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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

RICKY JOLLY, *et al.*, individually and on behalf of others similarly situated,

Plaintiffs,

v.

GLOBAL BLOOD THERAPEUTICS, INC. and PFIZER INC.,

Defendants.

Case No. 3:24-CV-09345-VC

DEFENDANTS GLOBAL BLOOD THERAPEUTICS, INC. AND PFIZER INC.'S NOTICE OF MOTION AND MOTION TO DISMISS THE COMPLAINT; MEMORANDUM OF POINTS AND AUTHORITIES

Date: May 1, 2025
Time: 10:00 a.m.
Place: Courtroom 4, 17th Floor
Judge: Hon. Vince Chhabria

NOTICE OF MOTION AND MOTION TO DISMISS

TO THE COURT, ALL PARTIES, AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that on May 1, 2025, at 10:00 a.m., or as soon thereafter as this matter may be heard, before the Honorable Vince Chhabria, Courtroom 4 on the 17th Floor of United States Courthouse located at 450 Golden Gate Avenue, San Francisco, California 94102, Defendants Global Blood Therapeutics, Inc. and Pfizer Inc. ("Defendants") will and hereby do move the Court for an order dismissing with prejudice Plaintiffs' Complaint pursuant to Federal Rules of Civil Procedure 12(b)(1), 12(b)(6), and 9(b).

The grounds for this Motion are:

(1) Plaintiffs' state-law claims (Counts 1, 2, 4–11) are preempted by federal law;

(2) Plaintiffs fail to plead their fraud-based claims (Counts 4, 6–11) with particularity as required by Rule 9(b), and therefore fail to state claims upon which relief can be granted under Rule 12(b)(6);

(3) Plaintiffs lack Article III standing to assert claims on behalf of a nationwide class (Counts 1, 2, 4, 5);

(4) Plaintiffs lack Article III standing to pursue claims for equitable relief (Counts 5, 6, 11);

(5) The Complaint fails to state a claim upon which relief may be granted for a violation of the Magnuson-Moss Warranty Act (Count 3);

(6) The Complaint fails to state claims upon which relief may be granted for violations of state consumer protection statutes (Counts 7–10) that contain safe-harbor provisions exempting federally-regulated conduct from their reach; and

(7) Plaintiffs fail to plausibly allege that they are entitled to punitive damages.

Defendants respectfully request an order dismissing with prejudice all causes of action brought against them in the above-captioned matter. This Motion is based upon this Notice of Motion and Motion to Dismiss; the attached Memorandum of Points and Authorities; the accompanying Request for Judicial Notice and Declaration of Teresa M. Wogoman; any reply

memorandum; the pleadings and files in this action; and such other matters Defendants may present at or before the hearing.

DATED: February 26, 2025

Respectfully submitted,

By: */s/ Jessica Bodger Rydstrom*

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TABLE OF CONTENTS

I. INTRODUCTION 1

II. BACKGROUND 2

III. ISSUES TO BE DECIDED 4

IV. LEGAL STANDARD 5

V. ARGUMENT 5

A. Plaintiffs' State-Law Claims Are Preempted (Counts 1, 2, 4–11). 5

B. Plaintiffs' Fraud-Based Claims Should be Dismissed (Counts 4, 6–11). 7

1. Plaintiffs Fail to Plausibly Allege Any Affirmative Misrepresentation. 8

2. Plaintiffs Fail to Allege "Active Concealment" With Particularity. 9

3. Plaintiffs Fail to Allege an Actionable Omission. 9

C. Plaintiffs Lack Article III Standing For a Nationwide Class or Equitable Relief. 10

1. Plaintiffs Lack Standing to Assert Nationwide Class Claims (Counts 1, 2, 4, 5). 10

2. Plaintiffs Lack Standing to Pursue Equitable Relief (Counts 5, 6, 11). 11

D. Plaintiffs' Magnuson-Moss Warranty Act Claim Fails (Count 3). 13

E. Plaintiffs' Claims Under State Consumer Protection Statutes Are Barred by Those Statutes' Safe Harbor Provisions (Counts 7–10). 14

F. Plaintiffs Fail to Plausibly Plead Entitlement to Punitive Damages. 15

VI. CONCLUSION 15

TABLE OF AUTHORITIES

CASES

Abbasfar v. Chertoff,
2007 WL 2409538 (N.D. Cal. Aug. 21, 2007) 5

Ablaza v. Sanofi-Aventis U.S. LLC,
2023 WL 2942983 (N.D. Cal. Apr. 13, 2023) 11

Ahern v. Apple Inc.,
411 F. Supp. 3d 541 (N.D. Cal. 2019) 9

Andren v. Alere, Inc.,
207 F. Supp. 3d 1133 (S.D. Cal. 2016).....10

Ashcroft v. Iqbal,
556 U.S. 662 (2009).....5

Azar v. Gateway Genomics, LLC,
2017 WL 1479184 (S.D. Cal. Apr. 25, 2017) 8, 10

Ball v. Takeda Pharms. Am., Inc.,
963 F. Supp. 2d 497 (E.D. Va. 2013) 15

Bell Atl. Corp. v. Twombly,
550 U.S. 544 (2007).....5

Biederman v. FCA US LLC,
2025 WL 458831 (N.D. Cal. Feb. 11, 2025) 10

Cafasso, ex rel. United States v. Gen. Dynamics C4 Sys., Inc.,
637 F.3d 1047 (9th Cir. 2011) 5, 8

Cho v. Hyundai Motor Co., Ltd.,
636 F. Supp. 3d 1149 (C.D. Cal. 2022) 12

Cipollone v. Liggett Grp., Inc.,
505 U.S. 504 (1992).....5

City of Los Angeles v. Lyons,
461 U.S. 95 (1982).....12

Clemens v. DaimlerChrysler Corp.,
534 F.3d 1017, 1022 (9th Cir. 2008) 13

Corcoran v. CVS Health Corp.,
169 F. Supp. 3d 970 (N.D. Cal. 2016) 14

Floyd v. Am. Honda Motor Co., Inc.,
966 F.3d 1027 (9th Cir. 2020) 13

Funke v. Sorin Group, USA, Inc.,
147 F. Supp. 3d 1017 (C.D. Cal. 2015) 15

Gatling-Lee v. Del Monte Foods, Inc.,
2023 WL 11113888 (N.D. Cal. Mar. 28, 2023).....12

Gayle v. Pfizer Inc.,
452 F. Supp. 3d 78 (S.D.N.Y. 2020).....6

Gustavson v. Wrigley Sales Co.,
961 F. Supp. 2d 1100 (N.D. Cal. 2013) 3

Gutierrez v. Kaiser Permanente,
2018 WL 2412319 (E.D. Cal. May 29, 2018) 15

Herron v. Best Buy Co.,
924 F. Supp. 2d 1161 (E.D. Cal. 2013).....9

Hovsepian v. Apple, Inc.,
2009 WL 5069144 (N.D. Cal. Dec. 17, 2009).....10

In re Chantix (Varenicline) Mktg., Sales Pracs. & Prods. Liab. Litig. (No. II),
735 F. Supp. 3d 352 (S.D.N.Y. 2024).....7

In re Nexus 6P Prods. Liab. Litig.,
293 F. Supp. 3d 888 (N.D. Cal. 2018) 10, 11

In re NJOY, Inc. Consumer Class Action Litig.,
2014 WL 12586074 (C.D. Cal. Oct. 20, 2014).....9

In re Volkswagen "Clean Diesel" Mktg., Sales Pracs., & Prods. Liab. Litig.,
349 F. Supp. 3d 881 (N.D. Cal. 2018) 9

Jones v. Micron Tech. Inc.,
400 F. Supp. 3d 897 (N.D. Cal. 2019) 11

Kanter v. Warner-Lambert Co.,
99 Cal. App. 4th 780 (2002) 13

Kearns v. Ford Motor Co.,
567 F.3d 1120 (9th Cir. 2009) 7, 8

Lujan v. Defenders of Wildlife,
504 U.S. 555 (1992).....10

Mahnke v. Bayer Corp.,
2019 WL 8621437 (C.D. Cal. Dec. 19, 2019) 6

Mandani v. Volkswagen,
2019 WL 652867 (N.D. Cal. Feb. 15, 2019) 10

Melendres v. Arpaio,
784 F.3d 1254 (9th Cir. 2015) 11

Merck Sharp & Dohme Corp. v. Albrecht,
587 U.S. 299 (2019).....6

Min Sook Shin v. Umeken USA, Inc.,
773 F. App'x 373 (9th Cir. 2019) 12

Mollicone v. Universal Handicraft, Inc.,
2017 WL 440257 (C.D. Cal. Jan. 30, 2017) 13

Moore v. Kayport Package Express, Inc.,
885 F.2d 531 (9th Cir. 1989) 5

Morrison v. Ross Stores, Inc.,
2018 WL 5982006 (N.D. Cal. Nov. 14, 2018) 14

Nadler v. Nature's Way Prods., LLC,
2014 WL 12601567 (C.D. Cal. Mar. 27, 2014).....14

Pardini v. Unilever United States Inc.,
961 F. Supp. 2d 1048 (N.D. Cal. 2013).....11

Patterson v. RW Direct, Inc.,
2018 WL 6106379 (N.D. Cal. Nov. 21, 2018) 13

Pirozzi v. Apple Inc.,
913 F. Supp. 2d 840 (N.D. Cal. 2012).....5

PLIVA, Inc. v. Mensing,
564 U.S. 604 (2011).....6

Prohias v. Pfizer, Inc.,
490 F. Supp. 2d 1228 (S.D. Fla. 2007) 15

Purcell v. Spokeo, Inc.,
2014 WL 4187157 (C.D. Cal. Aug. 25, 2014).....12

Seufert v. Merck Sharp & Dohme Corp.,
187 F. Supp. 3d 1163 (S.D. Cal. 2016).....6

Sidhu v. Bayer Healthcare Pharms. Inc.,
2022 WL 17170159 (N.D. Cal. Nov. 22, 2022) 7, 11

Sonner v. Premier Nutrition Corp.,
971 F.3d 834 (9th Cir. 2020) 12

Sprewell v. Golden State Warriors,
266 F.3d 979 (9th Cir. 2001) 5

Stearns v. Select Comfort Retail Corp.,
763 F. Supp. 2d 1128 (N.D. Cal. 2010) 14

Tabler v. Panera LLC,
2019 WL 5579529 (N.D. Cal. Oct. 29, 2019).....8

Utts v. Bristol-Myers Squibb Co.,
226 F. Supp. 3d 166 (S.D.N.Y. 2016).....6

Vess v. Ciba-Geigy Corp. USA,
317 F.3d 1097 (9th Cir. 2003) 7

Victorino v. FCA US LLC,
2018 WL 1083395 (S.D. Cal. Feb. 27, 2018) 9

Willingham v. Glob. Payments, Inc.,
2013 WL 440702 (N.D. Ga. Feb. 5, 2013) 12

STATUTES, RULES & REGULATIONS

21 C.F.R. § 201.56 15

21 C.F.R. § 202.1 15

21 C.F.R. § 314.50 15

21 C.F.R. § 314.70 .....6, 15

21 C.F.R. § 314.125 8

21 C.F.R. § 314.500 3

21 C.F.R. § 314.510 3

21 C.F.R. § 314.550 ..... 3, 15

15 U.S.C. § 2301 13

15 U.S.C. § 2310 ..... 13, 14

21 U.S.C. § 321 13

Federal Rule of Civil Procedure 9(b) 5

Federal Rule of Civil Procedure 12(b)(1) 5

Federal Rule of Civil Procedure 12(b)(6) 5

Ga. Code. Ann. § 10-1-396 14

Ga. Code Ann. § 10-1-399(a) 14

815 Ill. Comp. Stat. 505/10b 14

Ind. Code § 24-5-0.5-6 14

Va. Code Ann. § 59.1–199(A) 14

CONSTITUTIONAL PROVISIONS

U.S. Const. art. VI, cl. 2 5

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

Plaintiffs Ricky Jolly, Amanda Winbush, Darryl Weekly, and Antonio Johnson are former purchasers of Oxbryta (voxelotor), a prescription medication approved by the FDA for the treatment of sickle cell disease ("SCD"). In their putative class action Complaint, Plaintiffs contend that Oxbryta was "worth nothing" when they paid for it because recent clinical data suggested an "imbalance" in vaso-occlusive crises and fatal events in certain patients taking the medication. Notably, Plaintiffs do ***not*** allege that they suffered any adverse physical effects from Oxbryta—nor that they even took it at all. Instead, Plaintiffs seek monetary damages to reimburse them for some unspecified amount of "out-of-pocket costs" incurred in "acquiring Oxbryta"—alleging wide-ranging claims of fraud and breach of warranties against Defendants Global Blood Therapeutics, Inc. ("GBT") and Pfizer Inc. Plaintiffs' claims fail for multiple reasons, and so the Complaint should be dismissed.

Plaintiffs' state-law claims—all of which are premised on a failure-to-warn theory—are preempted by federal law. Under Supreme Court precedent, state-law failure-to-warn claims are preempted unless the defendant can unilaterally change the drug's label under an FDA regulation called "Changes Being Effected" ("CBE"). The Complaint does not even acknowledge that regulation—nor does it offer facts demonstrating that it would have applied here, which is necessary to avoid preemption. On this basis alone, all of Plaintiffs' state-law claims premised on a failure-to-warn theory should be dismissed.

In addition to being preempted, Plaintiffs' state-law claims fail for multiple other reasons. Plaintiffs assert claims for common law fraud (Count 4) and violations of state consumer protection statutes (Counts 6–11). All of those claims "sound in fraud," and so must be stated with particularity under Rule 9(b). Plainitffs' conclusory statements about Defendants' efforts to "actively conceal" information about Oxbryta or "intentionally mislead" consumers fall far short of this standard, and so those claims must be dismissed. As to their claim for unjust enrichment

(Count 5), Plaintiffs fail to establish that their request for money damages (highlighted in the first paragraph of the Complaint) would be an inadequate remedy, precluding them from pursuing equitable relief for this claim. Similarly, Plaintiffs offer no basis to support their claims for injunctive relief (Counts 6, 11) because they do not (and cannot) plead that they are likely to suffer an "imminent" injury from future purchases of Oxbryta. Plaintiffs further lack standing to pursue state-law claims on behalf of a nationwide class, barring their class allegations in connection with their claims for breach of express and implied warranties (Counts 1, 2), unjust enrichment (Count 5), and common law fraud (Count 4).

Plaintiffs' sole federal claim, for a violation of the Magnuson-Moss Warranty Act ("MMWA") (Count 3), also fails. To begin, Oxbryta is not a "consumer product" within the meaning of the MMWA, which precludes any individual or class-wide claims based on this statute. Separately, Plaintiffs plainly do not meet the 100-named-plaintiff requirement to bring a class action under the MMWA, nor do they allege adequate pre-suit notice. For all these reasons, the Complaint should be dismissed.

II. BACKGROUND

This case is about Oxbryta (voxelotor), a prescription medicine developed by GBT for the treatment of sickle cell disease. SCD is a rare inherited blood disorder affecting approximately 100,000 people in the United States. It is caused by a gene mutation that affects hemoglobin, the protein in red blood cells that is responsible for delivering oxygen throughout the body. Compl. ¶¶ 32, 33. In patients with SCD, abnormal hemoglobin causes red blood cells to become rigid, sticky, and "sickle"-shaped; these sickled red blood cells clump together and restrict the flow of oxygen, causing pain events called vaso-occlusive crises ("VOCs"), acute chest syndrome, swelling, anemia, and strokes—among other complications. *Id.*

In November 2019, the FDA granted Oxbryta accelerated approval for use by adults and pediatric patients aged 12 years and older, and, in December 2021, expanded the medication's approved use to patients as young as 4 years old. *Id.* ¶ 36. The FDA's accelerated approval program expedites review of medications designed to address unmet medical needs in the

treatment of serious or life-threatening conditions. *See* 21 C.F.R. § 314.500. Eligible medications can obtain accelerated approval "on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint" that is reasonably likely "to predict clinical benefit." *Id.* § 314.510. The FDA's approval of Oxbryta was based on (among other data) the results of the HOPE clinical trial, a randomized, double-blind, placebo-controlled, multi-center clinical trial that demonstrated an improvement in hemoglobin response (the FDA-sanctioned endpoint "reasonably likely to predict clinical benefit"). *See* Wogoman Decl. Ex. 1 at 4, 12 (FDA, Summary Review for Regulatory Action).[1] Oxbryta's FDA-approved label included information about the HOPE trial, and disclosed that the drug's indication was "approved under accelerated approval based on increase in hemoglobin."[2] *See* Wogoman Decl. Ex. 2 at 1 (Oxbryta Label). As it does for all medicines in the accelerated approval program, the FDA required GBT to conduct post-marketing studies demonstrating Oxbryta's clinical benefits and assessing its long-term safety. *See* Wogoman Decl. Ex. 3 at 2–5 (FDA Approval Letter).

After Pfizer acquired GBT in October 2022, it continued to study the benefits and safety of Oxbryta. In September 2024, Pfizer announced the voluntary withdrawal of Oxbryta following an initial review of available data from post-marketing and patient registry-based studies, which appeared to show an imbalance in VOCs in certain patients and a small number of fatal events which required further assessment. *See* Compl. ¶¶ 39, 40.

Shortly thereafter, Plaintiffs filed this putative class action. The four named Plaintiffs, who are residents of Indiana, Virginia, Illinois, and Georgia, each allege that they "paid out of pocket for Oxbryta" when "purchas[ing] [it] for personal, family, or household purposes." *Id.* ¶¶ 10, 12,

[1] The Court may take judicial notice of documents posted to the FDA's public website without converting a motion to dismiss into one for summary judgment. *See Gustavson v. Wrigley Sales Co.*, 961 F. Supp. 2d 1100, 1113 n.1 (N.D. Cal. 2013).

[2] Sponsors of medications that are granted accelerated approval must submit to the FDA "copies of all promotional materials, including promotional labeling as well as advertisements" within 120 days after approval. 21 C.F.R. § 314.550. Even after that initial 120-day time period, the sponsor is required to submit any "promotional material" or labeling at least 30 days prior to the dissemination of the labeling or initial publication of the advertisement. *Id.*

14, 16. No Plaintiff specifies whether he or she "personal[ly]" used Oxbryta. And notably, ***none*** of the Plaintiffs allege that he or she suffered ***any*** adverse effect from the medication. *See id.* ¶ 60 (excluding "claims for personal injury or wrongful death"). Instead, Plaintiffs contend that Oxbryta was "worth nothing," and they "would not have bought [Oxbryta] or would have paid less for it," had they known about "the true risks" of the medication. *Id.* ¶¶ 54, 87, 131. Plaintiffs assert claims of breach of express and implied warranties (Counts 1, 2), violation of the Magnuson-Moss Federal Warranty Act ("MMWA") (Count 3), common law fraud (Count 4), unjust enrichment (Count 5), and violations of Indiana, Virginia, Illinois, and Georgia consumer protection statutes (Counts 6–11).[3] In addition to their individual claims, Plaintiffs seek to represent a nationwide class and four state subclasses of purchasers who paid at least some portion of Oxbryta "out-of-pocket" from November 1, 2019 to the present. *Id.* ¶ 59.

III. ISSUES TO BE DECIDED

1. Are Plaintiffs' state-law claims based on a failure-to-warn theory preempted by federal law?
2. Do Plaintiffs fail to plead their fraud-based claims with particularity as required by Rule 9(b)?
3. Do Plaintiffs lack Article III standing to assert claims on behalf of a nationwide class?
4. Do Plaintiffs lack Article III standing to seek equitable relief?
5. Do Plaintiffs fail to state a claim for violation of the MMWA?
6. Are Plaintiffs' claims under under the Georgia, Indiana, Virginia, and Illinois consumer

[3] Plaintiff Johnson brings claims alleging violations of the Georgia Uniform Deceptive Trade Practices Act ("GUDTPA"), Ga. Code. Ann. § 10-1-370 *et seq.* (Count 6) and the Georgia Fair Business Practices Act ("GFBPA"), Ga. Code. Ann. § 10-1-390 *et seq.* (Count 7). Plaintiff Jolly brings a claim alleging violations of the Indiana Deceptive Consumer Sales Act ("IDCSA"), Ind. Code § 24-5-0.5-1 *et seq.* (Count 8). Plaintiff Winbush brings a claim alleging violations of the Virginia Consumer Protection Act ("VCPA"), Va. Code Ann. § 59.1-196 *et seq.* (Count 9). Plaintiff Weekly brings claims alleging violations of the Illinois Consumer Fraud and Deceptive Business Practices Act ("ICFDBPA"), 815 Ill. Comp. Stat. 505/1 *et seq.* (Count 10), and the Illinois Uniform Deceptive Trade Practices Act ("IUDTPA"), 815 Ill. Comp. Stat. 510/1 *et seq.* (Count 11).

protection statutes barred by those statutes' safe harbor provisions?

7. Do Plaintiffs fail to plausibly plead that they are entitled to punitive damages?

IV. LEGAL STANDARD

Federal Rule of Civil Procedure 12(b)(1). A complaint must be dismissed if the court lacks subject matter jurisdiction. Fed. R. Civ. P. 12(b)(1). "[T]he plaintiff bears the burden of establishing subject matter jurisdiction." *Abbasfar v. Chertoff*, 2007 WL 2409538, at *2 (N.D. Cal. Aug. 21, 2007). "A court must presume lack of jurisdiction until the plaintiff establishes otherwise." *Id.* If a plaintiff lacks standing, then the Court lacks subject matter jurisdiction. *Pirozzi v. Apple Inc.*, 913 F. Supp. 2d 840, 846 (N.D. Cal. 2012).

Federal Rule of Civil Procedure 12(b)(6). To avoid dismissal under Rule 12(b)(6), a complaint must "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The Court need not "accept as true allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir. 2001).

Federal Rule of Civil Procedure 9(b). Claims sounding in fraud must be stated with "particularity." Fed. R. Civ. P. 9(b). To satisfy this requirement, plaintiffs must "identify 'the who, what, when, where, and how of the misconduct charged,' as well as 'what is false or misleading about [the purportedly fraudulent conduct], and why it is false." *Cafasso, ex rel. United States v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1055 (9th Cir. 2011) (citation omitted). "[M]ere conclusory allegations of fraud are insufficient." *Moore v. Kayport Package Express, Inc.*, 885 F.2d 531, 540 (9th Cir. 1989).

V. ARGUMENT

A. Plaintiffs' State-Law Claims Are Preempted (Counts 1, 2, 4–11).

The Supremacy Clause provides that "the Laws of the United States . . . shall be the supreme Law of the Land." U.S. Const. art. VI, cl. 2. State laws "that conflict[] with federal law" are thus "without effect." *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (citation

omitted). There are two types of preemption: express and implied. Implied preemption occurs when "state and federal law conflict" such that it is "impossible for a private party to comply with both state and federal requirements." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011) (citation omitted). As to pharmaceutical products, implied conflict preemption bars state-law claims "when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency." *Id.* at 623–24. That doctrine applies here, requiring dismissal of Plaintiffs' claims—***all*** of which are premised on a theory that Defendants failed to warn "Oxbryta users" of "the risk of increased VOCs, infections, stroke, and/or death." *See, e.g.*, Compl. ¶¶ 7, 74(b), 81.

"[F]ederal law expressly forbids a manufacturer from changing its label after the label has received FDA approval unless such changes are made pursuant to the CBE regulation." *Utts v. Bristol-Myers Squibb Co.*, 226 F. Supp. 3d 166, 184–85 (S.D.N.Y. 2016). Accordingly, to avoid dismissal on preemption grounds, Plaintiffs "must allege facts showing that [defendants] could have unilaterally changed [the drug's] label under the CBE regulation." *Mahnke v. Bayer Corp.*, 2019 WL 8621437, at *3 (C.D. Cal. Dec. 19, 2019) (citation omitted). The CBE regulation permits a manufacturer to unilaterally change an approved drug's label only if there is (1) "newly acquired information," 21 C.F.R. § 314.70(c)(6)(iii), that shows (2) "more than an indeterminate or inconclusive relationship" between the drug and a clinically significant risk, *Seufert v. Merck Sharp & Dohme Corp.*, 187 F. Supp. 3d 1163, 1175 (S.D. Cal. 2016); *see also Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 305 (2019).

Here, Plaintiffs cannot escape preemption because the Complaint fails to allege ***any*** facts establishing that Defendants could have altered Oxbryta's label without the FDA's approval. Plaintiffs instead rely on conclusory assertions that Defendants "knew or should have known for decades" that Oxbryta can "cause or substantially contribute to VOCs, infections, stroke, and even death." Compl. ¶ 5; *see also id.* ¶¶ 54, 79, 112, 137, 163, 176, 191 (alleging that Defendants "knew" about risks of Oxbryta). These rote allegations, bereft of factual support, fail to establish any "newly acquired information" sufficient to invoke the CBE regulation. *See, e.g.*, *Gayle v.*

Pfizer Inc., 452 F. Supp. 3d 78, 87–88 (S.D.N.Y. 2020) ("[C]onclusory allegations that Pfizer knew that Lipitor causes type 2 diabetes" fall short of "alleging 'newly acquired information' on which Pfizer could have updated the label through the CBE regulations.").

Importantly, the Complaint does not specify whether—and, if so, when—any "newly acquired" analysis of clinical data was available to Defendants with sufficient time to initiate a label change before the product was withdrawn from the market in September 2024. *See In re Chantix (Varenicline) Mktg., Sales Pracs. & Prods. Liab. Litig. (No. II)*, 735 F. Supp. 3d 352, 388 (S.D.N.Y. 2024) (dismissing failure-to-warn claim where "Plaintiffs fail[ed] to plausibly allege that Defendant was in possession of that newly acquired information at any point prior to its decision to recall [the drug]" and observing that the defendant "opt[ed] to address the issue with a recall, rather than an application pursuant to the CBE process"); *Sidhu v. Bayer Healthcare Pharms. Inc.*, 2022 WL 17170159, at *6 (N.D. Cal. Nov. 22, 2022) (dismissing as preempted common law and statutory claims based on a failure-to-warn theory in putative consumer class action where plaintiff "ha[d] not alleged what [newly acquired] information was provided . . . and when"). Because the Complaint fails to state a plausible claim that Defendants could have unilaterally changed Oxbryta's label without FDA approval, all of Plaintiffs' state-law claims are preempted and should be dismissed.

B. Plaintiffs' Fraud-Based Claims Should be Dismissed (Counts 4, 6–11).

Even if Plaintiffs' state-law claims could survive preemption, their fraud-based claims must be dismissed under Rules 9(b) and 12(b)(6). The Complaint asserts a "common law fraud" claim (Count 4) as well as claims under four states' consumer fraud statutes (Counts 6–11). Underlying ***all*** of these claims are allegations that Defendants engaged in "fraudulent" or "deceptive" conduct by making intentional and material "misrepresentations" about the safety of Oxbryta and "omitt[ing]" or "actively conceal[ing]" information about alleged risks.[4] Because all of these claims are "grounded in fraud," they must be pled with particularity under Rule 9(b). *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1103–04 (9th Cir. 2003); *see also Kearns v. Ford Motor*

[4] *See* Compl. ¶¶ 7, 142–149, 163–169, 176–180, 183, 191–194, 200, 207–211, 221–226, 235–238.

Co., 567 F.3d 1120, 1125 (9th Cir. 2009) (a claim can be "grounded in fraud" or "sound in fraud" even if fraud is not a necessary element of the claim). The Complaint's allegations fail entirely to meet Rule 9(b)'s pleading standard, and so Plaintiffs' fraud-based claims should be dismissed.

1. Plaintiffs Fail to Plausibly Allege Any Affirmative Misrepresentation.

Plaintiffs first allege that Defendants "affirmatively misrepresented" material facts about the "safety" or "benefits" of Oxbryta. Compl. ¶¶ 6, 54(c), 54(e), 54(f), 179. But the ***only*** specific information each Plaintiff claims that he or she relied on in deciding to purchase Oxbryta was the "product packaging," which included the (FDA-required) statement that the medication was "indicated for the treatment of sickle cell disease."[5] Compl. ¶¶ 10, 12, 14, 16, 75. This allegation cannot support a plausible claim for a "misrepresentation"; any information included on the labeling of an FDA-approved drug is directed by strict regulations and reflects FDA's determination that the information is not "false or misleading." 21 C.F.R. § 314.125(b)(6).

Although the Complaint provides additional examples of Defendants' advertisements and promotional materials, Compl. ¶¶ 37–38, 77, there are ***no*** allegations explaining ***why*** these materials are "false." *Cafasso*, 637 F.3d at 1055. Nor do Plaintiffs identify which, if any, of these statements they ***actually saw or relied on*** in deciding to purchase Oxbryta. *See Kearns*, 567 F.3d at 1126 (affirming dismissal where plaintiff "failed to specify which sales material he relied upon in making his decision to buy" the product); *Tabler v. Panera LLC*, 2019 WL 5579529, at *12 (N.D. Cal. Oct. 29, 2019) ("[C]ourts in this circuit have held that a plaintiff does not satisfy Rule 9(b) when the plaintiff generally identifies allegedly misleading statements but fails to specify which statements the plaintiff actually saw and relied upon.").

Finally, Plaintiffs fail to allege the "particular circumstances" surrounding any alleged misrepresentation. *Kearns*, 567 F.3d at 1126; *Azar v. Gateway Genomics, LLC*, 2017 WL 1479184, at *7 (S.D. Cal. Apr. 25, 2017) (requiring plaintiffs to allege the "who, what, when,

[5] Plaintiffs also claim to have relied on the "Pfizer brand name," but that is not an actionable "statement" to support a fraud claim. And, as a practical matter, Pfizer did not acquire GBT until October 2022, and so the notion that Plaintiffs have been relying on the Pfizer "brand" since 2019 is literally impossible.

where, and how" of the fraud). For example, Plaintiffs fail to allege "when" they saw allegedly fraudulent ads or labels, "where" they saw them, and "under what circumstances." *Id.*; *see also In re Volkswagen "Clean Diesel" Mktg., Sales Pracs., & Prods. Liab. Litig.*, 349 F. Supp. 3d 881, 914 (N.D. Cal. 2018) (holding that the plaintiff failed to satisfy Rule 9(b) where the complaint failed to identify "where she saw this advertising," as well as "what type of advertising it was"); *In re NJOY, Inc. Consumer Class Action Litig.*, 2014 WL 12586074, at *10–11 (C.D. Cal. Oct. 20, 2014) (same). The failure to include these facts warrants dismissal of Plaintiffs' "misrepresentation" claims under Rule 9(b).

2. Plaintiffs Fail to Allege "Active Concealment" With Particularity.

Plaintiffs also allege that Defendants "actively concealed" facts about Oxbryta's safety. *See, e.g.*, Compl. ¶¶ 54, 56, 168, 181, 196, 211, 226, 239. To state a claim for "active concealment," Plaintiffs must point to "specific affirmative acts" Defendants took "in hiding, concealing or covering up the matters complained of." *Herron v. Best Buy Co.*, 924 F. Supp. 2d 1161, 1176 (E.D. Cal. 2013) (citation and quotation marks omitted). Plaintiffs' repeated "generalized allegations" that Defendants "actively concealed" information about Oxbryta's purported safety risks fall far short of this standard. *Id.* There are ***zero*** factual allegations of any "affirmative acts" taken by Defendants to "conceal" information about Oxbryta. Accordingly, Plaintiffs should not be permitted to proceed with their "active concealment" theory of fraud.

3. Plaintiffs Fail to Allege an Actionable Omission.

Plaintiffs' fraud-by-omission theory also fails. To state an omission-based claim, Plaintiffs must allege facts indicating that Defendants "knew" of the "risk of increased VOCs" ***at the time Plaintiffs filled their prescriptions***. *Ahern v. Apple Inc.*, 411 F. Supp. 3d 541, 564–66 (N.D. Cal. 2019) (citation omitted) ("[A] defendant 'must have known of the defect at the time of sale for a plaintiff to state a claim for fraud by omission.'"); *Victorino v. FCA US LLC*, 2018 WL 1083395, at *8 (S.D. Cal. Feb. 27, 2018) ("When addressing a defendant's pre-sale knowledge, courts have held that the defendant must have knowledge of the specific defect alleged[.]"). Although the Complaint repeatedly asserts that Defendants "knew or should have known" about "the risk of

increased VOCs," these threadbare legal conclusions merely recite the elements of Plaintiffs' fraud claim or the language of the relevant consumer protection statutes.[6] The Complaint contains ***no*** facts demonstrating that Defendants were "aware" of a "risk of increased VOCs" when Plaintiffs purchased Oxbryta at some unspecified time "within the last four years." Compl. ¶¶ 10–16. Absent "sufficient factual matter" to "make th[e] inference plausible" that Defendants "knew" about an alleged "defect" when Plaintiffs filled their prescriptions, Plaintiffs' omission-based claims fail. *In re Nexus 6P Prods. Liab. Litig.*, 293 F. Supp. 3d 888, 908 (N.D. Cal. 2018); *see also Azar*, 2017 WL 1479184, at *5 (dismissing fraud claims due to threadbare conclusions of knowledge); *Mandani v. Volkswagen*, 2019 WL 652867, at *7–8 (N.D. Cal. Feb. 15, 2019) (same).

Plaintiffs cannot salvage their fraud-by-omission claims by alleging that Defendants were "in a superior position to know" of Oxbryta's potential risks. Compl. ¶¶ 53, 141. These "generalized allegations" of "exclusive" or superior knowledge are insufficient to defeat a dismissal motion. *Hovsepian v. Apple, Inc.*, 2009 WL 5069144, at *3 (N.D. Cal. Dec. 17, 2009); *Andren v. Alere, Inc.*, 207 F. Supp. 3d 1133, 1142 (S.D. Cal. 2016).

C. Plaintiffs Lack Article III Standing For a Nationwide Class or Equitable Relief.

At an "irreducible constitutional minimum," Article III of the Constitution requires Plaintiffs to plead that they have personally suffered some actual or threatened injury due to Defendants' conduct and that the injury is "fairly traceable to the challenged action" and is "likely . . . [to be] redressed by a favorable decision." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992) (cleaned up). Plaintiffs do not have standing to: (a) assert claims under laws of states where Plaintiffs themselves did not purchase Oxbryta; or (b) seek injunctive relief.

1. Plaintiffs Lack Standing to Assert Nationwide Class Claims (Counts 1, 2, 4, 5).

Plaintiffs, who are residents of only four states, lack standing to pursue state-law claims on behalf of a nationwide class of consumers. *Biederman v. FCA US LLC*, 2025 WL 458831, at *4

[6] *See, e.g.*, Compl. ¶¶ 5, 7, 137, 138, 163, 176, 191, 207, 221, 235.

(N.D. Cal. Feb. 11, 2025). "[D]istrict courts in this Circuit routinely hold plaintiffs do not have standing to pursue class claims under the common laws of states to which the named plaintiffs have no connection[.]" *Id.* (cleaned up). Where, as here, a "representative plaintiff is lacking for a particular state, all claims based on that state's laws are subject to dismissal." *Pardini v. Unilever United States Inc.*, 961 F. Supp. 2d 1048, 1061 (N.D. Cal. 2013).[7] Plaintiffs can seek only to represent putative class members consisting of their own states' residents.

Moreover, Plaintiffs' claims for breach of express and implied warranties (Counts 1, 2), unjust enrichment (Count 5), and common law fraud (Count 4)—all pleaded on behalf of a "nationwide class"—should be dismissed because Plaintiffs have failed to allege ***which state's*** law governs them. "[C]ourts in this district have held that, due to variances among state laws, failure to allege which state law governs a common law claim is grounds for dismissal."[8] *Sidhu*, 2022 WL 17170159, at *3 (citation omitted); *see also In re Nexus*, 293 F. Supp. 3d at 933 (citation omitted) ("As this Court and other courts in this district have recognized, 'due to variances among state laws, failure to allege which state law governs a common law claim is grounds for dismissal.'"). Because Plaintiffs assert their common law claims on behalf of a nationwide class without alleging which state law governs, those claims should be dismissed.

2. Plaintiffs Lack Standing to Pursue Equitable Relief (Counts 5, 6, 11).

Despite declaring (in the first paragraph) that this is "an action for damages," the Complaint also seeks equitable relief, including "declaratory and injunctive relief," and equitable restitution,

[7] In *Melendres v. Arpaio*, the Ninth Circuit framed this issue as one of "class certification" as opposed to "standing." 784 F.3d 1254, 1262 (9th Cir. 2015). But courts in this jurisdiction have subsequently dismissed claims brought on behalf of a nationwide class prior to class certification where, as here, "plaintiffs brought claims under the laws of multiple states where they did not reside and where they were not injured." *Jones v. Micron Tech. Inc.*, 400 F. Supp. 3d 897, 909, 911 (N.D. Cal. 2019) ("*Melendres* does not, in the Court's view, stand for the proposition that this Court must delay its consideration of standing in sister state cases until class certification.").

[8] Although some courts in this jurisdiction have considered the failure to identify which state law governs as a "pleading problem," *see Ablaza v. Sanofi-Aventis U.S. LLC*, 2023 WL 2942983, at *4 (N.D. Cal. Apr. 13, 2023), others have addressed it as part of the standing analysis, *Sidhu*, 2022 WL 17170159, at *2–3 (dismissing common law claims asserted "on behalf of a nationwide class"). Under either analysis, the Complaint here is inadequate.

Compl. ¶¶ 1, 9, 66(h), 66(i), 69, 156. These requests fail at the outset because the Complaint contains ***no*** allegation that Plaintiffs lack an adequate remedy at law. *Sonner v. Premier Nutrition Corp.*, 971 F.3d 834, 844 (9th Cir. 2020) (affirming dismissal of claims for equitable relief where "the operative complaint does not allege that [plaintiff] lacks an adequate legal remedy"). On that basis alone, all claims seeking equitable relief should be dismissed. *See Cho v. Hyundai Motor Co., Ltd.*, 636 F. Supp. 3d 1149, 1173 (C.D. Cal. 2022). Because "unjust enrichment" is an equitable claim rather than a legal claim, it applies "only in the absence of an adequate remedy at law." *Id.* at 1172 (citation omitted). Plaintiffs seek in damages the "difference" between the price they paid for Oxbryta and its "actual value." Compl. ¶¶ 135, 149, 214, 229. Nothing in the Complaint indicates that this remedy would be "inadequate to make them whole." *Cho*, 636 F. Supp. 3d at 1173. Thus, Plaintiffs have failed to demonstrate that they are entitled to the equitable remedy of restitution associated with their unjust enrichment claim.

Plaintiffs' requests for injunctive relief fare no better. There are no factual allegations in the Complaint demonstrating that Plaintiffs face a "real and immediate threat" of harm from future purchases of Oxbryta—nor could there be at present, given that the medicine was voluntarily withdrawn from the market. *City of Los Angeles v. Lyons*, 461 U.S. 95, 105 (1982); *see Gatling-Lee v. Del Monte Foods, Inc.*, 2023 WL 11113888, at *5 (N.D. Cal. Mar. 28, 2023) (concluding that "Plaintiffs lack standing to seek injunctive relief" because they could not plausibly allege they would purchase the product in the future). Moreover, Plaintiffs' own allegation that Oxbryta was "worth nothing" when they purchased it, Compl. ¶ 131, undermines any plausible claim of future harm because a plaintiff "certainly will not purchase a worthless product in the future." *Min Sook Shin v. Umeken USA, Inc.*, 773 F. App'x 373, 375 (9th Cir. 2019).

Injunctive relief is the only remedy available for Plaintiffs' claims under the Georgia Uniform Deceptive Trade Practices Act ("GUDTPA") and Illinois Uniform Deceptive Trade Practices Act ("IUDTPA"). *See Willingham v. Glob. Payments, Inc.*, 2013 WL 440702, at *16 (N.D. Ga. Feb. 5, 2013) ("Injunctive relief is the sole remedy under the [G]UDTPA."); *Purcell v. Spokeo, Inc.*, 2014 WL 4187157, at *4 (C.D. Cal. Aug. 25, 2014) ("The IUDTPA's only remedy

is injunctive relief."). Given that Plaintiffs lack standing to pursue injunctive relief—the sole form of relief available under the GUDTPA and IUDTPA—Counts 6 and 11 should be dismissed.

D. Plaintiffs' Magnuson-Moss Warranty Act Claim Fails (Count 3).

Plaintiffs' MMWA claim fails for three independent reasons.[9] ***First***, the Complaint fails to state a claim under the MMWA—on an individual or class-wide basis—because Oxbryta is not a "consumer product" within the meaning of that statute. 15 U.S.C. § 2301. As the Complaint acknowledges, Oxbryta is a "prescription medication," Compl. ¶ 1, and so is regulated by the FDCA, 21 U.S.C. § 321(g)(1). A drug regulated by the FDCA is "not a consumer product within the meaning of Magnuson-Moss." *Kanter v. Warner-Lambert Co.*, 99 Cal. App. 4th 780, 798 (2002). As a result, "[w]here the FDCA governs the product at issue, a plaintiff may not state a claim under the MMWA." *Mollicone v. Universal Handicraft, Inc.*, 2017 WL 440257, at *12 (C.D. Cal. Jan. 30, 2017).

Second, under the MMWA, "[n]o claim shall be cognizable . . . if the action is brought as a class action, and the number of named plaintiffs is less than one hundred." 15 U.S.C. § 2310(d)(3)(C). Plaintiffs assert their MMWA claim on behalf of a putative class, but the Complaint names only four plaintiffs—96 short of the MMWA's requirement. On that basis, Plaintiffs' MMWA claim should be dismissed.[10] *See Patterson v. RW Direct, Inc.*, 2018 WL 6106379, at *2 (N.D. Cal. Nov. 21, 2018).

Third, Plaintiffs do not allege that they provided adequate pre-suit notice to proceed with their MMWA claim as a class action. The MMWA requires a named plaintiff to notify the defendant they are acting on behalf of the class and afford the defendants a "reasonable

[9] If the Court dismisses Plaintiffs' breach of express and implied warranty claims (Counts 1, 2), then the MMWA claim also fails. *Clemens v. DaimlerChrysler Corp.*, 534 F.3d 1017, 1022 (9th Cir. 2008) (MMWA claims "stand or fall with . . . express and implied warranty claims.").

[10] Plaintiffs cannot rely on the Class Action Fairness Act ("CAFA") to evade the MMWA's 100-plaintiff requirement. *See Floyd v. Am. Honda Motor Co., Inc.*, 966 F.3d 1027, 1034–35 (9th Cir. 2020) (holding that "a requirement for an MMWA class action in federal court is at least one hundred named plaintiffs" and "CAFA may not be used to evade or override the MMWA's specific numerosity requirement").

opportunity" to cure any failure to comply with the statute. *See* 15 U.S.C. § 2310(e); *Stearns v. Select Comfort Retail Corp.*, 763 F. Supp. 2d 1128, 1143 (N.D. Cal. 2010). The Complaint does not satisfy either requirement. Instead, Plaintiffs allege that they "need not have given" pre-suit notice for the MMWA claim because they "may give such notice . . . after class certification pursuant to 15 U.S.C. § 2310(e)." Compl. ¶ 134. Not so. *See Morrison v. Ross Stores, Inc.*, 2018 WL 5982006, at *5 (N.D. Cal. Nov. 14, 2018) ("[T]he argument that a class action plaintiff need not provide pre-suit notice is wholly without support."). Plaintiffs' failure to allege that they satisfied the requirements of § 2310(e) warrants dismissal of their MMWA claim with prejudice. *Nadler v. Nature's Way Prods., LLC*, 2014 WL 12601567, at *3–4 (C.D. Cal. Mar. 27, 2014).

E. Plaintiffs' Claims Under State Consumer Protection Statutes Are Barred by Those Statutes' Safe Harbor Provisions (Counts 7–10).

Plaintiffs' claims under the Georgia, Indiana, Virginia, and Illinois consumer protection statutes identified in Counts 7–10 should be dismissed because each statute contains a safe harbor provision explicitly excluding federally-regulated conduct from its reach. *See* Ga. Code. Ann. § 10-1-396 (GFBPA does not apply to "actions or transactions specifically authorized under laws administered by or rules and regulations promulgated" by a federal agency);[11] Ind. Code § 24-5-0.5-6 (IDCSA "does not apply to an act or practice that is . . . expressly permitted by federal law, rule, or regulation."); Va. Code Ann. § 59.1–199(A) (VCPA does not apply to "[a]ny aspect of a consumer transaction" that is "authorized under laws or regulations" of the United States); 815 Ill. Comp. Stat. 505/10b (ICFDBPA does not apply to "[a]ctions or transactions specifically authorized by laws administered" by a federal agency).

Plaintiffs allege that Defendants violated these state statutes by "misrepresenting" information about Oxbryta's "characteristics" and "benefits." Compl. ¶¶ 179, 194, 209, 223. These claims go to the heart of activities regulated by the FDA. Any statements about Oxbryta

[11] Separately, Plaintiff Johnson cannot pursue a claim under the GFBPA on behalf of "the Georgia Subclass" because an action under that statute cannot be brought "in a representative capacity." Ga. Code Ann. § 10-1-399(a); *see also Corcoran v. CVS Health Corp.*, 169 F. Supp. 3d 970, 993 (N.D. Cal. 2016) (dismissing GFBPA claim because "[t]he GFBPA indisputably forecloses claims brought 'in a representative capacity'").

included in the product's advertisements and labeling are subject to strict FDA regulations. *See, e.g.*, 21 C.F.R. §§ 201.56, 202.1(e)(4)(i)(a), 314.50(e), 314.70(b)(2)(v), 314.550. Plaintiffs have not offered any facts demonstrating that Defendants could have unilaterally altered those statements without the FDA's prior approval. *See supra* Section A. Accordingly, Plaintiffs' claims under these state consumer protection statutes are not actionable because they fall squarely within the relevant safe harbor provisions. *See, e.g.*, *Ball v. Takeda Pharms. Am., Inc.*, 963 F. Supp. 2d 497, 500 (E.D. Va. 2013) (concluding that statute consumer protection statutes do not apply to "transactions in federally-regulated prescription drugs"); *Prohias v. Pfizer, Inc.*, 490 F. Supp. 2d 1228, 1234 (S.D. Fla. 2007) (dismissing claims regarding advertisements "implicitly authorized" by the FDA based on substantially similar safe harbor provisions).

F. Plaintiffs Fail to Plausibly Plead Entitlement to Punitive Damages.

Although Plaintiffs request "punitive damages," they fail to plead that they are entitled to such relief. A plaintiff seeking punitive damages "must identify actual facts, as opposed to conclusory allegations showing that the defendant acted [with oppression, fraud or malice]." *Gutierrez v. Kaiser Permanente*, 2018 WL 2412319, at *5 (E.D. Cal. May 29, 2018) (dismissing complaint with boilerplate punitive allegations). In addition, to plausibly plead punitive damages against a corporation, Plaintiffs must allege facts to show that an officer, director, or managing agent acted with fraud, oppression or malice. *See Funke v. Sorin Group, USA, Inc.*, 147 F. Supp. 3d 1017, 1028 n.2 (C.D. Cal. 2015). The Complaint fails both requirements. For the reasons explained *supra* Section B, Plaintiffs have failed to plead facts establishing that Defendants acted with "fraud." They also make no attempt to plead "oppression, fraud or malice" on the part of any officer, director, or managing agent of these corporate defendants. Plaintiffs cannot pursue punitive damages based on these deficient allegations.

VI. CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court dismiss the Complaint in its entirety, with prejudice.

Dated: February 26, 2025

Respectfully submitted,

By: */s/ Jessica Bodger Rydstrom*

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CERTIFICATE OF SERVICE

I certify that on February 26, 2025, I electronically filed the foregoing Motion to Dismiss with the Clerk of Court using the ECF system, which sent notification of such filing to all counsel of record.

/s/ *Jessica Bodger Rydstrom*
Jessica Bodger Rydstrom