UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

RICHARD PARKER, 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.: 3:24-cv-00916-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. 9, 10, 11.]

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. 11.) Defendants also filed a motion to exclude or limit the opinion testimony of David Healy (Doc. No. 9), and a motion to exclude the opinions of Dima Mazen Qato, MPH, PhD (Doc. No. 10) (collectively, the "Daubert motions"). On July 9, 2024, Plaintiff Richard Parker ("Parker" or "Plaintiff") filed a response in opposition to Defendants' motion for summary judgment (Doc. Nos. 24, 25), and responses in opposition to Defendants' Daubert motions (Doc. Nos. 26, 27). On July 22, 2024, Defendants filed reply briefs in support of their Daubert motions. (Doc. Nos. 30, 31.) Defendants also filed objections to and motions to strike the individual declarations of David Healy (Doc. No. 30-2), and Dima Qato (Doc. No. 31-5), submitted by Plaintiff in opposition to Defendants' Daubert motions. 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. 32.) On July 30, 2024, Plaintiff filed his response to Defendants' statement of undisputed facts. (Doc. No. 33.)[1]

The Court held a hearing on Defendants' motion for summary judgment and Daubert motions on August 19, 2024. (Doc. No. 46.) 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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[1] Docket Entry No. 33 is Plaintiff's Response to Defendants' Statement of Undisputed Facts. On August 13, 2024, Defendants filed an objection to Plaintiff's response on the grounds that the response was not timely filed. (Doc. No. 39.) Defendants have failed to demonstrate how they have been prejudiced by the untimeliness of the filing. Thus, the Court overrules Defendants' objections to Plaintiff's Response to Defendants' Statement of Undisputed Facts.

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, Compl. ¶ 11.) One of these drugs is Singulair, which includes the active ingredient montelukast. (Id. ¶ 2; Doc. No. 11-6, 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 (also called hay fever). (Doc. No. 1, 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, 27; Doc. No. 11-4, Defs.' Ex. 1; Doc. No. 11-5, Defs.' Ex. 2.) The Merck Defendants were the exclusive manufacturers, distributors, and sellers of Singulair from 1998 to mid-2012. (Doc. No. 1, Compl. ¶ 12.) On August 3, 2012, Merck's patent expired and generic montelukast drugs entered the market. (Id. ¶ 27.) 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. ¶ 13.) 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. 33 ¶¶ 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. 33 ¶ 125; Doc. No. 11-87, Defs.' Ex. 83.1.)

B. Factual Background regarding Plaintiff's Use of Montelukast

Plaintiff Richard Parker ("Parker") is a citizen and resident of San Diego County, California. (Doc. No. 1, Compl. ¶ 7.) Parker's medical records indicate that he was prescribed montelukast from January 2016 to August 2021. (Doc. No. 33 ¶¶ 150, 159, 171,

177, 180, 186, 192, 204, 207, 227.)

1. Singulair Warnings in Effect When Parker Was Prescribed Montelukast

It is undisputed that, at the time Parker was first prescribed montelukast in 2016, the Singulair label included the following information.

The HIGHLIGHTS OF PRESCRIBING INFORMATION section on the first page of the November 2014 label, in effect on January 1, 2016, 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. 11-90, 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 agitation, aggressive behavior or hostility, anxiousness, depression, disorientation, disturbance in attention, dream abnormalities, hallucinations, insomnia, irritability, memory impairment, restlessness, somnambulism, suicidal thinking and behavior (including suicide), 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. 33 ¶ 152; Doc. No. 11-90, 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: agitation including aggressive behavior or hostility, anxiousness, depression, disorientation, disturbance in attention, dream abnormalities, hallucinations, insomnia, irritability, memory impairment, restlessness, somnambulism, suicidal thinking and behavior (including suicide), and tremor *[see Warnings and Precautions (5.4)]*.

(Doc. No. 33 ¶¶ 153–54; Doc. No. 11-90, 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. 33 ¶ 155; Doc. No. 11-90, 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. 11-90, 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:
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> - 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
> - restlessness
> - sleep walking
> - suicidal thoughts and actions (including suicide)
> - tremor
> - trouble sleeping

(Doc. No. 33 ¶ 156; Doc. No. 11-90, Defs.' Ex. 86 at 24.)

2. Healthcare Professionals Who Prescribed Parker Montelukast

In September 2017, Parker established care with allergist and immunologist, Dr. Reddy, because Parker's asthma and allergies had increased in severity over the previous

five to six years.[2] (Doc. No. 33 ¶ 184.) According to Dr. Reddy, at Parker's initial treatment date, Parker indicated that one month prior, in August 2017, he had an asthma exacerbation (Doc. No. 11-96, Defs.' Ex. 92 [Reddy Dep.] at 5:8-13, 10:15-22), but that he "was doing well" while taking montelukast, along with his other medications (id. at 7:19-22; Doc. No. 33 ¶ 185). Parker also shared that he had depression and anxiety. (Doc. No. 11-96, Defs.' Ex. 92 [Reddy Dep.] at 14:4-8.) Dr. Reddy continued his prescription for montelukast and testified that she did not want to titrate any medications down when Parker's asthma was unstable. (Id. at 16:23-25–17:1-9.) She also testified that at the time she prescribed montelukast to Parker, she was familiar with the risks and benefits of the medication. (Id. at 51:6-14.)

Parker saw Dr. Reddy again in October 2017, November 2017, December 2017, April 2018, and November 2018. (Doc. No. 33 ¶¶ 193, 198, 200, 202.) During this time, Parker continued taking montelukast. (Id. ¶ 199.) In November 2018, Dr. Reddy noted that Parker had been under tremendous stress because he lost his job because of his back problems, but that his asthma was "much improved on the current regimen," so she continued Parker on montelukast. (Id. ¶¶ 203–04.) Parker saw Dr. Reddy again in May 2019, December 2019, and June 2021. (Id. ¶¶ 205, 208, 211.) During this time, Parker never told Dr. Reddy that he had experienced panic attacks (id. ¶ 196), took opiates and used other illicit drugs (id. ¶ 197), that he had been hospitalized because he believed his parents were poisoning him, that his uncle had kicked him out of the house, that he was living out of a car, or that he had suicidal ideations (id. ¶ 206). It was not until June 2021, after the black box warning appeared on montelukast's label, that Dr. Reddy did not restart

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[2] Between 2016 and 2021, Parker was evaluated by six individuals who prescribed him montelukast. (Doc. No. 33 ¶¶ 159, 171, 177, 180, 186, 227.) But, in opposing Defendants' motion for summary judgment, Plaintiff relies solely on Plaintiff's treatment by Dr. Reddy to support his remaining claims. (Doc No. 24 at 15–16.) As such, the Court will focus on Plaintiff's treatment by Dr. Reddy and one subsequent provider in this Background section.

Parker on montelukast because of his history of depression and the recent emphasis of neuropsychiatric adverse effects associated with montelukast. (Id. ¶ 214.)

In August 2020, Parker was referred to an internist, Dr. Michael, for asthma and chronic neck trauma. (Id. ¶ 219.) Parker also saw Dr. Michael in June 2021 and August 2021, which was his last visit with Dr. Michael. (Id. ¶¶ 222, 227.) Unaware of Dr. Reddy's decision to stop Parker's montelukast prescription, at the August 2021 visit, Dr. Michael prescribed Parker montelukast. (Id. ¶¶ 227, 231.) Had Parker told Dr. Michael that Dr. Reddy stopped Parker's montelukast prescription in June 2021, Dr. Michael would have discontinued the prescription (id. ¶ 231), but Parker never shared that information with Dr. Michael (id.). Dr. Michael testified that at the time he treated Parker in August 2021, he was aware of montelukast's black box warning and with the risks and benefits of montelukast. (Doc. No. 11-98, Defs.' Ex. 94 [Michael Dep.] at 22:6-9, 25:2-5.) Additionally, Dr. Michael testified that since 2014, he has considered the warnings contained in montelukast's label regarding potential neuropsychiatric events whenever he prescribed it. (Id. at 26:13-17.)

3. Plaintiff's Additional Medical History

The record before the Court also reflects that at various points, Parker may have been diagnosed with cannabis-induced psychosis (Doc. No. 11-98, Defs.' Ex. 94 [Michael Dep.] at 18:12-16), complex post-traumatic stress disorder (PTSD) (id. at 16:25–17:1-19), religious trauma syndrome (id.), and schizophrenia (id.; Doc. No. 33 ¶ 225), amongst other neurologic disorders (Doc. No. 25-38, Pl.'s Ex. 27 at 15). The record also reflects that on October 2, 2020, Parker may have attempted suicide. (Doc. No. 33 ¶ 224; Doc. No. 11-98, Defs.' Ex. 94 [Michael Dep.] at 16:20-24.) Dr. Reddy was never informed about Parker's medical history regarding these conditions, Parker's hospitalizations affiliated with neuropsychiatric events, or of any suicidal ideations during her treatment of him. (Doc. No. 33 ¶¶ 195, 218, 221.)

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C. Procedural Background

On May 23, 2024, Richard Parker filed a complaint in this Court. (Doc. No. 1.)[3] The complaint asserts three causes of action: (1) strict liability—failure to warn (Count I); (2) negligence (Count II); and (3) negligent misrepresentation (Count III). (Doc. No. 1 ¶¶ 103–155.)

By the present motion, Defendants move for summary judgment on all of Parker's claims. (Doc. No. 11.) In response to Defendants' motion for summary judgment, Parker dismissed his claim for strict liability—failure to warn. (Doc. No. 24 at 5.) Parker now has two remaining claims for (1) negligence and (2) negligent misrepresentation.

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).

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[3] This case is related to Bueno v. Merck & Co., Inc. et al., United States District Court, Southern District of California, Case No. 3:22-cv-00522-H-BLM ("Bueno"). On March 3, 2022, Richard Parker and Spencer Bueno filed a complaint in the Superior Court of the State of California, County of San Diego, which was subsequently removed to this Court based on diversity jurisdiction. (Bueno, 22-cv-522-Doc. Nos. 1, 7.) On May 20, 2024, the Court granted a joint motion to sever the claims of Plaintiff Richard Parker, and Plaintiff Parker was severed from the Bueno litigation. (Bueno, 22-cv-522-Doc. No. 84.) Parker then filed an individual complaint in this Court. (Doc. No. 1.)

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. Plaintiff's Negligent Failure to Warn Claims

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).[4] "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

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[4] The parties agree that California law applies to Parker's claims. (See Doc. No. 11-1 at 20; Doc. No. 24 at 16–17.)

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 2016, 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. 33 ¶ 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. Reddy's testimony that, at the time she prescribed montelukast to Parker, she was familiar with its risks and benefits (Doc. No. 11-96, Defs.' Ex. 92 [Reddy Dep.] at 51:6-14), Plaintiff argues that the warnings in the montelukast label were inadequate (Doc. No. 24 at 5), and disputes whether Dr.

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Reddy was adequately warned of the risks of Singulair (Doc. No. 33 ¶ 186).[5] 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 "convinc[ing] the FDA to allow Merck to say some post-marketing reports involving Singulair 'appear consistent with a drug-induced effect'." (Doc. No. 24 at 6; see also id. at 11, 18-19, 33.)

(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 6; see also id. at 18, 33.)

(3) **Sending a "Dear doctor" letter following 2020 "black box" warning** - Third, Plaintiff asserts that Merck "could have also sent out a 'Dear Doctor' letter to let prescribers know that the black box warning was added to the label in March/April 2020, as that was the height of the Covid health crisis and many

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[5] 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).

practitioners were consumed with addressing Covid-related concerns." (Id. at 6; see also id. at 14, 19, 33.)

Plaintiff does not offer any evidence in support of his argument that Defendants were negligent by not taking these three recommended actions.[6] (Doc. No. 24 at 18–19.) 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. 11-100, Defs.' Ex. 96.) 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 Parker, 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. 11-1 at 21).[7] While Dr. Qato's report generally indicates that "the manufacturer (Merck) should have anticipated, monitored, and/or warned about . . . neuropsychiatric risks" (Doc. No. 10-4 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

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[6] 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. 11-1 at 20.)

[7] 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. 10-4 at 14–15), have no relevance to this case.

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))).

The same is true of the report written by Plaintiff's other expert, Dr. David Healy. (Doc. No. 25-38, Pl.'s Ex 27.) Dr. Healy does not discuss any specific inadequacies in the Singulair or montelukast label.[8] (See generally id.)

Because no evidence has been proffered to prove how Singulair's label was inadequate for physicians prescribing montelukast to adults like Parker, 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").

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[8] 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.

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. 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.

Six individuals prescribed Plaintiff montelukast: (1) Dr. Thiel, (2) Dr. Parikh, (3) nurse Milton, (4) nurse Ochoa, (5) Dr. Reddy, and (6) Dr. Michael. (Doc. No. 33 ¶¶ 159, 170, 177, 180, 186, 192, 227.) However, Plaintiff does not mention any prescriber besides Dr. Reddy in his opposition to Defendants' motion for summary judgment. (See generally Doc. No. 24.) In light of this failure to address the other prescribers in his briefing, Plaintiff has failed to demonstrate a triable issue of fact regarding causation as to those other five prescribers. 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. Reddy's prescribing decision, thereby causing injury to Parker.

As to causation, Plaintiff has not raised a triable issue of fact. Plaintiff has not demonstrated that Dr. Reddy would have changed her 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. 32 at 8.)

First, there is no testimony from any expert or Dr. Reddy, that a label change stating that adverse event reports "are consistent" with a drug-induced effect would have changed her decision to prescribe montelukast to Parker compared to the label at the time she prescribed the medication, which stated that adverse event reports "appear consistent" with a drug-induced effect. (See generally Doc. No. 25-39, Pl.'s Ex. 28 [Reddy Dep.].) Without any evidence from Dr. Reddy or an expert, Plaintiff does not meet his burden to prove that changing, "appear consistent" to "are consistent" on the 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's proposed contraindication for patients prescribed montelukast for allergic rhinitis, or allergies (but not asthma), could not have applied to Dr. Reddy's prescribing decisions given that the contraindication would only have affected patients prescribed montelukast for allergic rhinitis and nothing else, and it is undisputed that Parker was originally prescribed montelukast for asthma, and then later for asthma and allergies. (Doc. No. 33 ¶¶ 157–59 (undisputed that Dr. Thiel prescribed Singulair after "Parker established care with Dr. Thiel in early January 2016 for asthma"); ¶¶ 176–77 (undisputed that nurse Milton continued his prescription for montelukast after Parker established care with her in part due to "asthma and allergies"); ¶¶ 184–185 (undisputed that "Parker told Dr. Reddy he 'was doing well' with respect to the management of his asthma and allergies on medications including montelukast"); ¶¶ 200–01 (undisputed that in April 2018, Parker saw Dr. Reddy "because his cold exacerbated his asthma. . . [h]owever, Parker had continued to take montelukast and his asthma was much more stable"); ¶¶ 222–23, 227 (undisputed that Parker saw Dr. Michael in June 2021 for his "asthma and thoracic back pain" and "Dr. Michael again prescribed Parker montelukast in August 2021 during their last visit.").) Even if Plaintiff recommended a label change to include a contraindication

for patients prescribed montelukast for allergic rhinitis and asthma and experienced suicidality while taking Singulair, Plaintiff does not raise a triable issue of fact regarding causation because it is undisputed that Parker never told Dr. Reddy or Dr. Michael that he experienced suicidality. (Id. ¶ 218 (undisputed that "other than Parker's depression, Dr. Reddy knew of none of his past adverse psychiatric events"); id. ¶ 224 (undisputed that "Parker did not tell Dr. Michael he attempted suicide").)

Third, there is no evidence that a "Dear doctor" letter to Dr. Reddy following the addition of the black box warning to the Singulair label would have changed her prescribing decisions. Plaintiff asserts that Dr. Reddy "was adamant about taking [Parker] off Singulair as soon as she discovered the black box warning." (Doc. No. 24-1 ¶ 68.) Plaintiff proffers no evidence that a "Dear doctor" letter would have expedited or in any other way altered Dr. Reddy's decision to take Parker off Singulair. (See generally id.; Doc. No. 24.)

Plaintiff's argument that he can prove causation by showing that had the warnings been stronger, "an objectively prudent person in the patient's position would have . . . declined the treatment," regardless of a physician's recommendation (Doc. No. 24 at 20), fares no better. After the FDA added the black box warning to the montelukast label, Dr. Reddy stopped prescribing Plaintiff montelukast. (Doc. No. 24-1 ¶ 68.) However, Plaintiff did not follow Dr. Reddy's prescribing recommendation and did not stop taking montelukast. (Doc. No. 33 ¶¶ 220, 223 (undisputed that Parker's medical records reflected montelukast as "active" before his appointment with Dr. Michael in August 2020 and again in June 2021).) Following Dr. Reddy's decision to stop Parker's montelukast prescription, Dr. Michael, who was unaware of Dr. Reddy's decision, prescribed Parker montelukast again in August 2021 during their last visit. (Id. ¶¶ 227, 231.) It is undisputed that had Parker told Dr. Michael that Dr. Reddy stopped Parker's montelukast prescription in June 2021, Dr. Michael would have discontinued the prescription (id. ¶ 231), but Parker did not share that information with Dr. Michael (id.).

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. 11-1 at 10, 25.) 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 25.) 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. 24 at 23–33.)

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:

> [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. 24 at 27.) 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. 24.)[9] 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. 24 at 29), and (2) "the more mathematically rigorous calculations of existing Merck

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[9] In Plaintiff's Statement of Uncontested 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. 24-1 ¶ 48 ("Merck performed a 400-page analysis of this information, but as Dr. Qato demonstrated, an epidemiologist could perform a simple 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. 33 ¶¶ 238, 239), which would not have been available to Defendants prior to 2008.

clinical trials" (id. at 28).

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. 24 at 29.) These adverse events therefore do not constitute "newly acquired evidence." See 21 C.F.R. § 314.3(b) (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. 24 at 29), does not constitute "newly acquired information" and does not defeat Defendants' preemption defense.

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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 28–29.) 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. 11-61, 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. 11-100, 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. 25-30, Pl.'s Ex. 21 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) ("[E]xpert 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. 24 at 12; see also Doc. No. 25-30, 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. 25-30, 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. 25-30, 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. 33 ¶¶ 1–66). Specifically, in 2008, Merck, in a months-long collaboration with the FDA, drafted a Statistical Analysis Plan ("SAP"),[10] 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. 33 ¶ 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. 11-50, 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

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[10] 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. 33. ¶¶ 43, 44.) Later, on June 19, 2008, the FDA asked Merck to prepare the Statistical Analysis Plan (id. ¶ 53; Doc. No. 11-49, Defs.' Ex. 46), which Merck first submitted on August 14, 2008 (Doc. No. 33 ¶ 58), and later amended with input from the FDA (id. ¶ 60).

exceeding 400 pages. (See Doc. No. 11-55, Defs.' Ex. 52; see also Doc. No. 11-56, 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. 33 ¶ 238; Doc. No. 11-61, 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. 11-100, 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 statistically significant risk of neuropsychiatric adverse events. (Id. at 10; Doc. No. 11-61, 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. 11-99, Defs.' Ex. 95 [Qato Dep.] at 16:16-21), meaning a "calculation with an unadjusted rate of incidence and odds ratio" (Doc. No. 27 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. 10-1 at 21; Doc. No. 11-50, Defs.' Ex. 47 at 10–11; see also Doc. No. 33 ¶ 243 (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. 27 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).

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CONCLUSION

For the reasons stated above, the Court grants Defendants' motion for summary judgment regarding Plaintiff's remaining claims: Plaintiff's claims for negligence and negligent misrepresentation. 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 and motion to strike the Declaration of Dima Qato as moot.

IT IS SO ORDERED.

DATED: August 27, 2024

MARILYN L. HUFF, District Judge
UNITED STATES DISTRICT COURT