XAVIER BECERRA
Attorney General of California
HARRISON M. POLLAK
Supervising Deputy Attorney General
DENNIS A. RAGEN, State Bar No. 106468
ANDREW J. WIENER, State Bar No. 282414
LAURA J. ZUCKERMAN, State Bar No. 161896
Deputy Attorneys General
1515 Clay Street, 20th Floor
P.O. Box 70550
Oakland, CA 94612-0550
Telephone: (510) 879-1299
Fax: (510) 622-2270
E-mail: Laura.Zuckerman@doj.ca.gov
Attorneys for Xavier Becerra, Attorney General of the State of California

IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

NATIONAL ASSOCIATION OF WHEAT GROWERS ET AL., Plaintiffs, **v.** **XAVIER BECERRA, IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL OF THE STATE OF CALIFORNIA,** Defendant.	Case No. 2:17-cv-02401-WBS-EFB **DEFENDANT'S OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND DEFENDANT'S CROSS-MOTION FOR SUMMARY JUDGMENT** Date: March 23, 2020 Time: 1:30 p.m. Courtroom: 5 Judge: Hon. William Shubb Trial Date: Not set. Action Filed: November 15, 2017

TABLE OF CONTENTS

Page

INTRODUCTION 1

BACKGROUND 3

I. Investigations into the Carcinogenicity of Glyphosate 3

A. The International Agency for Research on Cancer 3

B. Reliance on IARC by U.S. Federal and State Government Entities 6

C. IARC's 2015 Classification of Glyphosate as a Carcinogen 8

D. EPA's and Other Regulatory Agencies' Conclusions 9

II. An Accumulation of Evidence Has Bolstered IARC's Classification of Glyphosate's Carcinogenicity, and Recent Developments Have Provided Clarification Regarding the Level of Exposure Posing a Significant Risk. 12

A. The California Court of Appeal Confirmed that IARC Could Appropriately Be Relied on for the Identification of Carcinogens Under Proposition 65. 12

B. OEHHA's Regulation Setting a "No Significant Risk Level" for Glyphosate Became Final, Providing a Defense to Proposition 65 Enforcement. 12

C. A Recently-Published Review of the Available Epidemiological Evidence Found a Link Between Glyphosate Exposure and Non-Hodgkin's Lymphoma. 14

D. Recent Court Rulings and Jury Verdicts Against Monsanto 14

1. Johnson v. Monsanto 15

2. Hardeman v. Monsanto Co. 17

3. Pilliod v. Monsanto Co. 19

III. Although EPA Disagrees With IARC, EPA's Assessment and Recent Letter to Registrants Do Not Provide the Definitive Word on the Carcinogenicity of Glyphosate. 20

A. There Was No Consensus Within EPA About the Carcinogenicity of Glyphosate. 20

TABLE OF CONTENTS
(continued)

Page

B. EPA's and IARC's Divergent Conclusions Reflect, at Least in Part, Reliance on Different Sets of Studies. 22

C. EPA's Conclusion Has Been Subject to Criticism. 23

1. EPA Failed to Follow Its Own Guidelines ... 23

2. EPA Was Influenced by Monsanto's Efforts to Skew the Scientific Debate 24

D. EPA's Recent Letter to Pesticide Registrants Was Not Prompted by any New Findings. 26

IV. Statutory and Regulatory Background: Proposition 65 26

A. Proposition 65's Warning Requirement and its Purpose. 26

B. The Listing Mechanisms. 28

C. The Listing Mechanism Applicable in This Case. 29

D. Standards for Including Chemicals that IARC has Listed as Carcinogens. 31

E. The Warning Requirement. 32

1. The No Significant Risk Level. 33

2. Businesses May Seek a Safe-Use Determination or an Interpretive Guideline for Glyphosate. 34

3. The Impact of the 1,100 Micrograms/Day NSRL. 35

4. Warning Language. 36

5. Proposition 65 Enforcement. 37

V. Procedural Background 39

LEGAL STANDARD 40

ARGUMENT 41

I. The First Amendment Issue Presented by this Case Is Unripe. 41

A. A Case Is Not Ripe Where There Is No Actual Controversy and No Credible Threat of Enforcement. 41

B. Plaintiffs' Allegations That They Will Be Required to Place Warnings on Their Products Are Speculative and Unfounded. 45

TABLE OF CONTENTS
(continued)

Page

1. Glyphosate Levels in Food Products Are Not Likely to Require a Warning. 45
2. There Is No Evidence That Use of Glyphosate-Based Pesticides by Consumers Will Cause Exposures in Excess of the NSRL. 47
3. Unique Proposition 65 Warnings Are Not Required for Occupational Exposures to Glyphosate Where Companies Comply with Federal OSHA Requirements, and Plaintiffs Have Provided No Evidence of Past or Future Actionable Violations. 48
4. The Possibility that Plaintiffs Will Face Meritless Proposition 65 Enforcement Actions Does Not Establish a Credible Threat of Prosecution for Purposes of the Ripeness Requirement. 49

II. A Glyphosate Warning Required by Proposition 65 Can Comply with the First Amendment. 50

A. Disclosure Requirements Like Proposition 65 Are Subject to Reduced Scrutiny. 51

B. The Supreme Court's Decision in *NIFLA* and two Recent Ninth Circuit Decisions Demonstrate that Proposition 65 Warnings are Subject to Reduced Scrutiny Under *Zauderer*. 52

1. *American Beverage* Makes Clear that *NIFLA* Did Not Change the Analysis of Compelled Health and Safety Warnings. 53
2. *CTIA II* Reaffirmed That the *Zauderer* Test Applies to Purely Factual and Uncontroversial Warnings. 55

C. A Proposition 65 Warning for Glyphosate Can Comply with the First Amendment and Meet the Requirements of the Statute. 58

1. The Warning Complies With *Zauderer* and its Progeny. 59
   a. The Warning is Factual. 59
   b. The Warning is Uncontroversial 63
   c. The Warning is Reasonably Related to the State's Substantial Interest in Providing Information to Consumers about Health Risks. 66
   d. The Warning is Not "Unduly Burdensome." 70

TABLE OF CONTENTS
(continued)

Page

2. The Proposed Form of Warning Would Also Survive Scrutiny Under Central Hudson. 72

D. The Warning Complies With Proposition 65. 75

III. Proposition 65's Warning Requirement Is Not Unconstitutionally Vague. 80

A. Plaintiffs Did Not Plead Constitutional Vagueness as a Ground for Relief. 80

B. The Court Should Reject Plaintiffs' Disfavored Facial Challenge to Proposition 65. 81

C. An As-Applied Challenge Would Also Fail, Because it is Clear What Proposition 65 Requires. 82

CONCLUSION 84

TABLE OF AUTHORITIES

Page

CASES

Abbott Lab. v. Gardner
387 U.S. 136 (1967).....42

AFL-CIO v. Deukmejian
212 Cal. App. 3d 425 (Cal. Ct. App. 1989).....*passim*

Alaska Right to Life Political Action Comm. v. Feldman
504 F.3d 840 (9th Cir. 2007).....41, 43-44

American Beverage Ass'n v. City and County of San Francisco
916 F.3d 749 (9th Cir. 2019) (en banc).....*passim*

American Meat Inst. v. U.S. Dep't of Agric.
760 F.3d 18 (D.C. Cir. 2014) (en banc).....56, 74-75

American-Arab Anti-Discrimination Comm. v. Reno
70 F.3d 1045 (9th Cir. 1995).....43

American-Arab Anti-Discrimination Comm. v. Thornburgh
970 F.2d 501 (9th Cir. 1992).....44-45

Anderson v. Liberty Lobby, Inc.
477 U.S. 242 (1986).....41

Bd. of Trs. v. Fox
492 U.S. 469 (1989).....51, 74

Broadrick v. Oklahoma
413 U.S. 601 (1973).....81

California Chamber of Commerce v. Brown
196 Cal. App. 4th 233 (Cal. Ct. App. 2011).....28, 30, 68

California Pro-Life Council, Inc. v. Getman
328 F.3d 1088 (9th Cir. 2003).....44, 47, 50

Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.
447 U.S. 557 (1980).....*passim*

Colwell v. Dep't of Health and Human Serv.
558 F.3d 1112 (9th Cir. 2009).....42

TABLE OF AUTHORITIES
(continued)

Page

CTIA-The Wireless Association v. City of Berkeley
854 F.3d 1105 (9th Cir. 2017) (*CTIA I*).....54

CTIA-The Wireless Association v. City of Berkeley
928 F.3d 832 (9th Cir. 2019)(*CTIA II*).....*passim*

Darring v. Kincheloe
783 F.2d 874 (9th Cir. 1986).....50

DiPirro v. American Isuzu Motors, Inc.
119 Cal. App. 4th 966 (Cal. Ct. App. 2004).....37

DiPirro v. Bondo Corp.
153 Cal. App. 4th 150 (Cal. Ct. App. 2007).....32

Duke Power Co. v. Carolina Envtl. Study Group, Inc.
438 U.S. 59 (1978).....43

Environmental Law Found. v. Wykle Research, Inc.
134 Cal. App. 4th 60 (Cal. Ct. App. 2005).....36

Gonzales v. Carhart
550 U.S. 124 (2007).....83

Grayned v. City of Rockford
408 U.S. 104 (1972).....82-83

Hardeman v. Monsanto Co.
385 F. Supp. 3d 1042 (N.D. CA 2019).....*passim*

Holder v. Humanitarian Law Project
561 U.S. 1 (2010).....82

Hurley v. Irish-American Gay, Lesbian & Bisexual Grp.
515 U.S. 557 (1995).....54

In re Roundup Products Liability Litigation
390 F. Supp. 3d 1102 (N.D. Cal. 2018).....4

In re Roundup Products Liability Litigation
No. 16-CV-0525-VC, 2019 WL 3219360 (N.D. Cal., July 12, 2019).....17-18

Ingredient Communication Council v. Lungren
2 Cal. App. 4th 1480 (Cal. Ct. App. 1992).....33, 36

TABLE OF AUTHORITIES
(continued)

Page

Italian Colors Restaurant v. Becerra
878 F.3d 1165 (9th Cir. 2018).....44

Janus v. Am. Fed'n of State, Cty., & Mun. Emps., Council 31
138 S. Ct. 2448 (2018).....54

John Doe No. 1 v. Reed
561 U.S. 186 (2010).....81

Knapp v. City of Coeur d'Alene
172 F. Supp. 3d 1118 (D. Idaho 2016).....47, 49

Legislature v. Deukmejian
34 Cal. 3d 658 (Cal. 1983).....30

Loan Payment Admin. LLC v. Hubanks
No. 14-CV-04420-LHK, 2018 WL 6438364 (N.D. Cal, Dec. 07, 2018).....80

Monsanto v. Office of Environmental Health Hazard Assessment
22 Cal. App. 5th 534 (Cal. Ct. App. 2018).....*passim*

Montana Env'l Info. Center v. Stone-Manning
766 F.3d 1184 (9th Cir. 2014).....42

Nat'l Ass'n of Mfrs. v. S.E.C.
800 F.3d 518 (D.C. Cir. 2015).....63, 72

Nat'l Elec. Mfrs. Ass'n v. Sorrell
272 F.3d 104 (2d Cir. 2001).....56, 66, 67, 82

Nat'l Inst. of Family and Life Advocates v. Becerra
138 S. Ct. 2361 (2018).....*passim*

Nat'l Inst. of Family and Life Advocates v. Harris
839 F.3d 823 (9th Cir. 2016).....50

Nat'l Park Hospitality Ass'n v. Dep't of Interior
538 U.S. 803 (2003).....42

Oracle USA, Inc. v. Rimini St., Inc.
191 F. Supp. 3d 1134 (D. Nev. 2016).....81

TABLE OF AUTHORITIES
(continued)

Page

Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n of Cal.
475 U.S. 1 (1986).....63

Philip Morris USA v. Williams
549 U.S. 346 (2007).....18

Ray Charles Found. v. Robinson
795 F.3d 1109 (9th Cir. 2015).....41

Rust v. Sullivan
500 U.S. 173 (1991).....81

Sabri v. United States
541 U.S. 600 (2004).....81

San Diego Cty. Gun Rights Comm. v. Reno
98 F.3d 1121 (9th Cir. 1996).....43

Stormans, Inc. v. Selecky
586 F.3d 1109 (9th Cir. 2009).....43

Styrene Info. and Research Ctr.
210 Cal. App. 4th 1082 (Cal. Ct. App. 2012).....5, 31-32

Thomas v. Anchorage Equal Rights Comm'n
220 F.3d 1134 (9th Cir. 2000).....*passim*

United States v. JP Morgan Chase Bank Account No. Ending 8215 in Name of Ladislao v. Samaniego, VL: $446,377.36
835 F.3d 1159 (9th Cir. 2016).....40

Wolfson v. Brammer
616 F.3d 1045 (9th Cir. 2010).....47-48

Zauderer v. Office of Disciplinary Counsel
471 U.S. 626 (1985).....*passim*

CONSTITUTIONAL PROVISIONS

First Amendment .....*passim*

FEDERAL STATUTES

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136 et seq.....21

TABLE OF AUTHORITIES
(continued)

Page

Toxic Substances Control Act, 15 U.S.C. §§ 2601 et seq. 6

FEDERAL REGULATIONS

29 C.F.R. § 1910.1200 48

29 C.F.R. § 1910.1200, Appendix A.6.1 .....31, 61

29 C.F.R. § 1910.1200, Appendix D 7, 48, 66

29 C.F.R., § 1910.1200, Appendix F 6

40 C.F.R., § 707.60(c)(2)(ii) 6

CALIFORNIA STATUTES

Cal. Educ. Code §§ 32062(a) and (b) 7

Cal. Health & Safety Code

§ 25249.6.....*passim*

§ 25249.7(c).....37

§ 25249.7(d).....34, 37

§ 25249.7(d)(1).....37

§§ 25249.7(e)(1)(A), (g).....38

§ 25249.7(h)(2).....50

§ 25249.8(a).....*passim*

§ 25249.8(b).....11

§ 25249.10(c).....32, 46

§§ 25249.5 – 25249.14.....7

§ 111791.5(b)(2).....7

Cal. Lab. Code

§ 6382(b)(1).....7, 29

§ 6382 (d).....29-30

TABLE OF AUTHORITIES
(continued)

Page

Cal. Penal Code § 374.8(c)(2)(D) 7

CALIFORNIA CODE OF REGULATIONS

Title 3, §§ 6700 et seq.....49, 71

Title 8, § 5194.....49, 71

Title 11, § 3202.....78

Title 27.....*passim*

§ 25203.....34

§ 25204.....34

§ 25306(l).....29

§ 25306(m).....11, 29

§ 25600(f).....75

§§ 25601 – 25607.33.....36

§ 25601.....36

§ 25601(c).....71

§ 25603(d).....59

§ 25606.....48, 71

§ 25703(a).....13

§ 25703(b).....32, 36

§ 25704.....8

§ 25705.....*passim*

§ 25705(a).....34

§ 25904(b).....32

OTHER STATE AUTHORITIES

TABLE OF AUTHORITIES
(continued)

Page

Penn. Admin. Code Code, Title 34, § 323.5(a)(6) 7

N.J. Admin. Code, Title 8:59-9.3, subd. (b)(7) 7

R.I. Gen. Laws, Title 28, § 28-21-2(13), (13) 7

OTHER AUTHORITIES

Berkeley Mun. Code § 9.96.030(A) (2015) 56, 70

Merriam Webster Dictionary, https://www.merriam-webster.com/dictionary/carcinogen.....61

INTRODUCTION

In 2015, the International Agency for Research on Cancer (IARC), the cancer research arm of the United Nations World Health Organization, determined that glyphosate is a probable human carcinogen. This case is about the State of California's ability to comply with the will of the voters who enacted the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) by requiring companies responsible for exposing people to threshold levels of glyphosate to inform them of IARC's carcinogenicity determination.

Two recent opinions from the Ninth Circuit in anticipation of which the Court had stayed this litigation have clarified the law relating to the applicability of the First Amendment to health and safety warnings, like those required by Proposition 65. In *American Beverage Ass'n v. City & County of San Francisco*, 916 F.3d 749 (9th Cir. 2019) (en banc) (*American Beverage*), the Ninth Circuit struck down a requirement to devote at least 20 percent of advertising space to a health warning, but in doing so it affirmed that the lower level of scrutiny for commercial compelled speech set forth in *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985) continues to be the appropriate standard in the First Amendment context to apply to laws, like Proposition 65, that compel the "disclosure of factual, noncontroversial information." *American Beverage*, 916 F.3d at 755. In *CTIA-The Wireless Ass'n v. City of Berkeley*, 928 F.3d 832, 845 (9th Cir. 2019), *cert. denied*, 2019 WL 6689680 (2019) (*CTIA II*), the Ninth Circuit noted that a purely factual statement is not "controversial" for purposes of applying

Zauderer merely because it can be "tied in some way to a controversial issue," *id.* at 845, and went on to uphold a requirement to provide a warning about cell phone radiation. *Id.* at 848. Both opinions make clear that, should the Court determine that this matter is ripe for adjudication, and that glyphosate exposures could be high enough to require Proposition 65 warnings, the built-in flexibility of the statutory warning scheme makes it possible to harmonize the statutory requirements with the dictates of the First Amendment. Plaintiffs can provide a nuanced warning about glyphosate that is wholly factual and noncontroversial, and that satisfies the California voters' mandate to inform consumers prior to exposures to a chemical that IARC determined is a probable human carcinogen.

In addition, after the Court granted plaintiffs' motion for a preliminary injunction in February 2018, three California juries awarded millions of dollars in compensatory damages and hundreds of millions more in punitive damages against plaintiff Monsanto Company (Monsanto), which manufactures the herbicide Roundup. These juries, the only ones to have considered the question, each found that the use of Roundup, whose active ingredient is glyphosate, was a substantial factor in causing four people to get cancer. All three punitive damage awards reflected the juries' disgust over Monsanto's efforts to distort the science around the carcinogenicity of glyphosate.

As there are no material facts in dispute, and defendant Xavier Becerra, Attorney General of the State of California, is entitled to a judgment as a matter of law, the Court should deny

plaintiffs' motion for summary judgment and grant defendant's cross-motion for summary judgment.

BACKGROUND

I. INVESTIGATIONS INTO THE CARCINOGENICITY OF GLYPHOSATE

A. The International Agency for Research on Cancer

The genesis of this lawsuit was the determination, on March 20, 2015, by the International Agency for Research on Cancer, that glyphosate, a widely-used herbicide manufactured by plaintiff Monsanto and others, is an animal carcinogen and a probable human carcinogen. IARC relied in part for this conclusion on evidence that there is a positive association in humans between exposures to high levels of glyphosate and non-Hodgkin's lymphoma, a type of cancer.

IARC was founded in 1965 as the cancer research arm of the United Nations World Health Organization (WHO), and exists to "promote international collaboration in cancer research."[1] The United States helped sponsor the creation of IARC and remains a participating member, despite industry efforts to encourage Congress to defund it.[2] It has a well-deserved reputation for scientific integrity. As the California Court of Appeal for the Fifth District has noted:

> [IARC] is an international agency created specifically to scientifically investigate potentially carcinogenic compounds. Its reputation and authority on the world stage—and relatedly its funding—is dependent, in part, on its work being accepted as scientifically sound. The Agency will thus be motivated to avoid arbitrarily defining compounds as carcinogenic and will be more than likely prone to utilizing accepted scientific protocols in its research.

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[1] Declaration of Laura Zuckerman (Zuckerman Decl.), Exh. C, at 5-6; Defendant's Separate Statement of Undisputed Facts (SUF) No. 2.

[2] Zuckerman Decl., Exh. C, at 27; SUF No.3.

Monsanto v. Office of Environmental Health Hazard Assessment, 22 Cal. App. 5th 534, 559 (Cal. Ct. App. 2018) (*Monsanto v. OEHHA*).

IARC evaluates potential carcinogens by drafting and publishing Monographs, which are "critical reviews and evaluations of evidence on the carcinogenicity of a wide range of human exposures."[3] IARC Monographs address whether an agent, like glyphosate, presents a cancer *hazard*; the Monograph does not evaluate the level of *risk* such a hazard poses for each agent.[4] Thus, according to Judge Vince Chhabria of the Northern District of California,

> [IARC] explains the "important" distinction between hazard identification and risk assessment, stating that "[a] cancer 'hazard' is an agent that is capable of causing cancer under some circumstances, while a cancer 'risk' is an estimate of the carcinogenic effects expected from exposure to a cancer hazard." As a result, the Monograph on glyphosate explains, the IARC classification process is only the "first step in carcinogen risk assessment," because the Monographs "identify cancer hazards even when risks are very low at current exposure levels, because new uses or unforeseen exposures could engender risks that are significantly higher."

In re Roundup Products Liability Litigation, 390 F. Supp. 3d 1102, 1113-1114 (N.D. Cal. 2018) (citations omitted).

Monographs are prepared by a "Working Group" of international scientific experts specifically selected to avoid conflicts of interest.[5] Each Working Group determines whether a chemical should be categorized as Group 1 (carcinogenic to humans), Group 2A (probably carcinogenic to humans), Group 2B (possibly

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[3] Zuckerman Decl., Exh. A, at 10; SUF No. 6.
[4] Zuckerman Decl., Exh. E, at 3, SUF No. 7.
[5] Zuckerman Decl., Exh. A, at 10; *see also* Zuckerman Decl., Exh. F; SUF No. 8.

carcinogenic to humans), or Group 3 (not classifiable as to its carcinogenicity to humans).[6] In so doing, the Working Group reviews both human and animal studies, because the principle that supports qualitative animal-to-human extrapolation from carcinogenesis "has been accepted by all health and regulatory agencies and is regarded widely by scientists in industry and academia as a justifiable and necessary inference." *AFL-CIO v. Deukmejian*, 212 Cal. App. 3d 425, 438 n.7 (Cal. Ct. App. 1989) (quoting Report, Office of Science and Technology Policy, 50 Fed. Reg. 10375 (Mar. 14, 1985)). Importantly, IARC's "Monographs do not select at random the agents evaluated for carcinogenicity."[7] IARC *only* reviews chemicals where (a) there is evidence of human exposure, and (b) there is some evidence or suspicion of carcinogenicity.[8] Currently, 11.8% of the agents that IARC evaluates have been assigned to Group 1, and another 8.2% have been assigned to Group 2A (probably carcinogenic to humans) – the same category as glyphosate – with the remaining 80% classified either as "possibly carcinogenic to humans" or "not classifiable as to its carcinogenicity to humans."[9]

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[6] Zuckerman Decl., Exh. A, at 30-31; SUF No. 9; *see also Styrene Info. and Research Ctr.*, 210 Cal. App. 4th 1082, 1090-91 (Cal. Ct. App. 2012). The IARC Preamble was amended in January 2019 to eliminate Group 4, and chemicals are now classified as either Group 1, Group 2A, Group 2B, or Group 3 agents.

[7] Zuckerman Decl., Exh. G, at 6; SUF No. 11.

[8] *Id.*; Zuckerman Decl., Exh. A, at 11.

[9] Zuckerman Decl., Exh. H; SUF No. 12. Specifically, and rounded to the nearest tenth of a percentage point: 11.8% of agents that IARC evaluates are assigned to Group 1; 8.2% of agents are assigned to Group 2A; 31% of agents are assigned to Group 2B, and 49% of agents are assigned to Group 3. *Id.* For a full list of the agents currently classified by IARC, *see* Zuckerman Decl., Exh. I.

B. Reliance on IARC by U.S. Federal and State Government Entities

In the United States, both federal and state entities consider IARC an authoritative source for carcinogen identification. For example, the U.S. Department of Health and Human Services notes that IARC "Monograph volumes are considered critical references that inform health policy and cancer research worldwide about carcinogenic risks to reduce cancer globally."[10] Regulations promulgated under the Toxic Substances Control Act, 15 U.S.C. § 2601 et seq., state that a chemical is a known or potential carcinogen if it is classified as Group 1, 2A, or 2B by IARC. 40 C.F.R., § 707.60(c)(2)(ii). With respect to occupational warnings for carcinogens, the Hazard Communication Standard established by the U.S. Occupational Safety and Health Administration (OSHA) recognizes IARC as a source for providing information regarding cancer hazards to workers. 29 C.F.R., § 1910.1200, App. F. In addition, employees who handle products containing chemicals IARC has listed as potential carcinogens must be informed, by means of a Safety Data Sheet (SDS), of IARC's determination. Federal law specifically requires the SDS to state:

> Whether the hazardous chemical . . . has been found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs (latest edition), or by OSHA.

29 C.F.R. § 1910.1200, App. D (emphasis added). Pursuant to this federal requirement, a number of manufacturers, including

[10] *See* Zuckerman Decl., Ex. J; SUF No. 13.

Monsanto, have included the 2015 IARC carcinogenicity finding for glyphosate on SDSs for their products.[11]

In California, the Safe Drinking Water and Toxic Substances Control Act of 1986, Cal. Health & Safety Code §§ 25249.5 – 25249.14[12] (Proposition 65), and other statutes rely on IARC's findings. These include Cal. Penal Code § 374.8(c)(2)(D), involving the illegal deposit of hazardous substances; Cal. Educ. Code §§ 32062(a) and (b), addressing toxic art supplies in schools; the California Safe Cosmetics Act of 2005, Cal. Health & Safety Code § 111791.5(b)(2), and Cal. Labor Code §6382(b)(1). Many other states rely on IARC's evaluations to create lists of hazardous chemicals and identify carcinogens for other public health purposes, including the states of Alaska, Connecticut, Illinois, Indiana, Louisiana, Massachusetts, Missouri, Nevada, New Hampshire, New Jersey, Oregon, Pennsylvania, Rhode Island, Tennessee, Texas, Vermont, Virginia, and Washington.[13] When IARC determines that the available scientific evidence does not support classifying a substance in Group 1, 2A or 2B (i.e., when

[11] Zuckerman Decl., Exh K; SUF No. 14.

[12] All statutory references are to the California Health & Safety Code unless otherwise noted.

[13] For example, Pennsylvania creates a hazardous substance list that includes all substances listed by IARC as having "sufficient evidence of carcinogenicity in animals." Penn. Statutes, tit. 35, § 7303(a)(6); Penn. Admin. Code, tit. 34, § 323.5(a)(6). New Jersey's "Right to Know Hazardous Substance List" must be updated based on the IARC Monograph Supplements. N.J. Admin. Code, tit. 8:59-9.3, subd. (b)(7). Rhode Island requires employers to maintain hazardous and/or toxic chemical lists that include chemicals listed as carcinogens by IARC. R.I. Gen. Laws, tit. 28, § 28-21-2(13), (13). Massachusetts creates a list of toxic or hazardous substances which includes substances found to have sufficient evidence of carcinogenicity in animals as indicated in the IARC Monographs. Mass. Reg., tit. 105, § 670.010(b)(1); *see also* Zuckerman Decl., Exh. L, Table of Reliance on IARC by Other States; SUF No. 15.

IARC places the substance in Group 3 — not classifiable as to its carcinogenicity to humans), governmental agencies have relied on that finding as well – as did the California Office of Environmental Health Hazard Assessment (OEHHA), the lead agency for Proposition 65, when it removed saccharin from the Proposition 65 list in 2001, and when it promulgated a regulation to establish that warnings are not required for chemicals in coffee created by roasting or brewing.[14]

C. IARC's 2015 Classification of Glyphosate as a Carcinogen

In March 2015, IARC convened a Working Group of internationally recognized scientific experts to review the evidence for the carcinogenicity of five organophosphate herbicides, including glyphosate.[15] These seventeen experts included representatives from the U.S. National Cancer Institute, the U.S. National Institute of Environmental Health, and the California Environmental Protection Agency; professors from Texas A&M University and Mississippi State University; and experts from Australia, Canada, Chile, France, Finland, Italy, New Zealand, and the Netherlands. Notably, the Working Group included a representative from the National Center for Computational Toxicology at the U.S. Environmental Protection Agency (EPA), as well as an observer from Monsanto.[16]

IARC examined three types of evidence from the available literature: studies in humans, studies in animals, and

[14] *See* Zuckerman Decl., Exh. M; 27 CCR, § 25704; SUF No. 20.
[15] Zuckerman Decl., Exh. A; SUF No. 21.
[16] Zuckerman Decl., Exh. N, at 3-5, and at 6, n.11 (observer from Monsanto); SUF Nos. 22-23. This is hardly a "closed door" process, as plaintiffs contend. Pltfs.' Br. at 15.

mechanistic data.[17] Because IARC is required to base its review on data from published reports (or reports that have been accepted for publication), and data from publicly available government agency reports, it did not review confidential research and data sponsored and produced by Monsanto.[18] After completing its review, IARC classified glyphosate as "probably carcinogenic to humans (Group 2A)," its second highest classification, based on "sufficient evidence" in animals and "limited evidence" in humans, as well as mechanistic analysis and other relevant data.[19] These were the consensus findings of the 17-member Working Group, which published its conclusions in a 78-page Monograph.[20]

D. EPA's and Other Regulatory Agencies' Conclusions

Plaintiffs assert that there is an "overwhelming scientific consensus" that glyphosate poses no risk of cancer. *E.g.*, Pltfs.' Br. at 2. Leaving aside the fact that at issue in this motion is whether glyphosate is a cancer *hazard*, not whether normal exposures to glyphosate present a cancer *risk* and are high enough to require a Proposition 65 warning, there is not overwhelming scientific consensus. It is true that the EPA has reviewed studies regarding the carcinogenicity of glyphosate

[17] Zuckerman Decl., Exh. A, at 331-350, 350-360; 361-393; SUF No. 24.

[18] Zuckerman Decl., Exh. A, at 12; SUF No. 25.

[19] Zuckerman Decl., Exh. A, at 361-394, 398-399; SUF No. 27; SUF No. 31. IARC uses the term "limited evidence" with regard to evidence in humans to mean that a positive association has been observed between exposure to the agent (in this case, glyphosate), and cancer in studies of humans, but that other explanations for the observations could not be ruled out. Zuckerman Decl., Exh. A, at 12; SUF No. 28.

[20] Zuckerman Decl., Exh. A, at 14; Zuckerman Decl. Exh. G at 2-4; SUF No. 32.

several times, and has repeatedly stated that it is "not likely to be carcinogenic to humans."[21] Most recently, EPA expressed this finding in a Proposed Interim Registration Review Decision and Responses to Public Comments for Glyphosate,[22] and reiterated it in a letter specifically referencing Proposition 65 (see Background Section III.D, *infra*). It is also true that regulatory agencies in other countries have concluded that there is insufficient evidence that glyphosate causes cancer, either at all (i.e., it is not a cancer *hazard*) (the European Chemical Agency [ECHA],[23] the European Food Safety Authority [EFSA],[24] and the New Zealand Environmental Protection Agency [NZEPA][25]), or at the levels to which humans are typically exposed (i.e., that it does not present a cancer *risk*) (Health Canada,[26] the Australian Pesticides and Veterinary Medicines Authority, the Food and

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[21] Proposed Interim Registration Review Decision and Responses to Public Comments for Glyphosate, April 2019, at 19.

[22] Proposed Interim Registration Review Decision and Responses to Public Comments for Glyphosate, April 2019, at 19-25.

[23] Zuckerman Decl., ¶ 19 and Exh. R, at 98. ("[N]o hazard classification for carcinogenicity is warranted for glyphosate according to the CLP criteria."); SUF No. 38.

[24] Zuckerman Decl., ¶ 20 and Exh. S, at 1 ("[G]lyphosate is unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential according to Regulation (EC) No 1272/2008."); SUF No. 38.

[25] Zuckerman Decl., ¶ 21 and Exh. T, at 16 ("[G]lyphosate is unlikely to be genotoxic or carcinogenic to humans and does not require classification . . . as a carcinogen or mutagen."); SUF No. 38.

[26] Zuckerman Decl., ¶ 22 and Exh. U ("Glyphosate is not genotoxic and is unlikely to pose a human cancer risk."); SUF No. 38.

Agricultural Organization,[27] and the World Health Organization Joint Meeting on Pesticide Residues[28]).

Yet the conclusions of ECHA, EFSA, and the NZEPA, the regulatory agencies cited other than EPA whose conclusions *directly* conflict with IARC's determination that glyphosate presents a cancer hazard, do not reflect a scientific consensus: indeed, they have been criticized by a number of prominent scientists. For example, 94 scientists concluded that EFSA's analysis of glyphosate contained serious flaws, and that the "most appropriate and scientifically based evaluation of the cancers reported in humans and laboratory animals as well as supportive mechanistic data is that glyphosate is a probable human carcinogen."[29] Another peer-reviewed article concluded that EFSA's report on glyphosate is "markedly flawed, and... relies heavily on industry-funded and industry-manipulated reviews": it calls for the withdrawal of the report of the New Zealand EPA, which was based on the EFSA report.[30] In any event, the conclusions of these four regulatory agencies, only one of which is considered authoritative under Proposition 65,[31] hardly constitute an "overwhelming scientific consensus" that glyphosate

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[27] Zuckerman Decl., ¶ 23 and Exh. V, at 9 ("[E]xposure to glyphosate does not pose a carcinogenic or genotoxic risk to humans."); SUF No. 38.

[28] Zuckerman Decl., ¶ 24 and Exh. W, at 36 ("[G]lyphosate is unlikely to pose a carcinogenic risk to humans via exposure from the diet."); SUF No. 38.

[29] Zuckerman Decl., Exh. X, at 741, 743; SUF No. 40.

[30] *See* Zuckerman Decl., Exh. Y at 83; SUF No. 41.

[31] EPA is considered an "authoritative body" for purposes of Proposition 65's "authoritative bodies" carcinogen listing provision. Cal. Health & Safety Code, § 25249.8(b); 27 CCR, § 25306(m). Others are IARC, the National Institute for Occupational Safety and Health, the National Toxicology Program, and the U.S. Food and Drug Administration.

is not a carcinogen, as plaintiffs suggest. *See* Pltfs.' Br. at 2.

II. AN ACCUMULATION OF EVIDENCE HAS BOLSTERED IARC'S CLASSIFICATION OF GLYPHOSATE'S CARCINOGENICITY, AND RECENT DEVELOPMENTS HAVE PROVIDED CLARIFICATION REGARDING THE LEVEL OF EXPOSURE POSING A SIGNIFICANT RISK.

A number of developments since this Court's rulings in February 2018 reinforce IARC's conclusion that glyphosate poses a cancer hazard and also clarify the level of risk accompanying exposure. These developments include the following:

A. The California Court of Appeal Confirmed that IARC Could Appropriately Be Relied on for the Identification of Carcinogens Under Proposition 65.

In April 2018, the California Fifth District Court of Appeal unanimously rejected a constitutional challenge by Monsanto to the listing of glyphosate as a carcinogen under Proposition 65. *Monsanto v. OEHHA*, 22 Cal. App. 5th 534, 559 (Cal. Ct. App. 2018), review den. (Cal. 2018). At the heart of the challenge was Monsanto's claim that IARC was an untrustworthy and unreliable foreign agency on whose determinations Proposition 65 could not constitutionally rely. The Court rejected this contention, concluding that Proposition 65 reasonably relies on IARC to perform its carcinogen identification function. *Id.*

B. OEHHA's Regulation Setting a "No Significant Risk Level" for Glyphosate Became Final, Providing a Defense to Proposition 65 Enforcement.

On July 1, 2018, OEHHA finalized a "safe-harbor" No Significant Risk Level (NSRL) for glyphosate of 1,100 micrograms per day (µg/day). Cal. Code Regs. tit. 27 (27 CCR), § 25705. Any exposure below this level is deemed not to require a Proposition 65 warning. In calculating the NSRL, the scientists

at OEHHA reviewed all the publicly available scientific literature, and received and considered over 1,300 public and industry comments.[32] OEHHA considered the scientific studies relied on by IARC and studies submitted by commenters arguing that glyphosate poses no cancer risk at all, or that it poses a higher risk, which would warrant a more-protective NSRL.[33] Ultimately, in conducting its review, OEHHA concluded that the studies on which IARC relied provided sufficient evidence of carcinogenicity in animals.[34] OEHHA also agreed with IARC's determination that there is strong evidence that glyphosate causes genotoxicity and oxidative stress, and that these effects can operate in humans.[35] Genotoxicity and oxidative stress are two of the ten key characteristics of carcinogens.[36] Ultimately, OEHHA calculated the NSRL by performing "a standard dose response analysis" using "the results of the most sensitive scientific study deemed to be of sufficient quality," as required by the governing regulation.[37]

Consistent with the fact that glyphosate is a weak carcinogen, the 1,100 µg/day NSRL for glyphosate is one of the highest OEHHA has set.[38] As discussed below (*infra* at Background

[32] *See* Zuckerman Decl., Exh. O, at 1-2, 46; SUF No. 44.

[33] Zuckerman Decl., Exh. O, at 1-2, 16-17, 33-45; SUF No. 44-47.

[34] Zuckerman Decl., Exh. O, at 1, 6-7. 9-10; SUF No. 48. OEHHA took note of the fact that IARC identified a significant increase in a particular type of malignant kidney tumors that is rare in the strain of mice being studied, which is a strong indication of carcinogenicity. Zuckerman Decl., Exh. O at 7. SUF No. 51.

[35] Zuckerman Decl., Exh. O at 4, 6-10, 23; SUF No. 23.

[36] *See* Zuckerman Decl., Exh. Z at 713-714; SUF No. 49.

[37] Zuckerman Decl., Exh. O at 1, 32; SUF No. 50; *see also* 27 CCR, § 25703(a).

[38] *See* 27 CCR, § 25705, which assigns glyphosate the third-highest NSRL that OEHHA has set for a carcinogen. Plaintiffs

Sections IV.E.3 and IV.E.5, and Argument Section I.B), the NSRL for glyphosate will be a significant deterrent to the filing of private actions.

C. A Recently-Published Review of the Available Epidemiological Evidence Found a Link Between Glyphosate Exposure and Non-Hodgkin's Lymphoma.

In an article published in 2019, scientists at the University of California Berkeley, the University of Washington, and the Icahn School of Medicine at Mount Sinai, New York, conducted a meta-analysis of the human cancer epidemiology studies of glyphosate exposure and non-Hodgkin's lymphoma (NHL), including the most recent update of the Agricultural Health Study, on which plaintiffs rely, and concluded that there is a "compelling link between exposures to [glyphosate-based herbicides[39]] and increased risk for NHL."[40] The article found that using the highest exposure levels in each study, the risk of non-Hodgkin's lymphoma was increased by 41%.[41]

D. Recent Court Rulings and Jury Verdicts Against Monsanto

In three recent cases, private plaintiffs who suffer from non-Hodgkin's lymphoma won massive compensatory and punitive damages verdicts holding Monsanto, the largest manufacturer of glyphosate-based pesticides, liable for its failure to warn them that glyphosate-based pesticides could cause cancer.

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complain that the NSRL for acrylamide did not deter all private enforcers from filing lawsuits over acrylamide exposures. Pltfs.' Br. at 23. But the NSRL for glyphosate is 5,500 times higher than the 0.2 µg/day NSRL that OEHHA set for acrylamide. 27 CCR, § 25705(b)(2).

[39] This brief uses the term pesticide and herbicide interchangeably, because glyphosate is both a pesticide and an herbicide.

[40] Zuckerman Decl., Exh. CC, at 186. SUF No. 59.

[41] Zuckerman Decl., Exh. CC, at 186; SUF No. 60.

Importantly, the plaintiffs' experts in the private cases (who did *not* just rely on the IARC determination, as plaintiffs imply, Pltfs.' Br. at 15) were required not just to show that glyphosate presents a general cancer risk significant enough to require a warning, but to meet the high bar of showing that glyphosate-based pesticides caused their particular cases of cancer. Thus, the juries found that glyphosate was more than simply a risk that warranted preventative health measures (like warnings); they found that it was a substantial factor in causing non-Hodgkin's lymphoma in four specific individuals. The findings of the courts and the juries in each of these cases are discussed below.

1. *Johnson v. Monsanto*

Dewayne Johnson, a father and husband with terminal non-Hodgkin's lymphoma, sued Monsanto in San Francisco County Superior Court, alleging that his cancer resulted from spraying high-concentration Roundup and Ranger Pro, glyphosate-based pesticides, 20-30 times a year for 2-3 hours a day in connection with his job as a groundskeeper and pesticide manager for a Northern California public school district.[42] Suffering from a spreading rash consistent with lymphoma, and fearful of its implications, Mr. Johnson called Monsanto with questions and increasing levels of concern about whether Monsanto's high-concentration Ranger Pro (a product containing 41% glyphosate) could cause cancer. No one returned his call.[43] Mr. Johnson

[42] Zuckerman Decl., Exh. JJ, at 3305:20-25; Zuckerman Decl., Exh. FF at 3-6; SUF No. 65.

[43] Zuckerman Decl., Exh. KK, at 5614:00029-01 – 5615:00031-18; 5617:00037:4-5618:00038-17; Zuckerman Decl., Exh. LL, at 6516; Zuckerman Decl., Exh. JJ, at 3274:5 – 3275:8; SUF No. 66.

subsequently called the Missouri Poison Control Center (MPCC), which had an arrangement to provide information to persons contacting Monsanto about its products.[44] The MPCC provided a report of this inquiry to Dr. Daniel Goldstein, Monsanto's director of medical toxicology, one week after IARC listed glyphosate as a probable human carcinogen. Dr. Goldstein was well aware of IARC's 2015 classification of glyphosate as a probable human carcinogen, as, at the time, he was preparing Monsanto's response to IARC's findings.[45] Nevertheless, neither Dr. Goldstein nor anyone at Monsanto contacted Mr. Johnson, who continued to use Ranger Pro until his non-Hodgkin's lymphoma became more aggressive.[46]

In a carefully reasoned pre-trial order dated May 17, 2018, Judge Curtis Karnow found there was sufficient evidence of both general and specific causation for the case to proceed to trial.[47] In ruling in Mr. Johnson's favor, the jury concluded, in part, that Monsanto failed to adequately warn of the potential risks of using Roundup Pro or Ranger Pro, and that the lack of a sufficient warning was a substantial factor is causing harm to Mr. Johnson.[48] In denying Monsanto's motion for a new trial, Judge Suzanne Bolanos held that the evidence presented at trial

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[44] Zuckerman Decl., Exh. KK, at 5622:00051-01 - 5623:00053; Zuckerman Decl., Ex. LL, at 6519; Zuckerman Decl., Exh. JJ, at 3275:11 – 3283:3; Zuckerman Decl., Exh. MM, at 7; SUF No. 67.

[45] Zuckerman Decl., Exh. LL, at 6519; Zuckerman Decl., Exh. KK, at 5642:000133:01-16; Zuckerman Decl., Exh. B, at 1; SUF No. 68.

[46] *See* Zuckerman Decl., Exh. KK, at 5622:00052-09 – 5624:00056-05; Zuckerman Decl., Exh. JJ, at 3283:2-13; 3236:4-13; SUF No. 69.

[47] Zuckerman Decl., Exh. NN; SUF No. 70.

[48] Zuckerman Decl., Exh. FF, at 4-5; SUF No. 73.

was sufficient to support the jury's verdict on causation, and that "the jury could conclude that Monsanto acted with malice by consciously disregarding a probable safety risk of [glyphosate-based herbicides] and continuing to market and sell its product without a warning."[49] The jury awarded Mr. Johnson $39.25 million in compensatory damages and $250 million in punitive damages, which the Court reduced to $39.25 million.[50]

2. *Hardeman v. Monsanto Co.*

In a lawsuit filed in U.S. District Court for the Northern District of California, Edwin Hardeman alleged that he acquired non-Hodgkin's lymphoma as a result of his use of Roundup. In a two-phase verdict, the jury found in March 2019 that "Mr. Hardeman prove[d] by a preponderance of the evidence that his exposure to Roundup was a substantial factor in causing his non-Hodgkin's lymphoma."[51] The jury also found that "Monsanto was negligent by not using reasonable care to warn about Roundup's [non-Hodgkin's lymphoma] risk," and that Mr. Hardeman proved by "clear and convincing evidence that he is entitled to punitive damages."[52] In denying Monsanto's motion for a new trial in July 2019, Judge Chhabria reiterated a pre-trial ruling that there was sufficient admissible evidence that plaintiff's use of glyphosate-based pesticides caused his cancer. *In re Roundup Products Liability Litigation*, No. 16-CV-0525-VC, 2019 WL 3219360, at *1 (N.D. Cal., July 12, 2019) ("There was no material difference between the quality of the causation evidence

[49] Zuckerman Decl., Exh. EE, at 3; SUF No. 74.
[50] Zuckerman Decl., Exh. FF, at 6-7; SUF No. 75.
[51] Zuckerman Decl., Exh. GG, at 1; SUF No. 77.
[52] Zuckerman Decl., Exh. HH, at 1-2; SUF No. 77-78].

presented pretrial and at trial. If anything, the testimony of the plaintiffs' causation experts at trial was more reliable than their testimony during the *Daubert* hearings . . . ."). In ruling that punitive damages were appropriate, Judge Chhabria took particular note of Monsanto's failure to produce evidence showing any interest in evaluating the reported safety risks of its product:

> ***Despite years of colorable claims in the scientific community that Roundup causes [non-Hodgkin's lymphoma], Monsanto presented minimal evidence suggesting that it was interested in getting to the bottom of those claims***. . . . . For example, while the jury was shown emails of Monsanto employees crassly attempting to combat, undermine or explain away challenges to Roundup's safety, not once was it shown an email suggesting that Monsanto officials were actively committed to conducting an objective assessment of its product. Moreover, because the jury was aware that Monsanto has repeatedly sold – and continues to sell – Roundup without any form of warning label, it was clear that Monsanto's "conduct involved repeated actions," rather than "an isolated incident." *Id.; see also Philip Morris USA v. Williams*, 549 U.S. 346, 355 (2007).

Hardeman v. Monsanto Co., 385 F. Supp. 3d 1042, 1046, 1047 (N.D. CA 2019) (emphasis added).

The jury awarded Mr. Hardeman $75 million in punitive damages and approximately $5.3 million in compensatory damages.[53] Even when reducing the award of punitive damages in July 2019 to $20 million, Judge Chhabria noted, "While Monsanto repeatedly intones that it stands by the safety of its product, the evidence at trial painted the picture of a company focused on attacking or undermining the people who raised concerns." *Hardeman*, 385 F. Supp. 3d at 1047.

[53] Zuckerman Decl., Exh. HH, at 2; SUF No. 79.

3. *Pilliod v. Monsanto Co.*

In a suit filed in Alameda County Superior Court, Alva and Alberta Pilliod claimed that use of Roundup caused their non-Hodgkin's lymphoma. The jury agreed. It found that Roundup's design was a substantial factor in causing the Pilliods' cancer, and that the risks of Roundup presented a substantial danger when used in accordance with widespread and commonly recognized practice.[54] It also found that Monsanto failed to adequately warn of potential risks, and that the lack of sufficient warning was a substantial factor in causing plaintiffs' harm.[55] The jury awarded the Pilliods $2 billion, which Judge Winifred Smith reduced to $86.7 million.[56] Like Judge Chhabria, Judge Smith found that there was sufficient evidence to support the verdict[57] and that Monsanto's efforts to distort the scientific inquiry on the carcinogenicity of glyphosate, including an attempt to discredit the IARC classification, justified an award of punitive damages:

> ***In this case there was clear and convincing evidence that Monsanto made efforts to impede, discourage, or distort scientific inquiry and the resulting science***. Monsanto conducted initial studies about glyphosate but decided to not look further when there were indications that glyphosate might cause cancers . . . [and thereby] showed a conscious disregard for public health.[58]

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[54] Zuckerman Decl., Exh. II, at 5746-5750, 5752-53, 5760-61; SUF No. 81.

[55] Zuckerman Decl., Exh. II, at 5746-5750; SUF No. 82.

[56] Zuckerman Decl., Exh. II, at 5748, 5751; SUF No. 82.

[57] Zuckerman Decl., Exh. OO, at 3; SUF No. 83.

[58] Zuckerman Decl., Exh. OO, at 2-3, 17-18, 21, 24 (emphasis added); SUF No. 84. Two recent articles discussed in footnote 76, below, detail the ways in which Monsanto influenced not only EPA but other global regulatory bodies.[59] Zuckerman Decl., Exh. P, at 7, 17, 19-25; SUF No. 37.

III. ALTHOUGH EPA DISAGREES WITH IARC, EPA'S ASSESSMENT AND RECENT LETTER TO REGISTRANTS DO NOT PROVIDE THE DEFINITIVE WORD ON THE CARCINOGENICITY OF GLYPHOSATE.

In 2019, EPA reaffirmed its 2017 conclusion that glyphosate is neither a cancer hazard nor a risk to humans at typical levels of exposure.[59] However, EPA's determination does not necessarily undercut the scientific basis of IARC's classification of glyphosate as a carcinogen. Recent evidence suggests a number of possible reasons for the disparity between the IARC and EPA conclusions, as well as for the differing opinions within EPA itself. The Attorney General does not ask the Court to decide the merits of these differing views. Instead, the Attorney General presents the information below to show that EPA's conclusions on glyphosate are open to question. It was in contemplation of circumstances like these that the California voters who enacted Proposition 65 decided that they wanted to receive warnings about IARC-listed carcinogens "*regardless of whether other identified listing agencies or processes agree.*" *Monsanto v. OEHHA*, 22 Cal. App. 5th at 556 (emphasis added).

A. There Was No Consensus Within EPA About the Carcinogenicity of Glyphosate.

EPA has concluded, most notably in December 2017, in its Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential, that glyphosate is "not likely to be carcinogenic to humans."[60] This was not at all times the consensus view within

[59] Zuckerman Decl., Exh. P, at 7, 17, 19-25; SUF No. 37.

[60] *Id.* at 5, 7-8. Although, as shown above, other regulatory agencies have found glyphosate not to be a cancer hazard, the Attorney General focuses in this motion (and in his proposed warning) on EPA's conclusion, rather than on the conclusions of other agencies, because EPA is the only one of those agencies with the special status of being an enumerated agency under

the agency.[61] Four scientists associated with EPA – the scientist from EPA's National Center for Computational Toxicology on the IARC Working Group,[62] and three members of the EPA Science Advisory Panel that reviewed glyphosate[63] – have agreed with IARC's finding that glyphosate is a probable human carcinogen.[64] They were not alone. Documents recently disclosed by the EPA show that in 2015, Vincent Cogliano, Ph.D., then a scientist at EPA's Office of Research and Development (ORD), the scientific research arm of EPA, referenced divided conclusions within the agency:

> I believe that ORD scientists would be split on whether there is adequate supporting experimental evidence. Some might classify glyphosate as "Likely to be carcinogenic"; others as "Suggestive evidence." . . I also believe that some ORD scientists might classify glyphosate as "Likely" based on experimental data alone . . ."[65]

Ultimately, as noted above, a different position prevailed.

Proposition 65 and its regulations.

[61] Zuckerman Decl., Exh. PP; SUF No. 87.

[62] Zuckerman Decl., Exh. A, at 3-7; 14; SUF No. 86.

[63] Professor Luoping Zhang, who served on US EPA's Food Quality Protection Act Science Review Board for the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel on Glyphosate, was the lead author on a meta-analysis published earlier this year which concluded that glyphosate is a probable human carcinogen, and Professors Elizabeth A. (Lianne) Sheppard and Emanuela Taioli, who also served on that Panel, were co-authors of that meta-analysis. Zuckerman Decl., Exh. BB, at 4-6, Zuckerman Decl., Exh. CC; SUF Nos. 57-58. Dr. Zhang is currently a member of OEHHA's Carcinogen Identification Committee.

[64] *See also* Zuckerman Decl., Exh. BB, at 17-18 (some EPA Science Advisory Panel members "argued that there is sufficient evidence to conclude that glyphosate is a weak rodent carcinogen and/or tumor promoter"); SUF No. 136.

[65] Zuckerman Decl., Exh. PP, at 4-5; SUF No. 87. Dr. Cogliano is currently Deputy Director for Scientific Programs at OEHHA.

B. EPA's and IARC's Divergent Conclusions Reflect, at Least in Part, Reliance on Different Sets of Studies.

Courts and commentators have suggested a number of explanations for the divergence in carcinogenicity findings among IARC, EPA, and other agencies. For example, with respect to the genotoxicity of glyphosate, there is evidence that (1) EPA relied mostly on unpublished studies commissioned by registrants like Monsanto, while IARC relied mostly on published, peer-reviewed studies;[66] (2) EPA focused on studies of pure glyphosate, while IARC considered studies of pure glyphosate as well as studies of exposures to glyphosate as it is actually sold, including formulations containing other chemicals in commercial products that are designed to ensure that glyphosate penetrates plant surfaces (and thus also more easily enters mammalian cells);[67] and (3) EPA focused on data for lower exposures typical of dietary exposures assuming the chemical was properly applied according to label instructions, while IARC did not limit its focus to those scenarios – its assessment encompassed data for the higher exposures encountered by workers and other persons who frequently apply large amounts of glyphosate.[68] This last explanation is consistent with OEHHA's more general conclusion, discussed in Background Section II.B, *supra*, that glyphosate is a weak carcinogen that does not pose a significant cancer risk at doses below 1,100 µg/day.

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[66] Zuckerman Decl., Exh. QQ, Benbrook, C.M. Environ Sci Eur (2019) 31: 2, https://doi.org/10.1186/s12302-018-0184-7, *How did the US EPA and IARC reach diametrically opposed conclusions on the genotoxicity of glyphosate-based herbicides?* Dr. Benbrook served as an expert witness for Mr. Hardeman in *Hardeman v. Monsanto*, discussed above.

[67] Zuckerman Decl., Exh. QQ, at 7-8; SUF No. 88.

[68] Zuckerman Decl., Exh. QQ, at 8-9; SUF No. 88.

C. EPA's Conclusion Has Been Subject to Criticism.

EPA's conclusion that glyphosate is not a carcinogen has been subject to criticism, among scientists and others, for at least two reasons: first, based on evidence that EPA failed to follow its own cancer guidelines, and, second, based on evidence that Monsanto improperly influenced EPA's scientific determination. These criticisms are discussed below.

1. EPA Failed to Follow Its Own Guidelines

Commentators have noted that EPA failed to follow its own guidelines in determining that glyphosate is not a carcinogen. Specifically:

(1) In its assessment of animal studies, EPA relied on one study (Reyna and Gordon (1973)), which concluded: "There were no treatment-related increases in tumor incidences observed in the study." But EPA had previously declared this study invalid because an audit of the laboratory revealed incidences of fraud.[69]

(2) EPA excluded all the studies that found a causal relationship between glyphosate or Roundup and non-Hodgkin's lymphoma or other types of cancer based on statistical determinations that have been disputed, without evaluating the validity of the dispute.[70]

(3) EPA excluded the results of one of the studies that showed a strong link between glyphosate and tumors on the grounds that there was a leukemia virus in the colony, even though independent observers found there was no evidence of health

[69] Zuckerman Decl., Exh. RR, at 1784-1787; SUF No. 89.
[70] Zuckerman Decl., Exh. RR, at 1788-1806; SUF No. 90.

deterioration due to viral infection, and thus the actual basis of EPA's decision to exclude the study is unknown.[71]

(4) EPA's own Science Advisory Panel concluded: "Overall the panel concluded that the EPA evaluation does not appear to follow the EPA 2005 cancer guidelines in several ways, notably for use of historical control data and statistical testing requirements."[72]

(5) In making its determination regarding the carcinogenicity of glyphosate, EPA relied on a large number of studies on bacteria (54 of 109), all of which were negative, which caused it to understate the overall genotoxicity of glyphosate.[73]

2. EPA Was Influenced by Monsanto's Efforts to Skew the Scientific Debate

Finally, three courts in the recent tort litigation against Monsanto, after hearing Monsanto's evidence during lengthy trials, concluded that the evidence supported jury findings that Monsanto engaged in conduct that skewed the scientific debate over the safety of glyphosate.

In affirming the jury's award of punitive damages against Monsanto, Judge Chhabria concluded that it was reasonable for the jury to conclude that Monsanto engaged in

> 'despicable conduct which [was] carried on by the defendant with a willful and conscious disregard of the rights or safety of others'. . . because the evidence easily supported a conclusion that Monsanto was more concerned with tamping down safety inquiries and manipulating public opinion than it was with ensuring its product is safe.

[71] Zuckerman Decl., Exh. RR, at 1807-1814; SUF No. 91.
[72] Zuckerman Decl., Exh. BB, at 18; SUF No. 92.
[73] Zuckerman Decl., Exh. QQ, at 5, 9; SUF No. 93.

In re Roundup Prods. Liab. Litig. (*Hardeman v. Monsanto Co.*)), 385 F. Supp. 3d 1042, 1046 (N.D. Cal. 2019) (quoting Cal. Civ. Code § 3294(c)(1)).

Similarly, in denying Monsanto's motion for summary adjudication of claims for punitive damages, Judge Karnow held:

> The internal correspondence noted by Johnson could support a jury finding that Monsanto has long been aware of the risk that its glyphosate-based herbicides are carcinogenic, and more dangerous than glyphosate in isolation, but has continuously sought to influence the scientific literature to prevent its internal concerns from reaching the public sphere and to bolster its defenses in products liability actions.[74]

Judge Smith's finding was the most explicit. In denying Monsanto's motion for a JNOV, she held that:

> Monsanto's efforts to impede, discourage, or distort the scientific inquiry about glyphosate, support a jury finding that ***it could not reasonably rely on the EPA's regulatory action or inaction that was based on that science***.[75]

These courts, which carefully reviewed Monsanto's evidence and defenses before trial (Judge Karnow in *Johnson v. Monsanto*) or after the trial (Judge Chhabria in *Hardeman v. Monsanto* and Judge Smith in *Pilliod v. Monsanto*) thus found that there was evidence that Monsanto improperly skewed the scientific debate. Judge Smith expressly concluded that this may explain why EPA reached a conclusion different from IARC's on the carcinogenicity of glyphosate.[76]

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[74] Zuckerman Decl., Exh. NN, at 45; SUF No. 96.

[75] Zuckerman Decl., Exh. OO, at 19 (emphasis added); SUF No. 99.

[76] The conclusions of Judges Karnow, Chhabria and Smith find support in two recently published papers. Zuckerman Decl., Exh. SS at 318 ("The findings include evidence of ghostwriting, interference in journal publication, and undue influence of a federal regulatory agency."); SUF No. 100; Zuckerman Decl., Exh. TT, at 193 ("The documents reveal Monsanto-sponsored ghostwriting of articles published in toxicology journals and the lay media, interference in the peer review process, behind-the-scenes

D. EPA's Recent Letter to Pesticide Registrants Was Not Prompted by any New Findings.

Subsequent to the flood of negative publicity after the jury verdicts against Monsanto, and the ever-increasing number of personal injury lawsuits filed against Monsanto related to Roundup (42,700 as of October 2019[77]), on August 7, 2019, Michael L. Goodis, Director of the Registration Division of the Office of Pesticide Programs at the EPA, issued a letter to pesticide registrants informing them that EPA had determined that glyphosate is "not likely to be carcinogenic to humans."[78] It relied on no new scientific findings or developments in reaching this conclusion.[79] Mr. Goodis wrote that EPA would not approve Proposition 65 warning labels for glyphosate products.[80] OEHHA responded with a statement posted on its website on August 12, 2019, in which it noted that it is "disrespectful of the scientific process for US EPA to categorically dismiss any warnings based on IARC's determinations as false."[81]

IV. STATUTORY AND REGULATORY BACKGROUND: PROPOSITION 65

A. Proposition 65's Warning Requirement and its Purpose.

The Safe Drinking Water and Toxic Enforcement Act, commonly known as Proposition 65, was enacted by initiative in 1986. The law requires the Governor of California to publish a "list of those chemicals known to the state to cause cancer or reproductive toxicity within the meaning of this chapter." §

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influence on retraction and the creation of a so-called academic website as a front for the defense of Monsanto products."); SUF No. 101.

[77] Zuckerman Decl., Exh. NNN; SUF No. 102.

[78] Zuckerman Decl., Exh. Q; SUF No. 102.

[79] *Id.*

[80] Zuckerman Decl., Exh. Q; SUF No. 104.

[81] Zuckerman Decl., Exh. VV; SUF No. 106.

25249.8(a). The law was passed in response to voters' concerns, expressly set out in the ballot materials and in the Preamble to the Act, that "'hazardous chemicals pose a serious potential threat to their health and well-being, [and] that state government agencies have failed to provide them with adequate protection. . . .'" *AFL-CIO v. Deukmejian*, 212 Cal. App. 3d 425, 430 (Cal. Ct. App. 1989) (quoting the Ballot Pamphlet for Proposition 65, at 53) (*Deukmejian*).

Proposition 65 has been highly effective in providing information to consumers and in encouraging businesses to remove toxic chemicals from their products so that they do not need to provide a warning. These successes have included the following:

- Reducing lead in candy, jewelry, soda bottles, and children's toys, among other consumer products;
- Removing lead and hexavalent chromium from dietary supplements;
- Reducing formaldehyde in hair-straightening products, and requiring that stylists who apply these products be warned of exposure;
- Reducing chemical flame retardant in children's mattress pads and other products;
- Reducing metal plating businesses' emissions of hexavalent chromium – a potent carcinogen – into residential neighborhoods, and providing precise exposure warnings;
- Reducing emissions of diesel exhaust in areas around the Ports of Los Angeles and Long Beach that are impacted by high levels of truck and ship traffic, and requiring

warnings so that residents can take action to protect their own health.[82]

B. The Listing Mechanisms.

The main purpose of the warning provision of Proposition 65 is to convey information: specifically, the voters wanted to be "informed about exposures to chemicals that cause cancer, birth defects, or other reproductive harm."[83] *California Chamber of Commerce v. Brown*, 196 Cal. App. 4th 233, 258 (Cal. Ct. App. 2011) (quoting Text of Proposition 65, Preamble, in the Ballot Pamphlet, at 53). Businesses are required to warn Californians before exposing them to listed chemicals, subject to the specific terms of the Act.[84]

In accordance with the statute's remedial purpose, the list of chemicals, and the definition of "chemicals that cause cancer," is intentionally broad: it includes chemicals that cause cancer in animals even if they have not been shown to cause cancer in humans. *Deukmejian*, 212 Cal. App. 3d at 441. Recognizing that scientific knowledge changes over time, and even highly regarded scientific agencies can disagree, the statute does not require consensus among the agencies on whose

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[82] Zuckerman Decl., Exh. XX; SUF No. 108.

[83] The preamble provides, in pertinent part, "The people of California find that hazardous chemicals pose a serious potential threat to their health and well-being, that state government agencies have failed to provide them with adequate protection, and that these failures have been serious enough to lead to investigations by federal agencies of the administration of California's toxic protection programs. The people therefore declare their rights: (a) To protect themselves and the water they drink against chemicals that cause cancer, birth defects, or other reproductive harm. (b) To be informed about exposures to chemicals that cause cancer, birth defects, or other reproductive harm. . . ." Zuckerman Decl., Exh. WW; SUF No. 109.

[84] Proposition 65 also prohibits the discharge of listed chemicals to sources of drinking water. § 25249.5.

determinations chemicals are listed as carcinogens.

Proposition 65 provides four separate mechanisms for listing chemicals, each with its own distinct and independent requirements. §§ 25249.8(a), (b). Three of the listing mechanisms rely on work conducted by outside scientific and regulatory entities. *Id.* These entities include the Food and Drug Administration, the EPA, the National Toxicology Program, and IARC. 27 CCR, § 25306(l), (m).

C. The Listing Mechanism Applicable in This Case.

Under the listing mechanism at issue here, the so-called Labor Code listing mechanism of section 25249.8(a), OEHHA must list "at a minimum those substances identified by reference in Labor Code section 6382(b)(1)," a provision of the California Labor Code concerned with workplace hazards. Section 6382(b)(1), in turn, identifies "[s]ubstances listed as human or animal carcinogens by [IARC]."

Consistent with their distrust of state agencies, the voters made a specific decision when they enacted the Proposition 65 warning requirement: they wanted to be informed before they were exposed to chemicals that had been identified by certain *outside* entities as causing cancer. *See* § 25249.8(a); Cal. Lab. Code §§ 6382(b)(1), (d). Among those outside entities was IARC, an "'organization[] of the most highly regarded national and international scientists.'" *Deukmejian*, 212 Cal. App. 3d at 436. The proponents of Proposition 65 made this clear in the ballot pamphlet:

> At a minimum, the Governor must include the chemicals already listed as known carcinogens by two organizations of the most highly regarded

> national and international scientists: the U.S.'s National Toxicology Program and the U.N.'s International Agency for Research on Cancer.[85]

Even if there were a disagreement between IARC, the only scientific authority specifically identified in the statute, Cal. Health and Safety Code section 25249.8(a), and another agency, the voters still wanted to be warned about exposures to chemicals that IARC had classified as carcinogens, so that they could make their own choices about their own cancer risks. The California Court of Appeal, in rejecting Monsanto's challenge to the listing of glyphosate, noted that the voters wanted the Proposition 65 list *always* to include IARC-identified chemicals:

> Thus, the various listing mechanisms were included to ensure "the Proposition 65 list of chemicals 'known to the state to cause cancer or reproductive toxicity' *always* includes 'at a minimum' those substances identified by reference to Labor Code section 6382, subdivisions (b)(1) and (d)."

Monsanto v. OEHHA, 22 Cal. App. 5th 534 at 552-553 (emphasis in original) (quoting *California Chamber of Commerce v. Brown*, 196 Cal. App. 4th at 259-260). The court specifically held that voters adopted an inclusionary process for creating the Proposition 65 list, which "allows one of the various mechanisms for listing a chemical as known to the state to cause cancer to ensure that chemical is on the list ***regardless of whether other identified listing agencies or processes agree***." *Id.* at 556, 552-553 (emphasis added).

[85] Zuckerman Decl., Exh. WW; SUF No. 110. "The courts often turn to the ballot summaries and arguments for the purpose of determining the voters' intent and understanding of a ballot measure." *Legislature v. Deukmejian*, 34 Cal. 3d 658, 673 (Cal. 1983) (citation and internal quotation marks omitted.)

D. Standards for Including Chemicals that IARC has Listed as Carcinogens.

The Labor Code listing mechanism does not limit the Proposition 65 list to chemicals that have been shown to cause cancer in humans – many animal carcinogens are also included on the list. *AFL-CIO v. Deukmejian*, 212 Cal. App. 3d at 441. The voters chose this approach for good reason: "It is unethical to test humans, and because of the 20-to 30-year latency period of many human cancers, epidemiological studies do not adequately warn humans and protect them from the risk of exposure to new carcinogens." *Deukmejian*, 212 Cal. App. 3d at 438 n.7. The principle that supports qualitative animal-to-human extrapolation from carcinogenesis "has been accepted by all health and regulatory agencies and is regarded widely by scientists in industry and academia as a justifiable and necessary inference." *Id.* (quoting Report, Office of Science and Technology Policy, 50 Fed. Reg. 10375 (Mar. 14, 1985)).[86]

Proposition 65 requires OEHHA to list chemicals that IARC has classified as carcinogenic to humans (Group 1), probably carcinogenic to humans (Group 2A), or possibly carcinogenic to humans (Group 2B), although it lists Group 2A and 2B chemicals only if IARC has found sufficient evidence of carcinogenicity in experimental animals. *Styrene Info. and Research Ctr. v. Office*

[86] This parallels federal agency understanding of the meaning of "carcinogen." *See, e.g.*, 29 C.F.R. § 1910.1200, App. A.6.1 ("Carcinogen means a substance or a mixture of substances which induce cancer or increase its incidence. Substances and mixtures which have induced benign and malignant tumors in well-performed experimental studies on animals are considered also to be presumed or suspected human carcinogens unless there is strong evidence that the mechanism of tumor formation is not relevant for humans.")

of Envtl. Health Hazard Assessment, 210 Cal. App. 4th at 1101; 27 CCR, § 25904 (b),(b)(2), (b)(3). OEHHA did so in this case, determining that IARC had concluded that there was "sufficient evidence of carcinogenicity in experimental animals and limited evidence in humans."[87] It placed glyphosate on the Proposition 65 list on July 7, 2017.

E. The Warning Requirement.

Twelve months after a chemical is listed, any business with ten or more employees must provide a clear and reasonable warning if it "knowingly and intentionally expose[s] any individual [in California] to a chemical known to the state to cause cancer or reproductive toxicity . . . ." §§ 25249.6, 25249.10(b). A business can cure a violation of § 25249.6 (the "warning requirement") either by discontinuing the exposure, or by providing a warning to those exposed.

A business need not provide a warning for a listed carcinogen if it can show that the exposure it causes "poses no significant risk assuming lifetime exposure at the level in question." § 25249.10(c); *Monsanto v. OEHHA*, 22 Cal. App. 5th at 559-560; *DiPirro v. Bondo Corp.*, 153 Cal. App. 4th 150, 188 (Cal. Ct. App. 2007). This "no significant risk" level (NSRL) is defined as an exposure that results in no more than "one excess case of cancer in an exposed population of 100,000, assuming lifetime exposure at the level in question."[88] 27 CCR, § 25703(b). In short, if a business shows that the exposure it causes will result in *no more than one excess case of cancer* per 100,000 exposed individuals,

[87] Zuckerman Decl., Exh. YY; SUF No. 111.
[88] *See* Glossary attached as Exhibit A.

it need not provide a warning.[89] This provides a safeguard against a requirement for warnings when there is no significant risk of cancer. *Monsanto v. OEHHA*, 22 Cal. App. 5th at 558. While OEHHA is not required to set a "relevant exposure level" for all listed chemicals, it did so for glyphosate.

1. The No Significant Risk Level.

For many chemicals, OEHHA has adopted an NSRL by regulation, commonly called a "safe harbor." *See* 27 CCR, § 25705. The safe-harbor level represents the level of exposure to a listed carcinogen that does not require a warning under Proposition 65. In this case, OEHHA conducted a formal rulemaking process in order to set an NSRL for glyphosate. As further noted at Background Section II.B, *supra*, OEHHA's scientists carefully reviewed the scientific record and the voluminous comments they received, and, in a 48-page analysis, determined the following: (1) the studies on which IARC relied provided sufficient evidence of carcinogenicity in animals; and (2) there is strong evidence that mechanisms by which glyphosate could cause cancer in animals (genotoxicity and oxidative stress) can operate in humans. Based on the most sensitive scientific study that OEHHA found to be of sufficient quality, OEHHA set an NSRL of 1,100 µg/day for glyphosate.[90]

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[89] This 1/100,000 cancer risk level is set by regulation. 27 CCR, § 25703(b). It is less strict than the "1 in 1,000,000 risk" level standard used by many regulatory agencies. *See Ingredient Communication Council v. Lungren*, 2 Cal. App. 4th 1480, 1494, n.8 (Cal. Ct. App. 1992) ("The threshold risk under Proposition 65 is not especially low compared to other epidemiological standards commonly used by regulatory bodies.")

[90] Zuckerman Decl., Exh. O; SUF No. 44-50. Plaintiffs' suggestion that OEHHA should have used this rulemaking to second-guess the underlying scientific basis for the glyphosate listing,

On July 1, 2018, OEHHA formally adopted this NSRL for glyphosate of 1,100 µg/day.[91] This is the third-highest NSRL that OEHHA has set. 27 CCR, § 25705. Businesses do not need to provide a warning for exposures shown to be below this safe harbor level. 27 CCR, § 25705(a). Moreover, since the NSRL is a "safe harbor" level, businesses are not bound by it, and, in defending a Proposition 65 action, they can seek to prove that a higher no significant risk level should apply. *Id.*

2. Businesses May Seek a Safe-Use Determination or an Interpretive Guideline for Glyphosate.

A business that has not received a notice from a private enforcer that it intends to enforce pursuant to section 25249.7(d) (60-day notice), but which is concerned about possible liability may also seek a "safe use determination" from OEHHA. 27 CCR, § 25204. A safe use determination represents OEHHA's best judgment on whether Proposition 65 requires a specific business to provide a warning. *Id.*, § 25204(a). Although a safe use determination does not bar a lawsuit, OEHHA is unaware of any instance in which a business that received a safe use determination was subsequently sued.[92]

A business can also submit a request to OEHHA for an interpretive guideline pursuant to 27 CCR, § 25203. No entity has requested that OEHHA make a safe use determination or provide an interpretive guideline relating to glyphosate.[93]

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see Pltfs.' Br. at 25 n.8, which was based on the 2015 IARC carcinogenicity determination, displays a fundamental misunderstanding of the distinction between the listing process and setting an NSRL for a listed chemical.

[91] Zuckerman Decl., Exh. AA; SUF No. 52.

[92] Declaration of Martha Sandy, Ph.D. (Sandy Decl.), ¶ 6; SUF No. 114.

[93] Sandy Decl., ¶ 6; SUF No. 115.

3. The Impact of the 1,100 Micrograms/Day NSRL.

It is undisputed that businesses causing exposures to glyphosate at levels below 1,100 µg/day need not provide a warning. 27 CCR, § 25705. Plaintiffs argue that they will need to place Proposition 65 warnings on their "finished food products," Pltfs.' Br. at 27, but provide no evidence of the levels of glyphosate residues for any of these products. To address this lack of information, the Attorney General asked an expert toxicologist, Dr. Brian Lee, to survey publicly available test results for glyphosate residue in food products. Dr. Lee found that the reported glyphosate levels in finished food products ranged from 8 to 2,837 parts per billion, and that none of the finished food products for which testing is available would require a Proposition 65 warning based on the NSRL.[94] With respect to the cost of testing the products, Dr. Lee reached the following conclusions:

- Many of the foods have glyphosate levels so low that significant product testing is not likely to be necessary.[95]
- If testing food products for glyphosate is necessary, it will not be overly costly. The rates for testing food products range from $211.50 to $300.[96]
- Calculating whether the glyphosate residue in a food product causes it to exceed the NSRL is not complex. The calculation involves multiplying the glyphosate level in

[94] Declaration of Brian Lee, Ph.D. (Lee Decl.), ¶¶ 7-21; SUF No. 116.
[95] Lee Decl., ¶ 24; SUF No. 118.
[96] Lee Decl., ¶ 22; SUF No. 117.

> the product by the average serving size and number of servings per day for that food. If the result is below 1,100 µg, no Proposition 65 warning is required.[97]

An accurate calculation showing an exposure of less than 1,100 µg/day is a complete defense to any Proposition 65 action alleging failure to provide a warning for exposure to the average consumer of a product to glyphosate. *See* 27 CCR, § 25703(b).

4. Warning Language.

Proposition 65 does not dictate the contents of the warning, as long as it is "clear and reasonable" in conveying that the chemical is "known to the state to cause cancer." § 25249.6. OEHHA has adopted "safe harbor" warning methods and content deemed to meet that standard. 27 CCR, §§ 25601-25607.33; *see also Environmental Law Found. v. Wykle Research, Inc.*, 134 Cal. App. 4th 60, 66 (Cal. Ct. App. 2005).

Use of the safe-harbor warning language, however, is *optional*. A business may use any other warning method or content that is clear and reasonable, § 25249.6; 27 CCR, § 25601, and a court may approve a more nuanced warning that it deems appropriate. Attached to the Declaration of Laura Zuckerman are several examples of Proposition 65 consent judgments in which courts have approved warnings that depart from the safe harbor language.[98] Whether a non-safe-harbor warning is clear and reasonable is determined on a case-by-case basis. *Ingredient Commc'n Council*, 2 Cal. App. 4th at 1480, 1492 (Cal. Ct. App. 1992).

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[97] Lee Declaration, ¶ 11; SUF No. 119.

[98] Zuckerman Decl., Exh. AAA; Zuckerman Decl., Exh. BBB; SUF No. 121.

5. Proposition 65 Enforcement.

Proposition 65 may be enforced by the Attorney General, by any district attorney, and by city attorneys in certain large cities. § 25249.7(c). Private citizens may also enforce the statute "in the public interest," with certain restrictions. § 25249.7(d). To file an enforcement action, a private enforcer must first provide notice of the alleged violation to the public prosecutors and to the alleged violator. § 25249.7(d)(1). If, after 60 days, no public prosecutor is diligently prosecuting the violation, then the private enforcer may file suit. *Id.*

In response to concerns over frivolous private enforcement actions, the California Legislature amended Proposition 65 in 2002 to require private enforcers to demonstrate the basis for their belief that an action has merit before proceeding with private enforcement. *DiPirro v. American Isuzu Motors, Inc.*, 119 Cal. App. 4th 966, 970 (Cal. Ct. App. 2004). The private enforcer must submit a "certificate of merit" with each 60-day notice stating that the person executing the certificate has consulted with relevant experts who have reviewed "facts, studies, and other data regarding the exposure" at issue and that, based on that consultation, the noticing party believes "there is a reasonable and meritorious case for the private action." § 25249.7(d)(1). The noticing party must submit confidential, factual information to the Attorney General "sufficient to establish the basis of the certificate of merit. . . ." *Id.*

In 2017, the Legislature further amended the law to strengthen the Attorney General's ability to impede frivolous

actions by private enforcers. If, after meeting and conferring with the noticing party, the Attorney General believes there is no merit to a 60-day notice, the Attorney General must send a letter to the noticing party and the alleged violator stating his view that it has no merit, and post the letter on the Attorney General's website.[99] §§ 25249.7(e)(1)(A), (g); *see also, e.g.*, letters attached as Exhibits CCC, DDD, and EEE to the Declaration of Laura Zuckerman. Plaintiffs' assertion that such letters are optional, Pltfs.' Br. at 21 n.7, is incorrect. §§ 25249.7(e)(1)(A), (g).

With respect to glyphosate residue in food products, a private enforcer who sends a 60-day notice will need to provide a certificate of merit that contains laboratory testing showing the concentration of glyphosate in the product.[100] The Attorney General's practice will be (1) to multiply that concentration by the estimated daily consumption of the food, and (2) if the result is an exposure of less than 1,100 µg/day, to demand that the sixty-day notice be withdrawn.[101] The Attorney General has seen no evidence of levels of glyphosate in food products that

[99] The cases cited in support of the plaintiffs' claim that the certificate of merit requirement is "trivial to satisfy" all pre-date the 2017 statutory change. Pltfs.' Br. at 16. Moreover, in the case of glyphosate, because it is likely that not all products in a class expose Californians to similar levels of the chemical (some may not expose them to any), the certificate of merit provision will require private enforcers to conduct laboratory testing of glyphosate residues in food products and estimate average daily consumption, and to provide reasonable exposure scenarios in cases involving non-food products.

[100] Declaration of Susan Fiering ("Fiering Decl."), ¶ 8; SUF No. 123.

[101] Fiering Decl., ¶ 8; SUF No. 123.

would expose consumers to more than 1,100 µg/day; indeed, the available evidence suggests otherwise.[102]

V. PROCEDURAL BACKGROUND

On December 6, 2017, plaintiffs filed a Motion for Preliminary Injunction, asking the Court to enjoin (1) OEHHA's listing of glyphosate as a chemical known to cause cancer, and (2) the warning requirement of Health & Safety Code section 25249.6 as applied to glyphosate. In an order dated February 26, 2018, the court denied plaintiffs' request to enjoin the listing, but preliminarily enjoined the warning requirement, finding, inter alia, that "the required warning for glyphosate does not appear to be factually accurate and uncontroversial because it conveys the message that glyphosate's carcinogenicity is an undisputed fact, when almost all other regulators have concluded that there is insufficient evidence that glyphosate causes cancer." Memorandum and Order Re: Motion for Preliminary Injunction, Docket No. 75, at 15.

On March 26, 2019, the Attorney General filed a motion to alter or amend the Court's Order. Docket No. 81. In the motion, the Attorney General (1) cited sources that supported IARC's determination that glyphosate is a carcinogen, and disagreeing with agencies that found it was not; and (2) proposed additional warning alternatives, including one that stated:

> **WARNING:** This product can expose you to glyphosate, a chemical listed as causing cancer pursuant to the requirements of California law. The listing is based on a

[102] Lee Decl.; ¶ 11-22; SUF No. 124. Thus, the need for warnings on such products, especially for food products – because glyphosate levels in these foods are not likely to exceed 1,100 µg of glyphosate per day for the average consumer – is completely speculative.

> determination by the United Nations International Agency for Research on Cancer that glyphosate presents a cancer hazard. The U.S. Environmental Protection Agency has tentatively concluded in a draft document that glyphosate does not present a cancer hazard. For more information go to www.P65warnings.ca.gov.

On June 12, 2018, the Court denied the motion. Memorandum and Order Re: Motion to Alter or Amend Preliminary Injunction Order, Docket No. 97. The Court found, inter alia, that: (1) the motion did not provide new evidence that warranted reconsideration, *id.* at 4; (2) the new studies did "not change the fact that the overwhelming majority of agencies that have examined glyphosate have determined it is not a cancer risk," *id.* at 5; and (3) the proposed warning was deficient because it "conveys the message that there is equal weight of authority for and against the proposition that glyphosate causes cancer, or that there is more evidence that it does, given the language stating that the EPA's findings were only tentative, when the heavy weight of evidence in the record is that glyphosate is not known to cause cancer[,]" *id.* at 9.

LEGAL STANDARD

"Summary judgment is appropriate when, viewing the evidence in the light most favorable to the nonmoving party, 'there is no genuine dispute as to any material fact.'" *United States v. JP Morgan Chase Bank Account No. Ending 8215 in Name of Ladislao v. Samaniego, VL: $446,377.36*, 835 F.3d 1159, 1162 (9th Cir. 2016) (quoting Fed. R. Civ. P. 56(a)). A material fact is one that could affect the outcome of the case, and a genuine dispute about a material fact is one that could permit a reasonable fact-finder

to enter a verdict in the non-moving party's favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

ARGUMENT

I. THE FIRST AMENDMENT ISSUE PRESENTED BY THIS CASE IS UNRIPE.

The complaint does not allege a controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment such as that sought here, and thus the matter fails both the constitutional and prudential tests for ripeness. The First Amendment claim related to enforcement of the warning requirement is devoid of factual context, because there is no evidence that Proposition 65 would require a warning for any of the plaintiffs in this case.

A. A Case Is Not Ripe Where There Is No Actual Controversy and No Credible Threat of Enforcement.

The role of the federal courts is "neither to issue advisory opinions nor to declare rights in hypothetical cases, but to adjudicate live cases or controversies consistent with the powers granted the judiciary in Article III of the Constitution." *Thomas v. Anchorage Equal Rights Comm'n*, 220 F.3d 1134, 1138 (9th Cir. 2000); *see also, e.g., Ray Charles Found. v. Robinson*, 795 F.3d 1109, 1116 (9th Cir. 2015) (ripeness goes to the court's subject matter jurisdiction to hear a case); *Alaska Right to Life Political Action Comm. v. Feldman*, 504 F.3d 840, 844 (9th Cir. 2007) (without fully developed factual record showing real threat of enforcement and hardship resulting from withholding federal adjudication, district court should have declined jurisdiction for lack of a justiciable case or controversy). The ripeness requirement "prevent[s] the courts, through avoidance of

premature adjudication, from entangling themselves in abstract disagreements . . . ." *Abbott Lab. v. Gardner*, 387 U.S. 136, 148 (1967), overruled on other grounds, *Califano v. Sanders*, 430 U.S. 99 (1977).

The ripeness inquiry has both constitutional and prudential components. *Nat'l Park Hospitality Ass'n v. Dep't of Interior*, 538 U.S. 803, 808 (2003). For a claim to be ripe in the constitutional sense in a declaratory judgment case, "the facts alleged, under all the circumstances, [must] show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Montana Env'l Info. Center v. Stone-Manning*, 766 F.3d 1184, 1188 (9th Cir. 2014) (citations and internal quotation marks omitted); *Colwell v. Dep't of Health & Human Serv.*, 558 F.3d 1112, 1123 (9th Cir. 2009) (dispute must "present concrete legal issues, presented in actual cases, not abstractions") (citations and internal quotation marks omitted). "[N]either the mere existence of a proscriptive statute nor a generalized threat of prosecution satisfies the 'case or controversy' requirement." *Thomas*, 220 F.3d at 1139.

Courts may also decline to exercise jurisdiction based on prudential considerations. *Thomas*, 220 F.3d at 1141. These prudential considerations are twofold: "'the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration.'" *Id.* (quoting *Abbott Lab.*, 387 U.S. at 149). When evaluating hardship, the court is to consider "whether the 'regulation requires an immediate and significant change in the plaintiffs' conduct of their affairs with serious

penalties attached to noncompliance.'" *Stormans, Inc. v. Selecky, 586 F.3d 1109, 1126 (9th Cir. 2009)* (quoting *Ass'n of Am. Med. Colls. v. United States, 217 F.3d 770, 783 (9th Cir. 2000)*).

The prudential considerations embodied in the ripeness doctrine weigh in favor of prompt federal court resolution of the claims presented only when delaying their adjudication would put the court in no better position to decide the issue. *See Duke Power Co. v. Carolina Envtl. Study Group, Inc.*, 438 U.S. 59, 81-82 (1978). When, as here, delaying adjudication will not prejudice plaintiffs' ability to "vindicate their constitutional claims later, with a better factual record," the issue is unripe from a prudential perspective. *Alaska Right to Life Political Action Comm.*, 504 F.3d at 852 (citing *San Diego Cty. Gun Rights Comm. v. Reno*, 98 F.3d 1121, 1133 (9th Cir. 1996) ("concluding that dismissal would not create undue hardship because '[p]laintiffs will have the opportunity to raise their constitutional objections . . . if and when the government initiates a criminal prosecution against them under the [challenged] statute")).

Although an allegation of injury to First Amendment rights more readily justifies a finding of ripeness "due to the chilling effect on protected expression which delay might produce[,]" *American-Arab Anti-Discrimination Comm. v. Reno*, 70 F.3d 1045, 1062 (9th Cir. 1995) (citation and internal quotation marks omitted), the Ninth Circuit has made clear that:

> [not] any plaintiff may challenge the constitutionality of a statute on First Amendment grounds by nakedly asserting that his or her speech was chilled by the statute. The self-

> censorship door to [justiciability] does not open for every plaintiff. *The potential plaintiff must have an actual and well-founded fear that the law will be enforced against [him or her].*

California Pro-Life Council, Inc. v. Getman, 328 F.3d 1088, 1093, 1095 (9th Cir. 2003) (citations and internal quotation marks omitted, emphasis added); *see also, e.g., Alaska Right to Life Political Action Comm.*, 504 F.3d at 851 (court may adopt this "somewhat relaxed approach to justiciability . . . only upon a showing that plaintiff is immediately in danger of sustaining a direct injury as a result of an executive or legislative action") (citations and internal quotation marks omitted); *Italian Colors Restaurant v. Becerra*, 878 F.3d 1165, 1171 (9th Cir. 2018) (even in First Amendment context, plaintiff must demonstrate "credible threat of enforcement").

In *Thomas*, landlords who refused to rent to unmarried couples brought a First Amendment pre-enforcement challenge to a statute and ordinance prohibiting marital status discrimination in rental decisions. 220 F.3d at 1138. The Ninth Circuit found the action unripe, both on constitutional and prudential grounds, because the record was "devoid of any specific factual context." *Id.* at 1141. The court explained:

> The record before us is remarkably thin and sketchy, consisting only of a few conclusory affidavits. "A concrete factual situation is necessary to delineate the boundaries of what conduct the government may or may not regulate." *San Diego County*, 98 F.3d at 1132. And yet, the landlords ask us to declare Alaska laws unconstitutional, in the absence of any identifiable tenants and with no concrete factual scenario that demonstrates how the laws, as applied, infringe their constitutional rights.

Id.; *see also, e.g., American-Arab Anti-Discrimination Comm. v. Thornburgh*, 970 F.2d 501, 510-11 (9th Cir. 1992) (case "with many

unknown facts" and a "sketchy record" is not fit for review); *Alaska Right to Life Political Action Comm.*, 504 F.3d at 849-51 (district court should have declined to exercise jurisdiction on prudential ripeness grounds, given inadequately developed record and absence of a showing that withholding jurisdiction would impose hardship on the parties) ("Not only is there a lack of any credible threat of enforcement, but neither plaintiff is potentially subject to enforcement of the Code"). In short, courts should not decide "'constitutional questions in a vacuum.'" *American-Arab Anti-Discrimination Comm. v. Thornburgh*, 970 F.2d at 511 (quoting *W.E.B. DuBois Clubs of America v. Clark*, 389 U.S. 309, 312 (1967)).

B. Plaintiffs' Allegations That They Will Be Required to Place Warnings on Their Products Are Speculative and Unfounded.

The plaintiffs brought this action before the glyphosate warning requirement took effect, and thus before there could have been any credible threat of enforcement. While this Court has determined that was a sufficient threat of enforcement to issue a preliminary injunction in February 2018, developments since that ruling make it even less likely that plaintiffs will be subject to enforcement. Most significantly, OEHHA adopted the NSRL of 1,100 µg/day, making enforcement of the warning requirement highly unlikely in most exposure contexts.

1. Glyphosate Levels in Food Products Are Not Likely to Require a Warning.

The food producer plaintiffs in this litigation make a variety of claims about how their free speech rights are

allegedly affected by the Proposition 65 warning requirement for glyphosate. All of these claims are highly speculative.

The first group of food producer plaintiffs, exemplified by the Missouri Chamber of Commerce and Industry and the Associated Industries of Missouri, is illustrative. This group claims that if the preliminary injunction is dissolved, their members, who include farmers and food producers, will have to "(1) refuse to include the false warning and face a very high likelihood of being sued and incurring expensive litigation costs; (2) provide a false warning regarding their products, the effect of which will be to reduce demand for their products; or (3) stop using glyphosate treated crops." *See, e.g.*, Mehan Decl., ¶ 11; McCarthy Decl., ¶ 9.

However, all of the data the Attorney General has reviewed to date on glyphosate concentrations in finished food products make clear that the levels would not be high enough to require a warning or justify a Proposition 65 enforcement action. In fact, the only evidence in this record for finished food products demonstrates that food producers would have a complete defense under California Health & Safety Code section 25249.10(c) based on the 1,100 µg/day NSRL issued by OEHHA on July 1, 2018. See Lee Decl., ¶¶ 13-21. The ***highest*** level of glyphosate found in any of the 263 samples, or composite samples, of finished food product was 2,837 parts per billion in Quaker Oat Meal Squares – Honey Nut. *Id.*, ¶ 15. A consumer would have to eat 13.68 ounces – nearly an entire box – of this cereal every day in order to be exposed to 1,100 micrograms of glyphosate. *Id.* Since an average

consumer does not eat a box of this cereal every day, no warning would be required. *Id.*

Because there is currently no "past or future actionable violation" of Proposition 65, there is no justiciable controversy regarding whether any warning compelled by the statute violates the First Amendment. *See, e.g., Knapp v. City of Coeur d'Alene*, 172 F. Supp. 3d 1118, 1135-36 (D. Idaho 2016).

2. There Is No Evidence That Use of Glyphosate-Based Pesticides by Consumers Will Cause Exposures in Excess of the NSRL.

Even manufacturers of glyphosate have nothing more than a speculative concern about possible Proposition 65 enforcement. Plaintiffs have presented no evidence that average exposures resulting from home, garden, and other non-occupational uses of glyphosate will exceed the NSRL. To the contrary, the lifetime average daily exposure to glyphosate from a concentrated glyphosate-based pesticide used by the average user for weed control purposes will not exceed 81.92 µg/day, and the lifetime average daily exposure to glyphosate from a dilute "ready-to-use" glyphosate-based pesticide used by the average user for weed control purposes will not exceed 2.78 µg/day, in both cases nowhere near the no significant risk level of 1,100 µg/day.[103]

In these circumstances, manufacturers cannot show that they possesses a "well-founded fear that the law will be enforced against [them]." *Getman*, 328 F.3d 1095 (internal quotation marks omitted); *see also, e.g., Wolfson v. Brammer*, 616 F.3d 1045, 1063

[103] Declaration of Martha Sandy, Ph.D., ¶ 5. This estimate does not apply to workers who may apply glyphosate more frequently and in greater quantities as part of their job requirements. *Id.*

(9th Cir. 2010) (fear concerning a possibility of enforcement "is insufficient to satisfy the constitutional component of ripeness").

3. Unique Proposition 65 Warnings Are Not Required for Occupational Exposures to Glyphosate Where Companies Comply with Federal OSHA Requirements, and Plaintiffs Have Provided No Evidence of Past or Future Actionable Violations.

Similarly, there is likely no viable past or future violation of Proposition 65 in the occupational context because a business's compliance with federal OSHA regulations also suffices to meet the requirements of Proposition 65. Under federal law, employees working with chemicals listed as carcinogens or potential carcinogens by certain authoritative bodies, including IARC, must be informed of the listing by means of an SDS.[104] 29 C.F.R. § 1910.1200, App. D. Thus, employees of Monsanto and other manufacturers of glyphosate, and other persons who are exposed to glyphosate in an occupational setting, must be informed, by means of an SDS, that IARC has listed glyphosate as a potential carcinogen. Providing this information on the SDS complies with the Proposition 65 requirement to warn about occupational exposures. *See* 27 CCR, § 25606 (providing that an occupational Proposition 65 warning is adequate if it meets the requirements of 29 C.F.R. § 1910.1200 (referenced above), Cal.

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[104] Federal law requires the SDS to state:

> **Whether the hazardous chemical** is listed in the National Toxicology Program (NTP) Report on Carcinogens (latest edition) or **has been found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs (latest edition)**, or by OSHA.

29 C.F.R. § 1910.1200, App. D (emphasis added).

Code Regs. tit. 8, § 5194, or, for pesticides, Cal. Code Regs. tit. 3, §§ 6700 et seq. Thus, any manufacturer that provides an SDS stating that IARC has classified glyphosate as a carcinogen has no "plausible and reasonable fear of prosecution." *Wolfson*, 616 F.3d at 1062.

4. The Possibility that Plaintiffs Will Face Meritless Proposition 65 Enforcement Actions Does Not Establish a Credible Threat of Prosecution for Purposes of the Ripeness Requirement.

Plaintiffs argue that the defenses to enforcement built in to Proposition 65 should be disregarded because private plaintiffs can always file non-meritorious actions. *E.g.*, Pltfs.' Br. at 27. This argument is specious. It is always the case that plaintiffs can file non-meritorious enforcement actions, but such actions do not give rise to a justiciable controversy, even in the First Amendment context. *See, e.g.*, *Wolfson*, 616 F.3d at 1062 (statute that does not at least arguably cover plaintiff's conduct does not give rise to reasonable fear of prosecution) (citing *Virginia v. Am. Booksellers Ass'n*, 484 U.S. 383, 392 (1988) and *Majors v. Abell*, 317 F.3d 719, 721 (7th Cir. 2003)); *Knapp v. City of Coeur d'Alene*, 172 F. Supp. 3d at 1135-36 (no justiciable First Amendment controversy where no past or future actionable violation). Further, as discussed above (*supra* at Background Section IV.E.5), the Attorney General, as the lead enforcer of Proposition 65, reviews the 60-day notices to determine if they appear to lack merit, and informs the parties in a public letter when he or she determines they do not. Declaration of Susan S. Fiering (Fiering Decl.), ¶¶ 6, 9. Faced with such a letter from the Attorney General, it is highly

speculative that a private enforcer would proceed to file a lawsuit, especially given the risk that the suit could ultimately be deemed frivolous under California Health & Safety Code section 25249.7(h)(2). *See, e.g.*, *Darring v. Kincheloe*, 783 F.2d 874, 877 (9th Cir. 1986) ("speculative" fears of prosecution are not ripe).

In sum, plaintiffs' fears of having to provide warnings, or being sued for not providing warnings, are speculative, and not likely to materialize. The Court should dismiss this case as unripe, because the plaintiffs cannot show that they possess the "actual and well-founded fear that the law will be enforced against [them]."[105] *Getman*, 328 F.3d 1095 (internal quotation marks omitted).

II. A GLYPHOSATE WARNING REQUIRED BY PROPOSITION 65 CAN COMPLY WITH THE FIRST AMENDMENT.

Because this matter is not ripe, the Court should not reach the question whether a Proposition 65 warning for glyphosate would comply with the First Amendment. Were the Court to reach the issue, however, the following discussion demonstrates that, even under the unique circumstances of two agencies, considered to be authoritative bodies under Proposition 65, having reached contemporaneous but contrary conclusions about a chemical, it is

[105] In this way, this case stands in stark contrast to *Nat'l Inst. of Family & Life Advocates v. Harris*, 839 F.3d 823, 833 (9th Cir. 2016), *rev'd and remanded sub nom. Nat'l Inst. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361 (2018), wherein the Ninth Circuit found the claims constitutionally ripe because the Appellants "explicitly stated that they will not comply with the Act, even if enforced. Appellants have made this pledge of disobedience although they are aware that violators of the Act are subject to civil penalties."

possible to create a Proposition 65 warning that complies with the First Amendment.

A. Disclosure Requirements Like Proposition 65 Are Subject to Reduced Scrutiny.

Although commercial speech is afforded First Amendment protection, Supreme Court "jurisprudence has emphasized that 'commercial speech [enjoys] a limited measure of protection, commensurate with its subordinate position in the scale of First Amendment values,' and is subject to 'modes of regulation that might be impermissible in the realm of noncommercial expression.'" *Bd. of Trs. v. Fox*, 492 U.S. 469, 477 (1989) (quoting *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 456 (1978)) (alteration in original). "First Amendment interests implicated by disclosure requirements" like those at issue in this case "are substantially weaker than those at stake when speech is actually suppressed."[106] *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 650 n.14 (1985); *Nat'l Inst. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361, 2372 (2018) (*NIFLA*) ("This Court's precedents have applied a lower level of scrutiny to laws that compel disclosures in certain contexts.").

In *Zauderer*, the Supreme Court upheld an Ohio regulation requiring attorneys who advertise their services on a contingent fee basis to state that a client may still bear certain expenses if the attorney loses. 471 U.S. at 651. The Court explained that First Amendment protection for commercial speech is "justified principally by the value to consumers of the

[106] For this reason, the numerous cases plaintiffs rely on that involve speech restrictions are inapposite.

information such speech provides," such that "[a party's] constitutionally protected interest in *not* providing any particular factual information in his advertising is minimal." *Id.* (emphasis in original). The Court emphasized that the regulation at issue only required the inclusion of "factual and uncontroversial information[,]" and held that there is no First Amendment violation where "disclosure requirements are *reasonably related* to the State's interest in preventing deception of consumers." *Id.* at 651 (emphasis added); *see also CTIA-The Wireless Ass'n v. City of Berkeley*, 928 F.3d 832, 845 (9th Cir. 2019), *cert. denied*, 2019 WL 6689680 (2019) (*CTIA II*) ("[u]nder *Zauderer*, compelled disclosure of commercial speech complies with the First Amendment if the information in the disclosure is reasonably related to a substantial government interest and is purely factual and uncontroversial.")

B. The Supreme Court's Decision in *NIFLA* and two Recent Ninth Circuit Decisions Demonstrate that Proposition 65 Warnings are Subject to Reduced Scrutiny Under *Zauderer*.

Since the Court preliminarily enjoined enforcement of the Proposition 65 warning requirement for exposures to glyphosate in February 2018, the Supreme Court issued its decision in *NIFLA*, in which the Court declined to apply the *Zauderer* test to a requirement that licensed pregnancy clinics provide patients with information about state-sponsored services, including abortion. 138 S. Ct. at 2372, 2378. The Court reaffirmed that it applies "a lower level of scrutiny to laws that compel disclosures in certain contexts," but held that *Zauderer* did not apply in that case because the notice at issue was not limited to "purely

factual and uncontroversial information about the terms under which . . . services will be available." *Id.* at 2372 (citation and quotation omitted) (noting that "abortion [is] anything but an 'uncontroversial' topic").

Following *NIFLA*, the Ninth Circuit has issued two opinions that provide further clarification on when and how to apply the test set forth in *Zauderer*.[107]

1. *American Beverage* Makes Clear that *NIFLA* Did Not Change the Analysis of Compelled Health and Safety Warnings.

In *American Beverage Ass'n v. City & County of San Francisco*, 916 F.3d 749 (9th Cir. 2019) (en banc), the Ninth Circuit evaluated the constitutionality under the First Amendment, in light of *NIFLA*, of a San Francisco ordinance requiring that certain advertisements for sugar-sweetened beverages include the following statement:

> WARNING: Drinking beverages with added sugar(s) contributes to obesity, diabetes, and tooth decay. This is a message from the City and County of San Francisco.

916 F.3d at 753. The ordinance at issue had detailed specifications for the form, content, and placement of these warnings on advertisements, including a requirement that the warning occupy at least 20% of the advertisement and be set off with a border. *Id.* at 754.

[107] It was for this very reason that the Court granted a stay of the litigation pending the issuance of these decisions. Order Re: Motion to Stay, Docket No. 109 ("Because *CTIA* and *American Beverage* concern the interpretation and application of *Zauderer's* "purely factual and uncontroversial" requirement, new decisions in those cases would assist the court in deciding any motion for summary judgment filed by the parties in this case.").

In beginning its analysis, the court rejected the argument that the heightened scrutiny that applies in situations in which speech is *restricted* should also apply whenever speech is *compelled*. *American Beverage*, 916 F.3d at 755. It also rejected the argument that *Zauderer* applies only in situations in which disclosure is required to prevent consumer deception, an argument plaintiffs make here.[108] *Id.*; Pltfs.' Br. at 32-33, n.11. The court held that *Zauderer's* reduced scrutiny standard applies to all laws that compel "disclosure of factual, noncontroversial information . . . in commercial speech." *American Beverage*, 916 F.3d at 755 (quoting *NIFLA*, 138 S. Ct. at 2372) (internal quotation marks omitted). It noted that in *CTIA-The Wireless Ass'n v. City of Berkeley*, 854 F.3d 1105, 1115-17 (9th Cir. 2017) (*CTIA I*), *vacated and remanded for reconsideration in light of NIFLA*, the Ninth Circuit rejected the notion that the enhanced scrutiny required for *restrictions* on commercial speech applied to *compelled* commercial speech. *American Beverage*, 916 F.3d at 755. Because the opinion in *NIFLA* had "preserved the exception to heightened scrutiny for health and safety warnings,"[109] and had

[108] Although plaintiffs contend that intermediate scrutiny should apply to this case because the Proposition 65 warning is not designed to prevent consumer deception, they acknowledge that they are bound by contrary Ninth Circuit authority. Pltfs.' Br. at 33, n.11. They do, however, suggest that the First Amendment prohibits regulations that compel speech to the same extent that it prohibits regulations that restrict speech. Pltfs.' Br. at 31. But nothing in *Janus v. Am. Fed'n of State, Cty., & Mun. Emps. Council 31*, 138 S. Ct. 2448 (2018), or *Hurley v. Irish-American Gay, Lesbian & Bisexual Grp.*, 515 U.S. 557 (1995), on which they rely, so holds.

[109] In *NIFLA*, addressing a point made by the dissent, the Court stated it did not call into question "the legality of health and safety warnings long considered permissible, or purely factual and uncontroversial disclosures about commercial products." 138 S. Ct. at 2376.

not disapproved the Ninth Circuit's precedents, including *CTIA I*, the court reaffirmed the "reasoning and conclusion in [*CTIA I*] that *Zauderer* provides the appropriate framework to analyze a First Amendment claim involving compelled commercial speech – even when the government requires health and safety warnings, rather than warnings to prevent the deception of consumers."[110] *American Beverage*, 916 F.3d at 756 (citing *CTIA I*, 854 F.3d at 1117).

2. *CTIA II* Reaffirmed That the *Zauderer* Test Applies to Purely Factual and Uncontroversial Warnings.

CTIA II involved a City of Berkeley ordinance that requires retailers of cell phones to inform prospective purchasers that carrying the phones in certain ways could cause them to exceed guidelines promulgated by the Federal Communications Commission (FCC) for radio-frequency radiation. *CTIA II*, 928 F.3d at 836.[111]

The compelled disclosure at issue in *CTIA II* stated:

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[110] In analyzing the facts of the case, the Ninth Circuit affirmed the panel's conclusion that the city had failed to carry its burden to show that the border and 20% size requirements for the warning language required by the ordinance were not unjustified and unduly burdensome." *American Beverage*, 916 F.3d at 757. The Court did not reach the issue whether the warning was factually accurate and noncontroversial. *Id.*

[111] The original *CTIA* opinion cited by the Ninth Circuit in *American Beverage*, *CTIA I*, affirmed the district court's denial of a preliminary injunction. After the industry association filed a petition for writ of certiorari, the Supreme Court granted the petition, vacated *CTIA I*, and remanded the case for further consideration in light of its decision in *NIFLA*. *Id.* at 837 citing *CTIA-The Wireless Ass'n v. City of Berkeley*, 138 S. Ct. 2708 (2018) (mem.)).

After considering the en banc opinion in *American Beverage* and the parties' supplemental briefing relating to *NIFLA*, the Court issued an amended opinion, *CTIA-The Wireless Ass'n v. City of Berkeley*, 928 F.3d 832 (9th Cir. 2019), *cert. denied*, 2019 WL 6689680 (2019) (*CTIA II*), which again affirmed the district court's decision, and substantially reaffirmed the reasoning and analysis of *CTIA I*, while addressing "*NIFLA*'s clarification of the *Zauderer* framework." *Id.*

> The City of Berkeley requires that you be provided the following notice:
>
> > To assure safety, the Federal Government requires that cell phones meet radio-frequency (RF) exposure guidelines. If you carry or use your phone in a pants or shirt pocket or tucked into a bra when the phone is ON and connected to a wireless network, you may exceed the federal guidelines for exposure to RF radiation. Refer to the instructions in your phone or user manual for information about how to use your phone safely.
>
> Berkeley Mun. Code § 9.96.030(A) (2015).

Id. at 846.

The parties in *CTIA II* agreed that the ordinance at issue was a regulation of commercial speech, but disagreed as to whether it should be analyzed under *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980), which applied intermediate scrutiny to a New York ordinance *restricting* advertising by a utility, or *Zauderer*. *CTIA II*, 928 F.3d at 841-42.

The court found that *Zauderer* applied. *CTIA II*, 928 F.3d at 844. After reviewing decisions from other circuits, including *American Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18 (D.C. Cir. 2014) (en banc) (*AMI*) (upholding regulation requiring country-of-origin labeling on meat products), and *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104 (2d Cir. 2001) (*Sorrell*) (upholding state statute requiring manufacturers to label products and packaging to inform consumers of mercury content in their products), the court held that "the governmental interest in furthering public health and safety is sufficient under

Zauderer so long as it is substantial."[112] *CTIA II*, 928 F.3d at 843-44. It asserted that *NIFLA* signaled the Supreme Court's agreement with this reading of *Zauderer*, and it noted that other substantial interests may also qualify for use of this more relaxed standard. *Id.* at 844.

Concluding that *NIFLA* "stands for the proposition that the *Zauderer* standard applies only if the compelled disclosure involves 'purely factual and uncontroversial' information[,]" it noted that "[w]e do not read the Court as saying broadly that any purely factual statement that can be tied in some way to a controversial issue is, for that reason alone, controversial." *CTIA II*, 928 F.3d at 845. As the court explained,

> The dispute in *NIFLA* was whether the state could require a clinic whose primary purpose was to oppose abortion to provide information about "state-sponsored services," including abortion. *While factual, the compelled statement took sides in a heated political controversy, forcing the clinic to convey a message fundamentally at odds with its mission. Under these circumstances, the compelled notice was deemed controversial within the meaning of Zauderer and NIFLA.*

Id. (emphasis added).

Next, the court examined the question whether the required disclosure was "purely factual" within the meaning of *Zauderer*. *CTIA II*, 928 F.3d at 846. The court acknowledged that "a statement may be literally true but nonetheless misleading and,

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[112] As the Second Circuit noted in *Sorrell*, "Innumerable federal and state regulatory programs require the disclosure of product and other commercial information. . . . To hold that the Vermont statute is insufficiently related to the state's interest in reducing mercury pollution would expose these long-established programs to searching scrutiny by unelected courts. Such a result is neither wise nor constitutionally required." 272 F.3d at 116 (citing among others, disclosure requirements for campaign contributions, securities, tobacco products, prescription drug advertisements, workplace hazards, and pesticide formulas).

in that sense, untrue." *Id.* at 847. It noted that the industry association argued that the required disclosure was "inflammatory and misleading," and therefore "controversial" and not "purely factual." *Id.* at 847-48. Examining the language of the warning sentence by sentence, however, the court disagreed, commenting that the warning provides reassuring information, uses phrases similar to those used by the FCC, and tells consumers to consult their user manuals for additional information. *Id.* at 847-848. The court also emphasized that the ordinance allows a retailer to add to the compelled disclosure, an important factor in the analysis. *Id.* The court concluded that the required disclosure was thus factual and not misleading, and rejected the argument that it was controversial. *Id.* at 848.

C. A Proposition 65 Warning for Glyphosate Can Comply with the First Amendment and Meet the Requirements of the Statute.

Plaintiffs' assertions to the contrary notwithstanding, it is possible to provide a warning for glyphosate that is "factual and uncontroversial" and "reasonably related" to the State's substantial interest in providing information to California consumers so they can make informed decisions about their exposure to glyphosate, and that complies with Proposition 65's requirement that it be "clear and reasonable." This case, however, presents a unique set of circumstances, in that two of the authoritative bodies recognized under Proposition 65 have reached different conclusions about a chemical within a few years of each other. Conveying that information within the warning itself ensures that consumers receive the information they

insisted on when adopting Proposition 65 in a manner that is truthful and not misleading.

For purposes of these motions, the Attorney General offers the following example of a warning that satisfies *Zauderer* and complies with Proposition 65:

> **WARNING:** This product can expose you to glyphosate. The State of California has determined that glyphosate is known to cause cancer under Proposition 65 because the International Agency for Research on Cancer has classified it as a carcinogen, concluding that there is sufficient evidence of carcinogenicity from studies in experimental animals and limited evidence in humans, and that it is probably carcinogenic to humans. The EPA has concluded that glyphosate is not likely to be carcinogenic to humans. For more information about glyphosate and Proposition 65, see www.P65warnings.ca.gov.[113]

1. The Warning Complies With *Zauderer* and its Progeny.

The warning survives First Amendment scrutiny under *Zauderer* and its progeny because it is (1) purely factual; (2) uncontroversial; (3) reasonably related to a substantial State interest; and (4) not unduly burdensome. *See CTIA II*, 928 F.3d at 845-849; *American Beverage*, 916 F.3d at 756.

a. The Warning is Factual.

First, the warning is purely factual. Each sentence is undeniably, uncontrovertibly true. *See CTIA II*, 928 F.3d at 846-

[113] Pesticide labels regulated by the EPA under FIFRA and the California Department of Pesticide Regulation may substitute the word "**NOTICE**" or "**ATTENTION**" for the word "**WARNING.**" 27 CCR, § 25603(d).

This warning is similar to the warning the People proposed in the Motion to Alter or Amend the Order Granting Preliminary Injunction, Docket No. 81 at 12, but has been revised to take into account *NIFLA*, *American Beverage*, and *CTIA II*; the concerns the Court expressed in its orders; EPA's recent publications; and a review of other court-approved, non-safe-harbor warning language used in consent judgments to which the Attorney General is a party.

47. Step by step, the proposed warning spells out how the State of California, through OEHHA, made its carcinogenicity determination under Proposition 65. It then provides the EPA's contrary determination. In this way, the warning discloses to consumers the conclusions of two authoritative agencies who take a position on the carcinogenicity of glyphosate without purporting to tell the consumer which position is correct. Moreover, as described below, it "provides in summary form information that [several federal agencies] ha[ve] concluded consumers should know in order to ensure their safety." *Id.* at 847.

The first sentence of the proposed warning is, "**WARNING:** This product can expose you to glyphosate." This sentence is necessarily factual because the warning would only be used on products that could expose people to glyphosate.

The second sentence is, "The State of California has determined that glyphosate is known to cause cancer under Proposition 65 *because* the International Agency for Research on Cancer has classified it as a carcinogen, concluding that there is sufficient evidence of carcinogenicity from studies in experimental animals, and that it is probably carcinogenic to humans." (Emphasis added.) Again, both parts of this sentence are incontestably true:

The State of California has determined that glyphosate is known to cause cancer under Proposition 65 . . . By putting glyphosate on the Proposition 65 list, an action whose constitutionality was upheld last year by a unanimous Court of Appeal, *Monsanto v. OEHHA*, 22 Cal. App. 5th 534, 559 (Cal. Ct.

App. 2018), the State of California, through OEHHA, the lead agency for Proposition 65, made a legal determination that glyphosate is "known to cause cancer" under Proposition 65 pursuant to Cal. Health & Safety Code section 25249.8(a).

. . . because the International Agency for Research on Cancer has classified [glyphosate] as a carcinogen, concluding that there exists sufficient evidence of carcinogenicity from studies in experimental animals and limited evidence in humans, and that it is probably carcinogenic to humans. This explains the basis for the State's determination. Specifically, IARC classified glyphosate as "probably carcinogenic to humans," and placed it in Group 2A, finding there is "limited" evidence of carcinogenicity in humans and "sufficient" evidence in animals. Zuckerman Decl., Exh. A, at 398; SUF Nos. 26-27. Because it is generally accepted in the scientific community that "[s]ubstances and mixtures which have induced benign and malignant tumors in well-performed experimental studies on animals are considered also to be presumed or suspected human carcinogens unless there is strong evidence that the mechanism for tumor formation is not relevant for humans[,]" 29 C.F.R. §1910.1200, App. A.6.1., this means that IARC classified glyphosate as a carcinogen. *See also* common definitions of "carcinogen" (*e.g.*, "a substance or agent causing cancer," https://www.merriam-webster.com/dictionary/carcinogen), which do not distinguish between human and animal carcinogens.

The third sentence in the warning is, "The EPA has concluded that glyphosate is not likely to be carcinogenic to humans." There is no dispute about the factual accuracy of this statement.

The last sentence provides an instruction, not a fact; it tells consumers to consult the official State of California Proposition 65 warnings website for more information. Like the warning at issue in *CTIA II*, which directed consumers to consult their user manuals for additional information, 928 F.3d at 838, the warning here directs consumers to the Proposition 65 warning website, whose fact sheet on glyphosate (https://www.P65warnings.ca.gov/sites/default/files/downloads/factsheets/glyphosate_fact_sheet.pdf) provides a source of more detailed information from six different agencies, along with information on how to reduce exposure.[114]

Plaintiffs contend that any warning that uses the phrases "known to the state to cause cancer" or "known to cause cancer" is inherently misleading, because it is not clear to the average consumer what the phrase means, and that it suggests complete consensus in the regulatory community that glyphosate is a carcinogen. *See* Pltfs.' Br. at 40-41 Pltfs.' Br. at 35. Recognizing that the typical consumer will not look to the statute or its regulatory background for the meaning of "known to the state to cause cancer," the warning here explains who made the carcinogenicity determination under the statute, and how. This type of stepwise explanation in the warning is not necessary for most Proposition 65 warnings, but it can be helpful in cases such as this one, in which different agencies recognized as

[114] *See* Zuckerman Decl., Exh. FFF; SUF No. 126. Although the information on the website is not incorporated into the warning for purposes of Proposition 65, it can be considered as part of the *Zauderer* analysis. *See, e.g., CTIA II*, 928 F.3d at 847 (discussing the statement, "Refer to the instructions in your phone or user manual for information about how to use your phone safely.")

authoritative bodies under Proposition 65 have reached different conclusions on whether or not a substance is a carcinogen.

Moreover, the plaintiffs' reliance on *Pacific Gas & Elec. Co. v. Public Utilities Comm'n of Cal.*, 475 U.S. 1, 13-14 (1986) (plurality op.), is misplaced. Pltfs.' Br. at 35. *Pacific Gas & Elec. Co.* was a case striking down an order requiring PG&E to broadcast others' subjective opinions and political messages. *Id.* at 5. Nor does *Nat'l Ass'n of Mfrs. v. S.E.C.*, 800 F.3d 518, 537 (D.C. Cir. 2015), have any relevance here: the Proposition 65 warning requirement is not compelling speech about "matters of opinion." Here, the Proposition 65 warning requirement, if made necessary by high levels of glyphosate exposure, does not require dissemination of subjective opinion. It requires dissemination only of facts.

b. The Warning is Uncontroversial

Despite Monsanto's efforts to influence the science, and to create the appearance of more of a scientific controversy about the safety of glyphosate than actually exists,[115] *the warning language itself* is uncontroversial under *CTIA II* and *NIFLA*, for three reasons.

First, as the Ninth Circuit held in *CTIA II*, if the speech to be compelled is factually accurate, the First Amendment does not prohibit compelled disclosures relating to every topic over which there exists some scientific disagreement. *See CTIA II*, 928 F.3d

[115] As Judge Smith found in *Pilliod*, "Monsanto made efforts to impede, discourage, or distort scientific inquiry and the resulting science.. . . . Monsanto worked to publish articles that it had ghostwritten. Monsanto made an aggressive attempt to discredit the IARC decision." Zuckerman Decl., Exh. OO, at 17; SUF No. 84.

at 848 (despite controversy over the risk from radio-frequency radiation from cell phones, Berkeley's required disclosure was "uncontroversial" for purposes of the First Amendment analysis). A risk does not have to be a "universally acknowledged health risk," as plaintiffs contend, Pltfs.' Br. at 1, to be the subject of a required warning. If it were otherwise, compelled speech on a broad range of public health and safety topics would be prohibited, hampering the exercise of government regulation long held to be permissible. *Cf*. *NIFLA*, 138 S. Ct. at 2376 (the Supreme Court does "not question the legality of health and safety warnings, long considered permissible").

Second, the scientific debate over whether glyphosate causes cancer is distinguishable from the kind of moral or ethical controversy at issue in *NIFLA*, where health care providers were required to post a message relating to abortion, one of the most politically divisive issues of our day. *NIFLA*, 138 S. Ct. at 2372. Indeed, the Ninth Circuit highlighted the distinction in *CTIA II*. Despite the parties' disagreement about the safety of cell phone radiation exposure, the court held Berkeley's required disclosure "uncontroversial within the meaning of NIFLA [because it] does not force cell phone retailers to take sides in a heated political controversy." *CTIA II*, 928 F.3d at 848 (citing *NIFLA*, 138 S. Ct. at 2376); *see also* 928 F.3d at 845 ("while factual, the compelled statement [in *NIFLA*] took sides in a heated political controversy, forcing the clinic to convey a message fundamentally at odds with its mission. Under these circumstances, the compelled notice was deemed controversial within the meaning of *Zauderer*."). Thus, although the potential

carcinogenicity of glyphosate has been a subject of intense press coverage, and, like the safety of radio-frequency radiation, the subject of scientific debate, this does not make the warning "controversial" for purposes of *Zauderer*. Unlike abortion, cancer is not a politically divisive or controversial subject. A factual Proposition 65 warning would not require plaintiffs "to convey a message fundamentally at odds with [their] mission." *CTIA II*, 928 F.3d at 845.

Third, as discussed below, the warning here conveys information similar to that provided by a federal agency charged with protecting public health and safety – the U.S. Department of Health and Human Services Agency for Toxic Substances and Disease Registry (ATSDR). The following information is from the ATSDR's online fact sheet about glyphosate:

> **Can glyphosate cause cancer?**
>
> There have been several agencies and organizations both in the United States and internationally that have reviewed studies and made an assessment about whether glyphosate could cause cancer.
>
> The U.S. Environmental Protection Agency (EPA) classification for glyphosate is "not likely" to be carcinogenic (causing cancer) to humans, based on evidence from animals and humans.
>
> The International Agency for Research on Cancer (IARC) has classified glyphosate as "probably" carcinogenic to humans, which means there was sufficient evidence to find cancer in animals, but limited evidence finding cancer in humans.

See Zuckerman Decl., ¶ 58 and Exh. GGG; SUF No. 126. In this regard, it is like the warning in *CTIA II*, which conveyed information about cell phone radiation also provided by the FCC. 928 F.3d at 840.

Three other federal agencies – the U.S. Food and Drug Administration, the National Toxicology Program, and EPA itself – also provide fact sheets about glyphosate to consumers. These fact sheets include information about the 2015 IARC carcinogenicity determination, followed by information about other international organizations' conclusions. Zuckerman Decl., ¶¶ 59-61 and Exhs. HHH-JJJ; SUF No. 126. A fourth agency, OSHA, requires that SDSs state "[whether] the hazardous chemical . . . has been found to be a potential carcinogen in the [IARC] Monographs (latest edition), or by OSHA." 29 C.F.R. § 1910.1200, App. D. These federal agencies do not all require the same organizations to be listed in the fact sheets, or, in OSHA's case, on the SDS, but all four federal agencies consider it important for consumers and workers to have the information about the IARC determination. *See* Zuckerman Decl., ¶¶ 58-61 and Exhs. GGG-JJJ; SUF No. 126.

c. The Warning is Reasonably Related to the State's Substantial Interest in Providing Information to Consumers about Health Risks.

The warnings required by Proposition 65 serve to protect public health and safety by providing Californians with information they wanted to receive about the products they purchase, a clearly legitimate state interest. *See Sorrell*, 272 F.3d at 115 (upholding mercury labeling law) ("[a]lthough the overall goal of the statute is plainly to reduce the amount of mercury released into the environment, it is inextricably intertwined with the goal of increasing consumer awareness of the presence of mercury in a variety of products"); *see also CTIA II*,

928 F.3d at 845 ("There is no question that protecting the health and safety of consumers is a substantial government interest."); *NIFLA*, 138 S. Ct. at 2376 (the Supreme Court does "not question the legality of health and safety warnings, long considered permissible[.]")

When voters enacted Proposition 65, they were concerned that state government agencies were not providing sufficient information about the health impacts of chemicals. With respect to what chemicals required a warning and when, the voters placed great weight on the findings of certain well-regarded governmental and non-governmental organizations. The voters wanted to make sure that consumers knew if *any* of these entities found that a chemical was likely to cause cancer or reproductive harm. The statute's emphasis on providing information that would allow individuals to make informed choices thus anticipated a situation like this; where IARC has found that a chemical can cause cancer but another equally respected agency, like EPA, has not. Under these circumstances, the voters specifically wanted persons who are exposed to significant amounts of the IARC-identified chemical to receive warnings "regardless of whether other identified listing agencies or processes agree." *Monsanto v. OEHHA*, 22 Cal. App. 5th at 556. There can be little doubt that California has a substantial interest in the dissemination of this information.

Moreover, this informational goal is "inextricably intertwined" with the public health and safety goals enumerated in the preamble to the statute. *Sorrell*, 272 F.3d at 115. It is for this reason that federal agencies tasked with protecting

human health, in addition to ATSDR, including the National Toxicology Program, the FDA, and the EPA itself, have deemed information about the 2015 IARC carcinogenicity determination important enough to provide to consumers.[116]

For all these reasons, this Court is "not in a position to disagree with the conclusions of [the State of California] that the required disclosure is 'reasonably related' to protection of the health and safety of consumers." CTIA II, 928 F.3d at 846.

Plaintiffs' narrow view of California's interest — permitting the State to provide information about a chemical only if there is 100% certainty and universal agreement that it causes cancer — is incorrect. *See* Pltfs.' Br. at 48-49. In support of their argument, plaintiffs rely heavily on *California Chamber of Commerce v. Brown*, 196 Cal. App. 4th 233, 258 (Cal. Ct. App. 2011), in which the California Court of Appeal noted that the preamble to Proposition 65 reflects that one of the statute's purposes is to inform the people "about exposures to chemicals that cause cancer[.]" But the court in that case was not addressing whether chemicals had to be known with absolutely certainty to cause cancer; instead, it merely considered OEHHA's authority to add chemicals to the Proposition 65 list under Health and Safety Code Section 25249.8(a). *Id.* at 248; *see also id.* at 258 ("Proposition 65 is a remedial statute and therefore should be broadly construed to achieve its protective purposes.").

Similarly, OEHHA's Pesticide and Toxicology Branch is not an entity on whose scientific determinations the statute relies to

[116] Zuckerman Decl., Exhs. GGG-JJJ; SUF 126.

list chemicals. The fact that the Pesticide and Toxicology Branch reached a different conclusion about the carcinogenicity of glyphosate in its 1997 and 2007 reviews than did IARC, which reviewed new studies published between 2007 and 2015, does not bear on the merits of this case, despite plaintiffs' suggestion to the contrary. *See* Pltfs.' Br. at 9; Zuckerman Decl., Exh. A, at 79-92; SUF No. 132.

Moreover, taken to its logical conclusion, plaintiffs' argument would mean that California has no interest in requiring warnings about any chemical unless and until everyone agrees beyond a shadow of a doubt that the chemical causes cancer. Such a consensus, if it is ever achievable, often takes decades to reach – as, for example, was the case for tobacco.[117] It was not until 1964 that the U.S. Surgeon General first issued a report on the health effects of smoking.[118] Since then, "evolving scientific evidence" has been a "key driver of the changes that have led to a dramatic shift in social norms around cigarette smoking."[119] The First Amendment does not require such an extensive incubation period before the government can compel the disclosure of information based on reliable scientific findings.

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[117] Zuckerman Decl., Exh. KKK, at 3; SUF 127-129.

[118] Zuckerman Decl., Exh. KKK, at I; SUF 127; *id.* at I; SUF No. 127.

[119] Zuckerman Decl., Exh. KKK, at 17; see also *id.* at 45 (noting that although the Surgeon General's 1964 report is "widely viewed as pivotal in establishing with certainty that cigarette smoking causes lung cancer, a similar conclusion with regard to causation had been reached earlier by several scientific reviews and by [a previous surgeon general]"); SUF 128-129.

d. The Warning is Not "Unduly Burdensome."

Finally, the warning would not be unduly burdensome such that it would threaten to chill plaintiffs' speech. *Cf. American Beverage*, 916 F.3d at 757. In *American Beverage*, the Ninth Circuit struck down a San Francisco ordinance requiring a warning to occupy 20% of the total space in advertisements for beverages with added sugar. *Id.* The court explained that the warning would "'drown out [p]laintiffs' message and 'effectively rule[] out the possibility of having [an advertisement] in the first place,'" *Id.* (quoting *NIFLA*, 138 S. Ct. at 2378). In contrast, in *CTIA II*, the Ninth Circuit held that Berkeley's ordinance requiring retailers to provide notice to customers regarding radio-frequency radiation exposure was not unduly burdensome because it could be satisfied with a single 8.5 by 11 inch posted notice or a 5 by 8 inch handout to which retailers could add additional information. 928 F.3d at 849. The court explained that such a requirement "does not interfere with advertising or threaten to drown out messaging" by the retailers. *Id.*

There is no reason a Proposition 65 warning requirement for glyphosate would be as cumbersome as the requirement struck down in *American Beverage* – i.e., covering at least 20 percent of the space allotted for the company's message. Proposition 65 warnings need only be "prominently displayed on a label, labeling, or sign, and must be displayed with such conspicuousness as compared with other words, statements, designs or devices on the label, labeling, or sign, as to render the warning likely to be seen, read, and understood by an ordinary individual under customary

conditions of purchase or use." 27 CCR, § 25601(c) (safe-harbor warnings). For occupational exposures, 27 CCR, section 25606, provides,

> (a) A warning to an exposed employee about a listed chemical meets the requirements of this subarticle if it fully complies with all warning information, training, and labeling requirements of the federal Hazard Communication Standard (29 Code of Federal Regulations, section 1910.1200 (Feb. 8, 2013)), hereby incorporated by reference, the California Hazard Communication Standard (Title 8, California Code of Regulations section 5194), or, for pesticides, the Pesticides and Worker Safety requirements (Title 3, California Code of Regulations section 6700 et seq.).

Thus, any required Proposition 65 warning would pose no risk of "drown[ing] out" plaintiffs' own speech. *See CTIA II*, 928 F.3d at 849.

Plaintiffs nevertheless claim they will suffer harm if the preliminary injunction is lifted, and Proposition 65 warnings for glyphosate were permitted. *See, e.g.*, Pltfs.' Br. at 26-29, 55-61. However, none of the declarations submitted by plaintiffs on this point acknowledges how unlikely it is that *any* warnings would be required by Proposition 65, given the 1,100 µg/day NSRL. *See* Background Section IV.E.3, *supra*. More importantly, the declarations address the potential business consequences of the public's learning of IARC's carcinogenicity determination. These potential consequences are irrelevant to the First Amendment inquiry, which asks how burdensome is the act of providing the warning. See *CTIA II*, 928 F.3d at 849 ("This minimal requirement does not interfere with advertising or threaten to drown out messaging by the cell phone retailers subject to the requirement.").[120] The First Amendment does not protect companies

[120] According to a report by one of Monsanto's consultants, warnings on labels of Roundup aren't going to make any difference

from warning requirements merely because they might be bad for business. *Cf., e.g., Nat'l Ass'n of Mfrs.*, 800 F.3d at 532-33 (Srinivasan, J., dissenting) ("If they mean to suggest that issuers would prefer to avoid the label 'not found to be "DRC conflict free"' because it invites public scrutiny, the same is true of all sorts of entirely permissible requirements to disclose factual information to consumers").

In sum, the warning the Attorney General has offered in this brief is an example of a Proposition 65 warning for glyphosate that survives scrutiny under *Zauderer* because the warning language is purely factual; because cancer is not controversial; and because disseminating the information about IARC's classification of glyphosate as a carcinogen is reasonably related to the State's substantial interests in health and safety and is not unduly burdensome.

2. The Proposed Form of Warning Would Also Survive Scrutiny Under *Central Hudson*.

Even if *NIFLA*, *American Beverage*, and *CTIA II* did not make clear that *Zauderer*'s relaxed scrutiny applies here, the proposed warning would pass constitutional muster under *Central Hudson*. Under *Central Hudson*, if a state wishes to regulate commercial speech that is neither misleading nor related to unlawful activity, the state "must assert a substantial interest to be achieved," "the regulatory technique must be in proportion to that interest[,]" and "[t]he limitation on expression must be

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to sales. *See* Zuckerman Decl., Exh. MMM, at MONGLY14441108. Haklyut reported that, according to a senior executive at one Home Depot, one of the major retailers of Roundup, "There's not likely to be much short-term risk for a product like RoundUp, and the label isn't really going to matter." *Id.*

designed carefully to achieve" the state's goal. *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557, 564 (1980). To survive scrutiny, the restriction must "directly advance" the state's interest, and the state's interest must not be capable of being "served as well by a more limited restriction." *Id.*

As outlined above, Proposition 65's warning requirement for glyphosate directly advances California's substantial interest in ensuring that its citizens receive information about exposures to a potentially harmful chemical. California's voters wanted to know if they would be exposed to chemicals that IARC and other authoritative bodies had determined are likely carcinogenic. California has a legitimate interest in providing that information, and a requirement that companies disclose this type of factual, uncontroversial information related to the good or service at issue necessarily advances this interest. In addition, Proposition 65's warning requirement is narrowly drawn to advance the State's interest in ensuring that its citizens are empowered to make informed decisions about their exposure to potentially harmful chemicals. *Central Hudson*, 447 U.S. at 569-570 (warning requirement must be "no more extensive than necessary" to advance the state's interest).

In *Central Hudson*, the Supreme Court invalidated a New York Public Service Commission ordinance that completely banned promotional advertising by a utility. 447 U.S. at 572. Likewise, in *American Beverage*, the Ninth Circuit rejected a San Francisco ordinance requiring a warning that occupied 20% of the space in advertisements for beverages with added sugar. 916 F.3d

at 757. The court highlighted an expert study, which suggested that the ordinance's goals could be accomplished with a smaller warning. *Id.*

In contrast to the speech at issue in *Central Hudson* and *American Beverage*, on this record there is no less burdensome way to effectively provide warnings about chemicals present in consumer products than to do so on product packaging or at the point of sale. *See NIFLA*, 138 S. Ct. at 2372; *AMI*, 760 F.3d at 26. OEHHA already provides information about glyphosate on its own website, www.oehha.ca.gov, and on the Proposition 65 warnings website, www.P65warnings.ca.gov;[121] and, tellingly, plaintiffs do not contend that California has less restrictive alternatives to ensure that the specific information voters wanted conveyed reaches consumers. And for good reason — advancing such a position would mean advocating for the wholesale invalidation of a host of health and safety warnings "long considered permissible." *See NIFLA*, 138 S.Ct. at 2376; *AMI*, 760 F.3d at 26 ("[t]he self-evident tendency of a disclosure mandate to assure that recipients get the mandated information may in part explain why, where that is the goal, many such mandates have persisted for decades without anyone questioning their constitutionality.").

Importantly, Proposition 65 allows for flexibility such that a variety of warnings are available to businesses required to provide them. These provisions create a careful "fit" between the state's ends and means. *Bd. of Trs. v. Fox*, 492 U.S. 469, 480 (1989) ("a fit that is not necessarily perfect, but

[121] Zuckerman Decl., Exh. FFF; SUF No. 133

reasonable; that represents not necessarily the single best disposition but one whose scope is in proportion to the interest served; that employs not necessarily the least restrictive means but . . . a means narrowly tailored to achieve the desired objective") (citations and internal quotation marks omitted). Proposition 65's warning requirement for glyphosate is no more extensive than necessary to accomplish the State's – and the voters' – objectives.

Plaintiffs argue that, under *Central Hudson*, the government has a heavy burden to demonstrate that harms to be addressed by a speech restriction are real, and the restriction will alleviate them to a material degree. Pltfs.' Br. at 46-47. But the speech restriction cases plaintiffs cite to support their argument are inapposite here, where plaintiffs challenge a disclosure mandate. As the Supreme Court implicitly recognized in *Zauderer*, and the D.C. Circuit emphasized in *AMI*, evidence of a measure's effectiveness, is not necessary "when the government uses a disclosure mandate to achieve a goal of informing consumers about a particular product trait, assuming of course that the reason for informing consumers qualifies as an adequate interest." *AMI*, 760 F.3d at 26; *Zauderer*, 47 U.S. at 651.

D. The Warning Complies With Proposition 65.

Under Proposition 65, a business may use any warning method or content that is clear and reasonable, § 25249.6 and 27 CCR, § 25600(f), and a court may approve a more nuanced warning that it deems appropriate. The Attorney General consistently has recognized, in this case and others, that companies *can* (though they are not required to, as plaintiffs' burden-shifting argument

erroneously implies) provide a more nuanced message in a Proposition 65 warning than what is in the safe-harbor warning in certain circumstances.

For example, in *Coordination Proceeding Proposition 65 Fish Cases*, Judicial Council Coordination Proceeding No. 4319 (Cal. Super. Ct. 2004), the San Francisco County Superior Court entered a consent judgment with Andronico's Markets, Inc., which required a nuanced notice that: (1) warned of the presence of mercury in fish; (2) advised pregnant and nursing women against eating certain species of fish; and (3) noted that "fish and shellfish are an important part of a healthy diet and a source of essential nutrients."[122]

In addition, in *Council for Education and Research on Toxics v. McDonald's Corporation et al.*, in a consent judgment entered into with Burger King Corporation, the Los Angeles County Superior Court approved three substantially-similar nuanced warnings for acrylamide in food products that placed the cancer risk posed by acrylamide in context in order to clarify the nature of the risks involved. One such warning stated:

> Chemicals known to the State of California to cause cancer, or birth defects or other reproductive harm may be present in foods or beverages sold or served here. Cooked potatoes that have been browned, such as french fries, hash browns, and cheesy tots, contain acrylamide, a chemical known to the State of California to cause

[122] *See* Zuckerman Decl., ¶ 54 and Exh. AAA, Consent Judgment between Plaintiffs People of the State of California and Andronico's Markets, Inc., *Coordination Proceeding Proposition 65 Fish Cases*, Judicial Council Coordination Proceeding No. 4319 (Cal. Super. Ct. 2004).

> cancer. This chemical is not added to our foods, but is created when certain foods are browned. Other foods sold here, such as hamburger buns, biscuits, croissants, and coffee also contain acrylamide, but generally in lower concentrations than fried potatoes. Your personal cancer risk is affected by a wide variety of factors. The FDA has not advised people to stop eating baked or fried potatoes. For more information see www.fda.gov.[123]

The core information to be communicated by the warning the Attorney General proposes in this case is that "the state of California has determined that glyphosate is known to cause cancer under Proposition 65 . . . ." *See supra*, Argument Section II.C.I.a. As illustrated by the nuanced warnings that have received approval from California courts, however, the additional information regarding a contrary determination by EPA – which is another authoritative body under Proposition 65 – provides context in these unique circumstances while still remaining "clear and reasonable." In this way, it is similar to the warning required by the court-approved Burger King consent judgment in *Council for Education and Research on Toxics*.[124]

Plaintiffs paint a disparaging, one-sided picture of Proposition 65 and its private enforcement mechanism. *See* Pltfs.' Br. at 16-26. Indeed, the brief uses the phrase "bounty hunter" no fewer than 17 times. But the First Amendment does not protect businesses from statutes merely because they disagree

[123] Zuckerman Decl. ¶ 55 and Exh. BBB at 4-5; SUF No. 125.

[124] *Id.* ("Your personal cancer risk is affected by a wide variety of factors. The FDA has not advised people to stop eating baked or fried potatoes. For more information see www.fda.gov.").

with the statute or with how it is enforced. Further, plaintiffs overstate the risk of frivolous enforcement. Now that the Attorney General has identified a warning that is an alternative to a safe-harbor warning, but is clear and reasonable, it is unlikely that a private enforcer would sue a company that uses such a warning – especially if this Court also recognizes that the warning complies with Proposition 65.

Plaintiffs' argument that the Attorney General's own regulations prohibit the use of "diluting and qualifying language" is misguided. Pltfs.' Br. at 53 n.13 (citing Cal. Code Regs. tit. 11, § 3202). The regulation plaintiffs cite simply provides guidelines that the Attorney General will consider in his review of Proposition 65 settlements. Moreover, the guidelines only disapprove of language in a warning that would "contradict or obfuscate otherwise acceptable warning language," while noting that "[n]othing in this guideline shall be construed . . . to preclude any warning that complies with the statute and regulations." Cal. Code Regs. tit. 11, § 3202 and subd. (b)(2); *see also* FSOR, Cal. Code Regs. tit. 11, § 3202 ("The requirements of section 3202(a) address commonly occurring problems in warning language, about which the Attorney General has been asked for guidance on numerous occasions"). The warning proposed in this brief would neither contradict nor obfuscate otherwise acceptable warning language.

Of course, it is not difficult to imagine a warning that crosses this line. In 2015, for example, the Attorney General demanded that a company stop using a purported warning that buried the warning message in a 390-word manifesto about

Proposition 65, which began, "A small amount of wood dust, brass, PVC or other elements on furniture and household items might seem trivial to many. The state of California, however, has taken the issue of ingredients in consumer products to a whole new level with its Safe Drinking Water and Toxic Enforcement Act, known as 'Proposition 65.'" [125] After finally reciting the safe-harbor warning, the so-called warning stated, "***We realize that this warning sounds very alarming. However, we want to reassure you based on the findings of reliable research . . . .***" *Id.* (emphasis in original). *This* is an example of a warning with surplus information that contradicts and obfuscates otherwise acceptable warning language. It is not comparable to the warning the Attorney General has offered in this case, which supplements the required warning message with factual information that provides context about the unique circumstances surrounding the listing of glyphosate as a known carcinogen.

Plaintiffs point to a court-approved McDonald's warning similar to that used in the Burger King consent judgment as an example of a warning with impermissible additional language that would not protect entities from private enforcement actions.[126] But no court disapproved the warning in the cited case, and McDonald's relies on the warning to this day.[127] A 60-day notice issued to McDonald's for acrylamide and certain other chemicals

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[125] Zuckerman Decl., ¶ 63 and Exh. LLL.; SUF No. 135.

[126] *See* Pltfs.' Br. at 53 n.13; Plaintiffs' Statement of Undisputed Facts, ¶ 46.

[127] *See* Declaration of Patricia Randal, ¶ 2 and Exh. A; SUF No. 130.

on June 13, 2018, was withdrawn by the entity that sent it 13 days later.[128]

In short, Proposition 65 allows flexibility to create a warning that satisfies the First Amendment and is clear and reasonable in the context of each case. Having established that there is at least one such warning, the Attorney General has met his burden to show, as a matter of law, that the Proposition 65 warning requirement for glyphosate does not violate the First Amendment.

III. PROPOSITION 65'S WARNING REQUIREMENT IS NOT UNCONSTITUTIONALLY VAGUE.

Plaintiffs also contend that Proposition 65 does not provide fair notice of acceptable warnings, such that they have been deprived of due process of law. Plaintiffs claim that they are unsure what warning they could give that would comply with the requirements of Proposition 65. Pltfs.' Br. at 51-53. The argument has no merit.

A. Plaintiffs Did Not Plead Constitutional Vagueness as a Ground for Relief.

As an initial matter, plaintiffs failed to plead anywhere in their Amended Complaint that Proposition 65 is so vague that they have not received fair notice of what the law requires. The Court should reject plaintiffs' due process argument for this reason alone. *See, e.g., Loan Payment Admin. LLC v. Hubanks*, No. 14-CV-04420-LHK, 2018 WL 6438364, at * 13 (N.D. Cal, Dec. 07, 2018) (rejecting argument that statute is unconstitutionally vague and noting that the plaintiff's operative complaint

[128] Zuckerman Decl., ¶ 66 and Exh. OOO; SUF No. 131

"conspicuously avoids any discussion of the constitutional basis for its vagueness claim").

B. The Court Should Reject Plaintiffs' Disfavored Facial Challenge to Proposition 65.

While plaintiffs attempt to couch their claim as applicable to glyphosate only, in reality, plaintiffs make a disfavored facial attack on Proposition 65, since the "clear and reasonable" warning requirement applies to all listed chemicals. A facial attack on a statute is one where a litigant argues that "no application of the statute would be constitutional." *Sabri v. United States*, 541 U.S. 600, 609 (2004).[129] In making a facial constitutional challenge, plaintiffs confront "a heavy burden." *Rust v. Sullivan*, 500 U.S. 173, 183 (1991). Facial invalidation of a statute "is, manifestly, strong medicine," and "has been employed . . . sparingly and only as a last resort." *Broadrick v. Oklahoma*, 413 U.S. 601, 613 (1973).

Plaintiffs argue that Proposition 65 does not fairly "'articulate its disclosure rules' to give a 'sure guide' to those tasked with following them." Pltfs.' Br. at 52 (quoting *Zauderer*, 47 U.S. at 653 n.15). Plaintiffs' due process argument applies with equal force to the entire regulated community, and plaintiffs' particular circumstances have no bearing on whether Proposition 65 provides enough guidance to be followed. *See John Doe No. 1 v. Reed*, 561 U.S. 186, 194 (2010) (citing *United States*

[129] In contrast, courts define an as-applied challenge as one "'under which the [party] argues that a statute, even though generally constitutional, operates unconstitutionally as to him or her because of [the party's] particular circumstances.'" *Oracle USA, Inc. v. Rimini St., Inc.*, 191 F. Supp. 3d 1134, 1148 (D. Nev. 2016) (quoting *Tex. Workers' Comp. Comm'n v. Garcia*, 893 S.W.2d 504, 518 (Tex. 1995)).

v. Stevens, 559 U.S. 460, 472-473 (2010)) ("The label is not what matters. The important point is that plaintiffs' claim and the relief that would follow . . . reach beyond the particular circumstances of these plaintiffs. They must therefore satisfy our standards for a facial challenge to the extent of that reach."). To strike down the 33-year-old warning requirement of Proposition 65 would be a result "neither wise nor constitutionally required." *Sorrell*, 272 F.3d at 116.

C. An As-Applied Challenge Would Also Fail, Because it is Clear What Proposition 65 Requires.

But even if the Court were to take plaintiffs at their word that they intend only to challenge Proposition 65 as applied to glyphosate, plaintiffs' vagueness argument still fails, because it is clear what Proposition 65 requires. Indeed, plaintiffs' accusation of First Amendment "gamesmanship" rings hollow. Pltfs.' Br. at 52. Plaintiffs have demonstrated a steadfast refusal to develop a warning for glyphosate that would satisfy Proposition 65. The Attorney General has offered different examples to show it can be done, but certainly was not required to do so in order to overcome a vagueness challenge.

The relevant inquiry in an as-applied challenge is whether the challenged statute is unconstitutionally vague as applied to the particular facts at issue such that the challenging party does not have sufficient notice that his or her conduct would be a violation of the statute. *Holder v. Humanitarian Law Project*, 561 U.S. 1, 18 (2010). "Condemned to the use of words, we can never expect mathematical certainty from our language." *Grayned v. City of Rockford*, 408 U.S. 104, 110 (1972). Accordingly, the

Constitution permits statutes that are "marked by 'flexibility and reasonable breadth, rather than meticulous specificity,"' *id.* (quoting *Esteban v. Cent. Mo. State Coll.*, 415 F.2d 1077, 1088 (8th Cir. 1969) (Blackmun, J.), *cert. denied*, 398 U.S. 965 (1970)). Further, in examining the purported "vagueness" of the Proposition 65, the Court should bear in mind "the elementary rule that every reasonable construction must be resorted to, in order to save a statute from unconstitutionality." *Gonzales v. Carhart*, 550 U.S. 124, 153 (2007) (citations and internal quotation marks omitted).

In *Grayned*, the Supreme Court upheld the criminal conviction of a protestor for violating a municipal ordinance that prohibited "willfully mak[ing] or assist[ing] in the making of any noise or diversion which disturbs or tends to disturb the peace or good order" of a school. 408 U.S. at 106-107. The Court explained that "it [was] clear what the ordinance as a whole [required,]" and emphasized that in the context of the ordinance's stated purpose of protecting schools, prohibited conduct was "easily measured by [its] impact on the normal activities of the school." *Id.* at 110-112.

Here, as with the ordinance at issue in *Grayned*, it is clear what Proposition 65 "as a whole" demands. It provides that "[n]o person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual[.]" Cal. Health & Safety Code § 25249.6. In short, businesses must provide a warning before exposing people to chemicals that have

been classified as harmful by certain designated entities, and thus listed as "known to the state to cause cancer or reproductive toxicity."

That the warning must be "clear and reasonable" does not render what the statute requires impermissibly unclear. Indeed, California courts have had little difficulty applying that standard to approve a variety of warnings in consent judgments that differ from, or go beyond, the safe harbor warnings set forth in the regulations implementing Proposition 65. These include lengthier, more nuanced warnings to fit the circumstances of the particular case, including where U.S. federal agencies have not deemed warnings necessary. For example, and as described above in Section II.D, in *Council for Education and Research on Toxics v. McDonald's Corporation et al.*, the Los Angeles County Superior Court approved a nuanced warning for acrylamide in a variety of cooked foods, including French fries and hash browns, and in the *Coordination Proceeding Proposition 65 Fish Cases*, the San Francisco County Superior Court approved a nuanced warning for mercury in fish. Insofar as warnings would even be necessary in this case, plaintiffs could surely tailor these, and many other court-approved warnings to their products. Indeed, the warning offered by the Attorney General in this brief does just this, incorporating language based on numerous warnings approved by California courts. Plaintiffs' vagueness argument is unfounded.

CONCLUSION

There is no genuine dispute of material fact here, and the Attorney General is entitled to judgment as a matter of law. For

all the reasons set forth above, the Attorney General respectfully requests that the Court deny plaintiffs' motion for summary judgment and grant his cross-motion for summary judgment.

Dated: December 11, 2019

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
HARRISON M. POLLAK
Supervising Deputy Attorney General

/s/ Laura J. Zuckerman

LAURA J. ZUCKERMAN
DENNIS A. RAGEN
ANDREW J. WIENER
Deputy Attorneys General
Attorneys for Xavier Becerra, Attorney General of the State of California

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