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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

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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

1 *Zauderer* merely because it can be "tied in some way to a
2 controversial issue," *id.* at 845, and went on to uphold a
3 requirement to provide a warning about cell phone radiation. *Id.*
4 at 848. Both opinions make clear that, should the Court
5 determine that this matter is ripe for adjudication, and that
6 glyphosate exposures could be high enough to require Proposition
7 65 warnings, the built-in flexibility of the statutory warning
8 scheme makes it possible to harmonize the statutory requirements
9 with the dictates of the First Amendment. Plaintiffs can provide
10 a nuanced warning about glyphosate that is wholly factual and
11 noncontroversial, and that satisfies the California voters'
12 mandate to inform consumers prior to exposures to a chemical that
13 IARC determined is a probable human carcinogen.

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

25 As there are no material facts in dispute, and defendant
26 Xavier Becerra, Attorney General of the State of California, is
27 entitled to a judgment as a matter of law, the Court should deny
28

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

3 BACKGROUND

4 I. INVESTIGATIONS INTO THE CARCINOGENICITY OF GLYPHOSATE

5 A. The International Agency for Research on Cancer

6 The genesis of this lawsuit was the determination, on March
7 20, 2015, by the International Agency for Research on Cancer,
8 that glyphosate, a widely-used herbicide manufactured by
9 plaintiff Monsanto and others, is an animal carcinogen and a
10 probable human carcinogen. IARC relied in part for this
11 conclusion on evidence that there is a positive association in
12 humans between exposures to high levels of glyphosate and non-
13 Hodgkin's lymphoma, a type of cancer.

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

22 [IARC] is an international agency created specifically to
23 scientifically investigate potentially carcinogenic
24 compounds. Its reputation and authority on the world stage—
25 and relatedly its funding—is dependent, in part, on its work
26 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.

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

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

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

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

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

25 *In re Roundup Products Liability Litigation*, 390 F. Supp. 3d
 26 1102, 1113-1114 (N.D. Cal. 2018) (citations omitted).

27 Monographs are prepared by a "Working Group" of international
 28 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

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.

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

21 ⁶ Zuckerman Decl., Exh. A, at 30-31; SUF No. 9; see also
 22 *Styrene Info. and Research Ctr.*, 210 Cal. App. 4th 1082, 1090-91
 23 (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.

24 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
 25 rounded to the nearest tenth of a percentage point: 11.8% of
 26 agents that IARC evaluates are assigned to Group 1; 8.2% of
 27 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.

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

3 In California, the Safe Drinking Water and Toxic Substances
4 Control Act of 1986, Cal. Health & Safety Code §§ 25249.5 -
5 25249.14¹² (Proposition 65), and other statutes rely on IARC's
6 findings. These include Cal. Penal Code § 374.8(c)(2)(D),
7 involving the illegal deposit of hazardous substances; Cal. Educ.
8 Code §§ 32062(a) and (b), addressing toxic art supplies in
9 schools; the California Safe Cosmetics Act of 2005, Cal. Health &
10 Safety Code § 111791.5(b)(2), and Cal. Labor Code §6382(b)(1).
11 Many other states rely on IARC's evaluations to create lists of
12 hazardous chemicals and identify carcinogens for other public
13 health purposes, including the states of Alaska, Connecticut,
14 Illinois, Indiana, Louisiana, Massachusetts, Missouri, Nevada,
15 New Hampshire, New Jersey, Oregon, Pennsylvania, Rhode Island,
16 Tennessee, Texas, Vermont, Virginia, and Washington.¹³ When IARC
17 determines that the available scientific evidence does not
18 support classifying a substance in Group 1, 2A or 2B (i.e., when

19 ¹¹ Zuckerman Decl., Exh K; SUF No. 14.

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

21 ¹³ For example, Pennsylvania creates a hazardous substance
list that includes all substances listed by IARC as having
22 "sufficient evidence of carcinogenicity in animals." Penn.
Statutes, tit. 35, § 7303(a)(6); Penn. Admin. Code, tit. 34, §
23 323.5(a)(6). New Jersey's "Right to Know Hazardous Substance
List" must be updated based on the IARC Monograph Supplements.
24 N.J. Admin. Code, tit. 8:59-9.3, subd. (b)(7). Rhode Island
requires employers to maintain hazardous and/or toxic chemical
25 lists that include chemicals listed as carcinogens by IARC. R.I.
Gen. Laws, tit. 28, § 28-21-2(13), (13). Massachusetts creates a
26 list of toxic or hazardous substances which includes substances
found to have sufficient evidence of carcinogenicity in animals
27 as indicated in the IARC Monographs. Mass. Reg., tit. 105, §
670.010(b)(1); see also Zuckerman Decl., Exh. L, Table of
28 Reliance on IARC by Other States; SUF No. 15.

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

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

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

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

26 ¹⁴ See Zuckerman Decl., Exh. M; 27 CCR, § 25704; SUF No. 20.

27 ¹⁵ Zuckerman Decl., Exh. A; SUF No. 21.

28 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.

1 mechanistic data.¹⁷ Because IARC is required to base its review
 2 on data from published reports (or reports that have been
 3 accepted for publication), and data from publicly available
 4 government agency reports, it did not review confidential
 5 research and data sponsored and produced by Monsanto.¹⁸ After
 6 completing its review, IARC classified glyphosate as “probably
 7 carcinogenic to humans (Group 2A),” its second highest
 8 classification, based on “sufficient evidence” in animals and
 9 “limited evidence” in humans, as well as mechanistic analysis and
 10 other relevant data.¹⁹ These were the consensus findings of the
 11 17-member Working Group, which published its conclusions in a 78-
 12 page Monograph.²⁰

13 **D. EPA’s and Other Regulatory Agencies’ Conclusions**

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

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

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

24 ¹⁹ Zuckerman Decl., Exh. A, at 361-394, 398-399; SUF No. 27;
 25 SUF No. 31. IARC uses the term “limited evidence” with regard to
 26 evidence in humans to mean that a positive association has been
 27 observed between exposure to the agent (in this case,
 28 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.

1 several times, and has repeatedly stated that it is "not likely
 2 to be carcinogenic to humans."²¹ Most recently, EPA expressed
 3 this finding in a Proposed Interim Registration Review Decision
 4 and Responses to Public Comments for Glyphosate,²² and reiterated
 5 it in a letter specifically referencing Proposition 65 (see
 6 Background Section III.D, *infra*). It is also true that
 7 regulatory agencies in other countries have concluded that there
 8 is insufficient evidence that glyphosate causes cancer, either at
 9 all (i.e., it is not a cancer *hazard*) (the European Chemical
 10 Agency [ECHA],²³ the European Food Safety Authority [EFSA],²⁴ and
 11 the New Zealand Environmental Protection Agency [NZEPA]²⁵), or at
 12 the levels to which humans are typically exposed (i.e., that it
 13 does not present a cancer *risk*) (Health Canada,²⁶ the Australian
 14 Pesticides and Veterinary Medicines Authority, the Food and
 15
 16
 17
 18

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

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

21 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.

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

25 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
 26 No. 38.

27 ²⁶ Zuckerman Decl., ¶ 22 and Exh. U ("Glyphosate is not
 genotoxic and is unlikely to pose a human cancer risk."); SUF No.
 28 38.

1 Agricultural Organization,²⁷ and the World Health Organization
2 Joint Meeting on Pesticide Residues²⁸).

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

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

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

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

28 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.

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

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

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

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

14 In April 2018, the California Fifth District Court of
15 Appeal unanimously rejected a constitutional challenge by
16 Monsanto to the listing of glyphosate as a carcinogen under
17 Proposition 65. *Monsanto v. OEHHA*, 22 Cal. App. 5th 534, 559
18 (Cal. Ct. App. 2018), review den. (Cal. 2018). At the heart of
19 the challenge was Monsanto's claim that IARC was an untrustworthy
20 and unreliable foreign agency on whose determinations Proposition
21 65 could not constitutionally rely. The Court rejected this
22 contention, concluding that Proposition 65 reasonably relies on
23 IARC to perform its carcinogen identification function. *Id.*

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

27 On July 1, 2018, OEHHA finalized a "safe-harbor" No
28 Significant Risk Level (NSRL) for glyphosate of 1,100 micrograms
per day ($\mu\text{g/day}$). 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

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

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

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

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

23 ³⁴ Zuckerman Decl., Exh. O, at 1, 6-7. 9-10; SUF No. 48. OEHHA
 24 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.

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

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

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

28 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 herbicides³⁹] 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.

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.

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

12 **1. *Johnson v. Monsanto***

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

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

27 ⁴³ Zuckerman Decl., Exh. KK, at 5614:00029-01 - 5615:00031-18;
 28 5617:00037:4-5618:00038-17; Zuckerman Decl., Exh. LL, at 6516;
 Zuckerman Decl., Exh. JJ, at 3274:5 - 3275:8; SUF No. 66.

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

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

22 ⁴⁴ Zuckerman Decl., Exh. KK, at 5622:00051-01 - 5623:00053;
 23 Zuckerman Decl., Ex. LL, at 6519; Zuckerman Decl., Exh. JJ, at
 24 3275:11 - 3283:3; Zuckerman Decl., Exh. MM, at 7; SUF No. 67.

25 ⁴⁵ Zuckerman Decl., Exh. LL, at 6519; Zuckerman Decl., Exh.
 26 KK, at 5642:000133:01-16; Zuckerman Decl., Exh. B, at 1; SUF No.
 27 68.

28 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.

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

8 **2. Hardeman v. Monsanto Co.**

9 In a lawsuit filed in U.S. District Court for the Northern
 10 District of California, Edwin Hardeman alleged that he acquired
 11 non-Hodgkin's lymphoma as a result of his use of Roundup. In a
 12 two-phase verdict, the jury found in March 2019 that "Mr.
 13 Hardeman prove[d] by a preponderance of the evidence that his
 14 exposure to Roundup was a substantial factor in causing his non-
 15 Hodgkin's lymphoma."⁵¹ The jury also found that "Monsanto was
 16 negligent by not using reasonable care to warn about Roundup's
 17 [non-Hodgkin's lymphoma] risk," and that Mr. Hardeman proved by
 18 "clear and convincing evidence that he is entitled to punitive
 19 damages."⁵² In denying Monsanto's motion for a new trial in July
 20 2019, Judge Chhabria reiterated a pre-trial ruling that there was
 21 sufficient admissible evidence that plaintiff's use of
 22 glyphosate-based pesticides caused his cancer. *In re Roundup*
 23 *Products Liability Litigation*, No. 16-CV-0525-VC, 2019 WL
 24 3219360, at *1 (N.D. Cal., July 12, 2019) ("There was no material
 25 difference between the quality of the causation evidence

26 ⁴⁹ Zuckerman Decl., Exh. EE, at 3; SUF No. 74.

27 ⁵⁰ Zuckerman Decl., Exh. FF, at 6-7; SUF No. 75.

28 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 verdict⁵⁷ 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

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

1 the agency.⁶¹ Four scientists associated with EPA – the scientist
 2 from EPA's National Center for Computational Toxicology on the
 3 IARC Working Group,⁶² and three members of the EPA Science
 4 Advisory Panel that reviewed glyphosate⁶³ – have agreed with
 5 IARC's finding that glyphosate is a probable human carcinogen.⁶⁴
 6 They were not alone. Documents recently disclosed by the EPA
 7 show that in 2015, Vincent Coglianò, Ph.D., then a scientist at
 8 EPA's Office of Research and Development (ORD), the scientific
 9 research arm of EPA, referenced divided conclusions within the
 10 agency:

11
 12 I believe that ORD scientists would be split on whether there
 13 is adequate supporting experimental evidence. Some might
 14 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

15 Ultimately, as noted above, a different position prevailed.
 16
 17

18 _____
 Proposition 65 and its regulations.

19 ⁶¹ Zuckerman Decl., Exh. PP; SUF No. 87.

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

21 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
 24 Nos. 57-58. Dr. Zhang is currently a member of OEHHA's
 Carcinogen Identification Committee.

25 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.

27 ⁶⁵ Zuckerman Decl., Exh. PP, at 4-5; SUF No. 87. Dr. Coglianò
 28 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.

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

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 2019⁷⁷), 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 OEHHHA 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." §

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

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.

1 determinations chemicals are listed as carcinogens.

2 Proposition 65 provides four separate mechanisms for listing
3 chemicals, each with its own distinct and independent
4 requirements. §§ 25249.8(a), (b). Three of the listing
5 mechanisms rely on work conducted by outside scientific and
6 regulatory entities. *Id.* These entities include the Food and
7 Drug Administration, the EPA, the National Toxicology Program,
8 and IARC. 27 CCR, § 25306(1), (m).

9 **C. The Listing Mechanism Applicable in This Case.**

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

17 Consistent with their distrust of state agencies, the voters
18 made a specific decision when they enacted the Proposition 65
19 warning requirement: they wanted to be informed before they were
20 exposed to chemicals that had been identified by certain *outside*
21 entities as causing cancer. See § 25249.8(a); Cal. Lab. Code §§
22 6382(b)(1), (d). Among those outside entities was IARC, an
23 "'organization[] of the most highly regarded national and
24 international scientists.'" *Deukmejian*, 212 Cal. App. 3d at 436.
25 The proponents of Proposition 65 made this clear in the ballot
26 pamphlet:

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

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

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

12 Thus, the various listing mechanisms were included to ensure
 13 "the Proposition 65 list of chemicals 'known to the state to
 14 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)."

15 *Monsanto v. OEHHA*, 22 Cal. App. 5th 534 at 552-553 (emphasis in
 16 original) (quoting *California Chamber of Commerce v. Brown*, 196
 17 Cal. App. 4th at 259-260). The court specifically held that
 18 voters adopted an inclusionary process for creating the
 19 Proposition 65 list, which "allows one of the various mechanisms
 20 for listing a chemical as known to the state to cause cancer to
 21 ensure that chemical is on the list **regardless of whether other**
 22 **identified listing agencies or processes agree.**" *Id.* at 556,
 23 552-553 (emphasis added).

24
 25
 26 ⁸⁵ Zuckerman Decl., Exh. WW; SUF No. 110. "The courts often
 27 turn to the ballot summaries and arguments for the purpose of
 28 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.”)

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

7 **E. The Warning Requirement.**

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

16 A business need not provide a warning for a listed carcinogen
 17 if it can show that the exposure it causes "poses no significant
 18 risk assuming lifetime exposure at the level in question." §
 19 25249.10(c); *Monsanto v. OEHHA*, 22 Cal. App. 5th at 559-560;
 20 *DiPirro v. Bondo Corp.*, 153 Cal. App. 4th 150, 188 (Cal. Ct. App.
 21 2007). This "no significant risk" level (NSRL) is defined as an
 22 exposure that results in no more than "one excess case of cancer
 23 in an exposed population of 100,000, assuming lifetime exposure
 24 at the level in question."⁸⁸ 27 CCR, § 25703(b). In short, if a
 25 business shows that the exposure it causes will result in *no more*
 26 *than one excess case of cancer* per 100,000 exposed individuals,

27 ⁸⁷ Zuckerman Decl., Exh. YY; SUF No. 111.

28 ⁸⁸ See Glossary attached as Exhibit A.

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

6 **1. The No Significant Risk Level.**

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

23 ⁸⁹ This 1/100,000 cancer risk level is set by regulation. 27
 24 CCR, § 25703(b). It is less strict than the "1 in 1,000,000 risk"
 25 level standard used by many regulatory agencies. See *Ingredient*
 26 *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.")

27 ⁹⁰ Zuckerman Decl., Exh. O; SUF No. 44-50. Plaintiffs'
 28 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

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.

1 the product by the average serving size and number of
 2 servings per day for that food. If the result is below
 3 1,100 µg, no Proposition 65 warning is required.⁹⁷
 4 An accurate calculation showing an exposure of less than 1,100
 5 µg/day is a complete defense to any Proposition 65 action
 6 alleging failure to provide a warning for exposure to the average
 7 consumer of a product to glyphosate. See 27 CCR, § 25703(b).

8 **4. Warning Language.**

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

16 Use of the safe-harbor warning language, however, is
 17 optional. A business may use any other warning method or content
 18 that is clear and reasonable, § 25249.6; 27 CCR, § 25601, and a
 19 court may approve a more nuanced warning that it deems
 20 appropriate. Attached to the Declaration of Laura Zuckerman are
 21 several examples of Proposition 65 consent judgments in which
 22 courts have approved warnings that depart from the safe harbor
 23 language.⁹⁸ Whether a non-safe-harbor warning is clear and
 24 reasonable is determined on a case-by-case basis. *Ingredient*
 25 *Comm'n Council*, 2 Cal. App. 4th at 1480, 1492 (Cal. Ct. App.
 26 1992).

27 ⁹⁷ Lee Declaration, ¶ 11; SUF No. 119.

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

1 **5. Proposition 65 Enforcement.**

2 Proposition 65 may be enforced by the Attorney General, by
3 any district attorney, and by city attorneys in certain large
4 cities. § 25249.7(c). Private citizens may also enforce the
5 statute "in the public interest," with certain restrictions. §
6 25249.7(d). To file an enforcement action, a private enforcer
7 must first provide notice of the alleged violation to the public
8 prosecutors and to the alleged violator. § 25249.7(d)(1). If,
9 after 60 days, no public prosecutor is diligently prosecuting the
10 violation, then the private enforcer may file suit. *Id.*

11 In response to concerns over frivolous private enforcement
12 actions, the California Legislature amended Proposition 65 in
13 2002 to require private enforcers to demonstrate the basis for
14 their belief that an action has merit before proceeding with
15 private enforcement. *DiPirro v. American Isuzu Motors, Inc.*, 119
16 Cal. App. 4th 966, 970 (Cal. Ct. App. 2004). The private
17 enforcer must submit a "certificate of merit" with each 60-day
18 notice stating that the person executing the certificate has
19 consulted with relevant experts who have reviewed "facts,
20 studies, and other data regarding the exposure" at issue and
21 that, based on that consultation, the noticing party believes
22 "there is a reasonable and meritorious case for the private
23 action." § 25249.7(d)(1). The noticing party must submit
24 confidential, factual information to the Attorney General
25 "sufficient to establish the basis of the certificate of merit. .
26 . ." *Id.*

27 In 2017, the Legislature further amended the law to
28 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.

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

3 **V. PROCEDURAL BACKGROUND**

4 On December 6, 2017, plaintiffs filed a Motion for
5 Preliminary Injunction, asking the Court to enjoin (1) OEHHA's
6 listing of glyphosate as a chemical known to cause cancer, and
7 (2) the warning requirement of Health & Safety Code section
8 25249.6 as applied to glyphosate. In an order dated February 26,
9 2018, the court denied plaintiffs' request to enjoin the listing,
10 but preliminarily enjoined the warning requirement, finding,
11 inter alia, that "the required warning for glyphosate does not
12 appear to be factually accurate and uncontroversial because it
13 conveys the message that glyphosate's carcinogenicity is an
14 undisputed fact, when almost all other regulators have concluded
15 that there is insufficient evidence that glyphosate causes
16 cancer." Memorandum and Order Re: Motion for Preliminary
17 Injunction, Docket No. 75, at 15.

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

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

26 ¹⁰² Lee Decl.; ¶ 11-22; SUF No. 124. Thus, the need for
27 warnings on such products, especially for food products - because
28 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

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

3 **ARGUMENT**

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

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

13 **A. A Case Is Not Ripe Where There Is No Actual** 14 **Controversy and No Credible Threat of Enforcement.**

15 The role of the federal courts is "neither to issue advisory
 16 opinions nor to declare rights in hypothetical cases, but to
 17 adjudicate live cases or controversies consistent with the powers
 18 granted the judiciary in Article III of the Constitution."
 19 *Thomas v. Anchorage Equal Rights Comm'n*, 220 F.3d 1134, 1138 (9th
 20 Cir. 2000); *see also, e.g., Ray Charles Found. v. Robinson*, 795
 21 F.3d 1109, 1116 (9th Cir. 2015) (ripeness goes to the court's
 22 subject matter jurisdiction to hear a case); *Alaska Right to Life*
 23 *Political Action Comm. v. Feldman*, 504 F.3d 840, 844 (9th Cir.
 24 2007) (without fully developed factual record showing real threat
 25 of enforcement and hardship resulting from withholding federal
 26 adjudication, district court should have declined jurisdiction
 27 for lack of a justiciable case or controversy). The ripeness
 28 requirement "prevent[s] the courts, through avoidance of

1 premature adjudication, from entangling themselves in abstract
2 disagreements” *Abbott Lab. v. Gardner*, 387 U.S. 136, 148
3 (1967), overruled on other grounds, *Califano v. Sanders*, 430 U.S.
4 99 (1977).

5 The ripeness inquiry has both constitutional and prudential
6 components. *Nat’l Park Hospitality Ass’n v. Dep’t of Interior*,
7 538 U.S. 803, 808 (2003). For a claim to be ripe in the
8 constitutional sense in a declaratory judgment case, “the facts
9 alleged, under all the circumstances, [must] show that there is a
10 substantial controversy, between parties having adverse legal
11 interests, of sufficient immediacy and reality to warrant the
12 issuance of a declaratory judgment.” *Montana Env’l Info. Center*
13 *v. Stone-Manning*, 766 F.3d 1184, 1188 (9th Cir. 2014) (citations
14 and internal quotation marks omitted); *Colwell v. Dep’t of Health*
15 *& Human Serv.*, 558 F.3d 1112, 1123 (9th Cir. 2009) (dispute must
16 “present concrete legal issues, presented in actual cases, not
17 abstractions”) (citations and internal quotation marks omitted).
18 “[N]either the mere existence of a proscriptive statute nor a
19 generalized threat of prosecution satisfies the ‘case or
20 controversy’ requirement.” *Thomas*, 220 F.3d at 1139.

21 Courts may also decline to exercise jurisdiction based on
22 prudential considerations. *Thomas*, 220 F.3d at 1141. These
23 prudential considerations are twofold: “the fitness of the
24 issues for judicial decision and the hardship to the parties of
25 withholding court consideration.” *Id.* (quoting *Abbott Lab.*, 387
26 U.S. at 149). When evaluating hardship, the court is to consider
27 “whether the ‘regulation requires an immediate and significant
28 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-

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

5 *California Pro-Life Council, Inc. v. Getman*, 328 F.3d 1088, 1093,
6 1095 (9th Cir. 2003) (citations and internal quotation marks
7 omitted, emphasis added); *see also, e.g., Alaska Right to Life*
8 *Political Action Comm.*, 504 F.3d at 851 (court may adopt this
9 “somewhat relaxed approach to justiciability . . . only upon a
10 showing that plaintiff is immediately in danger of sustaining a
11 direct injury as a result of an executive or legislative action”)
12 (citations and internal quotation marks omitted); *Italian Colors*
13 *Restaurant v. Becerra*, 878 F.3d 1165, 1171 (9th Cir. 2018) (even
14 in First Amendment context, plaintiff must demonstrate “credible
15 threat of enforcement”).

16 In *Thomas*, landlords who refused to rent to unmarried couples
17 brought a First Amendment pre-enforcement challenge to a statute
18 and ordinance prohibiting marital status discrimination in rental
19 decisions. 220 F.3d at 1138. The Ninth Circuit found the action
20 unripe, both on constitutional and prudential grounds, because
21 the record was “devoid of any specific factual context.” *Id.* at
22 1141. The court explained:

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

32 *Id.*; *see also, e.g., American-Arab Anti-Discrimination Comm. v.*
33 *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

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

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

14 However, all of the data the Attorney General has reviewed to
15 date on glyphosate concentrations in finished food products make
16 clear that the levels would not be high enough to require a
17 warning or justify a Proposition 65 enforcement action. In fact,
18 the only evidence in this record for finished food products
19 demonstrates that food producers would have a complete defense
20 under California Health & Safety Code section 25249.10(c) based
21 on the 1,100 µg/day NSRL issued by OEHHA on July 1, 2018. See
22 Lee Decl., ¶¶ 13-21. The **highest** level of glyphosate found in
23 any of the 263 samples, or composite samples, of finished food
24 product was 2,837 parts per billion in Quaker Oat Meal Squares -
25 Honey Nut. *Id.*, ¶ 15. A consumer would have to eat 13.68 ounces
26 - nearly an entire box - of this cereal every day in order to be
27 exposed to 1,100 micrograms of glyphosate. *Id.* Since an average
28

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

3 Because there is currently no "past or future actionable
4 violation" of Proposition 65, there is no justiciable controversy
5 regarding whether any warning compelled by the statute violates
6 the First Amendment. *See, e.g., Knapp v. City of Coeur d'Alene*,
7 172 F. Supp. 3d 1118, 1135-36 (D. Idaho 2016).

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

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

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

27 ¹⁰³ Declaration of Martha Sandy, Ph.D., ¶ 5. This estimate
28 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.

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

1 speculative that a private enforcer would proceed to file a
 2 lawsuit, especially given the risk that the suit could ultimately
 3 be deemed frivolous under California Health & Safety Code section
 4 25249.7(h)(2). See, e.g., *Darring v. Kincheloe*, 783 F.2d 874,
 5 877 (9th Cir. 1986) ("speculative" fears of prosecution are not
 6 ripe).

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

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

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

23 ¹⁰⁵ In this way, this case stands in stark contrast to *Nat'l*
 24 *Inst. of Family & Life Advocates v. Harris*, 839 F.3d 823, 833
 25 (9th Cir. 2016), *rev'd and remanded sub nom. Nat'l Inst. of*
 26 *Family & Life Advocates v. Becerra*, 138 S. Ct. 2361 (2018),
 27 wherein the Ninth Circuit found the claims constitutionally ripe
 28 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

1 factual and uncontroversial information about the terms under
 2 which . . . services will be available.” *Id.* at 2372 (citation
 3 and quotation omitted) (noting that “abortion [is] anything but
 4 an ‘uncontroversial’ topic”).

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

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

11 In *American Beverage Ass’n v. City & County of San Francisco*,
 12 916 F.3d 749 (9th Cir. 2019) (en banc), the Ninth Circuit
 13 evaluated the constitutionality under the First Amendment, in
 14 light of *NIFLA*, of a San Francisco ordinance requiring that
 15 certain advertisements for sugar-sweetened beverages include the
 16 following statement:

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

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

25 ¹⁰⁷ It was for this very reason that the Court granted a stay
 26 of the litigation pending the issuance of these decisions. Order
 27 Re: Motion to Stay, Docket No. 109 (“Because *CTIA* and *American*
 28 *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.”).

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

20 ¹⁰⁸ Although plaintiffs contend that intermediate scrutiny
 21 should apply to this case because the Proposition 65 warning is
 22 not designed to prevent consumer deception, they acknowledge that
 23 they are bound by contrary Ninth Circuit authority. Pltfs.' Br.
 24 at 33, n.11. They do, however, suggest that the First Amendment
 25 prohibits regulations that compel speech to the same extent that
 26 it prohibits regulations that restrict speech. Pltfs.' Br. at
 27 31. But nothing in *Janus v. Am. Fed'n of State, Cty., & Mun.*
 28 *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:

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.*

1 The City of Berkeley requires that you be provided the
2 following notice:

3 To assure safety, the Federal Government requires that
4 cell phones meet radio-frequency (RF) exposure
5 guidelines. If you carry or use your phone in a pants or
6 shirt pocket or tucked into a bra when the phone is ON
7 and connected to a wireless network, you may exceed the
8 federal guidelines for exposure to RF radiation. Refer
9 to the instructions in your phone or user manual for
10 information about how to use your phone safely.

11 Berkeley Mun. Code § 9.96.030(A) (2015).

12 *Id.* at 846.

13 The parties in *CTIA II* agreed that the ordinance at issue was
14 a regulation of commercial speech, but disagreed as to whether it
15 should be analyzed under *Central Hudson Gas & Elec. Corp. v. Pub.*
16 *Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980), which applied
17 intermediate scrutiny to a New York ordinance *restricting*
18 advertising by a utility, or *Zauderer*. *CTIA II*, 928 F.3d at 841-
19 42.

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

1 *Zauderer* so long as it is substantial.”¹¹² *CTIA II*, 928 F.3d at
 2 843-44. It asserted that *NIFLA* signaled the Supreme Court’s
 3 agreement with this reading of *Zauderer*, and it noted that other
 4 substantial interests may also qualify for use of this more
 5 relaxed standard. *Id.* at 844.

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

13 The dispute in *NIFLA* was whether the state could require a
 14 clinic whose primary purpose was to oppose abortion to
 15 provide information about “state-sponsored services,”
 16 including abortion. *While factual, the compelled statement*
 17 *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.

18 *Id.* (emphasis added).

19 Next, the court examined the question whether the required
 20 disclosure was “purely factual” within the meaning of *Zauderer*.
 21 *CTIA II*, 928 F.3d at 846. The court acknowledged that “a
 22 statement may be literally true but nonetheless misleading and,
 23

24 ¹¹² As the Second Circuit noted in *Sorrell*, “Innumerable
 25 federal and state regulatory programs require the disclosure of
 26 product and other commercial information. . . . To hold that the
 27 Vermont statute is insufficiently related to the state’s interest
 28 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).

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

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

17 Plaintiffs’ assertions to the contrary notwithstanding, it is
18 possible to provide a warning for glyphosate that is “factual and
19 uncontroversial” and “reasonably related” to the State’s
20 substantial interest in providing information to California
21 consumers so they can make informed decisions about their
22 exposure to glyphosate, and that complies with Proposition 65’s
23 requirement that it be “clear and reasonable.” This case,
24 however, presents a unique set of circumstances, in that two of
25 the authoritative bodies recognized under Proposition 65 have
26 reached different conclusions about a chemical within a few years
27 of each other. Conveying that information within the warning
28 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.

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

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

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

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

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

25 ¹¹⁴ See Zuckerman Decl., Exh. FFF; SUF No. 126. Although the
 26 information on the website is not incorporated into the warning
 27 for purposes of Proposition 65, it can be considered as part of
 28 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.”)

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

3 Moreover, the plaintiffs' reliance on *Pacific Gas & Elec. Co.*
4 *v. Public Utilities Comm'n of Cal.*, 475 U.S. 1, 13-14 (1986)
5 (plurality op.), is misplaced. Pltfs.' Br. at 35. *Pacific Gas &*
6 *Elec. Co.* was a case striking down an order requiring PG&E to
7 broadcast others' subjective opinions and political messages.
8 *Id.* at 5. Nor does *Nat'l Ass'n of Mfrs. v. S.E.C.*, 800 F.3d 518,
9 537 (D.C. Cir. 2015), have any relevance here: the Proposition
10 65 warning requirement is not compelling speech about "matters of
11 opinion." Here, the Proposition 65 warning requirement, if made
12 necessary by high levels of glyphosate exposure, does not require
13 dissemination of subjective opinion. It requires dissemination
14 only of facts.

15 **b. The Warning is Uncontroversial**

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

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

25 ¹¹⁵ As Judge Smith found in *Pilliod*, "Monsanto made efforts to
26 impede, discourage, or distort scientific inquiry and the
27 resulting science. . . . Monsanto worked to publish articles
28 that it had ghostwritten. Monsanto made an aggressive attempt to
discredit the IARC decision." Zuckerman Decl., Exh. 00, at 17;
SUF No. 84.

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

12 Second, the scientific debate over whether glyphosate causes
13 cancer is distinguishable from the kind of moral or ethical
14 controversy at issue in *NIFLA*, where health care providers were
15 required to post a message relating to abortion, one of the most
16 politically divisive issues of our day. *NIFLA*, 138 S. Ct. at
17 2372. Indeed, the Ninth Circuit highlighted the distinction in
18 *CTIA II*. Despite the parties' disagreement about the safety of
19 cell phone radiation exposure, the court held Berkeley's required
20 disclosure "uncontroversial within the meaning of *NIFLA* [because
21 it] does not force cell phone retailers to take sides in a heated
22 political controversy." *CTIA II*, 928 F.3d at 848 (citing *NIFLA*,
23 138 S. Ct. at 2376); see also 928 F.3d at 845 ("while factual,
24 the compelled statement [in *NIFLA*] took sides in a heated
25 political controversy, forcing the clinic to convey a message
26 fundamentally at odds with its mission. Under these
27 circumstances, the compelled notice was deemed controversial
28 within the meaning of *Zauderer*"). Thus, although the potential

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

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

15
 16 **Can glyphosate cause cancer?**

17 There have been several agencies and organizations both
 18 in the United States and internationally that have
 reviewed studies and made an assessment about whether
 glyphosate could cause cancer.

19 The U.S. Environmental Protection Agency (EPA)
 20 classification for glyphosate is "not likely" to be
 carcinogenic (causing cancer) to humans, based on
 evidence from animals and humans.

21
 22 The International Agency for Research on Cancer
 (IARC) has classified glyphosate as "probably"
 23 carcinogenic to humans, which means there was
 sufficient evidence to find cancer in animals, but
 24 limited evidence finding cancer in humans.

25 See Zuckerman Decl., ¶ 58 and Exh. GGG; SUF No. 126. In this
 26 regard, it is like the warning in *CTIA II*, which conveyed
 27 information about cell phone radiation also provided by the FCC.
 28 928 F.3d at 840.

1 Three other federal agencies – the U.S. Food and Drug
 2 Administration, the National Toxicology Program, and EPA itself –
 3 also provide fact sheets about glyphosate to consumers. These
 4 fact sheets include information about the 2015 IARC
 5 carcinogenicity determination, followed by information about
 6 other international organizations' conclusions. Zuckerman Decl.,
 7 ¶¶ 59-61 and Exhs. HHH-JJJ; SUF No. 126. A fourth agency, OSHA,
 8 requires that SDSs state “[whether] the hazardous chemical . . .
 9 has been found to be a potential carcinogen in the [IARC]
 10 Monographs (latest edition), or by OSHA.” 29 C.F.R. § 1910.1200,
 11 App. D. These federal agencies do not all require the same
 12 organizations to be listed in the fact sheets, or, in OSHA's
 13 case, on the SDS, but all four federal agencies consider it
 14 important for consumers and workers to have the information about
 15 the IARC determination. See Zuckerman Decl., ¶¶ 58-61 and Exhs.
 16 GGG-JJJ; SUF No. 126.

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

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

1 928 F.3d at 845 (“There is no question that protecting the health
2 and safety of consumers is a substantial government interest.”);
3 *NIFLA*, 138 S. Ct. at 2376 (the Supreme Court does “not question
4 the legality of health and safety warnings, long considered
5 permissible[.]”)

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

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

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

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

9 Plaintiffs’ narrow view of California’s interest – permitting
10 the State to provide information about a chemical only if there
11 is 100% certainty and universal agreement that it causes cancer –
12 is incorrect. See Pltfs.’ Br. at 48-49. In support of their
13 argument, plaintiffs rely heavily on *California Chamber of*
14 *Commerce v. Brown*, 196 Cal. App. 4th 233, 258 (Cal. Ct. App.
15 2011), in which the California Court of Appeal noted that the
16 preamble to Proposition 65 reflects that one of the statute’s
17 purposes is to inform the people “about exposures to chemicals
18 that cause cancer[.]” But the court in that case was not
19 addressing whether chemicals had to be known with absolutely
20 certainty to cause cancer; instead, it merely considered OEHHA’s
21 authority to add chemicals to the Proposition 65 list under
22 Health and Safety Code Section 25249.8(a). *Id.* at 248; see also
23 *id.* at 258 (“Proposition 65 is a remedial statute and therefore
24 should be broadly construed to achieve its protective
25 purposes.”).

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

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

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

8 Moreover, taken to its logical conclusion, plaintiffs'
 9 argument would mean that California has no interest in requiring
 10 warnings about any chemical unless and until everyone agrees
 11 beyond a shadow of a doubt that the chemical causes cancer. Such
 12 a consensus, if it is ever achievable, often takes decades to
 13 reach - as, for example, was the case for tobacco.¹¹⁷ It was not
 14 until 1964 that the U.S. Surgeon General first issued a report on
 15 the health effects of smoking.¹¹⁸ Since then, "evolving
 16 scientific evidence" has been a "key driver of the changes that
 17 have led to a dramatic shift in social norms around cigarette
 18 smoking."¹¹⁹ The First Amendment does not require such an
 19 extensive incubation period before the government can compel the
 20 disclosure of information based on reliable scientific findings.
 21
 22

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

24 ¹¹⁸ Zuckerman Decl., Exh. KKK, at I; SUF 127; *id.* at I; SUF
 25 No. 127.

26 ¹¹⁹ Zuckerman Decl., Exh. KKK, at 17; see also *id.* at 45
 27 (noting that although the Surgeon General's 1964 report is
 28 "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

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

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

16 **2. The Proposed Form of Warning Would Also Survive** 17 **Scrutiny Under *Central Hudson*.**

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

26 to sales. See Zuckerman Decl., Exh. MMM, at MONGLY14441108.
 27 Haklyut reported that, according to a senior executive at one
 28 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.*

1 designed carefully to achieve" the state's goal. *Central Hudson*
2 *Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557,
3 564 (1980). To survive scrutiny, the restriction must "directly
4 advance" the state's interest, and the state's interest must not
5 be capable of being "served as well by a more limited
6 restriction." *Id.*

7 As outlined above, Proposition 65's warning requirement for
8 glyphosate directly advances California's substantial interest in
9 ensuring that its citizens receive information about exposures to
10 a potentially harmful chemical. California's voters wanted to
11 know if they would be exposed to chemicals that IARC and other
12 authoritative bodies had determined are likely carcinogenic.
13 California has a legitimate interest in providing that
14 information, and a requirement that companies disclose this type
15 of factual, uncontroversial information related to the good or
16 service at issue necessarily advances this interest. In
17 addition, Proposition 65's warning requirement is narrowly drawn
18 to advance the State's interest in ensuring that its citizens are
19 empowered to make informed decisions about their exposure to
20 potentially harmful chemicals. *Central Hudson*, 447 U.S. at 569-
21 570 (warning requirement must be "no more extensive than
22 necessary" to advance the state's interest).

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

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

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

23 Importantly, Proposition 65 allows for flexibility such that
24 a variety of warnings are available to businesses required to
25 provide them. These provisions create a careful “fit” between
26 the state's ends and means. *Bd. of Trs. v. Fox*, 492 U.S. 469,
27 480 (1989) (“a fit that is not necessarily perfect, but

28 ¹²¹ Zuckerman Decl., Exh. FFF; SUF No. 133

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

9 Plaintiffs argue that, under *Central Hudson*, the government
10 has a heavy burden to demonstrate that harms to be addressed by a
11 speech restriction are real, and the restriction will alleviate
12 them to a material degree. Pltfs.’ Br. at 46-47. But the speech
13 restriction cases plaintiffs cite to support their argument are
14 inapposite here, where plaintiffs challenge a disclosure mandate.
15 As the Supreme Court implicitly recognized in *Zauderer*, and the
16 D.C. Circuit emphasized in *AMI*, evidence of a measure’s
17 effectiveness, is not necessary “when the government uses a
18 disclosure mandate to achieve a goal of informing consumers about
19 a particular product trait, assuming of course that the reason
20 for informing consumers qualifies as an adequate interest.” *AMI*,
21 760 F.3d at 26; *Zauderer*, 47 U.S. at 651.

22 **D. The Warning Complies With Proposition 65.**

23 Under Proposition 65, a business may use any warning method
24 or content that is clear and reasonable, § 25249.6 and 27 CCR, §
25 25600(f), and a court may approve a more nuanced warning that it
26 deems appropriate. The Attorney General consistently has
27 recognized, in this case and others, that companies *can* (though
28 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).

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

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

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

26
 27 ¹²³ Zuckerman Decl. ¶ 55 and Exh. BBB at 4-5; SUF No. 125.

28 ¹²⁴ *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").

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

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

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

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

17 Plaintiffs point to a court-approved McDonald's warning
 18 similar to that used in the Burger King consent judgment as an
 19 example of a warning with impermissible additional language that
 20 would not protect entities from private enforcement actions.¹²⁶
 21 But no court disapproved the warning in the cited case, and
 22 McDonald's relies on the warning to this day.¹²⁷ A 60-day notice
 23 issued to McDonald's for acrylamide and certain other chemicals
 24

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

26 ¹²⁶ See Pltfs.' Br. at 53 n.13; Plaintiffs' Statement of
 27 Undisputed Facts, ¶ 46.

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

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

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

10 **III. PROPOSITION 65'S WARNING REQUIREMENT IS NOT UNCONSTITUTIONALLY** 11 **VAGUE.**

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

18 **A. Plaintiffs Did Not Plead Constitutional Vagueness as** 19 **a Ground for Relief.**

20 As an initial matter, plaintiffs failed to plead anywhere in
21 their Amended Complaint that Proposition 65 is so vague that they
22 have not received fair notice of what the law requires. The
23 Court should reject plaintiffs' due process argument for this
24 reason alone. *See, e.g., Loan Payment Admin. LLC v. Hubanks*, No.
25 14-CV-04420-LHK, 2018 WL 6438364, at * 13 (N.D. Cal, Dec. 07,
26 2018) (rejecting argument that statute is unconstitutionally
27 vague and noting that the plaintiff's operative complaint

28 ¹²⁸ Zuckerman Decl., ¶ 66 and Exh. 000; SUF No. 131

1 “conspicuously avoids any discussion of the constitutional basis
2 for its vagueness claim”).

3 **B. The Court Should Reject Plaintiffs’ Disfavored Facial**
4 **Challenge to Proposition 65.**

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

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

25 ¹²⁹ In contrast, courts define an as-applied challenge as one
26 “‘under which the [party] argues that a statute, even though
27 generally constitutional, operates unconstitutionally as to him
28 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)).

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

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

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

21 The relevant inquiry in an as-applied challenge is whether
 22 the challenged statute is unconstitutionally vague as applied to
 23 the particular facts at issue such that the challenging party
 24 does not have sufficient notice that his or her conduct would be
 25 a violation of the statute. *Holder v. Humanitarian Law Project*,
 26 561 U.S. 1, 18 (2010). "Condemned to the use of words, we can
 27 never expect mathematical certainty from our language." *Grayned*
 28 *v. City of Rockford*, 408 U.S. 104, 110 (1972). Accordingly, the

1 Constitution permits statutes that are "marked by 'flexibility
 2 and reasonable breadth, rather than meticulous specificity,'" *id.*
 3 (quoting *Esteban v. Cent. Mo. State Coll.*, 415 F.2d 1077, 1088
 4 (8th Cir. 1969) (Blackmun, J.), *cert. denied*, 398 U.S. 965
 5 (1970)). Further, in examining the purported "vagueness" of the
 6 Proposition 65, the Court should bear in mind "the elementary
 7 rule that every reasonable construction must be resorted to, in
 8 order to save a statute from unconstitutionality." *Gonzales v.*
 9 *Carhart*, 550 U.S. 124, 153 (2007) (citations and internal
 10 quotation marks omitted).

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

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

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

4 That the warning must be "clear and reasonable" does not
5 render what the statute requires impermissibly unclear. Indeed,
6 California courts have had little difficulty applying that
7 standard to approve a variety of warnings in consent judgments
8 that differ from, or go beyond, the safe harbor warnings set
9 forth in the regulations implementing Proposition 65. These
10 include lengthier, more nuanced warnings to fit the circumstances
11 of the particular case, including where U.S. federal agencies
12 have not deemed warnings necessary. For example, and as
13 described above in Section II.D, in *Council for Education and*
14 *Research on Toxics v. McDonald's Corporation et al.*, the Los
15 Angeles County Superior Court approved a nuanced warning for
16 acrylamide in a variety of cooked foods, including French fries
17 and hash browns, and in the *Coordination Proceeding Proposition*
18 *65 Fish Cases*, the San Francisco County Superior Court approved a
19 nuanced warning for mercury in fish. Insofar as warnings would
20 even be necessary in this case, plaintiffs could surely tailor
21 these, and many other court-approved warnings to their products.
22 Indeed, the warning offered by the Attorney General in this brief
23 does just this, incorporating language based on numerous warnings
24 approved by California courts. Plaintiffs' vagueness argument is
25 unfounded.

26 CONCLUSION

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

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

4
5 Dated: December 11, 2019

Respectfully submitted,

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EXHIBIT A

Glossary

No Significant Risk Level (NSRL) - 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. A business that causes an exposure below this level need not provide a Proposition 65 warning.

Safe Harbor Level (also known as the Regulatory NSRL) - An NSRL for a particular chemical set by OEHHA pursuant to regulation (Cal. Code Regs. tit. 27, § 25705), which is deemed to satisfy the statutory defense of causing no significant risk of cancer. A business may rely on the Safe Harbor Level, but is not bound by it. OEHHA establishes the regulatory safe harbor level on a chemical by chemical basis. For glyphosate, the proposed safe harbor level is 1,100 micrograms per day. If that level is adopted into regulation, a business that causes an exposure to glyphosate below 1,100 micrograms per day need not provide a Proposition 65 warning.

Safe Harbor Warning - A safe harbor warning is standardized warning language that is deemed to be clear and reasonable if properly transmitted. There are multiple regulatory safe harbor warnings for different types of exposures and for different warning methods. Businesses are not required to use the safe harbor warning and can provide alternative warnings as long as the warnings are "clear and reasonable."

Safe Use Determination - A written statement issued by OEHHA which interprets Proposition 65 and its implementing regulations as applied to a specific set of facts in response to a request by a business or trade group. In a safe use determination, OEHHA will determine whether an exposure or discharge of a listed chemical resulting from specific business actions or the use of a specific product by the average consumer is subject to the warning requirement or discharge prohibition.

Warning Requirement - The requirement to provide a warning for a chemical on the Proposition 65 list, which automatically goes into effect one year after a chemical is added to the Proposition 65 list. For glyphosate, the warning requirement went into effect on July 7, 2018.

Labor Code Listing Mechanism - The provision of Proposition 65 that requires OEHHA to list chemicals that are identified as carcinogens in California Labor Code section 6832(b)(1). That section identifies "[s]ubstances listed as human or animal carcinogens by the International Agency for Research on Cancer (IARC)."