…The scope of a physician's communications to the patient…must be measured by the patient's need, and the need is whatever information is material to the decision. Thus the test for determining whether a potential peril must be divulged is its materiality to the patient's decision." Cobbs v. Grant (1972) 8 Cal.3d 229, 243, 245.

More recently, the Supreme Court "underlin[ed] the limited and essentially subsidiary role of expert testimony in informed consent litigation." See Arato, supra, 5 Cal.4th at 1191. The Supreme Court reiterated its rejection of "an absolute rule" that "filters the scope of patient disclosure entirely through the standards of the medical community." Id. "Nevertheless…there may be a limited number of occasions in the trial of informed consent claims where the adequacy of disclosure in a given case may turn on the standard of practice within the relevant medical community." Id.

Thus, breach of an applicable community standard of care is not necessarily an element of Plaintiff's 7th cause of action for medical malpractice based on lack of informed consent. Defendant Bromberg fails to demonstrate that Plaintiff's case is one of the "limited number of occasions…where the adequacy of disclosure in a given case may turn on the standard of practice within the relevant medical community." Arato, supra, 5 Cal.4th at 1191.

In addition, Plaintiff's allegations of medical negligence ("negligently" relying on Merck's marketing information and "negligently" failing to timely and properly diagnose Plaintiff's adverse vaccine reaction) are sufficient to allege breach of the applicable standard of care. By describing those acts as negligent, Plaintiff is alleging that that those acts fell below the standard of care and it is reasonable to infer the fact of breach. "[A]ll material facts pleaded in the complaint and those that arise by reasonable implication, but not conclusions of fact or law, are deemed admitted by the demurring party. The complaint must be construed liberally by drawing reasonable inferences from the facts pleaded." Rodas v. Spiegel (2001) 87 Cal.App.4th 513, 517.

Defendant argues Plaintiff will be unable to establish negligence based on the alleged facts. However, on demurrer, all allegations must be accepted as true. The Court does not consider the plausibility of those allegations or Plaintiff's ability to prove them, i.e. whether Plaintiff will be able to locate an expert willing to testify that Defendant Bromberg's conduct fell below an applicable standard of care. "Because a demurrer tests only the legal sufficiency of the pleading, we accept as true even the most improbable alleged facts, and we do not concern ourselves with the plaintiff's ability to prove its factual allegations." Nolte v. Cedars-Sinai Medical Center (2015) 236 Cal.App.4th 1401, 1406.

Finally, Defendant Bromberg argues Plaintiff's allegations of lack of informed consent are inconsistent with Plaintiff's allegations that Merck fraudulently concealed information regarding Gardasil's effectiveness, safety and the need for administration of the Gardasil vaccine." Bromberg argues Plaintiff does not allege that Bromberg knew the truth about Gardasil's effectiveness, and such knowledge would be inconsistent with Plaintiff's claim that Merck fraudulently concealed the truth about Gardasil from the general public, including physicians like Bromberg. Bromberg argues Plaintiff can allege inconsistent theories but not inconsistent facts.

Even if Plaintiff's lack of informed consent claim were based on inconsistent facts, Plaintiff's claims are not based solely on lack of informed consent. Plaintiff's claims against Bromberg also include allegations that Bromberg negligently failed to diagnose Plaintiff's condition as an adverse reaction to Gardasil. Bromberg's negligent failure to diagnose Plaintiff's condition does not rely upon the allegedly inconsistent facts.

In addition, the allegation that Bromberg negligently relied on Merck's general information regarding Gardasil's effectiveness, safety and need is not necessarily irreconcilable with or "antagonistic" to Plaintiff's allegation that Bromberg failed to fully disclose all material facts that she knew, or should have known as a physician, about Gardasil, about HPV generally, about cervical cancer generally and whether Gardasil should have been recommended to Plaintiff specifically. "[A]t most, they are alternative factual allegations relying on alternative legal

theories, which does not run afoul of truthful pleading." Williams v. Southern California Gas Co. (2009) 176 Cal.App.4th 591, 598 (no inconsistency between claim asserted against manufacturer of wall furnace based on malfunction of wall heater and claim asserted against property owners based on their failure to notice visible discoloration of the grate cover of wall furnace); Wells v. Brown (1950) 97 Cal.App.2d 361, 364 ("there is no prohibition against pleading inconsistent causes of action stated in as many way saspalintiff believes his evidence will show"; plaintiff properly alleged two inconsistent counts based on alternative facts that defendant either negligently killed plaintiff's dog by running his car into it or intentionally killed his dog by shooting it after the dog was hit by the car). Thus, when "a pleader is in doubt about what actually occurred or what can be established by the evidence, the modern practice allows that party to plead in the alternative and make inconsistent allegations." Fleet v. Bank of America, N.A. (2014) 229 Cal.App.4th 1403, 1413 (reversing order sustaining demurrer without leave as to promissory estoppel claim against bank defendant; allegations were sufficient to state a claim for both breach of contract and promissory estoppel as alternative theories of recovery).

Defendant Bromberg's Demurrer to the 7th cause of action for medical malpractice is OVERRULED.

III. 8th cause of action for medical battery—SUSTAIN WITHOUT LEAVE TO AMEND

To establish a medical battery claim, plaintiff must prove the following: 1. defendant performed a medical procedure without plaintiff's consent; or plaintiff consented to one medical procedure, but defendant performed a substantially different medical procedure; 2. That plaintiff was harmed; and 3. That defendant's conduct was a substantial factor in causing plaintiff's harm. See CACI 530A. A patient can consent to a medical procedure by words or conduct. Id.

"The battery theory should be reserved for those circumstances when a doctor performs an operation to which the patient has not consented. When the patient gives permission to perform one type of treatment and the doctor performs another, the requisite element of deliberate intent to deviate from the consent given is present. However, when the patient consents to certain

treatment and the doctor performs that treatment but an undisclosed inherent complication with a low probability occurs, no intentional deviation from the consent given appears; rather, the doctor in obtaining consent may have failed to meet his due care duty to disclose pertinent information. In that situation the action should be pleaded in negligence." Cobbs v. Grant (1971) 8 Cal.3d 229, 240; see Kaplan v. Mamelak (2008) 162 Cal.App.4th 637, 646-647)(consent form signed by plaintiff only agreed to surgery on disk T8-9 of spine and defendant performed surgery on T6-7 and T7-8; finder of fact had to determine whether surgery on an incorrect disk is a reasonable risk of surgery performed on plaintiff or if it qualified as entirely different procedure); Ashcraft v. King (1991) 228 Cal.App.3d 604, 611 (medical battery claim stated where patient only agreed to blood transfusions from family members and physician transfused nonfamily member blood, in violation of patient's consent and unwittingly infecting him with HIV).

Plaintiff's battery claim is based on lack of informed consent. Defendant Bromberg allegedly failed to fully disclose the risks of Gardasil before recommending and administering it to Plaintiff. See Complaint, ¶¶495-496. Plaintiff is not alleging that he consented to receive one drug, vaccination or treatment but received an entirely different drug or vaccine. Plaintiff is not alleging that his consent was conditional, that Defendant Bromberg knew of this condition and despite this knowledge, Gardasil was administered in violation of that condition. Based on Plaintiff's allegations, Plaintiff is alleging negligence based on lack of informed consent, not medical battery under Cobbs.

Defendant Bromberg's demurrer is SUSTAINED WITHOUT LEAVE TO AMEND.

IV. 9th cause of action for breach of fiduciary duty—OVERRULE

"The doctor-patient relationship is a fiduciary one and as a consequence of the physician's 'fiducial" obligations,' the physician is prohibited from misrepresenting the nature of the patient's medical condition." Hahn v. Mirada (2007) 147 Cal.App.4th 740, 748. A "fiduciary relationship exists between the patient and the physician. As a result, the physician has a duty to disclose fully and completely the nature and extent of injuries and any material concealment or

misrepresentation will amount to fraud sufficient to entitle the party injured thereby to a cause of action. The duty of disclosure is fiduciary in nature because of the confidential patient-physician relationship, the duty of disclosure is measured by fiduciary standards (not limited by medical standards), and the physician subjects himself to liability should he withhold facts necessary to a total disclosure." Nelson v. Gaunt (1981) 125 Cal.App.3d 623, 634.

"[I]n soliciting the patient's consent, a physician has a fiduciary duty to disclose all information material to the patient's decision." Moore v. Regents of University of California (1990) 51 Cal.3d 120, 129 (physician's fiduciary duty of disclosure of all information material to patient's decision includes physician's personal interests unrelated to patient's health that may affect the physician's professional judgment and failure to disclose such interests may give rise to either cause of action for lack of informed consent or breach of fiduciary duty).

Plaintiff alleges Defendant Bromberg failed to disclose all material information to his and his mother's decision to receive an injection of Gardasil, specifically the lack of efficacy and the existence of serious and disabling adverse events associated with the Gardasil vaccine. See Complaint, ¶503. Plaintiff alleges Defendant Bromberg provided false and misleading information regarding the efficacy and safety profile of Gardasil, claiming that Gardasil would prevent cancer and was perfectly safe with no major side effects other than temporary pain at the injection site. Id. at ¶504. Plaintiff therefore alleges a breach of Bromberg's fiduciary duty to disclose all information material to his decision to receive Gardasil. Such allegations can give rise to either lack of informed consent or breach of fiduciary duty. Moore, supra. Plaintiff is entitled to allege both theories at the pleading stage. See Fleet, supra, 229 Cal.App.4th at 1413.

Defendant's Demurrer to the 9th cause of action for breach of fiduciary duty is OVERRULED.

DEMURRER TO COMPLAINT WITH MOTION TO STRIKE

MOVING PARTY: Defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp.

TENTATIVE RULING

Defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp.'s Demurrer to Complaint is SUSTAINED WITH 20 DAYS LEAVE TO AMEND as to the 3rd cause of action for manufacturing defect and OVERRULED as to the 1st cause of action for negligence, 2nd cause of action for strict liability based on failure to warn, 4th cause of action for breach of express warranty, 5th cause of action for fraud and 6th cause of action for unfair competition

I. Defense of preemption based on design defect under Vaccine Act, 42 USC §300aa-22(b)(1)—OVERRULE

Under the Vaccine Act, design defect claims against vaccine manufacturers are preempted: "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." 42 USC §300aa-22(b)(1).

"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." Bruesewitz v. Wyeth LLC (2011) 562 U.S. 223, 231–232. "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." Id.

Defendants argue Plaintiff's causes of action are thinly-veiled design defect claims and therefore preempted by the 42 USC §300aa-22(b)(1). "[W]hile preemption can be decided on demurrer in a proper case, the implication that it should be decided on demurrer is erroneous. There are numerous circumstances in which the facts must be determined in order to decide whether a claim is preempted by federal law, and it is not uncommon to have preemption claims decided based on an evidentiary showing. Indeed, preemption is an affirmative defense as to which defendants have the burden of proof." Apollo Capital Fund, LLC v. Roth Capital Partners, LLC (2007) 158 Cal.App.4th 226, 250–251.

Moreover, in order to sustain demurrer based on an affirmative defense like preemption, Defendants must establish that the action is "necessarily" barred by preemption. A "demurrer based on an affirmative defense cannot properly be sustained where the action might be barred by the defense, but is not necessarily barred." CrossTalk Productions, Inc. v. Jacobson (1998) 65 Cal.App.4th 631, 635.

Defendants fail to establish that Plaintiff's causes of action are necessarily barred by preemption under the Vaccine Act. Plaintiff's complaint does not allege any cause of action for design defect. Plaintiff alleges negligence, strict liability (failure to warn), strict liability (manufacturing defect), breach of warranty, common law fraud and violation of unfair competition law. On its face, the complaint does not allege any design defect cause of action and is not preempted by 42 USC §300aa-22(b)(1).

In addition, Plaintiff's allegations that Defendants are designers of Gardasil are merely descriptive and do not form the basis of any wrongful conduct. These descriptive allegations do not establish preemption of all causes of action.

Finally, disregarding the labels attached to these causes of action and examining Plaintiff's substantive allegations, the causes of action are not clearly or solely based on design defect. Plaintiff's 1st cause of action for negligence is based on several categories of conduct, some of which clearly have nothing to do with the design of the production. See Complaint, ¶374 ("testing, marketing, supply, promotion, advertisement, packaging, labeling, sale and distribution of Gardasil"). Some of the alleged conduct may ultimately qualify as design defects, such as "research, development…testing…of Gardasil," but they are ambiguous and do not clearly implicate the design of Gardasil See Complaint, ¶374; ¶375 (failure to appropriately and adequately test safety and efficacy). Plaintiff does not expressly allege "design defect."

Because the negligence cause of action is based on conduct that is clearly not barred by the Vaccine Act and conduct that might be barred depending on the meaning of "research, development…testing," demurrer to the 1st cause of action based on the Vaccine Act is overruled. A "demurrer based on an affirmative defense cannot properly be sustained where the action might be barred by the defense, but is not necessarily barred." CrossTalk Productions, Inc. v. Jacobson (1998) 65 Cal.App.4th 631, 635.

Moreover, a demurrer cannot be sustained to part of a cause of action. "Ordinarily, a general demurrer does not lie as to a portion of a cause of action and if any part of a cause of action is properly pleaded, the demurrer will be overruled." Elder v. Pacific Bell Telephone Co. (2012) 205 Cal.App.4th 841, 856. Thus, even if the negligence claim contained some elements of a

design defect claim, it would not justify sustaining demurrer to the entire cause of action.

Plaintiff's 2nd cause of action for "failure to warn" is by definition not based on a design defect. In the 2nd cause of action, Plaintiff alleges that Merck should have known of the dangers of its product, and Merck "failed to adequately warn patients, parents, medical providers and reasonably foreseeable users of the risks." See Complaint, ¶394. The basis of this claim is therefore failure to warn, not negligent design. Design defect immunity under 42 USC §300aa-22(b)(1) only applies "given safe manufacture and warning." Bruesewitz, supra, 562 U.S. 223, 231–232. In the 2nd cause of action for failure to warn, Plaintiff is attacking the sufficiency of Defendants' warnings, not Gardasil's design. Demurrer to the 2nd cause of action for failure to warn based on the Vaccine Act is overruled.

Plaintiff's 3rd cause of action for "manufacturing defect" is likewise not based on a design defect by definition. Plaintiff alleges that "the Gardasil injected into Plaintiff was defectively and unreasonably dangerous because it failed to comply with the approved manufacturing specifications…" See Complaint, ¶¶413-414. Plaintiff alleges his specific dose of Gardasil was not manufactured to FDA-approved design specifications, because it contained dangerous and undisclosed components that were not included in those specifications. Id. at ¶412. These allegations do not allege a design defect and only allege a manufacturing defect.

Unlike Stratton v. Merck & Co., Inc., the Court has not been presented with judicially noticeable evidence establishing that the components were in fact part of the FDA-approved design specifications. See Stratton v. Merck & Co., Inc. (D.S.C., Nov. 17, 2021, No. CV 2:21-02211-RMG) 2021 WL 5416705, at *2 (granting 12(b)(6) motion to dismiss in part on grounds that judicially noticeable evidence established that manufacturing defect allegations were in fact design defect allegations based on components in Gardasil that were part of FDA-approved design). Demurrer to the 3rd cause of action based on the Vaccine Act is overruled.

Plaintiff's 4th cause of action for breach of express warranty is based on Defendants' express statements in Gardasil's label, publications, television advertisements, billboards, print advertisements, online advertisements and website, and other written materials intended for consumers, patients, parents of minor-aged patients, medical providers, and the general public, that Gardasil. See Complaint, ¶¶426-428. Plaintiff's 4th cause of action seeks to impose liability for breach of the warranties made in these statements. Id. at ¶429. Defendants fail to establish that the 4th cause of action for breach of express warranty is based on the design of Gardasil. Demurrer to the 4th cause of action based on the Vaccine Act is overruled.

Plaintiff's 5th cause of action for common law fraud is by definition based on Defendants'

statements regarding Gardasil, either for affirmative misrepresentations or intentional concealment. Plaintiff claims Defendants breached its duty of care to patients and medical providers by failing to provide true information regarding Gardasil's efficacy and risks. See Complaint, ¶441. A claim based on Defendants' statements about Gardasil is not an action based on Defendants' design of Gardasil. Demurrer to the 5th cause of action for common law fraud based on the Vaccine Act is overruled.

Plaintiff's 6th cause of action for unfair competition law is based on Merck's allegedly false and misleading advertising materials for Gardasil. See Complaint, ¶¶466-480. Plaintiff is not alleging that Merck's design of Gardasil was an unlawful, fraudulent and unfair business practice. Plaintiff's unlawful competition claim is based on the same conduct as the breach of warranty and fraud claims. For the same reasons, no design defect claim is contained in the 6th cause of action for unfair competition. Demurrer to the 6th cause of action for unfair competition based on the Vaccine Act is overruled.

II. Learned Intermediary Doctrine and Defense of preemption based on Vaccine Act, 42 USC §300aa-22(c) and to 2nd cause of action for failure to warn, 4th cause of action for breach of express warranty, 5th cause of action for fraud and 6th cause of action for Unfair Competition--OVERRULE

A. Vaccine Act, 42 USC §300aa-22(c)

"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 USC §300aa-22(c).

"Manufacturers are generally immunized from liability for failure to warn if they have complied with all regulatory requirements (including but not limited to warning requirements) and have given the warning either to the claimant or the claimant's physician." Bruesewitz, supra, 562 U.S. at 229 (citing 42 USC §300aa-22(c)); Stratton v. Merck & Co., Inc. (D.S.C., Nov. 17, 2021, No. CV 2:21-02211-RMG) 2021 WL 5416705, at *2. "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." Id. at

230, fn 25.

B. Learned Intermediary Doctrine

"[I]n the case of prescription drugs, the duty to warn runs to the physician, not to the patient." Carlin v. Supr. Ct. (1996) 13 Cal.4th 1104, 1116 (recognition of cause of action for strict liability based on failure to warn in connection with prescription drugs would not inevitably result in manufacturers inundating consumers with warnings of even speculative risks because duty to warn runs to physician, not patient). "[I]f adequate warning of potential dangers of a drug has been given to doctors, there is no duty by the drug manufacturer to insure that the warning reaches the doctor's patient for whom the drug is prescribed." Stevens v. Parke, Davis & Co. (1973) 9 Cal.3d 51, 65.

Under the learned intermediary doctrine, as this rule is known, "the physician stands in the shoes of the 'ordinary user' because it is through the physician that a patient learns of the properties and proper use of the drug or implant. Thus, the duty to warn in these cases runs to the physician, not the patient." Bigler-Engler v. Breg, Inc. (2017) 7 Cal.App.5th 276, 319.

C. Plaintiff's allegations sufficiently allege failure to provide adequate warnings to Plaintiff's medical providers

Plaintiff's failure to warn, breach of warranty, fraud and unfair competition causes of action are based on Defendants' representations regarding Gardasil. Plaintiff alleges that Defendants negligently and fraudulently provided inadequate warnings regarding Gardasil to medical providers, patients and the public, including his medical providers. See Complaint, ¶¶367, 377(m)-(p), 381, 393, 394, 404, 422, 429(a)-(b), 439, 448, 458, 463. Plaintiff alleges his medical providers would not have offered or recommended Gardasil to Plaintiff had they received adequate and truthful warnings. Id. Plaintiff alleges the information Merck negligently or fraudulently failed to include in warnings to medical providers, patients and the general public. Id. at ¶¶399-400.

Based on these allegations, Plaintiff's failure to warn, breach of warranty, fraud and unfair

competition causes of action are not necessarily barred by 42 USC §300aa-22(c). Plaintiff does not allege that his vaccine injury was "solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative)." Plaintiff alleges that his injuries were due to Defendants' failure to provide adequate warnings and information about Gardasil to Plaintiff's medical providers, as well as himself and his mother.

These same allegations refute Defendants' assertion that the learned intermediary doctrine necessarily bars Plaintiff's claims. Plaintiff is alleging failure to warn, breach of warranty, fraud and UCL based on the adequacy of statements and warnings to Plaintiff's medical providers. These same allegations also allege reliance, i.e. Plaintiff's medical providers would not have recommended or prescribed Gardasil to him had they known the true facts. See Complaint, ¶¶381, 404.

In addition, the learned intermediary doctrine is inapplicable to Plaintiff's claim for fraud based on misrepresentations directed by Defendants to him and his mother. Plaintiff's fraud claim alleges both fraud by concealment and intentional misrepresentation. As Plaintiff argues, the basis of a fraud claim is a defendant's breach of the duty not to engage in "deceit," as defined in Civil Code §1710. "One who willfully deceives another with intent to induce him to alter his position to his injury or risk, is liable or any damage which he thereby suffers." Civil Code §1709. The learned intermediary doctrine, however, governs the parameters of the affirmative duty to warn in connection with prescription drugs. See Carlin v. Supr. Ct. (1996) 13 Cal.4th 1104, 1116.

Defendants also fail to cite any provision of the Vaccine Act that would immunize a vaccine manufacturer from affirmative misrepresentations. Neither 42 USC §300aa-22(b)(1) nor 42 USC §300aa-22(c) indicate immunity from a state law claim for intentional fraud.

Defendants fail to establish that these causes of action are necessarily barred by either the Vaccine Act or that Plaintiff has failed to state a claim based on the Learned Intermediary Doctrine. Defendants' demurrer to the failure to warn, breach of warranty, fraud and unfair competition causes of action based on 42 USC §300aa-22(c) and Learned Intermediary Doctrine is overruled.

III. 1st cause of action for negligence based on failure to warn—OVERRULED

"To prevail in a negligence action, a plaintiff must show that the defendant owed a legal duty, the defendant breached that duty and the breach proximately caused injury to the plaintiff." Garcia v. W&W Community Development, Inc. (2010) 186 Cal.App.4th 1038, 1044. "Negligence law in a failure-to-warn case requires a plaintiff to 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, supra, 13 Cal.4th at 1112.

"Ordinarily, negligence may be alleged in general terms, without specific facts showing how the injury occurred, but there are limits to the generality with which a plaintiff is permitted to state his cause of action, and the plaintiff must indicate the acts or omissions which are said to have been negligently performed. He may not recover upon the bare statement that the defendant's negligence has caused him injury." Berkley v. Dowds (2007) 152 Cal.App.4th 518, 527.

The elements of a negligence claim based on failure to warn are: (1) that defendant manufactured, distributed and/or sold the product; (2) that defendant knew or reasonably should have known that the product was dangerous or was likely to be dangerous when used or misused in a reasonably foreseeable manner; (3) that defendant knew or reasonably should have known that users would not realize the danger; (4) that defendant failed to adequately warn of the danger or instruct on the safe use of the product; (5) that a reasonable manufacturer, distributor and/or seller under the same or similar circumstances would have warned of the danger or instructed on the safe use of the product; (6) that the defendant was a substantial factor in causing plaintiff's harm. CACI 1222. "The warning must be given to the prescribing physician and must include the potential risks or side effects that may follow the foreseeable use of the product." Id.

Plaintiff alleges that Defendants were the manufacturers and distributors of Gardasil. See Complaint, ¶390. Plaintiff alleges that Defendants knew or should have known that Gardasil posed an unreasonable risk of harm to patients, including increased risk of autoimmune disease. Id. at ¶¶370, 393-398. Plaintiff alleges Defendants knew or should have known that users would not realize the danger. See Complaint, ¶373. Plaintiff alleges Defendants failed to adequately warn plaintiff, his mother, plaintiff's medical providers, patients and medical providers in general of the dangers of autoimmune disease and other grave illnesses. Id. at ¶377(k)-(p). Plaintiff alleges that Defendants breached the duty of care when they failed to provide adequate warnings of these dangers. Id. at ¶¶374, 375, 377. Plaintiff alleges that "had Merck not engaged in the negligent and fraudulent conduct alleged…then upon information and belief, Plaintiff's medical providers would not have recommended or offered Gardasil to Plaintiff." Id. at ¶381. Plaintiff alleges that Defendants' conduct was the proximate cause of Plaintiff's injury. Id. at ¶382.

Plaintiff sufficiently alleges negligence based on failure to warn. Defendants' demurrer to the 1st cause of action for negligence is OVERRULED.

IV. 2nd cause of action for strict liability based on failure to warn—OVERRULED

"Failure to warn in strict liability differs markedly from failure to warn in the negligence context…Strict liability is not concerned with the standard of due care or the reasonableness of a manufacturer's conduct. The rules of strict liability require a plaintiff to 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. Thus, in strict liability, as opposed to negligence, the reasonableness of the defendant's failure to warn is immaterial. Stated another way, a reasonably prudent manufacturer might reasonably decide that the risk of harm was such as not to require a warning as, for example, if the manufacturer's own testing showed a result contrary to that of others in the scientific community. Such a manufacturer might escape liability under negligence principles. In contrast, under strict liability principles the manufacturer has no such leeway; the manufacturer is liable if it failed to give warning of dangers that were known to the scientific community at the time it manufactured or distributed the product. Similarly, a manufacturer could not escape liability under strict liability principles merely because its failure to warn of a known or reasonably scientifically knowable risk conformed to an industry-wide practice of failing to provide warnings that constituted the standard of reasonable care." Carlin, supra, 13 Cal.4th 1104, 1112–1113.

The elements of a strict liability for failure to warn cause of action are: (1) that defendant manufactured, distributed and/or sold the product; (2) that the product had potential risks, side effects or allergic reactions that were known or knowable in light of the scientific and/or medical knowledge that was generally accepted in the scientific community at the time of manufacture, distribution or sale; (3) that the potential risks, side effects, allergic reactions presented a substantial danger when the product is used or misused in an intended or reasonably foreseeable way; (4) that ordinary consumers would not have recognized the potential risks, side effects or allergic reactions; (5) that defendant failed to adequately warn or instruct of the potential risks, side effects, allergic reactions; (6) that plaintiff was harmed; and (7) that the lack of sufficient instructions or warnings was a substantial factor in causing plaintiff's harm. CACI 1205. "The warning must be given to the prescribing physician and must include the potential risks, side

effects, or allergic reactions that may follow the foreseeable use of the product." CACI 1205.

Plaintiff alleges that Defendants manufactured, sold and distributed Gardasil. See Complaint, ¶388. Plaintiff alleges that Gardasil's risk of cancer and autoimmune disease were known to Defendants or scientifically knowable to Defendants through appropriate research and testing by known methods. Id. at ¶393. Plaintiff alleges Gardasil was not safe and effective for its intended use due to these known risks. Id. at ¶¶377(q), 393. Plaintiff alleges that targeted consumers and patients, the parents of these patients and the children's medical providers were unaware of these risks. Id. at ¶¶373, 393. Plaintiff alleges Defendants failed to adequately warn or instruct of these risks and potential side effects, completely failing to warn of them. Id. at 393, 398. Plaintiff alleges Defendant's failure to provide adequate warnings to Plaintiff, his mother and his medical providers was a substantial factor in causing his injury. Id. at ¶403. Plaintiff alleges that, if adequate warnings had been provided, his medical providers would not have offered or recommended Gardasil, nor would he or his mother have consented to Plaintiff's injection with Gardasil. Id. at ¶404.

Plaintiff states a claim for strict liability failure to warn. Defendants' demurrer to the 2nd cause of action is OVERRULED.

III. 3rd cause of action for strict liability manufacturing defect—SUSTAINED WITH 20 DAYS LEAVE TO AMEND

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. (1978) 20 Cal. 3d 413, 429. Strict liability based on manufacturing defect 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. (2002) 99 Cal. App. 4th 594, 613.

"A manufacturing defect is one which results from an error in the production process. The product comes off the assembly line in a substandard condition: in some way it differs from the manufacturer's intended result or from other ostensibly identical units of the same product line. Such defective products are relatively easy to identify. [¶] The design defect is more difficult to identify. When the injury-producing agent is common to all the products of a certain line, the defect, if it exists, lies in the original design or model. To paraphrase Justice Traynor, there is

something 'wrong…not in the manufacturer's manner of production, but in his product.'"

Finn v. G. D. Searle & Co. (1984) 35 Cal.3d 691, 715–716.

A manufacturing defect claim is sufficiently pled where the plaintiff alleges that the product "failed to meet FDA-imposed manufacturing quality standards" and "failed to comply with FDA-mandated design and materials specifications." Mize v. Mentor Worldwide LLC (2020) 51 Cal.App.4th 850, 861-862. A plaintiff need not plead how the defendant manufacturer failed to comply with FDA requirements or how that failure affected the manufacture of the product. Id. at 861 (plaintiff sufficiently alleged manufacturing defect cause of action by pleading that "in years leading up to her implant surgery [defendant] failed to meet FDA imposed manufacturing quality standards, destroyed evidence of its implants' high rupture rates, sold contaminated implants, and failed to comply with FDA mandated design and materials specifications"); Coleman v. Medtronic, Inc. (2014) 223 Cal.App.4th 413, 435 (allegation that defendant failed to "comply with the manufacturing specifications required" by FDC Act was sufficient to plead state law claim for manufacturing defect and issue of preemption should not have been determined on demurrer).

Plaintiff alleges that the "Gardasil vaccines injected into Plaintiff were defective and unreasonably dangerous because they failed to comply with manufacturing specifications required by the governing manufacturing protocols and also required by the regulatory agencies, including but not limited to the FDA, by among other things, containing ingredients and toxins that were not disclosed in the FAD-approved specifications and/or otherwise not disclosed in the package insert." Complaint, ¶412. Plaintiff alleges "by way of example" that his doses of Gardasil contained dangerous and undisclosed HPV L1-DNA fragments and PMSF, a toxic nerve agent this is not intended for human consumption or injection. Id. at ¶414.

These allegations are sufficient to allege a manufacturing defect. Plaintiff alleges that the particular doses of Gardasil injected into him suffered from a manufacturing defect, because it deviated from the FDA approved design.

However, as Defendants point out, these allegations of a manufacturing defect are followed by an allegation that directly contradicts the existence of a manufacturing defect: "At all times relevant to this litigation, Merck's Gardasil products reached the intended consumers…including Plaintiff, without substantial change in their condition as designed…by Merck." Id. If the Gardasil doses received by Plaintiff were "as designed" and intended by Merck, there was no manufacturing defect by definition. See Finn, supra, 35 Cal.3d at 715–716 (product that suffers

from manufacturing defect "in some way it differs from the manufacturer's intended result or from other ostensibly identical units of the same product line"); Barker, supra, 20 Cal. 3d at 429 (same); Colbath v. Merck & Co., Inc. (S.D.Ca. Mar. 29, 2022) 2022 WL 935195 (granting 12(b)(6) motion to state law claim for manufacturing defect with leave to amend based on allegation that plaintiff's dose of Gardasil reached plaintiff "without substantial change in their condition as designed" by Merck).

Due to these directly contradictory allegations, Plaintiff's 3rd cause of action for manufacturing defect is SUSTAINED WITH 20 DAYS LEAVE TO AMEND.

IV. 4th cause of action for breach of express warranty—OVERRULED

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

"We emphasize, however, that the 'consumer expectation' aspect of a breach of warranty action is subject, in the prescription drug context, to the general rule, discussed above, that warnings concerning the drug's properties are properly directed to the physician rather than the patient…Thus, for purposes of liability for breach of warranty, ordinarily it is the prescribing doctor who in reality stands in the shoes of 'the ordinary consumer.'" Carlin, supra, 13 Cal.4th at 1118.

Defendants demur to the 4th cause of action for express warranty on grounds that (1) the Vaccine Act preempts any claim for express warranty based on representations to Plaintiff and his mother; (2) the learned intermediary doctrine also precludes any claim for breach of express warranty based on warranties to Plaintiff and his mother; and (3) there are no allegations that Plaintiff and/or his mother relied on any specific representations by Merck.

Plaintiff's breach of warranty claim is not based solely on representations or warranties made to him and his mother. Plaintiff alleges that the representations and warranties were made to "Plaintiff, his mother and/or his medical providers." See Complaint, ¶429. Plaintiff therefore alleges breach of warranty in conformity with the learned intermediary doctrine and Carlin.

Plaintiff also alleges that he and his mother relied on Defendants' warranties in consenting to Gardasil. See Complaint, ¶432. Plaintiff also alleges that his medical providers would not have offered or recommended Gardasil to Plaintiff were it not for Merck's representations in its labeling, advertisements and promotions. Id. at 381.

Finally, the sections of the Vaccine Act relied upon by Defendants do not bar a cause of action based on express warranty to a prescribing medical provider. Plaintiff does not allege that his vaccine injury was "solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative)." 42 USC §300aa-22(c). Plaintiff is alleging breach of express warranty based on representations made to his medical providers as well.

V. 5th cause of action for common law fraud--OVERRULED

The elements of fraud are: (1) misrepresentation (false representation, concealment, or nondisclosure); (2) knowledge of falsity (scienter); (3) intent to defraud or induce reliance; (4) justifiable reliance; and (5) damages. See Civil Code §1709. Fraud actions are subject to strict requirements of particularity in pleading. See Committee on Children's Television, Inc. v. General Foods Corp. (1983) 35 Cal. 3d 197, 216. A plaintiff must allege what was said, by whom, in what manner (i.e. oral or in writing), when, and, in the case of a corporate defendant, under what authority to bind the corporation. See Goldrich v. Natural Y Surgical Specialties, Inc. (1994) 25 Cal.App.4th 772, 782.

Plaintiff's 5th cause of action for fraud is based on numerous express representations made directly to him and his mother, as well as his prescribing physicians, regarding the safety and efficacy of Gardasil, the prevalence of cervical cancer, that Gardasil prevented cervical and anal cancer and that Gardasil's only risks were injection site pain and fever, when Defendants knew that there were numerous other serious potential side effects. See Complaint, ¶453. Plaintiff alleges that his mother was exposed to these misrepresentations through Defendants' marketing campaign entitled "One Less," which included television and print advertisements and posters at doctors' offices, and other advertising. See Complaint, ¶¶83, 85, 449. Plaintiff was exposed to Defendants' representations regarding Gardasil based on statements to him by his physician. Id. at ¶448. Plaintiff alleges these representations were made to the general public and to physicians specifically. Id. at ¶¶426, 429(a). Plaintiff alleges that one of the marketing campaigns directed

to the general public, including Plaintiff, his mother and his medical providers, was conducted in 2016.

These allegations sufficiently allege fraud against Defendants. The nature of the misrepresentations, including whether they were written or verbal, is alleged. The alleged misrepresentations were made in advertisements and marketing materials approved by and from Merck. The advertisements are specifically identified. Plaintiff alleges that he received his shot in 2018 and at least one of the campaigns was conducted in 2016. This is sufficient for Defendants to discern when the alleged representations were made. Moreover, Defendants would have better knowledge regarding when Defendants held the specific conferences to medical professionals and when they ran the specific campaigns identified by Plaintiff. "Each element of a fraud count must be pleaded with particularity so as to apprise the defendant of the specific grounds for the charge and enable the court to determine whether there is any basis for the cause of action, although less specificity is required if the defendant would likely have greater knowledge of the facts than the plaintiff." Chapman v. Skype Inc. (2013) 220 Cal.App.4th 217, 231.

On reply, Defendants argue the fraud claim fails, because Plaintiff cannot allege a duty of disclosure to support fraudulent concealment. However, Plaintiff's fraud claim alleges intentional misrepresentation in addition to fraudulent concealment. So long as the intentional misrepresentation claim is sufficiently pleaded, the demurrer must be overruled. A "general demurrer does not lie as to a portion of a cause of action and if any part of a cause of action is properly pleaded, the demurrer will be overruled." Elder v. Pacific Bell Telephone Co. (2012) 205 Cal.App.4th 841, 856.

Defendants also argue that the Vaccine Act and the Learned Intermediary Doctrine bar Plaintiff's intentional misrepresentation claim. As discussed above, Defendants fail to cite to any section of the Vaccine Act that would apply to an intentional misrepresentation claim based on intentional misrepresentations made directly to the patient.

Defendants argue that the learned intermediary doctrine applies to intentional misrepresentation claims involving prescription drugs. Defendants rely on Colbath for this proposition. Defendants' argument fails for several reasons. Colbath dismissed the plaintiff's intentional misrepresentation claim with leave to amend on grounds that the "plaintiff failed to allege that his medical providers saw, let alone relied on Defendants' affirmative misrepresentations." Colbath, supra, 2022 WL 935195, at *8. Here, Plaintiff alleges that his medical providers saw and relied on the Defendants' misrepresentations.

Defendants are correct that Colbath required plaintiff to allege his medical providers' exposure and reliance on the alleged misrepresentations based on the learned intermediary doctrine. "Under the Vaccine Act and the Learned Intermediary Doctrine, the duty to warn runts to the physician, not to the patient." Id. Colbath relies on Conte v. Wyeth (2008) 168 Cal.App.4th 89 and Saavedra v. Eli Lilly and Co. 2013 WL 6345442.

However, Saavedra expressly refrained from applying the learned intermediary doctrine to consumer protection claims and stated: "Defendant has failed to identify any California case holding that the learned intermediary doctrine bars a tort cause of action, despite the plethora of claims-strict liability, negligence, breach of implied and express warranties, fraudulent misrepresentation-that a failure to warn claim can give rise to." Saavedra, supra, 2013 WL 6345442, at *5.

Conte involved alleged misrepresentations by a drug manufacturer in the labeling of Reglan, a prescription drug, and in a monograph on Reglan provided by the manufacturer for the Physician's Desk Reference. See Conte, supra, 168 Cal.App.4th 89, 98. Conte held the undisputed evidence established lack of causation and reliance where the prescribing physician testified that he did not rely on either representation in prescribing Reglan to the plaintiff. Id. at 99. On that basis, the Court granted the drug manufacturer's motion for summary judgment of the fraud, fraudulent concealment and negligent misrepresentation causes of action. Id. at 95. The alleged misrepresentations were therefore contained in materials directed at prescribing physicians. Unlike Plaintiff Shain's complaint, the Conte complaint did not allege fraudulent misrepresentations made in advertising directed to patients.

Defendants fail to cite to any case law applying the learned intermediary doctrine to cases of fraud based on drug manufacturer's misrepresentations in advertisements intentionally directed at patients and the general public. As Plaintiff argues in opposition, the learned intermediary doctrine applies to the duty to warn as to prescription drugs, while Plaintiff's fraud claim is based in part on the duty not to make affirmative misrepresentations.

Defendants' demurrer to the 5th cause of action for common law fraud is OVERRULED.

VI. 6th cause of action for Unfair Competition—OVERRULED

Defendants demur to the 6th cause of action for unfair competition on the exact same grounds as

the 1st through 5th causes of action—Vaccine Injury Act, Learned Intermediary, failure to allege misrepresentations with specificity. For the same reasons stated in connection with the demurrer to these other causes of action, plaintiff states a cause of action for unfair competition. Defendants' demurrer is OVERRULED.

VII. Motion to Strike—DENY

Defendants' motion to strike the punitive damages claim is DENIED. Plaintiff sufficiently alleges claims for fraud and allegations that would support a finding of malice based on despicable conduct in conscious disregard of the rights and safety of other under CC §3294.

"An employer shall not be liable for damages pursuant to subdivision (a), based upon acts of an employee of the employer, unless the employer had advance knowledge of the unfitness of the employee and employed him or her with a conscious disregard of the rights or safety of others or authorized or ratified the wrongful conduct for which the damages are awarded or was personally guilty of oppression, fraud, or malice. With respect to a corporate employer, the advance knowledge and conscious disregard, authorization, ratification or act of oppression, fraud, or malice must be on the part of an officer, director, or managing agent of the corporation." CC §3294(c).

Plaintiff alleges liability based on Merck's actions toward the general public, e.g. Merck's corporate advertising, Merck's marketing, Merck's methodology of operating clinical trials and obtaining FDA approval and Merck's intentional failure to provide adequate warnings regarding Gardasil in medical literature. Plaintiff therefore need not satisfy the requirements of CC §3294(c). A reasonable inference is that such mass marketing campaigns and actions in Merck's name were done with the approval an officer, director or managing agent of Merck.

Defendants' Motion to Strike Plaintiff's Vioxx and Other Product Allegations as irrelevant is GRANTED per CCP §435. "An immaterial allegation in a pleading is any of the following: (1) An allegation that is not essential to the statement of a claim or defense. (2) An allegation that is neither pertinent to nor supported by an otherwise sufficient claim or defense. (3) A demand for judgment requesting relief not supported by the allegations of the complaint or cross-complaint." CCP §431.10. For purposes of pleading, the Vioxx allegations are irrelevant and immaterial as defined under CCP §430.10. The Vioxx allegations are not necessary to satisfy an essential element of Plaintiff's causes of action. At best, they are evidentiary facts which are immaterial to the complaint. To survive a demurrer, "each evidentiary fact that might eventually form part of

the plaintiff's proof need not be alleged." C.A. v. William S. Hart Union High School Dist. (2012) 53 Cal.4th 861, 872.

Defendants' Motion to Strike Plaintiff's "design defect" allegations is DENIED. As discussed in connection with the demurrer, Plaintiff's express allegations regarding "design" are descriptive of Defendants' role and duties as to Gardasil. Plaintiff's allegations regarding "research," "development" and "testing" are ambiguous and are not clearly "design defect" allegations from the face of the complaint.

Defendants' Motion to Strike the 3rd cause of action for manufacturing defect is MOOT in light of the Court's order sustaining demurrer with leave to amend.
**********END OF TENTATIVE RULINGS********** Pursuant to Government Code sections 68086, 70044, and California Rules of Court, rule 2.956, Tammie Moore, #11525, certified shorthand reporter is appointed as an official Court reporter pro tempore in these proceedings, and is ordered to comply with the terms of the Court Reporter Agreement. The Order is signed and filed this date.

The matters are called for hearing and held.

As to Defendant Alisa A. Bromberg, MD's Demurrer to the 7th, 8th and 9th causes of action, the Court adopts its tentative ruling as indicated above.

The Demurrer - without Motion to Strike filed by Alisa A. Bromberg, MD on 02/28/2022 is Sustained in Part. Defendant Alisa A. Bromberg, MD's Demurrer to the 7th, 8th and 9th causes of action is OVERRULED as to the 7th cause of action for medical malpractice and 9th cause of action for breach of fiduciary duty, and SUSTAINED WITHOUT LEAVE TO AMEND as to the 8th cause of action for battery. Defendant to answer in 10 days. Notice is waived.

As to Defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp.'s Demurrer to the Complaint, the Court adopts its tentative ruling as indicated above.

The Demurrer - with Motion to Strike (CCP 430.10) filed by Merck Sharp & Dohme Corp, Merck & Co, Inc. on 03/08/2022 is Sustained in Part. Defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp.'s Demurrer to Complaint is SUSTAINED WITH 20 DAYS LEAVE TO AMEND as to the 3rd cause of action for manufacturing defect; and OVERRULED as to the 1st cause of action for negligence, 2nd cause of action for strict liability based on failure to warn, 4th cause of action for breach of express warranty, 5th cause of action for fraud and 6th cause of action for unfair competition.

SUPERIOR COURT OF CALIFORNIA, COUNTY OF LOS ANGELES

Civil Division

West District, Santa Monica Courthouse, Department O

21STCV35340 August 4, 2022
HAYDEN SHAIN vs MERCK & CO, INC., et al. 8:30 AM

Judge: Honorable H. Jay Ford III
Judicial Assistant: K. Neal
Courtroom Assistant: A. Khleif

CSR: Tammie Moore (Telephonic), #11525
ERM: None
Deputy Sheriff: None

The Motion to Strike (not initial pleading) Portions of Plaintiff's Complaint filed by Merck & Co, Inc., Merck Sharp & Dohme Corp on 03/08/2022 is Denied.

Attorney Bijan Esfandiari is to submit the proposed Order.

A further Case Management Conference is held. No further notice is required.

CERTIFICATE OF SERVICE

I hereby certify that the foregoing document was filed on the date indicated below using the Court's ECF system, which will provide notice of this filing to all counsel of record.

This, the 20th day of September 2022.

/s/ Bijan Esfandiari
Bijan Esfandiari