Superior Court of California

County of Los Angeles

Spring Street Courthouse, Department 9

JENNIFER ROBI,

Plaintiff,

vs.

MERCK & CO., INC.; MERCK SHARP & DOHME CORP.; KAISER FOUNDATION HOSPITALS; SOUTHERN CALIFORNIA PERMANENTE MEDICAL GROUP; JUDITH GARZA, M.D.; CLAIRE VALENCIA FULLER, M.D.; ROBIN B. SCANLON, M.D.; *et al.*,

Defendants.

Case No.: BC628589

Hearing Date: October 9, 2024

FINAL ORDER RE:

MERCK DEFENDANTS' MOTION FOR SUMMARY JUDGMENT OR IN THE ALTERNATIVE SUMMARY ADJUDICATION

Background

This is an action for misleading advertising, products liability, and medical malpractice. Plaintiff Jennifer Robi alleges that she was injured by the administration of a human papillomavirus vaccine developed, manufactured, distributed, and marketed under the trade name of "Gardasil" by Defendants Merck & Co, Inc. and Merck Sharp & Dohme Corp. (jointly "Merck Defendants"). Plaintiff alleges that during the pre-approval process and thereafter, Merck Defendants failed to disclose to the FDA information regarding Gardasil's safety, effectiveness, and use. Plaintiff also alleges that Merck Defendants deceptively advertised

Gardasil and concealed potential risks from Plaintiff. Plaintiff further alleges that Kaiser Foundation Hospitals ("Kaiser Hospitals"), Southern California Permanente Group ("Permanente"), Judith Garza, M.D., Claire Valencia Fuller, M.D., and Robin Scanlon, M.D. (collectively "Kaiser Defendants") negligently administered Gardasil to Plaintiff and did so without her informed consent. Plaintiff further alleges that as a result of her Gardasil vaccinations, she suffered adverse reactions, culminating in a diagnosis of Postural Orthostatic Tachycardia Syndrome and an underlying small fiber neuropathy.

On July 27, 2016, Plaintiff filed her complaint, commencing case no. BC628589. In the complaint, Plaintiff asserts the following causes of action against the Merck Defendants: (1) fraud and deceit; (2) negligence; and (3) products liability—failure to warn and inform. Plaintiff asserts the following causes of action against Kaiser Defendants: (4) medical malpractice, and (5) medical battery.

On May 1, 2017, the instant action was deemed complex and assigned for all purposes to the Complex Litigation Program. (Minute Order 5/1/17.)

On July 12, 2024, Merck Defendants filed the instant motion for summary judgment or in the alternative summary adjudication. On September 11, 2024, Plaintiff filed an opposition. On September 20, 2024, Merck Defendants filed a reply. On October 8, 2024, Plaintiff filed objections to the reply evidence and to some of Merck Defendants' requests for judicial notice.

During the hearing on October 9, 2024, the Court ordered the parties to file a joint statement regarding Plaintiff's evidentiary objections by October 25, 2024. (Minute Order 10/9/24.) The Court also permitted the parties to file supplemental briefing as to leave to amend in the event that the Court grants Merck Defendants' motion for judgment on the pleadings. (Minute Order 10/9/24.)

On October 17, 2024, Merck Defendants filed their supplemental brief. On October 25, 2024, Plaintiff filed its supplemental opposition. In addition, on October 25, 2024, the parties

filed their joint statement regarding Plaintiff's evidentiary objections. On November 1, 2024, the Court took the matter under submission. The Court rules as follows:

Allegations of the Operative Complaint

The Complaint alleges in relevant part that:

Merck Defendants developed, manufactured, distributed, and marketed Gardasil, a vaccine for the Human Papillomavirus. (Complaint ¶ 5.) Gardasil "is a vaccine designed to prevent infection by certain strains of the Human Papillomavirus, particularly such infections in females. The Human Papillomavirus infection is primarily, if not always, sexually transmitted. The greater majority of such infections cause no clinical symptoms and are self-limited, being removed from the human body by its own immunological and other mechanisms. However, persistent Human Papillomavirus infections in a limited number of cases with certain strains of the virus may cause the development of precancerous lesions. These precancerous lesions are typically diagnosed through pap smears, and then removed through medical procedures. However when undiagnosed they can cause cervical cancer in females as well as other diseases such as genital warts. To be effective the vaccine must be administered prior to the recipient having been exposed to and infected by the virus." (*Id.* ¶ 6.)

On June 8, 2006, the FDA approved Gardasil. (*Id.* ¶ 13.) "Plaintiff is informed and believes and based upon such information and belief alleges that [Merck Defendants] ... wrongfully and deceitfully failed, during the preapproval processing period and thereafter, to disclose to the FDA and others material facts and information relating to the effectiveness and safety of Gardasil, as well as to whom the vaccine should or should not be administered, known to them and obtained through such scientific and medical investigations and studies which they have or should have caused to be conducted." (*Id.* ¶ 14.) Further on information and belief, Merck Defendants "wrongfully and deceitfully failed to perform in the preapproval processing

period and thereafter the material scientific and medical investigations and studies relating to the safety, effectiveness and need for the Gardasil vaccine as required by and under FDA directives and regulations as well as those to which a prudent manufacturer should and would comply." (*Id.* ¶ 15.)

Upon approval by the FDA, Merck Defendants "commenced and engaged in highly extensive, and aggressive, marketing practices which were designed primarily, if not solely, to increase the sales and profits from Gardasil." (*Id.* ¶ 16.) In this marketing, Merck Defendants "intentionally, wrongfully and deceitfully withheld, failed to provide and concealed from consumers, patients and others material facts and information with respect to the effectiveness, safety and need for the administration of the Gardasil vaccination, as well as the risks of serious adverse reaction related thereto and as in part hereafter set forth[.]" (*Ibid.*) "These marketing practices were initially directed at and targeted females aged 9 years through 26 years." (*Id.* ¶ 17.)

Merck Defendants "wrongfully and deceitfully failed to unambiguously inform those to whom the marketing was directed, of material facts and information which these Defendants knew or should have ascertained through their investigations and studies specific to the risk/benefit and quantitative risk assessments regarding and including, among other things, the following: ... [the effectiveness of the Gardasil vaccine against the Human Papillomavirus] ... [and] The nature and consequences as well as the likelihood of serious adverse reactions to the [Gardasil] vaccine[.]" (*Id.* ¶ 17.)

On information and belief, Merck Defendants also "negligently failed to provide during the preapproval processing period and thereafter, to disclose to the FDA and others material facts and information relating to the effectiveness and safety of Gardasil, as well as to whom the vaccine should or should not be administered, known to them and obtained through such scientific and medical investigations and studies which they have or should have caused to be

conducted." (*Id.* ¶ 21.) Further on information and belief, Merck Defendants "negligently failed to perform the material scientific and medical investigations and studies relating to the safety, effectiveness and need for the Gardasil vaccine as required by and under FDA directives and regulations as well as those to which a prudent manufacturer should and would comply." (*Id.* ¶ 22.)

"During the period from March 04, 2010 through January 20, 2011, Plaintiff, a female born on November 15, 1994, was administered a series of three Gardasil vaccinations, each, and a combination of which resulted in serious adverse immunological and other disease reactions commencing approximately in March 2011 and continuing thereafter to this date. Due to the complexity and heterogeneous nature of her disease processes Plaintiff's actual disease process remained medically undiagnosed until approximately August of 2015, when diagnosed as a Postural Orthostatic Tachycardia Syndrome ('POTS') with a further diagnosis in February 2016, of an underlying small fiber neuropathy existing within and throughout her body." (*Id.* ¶ 10.) "[B]ased upon the foregoing diagnoses Plaintiff is informed and believes and based upon such information and belief alleges that the foregoing Gardasil vaccinations which were administered to her from March 04, 2010 through January 20, 2011 were the proximate cause of her underlying disease process." (*Ibid.*)

On September 20, 2013, Plaintiff filed a petition under the National Vaccine Injury Compensation Program in the U.S. Court of Federal Claims seeking compensation for her Gardasil vaccine related injuries. (*Id.* ¶ 8.) "A judgment thereon was rendered on May 29, 2015. Plaintiff duly filed an election to file a civil action on June 15, 2015." (*Ibid.*)

Request for Judicial Notice

In conjunction with the opposition, Plaintiff requests that the Court take judicial notice of the following:

1. The August 4, 2022, Minute Order in the Los Angeles Superior Court case No. 21STCV35340, *Hayden Shain v. Merck & Co., Inc.*

In conjunction with the reply, Merck Defendants request that the Court take judicial notice of the following:

1. Respondent's Rule 4(c) Report and Response to Petitioner's Motion for Judgment on the Record, *Robi v. Sec'y of HHS* (Case No. 13-734V), filed March 27, 2015, a true and correct copy of which is attached as Exhibit 22 to the Esterkin Declaration in support of the moving papers for the instant motion.
2. A website printout from U.S. Food and Drug Administration ("FDA"), Gardasil Vaccine Safety, available at https://public4.pagefreezer.com/content/FDA/01-03-2022T00:42/https://www.fda.gov/vaccines-blood-biologics/vaccine-safety-availability/gardasilvaccine-safety (Statement Dated August 20, 2009, Content Current as of February 1, 2018), a true and correct copy of which is attached as Exhibit 25 to the Esterkin Declaration in support of the moving papers for the instant motion.
3. A website printout from FDA, Vaccine Development - 101, available at www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-development-101 (December 14, 2020), a true and correct copy of which is attached as Exhibit 29 to the Esterkin Declaration in support of the moving papers for the instant motion.
4. The National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 82 Fed. Reg. 6294 (Jan. 19, 2017), a true and correct copy of which is attached as Exhibit 32 to the Esterkin Declaration in support of the moving papers for the instant motion.
5. A website printout from CDC, HPV Vaccine Safety and Effectiveness Data, available at https://www.cdc.gov/hpv/hcp/vaccine-safety-data.html (November 1, 2021), a true and correct copy of which is attached as Exhibit 34 to the Esterkin Declaration in support of the moving papers for the instant motion.
6. A website printout from CDC, Human Papillomavirus (HPV) Vaccine, available at https://www.cdc.gov/vaccinesafety/vaccines/hpv-vaccine.html (September 9, 2020), a true and correct copy of which is attached as Exhibit 35 to the Esterkin Declaration in support of the moving papers for the instant motion.
7. A website printout from FDA, FDA Information on Gardasil – Presence of DNA Fragments Expected, No Safety Risk, available at https://public4.pagefreezer.com/content/FDA/21-02-2022T12:11/https://www.fda.gov/vaccines-blood-biologics/vaccines/fda-information-gardasilpresence-dna-fragments-expected-no-safety-risk (October 21, 2011). a true and correct copy of which is attached as Exhibit 37 to the Esterkin Declaration in support of the moving papers for the instant motion.

8. Excerpts from the Transcript of the September 9, 2009 FDA Meeting of the Vaccines and Related Biological Products Advisory Committee ("VRBPAC"), a true and correct copy of which is attached as Exhibit 38 to the Esterkin Declaration in support of the moving papers for the instant motion.
9. A website printout from FDA, Common Ingredients in FDA-Approved Vaccines, available at https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/commoningredients-fda-approved-vaccines (January 12, 2024), a true and correct copy of which is attached as Exhibit 39 to the Esterkin Declaration in support of the moving papers for the instant motion.
10. Excerpts from the Transcript of the May 18, 2006 FDA Meeting of the VRBPAC, a true and correct copy of which is attached as Exhibit 41 to the Esterkin Declaration in support of the moving papers for the instant motion.
11. Final Rule, National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 86 Fed. Reg. 6249 (Jan. 20, 2021), a true and correct copy of which is attached as Exhibit 42 to the Esterkin Declaration in support of the moving papers for the instant motion.
12. The journal article Shimabukuro et al., *Safety of the 9-Valent Human Papillomavirus Vaccine*, 144 PEDIATRICS 6 (2019), a true and correct copy of which is attached as Exhibit 43 to the Esterkin Declaration in support of the moving papers for the instant motion.
13. A website printout from CDC, Questions About HPV Vaccine Safety, available at https://www.cdc.gov/vaccinesafety/vaccines/hpv/hpv-safety-faqs.html (July 15, 2020), a true and correct copy of which is attached as Exhibit 44 to the Esterkin Declaration in support of the moving papers for the instant motion.
14. A website printout from CDC, Vaccine Adverse Event Reporting System (VAERS), available at https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html (October 19, 2023), a true and correct copy of which is attached as Exhibit 45 to the Esterkin Declaration in support of the moving papers for the instant motion.
15. A website printout from FDA, VAERS: A Critical Part of the National Vaccine Safety System, available at https://www.fda.gov/news-events/fda-voices/vaers-critical-part-national-vaccinesafety-system (November 21, 2023), a true and correct copy of which is attached as Exhibit 46 to the Esterkin Declaration in support of the moving papers for the instant motion.
16. A website printout from National Institute of Health ("NIH"), National Cancer Institute, Human Papillomavirus (HPV) Vaccines, available at https://www.cancer.gov/about-cancer/causesprevention/risk/infectious-agents/hpv-vaccine-fact-sheet (May 25, 2021), a true and correct copy of which is attached as Exhibit 69 to the Esterkin Declaration in support of the moving papers for the instant motion.

17. The September 12, 2008 FDA Approval Letter for Gardasil, a true and correct copy of which is attached as Exhibit 70 to the Esterkin Declaration in support of the moving papers for the instant motion.
18. The October 16, 2009 FDA Approval Letter for Gardasil, a true and correct copy of which is attached as Exhibit 71 to the Esterkin Declaration in support of the moving papers for the instant motion.
19. The December 22, 2010 FDA Approval Letter for Gardasil, a true and correct copy of which is attached as Exhibit 72 to the Esterkin Declaration in support of the moving papers for the instant motion.
20. The December 10, 2014 FDA Approval Letter for Gardasil 9, a true and correct copy of which is attached as Exhibit 73 to the Esterkin Declaration in support of the moving papers for the instant motion.
21. A website printout from U.S. Centers for Disease Control and Prevention ("CDC"), Reasons to Get HPV Vaccine, available at https://www.cdc.gov/hpv/parents/vaccine/six-reasons.html (November 10, 2021), a true and correct copy of which is attached as Exhibit 74 to the Esterkin Declaration in support of the moving papers for the instant motion.
22. A website printout from CDC, Human Papillomavirus (HPV) Vaccination & Cancer Prevention, available at https://www.cdc.gov/vaccines/vpd/hpv/index.html (November 16, 2021), a true and correct copy of which is attached as Exhibit 75 to the Esterkin Declaration in support of the moving papers for the instant motion.
23. A website printout from CDC, HPV Vaccination is Safe and Effective, available at https://www.cdc.gov/hpv/parents/vaccinesafety.html (July 23, 2021), a true and correct copy of which is attached as Exhibit 76 to the Esterkin Declaration in support of the moving papers for the instant motion.
24. A website printout from WHO, Safety of HPV Vaccines, available at https://www.who.int/groups/global-advisory-committee-on-vaccine-safety/topics/human-papillomavirus-vaccines/safety (July 14, 2017), a true and correct copy of which is attached as Exhibit 77 to the Esterkin Declaration in support of the moving papers for the instant motion.
25. A website printout from WHO, Global strategy to accelerate the elimination of cervical cancer as a public health problem, available at https://www.who.int/publications/i/item/9789240014107 (November 17, 2020), a true and correct copy of which is attached as Exhibit 78 to the Esterkin Declaration in support of the moving papers for the instant motion.
26. A website printout from European Medicines Agency, European Medicines Agency, Review concludes evidence does not support that HPV vaccines cause CRPS or POTS, available at https://www.ema.europa.eu/en/documents/press-release/review-concludes-evidence-does-not-supporthpv-vaccines-cause-crps-or-pots_en.pdf

(November 5, 2015), a true and correct copy of which is attached as Exhibit 79 to the Esterkin Declaration in support of the moving papers for the instant motion.

As to Merck Defendants' requests for judicial numbered 2, 3, 5-7, 9, 13-16, and 21-26, the requests for judicial notice must be denied. California has not recognized a provision for taking judicial notice of documents from websites. (See *Jolley v. Chase Home Finance, LLC* (2013) 213 Cal.App.4th 872, 888-889.) Furthermore, information on websites can reasonably be subject to dispute. (See *Ibid.; Huitt v. Southern Cal. Gas Co.* (2010) 188 Cal.App.4th 1586, 1605 n.10 ["Simply because information is on the Internet does not mean that it is not reasonably subject to dispute"]; *Ragland v. U.S. Bank Nat. Assn.* (2012) 209 Cal.App.4th 182, 194 ["Nor may we take judicial notice of the truth of the contents of the Web sites and blogs, including those of the Los Angeles Times and Orange County Register. . . The contents of the Web sites and blogs are 'plainly subject to interpretation and for that reason not subject to judicial notice. [Citation omitted]'"].)

As to Merck Defendants' requests for judicial notice numbered 8 and 10 requesting judicial notice of portions of transcripts of the September 9, 2009 and May 18, 2006 FDA Meetings of the Vaccines and Related Biological Products Advisory Committee, Merck Defendants cite no basis for judicial notice of these transcripts. Though the court may take judicial notice of the actions of the FDA such as the occurrence of these meetings and the outcome of said meetings, (Evid. Code § 452(c)), nothing permits the court to take judicial notice of transcripts of said meetings. Accordingly, Merck Defendants' requests for judicial notice numbered 8 and 10 are denied.

As to the remaining requests, the Court may take judicial notice of court records and matters and actions of the state and federal Government. (See Evid. Code, § 452(c)(d).) Thus, the parties' remaining unopposed requests for judicial notice are GRANTED. However, the

Court does not take judicial notice of the truth of assertions within. (See *Herrera v. Deutsche Bank National Trust Co.* (2011) 196 Cal.App.4th 1366, 1375.)

Evidentiary Objections

Plaintiff's Evidentiary Objections

In opposition, Plaintiff objects to various undisputed material facts. These objections to material facts are improper under California Rules of Court, Rule 3.1354.

Rule 3.1354 requires that the objecting party:

(1) Identify the name of the document in which the specific material objected to is located;

(2) State the exhibit, title, page, and line number of the material objected to;

(3) Quote or set forth the objectionable statement or material; and

(4) State the grounds for each objection to that statement or material.

Plaintiff's objections embedded in the response to the undisputed material facts fail to comply with Rule 3.1354 and are objections directed at Defendant's proposed undisputed material facts – not to evidence. A court must rule on individual objections only when they are timely and in the proper form. (*Demps v. San Francisco Housing Authority* (2007) 149 Cal.App.4th 564, 578.) Accordingly, the Court declines to rule on Plaintiff's improper objections to the undisputed material facts.

Plaintiff also objects to portions of the declaration of Jeremy B. Esterkin declaration filed in support of the instant motion. The Court rules as follows:

Declaration of Jeremy B. Esterkin

1. Sustained – Lack of Foundation
2. Sustained – Lack of Foundation
3. Sustained – Lack of Foundation
4. Sustained – Lack of Foundation
5. Sustained – Lack of Foundation

6. Sustained – Lack of Foundation
7. Sustained – Lack of Foundation
8. Sustained – Lack of Foundation
9. Sustained – Lack of Foundation
10. Sustained – Lack of Foundation
11. Sustained – Lack of Foundation
12. Sustained – Lack of Foundation
13. Sustained – Lack of Foundation
14. Sustained – Lack of Foundation
15. Sustained – Lack of Foundation, Hearsay
16. Sustained – Hearsay: Evid. Code § 1280 does not apply because Merck Defendants have failed to lay a foundation establishing that this writing ([t]he FDA and CDC "have been closely monitoring the safety of Gardasil" and have "not identified any issues affecting the safety, purity, and potency of Gardasil") was made at or near the time of the acts referred to in the writing. Relevance: the FDA's and CDC's monitoring activities are not at issue in light of Merck Defendants' own responsibility for the content of its labels at all times (*Wyeth, supra*, 555 U.S. at pp.570–571) and in light of the allegations of the complaint that Merck Defendants have been withholding information from the FDA and CDC. (Complaint ¶¶ 14, 21, 28.)
17. Sustained – Hearsay. Evid. Code § 1280 does not apply because Merck Defendants have failed to lay a foundation establishing that this writing ("Vaccines are closely monitored using various surveillance systems" by the FDA) was made at or near the time of the acts referred to in the writing, Relevance: the FDA's monitoring activities are not at issue in light of Merck Defendants' own responsibility for the content of its labels at all times (*Wyeth, supra*, 555 U.S. at pp.570–571) and in light of the allegations of the complaint that Merck Defendants have been withholding information from the FDA. (Complaint ¶¶ 14, 21, 28.)
18. (Left Blank by Plaintiff)
19. Sustained – Lack of Foundation, Hearsay
20. Sustained – Hearsay. Evid. Code § 1280 does not apply because Merck Defendants have failed to lay a foundation establishing that this writing ("To date, there is no medical or scientific evidence that the HPV vaccine causes POTS and safety monitoring has not shown any other problems") was made at or near the time of the acts referred to in the writing
21. Sustained – Hearsay. Evid. Code § 1280 does not apply because Merck Defendants have failed to lay a foundation establishing that this writing ("VAERS did not detect any unusual or unexpected patterns for POTS following HPV vaccination that would suggest a safety problem") was made at or near the time of the acts referred to in the writing Sustained – Hearsay, Evid. Code § 1280 does not apply, no foundation has

been laid that this writing was made at or near the time of the acts referred to in the writing

22. Sustained – Hearsay. Evid. Code § 1280 does not apply because Merck Defendants have failed to lay a foundation establishing that this writing ("Findings from many vaccine safety monitoring systems and more than 160 studies have shown that HPV vaccines have a favorable safety profile—the body of scientific evidence overwhelmingly supports their safety") was made at or near the time of the acts referred to in the writing
23. Sustained – Hearsay. Evid. Code § 1280 does not apply because Merck Defendants have failed to lay a foundation establishing that this writing (The FDA "continually reviews all reports of the Vaccine Adverse Event Reporting System after vaccination with Gardasil, and there is no evidence of unusual clinical patterns or high reporting rates of adverse events, including autoimmune diseases") was made at or near the time of the acts referred to in the writing
24. Sustained – Lack of Foundation, Lack of Authentication
25. Sustained – Hearsay. Evid. Code § 1280 does not apply because Merck Defendants have failed to lay a foundation establishing that this writing ("Aluminum salts are incorporated into some vaccine formulations as an adjuvant. . . . For example: aluminum salts are used in DTaP vaccines, the pneumococcal conjugate vaccine, the HPV vaccine, and hepatitis B vaccines. . . . Aluminum adjuvant containing vaccines have a demonstrated safety profile of over many decades of use and have only uncommonly been associated with severe local reactions. Of note, the most common source of exposure to aluminum is from eating food or drinking water") was made at or near the time of the acts referred to in the writing
26. Sustained – Lack of Foundation, Lack of Authentication
27. Sustained – Hearsay. Evid. Code § 1280 does not apply because Merck Defendants have failed to lay a foundation establishing that this writing (Gardasil "is a safe and effective HPV vaccine") was made at or near the time of the acts referred to in the writing, Relevance
28. Sustained – Hearsay
29. Sustained – Hearsay. Evid. Code § 1280 does not apply because Merck Defendants have failed to lay a foundation establishing that this writing (monitoring through VAERS has not detected any safety concerns related to POTS following HPV vaccination") was made at or near the time of the acts referred to in the writing
30. Sustained – Hearsay. Evid. Code § 1280 does not apply because Merck Defendants have failed to lay a foundation establishing that this writing (The CDC has stated that "a causal relationship cannot be established using information from VAERS reports alone") was made at or near the time of the acts referred to in the writing
31. Sustained – Hearsay. Evid. Code § 1280 does not apply because Merck Defendants have failed to lay a foundation establishing that this writing ("What VAERS doesn't

do, though, is tell us whether a vaccine caused a medical issue. That requires investigation") was made at or near the time of the acts referred to in the writing

32. Overruled
33. Overruled
34. Overruled
35. Overruled
36. Overruled
37. Overruled
38. Overruled
39. Overruled
40. Overruled
41. Overruled
42. Overruled
43. Overruled
44. Overruled
45. Overruled
46. Sustained – Hearsay. Evid. Code § 1280 does not apply because Merck Defendants have failed to lay a foundation establishing that this writing ("HPV types 6 and 11, which cause 90% of genital warts." "HPV types 16 and 18, two high-risk HPVs that cause about 70% of cervical cancers and an even higher percentage of some of the other HPV-caused cancers.") was made at or near the time of the acts referred to in the writing
47. Sustained – Lack of Foundation
48. Sustained – Lack of Foundation
49. Sustained – Lack of Foundation
50. Sustained – Lack of Foundation
51. Sustained – Hearsay. Evid. Code § 1280 does not apply because Merck Defendants have failed to lay a foundation establishing that this writing ("HPV infections, genital warts, and cervical precancers (abnormal cells on the cervix that can lead to cancer) have dropped since the vaccine has been in use in the United States.") was made at or near the time of the acts referred to in the writing
52. Sustained – Hearsay. Evid. Code § 1280 does not apply because Merck Defendants have failed to lay a foundation establishing that this writing ("HPV vaccination provides safe, effective, and lasting protection against the HPV infections that most commonly cause cancer") was made at or near the time of the acts referred to in the writing
53. Sustained – Hearsay. Evid. Code § 1280 does not apply because Merck Defendants have failed to lay a foundation establishing that this writing ("Each HPV vaccine— 9-valent HPV vaccine (Gardasil® 9), quadrivalent HPV vaccine (Gardasil®), and bivalent HPV vaccine (Cervarix®)—went through strict safety testing before the U.S.

Food and Drug Administration (FDA) licensed them. Over 15 years of monitoring and research during the vaccination program have continued to show that HPV vaccination is safe") was made at or near the time of the acts referred to in the writing

54. Sustained – Hearsay. Evid. Code § 1280 does not apply because Merck Defendants have failed to lay a foundation establishing that this writing (The WHO's Global Advisory Committee on Vaccine Safety "considers HPV vaccines to be extremely safe. . . . there is still no evidence to suggest a causal association between HPV vaccine and CRPS, POTS or the diverse symptoms that include pain and motor dysfunction") was made at or near the time of the acts referred to in the writing
55. Sustained – Hearsay. Evid. Code § 1280 does not apply because Merck Defendants have failed to lay a foundation establishing that this writing ("This global strategy to eliminate cervical cancer proposes: . . . [that] 90% of girls [be] fully vaccinated with HPV vaccine by age 15 years") was made at or near the time of the acts referred to in the writing
56. Sustained – Hearsay. Evid. Code § 1280 does not apply because Merck Defendants have failed to lay a foundation establishing that this writing ("The PRAC concluded that the available evidence does not support that CRPS and POTS are caused by HPV vaccines. . . . Use of these vaccines is expected to prevent many cases of cervical cancer (cancer of the neck of the womb, which is responsible for tens of thousands of deaths in Europe each year) and various other cancers and conditions caused by HPV. The benefits of HPV vaccines therefore continue to outweigh their risks") was made at or near the time of the acts referred to in the writing

Plaintiff's General Objection to Reply Evidence

Plaintiff has filed a general objection to the entirety of the September 20, 2024 declaration of Deanne Miller, Esq. submitted in support of Merck Defendant's reply on the grounds that reply. Plaintiff objects evidence is not generally permitted.

In general, for due process reasons, the moving party generally may not rely on additional evidence filed with its reply papers. (*San Diego Watercrafts, Inc. v. Wells Fargo Bank, N.A.* (2002) 102 Cal.App.4th 308, 316.) Evidence filed for the first time in a reply may violate the opposing party's due process rights if considered by the Court. (*Ibid.*) Thus, evidence and exhibits presented in support of a reply are not generally allowed. (*Nazir v. United Airlines, Inc.* (2009) 178 Cal.App.4th 243, 249.)

Here, much of the reply evidence is not new but rather a refiling of evidence that was submitted with the moving papers together with supplemental authenticating evidence. Exhibits 1-3 of the September 20, 2024 declaration of Deanne Miller, Esq. are not substantively new evidence but rather merely authenticate some of the evidence originally submitted with the moving papers.

However, the remaining exhibits of the September 20, 2024 declaration of Deanne Miller, Esq. – Exhibits 4-6 – are substantively new evidence, and the Court will not consider them.

Merck Defendants Evidentiary Objections

Merck Defendants object to portions of the declaration of Bijan Esfandiari submitted in support of the Plaintiff's opposition. The Court rules as follows:

Declaration of Bijan Esfandiari

1-46, 48-119. Overruled

47. Sustained – Lack of Foundation

Undisputed Material Facts

Merck Defendants and Plaintiff have each submitted Undisputed Material Facts, which the court will reference as "DMF" for Merck Defendants' Undisputed Material Facts and "PMF" for Plaintiff's Additional Material Facts.

"Plaintiff was first administered Gardasil on March 4, 2010." (DMF 1.)

"On March 18, 2010, Plaintiff's back pain was described by one of her medical records as 'daily and sharp in quality.'" (DMF 2.)[1] "On March 18, 2010, Plaintiff's back pain was

[1] Plaintiff claims that various DMFs including DMFs 2-4, 10-12, 14, 16, and 18 are disputed but fails to cite any evidence to support her claim. "An opposing party who contends that a fact is disputed must state, on the right side of the page directly opposite the fact in dispute, the nature of the dispute and ***describe the evidence that supports the position that the fact is controverted.***" (Cal. Rules of Court, Rule 3.1350(f)(2), [bold and italics added].) Because

described by one of her medical records as 'daily and sharp in quality.'" ('DMF 3.) "A chiropractic note from April 12, 2010, describes Plaintiff as having 'constant lower back pain.'" (DMF 4.)

"Plaintiff developed bilateral ankle pain in June 2010." (DMF 5.) "On June 29, 2010, Plaintiff was seen by Dr. Claire Fuller due to a reported two-week history of bilateral ankle pain. The pain was described as 'sharp stabbing.'" (DMF 6.) "Plaintiff was administered her second dose of Gardasil at the June 29, 2010, visit with Dr. Fuller." (DMF 7.)

"On August 5, 2010, Plaintiff presented for an acute care visit with Dr. Scanlon complaining of headache, dizziness, nausea, and fatigue. She reported an episode of vomiting, and she reported that she felt faint, starting four days ago." (DMF 8.) "During the period from about the end of July or the first part of August, 2010, Jennifer experienced an onset of severe headaches, tender feeling over portions of her body, and was at times dizzy, nauseated, tired and fatigued." (DMF 9.) "On August 28, 2010, Plaintiff complained of severe headache, migraine, increased pain and hypersensitivity." (DMF 10.)

"On August 30, 2010, in a pediatric acute visit with Dr. Fuller, Plaintiff was seen for persistent nightly headaches and shoulder discomfort. She also reported malaise/fatigue, tiredness, nausea, headaches, and chronic low back pain." (DMF 11.) "On September 9, 2010, Plaintiff was seen for a neurology consultation with a chief complaint of headaches. She described her headaches as being an 8/10. She also reported nausea daily, difficulty concentrating and fatigue. The neurologist noted her as positive for 'malaise/fatigue.'" (DMF 12.)

"On September 16, 2010, Plaintiff was seen by Dr. Scanlon for worsening headaches. Plaintiff reported that she also had blurry vision and some blind spots in her vision. The note also indicates she 'has been clammy at night.' She reported her headache pain as rising to 10/10

Plaintiff fails to cite any facts to support that these facts are disputed, the Court will consider these facts as undisputed.

the night before." (DMF 14.) "On October 7, 2010, Plaintiff saw Dr. Garza, a rheumatologist, and reported that during the summer she started to feel very tired, started having headaches, and saw spots prior to the onset of the headaches. She reported that she had nausea a few times a week, felt tired all the time, even after sleeping 15-16 hours. Plaintiff also reported that there were times she could not walk because of pain. Dr. Garza diagnosed her with fibromyalgia." (DMF 15.) "The symptoms Plaintiff reported on October 7, 2010, were 'similar symptoms with continuation of her symptoms.'" (DMF 18.)

"On January 20, 2011, Plaintiff was seen by Dr. Scanlon for increased nausea and diarrhea, as well as headaches. At that appointment, she was administered a third dose of Gardasil, the last dose of a three-dose series." (DMF 17.)

"Plaintiff filed a petition in Vaccine Court on behalf of Plaintiff on September 25, 2013." (DMF 23.)

"Plaintiff filed the instant Complaint on July 27, 2016, and in it alleged that she was diagnosed with Postural Orthostatic Tachycardia Syndrome ('POTS') in approximately August of 2015 and with small fiber neuropathy in February 2016 and that the 'vaccinations which were administered to her from March 04, 2010 through January 20, 2011 were the proximate cause of her underlying disease process.'" (DMF 25.)

"Plaintiff filed the present action on July 27, 2016, against Merck (and other Kaiser-related defendants)." (DMF 68.) "Merck is the manufacturer of Gardasil." (DMF 69.) "The Complaint alleges three causes of action against Merck: Fraud and Deceit, Negligence, and Product Liability – Failure to Warn and Inform." (DMF 70.)

"'Nausea' and 'dizziness' were included in the 'Adverse Reactions' section of the Gardasil label dated October 2009." (DMF 33.) "At the September 9, 2009 meeting of the Vaccines and Related Biological Products Advisory Committee, the FDA heard allegations from members of the public that Gardasil ingredient polysorbate 80 poses certain health risks."

(DMF 42.)[2] "Polysorbate 80 is listed as an ingredient on Gardasil's FDA-approved label." (DMF 44.)

"The United States Centers for Disease Control and Prevention ('CDC') has stated: 'Ongoing safety monitoring through VAERS has not detected any safety concerns related to POTS following HPV vaccination.'" (DMF 51.) "The CDC has stated that 'VAERS did not detect any unusual or unexpected patterns for POTS following HPV vaccination that would suggest a safety problem.'" (DMF 52.) "The CDC has stated that 'a causal relationship cannot be established using information from VAERS reports alone.'" (DMF 53.) "The FDA has stated: 'What VAERS doesn't do, though, is tell us whether a vaccine caused a medical issue. That requires investigation.'" (DMF 54.)

"At all times after its initial approval until Plaintiff was administered each of the Gardasil doses to which she attributes her allegedly vaccine-related injury, Gardasil was and remained an FDA-approved vaccine." (DMF 56.) "FDA-approved labeling providing, among other things, that Gardasil is not a replacement for cervical cancer screening accompanied each vaccine dose administered to Plaintiff and at all times relevant to this case." (DMF 58.) "FDA-approved labeling providing, among other things, that Gardasil 'has not been demonstrated to protect against diseases due to HPV types not contained in the vaccine' accompanied each vaccine dose administered to Plaintiff and at all times relevant to this case." (DMF 59.) "FDA-approved labeling providing, among other things, that vaccination 'with GARDASIL may not result in protection in all vaccine recipients' accompanied each vaccine dose administered to Plaintiff and at all times relevant to this case." (DMF 60.)

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[2] Plaintiff's response to various DMFs such as DMF 42 fail to specify whether the DMF is disputed or not and are therefore improper because they do not unequivocally state whether the fact is disputed or undisputed. California Rules of Court, Rule 3.1350(f)(2) requires that "[o]n the right side of the page, directly opposite the recitation of the moving party's statement of material facts and supporting evidence, ***the response must unequivocally state whether that fact is 'disputed' or 'undisputed.'***" (*Ibid.*, [bold and italics added].) Accordingly, the Court will consider these facts as undisputed.

"Before and when Plaintiff was administered each of the Gardasil doses to which she attributes her allegedly vaccine-related injury, Merck submitted the annual reports required by 21 C.F.R. § 601.12(f)(3) for Gardasil in compliance with federal regulations." (DMF 63.)

Legal Standard

The function of a motion for summary judgment or adjudication is to allow a determination as to whether an opposing party cannot show evidentiary support for a pleading or claim and to enable an order of summary dismissal without the need for trial. (*Aguilar v. Atlantic Richfield Co.* (2001) 25 Cal.4th 826, 843.) Code of Civil Procedure § 437c(c) "requires the trial judge to grant summary judgment if all the evidence submitted, and 'all inferences reasonably deducible from the evidence' and uncontradicted by other inferences or evidence, show that there is no triable issue as to any material fact and that the moving party is entitled to judgment as a matter of law." (*Adler v. Manor Healthcare Corp.* (1992) 7 Cal.App.4th 1110, 1119.)

As to each claim as framed by the complaint, the defendant moving for summary judgment must satisfy the initial burden of proof by presenting facts to negate an essential element or to establish a defense. (CCP § 437c(p)(2); *Scalf v. D. B. Log Homes, Inc.* (2005) 128 Cal.App.4th 1510, 1520.) Courts "liberally construe the evidence in support of the party opposing summary judgment and resolve doubts concerning the evidence in favor of that party." (*Dore v. Arnold Worldwide, Inc.* (2006) 39 Cal.4th 384, 389.)

"If [the defendant] satisfies this burden, then the burden of production shifts to [the plaintiff] 'to show that a triable issue of one or more material facts exists as to the cause of action or a defense.' [Citation.]" (*Donohue v. AMN Services, LLC* (2021) 11 Cal.5th 58, 79.) "A triable issue of material fact may not be created by speculation or a 'stream of conjecture and surmise.' [Citations.] Instead, the plaintiff must produce 'substantial responsive evidence.'

[Citation.]" (*Miller v. Fortune Commercial Corp.* (2017) 15 Cal.App.5th 214, 221.) "There is a triable issue of material fact if, and only if, the evidence would allow a reasonable trier of fact to find the underlying fact in favor of the party opposing the motion in accordance with the applicable standard of proof. [Citation.]' [Citation.]" (*Gabrielle A. v. County of Orange* (2017) 10 Cal.App.5th 1268, 1282.)

Discussion

A. Merck Defendants' Motion for Summary Judgment

Merck Defendants move for summary judgment on the grounds that (1) Plaintiff failed to timely file her claim in Vaccine Court, (2) Plaintiff's claims fail because they are preempted by federal law and regulations governing vaccine warning labels, (3) Plaintiff cannot overcome the statutory presumption that legally adequate warnings accompanied the Gardasil Vaccine, (4) Plaintiff's claims are barred by the Vaccine Act and California's Learned Intermediary Doctrine, and (5) Plaintiff cannot prove causation because Plaintiff's prescribing physicians continue to affirm their decision to prescribe the Gardasil vaccine. Alternatively, Merck Defendants seek summary adjudication of (1) Plaintiff's prayer for punitive damages, (2) damages beyond those sought in Vaccine Court, and (3) Plaintiff's claims for negligence and fraud on the grounds that Merck Defendants' statements were true.

1. Failure to Timely File Claim in Vaccine Court

Merck Defendants' Moving Burden

Merck Defendants contend that the entire action against them fails because Plaintiff failed to comply with the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-10 *et seq.* ("Vaccine Act").

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* (2011) 562 U.S. 223, 243.) Under the Vaccine Act, "[a] person injured by a vaccine, or his legal guardian, may file a petition for compensation in the United States Court of Federal Claims, naming the Secretary of Health and Human Services as the respondent. A special master then makes an informal adjudication of the petition within (except for two limited exceptions) 240 days. The Court of Federal Claims must review objections to the special master's decision and enter final judgment under a similarly tight statutory deadline. At that point, a claimant has two options: to accept the court's judgment and forgo a traditional tort suit for damages, or to reject the judgment and seek tort relief from the vaccine manufacturer." (*Id.* at p.228, [Footnotes Omitted].)

However, "[n]o person may bring a civil action for damages … against a vaccine … manufacturer in a State or Federal court for damages arising from a vaccine-related injury … unless a petition has been filed, in accordance with section 300aa-16 of this title …" (42 U.S.C. § 300aa-11(a)(2)(A).) Section 300aa-16 of the Vaccine Act provides – in relevant part –that "if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation . . . for such injury after the expiration of 36 months [1] after the date of the occurrence of the first symptom or manifestation of onset [2] or of the significant aggravation of such injury." (42 U.S.C. § 300aa-16(a)(2) [Underline added].) For purposes of the Vaccine Act, " 'significant aggravation' means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." (42 U.S.C. § 300aa-33.)

The Vaccine Act's text describes a two-pronged test. First, for a petition under the Act to be allowed, the petition must be filed within 36 months of the date of the occurrence of the first symptom or manifestation of onset. Failing this, the petition must instead be filed within 36

months after the date of a significant aggravation of such injury. Accordingly, to warrant a grant of summary judgment in their favor, Merck Defendants must show that the Plaintiff's petition was time-barred by virtue of Plaintiff's failure to satisfy either of the two Vaccine Act prongs – i.e., that Plaintiff did not file a petition within 36 months of either a) the date of occurrence of the first symptom or manifestation of onset or b) the date of a significant aggravation of such injury.

However, Merck Defendant's motion addresses only the first of these two prongs and ignores the second prong. Merck Defendant moving papers simply do not address whether Plaintiff satisfies the second prong, namely, whether Plaintiff filed her petition within 36 months of a significant aggravation of her injury. Merck Defendants' motion on this point is therefore insufficient to warrant summary judgment on this issue.

In a motion for summary judgment, the moving party bears the burden of persuasion and proof. (*Aguilar v. Atlantic Richfield Co.* (2001) 25 Cal.4th 826, 845 ["From commencement to conclusion, the moving party bears the burden of persuasion that there is no genuine issue of material fact and that he is entitled to judgment as a matter of law."].)

A defendant moving for summary judgment must show either that one or more elements of the cause of action cannot be established, or that there is a complete defense to that cause of action. (CCP § 437c(p)(2).) This means that if the plaintiff bears the burden of preponderance of the evidence at trial, then the defendant in a summary judgment motion "must present evidence that would require a reasonable trier of fact *not* to find any underlying material fact more likely than not—otherwise, [the defendant] would not be entitled to judgment *as a matter of law*, but would have to present *his* evidence to a trier of fact." (*Aguilar, supra,* 25 Cal.4th at p.851.) "Summary judgment law in [California] continues to require a defendant moving for summary judgment to *present evidence*, and not simply point out that the plaintiff does not possess, and cannot reasonably obtain, needed evidence. In this particular at least, it still

diverges from federal law." (*Id.* at pp. 854–855.) To meet this burden, a defendant must present evidence that shows not only "that the plaintiff *does not possess* needed evidence" but also that "the plaintiff *cannot reasonably obtain* needed evidence." (*Id.* at p.854.) It is insufficient for the defendant to merely point out the absence of evidence. (*Gaggero v. Yura* (2003) 108 Cal.App.4th 884, 891). The defendant "must also *produce evidence* that the plaintiff cannot reasonably obtain evidence to support his or her claim." (*Ibid* [italics added].) The supporting evidence can be in the form of affidavits, declarations, admissions, depositions, answers to interrogatories, and matters of which judicial notice may be taken. (*Aguilar*, *supra*, 25 Cal.4th at p.855.)

Here, Merck Defendants fail to show that more than 36 months elapsed between a significant aggravation of Plaintiff's injury and Plaintiff's filing of her petition. Plaintiff received her first Gardasil vaccination shot on March 4, 2010. (DMF 1.) Soon thereafter, on March 18, 2020, Plaintiff began experiencing sharp lower back pain. (DMFs 3-4.) In relevant part, Plaintiff confirmed in discovery responses that she sustained "low back pain" due to the Gardasil vaccine. (DMF 21.) Plaintiff did not file a petition in Vaccine Court relating to the alleged Gardasil injuries until September 25, 2013. (DMF 35.) Thus, Defendant's moving evidence indicates that Plaintiff did not file the petition until 42 months and 7 days after first experiencing symptoms from the Gardasil vaccine – more than the 36-month limit imposed by the Vaccine Act.

However, Merck Defendants' separate statement is devoid of any evidence affirmatively showing that Plaintiff did not experience a "significant aggravation" of her injury in the 36 months prior to filing the petition with the Vaccine Court – i.e., September 25, 2010 through September 25, 2013. (*City of Pasadena v. Superior Court* (2014) 228 Cal.App.4th 1228, 1238, Fn. 4, [" '[t]his is the Golden Rule of Summary Adjudication: if it is not set forth in the separate statement, *it does not exist.*' "].) Similarly, Merck Defendants' memorandum fails to cite any

evidence demonstrating that Plaintiff did not experience a "significant aggravation" in the 36 months prior to filing the petition with the Vaccine Court. (*See* Cal. Rules of Court, Rule 3.1113(b).)[3]

Moreover, Plaintiff received *three* Gardasil vaccinations. Plaintiff received the third vaccination on January 20, 2011 – well within the 36-month limitation period. Given that the Gardasil administration was recurring, the 36-month limitation period restarts. "Generally speaking, continuous accrual applies whenever there is a continuing or recurring obligation: 'When an obligation or liability arises on a recurring basis, a cause of action accrues each time a wrongful act occurs, triggering a new limitations period.' [Citation.]" (*Aryeh v. Canon Business Solutions, Inc.* (2013) 55 Cal.4th 1185, 1199.)

Accordingly, Merck Defendants fail to meet their moving burden in showing that Plaintiff failed to timely file her claim in Vaccine Court.

2. Preemption by Federal Law Governing Vaccine Labels

Merck Defendants contend that as a matter of law, all of Plaintiff's claims against them are preempted by federal laws and regulations governing vaccine warning labels. This contention fails on several grounds.

Under California products liability law, a drug manufacturer is strictly liable if it " '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

[3] California Rules of Court, rule 3.1113(b) provides that "[t]he memorandum must contain a statement of facts, a concise statement of the law, evidence and arguments relied on, and a discussion of the statutes, cases, and textbooks cited in support of the position advanced." The Court has "no obligation to undertake its own search of the record 'backwards and forwards to try to figure out how the law applies to the facts' of the case." (*Quantum Cooking Concepts, Inc. v. LV Associates, Inc.* (2011) 197 Cal.App.4th 927, 934; see also *Chavez v. Netflix, Inc.* (2008) 162 Cal.App.4th 43, 52 [where appellant's motion was supported by deficient memorandum, trial court was justified in denying the motion on procedural grounds].)

manufacture and distribution.' " (*Carlin v. Superior Court* (1996) 13 Cal.4th 1104, 1112.) In contrast, under a general negligence theory in California, "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." (*Anderson v. Owens-Corning Fiberglas Corp.* (1991) 53 Cal.3d 987, 1002.)

However, failure to warn claims may be preempted by federal law – namely the FDA's labeling requirements. (See e.g., *PLIVA, Inc. v. Mensing* (2011) 564 U.S. 604.) "[F]ederal pre-emption, which as relevant here, takes place when it is ' "impossible for a private party to comply with both state and federal requirements." ' " (*Merck Sharp & Dohme Corp. v. Albrecht* (2019) 587 U.S. 299, 303.) "Impossibility pre-emption is a demanding defense." (*Wyeth v. Levine* (2009) 555 U.S. 555, 573.)

"The FDA regulates the safety information that appears on the labels of prescription drugs that are marketed in the United States. 21 U.S.C. § 355(b)(1)(F); 21 C.F.R. § 201.57(a) (2018). Although we commonly understand a drug's 'label' to refer to the sticker affixed to a prescription bottle, in this context the term refers more broadly to the written material that is sent to the physician who prescribes the drug and the written material that comes with the prescription bottle when the drug is handed to the patient at the pharmacy. 21 U.S.C. § 321(m)." (*Merck Sharp & Dohme Corp., supra,* 587 U.S. at pp.303–304.)

Despite numerous amendments to FDA regulations, "it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." (*Wyeth, supra,* 555 U.S. at pp.570–571.) "Thus, when the risks of a particular drug become apparent, the manufacturer has 'a duty to

provide a warning that adequately describe[s] that risk.'" (*Merck Sharp & Dohme Corp., supra,* 587 U.S. at p.312.)

Accordingly, "[p]rospective drug manufacturers work with the FDA to develop an appropriate label when they apply for FDA approval of a new drug. 21 U.S.C. §§ 355(a), 355(b), 355(d)(7); 21 C.F.R. § 314.125(b)(6). But FDA regulations also acknowledge that information about drug safety may change over time, and that new information may require changes to the drug label. §§ 314.80(c), 314.81(b)(2)(i). Drug manufacturers generally seek advance permission from the FDA to make substantive changes to their drug labels. However, an FDA regulation called the 'changes being effected' or 'CBE' regulation permits drug manufacturers to change a label without prior FDA approval if the change is designed to 'add or strengthen a ... warning' where there is 'newly acquired information' about the 'evidence of a causal association' between the drug and a risk of harm. 21 C.F.R. § 314.70(c)(6)(iii)(A)." (*Merck Sharp & Dohme Corp., supra,* 587 U.S. at pp.304–305.)

"Post–FDA approval preemption analysis proceeds in two stages. First, the plaintiff must show that there existed 'newly acquired information' such that the defendants could unilaterally change the label pursuant to the CBE regulation without FDA approval." (*Utts v. Bristol-Myers Squibb Company* (S.D.N.Y. 2017) 251 F.Supp.3d 644, 661, *aff'd sub nom. Gibbons v. Bristol-Myers Squibb Company* (2d Cir. 2019) 919 F.3d 699.) Second "[b]ecause the FDA 'retains the authority to reject labeling changes,' a manufacturer may still—even after the plaintiff has identified 'newly acquired information'—establish an impossibility preemption defense through 'clear evidence that the FDA would not have approved a change' to the label." (*Ibid.*; see also *Merck Sharp & Dohme Corp., supra,* 587 U.S. at pp.302–303 [explaining that the Supreme Court has "previously held that 'clear evidence' that the FDA would not have approved a change to the drug's label pre-empts a claim, grounded in state law, that a drug manufacturer failed to warn consumers of the change-related risks associated with using the

drug."].) The "question of pre-emption is one for a judge to decide, not a jury." (*Merck Sharp & Dohme Corp., supra,* 587 U.S. at p.303.)

Merck Defendants Fail to Meet Their Moving Burden in Showing that the Action is Preempted by Federal Law Regulating Labels

"[T]he pleadings determine the scope of relevant issues on a summary judgment motion." (*Nieto v. Blue Shield of California Life & Health Ins. Co.* (2010) 181 Cal.App.4th 60, 74.) On a motion for summary judgment, or adjudication, a defendant need only "negate plaintiff's theories of liability as alleged in the complaint; that is, a moving party need not refute liability on some theoretical possibility not included in the pleadings." (*Hutton v. Fidelity National Title Company* (2013) 213 Cal.App.4th 486, 493.)

Here, Plaintiff asserts three causes of action against Merck Defendants: (1) Fraud and Deceit, (2) Negligence, and (3) Product Liability – Failure to Warn and Inform. (Complaint ¶¶ 11-32.)

As to the first cause of action for fraud, Plaintiff alleges that Merck Defendants "wrongfully and deceitfully failed, *during the preapproval processing period and thereafter, to disclose to the FDA and others* material facts and information relating to the effectiveness and safety of Gardasil, as well as to whom the vaccine should or should not be administered, known to them and obtained through such scientific and medical investigations and studies which they have or should have caused to be conducted." (*Id.* ¶ 14 [italics added].) Plaintiff further alleges that "Merck Defendants] wrongfully and deceitfully failed to perform in the preapproval processing period and thereafter the material scientific and medical investigations and studies relating to the safety, effectiveness and need for the Gardasil vaccine as required by and under FDA directives and regulations as well as those to which a prudent manufacturer should and would comply." (*Id.* ¶ 15.) Merck Defendants "commenced and engaged in highly extensive,

and aggressive, marketing practices which were designed primarily, if not solely, to increase the sales and profits from Gardasil. In doing so, [Merck Defendants], in order to preclude any and all questions by consumers, patients and others as to the effectiveness, safety and need for the administration of the Gardasil vaccination as well as the risks of serious adverse reaction related thereto, intentionally, wrongfully and deceitfully withheld, failed to provide and concealed from consumers, patients and others material facts and information with respect to the effectiveness, safety and need of the administration of the Gardasil vaccination, as well as the risks of serious adverse reaction related thereto and as in part hereafter set forth[.]" (*Id.* ¶ 16.) Merck Defendants "wrongfully and deceitfully failed to unambiguously inform those to whom the marketing was directed, of material facts and information which these Defendants knew or should have ascertained through their investigations and studies specific to the risk/benefit and quantitative risk assessments regarding and including, among other things, the following: … The nature and consequences as well as the likelihood of serious adverse reactions to the HPV vaccine[.]" (*Id.* ¶ 17.) In sum, with regard to the first cause of action, Plaintiff alleges that Defendant intentionally failed to warn and failed to disclose certain information. Thus, federal law regarding labeling could potentially preempt the first cause of action.

The second and third causes of action for negligence and product liability are likewise premised upon a failure to warn. (*Id.* ¶ 21 ["[Merck Defendants] negligently failed, *during the preapproval processing period and thereafter, to disclose to the FDA and others* material facts and information relating to the effectiveness and safety of Gardasil, as well as to whom the vaccine should or should not be administered, known to them and obtained through such scientific and medical investigations and studies which they have or should have caused to be conducted"] [italics added], ¶ 23 ["[Merck Defendants] negligently withheld from and failed to provide consumers, patients and others with material facts and information with respect to … the risks of serious adverse reactions related thereto and as in part hereafter set forth."]; ¶ 28

["[Merck Defendants] failed *during the preapproval processing period and thereafter to disclose and concealed from the FDA and others* material facts and information relating to the effectiveness and safety of Gardasil, as well as to whom the vaccine should or should not be administered, known to them and obtained through such scientific and medical investigations and studies which they have or should have caused to be conducted."] [italics added].) Thus, federal law regulating labels could also potentially preempt Plaintiffs' second and third causes of action.

Though Plaintiff's claims against Merck Defendants *could potentially* be preempted by federal law, Merck Defendants fail to meet their moving burden in showing that Plaintiff's claims *are* preempted.

Merck Defendants' Preemption Argument Fails to Address the Complaint's Allegations of Pre-Approval Fraud and Withholding

Merck Defendants argue that "Plaintiff Cannot Demonstrate Any Labeling Deficiency Merck Could Have Corrected Using the CBE Regulation," and "Clear Evidence Demonstrates that the FDA Would Have Rejected the Warnings Plaintiff Demands." (8/21/24 Merck's Memorandum pp. 9-15.) As such, Merck Defendants' "impossibility preemption" defense focuses exclusively on Plaintiff's alleged lack of evidence of "newly acquired information" -- newly acquired *after* FDA approval -- that would have warranted a *change* to Gardasil's warning label using "the CBE regulation." (*Id.* at pp. 10-13.) In focusing only on evidence of "newly acquired information, Merck Defendants ignore the extensive allegations of the Complaint that Merck Defendants fraudulently concealed material information relating to the safety of Gardasil not only after but also *before* FDA approval.

Each of the three causes of action against Merck Defendants is premised at least in part on Merck Defendants' wrongful concealment of material facts from the FDA *during the*

preapproval period. With regard to the first cause of action for fraud, the Complaint alleges that Merck Defendants "wrongfully and deceitfully failed, *during the preapproval processing period* and thereafter, to disclose to the FDA and others material facts and information relating to the effectiveness and safety of Gardasil, as well as to whom the vaccine should or should not be administered, known to them and obtained through such scientific and medical investigations and studies which they have or should have caused to be conducted." (Complaint ¶ 14 [italics added].) With respect to Plaintiff's negligence claim, the Complaint similarly alleges that "Merck . . negligently failed, *during the preapproval processing period* and thereafter, to disclose to the FDA and others material facts and information relating to the effectiveness and safety of Gardasil, as well as to whom the vaccine should or should not be administered, known to them and obtained through such scientific and medical investigations and studies which they have or should have caused to be conducted." (Complaint ¶ 21 [italics added].) Likewise, with respect to the products liability claim, the Complaint alleges that "Merck . . failed *during the preapproval processing period* and thereafter to disclose and concealed from the FDA and others material facts and information relating to the effectiveness and safety of Gardasil, as well as to whom the vaccine should or should not be administered, known to them and obtained through such scientific and medical investigations and studies which they have or have caused to be conducted." (Complaint ¶ 28 [italics added].)

Merck Defendants' preemption argument fails to address these express allegations of the Complaint that Merck Defendants wrongfully withheld material information about the safety and risks of Gardasil during the preapproval processing period. Merck Defendants' moving papers do not include any declaration or deposition transcript of testimony by a Merck employee professing Merck Defendants' lack of any knowledge of any causal connection between Gardasil and POTS or any of the other injuries that Plaintiff alleges in the Complaint before the FDA granted approval in 2006. Nor do the moving papers include any attestation

from a Merck employee that Merck Defendants shared all relevant information within their knowledge and possession regarding Gardasil's risks in seeking FDA approval. Merck Defendants also fail to submit any discovery responses from Plaintiff – such as responses to requests for admission or to interrogatories -- conceding that Plaintiff has no evidence demonstrating that Merck Defendants shared with the FDA all relevant, available information regarding Gardasil's risks. Instead, Merck Defendants' motion for summary judgment – including the preemption defense raised within the motion for summary judgment is completely silent as to Merck Defendants' state of knowledge during the preapproval process and the completeness of Merck Defendants' disclosures to the FDA during the preapproval process.

Accordingly, summary judgment cannot be granted on the basis of Merck Defendants' preemption argument.

As to the Post-FDA Approval Period, Merck Defendants Fail to Cite Any Evidence that Plaintiff Cannot Show that Merck Defendants Received "Newly Acquired Information"

Merck Defendants also fail to meet their moving burden with respect to post-FDA approval preemption.

As noted above, "[p]rospective drug manufacturers work with the FDA to develop an appropriate label when they apply for FDA approval of a new drug. 21 U.S.C. §§ 355(a), 355(b), 355(d)(7); 21 C.F.R. § 314.125(b)(6). But FDA regulations also acknowledge that information about drug safety may change over time, and that new information may require changes to the drug label. §§ 314.80(c), 314.81(b)(2)(i). Drug manufacturers generally seek advance permission from the FDA to make substantive changes to their drug labels. However, an FDA regulation called the 'changes being effected' or 'CBE' regulation permits drug manufacturers to change a label without prior FDA approval if the change is designed to 'add or

strengthen a ... warning' where there is 'newly acquired information' about the 'evidence of a causal association' between the drug and a risk of harm. 21 C.F.R. § 314.70(c)(6)(iii)(A)." (*Merck Sharp & Dohme Corp., supra,* 587 U.S. at pp.304–305.)

" 'Newly acquired information is data, analyses, or other information not previously submitted to the [FDA], which may include (but is not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events, or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA.' (21 C.F.R. § 314.3(b) (2019), italics omitted.)" (*Risperdal and Invega Cases* (2020) 49 Cal.App.5th 942, 955.)

With respect to the period after Gardasil's 2006 approval, Merck Defendants first argue that "[i]n her Complaint, Plaintiff pleads no "newly acquired information" showing reasonable evidence of a causal association between Gardasil and any "clinically significant" "adverse reaction[]" relevant to the injuries she alleges." (8/21/24 Merck's Memorandum pp. 9-15.) Even if true, Plaintiff's failure to plead "newly acquired information" would be inapposite because "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, 251.) As such, Plaintiff was not required to anticipate that Merck Defendants might assert this defense or allege facts to rebut this potential defense. (*Seltzer v. Barnes* (2010) 182 Cal.App.4th 953, 969 ["a defendant that advances an affirmative defense to the plaintiff's claims bears the burden of proof on the defense."].) Thus, " '[t]he burden on a defendant moving for summary judgment based upon the assertion of an affirmative defense is [different] than the burden to show [that] one or more elements of the plaintiff's cause of action cannot be established. Instead of merely submitting evidence to negate a single element of the plaintiff's cause of action, or offering evidence such as vague or insufficient discovery responses that the plaintiff does not have evidence to create an issue of fact as to one or more elements of his or

her case ... "the defendant has the initial burden to show that undisputed facts support each element of the affirmative defense".... If the defendant does not meet this burden, the motion must be denied.' [Citations.]" (*Consumer Cause, Inc. v. SmileCare* (2001) 91 Cal.App.4th 454, 467–468.)

More importantly, Merck Defendants have ignored the express allegations of the Complaint that Merck Defendants "wrongfully and deceitfully failed, during the preapproval processing period *and thereafter, to disclose to the FDA* and others material facts and information relating to the effectiveness and safety of Gardasil . . . *known to them* and obtained through such scientific and medical investigations and studies which they have or should have caused to be conducted." (*Id.* ¶ 14 [italics added]; see also *Id.* ¶ 15 ["[Merck Defendants], . . . intentionally, wrongfully and deceitfully withheld, failed to provide and concealed from consumers, patients and others material facts and information with respect to the . . safety . . of the administration of the Gardasil vaccination, as well as the risks of serious adverse reaction related thereto"]; *Id.* ¶ 16 [Merck Defendants "wrongfully and deceitfully failed to unambiguously inform those to whom the marketing was directed, of material facts and information which these Defendants knew or should have ascertained through their investigations and studies specific to the risk/benefit and quantitative risk assessments regarding and including, among other things, ... [t]he nature and consequences as well as the likelihood of serious adverse reactions to the HPV vaccine"]; *Id.* ¶¶ 21, 28.) Accordingly, contrary to Merck Defendants' argument, the Complaint does in fact include allegations that Merck Defendants had newly acquired information as to the risk of serious adverse reactions to Gardasil – information that Merck Defendants knew or should have ascertained through their investigations and studies.

"[P]reemption 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,

251.) As the party moving for summary judgment, Merck Defendants "bear[] the burden of persuasion that there is no genuine issue of material fact and that [they] [are] entitled to judgment as a matter of law." (*Aguilar, supra,* 25 Cal.4th at p.845.) It is insufficient for the defendant to merely point out the absence of evidence. (*Gaggero v. Yura* (2003) 108 Cal.App.4th 884, 891). The defendant "must also produce evidence that the plaintiff cannot reasonably obtain evidence to support his or her claim." (*Ibid.*) Merck Defendants fail to do so.

Merck Defendants' separate statement fails to identify any fact indicating that Plaintiff lacks evidence of the existence of "newly acquired information" post-dating FDA approval based on which Merck Defendants could have unilaterally changed Gardasil's warning label pursuant to the CBE regulation. Merck Defendants' separate statement also fails to identify any fact indicating that Plaintiff lacks evidence that Merck Defendants learned of risks from the Gardasil vaccine that were previously unknown to the FDA. (*City of Pasadena, supra,* 228 Cal.App.4th at p.1238, Fn. 4, [" '[t]his is the Golden Rule of Summary Adjudication: if it is not set forth in the separate statement, *it does not exist.*' "].)

Nor do Merck Defendants cite any evidence showing that Plaintiffs are unable to obtain evidence of Merck Defendants' knowledge and wrongful concealment of newly acquired information as to risks of developing POTS or other serious adverse effects from administration of Gardasil, as alleged in the Complaint. For example, Merck Defendants do not submit any declaration from any Merck employee identifying what, if anything, Merck studies or investigations revealed either "during the preapproval processing period *or thereafter*" about the risk of developing POTS as a result of the Gardasil vaccine. Merck Defendants have not presented any declaration by any Merck employee attesting that following Gardasil approval, Merck Defendants did not receive any newly acquired information concerning POTS or other adverse reactions beyond what was already known to the FDA. Merck Defendants also fail to submit any discovery responses from Plaintiff – such as responses to requests for admission or

to interrogatories – conceding that Plaintiff has no evidence demonstrating that Merck Defendants had received "newly acquired information" based on which Merck Defendants could have unilaterally changed Gardasil's warning label pursuant to the CBE regulation.

Instead, Merck Defendants simply argue that "the FDA's decision not to require the warnings Plaintiff demands confirms that no information supporting such warnings existed before Plaintiff's last dose in January 2011." (8/21/24 Merck's Memorandum p. 12.) This argument misses the mark for several reasons. First, it ignores "a central premise of federal drug regulation that the *manufacturer* [not the FDA] bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." (*Wyeth, supra,* 555 U.S. at pp.570–571 [italics added].) "Thus, when the risks of a particular drug become apparent, the manufacturer has 'a duty to provide a warning that adequately describe[s] that risk.'" (*Merck Sharp & Dohme Corp., supra,* 587 U.S. at p.312.) Second, Merck Defendants' argument also fails to take into consideration the numerous allegations of the Complaint cited above that during the preapproval period and *thereafter*, Merck Defendants "wrongfully and deceitfully" withheld from the FDA material information within Merck Defendants' concerning the safety of Gardasil and risks of serious adverse reactions – information known to Merck Defendants by virtue of their scientific and medical investigations. (*Id.* ¶¶ 14, 16, 21, 28.) In light of these allegations that Merck Defendants kept the FDA in the dark about risks of serious adverse reactions that Merck Defendants' scientific studies and investigations revealed – allegations which Merck Defendants' moving evidence fails to address – it would be neither surprising nor remarkable that the FDA did not require more stringent warnings for Gardasil, and the FDA's failure to require more stringent warnings does not indicate that no newly acquired evidence existed.

The only undisputed material fact that Merck Defendants cite in support of their argument that Plaintiff lacks evidence that Merck learned of risks previously unknown to the FDA is Undisputed Material Fact 34. (8/21/24 Merck's Memorandum p. 13.) Undisputed Material Fact 34 states: "The FDA has stated that it "closely monitor[]s]" "vaccines . . . using various surveillance systems." (DMF 34.) The only evidence cited in support of Undisputed Material Fact 34 is Exhibit 29, a website printout from FDA, Vaccine Development – 101, available at https://www.fda.gov/vaccines-bloodbiologics/development-approval-process-cber/vaccine-development-101 (December 14, 2020). However, the Court has sustained Plaintiff's hearsay and relevance objections to this exhibit. (Plaintiff's Objection 17.) As noted above, Merck Defendants' reliance on Evidence Code § 1280 is misplaced. Merck Defendants have failed to lay a foundation that this writing was made at or near the time of the acts referred to in the writing, and thus, the exhibit does not fall within the scope of section 1280. Moreover, the fact that the FDA has been closely monitoring the safety of Gardasil is irrelevant in light of the allegations of the Complaint that the Merck Defendants have been actively withholding information about the risks of Gardasil from the FDA. (Complaint ¶¶ 14, 21, 28.)

In sum, Merck Defendants fail to meet their moving burden of showing that Plaintiff has no evidence of "newly acquired information."

Merck Defendants Fail to Show Clear Evidence that the FDA Would Not Have Approved a Change to the Gardasil Label

As noted above, "[b]ecause the FDA 'retains the authority to reject labeling changes,' a manufacturer may still—even after the plaintiff has identified 'newly acquired information'—establish an impossibility preemption defense through 'clear evidence that the FDA would not have approved a change' to the label." (*Utts, supra,* 251 F.Supp.3d at p.661.) "'Clear evidence' is evidence that shows the court that the drug manufacturer fully informed the FDA

of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning." (*Merck Sharp & Dohme Corp., supra,* 587 U.S. at p.300.)

"In this context clear evidence is not a typical standard of proof. 'Standards of proof, such as preponderance of the evidence and clear and convincing evidence, have no place in the resolution of this question of law.'" (*Risperdal and Invega Cases* (2020) 49 Cal.App.5th 942, 956.) Rather, the party seeking to show this impossibility preemption defense, must show that "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." (*Merck Sharp & Dohme Corp., supra,* 587 U.S. at pp.313–314.)

"Impossibility pre-emption is a demanding defense." (*Wyeth, supra,* 555 U.S. at p.573.) This is because "the CBE regulation permits changes, so a drug manufacturer will not ordinarily be able to show that there is an actual conflict between state and federal law such that it was impossible to comply with both." (*Merck Sharp & Dohme Corp., supra,* 587 U.S. at p.315.) Further, "the only agency actions that can determine the answer to the pre-emption question, of course, are agency actions taken pursuant to the FDA's congressionally delegated authority." (*Ibid.*) As the Supreme Court has noted, "the very idea that the FDA would bring an enforcement action against a manufacturer for strengthening a warning pursuant to the CBE regulation is difficult to accept[.]" (*Wyeth, supra,* 555 U.S. at p.570.)

Here, the evidence that Merck Defendants cite does not constitute "clear evidence" that the FDA would have rejected a proposed change to strengthen Gardasil's label by adding the potential risk of developing POTS or the other injuries that Plaintiff has claimed following administration of the Gardasil vaccine.

The first piece of evidence Merck Defendants cite is the Department of Health and Human Services' response in the 2017 Federal Register to a commenter's request for additional

consideration of the Gardasil vaccine as a cause of POTS and for an indefinite review period. (Esterkin Decl. ¶ 33, Exh. 32 [82 Fed. Reg. 6294, 6298 (Jan. 19, 2017)].) The Department of Health and Human Services responded that "[t]o date, there is no medical or scientific evidence that the [Gardasil Vaccine] causes POTS... [and] [e]xtending the review period ... would require a statutory amendment[.]" (Esterkin Decl. ¶ 33, Exh. 32 [82 Fed. Reg. 6294, 6298 (Jan. 19, 2017)].)

The second and third pieces of evidence that Merck Defendants cite consist of peer-reviewed journal articles authored by certain specific officials of the FDA. In the first journal article dated 2017 and entitled "Reports of postural orthostatic tachycardia syndrome after human papillomavirus vaccination in the Vaccine Adverse Event Reporting System," the authors including Arana, concluded that "POTS is rarely reported following HPV vaccination. [The authors'] review did not detect any unusual or unexpected reporting patterns that would suggest a safety problem." (Esterkin Decl. ¶ 34, Exh. 33, [61 *J Adolesc Health* 577–582 (2017)].) In the second journal article dated in 2018 and entitled "Post-licensure safety monitoring of quadrivalent human papillomavirus vaccine in the Vaccine Adverse Event Reporting System (VAERS) 2009–2015," the authors (including Arana) concluded that the Gardasil vaccine did not pose safety concerns. (Esterkin Decl. ¶ 37, Exh. 36, [36 *Vaccine* 1781, 1786 (2018)].) The authors of this second journal article further noted that "the temporally-associated onset of autoimmune disease [such as POTS] following vaccination may occur due to chance alone, and assessing a possible causal association is challenging." (Esterkin Decl. ¶ 37, Exh. 36, [36 *Vaccine* 1781, 1786 (2018)].)

Merck Defendants' fourth piece of evidence consists of a newsletter from the FDA website dated October 21, 2011. (Esterkin Decl. ¶ 38, Exh. 37, [FDA Webpage Printout].) In this newsletter, the FDA stated that it "continually reviews all reports of the Vaccine Adverse Event Reporting System after vaccination with Gardasil, and there is no evidence of unusual

clinical patterns or high reporting rates of adverse events, including autoimmune diseases." (Esterkin Decl. ¶ 38, Exh. 37, [FDA Webpage Printout].)

Finally, Merck Defendants rely on an FDA webpage on Gardasil Vaccine Safety dated August 20, 2009. (Esterkin Decl. ¶ 26, Exh. 25.) The FDA webpage summarizes that "[b]ased on the review of available information by FDA and CDC, Gardasil continues to be safe and effective, and its benefits continue to outweigh its risks." (Esterkin Decl. ¶ 26, Exh. 25.)

In sum, Merck Defendants refer to newsletters and journal articles indicating that overall, the Gardasil vaccine is safe for use and that any causal connection between the Gardasil vaccine and autoimmune diseases such as POTS is uncommon and unclear. However, the Supreme Court has made clear that "only agency actions that can determine the answer to the pre-emption question, of course, are agency actions taken pursuant to the FDA's congressionally delegated authority." (*Merck Sharp & Dohme Corp., supra,* 587 U.S. at p.315.) "Federal law permits the FDA to communicate its disapproval of a warning by means of notice-and-comment rulemaking setting forth labeling standards, see, *e.g.*, 21 U.S.C. § 355(d); 21 C.F.R. §§ 201.57, 314.105; by formally rejecting a warning label that would have been adequate under state law, see, *e.g.,* 21 C.F.R. §§ 314.110(a), 314.125(b)(6); or with other agency action carrying the force of law, cf., *e.g.,* 21 U.S.C. § 355(o)(4)(A)." (*Merck Sharp & Dohme Corp., supra,* 587 U.S. at pp.315-316.) Here, none of the evidence on which Merck Defendants rely – journal articles by various FDA officials, response to comments in the Federal Register by a different agency on issues not involving labeling, and FDA newsletters – constitutes an act within the FDA's congressionally delegated authority. Moreover, whether the FDA itself would require the Gardasil label to include warnings about the risks of autoimmune diseases such as POTS is a different matter from whether the FDA would have rejected a proposal *by Merck Defendants* to add the potential risk of developing autoimmune diseases to the Gardasil vaccine label. There is no reason to presume that just because the FDA did not itself see a need to add the risk of

developing autoimmune diseases to Gardasil's label the FDA would have gone further and prohibited Merck Defendants from adding such a warning to Gardasil's label. As the Supreme Court has noted, "the very idea that the FDA would bring an enforcement action against a manufacturer for strengthening a warning pursuant to the CBE regulation is difficult to accept[.]" (*Wyeth, supra,* 555 U.S. at p.570.) The evidence on which Merck Defendants rely does not constitute clear evidence that the FDA would have rejected a proposal by Merck Defendants to add the potential risk of developing POTS to the Gardasil vaccine label.

Accordingly, Merck Defendants fail to meet their moving burden in showing that Plaintiff's claims are preempted.

3. The Statutory Presumption of Legally Adequate Warnings

Merck Defendants contend that Plaintiff cannot overcome the statutory presumption that legally adequate warnings accompanied the Gardasil Vaccine.

Pursuant to Section 22(b) of the Vaccine Act, "[n]o vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury … if the injury … resulted from side effects that were unavoidable even though the vaccine was properly prepared and was *accompanied by proper directions and warnings*." (42 U.S.C. § 300aa-22(b)(1), [italics added].) Further, "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 (*including regulations issued under such provisions*) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought[.]" (42 U.S.C. § 300aa-22(b)(2), [italics added].) "To rebut this presumption, the [Vaccine] Act requires a plaintiff to show that the manufacturer had (1) engaged in conduct that would subject it to punitive

damages under the Vaccine Act; or (2) failed to exercise due care. § 300aa–22(b)(2)(A)–(B)." (*Holmes v. Merck & Co., Inc.* (9th Cir. 2012) 697 F.3d 1080, 1085.)

As the party seeking summary judgment, Merck Defendants bear the moving burden to show that the statutory presumption of a legal adequate warnings applies. (*Aguilar, supra,* 25 Cal.4th at p.845 ["From commencement to conclusion, the moving party bears the burden of persuasion that there is no genuine issue of material fact and that he is entitled to judgment as a matter of law."].) By the Vaccine Act's plain language, Merck Defendants must show that they complied with all applicable regulations in order for the presumption to apply. (42 U.S.C. § 300aa-22(b)(2).) Merck Defendants fail to do so.

Despite "many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market. See, *e.g.*, 21 CFR § 201.80(e) (requiring a manufacturer to revise its label 'to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug'); § 314.80(b) (placing responsibility for postmarketing surveillance on the manufacturer); 73 Fed.Reg. 49605 ('Manufacturers continue to have a responsibility under Federal law ... to maintain their labeling and update the labeling with new safety information')." (*Wyeth, supra,* 555 U.S. 555, 570–571.) Thus, the applicable federal regulations impose a duty on Merck Defendants to update the Gardasil label with new safety information as it becomes available.

Merck Defendants' moving evidence fails to demonstrate an absence of triable issue as to their compliance in all material respects with all federal regulations, including their duty to update the Gardasil label with new safety information. Merck Defendants argue simply that the FDA's approval of the Gardasil label and receipt of Merck's annual reports and pharmacovigilance demonstrate that "Merck materially complied with its relevant regulatory

obligations and is, as a matter of law, entitled to a presumption that 'proper directions and warnings' accompanied the Gardasil administered to Plaintiff. 42 U.S.C. § 300aa-22(b)(2)." (8/21/24 Merck's Memorandum p. 16.)

The mere fact that the FDA approved Gardasil's label and received Merck's annual reports and pharmacovigilance demonstrates only that *based on the information that Merck Defendants shared with the FDA*, the FDA granted approval of the label and its warnings. However, FDA approval in and of itself does not speak to the completeness of Merck Defendants' disclosures to the FDA or whether Merck Defendants complied with their regulatory obligations. Merck Defendants' moving papers do not include any declaration or deposition by any Merck employee describing the state of Merck's knowledge at any time -- preapproval or postapproval -- of the risks of developing POTS or other autoimmune diseases from the Gardasil vaccine. The record is silent as to what postmarketing surveillance Merck conducted. The record is also silent as to what new safety information may have become available to Merck during any such postmarketing surveillance. Merck Defendants also fail to submit any discovery responses from Plaintiff – such as responses to requests for admission or to interrogatories – indicating that Plaintiff has no evidence that Merck Defendants became aware of new safety information that imposed upon them a duty to update the Gardasil label with such information.

The absence of any evidence at all as to what if any new safety information was available to Merck Defendants before Plaintiff's last Gardasil injection is especially notable in light of the Supreme Court's observation that "manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge." (*Wyeth, supra*, 555 U.S. at pp. 578-579.) In light of Merck Defendants' superior knowledge of new risks of their Gardasil vaccine, Merck Defendants have failed to demonstrate an absence of

triable issue as to their compliance with their regulatory responsibility to update the Gardasil label so as to trigger the applicability of the presumption of a legally adequate warning.

Regardless, even if the Court were to find that the statutory presumption of a legally adequate warning applies, the Complaint alleges numerous exemptions to the presumption. Specifically, Plaintiff alleges that Merck Defendants intentionally withheld information from the FDA in obtaining approval of the Gardasil vaccine. (Complaint ¶ 14.) Intentionally withholding information from the FDA in obtaining approval warrants punitive damages under the Vaccine Act. (42 U.S.C. § 300aa-23(d)(2)(A).) Engaging in conduct that would subject a party to punitive damages under the Vaccine Act in turn rebuts the presumption of a legally adequate warning. (42 U.S.C. § 300aa–22(b)(2)(A).) The complaint also alleges that Merck Defendants failed to exercise due care, which would also rebut the presumption. (Complaint ¶¶ 19-25; 42 U.S.C. § 300aa–22(b)(2)(B).) Merck Defendants fail to cite any evidence in their moving papers that would refute or challenge these allegations. Thus, Merck Defendants fail to shift the burden as to the applicability of the presumption of legally adequate warnings.

4. Whether the Vaccine Act and California's Learned Intermediary Doctrine Bar the Allegations of the Complaint

The Vaccine Act provides that no "vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death . . . 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.) Similarly, under California's Learned Intermediary Doctrine, "[t]he patient cannot sue the manufacturer for failing to warn him or her directly: As long as the manufacturer has adequately warned the patient's physician of the non-negligible

risks of its prescription drug or medical device, the manufacturer has fulfilled its duty to warn." (*Himes v. Somatics, LLC* (2024) 16 Cal.5th 209, 221.)

In their briefing, Merck Defendants assert that the complaint alleges solely a failure to provide direct warnings to Plaintiff and her parents, and thus, all of Plaintiff's claims are barred by the Vaccine Act and California's Learned Intermediary Doctrine. As a threshold matter, the Court notes that Merck Defendants' argument is a challenge to the Complaint – not a challenge to the sufficiency of Plaintiff's evidence. In support of their contention that the sole basis for liability against Merck Defendants is that they failed to directly warn Plaintiff and her parents, Merck Defendants cite only to the allegations of the complaint – not to any evidence. (DMFs 71-79.)

A defendant's motion for summary judgment or summary adjudication "necessarily includes a test of the sufficiency of the complaint," and its legal effect is the same as a demurrer or motion for judgment on the pleadings. (See B.Role of Pleadings in Summary Judgment Procedure, Rutter Cal. Prac. Guide Civ. Pro. Before Trial Ch. 10-B [citing *American Airlines, Inc. v. County of San Mateo* (1996) 12 Cal.4th 1110, 1118; *Prue v. Brady Co./San Diego, Inc.* (2015) 242 Cal.App.4th 1367, 1375-1376, 1384; *Slaughter v. Legal Process & Courier Service* (1984) 162 Cal.App.3d 1236, 1244].) If the court concludes the complaint (or any claim or defense) is insufficient as a matter of law, it "may elect to treat the hearing of a summary judgment motion as a motion for judgment on the pleadings and grant the opposing party an opportunity to file an amended complaint to correct the defect." (See B.Role of Pleadings in Summary Judgment Procedure, Rutter Cal. Prac. Guide Civ. Pro. Before Trial Ch. 10-B [citing *Hobson v. Raychem Corp.* (1999) 73 Cal.App.4th 614, 625 (disapproved on other grounds by *Colmenares v. Braemar Country Club, Inc.* (2003) 29 Cal.4th 1019, 1031 fn. 6); *People ex rel. Dept. of Transp. v. Outdoor Media Group* (1993) 13 Cal.App.4th 1067, 1074.].)

At the October 9, 2024 hearing, Merck Defendants confirmed that this argument that they raise on pages 17 through 19 of the brief is an attack on the pleadings and not premised on a lack of evidence.

Here, the complaint clearly alleges that Defendant is the manufacturer of Gardasil. (Complaint ¶ 5.) The Vaccine Act and California's Learned Intermediary Doctrine bar any claim against Merck Defendants that is premised solely on a failure to provide direct warnings to Plaintiff and her parents. Merck Defendants correctly note that the Complaint alleges that Merck Defendants failed to make adequate disclosures directly to Plaintiff and her parents regarding the safety of Gardasil. (Complaint ¶ 18 ["Plaintiff and her parents were exposed to, were aware of, heard and relied on the facts and information provided by [the Merck Defendants] in their marketing campaign as heretofore set forth, and while lacking such material facts and information reasonably required for an informed consent, agreed to Plaintiff being administered the series of the three Gardasil vaccinations."].) The pivotal question then is whether Plaintiff alleges any alternative theory of liability that is not premised on a failure to provide a direct warning. The complaint clearly does. The Complaint includes numerous other factual allegations that give rise to liability on at least two alternative theories apart from Merck Defendants' failure to provide direct warnings to Plaintiff and her parents, one of which relates to Merck Defendants' actions pre-approval and the other of which relates to Merck Defendants' actions post-approval.

With regard to the pre-approval period, the Complaint alleges that Merck Defendants "wrongfully and deceitfully failed, during the preapproval processing period and thereafter, to disclose to the *FDA* and others material facts and information relating to the effectiveness and safety of Gardasil, as well as to whom the vaccine should or should not be administered, known to them and obtained through such scientific and medical investigations and studies which they have or should have caused to be conducted." (Complaint ¶ 14 [italics added].) Material

nondisclosures to the FDA under the circumstances alleged in the Complaint form a clearly distinct theory of liability – separate and apart from a failure to provide direct warnings to Plaintiff and her parents. Merck Defendants' motion fails to address the viability of this separate and independent theory of liability alleged in the Complaint. A "[judgment on the pleading] 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 [judgment on the pleading] will be [denied]." (*Elder v. Pacific Bell Telephone Co.* (2012) 205 Cal.App.4th 841, 856, Fn. 14.) As each of the causes of action is premised at least in part on Merck Defendants' alleged wrongful and deceitful withholding of information from the FDA during the pre-approval process, Merck Defendants' judgment on the pleading is **DENIED**.

Moreover, and separately, Plaintiff sufficiently alleges material non-disclosures to individuals other than Plaintiff and her parents during the post-approval period. The complaint alleges in relevant part that Merck Defendants "intentionally, wrongfully and deceitfully withheld, failed to provide and concealed from consumers, patients *and others* material facts and information with respect to the effectiveness, safety and need for the administration of the Gardasil vaccination, as well as the risks of serious adverse reaction related thereto[.]" (*Id.* ¶ 16 [italics added].) The Complaint further alleges that "Defendant Medical Providers negligently *relied upon facts and information provided to them by [the Merck Defendants]*[.]" (*Id.* ¶ 36 [italics added].)

In assessing the adequacy of the complaint, the Court must be mindful that "allegations must be liberally construed, with a view to substantial justice between the parties." (CCP § 452.) Though the complaint here may not be a model pleading, it is sufficient to place Merck Defendants on notice that Merck Defendants are alleged to have withheld information from "others," including "Defendant Medical Providers [who] negligently *relied upon facts and information provided to them by [the Merck Defendants]*[.]" (*Id.* ¶¶ 16, 36 [italics added].) Any

lack of clarity as to whether the Complaint encompasses a claim that the Merck Defendants failed to make adequate disclosures to the Defendant Medical Providers has been remedied via the extensive discovery that the parties, including Merck Defendants, have pursued as to the learned intermediatory doctrine. In a May 17, 2019 "letter brief" regarding various discovery requests, Plaintiff explained that communications between Merck Defendants and Plaintiff's treaters regarding Gardasil was "relevant as it goes to the issue of proximate cause and what **warnings and information Merck relayed to Kaiser and its doctors** concerning the safety and efficacy of Gardasil so as to encourage Kaiser physicians to recommend Gardasil to children." (Supp. Esfandiari Decl. ¶ 3, Exh. 1 at p.22.) In the depositions of Plaintiff's treating physicians – Dr. Fuller and Dr. Scanlon – the parties raised the issue of whether the prescribers were adequately warned and, if they had been warned, would they have relayed those warnings to Plaintiff. (Supp. Esfandiari Decl. ¶¶ 5-6, Exhs. 3-4.) Notably, Merck Defendants have failed to identify any additional discovery that they would need to pursue on the Learned Intermediary Doctrine, demonstrating that Merck Defendants have not been prejudiced by any lack of clarity as to whether the "others" from whom Merck Defendants allegedly withheld information included Plaintiff's treating physicians. (*See generally*, Supp. Brief.)

Accordingly, the Court hereby denies Merck Defendants' motion for judgment on the pleadings. The Court finds that the Complaint adequately alleges additional theories of liability apart from Merck Defendants' failure to provide direct warnings to Plaintiff and her parents.

5. Causation for Plaintiff's Failure to Warn Claim

Merck Defendants contend that even if Plaintiff alleged a viable failure-to-warn claim, Plaintiff cannot prove causation because Plaintiff's prescribing Physicians continue to affirm their decision to prescribe the Gardasil vaccine. (8/21/24 Merck's Memorandum pp. 20-21.)

As the Court of Appeal has noted , "[c]ausality is normally a fact issue for the jury except in those cases where reasonable men cannot differ." (*Lysick v. Walcom* (1968) 258 Cal.App.2d 136, 153;

Under the California Learned Intermediary Doctrine, "manufacturers have a duty to warn physicians, but not the physicians' patients, about certain risks accompanying use of their prescription drugs and many medical devices." (*Himes v. Somatics, LLC* (2024) 16 Cal.5th 209, 221.) "The manufacturer need not "warn of risks that are 'merely speculative or conjectural, or so remote and insignificant as to be negligible.' " [...] Nor must the manufacturer warn of risks that are already known to the medical community." (*Ibid.* [Internal citations omitted].) However, "the manufacturer is required to warn physicians of any non-negligible risks that are generally unknown to the medical community, as this will "allow the health-care provider, and thereby the patient, to make an informed choice whether to utilize the drug or medical device." (*Ibid.*) "The doctrine does not create an immunity from a prescription drug or medical device manufacturer's general duty of care owed to patients, however. Pursuant to the doctrine, the manufacturer fulfills its general duty of care owed to the patient by providing an adequate warning to the patient's physician." (*Himes, supra,* 16 Cal.5th at p.222.) "Moreover, '[t]he manufacturer cannot be held liable if it has provided appropriate warnings and the doctor fails in his [or her] duty to transmit these warnings to the patient.'" (*Ibid.*)

For purposes of causation, "[a] plaintiff is not required to show that a stronger warning would have altered the physician's decision to prescribe the product to establish causation. A plaintiff may instead establish causation by showing that the physician would have communicated the stronger warning to the patient and an objectively prudent person in the patient's position would have thereafter declined the treatment notwithstanding the physician's continued recommendation of the treatment." (*Himes, supra,* 16 Cal.5th at pp.235–36.)

Merck Defendants contend that Plaintiff's prescribing Physicians' continued affirmance of their decision to prescribe the Gardasil vaccine precludes Plaintiff from proving causation. In advancing this argument, Merck Defendants misstate Plaintiff's burden in proving causation for her failure to warn claim. Plaintiff does not bear the burden of proving that her prescribing doctor would not have prescribed Gardasil if Merck Defendants had provided a different warning. In *Himes*, the California Supreme Court expressly rejected such a standard of causation and clarified that a plaintiff injured by a prescription product need not establish that the prescribing doctor would not have prescribed the product had the doctor been adequately warned but may instead establish causation by showing that the physician would have communicated the stronger warning to the patient, and an objectively prudent person in the patient's position would have thereafter declined the treatment, notwithstanding the physician's continued recommendation of the treatment. (*Himes, supra,* 16 Cal.5th at pp.235–36.)

Nothing in Merck Defendants' evidence demonstrates that Plaintiff's prescribing doctors would not have communicated a stronger warning to Plaintiff and her parents if her doctors had received more information about the risks of serious adverse effects, such as POTs. To the contrary, Merck Defendants' declarations demonstrate that Plaintiff's prescribing doctors read and relied upon Defendants' warnings on the Gardasil package labels relating to the risks of the vaccine. (Esterkin Declaration ¶ 4, Exh. 3 [Declaration of Robin Scanlon] ¶ 9; Esterkin Declaration ¶ 11, Exh. 10 [Declaration of Dr. Claire Fuller] ¶ 9.) Further, Merck Defendants' own evidence demonstrates that Plaintiff's prescribing doctors generally relay information to their patients consistent with the information that was contained in the Gardasil packaging. (Esterkin Declaration ¶ 4, Exh. 3 [Declaration of Robin Scanlon] ¶¶ 8-9; Esterkin Declaration ¶ 11, Exh. 10 [Declaration of Dr. Claire Fuller] ¶ 8.) Plaintiff's prescribing doctors did not relay warnings about the risks of developing autoimmune to Plaintiff or her mother as part of the consent process because the Gardasil packaging did not contain warnings about autoimmune or

autonomic risks. (Esterkin Declaration ¶ 4, Exh. 3 [Declaration of Robin Scanlon] ¶ 9; Esterkin Declaration ¶ 11, Exh. 10 [Declaration of Dr. Claire Fuller] ¶ 9.) Plaintiff's prescribing doctors state that if the Gardasil packaging had contained warnings about the vaccine's autoimmune risks, Plaintiff's prescribing doctors would have relayed the warnings to Plaintiff and her mother. (Esterkin Declaration ¶ 4, Exh. 3 [Declaration of Robin Scanlon] ¶ 9; Esterkin Declaration ¶ 11, Exh. 10 [Declaration of Dr. Claire Fuller] ¶ 9.) Further, Dr. Scanlon and Dr. Fuller testified that they would respect the wishes of the patient or her parent and not administer a vaccine if a patient or parent refused to consent to the vaccine after learning about its risks. (Esterkin Declaration ¶ 4, Exh. 3 [Declaration of Robin Scanlon] ¶ 10; Esterkin Declaration ¶ 11, Exh. 10 [Declaration of Dr. Claire Fuller] ¶ 10.) Finally, Plaintiff's mother testified that had she been correctly warned of the risks of Gardasil, she would not have consented to Plaintiff receiving the Gardasil vaccine injections. (Esterkin Declaration ¶ 66, Exh. 65 [Deposition of Katherine Robi] Vol. 1, p.242.) Thus, this evidence does not fulfill Merck Defendants' evidentiary burden of showing that Plaintiff's prescribing doctors would not have communicated a stronger warning to the patient if they were provided with a different warning with Gardasil. The burden does not shift to Plaintiff.

Thus, Merck Defendant's motion for summary judgment fails.

B. Merck Defendants' Motion for Summary Adjudication

In the alternative to summary judgment, Merck Defendants seek summary adjudication of (1) Plaintiff's punitive damage claim, (2) Plaintiff's right to recover for any injury not claimed in Vaccine Court, and (3) Plaintiff's fraud and negligence claims on the ground that Merck Defendants had a reasonable basis to believe that the relied upon statements were true.

1. Punitive Damages

Merck Defendants Fail to Meet Their Moving Burden to Show That Federal Law Bars Plaintiff's Claim for Punitive Damages

Merck Defendants contend that because it complied with applicable law, "the Vaccine Act prohibits Plaintiff from recovering punitive damages unless she can produce evidence that Merck 'engaged in ***reprehensible behavior***'—and she cannot do so." (8/21/24 Merck's Memorandum p.21:18-21.)

"[T]he pleadings determine the scope of relevant issues on a summary judgment motion." (*Nieto, supra,* 181 Cal.App.4th at p.74.) The complaint alleges that Merck Defendants "*wrongfully and deceitfully failed, during the preapproval processing period and thereafter*, to *disclose to the FDA* and others material facts and information relating to the effectiveness and safety of Gardasil, as well as to whom the vaccine should or should not be administered, known to them and obtained through such scientific and medical investigations and studies which they have or should have caused to be conducted." (Complaint ¶ 14 [italics added].) This alleged intentional withholding of information from the FDA in the preapproval process is a basis for punitive damages under the Vaccine Act.

The Vaccine Act provides that a manufacturer shall not be held liable for punitive damages if it shows that it complied "in all material respects, with all requirements under the Federal Food, Drug, and Cosmetic Act and this chapter applicable to the vaccine and related to the vaccine injury or death with respect to which the action was brought [. . .] ***unless*** the manufacturer engaged in -- (A) *fraud or intentional and wrongful withholding of information from the Secretary during any phase of a proceeding for approval of the vaccine under section 262 of this title*, (B) *intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine after its approval*, or (C) other criminal or illegal activity relating to the safety and effectiveness of vaccines, which activity related to the vaccine-related injury or death for which the civil action was brought." (42 U.S.C. § 300aa-23(d)(2) [italics added].) Thus,

under the Vaccine Act, intentionally withholding information from the FDA during or after the preapproval process is a ground for punitive damages – regardless of whether Merck Defendants otherwise complied with the requirements of the Vaccine Act.

Accordingly, because the Complaint alleges that Merck Defendants intentionally withheld information from the FDA in order to obtain approval of the Gardasil vaccine and thereafter, Merck Defendants cannot merely assert – without presenting evidence – that they complied with the Vaccine Act. "Summary judgment law in [California] continues to require a defendant moving for summary judgment to *present evidence*, and not simply point out that the plaintiff does not possess, and cannot reasonably obtain, needed evidence. In this particular at least, it still diverges from federal law." (*Aguilar, supra,* 25 Cal.4th at pp.854–855.) To meet this burden, a defendant must present evidence that shows not only "that the plaintiff *does not possess* needed evidence" but also that "the plaintiff *cannot reasonably obtain* needed evidence." (*Id.* at p.854.)

Pursuant to *Aguilar*, Merck Defendants were required to present *evidence* disproving Plaintiff's allegation that Merck Defendants intentionally withheld information during the preapproval process from the FDA to obtain approval of the Gardasil vaccine and also thereafter or present *evidence* showing that Plaintiff does not possess evidence to prove that Merck Defendants intentionally withheld information during the preapproval process and thereafter from the FDA and Plaintiff cannot reasonably obtain such evidence. Merck Defendants fail to do so.

In their memorandum and separate statement, Merck Defendants cite merely to letters confirming Gardasil's approval for general use due to indications that it could assist in prevention of certain cancers, anal intraepithelial neoplasia, and genital warts from HPV, as well as for concomitant administration with other medications. (Esterkin Decl. ¶¶ 48-52, Exh. 47 [December 22, 2010, Letter from W. Sun to P. Brill-Edwards (MRKGAR00095897 to 900)];

Exh. 48 [June 9, 2010, Letter from W. Sun to P. Brill-Edwards (MRKGAR01267987)]; Exh. 49 [October 16, 2009, Letter from W. Sun to P. Brill-Edwards (MRKGAR00834836 to 38)]; Exh. 50 [September 12, 2008, Letter from W. Sun to P. Brill-Edwards (MRKGAR00095790 to 91)]; Exh. 51 [June 8, 2006, Letter from N. Baylor to P. Brill-Edwards (MRKGAR00095646 to 53)].) None of this evidence addresses whether Merck Defendants withheld information – such as the risk of autoimmune disorders – from the FDA in order to obtain approval of the Gardasil Vaccine as alleged in the complaint. Nor does any of this evidence show that Plaintiff does not have such evidence and cannot reasonably obtain such evidence. To the extent such evidence exists, Merck Defendants failed to cite it in the separate statement or the moving memorandum. (*City of Pasadena, supra,* 228 Cal.App.4th at p.1238, Fn. 4, [" '[t]his is the Golden Rule of Summary Adjudication: if it is not set forth in the separate statement, *it does not exist.*' "]; *See* Cal. Rules of Court, Rule 3.1113(b).)

Accordingly, Merck Defendants fail to meet their moving burden in showing that the Vaccine Act bars Plaintiff's prayer for punitive damages.

Merck Defendants Fail to Meet Their Moving Burden to Show that State Law Bars Plaintiff's Claim for Punitive Damages

Merck Defendants further claim that Plaintiff's prayer for punitive damages is barred because Plaintiff cannot prove by clear and convincing evidence that Merck Defendants are guilty of "oppression, fraud, or malice."

"[Civil c]ode section 3294 provides that punitive damages may be awarded in an action for breach of an obligation not arising from contract, if the plaintiff proves by clear and convincing evidence that the Defendants has been guilty of oppression, fraud, or malice." (*Scott v. Phoenix Schools, Inc.* (2009) 175 Cal.App.4th 702, 715.) "The clear and convincing standard ''requires a finding of high probability . . . . ''so clear as to leave no substantial doubt';

'sufficiently strong to command the unhesitating assent of every reasonable mind.'' [Citation.]' [Citations.]' [Citation.]" (*Ibid.*) "Summary judgment or summary adjudication '''on the issue of punitive damages is proper' only 'when no reasonable jury could find the plaintiff's evidence to be clear and convincing proof of malice, fraud or oppression.''' [Citation.]" (*Pacific Gas and Electric Company v. Superior Court* (2018) 24 Cal.App.5th 1150, 1159.)

As set forth above, Plaintiff alleges that Merck Defendants intentionally withheld information from the FDA to obtain approval of the Gardasil vaccine – *i.e.*, fraud by omission. (Complaint ¶ 14.) Merck Defendants' separate statement fails to address whether Merck Defendants withheld information from the FDA in order to obtain approval of the Gardasil Vaccine. Nor do Merck Defendants present any evidence showing that Plaintiff does not have such evidence and cannot reasonably obtain such evidence. Rather, Merck Defendants merely contend that Plaintiff will be unable to prove by clear and convincing evidence that Merck Defendants are guilty of "oppression, fraud, or malice." Simply arguing that Plaintiff does not possess the required evidence is insufficient as a matter of law. "Summary judgment law in [California] continues to require a defendant moving for summary judgment to *present evidence*, and not simply point out that the plaintiff does not possess, and cannot reasonably obtain, needed evidence. In this particular at least, it still diverges from federal law." (*Aguilar, supra,* 25 Cal.4th at pp.854–855.)

Accordingly, Merck Defendants fail to meet their moving burden in showing that they are entitled to summary adjudication of Plaintiff's prayer for punitive damages.

2. Defendant's Motion for Summary Adjudication under the Vaccine Act

Merck Defendants contend that Plaintiff is barred from recovering for any injury not claimed in Vaccine Court. This is argument not a proper basis for summary adjudication.

Code of Civil Procedure section 437c(f)(1) provides that "[a] party may move for summary adjudication as to one or more causes of action within an action, one or more affirmative defenses, one or more claims for damages, or one or more issues of duty, if the party contends that the cause of action has no merit, that there is no affirmative defense to the cause of action, that there is no merit to an affirmative defense as to any cause of action, that there is **no merit to a claim for damages, as specified in Section 3294 of the Civil Code**, or that one or more defendants either owed or did not owe a duty to the plaintiff or plaintiffs. *A motion for summary adjudication shall be granted only if it completely disposes of a cause of action, an affirmative defense, a claim for damages, or an issue of duty.*" (CCP § 437c(f)(1) [italics and bold added].)

Whether Plaintiff is barred from recovering damages for some – but not all – of her claimed injuries does not completely dispose of a cause of action, an affirmative defense, or an issue of duty. Nor does this issue completely dispose of an entire claim for damages. Summary adjudication of a portion of damages sought is limited to damages under Civil Code § 3294 – *i.e.*, punitive damages. Thus, whether Plaintiff is barred from recovering damages for some subset of her injuries which she allegedly failed to specify in the Vaccine Court is not a basis for summary adjudication.

Moreover, even assuming this were a proper basis for summary adjudication, Plaintiff raises a triable issue as to whether she raised all of the injuries claimed in the instant action in the Vaccine Court proceeding. For example, at the time of the Vaccine Court proceedings, Plaintiff reported her diagnosis and symptoms – including the symptoms of POTS – in both her petition and in the declaration in support of the petition. (Esfandiari Decl. ¶¶ 87-88, Exh. 85 [Robi VICP Petition]; Exh. 86, [Robi Declaration in Support of VICP Petition].)

Accordingly, Merck Defendants motion for summary adjudication of the bar to recovery of damages for certain injuries not specified in the Vaccine Court is denied.

3. Plaintiff's Causes of Action for Fraud, Deceit and Negligence

Plaintiff's Fraud and Deceit Claim

Merck Defendants contend that "Plaintiff's causes of action for Fraud and Deceit and Negligence fail because [Merck Defendants] had a reasonable basis to believe that the statement allegedly relied on by Plaintiff was true." (8/21/24 Merck's Memorandum pp.23:27-24:1, [bold and capitalization removed].)

"[T]he pleadings determine the scope of relevant issues on a summary judgment motion." (*Nieto, supra,* 181 Cal.App.4th at p.74.)

As to the first cause of action for fraud, Plaintiff alleges that Merck Defendants "wrongfully and *deceitfully* failed, *during the preapproval processing period and thereafter, to disclose to the FDA and others* material facts and information relating to the effectiveness and safety of Gardasil, as well as to whom the vaccine should or should not be administered, known to them and obtained through such scientific and medical investigations and studies which they have or should have caused to be conducted." (*Id.* ¶ 14 [italics added].) Plaintiff further alleges that [Merck Defendants] wrongfully and *deceitfully* failed to perform in the preapproval processing period and thereafter the material scientific and medical investigations and studies relating to the safety, effectiveness and need for the Gardasil vaccine as required by and under FDA directives and regulations as well as those to which a prudent manufacturer should and would comply." (*Id.* ¶ 15 [italics added].) Merck Defendants "commenced and engaged in highly extensive, and aggressive, marketing practices which were designed primarily, if not solely, to increase the sales and profits from Gardasil. In doing so, [Merck Defendants], in order to preclude any and all questions by consumers, patients and others as to the effectiveness, safety and need for the administration of the Gardasil vaccination as well as the risks of serious adverse reaction related thereto, *intentionally, wrongfully and deceitfully* withheld, failed to provide and

concealed from consumers, patients and others material facts and information with respect to the effectiveness, safety and need of the administration of the Gardasil vaccination, as well as the risks of serious adverse reaction related thereto and as in part hereafter set forth[.]" (*Id.* ¶ 16 [italics added].) Merck Defendants "wrongfully and deceitfully failed to unambiguously inform those to whom the marketing was directed, of material facts and information which these Defendants knew or should have ascertained through their investigations and studies specific to the risk/benefit and quantitative risk assessments regarding and including, among other things, the following: … The nature and consequences as well as the likelihood of serious adverse reactions to the HPV vaccine[.]" (*Id.* ¶ 17.) In sum, with regard to the first cause of action, Plaintiff alleges that Defendant intentionally, wrongfully, and deceitfully failed to warn and failed to disclose certain information – i.e., fraud based on omission/concealment.

"[T]he elements of an action for fraud and deceit based on concealment are: (1) the defendant must have concealed or suppressed a material fact, (2) the defendant must have been under a duty to disclose the fact to the plaintiff, (3) the defendant must have intentionally concealed or suppressed the fact with the intent to defraud the plaintiff, (4) the plaintiff must have been unaware of the fact and would not have acted as he did if he had known of the concealed or suppressed fact, and (5) as a result of the concealment or suppression of the fact, the plaintiff must have sustained damage." (*Boschma v. Home Loan Ctr., Inc.* (2011) 198 Cal. App. 4th 230, 248, [internal citations omitted].)

Merck Defendants' evidence and arguments fail to address the complaint's allegations of deceitful/fraudulent concealment. Instead, Merck Defendants focus exclusively on the allegations of marketing directed to Plaintiff and her parents. For example, Merck Defendants cite Plaintiff's discovery response stating that she and her mother recalled relying on a commercial by Merck Defendants for Gardasil that used the phrase "one less" in deciding to consent to the Gardasil Vaccine. (DMFs 116-123.) Merck Defendants' memorandum of points

and authority asserts that its "one less" commercial purportedly states "that receiving Gardasil could make a person 'one less' to develop cervical cancer ..." (8/21/24 Merck's Memorandum p.25:11-12.) Merck Defendants then claim that "[t]he FDA's approval of the vaccine for the prevention of cervical cancer provides an objectively reasonable basis for [Merck Defendants'] use of the phrase 'one less,' and thus the phrase cannot serve as a basis for Plaintiff's causes of action for fraud and deceit or negligence." (8/21/24 Merck's Memorandum p.25:14-16.) This contention is factually unsupported and misconstrues the basic allegations of the complaint.

First, Merck Defendants fail to present any evidence of the specific statement in the commercial to which Merck Defendants are referring. (*Turrieta v. Lyft, Inc.* (2024) 16 Cal.5th 664 [" '[I]t is axiomatic that statements made in briefs are not evidence' [Citation.]"].) Moreover, Merck Defendants' separate statement does not identify the alleged representation that Merck Defendants had a reasonable belief was true. (*City of Pasadena, supra,* 228 Cal.App.4th at p.1238, Fn. 4, [" '[t]his is the Golden Rule of Summary Adjudication: if it is not set forth in the separate statement, *it does not exist.*' "].) Second, there is no evidence of what Merck Defendants believed or knew. There is no evidence from any Merck employee or ***anyone*** else on behalf of Merck Defendants stating that Merck Defendants knew or reasonably believed that the unspecified statements in the "one less" commercial were true. Rather, Merck Defendants rely exclusively on the FDA's approval of Gardasil. (DMF 127.) The FDA's approval of Gardasil does not evidence what Merck Defendants knew or did not know especially in light of the allegations of the complaint that Merck Defendants deceitfully withheld information from the FDA and in light of Merck Defendants' superior access to information about their drugs. (Complaint ¶ 14 ["Plaintiff is informed and believes and based upon such information and belief alleges that [Merck Defendants] ... wrongfully and deceitfully failed, during the preapproval processing period and thereafter, to disclose to the FDA and others material facts and information relating to the effectiveness and safety of Gardasil, as well as to

whom the vaccine should or should not be administered, known to them and obtained through such scientific and medical investigations and studies which they have or should have caused to be conducted."]; *Wyeth, supra*, 555 U.S. at pp. 578-579.) In short, Merck Defendants fail to present any evidence that they had a reasonable belief in the truth of their advertising statements.

Finally, and more importantly, whether Merck Defendants' belief that their affirmative statements in the "one less" commercial was reasonable is irrelevant. Plaintiff's fraud claim is based on fraud *by omission* – i.e., withholding information. Merck Defendants fail to address Plaintiff's claim for fraud *by omission*. Plaintiff does not exclusively assert an affirmative misrepresentation. Accordingly, Merck Defendants' motion for summary adjudication of the fraud and deceit claim is DENIED.[4]

Plaintiff's Negligence Claim

Merck Defendants' motion for summary adjudication of Plaintiff's negligence claim also fails. "To succeed in a negligence action, the plaintiff must show that (1) the defendant owed the plaintiff a legal duty, (2) the defendant breached the duty, and (3) the breach proximately or legally caused (4) the plaintiff's damages or injuries." (*Thomas v. Stenberg* (2012) 206 Cal.App.4th 654, 662.)

Here, Plaintiff alleges that Merck Defendants "negligently failed to provide during the preapproval processing period and thereafter, to disclose to the FDA and others material facts and information relating to the effectiveness and safety of Gardasil, as well as to whom the

[4] In a footnote, Merck Defendants contend that the Court should grant summary adjudication of Plaintiff's fraud and deceit claim on the grounds that Plaintiff's claim is not pled with the required specificity. Merck Defendants fail to cite any binding authority for the proposition that summary adjudication can be granted on the grounds that a fraud claim is not pled with sufficient specificity. In any event, fraud by omission does not require the same specificity as fraud by way of an affirmative misrepresentation. "As one court has aptly observed, "it is harder to apply [the requirement of specificity] to a case of simple nondisclosure. 'How does one show "how" and "by what means" something didn't happen, or "when" it never happened, or "where" it never happened?'" (*Jones v. ConocoPhillips Co.* (2011) 198 Cal.App.4th 1187, 1199 [citing *Alfaro v. Community Housing Improvement System & Planning Assn., Inc.* (2009) 171 Cal.App.4th 1356, 1384 and *Committee on Children's Television, Inc. v. General Foods Corp.* (1983) 35 Cal.3d 197, 217, ["'[e]ven under the strict rules of common law pleading, one of the canons was that less particularity is required when the facts lie more in the knowledge of the opposite party ...'"].)

vaccine should or should not be administered, known to them and obtained through such scientific and medical investigations and studies which they have or should have caused to be conducted." (Complaint ¶ 21.) Plaintiff further alleges that Merck Defendants "negligently failed to perform the material scientific and medical investigations and studies relating to the safety, effectiveness and need for the Gardasil vaccine as required by and under FDA directives and regulations as well as those to which a prudent manufacturer should and would comply." (*Id.* ¶ 22.) In sum, the complaint alleges that Merck Defendants negligently failed to disclose critical information and failed to perform scientific and medical investigations and studies relating to the safety, effectiveness and need for the Gardasil vaccine.

Based on the complaint's allegations of negligence, Merck Defendants' reasonable belief in its affirmative statements in its commercial is irrelevant. Merck Defendants' beliefs are immaterial as to whether they negligently failed to disclose critical information or failed to perform safety studies. Accordingly, Merck Defendants' motion for summary adjudication of Plaintiff's negligence claim is DENIED.

CONCLUSION AND ORDER

Based on the foregoing, Defendants Merck & Co, Inc. and Merck Sharp & Dohme Corp.'s motion for summary judgment or in the alternative summary adjudication is **DENIED** in its entirety.

The Court's Judicial Assistant is ordered to give notice to all parties.

DATED: December 20, 2024

Elaine Lu
Judge of the Superior Court