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17 **SUPERIOR COURT OF THE STATE OF CALIFORNIA**

18 **COUNTY OF LOS ANGELES**

19 DESTINY CLARK, ON BEHALF OF HER
20 MINOR CHILD, EZRA CLARK

21 Plaintiff,

22 v.

23 MONSANTO COMPANY, ET AL.,

24 Defendants.

Civil Case No. 20STCV46616

*Assigned for All Purposes to the Hon. Daniel
J. Buckley, Dept 1.*

**PLAINTIFF'S OPPOSITION TO
DEFENDANT MONSANTO
COMPANY'S MOTION FOR
SUMMARY JUDGMENT OR, IN
THE ALTERNATIVE, SUMMARY
ADJUDICATION**

Department: 1
Judge: Hon. Daniel J. Buckley
Hearing Date: TBD
Time: TBD

Complaint Filed: December 4, 2020
Trial Date: September 13, 2021

1 **TABLE OF CONTENTS**

2 INTRODUCTION 1

3 I. Ezra Clark’s Roundup Exposure and Medical History 1

4 II. Monsanto Has Known of an Association Between Glyphosate-Based Herbicides and Cancer

5 for Decades 1

6 III. Monsanto Refuses to Test Its Formulated Products 3

7 IV. Monsanto Floods The Scientific Literature With Ghostwritten Articles to Falsely Bolster

8 The Safety Profile of GBHs 4

9 V. Monsanto Deliberately Keeps Safety Information From the Public 5

10 VI. EPA’s Review of Glyphosate 6

11 VII. Monsanto’s Undue Influence on EPA and Efforts to Undermine IARC’s Classification of

12 Glyphosate 6

13 VIII. California’s Review of Glyphosate 7

14 LEGAL STANDARD 7

15 ARGUMENT 8

16 I. Plaintiff’s Claims Are Not Barred Or Displaced By California’s Statutory and Regulatory

17 Regime Governing Pesticides 8

18 A. DPR Does Not Have Exclusive Authority Over Pesticide Regulation 8

19 B. DPR Relies Exclusively On EPA And EPA’s Conclusions Are Based On Oral

20 Ingestion Of Technical Glyphosate Which Is Irrelevant In This Case 9

21 C. The Legislature Makes Clear That FAC Is Not Intended To Preempt Or Displace

22 Common Law Causes Of Action 10

23 II. Plaintiff Has A Viable Fraud Claim 12

24 III. Plaintiff’s Claims Are Not Preempted by Federal Law 14

25 A. The First Appellate District in *Pilliod v. Monsanto Co.* Has Rejected Monsanto’s

26 Express and Implied Preemption Arguments 14

27 B. Plaintiff’s Claims Are Not Preempted By The Express Preemption Doctrine 14

28 C. Plaintiff’s Claims Are Not Preempted By The Implied Preemption Doctrine 16

1 CONCLUSION.....20

2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

TABLE OF AUTHORITIES

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

Cases	Page(s)
<i>American T. Co. v. California etc. Ins. Co. (1940)</i> , 15 Cal.2d 42.....	11
<i>Ansagay v. Dow Agrosciences LLC</i> , (D. Haw. 2015)153 F.Supp.3d 1270.....	15, 16
<i>Bates v. Dow Agrosciences LLC</i> , (2005) 544 U.S. 431	13, 14, 15, 16
<i>Bigler-Engler v. Breg, Inc.</i> , (2017) 7 Cal.App.5th 276.....	12
<i>Blitz v. Monsanto Co.</i> , (W.D. Wis. 2018) 317 F.Supp.3d 1042.....	14, 16
<i>Contra Zengen, Inc. v. Comerica Bank</i> , (2007) 41 Cal.4th 239	11
<i>Dudum v. San Mateo</i> , (1959) 167 Cal. App. 2d 593	7
<i>Farm Raised Salmon Cases</i> , (2008) 42 Cal.4th 1077, 175 P. 3d 1170.....	16
<i>Fellner v. Tri-Union Seafoods</i> , 539 F.3d 237 (3d Cir. 2008)	18
<i>Ferebee v. Chevron Chemical Co.</i> , (D.C. Cir. 1984) 736 F.2d 1529.....	13, 14
<i>Fernandez v. California Department of Pesticide Regulation</i> , (Cal. Ct. App. 2008) 164 Cal.App.4th 1214.....	7, 8
<i>Geernaert v. Mitchell</i> , (1995) 31 Cal.App.4th 601	12
<i>Gross v. Pfizer</i> , (D. Md. 2011) 825 F. Supp. 2d 654.....	16
<i>Hardeman v. Monsanto Co.</i> , (N.D. Cal. 2016) 216 F. Supp. 3d 1037.....	9, 15
<i>Hasso v. Hapke</i> , (2014) 227 Cal.App.4th 107	11
<i>Jacobs Farm/Del Cabo, Inc. v. Western Farm Service, Inc.</i> , (2010) 190 Cal.App.4th 1502.....	10, 11
<i>I.E. Associates v. Safeco Title Ins. Co.</i> , (1985) 39 Cal.3d 281	10
<i>In re Roundup Prod. Liab. Litig.</i> , 364 F. Supp. 3d at 1087	14, 15, 16
<i>Johnson</i> , 2018 WL 2324413	15
<i>K.C. Multimedia, Inc. v. Bank of America Technology & Operations, Inc.</i> , (2009) 171 Cal.App.4th 939	10
<i>Lazar v. Superior Court</i> , (1996) 12 Cal.4th 631	11, 12

1	<i>Merck Sharp & Dohme Corp. v. Albrecht</i> ,	
	(2019)139 S. Ct. 1668.....	16, 17
2	<i>Pilliod v. Monsanto Co.</i> ,	
	(1st App. Dist. Aug. 9, 2021) A158228.....	13, 15
3	<i>PLIVA, Inc. v. Mensing</i> ,	
4	(2011) 564 U.S. 604	15
	<i>Reid v. Johnson & Johnson</i> ,	
5	(9th Cir. 2015) 780 F.3d 952	17, 18
	<i>Reckitt Benckiser, Inc. v. Jackson</i> ,	
6	(D.D.C. 2011) 762 F.Supp.2d 34.....	18
7	<i>Shapiro v. Sutherland</i> ,	
	(1998) 64 Cal.App.4th 1534	12
8	<i>Simone v. McKee (1956)</i> ,	
9	142 Cal.App. 2d 307	11
	<i>Viva! Internat. Voice for Animals v. Adidas Promotional Retail Operations, Inc.</i> ,	
10	(2007) 41 Cal.4th 929	15, 16
11	<i>Whiteley v. Philip Morris Inc.</i> ,	
	(2004) 117 Cal.App.4th 635	12
12	<i>Wisconsin Public Intervenor v. Mortier</i> ,	
	(1991) 501 U.S. 597	14
13	<i>Wyeth v. Levine</i> ,	
14	555 U.S. 555 (2009)	15, 16, 17
15	Other Authorities	
16	5 Witkin, Summary of Cal. Law (9th ed. 1988) Torts, § 707	12
17	Restatement (Second) of Torts § 533.....	11
18	Sen.Rep. No. 838 92d Cong., 2d Sess. 30 (1972) reprinted in 1972 U.S.Code Cong. & Admin.News 4021	14
19	Statutes	
20	Cal. Code Civ. Proc. 437c (2011).....	7
21	CA Food & Agri Code § 1 (2020), et al. (FAC).....	8, 9, 10, 11
22	Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S. Code § 301 et seq.	15, 16
23	Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C.S. §136 et seq.	13, 14, 15, 16, 18
24	Regulations	
25	40 C.F.R. § 152.50(e)	
26		
27		
28		

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INTRODUCTION

Defendant Monsanto Company’s (“Defendant” or “Monsanto”) motion is premised on three fundamental arguments: (1) Plaintiff’s claims are barred and displaced by California’s statutory and regulatory regime governing pesticides; (2) Plaintiff’s claims are preempted by federal law; and (3) that Plaintiff did not have the type of relationship necessary to support a fraud claim premised on a duty to disclose information. For the reasons set forth below, Defendant’s motion should be denied.

STATEMENT OF FACTS

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I. Ezra Clark’s Roundup Exposure and Medical History

From November 2011 to August 2012 and from August 2013 to February 2016, Ezra Clark (“Ezra”) was directly exposed to Roundup when accompanying his mother, Plaintiff Destiny Clark (“Plaintiff”), as she sprayed Roundup to control weeds at the family’s residence. In addition, Ezra was exposed to Roundup when he played in areas that had been freshly sprayed by family members. PSUF ¶ 1. On February 29, 2016 at the age of 4, Plaintiff was diagnosed with Burkitt’s lymphoma, a rare and aggressive form of non-Hodgkin’s lymphoma (“NHL”). PSUF ¶ 2. After performing a differential diagnosis following a review of Ezra’s medical history, Plaintiff’s experts have concluded, to a reasonable degree of medical certainty, that Ezra’s exposure to Roundup was a substantial factor in causing his NHL. PSUF ¶ 3. Had Plaintiff known of the risk of NHL associated with the use of Roundup at the time she read the Roundup label prior to starting to use Roundup, she would not have used it. PSUF ¶ 4.

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II. Monsanto Has Known of an Association Between Glyphosate-Based Herbicides and Cancer for Decades

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EPA’s Office of Pesticide Programs processed the initial petition and registration application for glyphosate in the 1970’s. It is undisputed that the majority of the initial studies relied upon by Monsanto for the registration of glyphosate were based on fraudulent data. PSUF ¶¶ 5-6. EPA had serious concerns and uncertainty about the potential hazards of glyphosate, however, the Agency was restricted from withdrawing the registration approvals for the pesticides that utilized IBT fraudulent data for its initial approval. PSUF ¶ 6. Unable to remove these products from the market, EPA required Monsanto to redo toxicological and carcinogenicity studies on glyphosate. In 1983, following its review of a mouse oncogenicity study, EPA concluded that glyphosate “was oncogenic in male mice causing renal tubule adenomas . . . in a dose-related manner.” PSUF ¶ 7. Understanding

1 the negative effect of the oncogenicity finding, Monsanto set out “to do all that is possible in order
2 to have the Agency reverse its decision.” PSUF ¶ 8. Monsanto refused EPA’s request to repeat the
3 study and pushed back on the significance of the oncogenicity finding. PSUF ¶ 9. Nonetheless, EPA
4 concluded that glyphosate was a Category C oncogene: a possible human carcinogen. PSUF ¶ 10.
5 Monsanto was acutely aware that the classification of glyphosate as a Class C oncogene would have
6 “serious negative economic repercussions.” PSUF ¶ 7. Monsanto found a pathologist to review the
7 slides “in an effort to persuade the agency that the tumors are not related to glyphosate.” PSUF ¶
8 11. The actual slides were received by the pathologist *after* he had agreed to assist Monsanto in their
9 efforts to change EPA’s decision. PSUF ¶ 12.

10 Following the review, Monsanto argued to EPA that there was a kidney tumor in the control
11 group which would destroy any significance of the tumor finding in the mouse study. *Id.*
12 Monsanto’s influence prevailed and the Scientific Advisory Panel (SAP) changed the classification
13 to a Group E carcinogen. *Id.* However, the SAP did find the occurrence of three neoplasms in male
14 mice to be “unusual” and recommended that Monsanto repeat both the rat and mouse studies. PSUF
15 ¶ 13. EPA provided Monsanto with recommendations regarding the proper design of the study to
16 return proper results. *Id.* Again, Monsanto refused to repeat the mouse oncogenicity study.
17 Monsanto not only refused to conduct studies required by EPA to determine whether glyphosate
18 and glyphosate-based herbicides (“GBHs”) were oncogenic and/or carcinogenic; they also refused
19 to conduct studies recommended by their own consultants. In the 1990’s, several published studies
20 concluded that glyphosate was genotoxic. PSUF ¶ 14. Monsanto’s chief toxicologist, Dr. Donna
21 Farmer, conceded that these studies “may present an even bigger problem because the studies are
22 with glyphosate and are on more standard endpoints.” *Id.* Publicly, however, Monsanto took a
23 different tone. In a draft press release, Dr. Farmer wrote:

24 Several genotoxicity studies have been conducted on glyphosate ... None of these
25 studies have shown any adverse findings. Based on all these results, we are confident
26 that glyphosate herbicide products are not genotoxic and therefore [d]o not present a
27 mutagenic or carcinogenic risk to humans and animals. PSUF ¶ 15.

28 Concerned about the genotoxicity studies, Monsanto retained Dr. James Parry, a world-
renowned expert in genotoxicity, to review the data and offer his conclusions. PSUF ¶ 16. Following
his review, Dr. Parry provided a report to Monsanto which stated that “glyphosate is a potential
clastogenic *in vitro*” and that “glyphosate mixtures may be capable of inducing oxidative damage

1 in vivo.” *Id.* In other words, “glyphosate is capable of producing genotoxicity both in vivo and in
2 vitro. . .” *Id.* Dr. Parry recommended that Monsanto conduct research on the genotoxicity of GBHs;
3 the mechanisms giving rise to genotoxicity; and the relevance of these mechanisms to the safety of
4 GBHs. *Id.* Monsanto decided that it “simply [was not] going to do the studies Parry suggests.” PSUF
5 ¶ 17. Monsanto’s goal was not to actually determine whether GBHs caused cancer but rather to find
6 an expert that could influence regulators when genotoxicity issues arose. *Id.* Monsanto failed to
7 produce the Parry Report to EPA as required under 40 CFR ¶ 159.158. PSUF ¶ 18. Because Dr.
8 Parry never came around to Monsanto’s view of the science, Monsanto would not let him speak to
9 regulators and his report was never submitted to EPA. PSUF ¶ 19.

10 **III. Monsanto Refuses to Test Its Formulated Products**

11 Any review by EPA is limited to the active ingredient, glyphosate, and does not consider the
12 carcinogenic effect of formulated products. However, consumers, such as Plaintiff, are never
13 exposed to glyphosate alone; they are always exposed to glyphosate and a mix of other ingredients,
14 including surfactants. PSUF ¶ 20. Published studies have consistently demonstrated that the risks
15 posed by formulated GBHs are considerably greater than with pure glyphosate alone. For this
16 reason, Monsanto was not surprised when their own expert consultants concluded that “[Monsanto
17 is] in pretty good shape with glyphosate but vulnerable with surfactants.” PSUF ¶ 21.

18 Over the last decade, European regulators forced Monsanto to phase out the use of
19 polyoxyethelated tallowamine (POEA) surfactants in GBHs, but POEA surfactants are still used in
20 several Roundup products in the United States. PSUF ¶ 22. In a PowerPoint created by Monsanto,
21 its scientists recognized that the company must address the toxicity of surfactants. PSUF ¶ 23.
22 Monsanto even noted that there were safer POEA-free surfactants available, causing one employee
23 to inquire: “[T]here are non-hazardous formulations so why sell a hazardous one?” PSUF ¶ 24. The
24 lack of evidence regarding glyphosate’s surfactants was no accident. Since the registration of
25 glyphosate, Monsanto has worked diligently to avoid having to conduct any genotoxicity testing on
26 the formulated product *i.e.*, Roundup. In response to European regulators’ request for genotoxicity
27 studies on the formulation, Monsanto affirmed that it would “not support doing any studies on
28 glyphosate, formulations, or other surfactants ingredients” and would only do so if “ultimately
forced to do it.” PSUF ¶ 25. Despite internal concerns regarding the effect of surfactants and other
inert ingredients and the safety of the formulations, Monsanto opted to focus on the carcinogenic
potential of glyphosate *alone*. PSUF ¶ 26. Indeed, on September 21, 2009, Monsanto’s Donna

1 Farmer confirmed that Monsanto “cannot say that Roundup does not cause cancer ... we have
2 not done carcinogenicity studies with ‘Roundup.’” PSUF ¶ 27.

3 **IV. Monsanto Floods The Scientific Literature With Ghostwritten Articles To Falsely**
4 **Bolster The Safety Profile of GBHs**

5 As more and more studies began to establish an association between GBHs and NHL,
6 Monsanto developed a strategy to level the playing field via ghostwritten literature supporting the
7 safety of GBHs. Rather than submit the Parry Report to EPA and conduct the recommended studies,
8 Monsanto ghostwrote articles concluding that the “Roundup herbicide does not pose a health risk to
9 humans.” PSUF ¶ 28. Although no Monsanto employee is listed as an author, William Heydens, a
10 Monsanto employee, admits that he wrote the manuscript and provided final edits to the paper. PSUF
11 ¶ 29. EPA has consistently relied on this paper when considering the safety of GBHs. PSUF ¶ 30.
12 In 2013, Monsanto ghostwrote another article titled, “Review of genotoxicity studies of glyphosate
13 and glyphosate-based formulations.” PSUF ¶ 31. Monsanto found specialists in the field of
14 genotoxicity to sign off on their paper to “help enhance [the] credibility” of their work. PSUF ¶ 32.
15 Monsanto identified Dr. David Kirkland as the best candidate. *Id.* Again, EPA has consistently relied
16 on this ghostwritten article in evaluating the safety of GBHs. PSUF ¶ 31-32. Monsanto had also
17 ghostwritten articles for purposes of supporting their position in litigation involving NHL and to
18 support its position during EPA’s re-registration decision for glyphosate. PSUF ¶ 33.

19 Immediately after IARC deemed glyphosate a carcinogen in 2015, Monsanto devised a
20 response plan that included convening an expert panel to “[p]ublish [a] comprehensive evaluation
21 of carcinogenic potential by credible scientists” that could later be used for “future litigation
22 support.” *Id.* It worked with Intertek, an industry consultancy firm, to create a false impression that
23 the expert panel was independent. On September 28, 2016, the “independent” expert panel of 12
24 scientists published its preordained conclusions in the *Critical Reviews in Toxicology* journal in a
25 paper entitled, “A Review of the Carcinogenic Potential of Glyphosate by Four Independent Expert
26 Panels and Comparison to the IARC Assessment.”¹ PSUF ¶ 34. Prior to the publication of the article,
27 the editor of *Critical Reviews in Toxicology* sent an email to Intertek which was forwarded to
28 Monsanto stating the Declaration of Interest needs “further attention” and that if there was any
review of the reports by Monsanto that would need to be disclosed. PSUF ¶ 35. William Heydens

¹ The ghostwritten Kier and Kirkland study was also published in *Clinical Reviews of Toxicology*.

1 from Monsanto specifically approved the Declaration of Interest which stated: “[t]he Expert
2 Panelists ... were not directly contacted by the Monsanto Company” and that “[n]either any
3 Monsanto Company employees nor any attorneys reviewed any of the Expert Panel’s manuscripts
4 prior to submission to the journal.” PSUF ¶ 36. These statements are blatant lies. Monsanto
5 recruited, contacted, and obtained legal approval of the selection of the experts despite the claim
6 that the experts were “not directly contacted” by Monsanto. *Id.* Additionally, and most egregiously,
7 not only did Monsanto review the manuscripts before they were submitted, but they also actually
8 wrote parts of the manuscripts before the experts concluded their meeting and commented upon and
9 revised the parts that they did not write. PSUF ¶ 37. Although the independent experts did make
10 edits and contributions to the summary manuscript, it was Monsanto that had ultimate authority over
the content. PSUF ¶ 38.

11 **V. Monsanto Deliberately Keeps Safety Information From the Public**

12 On May 12, 2000, Monsanto became aware of an Abstract from McDuffie, et al., showing
13 an increased risk of NHL from glyphosate in a Canadian epidemiology study. PSUF ¶ 39. Monsanto
14 sent its chief epidemiologist, Dr. John Acquavella, to a conference in August 2000, to speak to Dr.
15 McDuffie regarding the safety of GBHs. *Id.* At the conference, Dr. Acquavella met with Dr.
16 McDuffie and provided her with a copy of the ghostwritten Williams (2000) article. *Id.* When the
17 McDuffie paper was published, glyphosate was no longer mentioned in the abstract. *Id.* The
18 following year, Donna Farmer congratulated John Acquavella and another executive at Monsanto
19 for being able to remove the glyphosate results from the abstract. *Id.* The fact that glyphosate is not
20 mentioned in the Abstract of this scientific study is significant. Any physician, consumer, or
21 regulator undertaking an “abstract search” for epidemiology regarding an association between
22 glyphosate and cancer is unlikely to locate the McDuffie article based on basic search criteria. *Id.*
23 In 2002, Monsanto recognized that there were at least six published studies associating GBHs with
24 NHL, that the mounting epidemiology affected the company’s “freedom to operate,” and that the
25 stage was set “for more allegations about human effects associated with glyphosate and other
pesticides.” PSUF ¶ 40.

26 Despite the mounting scientific evidence, Monsanto never warned consumers of the
27 potential safety risk and continued its efforts to combat these studies. In 2008, the Eriksson study
28 was published, showing a statistically significant doubling of the risk of NHL for glyphosate users.
PSUF ¶ 41. Although Monsanto was aware of the Eriksson paper for some time, Monsanto still did

1 not warn consumers about the results. PSUF ¶ 42. Rather, Monsanto was concerned that “activists”
2 were using the Eriksson study to recommend that people “[a]void carcinogenic herbicides . . . on
3 lawns by using non-toxic land care strategies that rely on soil health, not toxic herbicides.” *Id.* Donna
4 Farmer wanted to know “how do we combat this?” *Id.*

5 **VI. EPA’s Review of Glyphosate**

6 EPA has only reviewed and considered the carcinogenicity of the active ingredient
7 glyphosate and has *never reviewed the formulated product, Roundup*. PSUF ¶ 43. EPA relies on
8 the *manufacturer* to submit data and has never conducted its own testing on glyphosate or any
9 Monsanto glyphosate formulations. *Id.* Since 1991, EPA has designated glyphosate as a Group E
10 carcinogen but has cautioned that the designation “should not be interpreted as a definitive
11 conclusion that the agent will not be a carcinogen under any circumstances.” PSUF ¶ 44. Recently,
12 three of the scientists from the SAP Panel published a manuscript finding that: “Overall, in
13 accordance with evidence from experimental animal and mechanistic studies our current meta-
14 analysis of human epidemiological studies suggests a compelling link between exposures to GBHs
and increased risk for NHL.” *Id.*

15 **VII. Monsanto’s Undue Influence on EPA and Efforts to Undermine IARC’s 16 Classification of Glyphosate**

17 Even before the IARC Monograph was published, Monsanto developed a strategy to
18 “Orchestrate [an] Outcry with [the] IARC Decision” through “robust media/social media outreach.”
19 PSUF ¶ 45. Shortly after the publication of the IARC Monograph, Monsanto’s stated goals included:
20 (1) invalidating the relevance of IARC, (2) preparing for their litigation defense, and (3) protecting
21 global sales. PSUF ¶ 46. Monsanto then developed unusually close relationships with key officials
22 and scientists at EPA’s Office of Pesticide Programs. PSUF ¶ 47. In 2015, Monsanto had several
23 discussions with Jess Rowland, then Deputy Director of the Office of Pesticide Programs (“OPP”)
24 Health Effects Division, regarding a review of glyphosate by the Agency for Toxic Substances and
25 Disease Registry (“ATSDR”), the U.S. agency responsible for assessing toxicity of chemicals. *Id.*
26 Monsanto was concerned that ATSDR would reach a conclusion on glyphosate similar to IARC. *Id.*

27 During a discussion with Monsanto, Rowland asked for a contact name at ATSDR and
28 remarked “If I can kill this [the ATSDR review] I should get a medal.” PSUF ¶ 48. Monsanto
recognized Rowland’s efforts in combating the IARC classification. *Id.* Furthermore, Jack

1 Housenger, Director of the OPP worked with Monsanto to put ATSDR’s glyphosate review on hold
2 and to remove a prominent epidemiologist from the SAP Panel. PSUF ¶ 49. Monsanto also made
3 true on its campaign to attack IARC and its classification of glyphosate. In February of 2018, the
4 House of Representatives Minority Staff Report notes Monsanto’s efforts to: (1) launch a
5 “disinformation campaign” to undermine IARC’s classification of glyphosate, (2) ghostwrite
6 articles on glyphosate, (3) collude with regulators to conduct a biased review of glyphosate, and (4)
7 hire journalists to discredit IARC. PSUF ¶ 50. The Minority Report concludes that Monsanto’s
8 efforts were “aimed at corrupting and disrupting any honest, thorough, and complete scientific
9 evaluation of glyphosate and its potential adverse impact on the public’s health.” *Id.*

10 **VIII. California’s Review of Glyphosate**

11 Within the California Environmental Protection Agency (“CalEPA”), there are two
12 departments that play a role in the regulation of the use of pesticides in California, the Office of
13 Environmental Health Hazard Assessment (“OEHHA”) and the Department of Pesticide Regulation
14 (“DPR”). *Fernandez v. California Department of Pesticide Regulation* (Cal. Ct. App. 2008) 164
15 Cal.App.4th 1214, 1218. OEHHA is the risk assessment arm of CalEPA and evaluates all currently
16 available scientific information on substances and helps establish the scientific basis for the risk
17 management decisions of EPA’s regulatory departments, such as the DPR. *Id.* With regard to
18 pesticide safety, OEHHA and DPR have shared responsibility for developing regulations. *Id.* That
19 being said, in the context of glyphosate, OEHHA and DPR diverge. OEHHA identifies glyphosate
20 as a known carcinogen, following IARC. PSUF ¶ 51. In contrast, DPR identifies glyphosate as non-
21 cariogenic, following EPA (DPR relies exclusively on EPA, stating it is “not conducting a human
22 health risk assessment on glyphosate at this time,” and “will rely on the [EPA’s] assessment of the
23 potential health risks from glyphosate exposure to determine if additional mitigation measures are
24 necessary.”). PSUF ¶ 52.

25 **LEGAL STANDARD**

26 Summary judgment should be granted only when all the papers submitted demonstrate that
27 there is “no triable issue as to any material fact and that the moving party is entitled to a judgment
28 as a matter of law.” Cal. Code Civ. Proc. 437c (2011). Summary judgment is a drastic remedy and
should not be used as a substitute for existing methods for the determination of issues of fact. *Dudum*
v. San Mateo, (1959) 167 Cal. App. 2d 593.

1
2 **ARGUMENT**

3 **I. Plaintiff’s Claims Are Not Barred Or Displaced By California’s Statutory and**
4 **Regulatory Regime Governing Pesticides**

5 Monsanto’s argument posits that DPR through California’s Food and Agricultural Code
6 (“FAC”) has exclusive authority to assess the risks and benefits of pesticides. Monsanto alleges that,
7 because DPR has concluded vis-à-vis EPA that glyphosate alone is not a carcinogenic risk,
8 Plaintiff’s common law causes of action must fail. This is incorrect for three primary reasons: (1)
9 First, DPR does *not* have exclusive authority over pesticide regulation; (2) Second, DPR is relying
10 exclusively on EPA, and EPA’s conclusions are based on oral ingestion of technical glyphosate
11 which is irrelevant in this case; and (3) Third, the Legislature makes clear that FAC is not intended
12 to preclude common law causes of action and associated remedies

13 **A. DPR Does Not Have Exclusive Authority Over Pesticide Regulation**

14 Monsanto’s premise that DPR has exclusive authority to assess the risks and benefits of
15 pesticides is erroneous. As noted *supra*, regarding pesticide safety, OEHHA and DPR have *shared*
16 *responsibility for developing pesticide regulations*. *Fernandez* (Cal. Ct. App. 2008) 164
17 Cal.App.4th at 1218. OEHHA is responsible for developing and providing DPR with toxicological
18 information relevant to its risk management decisions. *Id.* Although the primary responsibility to
19 ensure the safe use of pesticides rests with DPR, it is required to consult with OEHHA concerning
20 risk assessment before adopting those regulations. *Id.* As such, DPR is required by statute to work
21 jointly with OEHHA while formulating regulations relating to pesticide safety and “DPR may not
22 ignore OEHHA or its input.” *Id.* In *Fernandez*, for example, the Appellate Court found that DPR
23 violated its mandatory statutory duties by failing to include OEHHA in the process of determining
24 the health effects and the developing regulations relating to the fumigant and pesticide, methyl
25 bromide. *Id.*

26 In the context of glyphosate, DPR relies exclusively on EPA’s non-carcinogenic finding,
27 stating “**DPR not conducting a human health risk assessment on glyphosate at this time,**” and
28 “**will rely on the [EPA’s] assessment of the potential health risks from glyphosate exposure to**
determine if additional mitigation measures are necessary.” PSUF ¶ 52 (emphasis added). In
contrast, OEHHA identifies glyphosate as a known carcinogen, relying on the determination of
IARC. PSUF ¶ 51. By relying exclusively on EPA, DPR has committed the same error it committed

1 in *Fernandez* by ignoring OEHHA’s IARC-based findings. Indeed, DPR’s reliance on EPA is, itself,
2 problematic given the troubling history between Monsanto and EPA noted *supra* and raises a
3 question of fact about the legitimacy of DRP’s findings. Clearly, Monsanto’s claim that DPR has
4 exclusive authority to regulate pesticides is invalid; another authoritative branch — OEHHA — has
5 determined through the findings of IARC that glyphosate is carcinogenic. Which entity’s findings
6 are correct raises yet another question of fact.

7 Furthermore, even if DPR did have exclusive authority to regulate pesticides, the mere fact
8 that DPR has approved a product label does not prevent a jury from finding that the same label
9 violates FAC. *Hardeman v. Monsanto Co.* (N.D. Cal. 2016) 216 F. Supp. 3d 1037, 1038. A jury is
10 still entitled to conclude that DPR failed to enforce FAC correctly when it approved that label. *Id.*
11 at 1039. This is particularly important point given DRP’s reliance on EPA. As noted *supra*, EPA
12 has only reviewed and considered the carcinogenicity of the active ingredient glyphosate and has
13 ***never reviewed the formulated product, Roundup***, that Ezra Clark was actually exposed to. PSUF
14 ¶ 20-7. Given DRP’s reliance on EPA, it is clear that DRP, similarly, has not considered the actual
15 formulated product. This is also made clear by DPR’s risk assessment documents, which show that
16 DPR ***did not*** evaluate Roundup, itself. PSUF ¶ 52. This omission is vital; it is well established that
17 Roundup is more carcinogenic than glyphosate, alone, due to other carcinogens in the formulated
18 product, the surfactant added to glyphosate, and the increased absorption of the formulation through
19 the skin due to surfactants in the formulation. PSUF ¶ 20-7.

20 **B. DPR Relies Exclusively On EPA And EPA’s Conclusions Are Based On Oral Ingestion
21 Of Technical Glyphosate Which Is Irrelevant In This Case**

22 As already discussed, DPR is relying exclusively on EPA. This is problematic for a number
23 of reasons, including EPA’s assessment of technical glyphosate alone and not the formulated
24 product and EPA’s concerning history with Monsanto. A further issue with DRP’s reliance on EPA
25 is that EPA’s conclusion that technical glyphosate is non-carcinogenic is based on ***oral ingestion of***
26 ***glyphosate***, not ***dermal absorption of Roundup***. PSUF ¶ 52. The major focus of EPA’s 2017
27 Revised Glyphosate Issue Paper is on ***oral exposure of glyphosate***, as “Oral exposure is considered
28 the primary route of concern for glyphosate.” *Id.* This modality of exposure is irrelevant to the case
at bar which has to do with ***dermal absorption of formulated Roundup***. As Monsanto, itself, has
admitted the two modalities are ***not synonymous***. *Id.* (“The movement of glyphosate in the blood
flow from dermal contact is different to that through oral or intravenous exposure.”). As such,

1 Monsanto’s application of EPA’s conclusions to this case is doubly flawed; not only did EPA assess
2 technical glyphosate alone and not the formulate product, Roundup, but EPA’s focus was on oral
3 exposure to glyphosate, not dermal exposure to Roundup. Given DPR’s reliance on EPA, DPR’s
4 conclusions about glyphosate are entirely inapplicable to the case at bar. For these reasons, DPR’s
5 conclusions about glyphosate have no impact on Plaintiff’s common law causes of action at all.

6 **C. The Legislature Makes Clear That FAC Is Not Intended To Preempt Or Displace
7 Common Law Causes Of Action**

8 Even assuming *arguendo* FAC had delegated exclusive authority to DPR and that DPR’s
9 conclusions about technical glyphosate were somehow relevant, the Legislature makes clear that
10 FAC is not intended to preclude common law causes of action and associated remedies. Monsanto
11 is incorrect in arguing that FAC has a preemptive effect that occupies the whole field at the exclusion
12 of common law causes of action. FAC § 11501(a) sets up a preemption schematic only applicable
13 in the context of precluding *local governments below the state level* from regulating pesticides.
14 When this statute was passed, the Legislature clearly articulated its intent that “matters relating to
15 [pesticides] are of *statewide* concern and are to be administered on a *statewide basis*, unless specific
16 exceptions are made in state legislation for local administration.” *See* Section 3, Chapter 1386, Stats.
17 of 1984. FAC goes on to provide that

18 This division [Division 6] and Division 7 are of *statewide* concern and occupy the
19 *whole field of regulation* regarding the registration, sale, transportation, or use of
20 pesticides *to the exclusion of all local regulation*. Except as otherwise specifically
21 provided in this code, no ordinance or regulation of local government, including, but
22 not limited to, an action by a local governmental agency or department, a county
23 board of supervisors or a city council, or a local regulation adopted by the use of an
24 initiative measure, may prohibit or in any way attempt to regulate any matter relating
25 to the registration, sale, transportation, or use of pesticides, and any of these
26 ordinances, laws, or regulations are void and of no force or effect.

27 *See* FAC § 11501.1(a) [emphasis added].

28 FAC does not, however, block pesticide regulations *at the state level*. That is, FAC does not
prohibit state agencies from regulating pesticides when administering other state laws. As such,
FAC § 11501.1(c) states:

Neither this division nor Division 7 (commencing with Section 12501) is a limitation
on the authority of a *state agency or department* to enforce or administer any law
that the agency or department is authorized or required to enforce or administer.

1 [emphasis added]. *See also Jacobs Farm/Del Cabo, Inc. v. Western Farm Service, Inc.* (2010) 190
2 Cal.App.4th 1502, 1521-22 (“*Jacobs Farm*”) (“section 11501.1 expressly prohibits all local
3 ordinances on the subject.... One obvious Legislative aim, made clear by the passage of section
4 11501.1, is that pesticide use be regulated on a statewide basis.”).

5 Any preemptive effect Monsanto posits as to common law causes of action is clearly
6 inapplicable based on the statutory schematic of FAC § 11501.1, itself, but it is a principle made
7 further inapposite by virtue of the case law Monsanto cites in its motion. As stated in *Jacobs Farm*,
8 “[p]reemption applies where federal law supersedes state law or *state law supersedes local law*.”
9 (2010) 190 Cal.App.4th at 1521, quoting *Zengen, Inc. v. Comerica Bank* (2007) 41 Cal.4th 239,
10 247. [emphasis added]. However, there can be no preemption in the context of “co-equal state laws.”
11 *Id.* (“This case does not involve the preemption doctrine because it concerns allegedly conflicting
12 provisions of co-equal state laws—state statutes and state common law.”). Clearly, then, any
13 preemptive effect FAC has only goes to local regulations below the state level.

14 Furthermore, FAC does not somehow displace Plaintiff’s common law causes of action. It
15 is black letter law that statutes do not displace the common law “unless it appears that the Legislature
16 intended to cover the entire subject or, in other words, to ‘occupy the field.’” *I.E. Associates v.*
17 *Safeco Title Ins. Co.* (1985) 39 Cal.3d 281, 285; *K.C. Multimedia, Inc. v. Bank of America*
18 *Technology & Operations, Inc.* (2009) 171 Cal.App.4th 939, 953. As explained *supra*, FAC only
19 occupies the “field” as a means of excluding regulations at the local, below state level; there is no
20 barrier at the state level, itself.

21 Indeed, although the scope of the statutory and regulatory schematic of FAC is broad, it
22 provides no remedy for injuries sustained from pesticide use or exposure. Since the law makes no
23 provision for a damages remedy, § 14003 of FAC implies that injured persons retain the right to sue
24 for damages under the common law. Further, FAC § 12999.2 expressly confirms that the “remedies
25 or penalties” provided by FAC division 7 are “in addition to the remedies or penalties available
26 under any other law.” Given these savings clauses, it is reasonable to conclude that the Legislature
27 intended, as a general matter, to allow for common law claims seeking damages. *See Jacobs Farms*
28 (2010) 190 Cal.App.4th at 1521; *contra Zengen, Inc. v. Comerica Bank* (2007) 41 Cal.4th 239, 255
 (“Because the California Uniform Commercial Code provides a remedy to Zengen under these
 circumstances, it preempts the common law causes of action alleged in the Zengen’s complaint.”).

1 For these reasons, it is clear that Plaintiff’s common law causes of action are neither preempted nor
2 displaced. Consequently, summary judgment must be denied.

3 **II. Plaintiff Has A Viable Fraud Claim**

4 Monsanto alleges that Plaintiff’s fraud claim must fail because there is no specific
5 relationship between Monsanto and Plaintiff.² This argument is meritless. Under California law, the
6 elements of fraud are: (a) a misrepresentation (concealment, nondisclosure, or false representation);
7 (b) scienter or knowledge of its falsity; (c) intent to induce reliance; (d) justifiable reliance; and (e)
8 resulting damage. *Lazar v. Superior Court* (1996) 12 Cal.4th 631, 638.

9 Monsanto has erroneously cabined the first element of fraud as involving concealment or
10 nondisclosure only. However, as noted in *Lazar*, a misrepresentation can take the form of
11 ***concealment, nondisclosure, or false representation***. While a claim for fraud under a theory of
12 concealment or nondisclosure may call for a relationship between the defendant and the plaintiff
13 that gives rise to duty to disclose, fraud vis-à-vis a false misrepresentation does not. Section 533 of
14 the Restatement Second of Torts (“Section 533”).

15 Section 533, which California has adopted, states:

16 The maker of a fraudulent misrepresentation is subject to liability for pecuniary loss
17 to another who acts in justifiable reliance upon it if the misrepresentation, although
18 not made directly to the other, is made to a third person and the maker intends or has
19 reason to expect that its terms will be repeated or its substance communicated to the
20 other, and that it will influence his conduct in the transaction or type of transaction
21 involved.³

22 *See also* Hasso v. Hapke (2014) 227 Cal.App.4th 107, 129; *Shapiro v. Sutherland* (1998) 64
23 Cal.App.4th 1534, 1549.

24 ² Monsanto made an essentially identical argument in its motion for summary judgment in *Stephens v. Monsanto* (Cal.
25 Super. Ct. San Bernardino. Cnty. June 9, 2021) CIVSB2104801. In that case, the plaintiff also used but did not buy
26 Roundup herself. Originally ruling in Monsanto favor on the fraud case of action, the Honorable Vincent Ochoa
27 subsequently reversed himself *in toto*, providing that a cause of action for fraud could proceed without privity. PSUF ¶
28 54.

³ Monsanto seems to posit that the term, “transaction” requires a monetary exchange. Comment *d* to Section 333
makes it clear that this is not so. Comment *d* notes how it is “conduct” that must be “influence;” there is no
requirement that such conduct requires a monetary exchange (“He must make the misrepresentation with the intent or
must have information that gives him special reason to expect that it will be communicated to others and will
influence their conduct.” (emphasis added). Additionally, to require a monetary transaction would simply be bad
policy. Such a policy would preclude almost any child from recovering for fraud, since children do not typically
engage in monetary transactions.

1 Comment *d* to Section 533 makes it clear that the defendant will not escape liability if he
2 makes a misrepresentation to one person intending that it be repeated and acted upon by the plaintiff.
3 See also *Simone v. McKee* (1956) 142 Cal.App. 2d 307, 313-314; *American T. Co. v. California etc.*
4 *Ins. Co.* (1940) 15 Cal.2d 42, 67. Comment *g* also goes on to explain that it is not necessary that the
5 maker of the misrepresentation have the particular person in mind; it is enough that it is intended to
6 be repeated to a particular class of persons. See also *Shapiro v. Sutherland* (1998) 64 Cal.App.4th
7 1534, 1548; *Geernaert v. Mitchell* (1995) 31 Cal.App.4th 601, 605-606. If the defendant makes the
8 misrepresentation to a particular class of persons, he is deemed to have deceived everyone in that
9 class. 5 Witkin, Summary of Cal. Law (9th ed. 1988) Torts, § 707, 808.

10 In *Whiteley v. Philip Morris Inc.* (2004) 117 Cal.App.4th 635, 646, cigarette manufacturer
11 and defendant, Philip Morris, engaged in a disinformation campaign to keep the public smoking
12 without fear. Destroying incriminating documents and hiding reports containing adverse data, Philip
13 Morris did everything possible to maintain the illusion that its carcinogenic product was safe. *Id.* at
14 646. Philip Morris also made every effort to stay ignorant of the ill effects of smoking in order to
15 avoid liability, intentionally failing to do essential “whole product” testing of cigarettes, which
16 would have tested the synergy of components. *Id.* at 647. With this strategy in place, Philip Morris
17 was able to relay a safety message that the defendant intended to convey, and that the plaintiff
18 received. *Id.* at 693. As such, the court found that Philip Morris had made a fraudulent
19 misrepresentation and that the plaintiff’s fraud claim was actionable pursuant to Section 533. *Id.*

20 The facts of *Whiteley* are almost identical to the case at bar. As discussed in-depth *supra*,
21 Monsanto engaged in the self-same disinformation campaign as Philip Morris, destroying and
22 hiding studies, reports, and data, and intentionally refusing to test the formulated product so that its
23 blockbuster product, Roundup, would be used. Similarly, Monsanto continued to relay a message
24 that Roundup was safe. Monsanto made this misrepresentation with the intention and expectation
25 that this misrepresentation would circulate among and influence the conduct of all Americans who
26 do yardwork, including Plaintiff. And Plaintiff believed it. As such, after seeing Roundup in the
27 store and after reading the Roundup label and finding no substantive warnings *at all*, Plaintiff acted
28 upon this safety message and used Roundup for years, resulting in Ezra Clark developing NHL.⁴⁴

⁴⁴ Monsanto claims that Plaintiff never saw an advertisement for Roundup. However, Plaintiff did see Roundup in the store, and the bottles of Roundup, themselves, are advertisements for the product. See PSUF ¶ 54 (Photos of Roundup bottles used by Destiny Clark. The bottle includes statements such as, “Weed and Grass Killer.” “Visible results in 6

1 Clearly, then, just as in *Whiteley*, the elements of Section 533 are satisfied here, as are the overall
2 elements of fraud as set out in *Lazar v. Superior Court* (1996) 12 Cal.4th 631, 638.

3 Additionally, even if Monsanto’s insular view of fraud was correct—which it is not—
4 *Bigler-Engler v. Breg, Inc.*, the case Monsanto relies on, dictates that summary judgement in this
5 case must be denied. (2017) 7 Cal.App.5th 276, 312. As the *Bigler* Court notes, “an affirmative
6 statement may be so misleading that it may give rise to a fraud cause of action even where the
7 relationship or transaction would be insufficient to give rise to a generalized duty to disclose.” *Id.*
8 Here, a question of fact remains as to whether Monsanto touting its carcinogenic product as safe
9 rises to this level. As such, on both grounds, summary judgment must be denied.

9 **III. Plaintiff’s Claims Are Not Preempted by Federal Law**

10 **A. The First Appellate District in *Pilliod v. Monsanto Co.* Has Rejected Monsanto’s**
11 **Express and Implied Preemption Arguments**

12 On August 9, 2021, the First Appellate District issued and certified for publication an
13 opinion in *Pilliod v. Monsanto Co.*, rejecting Monsanto’s arguments that plaintiffs’ failure-to-warn
14 and design defect claims were expressly or implied preempted by the Federal Insecticide and
15 Rodenticide Act (“FIFRA”). *See Pilliod v. Monsanto Co.* (1st App. Dist. Aug. 9, 2021) A158228.
16 This decision is binding on this Court. *See, e.g., Auto Equity Sale, Inc. v. Super. Ct. of Santa Clara*
17 *Cnty.*, 57 Cal. 2d 450, 455 (1962). Because Monsanto has, nevertheless, put forward a federal
18 preemption argument, Plaintiff responds accordingly.

19 The U.S. Supreme Court decision in *Bates v. Dow Agrosciences LLC* (2005) 554 U.S. 431,
20 interpreting the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C.S. §136 *et*
21 *seq.*, forecloses Monsanto’s arguments that the Plaintiff’s state law claims are expressly or impliedly
22 preempted by federal law. Instead, *Bates* recognizes and emphasizes the important role of jury trials,
23 stating “tort suits can serve as a catalyst” in identifying risks of pesticides not yet recognized by
24 EPA. *Bates*, 544 U.S. at 451 (*citing Ferebee v. Chevron Chemical Co.* (D.C. Cir. 1984) 736 F.2d
25 1529). FIFRA is “aimed at protecting citizens from the hazards of modern pesticides.” It is not a
26 “subsidization of the pesticide industry that command[s] states to accept the use of EPA-registered
27 pesticides.” *Ferebee*, 736 F.2d at 1541-1542.

27 **B. Plaintiff’s Claims Are Not Preempted By The Express Preemption Doctrine**

28 _____
hours!” “Kills the root!” “Guaranteed!” “Rainproof in 10 minutes!” This is certainly advertising [a notice or
announcement in a public medium promoting a product. Oxford Language Dictionary]).

1 The *Pilliod* Appellate Court rejected outright Monsanto’s express preemption argument,
2 holding “we conclude that there is no express preemption here. That is because Monsanto identifies
3 no state-law requirements that are in addition to or different from the misbranding requirements
4 imposed by FIFRA, which is what it must do to show that the claims are preempted.”). *Pilliod* (1st
5 App. Dist. Aug. 9, 2021) A158228 at 23.

6 Further, *Bates* explicitly rejected the argument that FIFRA’s misbranding provisions and
7 FIFRA itself were “intended by Congress to be interpreted authoritatively by EPA.” *Bates*, 544 U.S.
8 at 448. In enacting FIFRA, Congress preserved a state’s right to “regulate the sale or use of any
9 federally registered pesticide...” 7 U.S.C. § 136v(a.) “Generally, *the intent of the provision is to*
10 *leave to the States the authority to impose stricter regulation on pesticides* uses than that required
11 under the Act.” (Sen.Rep. No. 838 92d Cong., 2d Sess. 30 (1972) reprinted in 1972 U.S. Code Cong.
12 & Admin.News 4021 (emphasis added.) The 1972 amendments to FIFRA were intended to address
13 growing environmental concerns and “strengthen existing labeling requirements and ensure that
14 these requirements were followed in practice.” *Wisconsin Public Intervenor v. Mortier* (1991) 501
15 U.S. 597, 613. Congress refused to place “a *ceiling* on the ability of states to protect their citizens.”
16 *Ferebee*, 736 F.2d 1529, 1543. FIFRA thus authorizes “concurrent authority of the Federal and State
17 Governments in this sphere.” *Bates*, 544 U.S. at 451). “[P]rotection of pesticide users and victims
18 by *both* federal and state law lies at the center of the Act’s design.” *Ferebee*, 736 F.2d at 1543.

19 FIFRA’s only limitation on state authority is set forth in the Act’s express preemption clause,
20 which provides that states “shall not impose or continue in effect any requirements for labeling or
21 packaging in addition to or different from those required under this Act.” 7 U.S.C. § 136v(b.)
22 However, “[n]othing in the text of FIFRA would prevent a State from making the violation of a
23 federal labeling or packaging requirement a state offense, thereby imposing its own sanctions on
24 pesticide manufacturers who violate federal law.” *Bates*, 544 U.S. at 442. There is thus a simple
25 two-part test for determining whether FIFRA preempts certain state law claims: “First, it must be a
26 requirement ‘*for labeling or packaging*’ ... Second, it must impose a labeling or packaging
27 requirement that is ‘*in addition to or different from*’ those required under this subchapter.” *Id.* at
28 444. The Court explained that a state-law requirement is not preempted if it is equivalent and “fully
consistent” with the federal requirement even if it is not “phrased in the *identical* language as its
corresponding FIFRA requirement” *Id.* at 452, 454. Courts ruling on this issue has repeatedly held

1 that Roundup claims based on state law are fully consistent with the federal requirement. *Blitz v.*
2 *Monsanto Co.* (W.D. Wis. 2018) 317 F.Supp.3d 1042. 1050.

3 Here, Plaintiff's claims based on the product label do constitute requirements for labeling
4 but are not "in addition to or different from" those required by Congress and are thus not preempted
5 by FIFRA. *Bates*, 544 U.S. at 444. The equivalency test is straight-forward—state law and FIFRA
6 are "equivalent" when a violation of state law would also violate FIFRA's misbranding provisions.
7 *Id.* at 454. FIFRA requires manufacturers to provide a warning that "may be necessary and if
8 complied with ... is adequate to protect health." 7 U.S.C. § 136(q)(1)(G). "California law – which
9 asks whether a risk is known or knowable (for strict liability) or reasonably should have been known
10 (for negligence) – is consistent with this requirement." *In re Roundup Products Liability*
11 *Litigation* (N.D. Cal. 2018) 390 F.Supp.3d 1087. To the extent Plaintiff's California common law
12 "... claims attack Roundup's product labeling, they are consistent with FIFRA" and not preempted.
13 *Hardeman*, 216 F.Supp.3d at 1038; *see also Pilliod* (Cal. App. Ct. Alameda Cnty. August 9, 2021)
14 RG 17862702 at 23.

14 **C. Plaintiff's Claims Are Not Preempted By The Implied Preemption Doctrine**

15 As with express preemption, the *Pilliod* Appellate Court also rejected Monsanto's implied
16 preemption argument. (1st App. Dist. Aug. 9, 2021) A158228 at 23. Unlike federal statutes
17 governing cigarettes and smokeless tobacco, FIFRA does not mandate the precise wording for
18 pesticide labels. Rather, FIFRA registrants are entirely responsible for drafting their own labeling.
19 7 U.S.C. §136a(c)(1)(C); 40 C.F.R. §152.50(e.) And, "[b]ecause it is unlawful under the statute to
20 sell a pesticide that is registered but nevertheless misbranded, manufacturers have a continuing
21 obligation to adhere to FIFRA's labeling requirements." *Bates*, 544 U.S. at 438. These obligations
22 include a duty to seek approval to amend a label that does not contain all "necessary warnings or
23 cautionary statements." *Id.* at 438-39. Further, in reversing the lower court and rejecting the
24 "inducement" test, the Supreme Court in *Ansagay v. Dow Agrosciences LLC* necessarily dismissed
25 the possibility of implied preemption under FIFRA. (D. Haw. 2015) 153 F.Supp.3d 1270, 1282
26 ("once the Court concluded that the claims were not expressly preempted, it would have been
27 inconsistent for the Court to have concluded that FIFRA somehow impliedly preempted those same
28 claims.").

In its implied preemption argument, Monsanto relies entirely on cases considering
preemption under the Federal Food, Drug, and Cosmetic Act (FDCA). However, courts should "not

1 distort the Supremacy Clause in order to create similar pre-emption across a dissimilar statutory
2 scheme.” *PLIVA, Inc. v. Mensing* (2011) 564 U.S. 604, 626; *Wyeth v. Levine*, 555 U.S. 555 (2009).
3 Courts must pay attention to “textual differences between [] pre-emption clauses.” *Bates*, 544 U.S.
4 at 441. There are three key FIFRA provisions, absent from the FDCA, that precluded application of
5 “*Wyeth* and its progeny” to this case. *Johnson*, 2018 WL 2324413, at *21. (1) FIFRA contains an
6 express preemption clause which manifests Congressional intent as to the scope of preemption; (2)
7 FIFRA allows states to independently restrict and ban the use of EPA approved pesticides; and (3)
8 “Under the express terms of the statute, EPA approval of a pesticide is not a defense for the
9 commission of any offense under FIFRA...” *Id.* Where “Congress has expressly identified the scope
10 of the state law it intends to preempt,” courts should “infer Congress intended to preempt no more
11 than that absent sound contrary evidence.” *Viva! Internat. Voice for Animals v. Adidas Promotional*
12 *Retail Operations, Inc.* (2007) 41 Cal.4th 929, 945. The existence of an express preemption clause
13 should inform the court’s “analysis of the existence of any implied preemption.” *In re Farm Raised*
14 *Salmon Cases* (2008) 42 Cal.4th 1077, 1092.

15 A finding that the Plaintiff’s labeling claims are preempted, even though they are not “in
16 addition to or different from” those required under FIFRA, would eradicate Congress’ delineation
17 of which claims it sought to preempt, rendering § 136v(b) superfluous. Conversely, it was “[b]ecause
18 the FDCA did not contain an express preemption provision, the Court turned to implied conflict
19 preemption” for FDCA cases. *Ansagay* 153 F.Supp.3d at 1284.) FIFRA expressly contemplates that
20 states can disallow what EPA permits. See 7 U.S.C. § 136v. Under FIFRA, “A state may regulate
21 the sale or use of any federally registered pesticide or device in the State...” 7 U.S.C. § 136v(a).
22 Thus, “Monsanto’s reliance on an implied preemption theory is difficult – if not impossible – to
23 square with *Bates*.” *In re Roundup*, 364 F. Supp.3d at 1087. “[I]f California can stop Monsanto from
24 selling Roundup entirely, surely it can impose state-law duties that might require Monsanto to seek
25 EPA approval before selling an altered version of Roundup in California.” *Id.* at 1088. In stark
26 contrast to FIFRA’s decentralized scheme designed to preserve states’ police powers—including
27 the express authority to ban the sale of any pesticide outright—the FDCA’s regulatory scheme is
28 highly centralized. Through the FDCA, “Congress vested sole authority in the FDA to determine
whether a drug may be marketed in interstate commerce.” *Gross v. Pfizer* (D. Md. 2011) 825 F.
Supp. 2d 654, 659 *citing* 21 U.S.C. § 301 *et seq.* As the Court explained in *Bates* “...[i]t is highly
unlikely that Congress endeavored to draw a line between the type of indirect pressure caused by a

1 State's power to impose sales and use restrictions and the even more attenuated pressure exerted by
2 common-law suits." *Bates*, 544 U.S. at 446; *Ansagay*, 153 F.Supp.3d at 1283 ["A state's ability to
3 ban or restrict the use of an EPA-approved pesticide clearly undercuts Dow's sweeping contention
4 that any state law that impedes Dow's ability to sell its registered product runs afoul of FIFRA."])
5 Finally, the FDCA has no provision similar to section 136a(f)(2) which states "[i]n no event shall
6 registration of [a pesticide] be construed as a defense for the commission of any offense under this
7 subchapter." "In no event" is a straight-forward, unambiguous term. Therefore, "to the extent that
8 defendant is arguing that EPA's registration of glyphosate and approval of the Roundup label carry
9 any preemptive force, defendant is simply mistaken." *Blitz*, 317 F.Supp.3d at 1050.

10 If credence is given to Monsanto's implied preemption theory, Monsanto could still not meet
11 the heavy "clear evidence" burden set out in *Wyeth* and *Merck Sharp & Dohme Corp. v. Albrecht*.
12 A defendant's burden in proving "clear evidence" is a heavy one and "is a demanding defense." *See*
13 *Wyeth*, 555 U.S. at 573. The U.S. Supreme Court highlights four hurdles a company must overcome
14 to succeed on an impossibility preemption defense. A defendant must show by clear evidence that:

- 14 (1) ...[I]t fully informed the [Agency] of the justifications for the warning required
15 by state law; (2) "that the [Agency], in turn, informed the []manufacturer that the
16 [Agency] would not approve changing the drug's label to include that warning;"
- 17 (3) The proposed warnings must constitute "any and all warnings to the drug label
18 that would satisfy state law;" and
- 19 (4) the agency action rejecting the warning must carry the "force of law..."

20 *Merck Sharp & Dohme Corp.* (2019) 139 S.Ct. at 1678.

21 The "possibility of impossibility" is not enough. *Id.* at 1678-1679. Monsanto cannot
22 surmount any of these hurdles. First, there is no evidence that Monsanto applied to change the
23 product or the label. Having never requested a label change, Monsanto cannot say it fully informed
24 EPA of the basis for a label change or the cancer risk associated with Roundup. For example, rather
25 than following regulations and submitting Dr. Parry's report to EPA, Monsanto submitted
26 ghostwritten reports. Monsanto cannot claim that EPA is fully informed where there are tests that
27 could be done, but have yet to be done.

28 Second, EPA has never informed Monsanto that it "would not approve changing" the
Roundup label to include a cancer warning. *Merck*, 139 S.Ct. at 1678-1679.

Third, to the extent that EPA's August 7, 2019 letter has any relevance to this case (which it
does not) it is far from sufficient to carry Monsanto's burden of showing that EPA would have

1 rejected any and all cancer warnings advocated by Plaintiff. *Merck* requires clear evidence that the
2 FDA would reject “any and all warnings to the drug label that would satisfy state law.” 139 S.Ct. at
3 1678. Here, the EPA letter applies only to a very narrow set of warnings (and only in 2019.) The
4 EPA letter applies only to warnings “*exclusively on the basis that it contains glyphosate.*”
5 However, Plaintiff’s claim in this case is that the formulated product, Roundup (which contains
6 other carcinogens in addition to glyphosate) more likely than not causes NHL. The EPA studies
7 were for glyphosate only, not for the formulated product, Roundup, which includes surfactants.

8 Fourth, the August 2019 EPA letter does not constitute an agency action which would have
9 the force of law sufficient to preempt Plaintiff’s claims. Agency actions must be conducted through
10 “congressionally delegated authority” to have any preemptive effect, such as through “notice- and-
11 comment rulemaking setting forth labeling standards.” *Merck*, 139 S.Ct. at 1679. Agency letters that
12 eschew statutory requirements have no preemptive effect. *Reid v. Johnson & Johnson* (9th Cir.
13 2015) 780 F.3d 952, 964. In *Fellner* (cited with approval in *Reid*) the Third Circuit held that a letter
14 from the FDA to California stating that a Prop 65 warning on defendant’s product would be false
15 and misleading had no preemptive effect on a plaintiff’s failure to warn claim against that defendant.
16 539 F.3d at 254. The FDA’s letter merited a “particularly low level of deference” as it was “offering
17 a legal theory for the litigation in California.” *Id.* at 251. *Fellner* held that the FDA “must actually
18 exercise its authority in a manner in fact establishing the state warning as false or misleading under
19 federal law” to have preemptive effect. *Id.* at 255. A statement by the FDA that it would reject a
20 label change is not enough. If EPA believes that glyphosate labels with cancer warnings are
21 misbranded, then there is “a detailed, multi-step process that EPA *must* follow.” *Reckitt Benckiser,*
22 *Inc. v. Jackson* (D.D.C. 2011) 762 F.Supp.2d 34, 42. Unless and until Monsanto makes use of the
23 procedural protections embodied in FIFRA, and fully presses its case for a cancer warning, there is
24 no agency action to be considered. To date, however, Monsanto has done everything in its power to
25 prevent EPA from adding a cancer warning to the Roundup label.

26 Further, as stated by the 9th Circuit Court of Appeals in *Monsanto Co. v. Hardeman*, implied
27 preemption cannot be claimed based on an inability of Monsanto to unilaterally make a label change.
28 (9th Cir. Ct. May 14, 2021) 3:16-md-02741-VC at 25-8. FIFRA and EPA hold that pesticide
manufacturers are responsible for drafting their own product labels. 7 U.S.C. § 136a(c)(1)(C). When
a label needs to be changed, the manufacturer is also responsible for changing the label by drafting
and submitting the label to EPA for approval. 40 C.F.R. § 152.50(e). EPA “shall” approve the

1 change if the change is determined to not violate FIFRA. 7 U.S.C. § 136a(f)(1). Furthermore, EPA
2 also permits pesticide manufacturers to make certain changes to labels *even without prior approval*
3 so long as EPA is notified of the change. *PLIVA*, 564 U.S. 604 at 623; *See also*, 40 C.F.R. §
4 152.46(a); EPA, Office of Pesticide Programs, *Pesticide Registration Notice 98-10* (Oct. 22, 1998)
5 (“PRN 98-10”). In terms of the nature of these changes, EPA has repeatedly allowed pesticide
6 manufacturers to utilize this notification procedure to add cancer warnings to product labels.⁵ As
7 such, Monsanto could have unilaterally made a change to the Roundup label to warn of cancer, and
8 there is no implied preemption.

9 For these reasons, it is clear that Plaintiff’s causes of action are not preempted by federal law
10 and that summary judgment must be denied.

11 CONCLUSION

12 For the foregoing reasons, Defendant’s Motion for Summary Judgment or Summary
13 Adjudication must be denied in its entirety.

14 Dated: August 23, 2021

15 Respectfully submitted,

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26 ⁵ Pursuant to PRN 98-10, pesticide manufacturer Bayer CropScience notified EPA “of a minor labeling amendment
27 for LARVIN Technical,” informing EPA that “[a]s required by California Proposition 65, the following statement has
28 been added to the label, ‘This product contains a chemical known to the state of California to cause cancer.’” Letter
from Larry R. Hodges, Registration Manager, Bayer CropScience, to EPA, Office of Pesticide Programs 4 (Nov. 29,
2012), www3.epa.gov/pesticides/chem_search/ppls/000264-00343-20131217.pdf. In response, EPA’s Registration
Division “conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s)
requested fall within the scope of PRN 98-10.” Letter from Jennifer Gaines, EPA, Office of Pesticide Programs, to
Larry Hodges, Bayer CropScience 2 (Dec. 17, 2012), www3.epa.gov/pesticides/chem_search/ppls/000264-00343-20131217.pdf.