UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

SPENCER BUENO, an individual

Plaintiff,

v.

MERCK & CO., INC., a New Jersey Corporation; MERCK SHARP & DOHME CORP., a New Jersey Corporation; ORGANON & CO., a Delaware Corporation; ORGANON LLC, a Delaware Limited Liability Company; and DOES 1-10, inclusive,

Defendants.

Case No.: 3:22-cv-00522-H-BLM

ORDER:

(1) GRANTING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT;

(2) DENYING AS MOOT DEFENDANTS' MOTION TO EXCLUDE OR LIMIT OPINION TESTIMONY OF DAVID HEALY; AND

(3) DENYING AS MOOT DEFENDANTS' MOTION TO EXCLUDE OPINIONS OF DIMA MAZEN QATO

[Doc. Nos. 87, 89, 90.]

On May 30, 2024, Defendants Merck & Co., Inc. ("Merck"), Merck Sharp & Dohme Corp. LLC ("MSD"), Organon & Co., and Organon LLC ("Defendants") filed a motion for summary judgment, or in the alternative, partial summary judgment. (Doc. No. 90.) Defendants also filed a motion to exclude or limit the opinion testimony of David Healy (Doc. No. 87), and a motion to exclude the opinions of Dima Mazen Qato, MPH, PhD (Doc. No. 89) (collectively, the "Daubert motions"). On July 8, 2024, Plaintiff Spencer Bueno ("Bueno" or "Plaintiff") filed a response in opposition to Defendants' motion to exclude or limit the opinion testimony of David Healy (Doc. No. 97), and a response in opposition to Defendants' motion for summary judgment or partial summary judgment (Doc. No. 98). On July 9, 2024, Plaintiff filed supplemental documents in opposition to Defendants' motion for summary judgment. (Doc. Nos. 99, 100, 101.) Plaintiff also filed a response in opposition to the motion to exclude the opinions of Dima Mazen Qato, MPH, PhD. (Doc. No. 102.) On July 22, 2024, Defendants filed reply briefs in support of their Daubert motions. (Doc. Nos. 105, 106.) Defendants also filed objections to and motions to strike the individual declarations of Dima Qato (Doc. No. 105-5), and David Healy (Doc. No. 106-2), submitted by Plaintiff in opposition to Defendants' motion to exclude. On July 23, 2024, Defendants filed a reply in support of their motion for summary judgment or, in the alternative, partial summary judgment. (Doc. No. 107.) Defendants also filed objections to and a motion to strike the declaration of Dr. Pablo Arango, submitted as Plaintiff's Exhibit 29. (Doc. No. 107-8.)

The Court held a hearing on Defendants' motion for summary judgment and Daubert motions on August 19, 2024. (Doc. No. 120.) Kimberly L. Beck, Lynne M. Kizis, and Shehnaz M. Bhujwala appeared telephonically for Plaintiff. Paul R. Johnson and Susan V. Vargas appeared for Defendants. (Id.) For the reasons below, the Court grants Defendants' motion for summary judgment and denies Defendants' Daubert motions and motions to strike as moot.

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BACKGROUND

A. Singulair's Regulatory Background

Defendants Merck and MSD (the "Merck Defendants") are New Jersey corporations that manufacture and sell pharmaceutical drugs. (Doc. No. 1-2, Compl. ¶¶ 12–13.) One of these drugs is Singulair, which includes the active ingredient montelukast. (Id. ¶ 2; Doc. No. 90-6, Defs.' Ex. 3, at 13 ¶ 11.) Singulair is prescribed for the treatment of asthma, the prevention of exercise-induced bronchoconstriction, and relief of symptoms of allergic rhinitis. (Doc. No. 1-2, Compl. ¶ 1.) Merck patented Singulair in 1996 and the Merck Defendants began selling Singulair in 1998 after it was approved by the United States Food and Drug Administration (FDA). (Id. ¶¶ 2, 28; Doc. No. 90-4, Defs.' Ex. 1; Doc. No. 90-5, Defs.' Ex. 2.) The Merck Defendants were the exclusive manufacturers, distributors, and sellers of Singulair from 1998 to mid-2012. (Doc. No. 1-2, Compl. ¶ 13.) On August 3, 2012, Merck's patent expired and generic montelukast drugs entered the market. (Id. ¶ 28.) At some point after March 4, 2020, the Merck Defendants assigned some unspecified rights, liabilities, or control over Singulair to their subsidiary, Organon & Co., and its subsidiary, Organon LLC (the "Organon Defendants"). (Id. ¶ 14.) The Organon Defendants are organized under the laws of Delaware and have their principal places of business in New Jersey. (Id.)

Originally, the Singulair label contained no warnings regarding neuropsychiatric events. (Id. ¶ 3.) Since its introduction, however, Defendants have added warnings to Singulair's product label regarding neuropsychiatric events. (Id., see Doc. No. 99 ¶¶ 1–156.) On March 4, 2020, the FDA required Defendants to add the strongest type of warning (a "black box warning") to Singulair's label regarding neuropsychiatric events. (Doc. No. 99 ¶ 144; Doc. No. 90-87, Defs.' Ex. 83.1.)

B. Factual Background regarding Plaintiff's Use of Montelukast

Plaintiff Spencer Bueno's ("Bueno") medical records indicate that he was prescribed montelukast by Florida physicians from October 2019 to December 2020, and last filled his montelukast prescription on March 5, 2021. (Doc. No. 99 ¶¶ 158, 159, 168, 180, 188.)

1. Singulair Warnings in Effect When Bueno Was Prescribed Montelukast

It is undisputed that at the time Bueno was first prescribed montelukast in 2019, the Singulair label included the following information.

The HIGHLIGHTS OF PRESCRIBING INFORMATION section on the first page of the December 2018 label, in effect in 2019, included the following warning:

> Neuropsychiatric events have been reported with SINGULAIR. Instruct patients to be alert for neuropsychiatric events. Evaluate the risks and benefits of continuing treatment with SINGULAIR if such events occur (5.4 and 6.2).

(Id. ¶ 151; Doc. No. 90-90, Defs.' Ex. 86 at 2.)

The WARNINGS AND PRECAUTIONS section of the label stated the following:

> **5.4 Neuropsychiatric Events**
>
> Neuropsychiatric events have been reported in adult, adolescent, and pediatric patients taking SINGULAIR. Post-marketing reports with SINGULAIR use include, but are not limited to, agitation, aggressive behavior or hostility, anxiousness, depression, disorientation, disturbance in attention, dream abnormalities, hallucinations, insomnia, irritability, memory impairment, obsessive-compulsive symptoms, restlessness, somnambulism, suicidal thinking and behavior (including suicide), tic, and tremor. The clinical details of some post-marketing reports involving SINGULAIR appear consistent with a drug-induced effect.
>
> Patients and prescribers should be alert for neuropsychiatric events. Patients should be instructed to notify their prescriber if these changes occur. Prescribers should carefully evaluate the risks and benefits of continuing treatment with SINGULAIR if such events occur [*see Adverse Reactions (6.2)*].

(Doc. No. 99 ¶ 152; Doc. No. 90-90, Defs.' Ex. 86 at 4–5.)

Under ADVERSE REACTIONS, Section 6.2 Post-Marketing Experience of the November 2014 label included the statement:

> The following adverse reactions have been identified during post-approval

> use of SINGULAIR. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure . . . .
>
> Psychiatric disorders: including, but not limited to, agitation, aggressive behavior or hostility, anxiousness, depression, disorientation, disturbance in attention, dream abnormalities, hallucinations, insomnia, irritability, memory impairment, obsessive-compulsive symptoms, restlessness, somnambulism, suicidal thinking and behavior (including suicide), tic, and tremor *[see Warnings and Precautions (5.4)]*.

(Doc. No. 99 ¶¶ 153–54; Doc. No. 90-90, Defs.' Ex. 86 at 7.)

Section 17, Patient Counseling Information, stated: "Patients should be instructed to notify their physician if neuropsychiatric events occur while using SINGULAIR." (Doc. No. 99 ¶ 155; Doc. No. 90-90, Defs.' Ex. 86 at 20.)

The Patient Information leaflet, that comes with Singulair, directs patients to read it "before you start taking [Singulair] and each time you get a refill." (Doc. No. 90-90, Defs.' Ex. 86 at 22.) The leaflet identifies the following side effects:

> **Behavior and mood-related changes**. Tell your healthcare provider right away if you or your child have any of these symptoms while taking SINGULAIR:
>
> - agitation including aggressive behavior or hostility
> - attention problems
> - bad or vivid dreams
> - depression
> - disorientation (confusion)
> - feeling anxious
> - hallucinations (seeing or hearing things that are not really there)
> - irritability
> - memory problems
> - obsessive-compulsive symptoms
> - restlessness
> - sleep walking
> - suicidal thoughts and actions (including suicide)
> - tremor
> - trouble sleeping
> - uncontrolled muscle movements

(Doc. No. 99 ¶ 156; Doc. No. 90-90, Defs.' Ex. 86 at 24.)

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2. Healthcare Professionals Who Prescribed Bueno Montelukast

Bueno saw two Florida physicians who prescribed him montelukast for treatment of allergies, Dr. Pablo Arango and Dr. Jessica Schwartz.[1] (Doc. No. 99 ¶¶ 158, 180; Doc. No. 100-37, Pl.'s Ex. 26 [Bueno Dep.] at 83:22-25; Doc. No. 90-96, Defs.' Ex. 92 [Schwartz Dep.] at 4:25–6:1-25.) In October 2019, Bueno established care with Dr. Arango for evaluation and treatment of chronic sinusitis. (Doc. No. 99 ¶ 157.) On October 2, 2019, in Miami Beach, Florida, Dr. Arango prescribed Bueno 10 mg of montelukast (id. ¶ 158), believing at the time that the benefits to Bueno outweighed the risks. (Doc. No. 90-31, Defs.' Ex. 28 [Arango Dep.] at 16:15-18, 17:14-18.) Bueno never told Dr. Arango that Bueno experienced suicidality. (Doc. No. 107-5, Defs.' Reply Ex. 102 [Arango Dep.] at 112:25–113:24, 119:6–120:4, 123:17–124:22, 128:18–129:11, 133:2–134:13, 161:5–162:4). Bueno filled his prescription for montelukast from Dr. Arango at a CVS pharmacy in Hallandale Beach, Florida on October 2, 2019, November 6, 2019, January 23, 2020, February 20, 2019, March 16, 2020, June 10, 2020, and September 6, 2020. (Doc. No. 99 ¶ 159.) Dr. Arango did not treat Bueno after November 2019. (Id. ¶ 167.)

In April 2020, Dr. Schwartz, who practiced in Baco Raton, Florida, first saw Bueno to address Bueno's anxiety and history of taking Zantac. (Id. ¶ 173; Doc. No. 90-96, Defs.' Ex. 92 [Schwartz Dep.] at 6:6-25, 8:13-21.) On September 29, 2020, Dr. Schwartz renewed Bueno's montelukast prescription. (Doc. No. 99 ¶ 180.) Bueno filled his prescription for montelukast from Dr. Schwartz at a Walgreens in Pompano Beach, Florida, on September 29, 2020, and March 5, 2021. (Id. ¶ 188.) Dr. Schwartz testified that the last time she saw Bueno as a patient was December 10, 2020. (Doc. No. 90-96, Defs.' Ex. 92 [Schwartz Dep.] at 36:18-21.) At the visit, Bueno denied any suicidal/homicidal ideation. (Id. at 30:13-25.)

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[1] It is undisputed that Bueno only consumed generic montelukast rather than the brand-name version of the medication, Singulair. (Doc. No. 81 at 2 n.3 (The parties' joint motion stating: "Discovery has confirmed both Plaintiffs [Spencer Bueno and Richard Parker] only ingested generic montelukast.").)

Bueno testified that his onset of symptoms, including aggression, hostility, suicidality, self-harm, depression, OCD, and tics and tremors, began one to two months after he first took montelukast, at the end of 2019. (Doc. No. 90-93, Defs.' Ex. 89 [Bueno Dep.] at 16:4–20:21.) Bueno also testified that in December 2022, he attempted to jump out of a moving vehicle in Miami, Florida, which he characterizes as a suicide attempt. (Doc. No. 100-37, Pl.'s Ex. 26 [Bueno Dep.] at 54:16-25–55:1-12.)

3. Plaintiff's Residency

Bueno has spent significant time in California and Florida. Bueno was born in California in 1978, has a California driver's license, and identifies himself as a "life-long California resident." (Doc. No. 101 ¶ 64; Doc. No. 100-37, Pl.'s Ex. 26 [Bueno Dep.] at 26:13-25–27:6-8; Doc. No. 98 at 18.) Beginning in 2017, he rented a house in San Diego, California with his friends that he used as a "crash pad" while traveling, and which he continues to use. (Doc. No. 100-37, Pl.'s Ex. 26 [Bueno Dep.] at 27:13-25–28:1-8.)

Beginning in 2019, Plaintiff Bueno started spending significant time in Florida with his girlfriend (now fiancée), while maintaining his California residence. (Doc. No. 107-1 ¶ 66; Doc. No. 100-37, Pl.'s Ex. 26 [Bueno Dep.] at 29:8-23, 38:7-25–39:1-17.) During this time, Defendants assert that Bueno also had a Florida driver's license and filed taxes in Florida. (Doc. No. 107-1 ¶ 64.) Bueno testified that in 2020, 2022, and 2023 he spent more time in Florida than in California. (Doc. No. 100-37, Pl.'s Ex. 26 [Bueno Dep.] at 29:8-23.) Bueno estimates that in 2021, he split his time equally between California and Florida. (Id. at 29:16-19.)

C. Procedural Background

On March 3, 2022, Bueno and Richard Parker ("Parker") filed their complaint in the Superior Court of the State of California, County of San Diego. (Doc. No. 1-2.) The case was subsequently removed and then transferred to this Court based on diversity jurisdiction. (Doc. Nos. 1, 7.) The complaint asserts six causes of action: (1) strict liability—design defect (Count I); (2) strict liability—failure to warn (Count II); (3) negligence (Count III); (4) negligent misrepresentation (Count IV); (5) breach of express

warranty (Count V); and (6) breach of implied warranty (Count IV). (Doc. No. 1-2, Compl. ¶¶ 104–234.)

On April 22, 2022, Defendants moved to dismiss all claims pursuant to Fed. R. Civ. P. 12(b)(2) on the basis that the Court lacked personal jurisdiction over them and moved to dismiss most claims pursuant to Fed. R. Civ. P. 12(b)(6) on the basis that Plaintiffs Bueno and Parker ("Plaintiffs") failed to state a claim for which relief may be granted. (Doc. No. 6.) On September 8, 2022, the Court granted in part and denied in part Defendants' motion to dismiss. (Doc. No. 16.) The Court dismissed Plaintiffs' claims for strict liability—design defect (Count I) and manufacturing defect (part of Count III). (Id.) The Court denied Defendants' motion as to all other claims. (Id.)

On July 20, 2023, Defendants filed a motion to dismiss Bueno's remaining claims for lack of personal jurisdiction. (Doc. No. 62.) On October 16, 2023, the Court denied the motion to dismiss. (Doc. No. 71.)

On May 10, 2024, the parties filed a joint motion to sever Parker's claims ("Joint Motion to Sever"). (Doc. No. 81.) On May 20, 2024, the Court granted the Joint Motion to Sever, and Plaintiff Parker was severed from this case.[2] (Doc. No. 84.)

By the present motion, Defendants move for summary judgment on all remaining claims brought by Bueno. (Doc. No. 90.) In response to Defendants' motion, Bueno voluntarily dismissed all his causes of action other than two claims related to his use of generic montelukast: (1) negligence (Count III) and (2) negligent misrepresentation (Count IV). (Doc. No. 98 at 6.)

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[2] On May 23, 2024, pursuant to the Court's May 20, 2024 order, Plaintiff Parker filed a new action against Defendants. See Parker v. Merck & Co., Inc., 24-cv-916-H-BLM, Docket Entry No. 1 (S.D. Cal., filed May 23, 2024).

DISCUSSION

I. Legal Standards Governing Summary Judgment

Summary judgment is appropriate under Federal Rule of Civil Procedure 56 if the moving party demonstrates "that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). Material facts are facts that, under the governing substantive law, may affect the outcome of the case. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A dispute as to a material fact is genuine if there is sufficient evidence for a reasonable jury to return a verdict for the non-moving party. Id. "Disputes over irrelevant or unnecessary facts will not preclude a grant of summary judgment." T.W. Elec. Serv., Inc. v. Pac. Elec. Contractors Ass'n, 809 F.2d 626, 630 (9th Cir. 1987).

A party seeking summary judgment always bears the initial burden of demonstrating that there is no genuine dispute as to any material fact. Celotex, 477 U.S. at 323. A moving party without the ultimate burden of proof at trial can satisfy its burden in two ways: (1) by presenting "evidence negating an essential element of the nonmoving party's claim or defense;" or (2) by demonstrating "that the nonmoving party does not have enough evidence of an essential element to carry its ultimate burden of persuasion at trial." Nissan Fire & Marine Ins. Co. v. Fritz Companies, Inc., 210 F.3d 1099, 1102 (9th Cir. 2000).

Once the moving party establishes the absence of a genuine dispute as to any material fact, the burden shifts to the nonmoving party to "set forth, by affidavit or as otherwise provided in Rule 56, 'specific facts showing that there is a genuine issue for trial.'" T.W. Elec. Serv., 809 F.2d at 630 (quoting former Fed. R. Civ. P. 56(e)); accord Horphag Research Ltd. v. Garcia, 475 F.3d 1029, 1035 (9th Cir. 2007). To carry this burden, the non-moving party "may not rest upon mere allegation or denials of his pleadings." Anderson, 477 U.S. at 256; see also Behrens v. Pelletier, 516 U.S. 299, 309 (1996) ("On summary judgment, . . . the plaintiff can no longer rest on the pleadings."). Rather, the nonmoving party "must present affirmative evidence . . . from which a jury might return a verdict in his favor." Anderson, 477 U.S. at 256.

When ruling on a summary judgment motion, the court must view the facts and draw all reasonable inferences in the light most favorable to the non-moving party. Scott v. Harris, 550 U.S. 372, 378 (2007). The court should not weigh the evidence or make credibility determinations. See Anderson, 477 U.S. at 255. "The evidence of the non-movant is to be believed." Id. Further, the court may consider other materials in the record not cited to by the parties, but it is not required to do so. See Fed. R. Civ. P. 56(c)(3); see also Simmons v. Navajo Cnty., 609 F.3d 1011, 1017 (9th Cir. 2010) ("[A] district court has no independent duty 'to scour the record in search of a genuine issue of triable fact.'").

II. Choice of Law

The parties disagree as to whether California or Florida substantive law applies—Defendants argue that Florida law applies, barring innovator liability (Doc. No. 90-1 at 17–20), whereas Plaintiff argues that California law applies (Doc. No. 98 at 18–19). "A federal court sitting in diversity must look to the forum state's choice of law rules to determine the controlling substantive law." Zinser v. Accufix Research Institute, Inc., 253 F.3d 1180, 1187 (9th Cir. 2001), opinion amended on denial of reh'g, 273 F.3d 1266 (9th Cir. 2001). California district courts sitting in diversity determine questions of choice of law by the "governmental interest analysis". See id.; see also Offshore Rental Co. v. Continental Oil Co., 22 Cal. 3d 157, 161 (1978). The governmental interest analysis involves three steps:

> First, the court must determine whether the substantive laws of California and the foreign jurisdiction differ on the issue before it. Second, if the laws do differ, then the court must determine what interest, if any, the competing jurisdictions have in the application of their respective laws. If only one jurisdiction has a legitimate interest in the application of its rule of decision, there is a "false conflict" and the law of the interested jurisdiction is applied. But if more than one jurisdiction has a legitimate interest, the court must move to the third stage of the analysis, which focuses on the comparative impairment of the interested jurisdictions. This third step requires the court to identify and apply the law of the state whose interest would be the more impaired if its law were not applied.

Rustico v. Intuitive Surgical, Inc., 993 F.3d 1085, 1091 (9th Cir. 2021) (quoting Cooper v. Tokyo Elec. Power Co. Holdings, 960 F.3d 549, 599 (9th Cir. 2020) (internal citations omitted)).

First, the parties agree that California and Florida substantive law differ on the issue before the Court. (Doc. No. 90-1 at 19; Doc. No. 98 at 18.) Under California law, brand name pharmaceutical manufacturers can be held liable for representations made on their product label, regardless of whether a consumer is prescribed the brand-name drug or its generic bioequivalent. See T.H. v. Novartis Pharmaceuticals Corp., 4 Cal. 5th 145, 165 (2017). By contrast, "Florida law does not recognize a claim against the brand manufacturer of a prescription drug when the plaintiff is known to have consumed only the generic form." Guarino v. Wyeth, LLC, 719 F.3d 1245, 1253 (11th Cir. 2013). Because it is undisputed that Bueno only consumed generic montelukast, and not the brand-name version, Singulair (see Doc. No. 81 at 2 n.3), California and Florida substantive law differ as to Defendants' potential liability for Plaintiff's remaining claims.

Second, both California and Florida have legitimate interests in the application of their respective laws. California has an interest in its products liability and consumer protection laws applying to California residents and persons injured within its borders. Chen v. Lo Angeles Truck Centers, LLC, 42 Cal. App. 5th 488, 502–03 (2019). Plaintiff has a California driver's license, identifies as a California resident, ingested montelukast in California, and claims to have experienced injury in California. (Doc. No. 107-1 ¶ 72; Doc. No. 98 at 18). Florida also has legitimate interests. Bueno lived in Florida, had a Florida driver's license, and filed taxes in Florida. (Doc. No. 107-1 ¶ 64.) Bueno's claims arise out of events that occurred in Florida—Bueno was prescribed montelukast in Florida, by physicians based in Florida, while Bueno resided in Florida. (Doc. No. 99 ¶¶ 158, 180; Doc. No. 100-37, Pl.'s Ex. 26 [Bueno Dep.] at 83:22-25; Doc. No. 90-96, Defs.' Ex. 92 [Schwartz Dep.] at 6:6-25.) Bueno also claims he was injured in Florida. (Doc. No. 107-1 ¶ 77; Doc. No. 100-37, Pl.'s Ex. 26 [Bueno Dep.] at 54:16-20.)

The California Supreme Court case, McCann v. Foster Wheeler LLC, 48 Cal. 4th 68, 96–102 (2010), is instructive here for comparing the relative impairment of the interested jurisdictions. In McCann, a former construction worker brought a personal injury action against a boiler manufacturer for mesothelioma, allegedly caused by asbestos exposure in Oklahoma. 48 Cal. 4th at 74. After his alleged exposure to asbestos, the worker resided in several different states, but eventually took residence in California, where he filed his personal injury action after becoming ill. Id. The McCann court determined that California's interest should be subordinate to Oklahoma's interest because the allegedly tortious conduct occurred in Oklahoma and Oklahoma had adopted a "statute of repose," limiting the liability for commercial activity conducted within the state to provide "fair treatment to, and an appropriate incentive for, business enterprises." Id. at 91. The McCann court held, "when the law of the other state limits or denies liability for the conduct engaged in by the defendant in its territory, that state's interest is predominant, and California's legitimate interest in providing a remedy for, or in facilitating recovery by, a current California resident properly must be subordinated because of this state's diminished authority over activity that occurs in another state." Id. at 101.

Here, the relevant conduct underlying Plaintiff's remaining claims is Defendants' alleged failure to adequately warn Plaintiff's prescribers of the risks of montelukast. Under both California and Florida law, the learned intermediary doctrine provides that manufacturers have a duty to warn physicians, but not the physicians' patients, about certain risks accompanying the use of prescription drugs. See Himes v. Somatics, LLC, 16 Cal. 5th 209, 221 (2024) (California Supreme Court applying learned intermediary doctrine to failure to warn claim); Beale v. Biomet, Inc., 492 F. Supp. 2d 1360, 1365 (S.D. Fla. 2007) ("Florida recognizes the learned intermediary doctrine, which provides that, in cases of prescription drugs, the manufacturer's duty runs to the physician, rather than the patient.") (citing Felix v. Hoffmann-LaRoche, Inc., 540 So. 2d 102, 104 (Fla. 1989)). The relevant conduct at issue here occurred entirely in Florida. The two individuals from whom Bueno received montelukast prescriptions, Dr. Arango and Dr. Schwartz, practiced in

Florida, saw Bueno in Florida, and issued prescriptions for montelukast in Florida. (See Doc. No. 99 ¶ 158; Doc. No. 90-96, Defs.' Ex. 92 [Schwartz Dep.] at 6:6-25.) Bueno also filled his montelukast prescriptions in Florida. (See Doc. No. 99 ¶¶ 159, 188.) In addition, similar to the Oklahoma law in McCann that limited liability to out-of-state companies that conducted business in Oklahoma, 48 Cal. 4th at 91, here, Florida law denies brand-name pharmaceutical manufacturers liability for a consumer who only ingested the generic form of a drug, rather than the brand-name, see Guarino, 719 F.3d at 1253. Given that Bueno only ingested generic montelukast and not Singulair (Doc. No. 81 at 1 n.3), and Florida law bars innovator liability for generic drugs, the reasoning in McCann favors the application of Florida law over California law. See McCann 48 Cal. 4th at 97.

Bueno asserts that he experienced injury in California. (Doc. No. 98 at 18.) But the purported situs of the injury "does not automatically control which state's laws apply to [a plaintiff's] claims." Nelson v. F. Hoffmann-La Roche, Inc., 642 F. Supp. 3d 1115, 1135 (N.D. Cal. 2022) (citing Boaz v. Boyle & Co., 40 Cal. App. 4th 700, 713 (1995)). Rather, it is merely a "'relevant consideration.'" Id. And, here, Plaintiff's assertion that he experienced injury in California is only a minor consideration given that he asserts that he experienced injury in Florida as well. (See Doc. No. 98 at 18.) Further, the fact that Bueno may currently be a California resident is not dispositive. See McCann, 48 Cal. 4th at 97–103 (finding Oklahoma law applied even though the plaintiff was a current California resident). In sum, Florida law applies.

Because Bueno only ingested generic montelukast, (Doc. No. 81 at 1 n.3), and Florida law bars all innovator liability for individuals who take the generic form of a drug, see Guarino, 719 F.3d at 1253, Bueno's two remaining claims for negligence and negligent misrepresentation are barred. As a result, the Court grants summary judgment of Plaintiff's negligence and negligent misrepresentation claims in favor of Defendants.

III. Plaintiff's Negligent Failure to Warn Claims

While the Court grants Defendants' motion for summary judgment for the reasons set forth above, the Court will also address Defendants' additional grounds for summary

judgment. Bueno's negligent failure-to-warn claims also fail under California law. California's learned intermediary doctrine applies to negligent failure-to-warn claims. Himes v. Somatics, LLC, 16 Cal. 5th 209, 221 (2024); see also Thomas v. Abbott Lab'ys, 2014 WL 4197494, at *5 (C.D. Cal. July 29, 2014). "The learned intermediary doctrine provides that 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, 16 Cal. 5th at 221; see also Carlin v. Superior Ct., 13 Cal. 4th 1104, 1116 (1996) ("[I]n the case of prescription drugs, the duty to warn runs *to the physician*, not to the patient." (emphasis in original)). "The doctrine's rationale is that warnings pertaining to prescription drugs and medical devices should be relayed to patients by their physicians—rather than by the manufacturer—because physicians are in a better position to assist patients in deciphering and evaluating the warnings." Himes, 16 Cal. 5th at 227. In other words, "[a]s 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." Id. at 221. Under California law, a drug manufacturer's duty to warn by providing an adequate label extends to the generic equivalent version of a brand-name drug because "[g]eneric drug manufacturers are required to follow the brand-name manufacturer's label to the letter." T.H. v. Novartis Pharms. Corp., 4 Cal. 5th 145, 155 (2017).

The determination as to whether a warning for a prescription medication is adequate "depends on 'how a prescribing doctor would understand the label.'" Rodman v. Otsuka Am. Pharm., Inc., 564 F. Supp. 3d 879, 891 (N.D. Cal. 2020), aff'd, No. 20-16646, 2021 WL 5850914 (9th Cir. Dec. 9, 2021) (citing Hexum v. Eli Lilly & Co., 2015 WL 5008263 at *7 (C.D. Cal. 2015)). "There can be no genuine dispute about the adequacy of a warning that directly warns in plain and explicit terms of the specific risk that has caused injury to the plaintiff." Id. (internal quotation marks omitted).

"'A plaintiff asserting causes of action based on a failure to warn must prove not only that no warning was provided or the warning was inadequate, but also that the

inadequacy or absence of the warning caused the plaintiff's injury.'" Himes v. Somatics, LLC, 29 F.4th 1125, 1126 (9th Cir. 2022), certified question answered, 16 Cal. 5th 209, (2024) (quoting Motus v. Pfizer Inc., 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001), aff'd, 358 F.3d 659 (9th Cir. 2004)); see also Rodman, 564 F. Supp. 3d at 892 ("[E]ven if a warning was inadequate, 'a product defect claim based on insufficient warnings cannot survive summary judgment if stronger warnings would not have altered the conduct of the prescribing physician.'" (quoting Motus v. Pfizer Inc. (Roerig Div.), 358 F.3d 659, 661 (9th Cir. 2004))). To prove causation, the plaintiff must prove that a failure to warn was a "substantial factor" in causing the injury. See Himes, 16 Cal. 5th at 222. Additionally, "[w]here the evidence shows that the physician would have continued to recommend the treatment notwithstanding the stronger warning," a plaintiff can also prove causation by proving "that an objectively prudent person in the patient's position would have declined treatment despite the physician's assessment that the benefits of the treatment for the patient would still outweigh any risks disclosed by a stronger warning." Id. at 219.

A. Duty to Adequately Warn Physicians

It is undisputed that at the time Plaintiff was first prescribed montelukast in 2019, the Singulair label contained warnings regarding neuropsychiatric events and psychiatric disorders in the Highlights of Prescribing Information section on the first page of the label (Doc. No. 99 ¶ 151), in the Warnings and Precautions section (id. ¶ 152), in the Post-Marketing Experience section (id. ¶¶ 153, 154), in the Patient Counseling Information section (id. ¶ 155), and as side effects in the Patient Information sheet (id. ¶ 156). Despite the plain warnings regarding neuropsychiatric events and Dr. Arango's testimony that at the time he prescribed montelukast to Bueno, he was familiar with its risks and benefits (Doc. No. 90-31, Defs.' Ex. 28 [Arango Dep.] at 16:15-18; 17:14-18), Plaintiff argues that the warnings in the montelukast label were inadequate (Doc. No. 98 at 6), and disputes whether Dr. Arango was adequately warned of the risks of Singulair (Doc. No. 99 ¶¶ 162,

164–66).[3] Specifically, Plaintiff asserts that Merck breached its duty to adequately warn physicians of the neuropsychiatric conditions affiliated with montelukast by failing to take the following three actions:

(1) **Changing the Language of the Prescriber's Information regarding Adverse Events** - First, Plaintiff argues that Merck could have accepted FDA's suggestion to warn that the adverse event reports "are consistent with a drug-induced effect," instead of "merely stating that 'Adverse Events appear consistent with a drug-induced effect'." (Doc. No. 98 at 21; see also id. at 7, 17, 33, 36.)

(2) **Adding a Contraindication** - Second, Plaintiff asserts that "Merck could have added a contraindication for people who were prescribed Singulair for allergic rhinitis and experienced suicidality while taking Singulair." (Id. at 7; see also id. at 18, 21, 22, 31, 36.)

(3) **Sending a "Dear doctor" letter following 2020 "black box" warning** - Third, Plaintiff asserts that Merck "should have se[n]t a 'Dear Doctor' letter notifying prescribers of the Black Box [warning]" because "[i]n March and April 2020 medical providers across America—particularly pulmonary specialists—were focused on Covid." (Id. at 37; see also id. at 15, 21.)

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[3] Plaintiff does not argue that Defendants could have or should have unilaterally added a black box warning to montelukast's label before 2020. At the August 19, 2024, hearing, Plaintiff conceded that Defendants could not have unilaterally added a black box warning. See also Rosewolf v. Merck., 4:22-cv-02072-JSW, slip op. at 15 (N.D. Cal. Dec. 2, 2022) (Plaintiff's counsel stating in a related case: "Plaintiffs agree that Defendants could not have unilaterally added the Black Box Warning."). "A black box warning is the strongest type of warning allowed in drug labeling, and to ensure their significance is undiluted, use of a black box warning is permitted only where specifically required by the FDA." Amos v. Biogen Idec Inc., 249 F. Supp. 3d 690, 694 (W.D.N.Y. 2017).

Plaintiff does not offer any evidence in support of his argument that Defendants were negligent by not taking these three recommended actions.[4] (Doc. No. 98 at 19–21.) The expert report of Plaintiff's expert, Dr. Dima Mazen Qato, PharmD, MPH, PhD, does not mention, let alone explain, how the language in montelukast's warning label about "marketing reports that 'appear consistent' with a drug-induced effect" differs in meaning from, or is inadequate to, the language, "marketing reports that 'are consistent' with a drug-induced effect." (See generally Doc. No. 100-29, Pl.'s Ex. 20.) She also does not offer any opinion or evidence on contraindications for individuals experiencing suicidal ideations or suicidality, or "Dear doctor" letters. (Id.) Furthermore, Plaintiff does not challenge Defendants' argument that the labeling critiques that appear in Dr. Qato's report concerning recommended warnings to "pediatric populations," modified instructions in dosage and administration for "adolescents," and the "food effects" on levels of montelukast (see id. at 14–15), have no relevance to Bueno, who was an adult when he was first prescribed montelukast and has never alleged an inadequacy of montelukast's label with respect to "food effects" (Doc. No. 90-1 at 22).[5] While Dr. Qato's report generally indicates that "the manufacturer (Merck) should have anticipated, monitored, and/or warned about . . . neuropsychiatric risks" (Doc. No. 100-29 at 14), she does not explain how the neuropsychiatric warnings that existed on the montelukast label were inadequate. See Oregon v. Bos. Sci. Corp., 2022 WL 1607960, at *4 (E.D. Cal. May 20, 2022) ("'[M]erely stating that the Defendants failed to 'adequately warn' of [the alleged injury] is a bare legal conclusion' and would be insufficient to state a cognizable failure to warn claim." (quoting Marroquin v. Pfizer, Inc., 367 F. Supp. 3d 1152, 1161 (E.D. Cal. 2019))).

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[4] Plaintiff does not dispute that prior to Defendants' filing their motion for summary judgment, Plaintiff withdrew his "warnings expert," Jack E. Fincham, PhD, R.Ph. (Doc. No. 90-1 at 21.)

[5] At the August 19, 2024, hearing, Plaintiff's counsel conceded that the sections of Dr. Qato's report regarding inadequate warnings for children, adolescents, and the "food effects" of montelukast (Doc. No. 100-29 at 14–15), have no relevance to this case.

The same is true of the report written by Plaintiff's other expert, Dr. David Healy. (Doc. No. 100-39, Pl.'s Ex 28.) Dr. Healy does not discuss any specific inadequacies in the Singulair or montelukast label.[6] (See generally id.)

Because no evidence has been proffered to prove how Singulair's label was inadequate for physicians prescribing montelukast to adults like Bueno, Plaintiff has failed to carry his burden of demonstrating that he has sufficient evidence to allow a jury to determine that the warnings on the Singulair label were inadequate. Thus, Defendants are entitled to summary judgment of Plaintiff's remaining claims on this basis. See Garber v. United States, 2017 WL 797096, at *8 (C.D. Cal. Feb. 27, 2017), aff'd, 709 F. App'x 485 (9th Cir. 2018) ("[T]he adequacy of defendant's warnings [is] beyond the common knowledge of a layperson. Accordingly, [it] must be established through expert testimony."); Rodman, 564 F. Supp. 3d. at 891 (granting summary judgment on failure-to-warn claim after excluding plaintiff's expert's labeling opinions because "[w]hether a warning is adequate depends on how a prescribing doctor would understand the label" (internal quotation marks and citations omitted)); Kamerik v. Depuy Orthopedics, Inc., 2013 WL 12322041, *4 (C.D. Cal. Jan. 28, 2013) (granting summary judgment on negligence and warnings-based claims in the absence of expert testimony as the standard of care for manufacturer of complex medical device was "'beyond the common knowledge of [laypeople]'" (quoting Torres v. Taser Int'l, Inc., 277 F. App'x 684, 687 (9th Cir. 2008))); see also Anderson, 477 U.S. at 257 (explaining that "in order to defeat a properly supported motion for summary judgment," a plaintiff must present "affirmative evidence" "from which a jury might return a verdict in his favor").

B. Causation

Since Plaintiff does not prevail on demonstrating the inadequacy of the Singulair warning label, causation is rendered moot. Nevertheless, the Court will address causation.

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[6] At the August 19, 2024 hearing, Plaintiff conceded that Plaintiff does not rely on Dr. Healy's report for any evidence of inadequacies in the Singulair or montelukast label.

Plaintiff bears the burden of proving that any inadequacies by Defendants in warning Plaintiff's physicians of the risks associated with Singulair caused his injuries. See Himes, 16 Cal. 5th at 222–23. To prove causation, the plaintiff must prove that a failure to warn was a "substantial factor" in causing the injury. Id. at 222.

Two individuals prescribed Plaintiff montelukast: (1) Dr. Arango, and (2) Dr. Schwartz. (Doc. No. 99 ¶¶ 158, 168, 180.) However, because Plaintiff does not address causation as to Dr. Schwartz in his opposition to Defendants' motion for summary judgment (see generally Doc. No. 98), Plaintiff has failed to demonstrate a triable issue of fact regarding causation as to Dr. Schwartz. See Hartranft v. Encore Capital Group., Inc., 543 F. Supp. 3d 893, 913 (S.D. Cal. 2021) ("[W]here a non-moving party fails to address an argument raised by the moving party in the opposition brief, the Court may consider any arguments unaddressed by the non-moving party as waived."); see also Pacific Dawn LLC v. Pritzker, 831 F.3d 1166, 1178 n.7 (9th Cir. 2016) (noting that because "plaintiffs did not raise . . . [the] argument to the district court in their . . . opposition to the defendants' motion for summary judgment. . . the argument was waived"). Accordingly, the Court will only address the extent to which any inadequacies to the montelukast label might have affected Dr. Arango's prescribing decision, thereby causing injury to Bueno.

As to causation, Plaintiff has not raised a triable issue of fact. Plaintiff has not demonstrated that Dr. Arango would have changed his prescribing decisions had Defendants followed any of Plaintiff's three proposals to: (1) accept FDA's suggestion to warn that the adverse event reports "are consistent with a drug-induced effect," rather than that adverse event reports "appear consistent with a drug-induced effect," (2) add a contraindication for patients with allergic rhinitis "who experienced suicidality while taking Singulair," or (3) issue a "Dear doctor" letter to physicians following the addition of the black box warning in 2020. (See Doc. No. 107 at 9.)

First, there is no expert testimony that a label change stating that adverse event reports "are consistent" with a drug-induced effect, would have changed a physician's decision to prescribe montelukast to Bueno compared to the label at the time Dr. Arango

prescribed the medication to Bueno, which stated that adverse event reports "appear consistent" with a drug-induced effect. (Doc. No. 99 ¶ 152.) After Dr. Arango was shown a January 13, 2009, FDA communication intended to "reflect[] FDA's current analysis of available data concerning [Singulair]" that included the "are consistent" language, and asked whether this language changed the way he prescribed Singulair, he testified, "No, not really." (Doc. No. 107-5, Defs.' Ex. 102 [Arango Dep.] at 4:8–6:19.)[7] Without any evidence from an expert, Plaintiff does not meet his burden to prove that changing, "appear consistent" to "are consistent" on the Singulair label, would materially affect his physician's prescribing decisions. See Anderson, 477 U.S. at 257 (explaining that "in order to defeat a properly supported motion for summary judgment," a plaintiff must present "affirmative evidence" "from which a jury might return a verdict in his favor").

Second, Plaintiff does not raise a triable issue of fact with respect to Plaintiff's proposed contraindication for patients prescribed montelukast for allergic rhinitis, or allergies, who experienced suicidality while using Singulair. The record before the Court does not demonstrate that Plaintiff ever reported suicidality or suicidal ideation to Dr. Arango. (Doc. No. 107-5, Defs.' Ex. 102 [Arango Dep.] at 7:25–8:24, 9:6–10:4, 11:17–12:22, 13:18–14:11, 15:2–16:13, 17:5–18:4.) After Bueno's first visit with Dr. Arango, Bueno told Dr. Arango that he "felt better" and Dr. Arango testified that "there were no

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[7] The Declaration of Dr. Pablo Arango (Doc. No. 100-40), untimely submitted after the close of discovery and after Dr. Arango's deposition, improperly addresses hypotheticals regarding causation. See United States v. Urena, 659 F.3d 903, 908 (9th Cir. 2011) (agreeing "with [its] sister circuits," that "a physician's assessment of the cause of an injury is expert testimony"). Plaintiff did not designate Dr. Arango as an expert witness and has not provided a required expert written disclosure under Federal Rule of Civil Procedure 26(a)(2)(C). Moreover, after Dr. Arango was shown a January 13, 2009, FDA communication intended to "reflect[] FDA's current analysis of available data concerning [Singulair]" that included the "are consistent" language, and asked whether this language changed the way he prescribed Singulair, he testified, "No, not really." (Doc. No. 107-5, Defs.' Ex. 102 [Arango Dep.] at 4:8–6:19.) At the August 19, 2024, hearing, Plaintiff's counsel conceded that Plaintiff only ingested generic montelukast, not the brand-name Singulair.

concerns expressed to me." (Id. at 9:6–10:4.) Other than Bueno requesting montelukast refills, Bueno never contacted Dr. Arango regarding treatment since November 2019. (Id. at 25:20-23.) Plaintiff also did not report that he experienced suicidal ideation with Dr. Schwartz, the physician who prescribed him montelukast in 2020 and 2021. (Doc. No. 99 ¶ 195 (undisputed that "Bueno never told Dr. Schwartz he had depression . . . [or] suicidal ideation. . . .").) Bueno's single suicide attempt was in December 2022 (Doc. No. 107-4, Defs.' Ex. 101 at 7:3-7), three years following his last contact with Dr. Arango and at least a year after his contact with Dr. Schwartz. The evidence does not demonstrate that Singulair's label's omission of Plaintiff's proposed contraindication caused Plaintiff's injury.

Third, sending Dr. Arango a "Dear doctor" letter following the 2020 addition of the black box warning to the Singulair label would not have changed Dr. Arango's prescribing decisions for Bueno because Dr. Arango did not treat Bueno after November 2019. (Doc. No. 99 ¶ 167.) Moreover, Plaintiff neither argues, nor presents any evidence that a "Dear doctor" letter would have changed Dr. Schwartz's prescribing decisions. Given the foregoing, Plaintiff has not proven causation. See Anderson, 477 U.S. at 257.

In sum, Plaintiff has failed to present sufficient evidence as to how Plaintiff's three suggested enhanced label warnings would have altered the conduct of Plaintiff's prescribing physicians, or even an objectively reasonable consumer's decision to ingest montelukast. As such, Defendants are entitled to summary judgment of Plaintiff's remaining claims on this basis. See Motus v. Pfizer Inc. (Roerig Div.), 358 F.3d 659, 661 (9th Cir. 2004) (affirming summary judgment where plaintiff "failed to establish proof that stronger warnings would have changed her husband's medical treatment or averted his suicide").

IV. Preemption

Even though Defendants are entitled to summary judgment as to Plaintiff's negligence and negligent misrepresentation claims, the Court will nevertheless address preemption. Defendants argue that even if the Singulair warnings were inadequate,

Defendants are entitled to summary judgment because Plaintiff's failure-to-warn claims are preempted by the federal Food, Drug, and Cosmetic Act ("FDCA"). (Doc. No. 90-1 at 9, 26.) Specifically, Defendants assert that because a pharmaceutical manufacturer typically cannot change an FDA-approved drug's label without the FDA's preapproval of any proposed changes, a state's product liability law is preempted by the FDCA unless the manufacturer could unilaterally correct the alleged labeling deficiency using the "changes being effected" ("CBE") regulation. (Id. at 26–27.) Plaintiff responds that federal law does not preempt California law, which required Merck to provide a stronger warning, and Merck could have strengthened its warnings through the CBE process. (Doc. No. 98 at 26–37.)

Under the Supremacy Clause of the Constitution, "when federal and state law conflict, federal law prevails and state law is preempted." Knox v. Brnovich, 907 F.3d 1167, 1173 (9th Cir. 2018) (quoting New Jersey Thoroughbred Horsemen's Ass'n v. Nat'l Collegiate Athletic Ass'n, 584 U.S. 453, 471 (2018)). State law includes "state common law or state statutes that require drug manufactures to warn drug consumers of the risks associated with drugs." Merck Sharp & Dohme Corp. v. Albrecht, 587 U.S. 299, 303 (2019). Absent express preemption, state law may be "impliedly pre-empted where it is impossible for a private party to comply with both state and federal requirements." Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 480 (2013) (internal quotation marks and citation omitted). The question of preemption is "one for a judge to decide, not a jury." Albrecht, 587 U.S. at 303.

The federal law at issue here is the "statutory and regulatory scheme through which the FDA regulates the information that appears on brand-name prescription drug labels." Id. "Prospective drug manufacturers work with the FDA to develop an appropriate label when they apply for FDA approval of a new drug." Id. at 304. Because research about drug safety may evolve over time, drug manufacturers "generally seek advance permission from the FDA to make substantive changes to their drug labels." Id. "In general, the FDA must approve any subsequent label change through a supplemental application process."

Krantz v. Regeneron Pharms., Inc., 2024 WL 1792769, at *6 (C.D. Cal. Apr. 24, 2024) (citing 21 C.F.R. § 314.70b(2)(v)(A)). However, the FDA's CBE regulation "permits drug manufacturers to change a label to 'reflect newly acquired information' if the changes 'add or strengthen a . . . warning for which there is 'evidence of a causal association,' without prior approval from the FDA." Albrecht, 587 U.S. at 314–15 (citing 21 C.F.R. § 314.70(c)(6)(iii)(A)).

> The CBE regulation defines the term, "newly acquired information," as:
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> [D]ata, analyses, or other information not previously submitted to the Agency, 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). "Newly acquired information" is not limited to new data, but "also encompasses 'new analyses of previously submitted data.'" Wyeth v. Levine, 555 U.S. 555, 569 (2009) (quoting 73 Fed. Reg. 49603-01, 49604 (Aug. 22, 2008)). This is because "risk information accumulates over time and . . . the same data may take on a different meaning in light of subsequent developments. . . ." Id.; see also id. at 570 (finding that, "[i]n later years, as amputations continued to occur, Wyeth could have analyzed the accumulating data and added a stronger warning about IV-push administration of the drug").

In conducting a preemption analysis in pharmaceutical litigation, "[w]hether federal and state laws irreconcilably conflict entails the threshold inquiry of whether there is 'newly acquired information' to support a CBE submission." In re Incretin-Based Therapies Prod. Liab. Litig., 524 F. Supp. 3d 1007, 1018 (S.D. Cal. 2021), aff'd, 2022 WL 898595 (9th Cir. Mar. 28, 2022) (quoting Albrecht, 587 U.S. at 314); see also Krantz v. Regeneron Pharms., Inc., 2024 WL 1792769, at *7 (C.D. Cal. Apr. 24, 2024) ("In the context of preemption by the FDCA of claims of failure-to-warn, the burden is first on the Plaintiffs to allege facts showing that [defendant] could have unilaterally changed [the

drugs'] label under the CBE regulation") (internal quotation marks and citation omitted). "If the answer is no, then the state law claim is preempted." In re Incretin, 524 F. Supp. 3d at 1018; see also Knight v. Boehringer Ingelheim Pharm., Inc., 984 F.3d 329, 332 (4th Cir. 2021) (finding that because the manufacturer did not have "newly acquired information" to unilaterally change its label, the state law claim is preempted). "If the answer is yes, then the Court considers whether there is clear evidence 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.'" In re Incretin, 524 F. Supp. 3d at 1018 (quoting Albrecht, 587 U.S at 315).

In the context of pharmaceutical litigation, "[i]mpossibility pre-emption is a demanding defense." Wyeth, 555 U.S. at 573. Because the CBE regulation permits manufacturers to make changes effective immediately while pending FDA review, "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." Albrecht, 587 U.S. at 315. Nevertheless, a drug manufacturer "cannot propose a change that is not based on reasonable evidence." Id.

A. CBE Change Prior to 2008

Plaintiff first argues that prior to 2008, before the codification of the "newly acquired information" requirement, Merck "could have submitted a label change based on the many adverse event reports that were piling up" or "could have provided to the FDA the very simply [sic] calculation Dr. Qato provided." (Doc. No. 98 at 31.) Plaintiff does not cite to any evidence of "the many adverse event reports that were piling up" (id.), nor does Plaintiff cite to the "simpl[e] calculation" to which he refers. (See generally Doc. No. 98.)[8]

[8] In Plaintiff's Statement of Undisputed Facts, Plaintiff refers to a "simple analysis" performed by Dr. Qato that could possibly reference the "simple calculation" to which he refers here. (See Doc. No. 101 ¶ 48 ("Merck performed a 400-page analysis of this information, but as Dr. Qato demonstrated, an epidemiologist could perform a simple

Without evidence to substantiate his assertion, Plaintiff does not meet his burden to prove that prior to 2008, Merck could have submitted a CBE label change. See Opara v. Yellen, 57 F.4th 709, 728 (9th Cir. 2023) (mere conclusory allegations are insufficient to raise a fact issue that would preclude summary judgment).

B. CBE Change Following 2008 "Newly Acquired Information" Requirement

Following the 2008 addition of the "newly acquired information" requirement in the CBE regulation, 21 C.F.R. § 314.3(b), Plaintiff argues "two forms of 'newly acquired information,'" could have justified a CBE change to Singulair's label: (1) "[a]pproximately ten thousand reports regarding neuropsychiatric adverse events [that] were in the FDA database[,]" "any one" of which could have been "sufficient to justify a label change" (Doc. No. 98 at 33), and (2) "the more mathematically rigorous calculations of existing Merck clinical trials" (id. at 31).

1. Adverse Event Reports in the FDA Database

Information previously made available to the FDA does not constitute "newly acquired information." See In re Incretin, 524 F. Supp. 3d at 1023 (citing 21 C.F.R. § 314.3); see also Roshkovan v. Bristol-Myers Squibb Co., No. 221CV08590FWSAGR, 2023 WL 6787444, at *7 (C.D. Cal. Sept. 19, 2023) (dismissing failure-to-warn negligence claim on preemption grounds because allegations of adverse-event reports in the FAERS, "a public dashboard maintained by the FDA," did not sufficiently allege "newly acquired information," but rather "suggest[ed] that the FDA was aware of the adverse event reports but did not take further action"). Plaintiff concedes that the adverse event reports at issue "were in the FDA database." (Doc. No. 98 at 33.) These adverse events therefore do not constitute "newly acquired evidence." See 21 C.F.R. § 314.3(b)

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analysis in five to ten minutes to see this data is flawed.").) However, it is undisputed that Dr. Qato performed her analysis using data published in 2009 (Doc. No. 99 ¶¶ 206, 207), which would not have been available to Defendants prior to 2008.

(Newly acquired information is "data, analyses, or other information not previously submitted to the Agency. . . .").

Plaintiff also does not attempt to explain how "any one" of the adverse event reports "reveal[ed] risks of a different type or greater severity or frequency than previously included in submissions to FDA." 21 C.F.R. § 314.3(b). Nor does Plaintiff explain how any of the adverse event reports revealed a causal relationship between montelukast and the adverse event that could justify a CBE change. See Utts v. Bristol-Myers Squibb Co., 251 F. Supp. 3d 644, 664 (S.D.N.Y. 2017), aff'd sub nom. Gibbons v. Bristol-Myers Squibb Co., 919 F.3d 699 (2d Cir. 2019) ("[T]he mere existence of reports of adverse events . . . says nothing in and of itself about whether the drug is causing the adverse events." (quoting Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 44 (2011)) (applying California law)). Here, Plaintiff's vague citation to "[a]pproximately ten thousand reports regarding neuropsychiatric adverse events" that "were in the FDA database" (Doc. No. 98 at 33), does not constitute "newly acquired information" and does not defeat Defendants' preemption defense.

2. Dr. Qato's recalculation of Merck's clinical trial data

Plaintiff next asserts that Dr. Qato's analysis of existing Merck clinical trial data can constitute "newly acquired information." (Id. at 33–34.) Plaintiff points to Dr. Qato's analysis of data that Merck had previously submitted to the FDA, and subsequently published in 2009 in the peer-reviewed Journal of Allergy and Clinical Immunology, ("the Philip Paper"). (Doc. No. 90-61, Defs.' Ex. 58) (Philip, et al., Analysis of behavior-related adverse experiences in clinical trials of montelukast, 124(4) J. Allergy Clin. Immunol. 699 (Oct. 2009)). The Philip Paper concluded that "[r]eports of [behavior-related adverse experiences] were infrequent in clinical trials of montelukast. Those leading to study discontinuation or considered serious were rare. Frequencies were similar regardless of treatment group." (Id. at 2.) Plaintiff's expert, Dr. Qato, argues that the conclusions in the Philip Paper are "flawed" and that the paper includes "a miscalculation of their statistical analysis that erroneously concludes that montelukast is not significantly associated with

such [neuropsychiatric effects] risk." (Doc. No. 90-100, Defs.' Ex. 96 at 11.) In 2023-2024, Dr. Qato conducted her own calculations, finding that montelukast is significantly associated with behavior-related adverse experiences. (Id. at 12; Doc. No. 100-29, Pl.'s Ex. 20 at 52, 54.)

The Court rejects Plaintiff's argument. While "new analyses of previously submitted data" can constitute "newly acquired information" in certain circumstances, 21 C.F.R. § 314.3(b), new analyses do not comprise "newly acquired information" when "conducted by an expert in preparation for litigation with the benefit of hindsight." R.S.B. v. Merck & Co., 2021 WL 6128161, *4 (E.D. Wis. Dec. 28, 2021); see also In re Incretin, 524 F. Supp. 3d at 1024–25 (finding "expert report [that] was generated in preparation for litigation and . . . not supported by published research" did not constitute "newly acquired information"); see also In re Zofran (Ondansetron) Prod. Liab. Litig., 57 F.4th 327, 340 (1st Cir. 2023) ("expert report [that] was not prepared, and thus not available to or possessed by [manufacturer], until [after plaintiff filed complaint] . . . cannot serve as newly acquired information that would have triggered an obligation by [manufacturer] to unilaterally amend Zofran's label . . . ."). Additionally, "asserting that [a] manufacturer could or should have done more studies—i.e., that a manufacturer should have created the 'newly acquired information'—is insufficient to avoid preemption under the CBE regulation." Holley v. Gilead Scis., Inc., 2023 WL 6390598, at *8 (N.D. Cal. Sept. 28, 2023).

Here, Dr. Qato's "five to ten minute[]" "simple analysis" conducted after Plaintiff filed the complaint, cannot constitute "newly acquired information" that would justify a CBE label change. (See Doc. No. 98 at 13; see also Doc. No. 100-30, Pl.'s Ex. 21 [Qato Dep.] at 55:3-7 (Dr. Qato testifying that her recalculations of Merck's trial data took "five to ten minutes.").) Dr. Qato conducted her recalculation analyses after having been retained as an expert for Plaintiffs Parker and Bueno in the related Bueno litigation. (Doc. No. 100-30, Pl.'s Ex. 21 [Qato Dep.] at 52:15-22, 54:7-13.) Because Dr. Qato's analysis was conducted in preparation for litigation and is unsupported by any published research,

it does not constitute "newly acquired information." See R.S.B. by & through Hammar v. Merck & Co., 2022 WL 3927868, at *4 (E.D. Wis. Aug. 31, 2022) (granting Merck's motion for summary judgment on preemption grounds in case involving products liability/negligence claims involving Singulair and explaining "even were the Court to consider Dr. Qato's opinion, her conclusions are litigation-driven and unsupported by any published research, and therefore do not constitute newly acquired information"); see also In re Incretin, 524 F. Supp. 3d at 1024–25 ("Additionally, to the extent Plaintiffs argue that their expert's re-analysis of the slide images . . . amounts to newly acquired information, the Court disagrees. This expert report was generated in preparation for litigation and is not supported by published research.") (internal citations omitted); see also R.S.B., 2021 WL 6128161, *4 ("Plaintiffs are not entitled to create their own 'newly acquired information' through the use of experts.").

Further, even if the Court were to assume that Dr. Qato's analysis was timely, her analysis is insufficient to support a CBE label change. "[N]ew analyses of previously submitted data" could only prompt a CBE label change if the new analyses are "based on reasonable evidence." Albrecht, 587 U.S. at 315. Put simply, the new analyses must provide "reliable evidence of new risks." Knight, 984 F.3d at 340 (quoting Roberto v. Boehringer Ingelheim Pharms., Inc., 2019 WL 5068452, at *16 (Conn. Super. Ct. Sept. 11, 2019)). To evaluate whether new analyses may be "newly acquired information" to support a CBE submission, it is appropriate to consider the information "against the backdrop of the FDA's year-long attention to, and evaluation of, the [specific safety issue raised by Plaintiff]." In re Incretin, 524 F. Supp. 3d at 1018–19.

Prior to Dr. Qato's 2023-2024 recalculations of Merck clinical trial data (Doc. No. 100-30, Pl.'s Ex. 21 [Qato Dep.] at 52:15-22, 54:7-13), Merck and the FDA had "devoted considerable time and attention" to designing, conducting, implementing, and interpreting clinical trials to evaluate the risk of suicidality (suicidal ideation and behavior) and behavior-related adverse experiences with Singulair, the "specific safety issue raised by plaintiffs." See In re Incretin, 524 F. Supp. 3d at 1018; (see also Doc. No. 99 ¶¶ 1–66).

Specifically, in 2008, Merck, in a months-long collaboration with the FDA, drafted a Statistical Analysis Plan ("SAP"),[9] which "intended to be a comprehensive and detailed description of the strategy, rationale, and statistical techniques that will be used for retrospective analysis of adjudicated PSRAEs ['Possibly Suicide-Related' Adverse Events] from the montelukast program." (Doc. No. 99 ¶ 56). The SAP included the generally accepted methodology requested, and approved, by the FDA by which Merck was to conduct its clinical trials. (Id. ¶¶ 53–61; Doc. No. 90-50, Defs.' Ex. 47 at 10 (SAP identifying the "analysis methods" and "primary method" for Merck to conduct its analyses of individual montelukast trials).) Merck then analyzed data from more than 40 clinical trials and submitted its data to the FDA in two separate submissions, each exceeding 400 pages. (See Doc. No. 90-55, Defs.' Ex. 52; see also Doc. No. 90-56, Defs.' Ex. 53 at 18 ("In total, 41 completed (as of 25-Apr-2008) placebo-controlled adult . . . and pediatric . . . studies were included in the adjudication process.").) In October 2009, Merck published its analyses of suicidality and behavior-related adverse events in the Philip Paper. (Doc. No. 99 ¶ 238; Doc. No. 90-61, Defs.' Ex. 58.)

In her report, Dr. Qato opines that a figure in the Philip Paper "depicts incorrect Odds Ratio (OR) estimates and statistical significance (p-value)" such that when she recalculates the Odds Ratio and corresponding p-value to measure statistical significance, she finds that montelukast is "significantly associated with a 21% increased odds or likelihood of experience a [Behavior Related Adverse Event] . . . and for Psychiatric SOC+Other." (Doc. No. 90-100, Defs.' Ex. 96 at 11–12.) Her calculations differ from the findings in Merck's submission to the FDA and in the Philip Paper, which found no

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[9] It is undisputed that on March 27, 2008, the FDA initially requested from Merck a "more thorough evaluation of [Merck's] controlled clinical trial data." (Doc. No. 99. ¶¶ 43, 44.) Later, on June 19, 2008, the FDA asked Merck to prepare the Statistical Analysis Plan (id. ¶¶ 53–55; Doc. No. 90-49, Defs.' Ex. 46), which Merck first submitted on August 14, 2008 (Doc. No. 99 ¶ 58), and later amended with input from the FDA (id. ¶ 60).

statistically significant risk of neuropsychiatric adverse events. (Id. at 10; Doc. No. 90-61, Defs.' Ex. 58 at 2.)

Dr. Qato's recalculations of Merck's clinical trial data cannot constitute "newly acquired information" because Plaintiff has not demonstrated that her calculations are reliable or based on the generally accepted methodology approved by the FDA in the SAP.

Indeed, Dr. Qato's calculations were divorced from the FDA's requested and generally accepted methodology. Dr. Qato describes her odds-ratio as a "crude" analysis (Doc. 90-99, Defs.' Ex. 95 [Qato Dep.] at 16:16-21), meaning a "calculation with an unadjusted rate of incidence and odds ratio" (Doc. No. 102 at 8). Her "crude estimates" deviated from the SAP's methodology that required Merck to make adjustments to the odds ratio calculation "to account for the heterogeneity of the underlying studies." (Doc. No. 89-1 at 21; Doc. No. 90-50, Defs.' Ex. 47 at 10–11; see also Doc. No. 99 ¶ 211 (undisputed that Dr. Qato did not review the statistical analysis plan, despite testifying that it would be helpful to do so).) "[F]ailing to take account of likely confounders by presenting and relying upon only unadjusted (or minimally adjusted) estimates is a serious methodological concern." In re Roundup Prod. Liab. Litig., 390 F. Supp. 3d 1102, 1140 (N.D. Cal. 2018), aff'd sub nom. Hardeman v. Monsanto Co., 997 F.3d 941 (9th Cir. 2021). More than just an oversight, neglecting to account for relevant evidence in conducting her analysis calls into question the reliability of her methods and the reasonableness of her conclusions. See Carnegie Mellon Univ. v. Hoffmann-LaRoche, Inc., 55 F. Supp. 2d 1024, 1039 (N.D. Cal. 1999) (excluding expert's proposed testimony and noting that he ignored available information and samples); In re Mirena Prods. Liability. Litig. (No. II), 341 F. Supp. 3d 213, 242 (S.D.N.Y. 2018), aff'd sub nom. In re Mirena IUS Levonorgestrel-Related Prod. Liab. Litig. (No. II), 982 F.3d 113 (2d Cir. 2020) (explaining that when an expert "ignores evidence that is highly relevant to his conclusion," exclusion of the expert's testimony is warranted).

Additionally, in Plaintiff's response to Defendants' Daubert motion, Plaintiff recognizes, but does not dispute, Defendants' characterization that Dr. Qato "came to a

faulty mathematical conclusion because she used some of the information in one of the table[s] in Dr. Philip's publication that she should not have used." (Doc. No. 102 at 16.) While Plaintiff argues, "[i]ncorrectly using a row of numbers in the analysis does not damn an opinion based on solid methodology" (id.), analyses using incorrect data, unsupported by published research, cannot constitute reasonable or reliable evidence. See In re Incretin, 524 F. Supp. 3d at 1025 ("[O]ne unpublished and litigation-driven animal study does not make a risk apparent or otherwise constitute reasonable evidence of association." (internal quotation marks and citation omitted)). The record before the Court does not support a finding that Dr. Qato's calculations constitute "reasonable evidence," Albrecht, 587 U.S. at 315, and the Court concludes that Dr. Qato's analysis does not constitute "newly acquired information." As such, Defendants are also entitled to summary judgment of Plaintiff's remaining claims based on preemption. See, e.g., R.S.B., 2022 WL 3927868, at *4–*5 (granting Merck's motion for summary judgment on preemption grounds in case involving products liability/negligence claims involving Singulair).

CONCLUSION

For the reasons stated above, the Court grants Defendants' motion for summary judgment regarding Plaintiff's negligence and negligent misrepresentation claims. The Court directs the Clerk of Court to enter a judgment in favor of Defendants and against Plaintiff.

In addition, the Court denies Defendants' motion to exclude the opinions of Dima Mazen Qato and motion to exclude or limit the opinion testimony of David Healy as moot. The Court also denies Defendants' motion to strike the declaration of David Healy, motion to strike the declaration of Dima Qato, and motion to strike the declaration of Pablo Arango as moot.

IT IS SO ORDERED.

DATED: August 27, 2024

MARILYN L. HUFF, District Judge
UNITED STATES DISTRICT COURT