XAVIER BECERRA
Attorney General of California
SUSAN S. FIERING, State Bar No. 121621
Supervising Deputy Attorney General
DENNIS A. RAGEN, State Bar No. 106468
HEATHER C. LESLIE, State Bar No. 305095
LAURA J. ZUCKERMAN, State Bar No. 161896
Deputy Attorneys General
1515 Clay Street, 20th Floor
P.O. Box 70550
Oakland, CA 94612-0550
Telephone: (510) 879-1299
Fax: (510) 622-2270
E-mail: Laura.Zuckerman@doj.ca.gov
Attorneys for Defendants Dr. Lauren Zeise, Director, Office of Environmental Health Hazard Assessment, and Xavier Becerra, Attorney General of the State of California

IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF CALIFORNIA

NATIONAL ASSOCIATION OF WHEAT GROWERS ET AL.,

Plaintiffs,

v.

LAUREN ZEISE, IN HER OFFICIAL CAPACITY AS DIRECTOR OF THE OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT; AND XAVIER BECERRA, IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL OF THE STATE OF CALIFORNIA,

Defendants.

DEFENDANTS' OPPOSITION TO MOTION FOR PRELIMINARY INJUNCTION

Date:	February 20, 2018
Time:	1:30 p.m.
Courtroom:	5
Judge:	The Honorable William B. Shubb
Trial Date:	None set.
Action Filed:	November 15, 2017

TABLE OF CONTENTS

TABLE OF CONTENTS
(continued)

Page

TABLE OF AUTHORITIES

Page

CASES

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

California Code of Regulations, Title 27 (continued)

INTRODUCTION

Having failed thus far in its state court challenge to the constitutionality of the listing mechanism by which the California Office of Environmental Health Hazard Assessment ("OEHHA") proposed to list the chemical glyphosate as a carcinogen, and having subsequently failed to obtain a stay of the listing, Plaintiff Monsanto Company ("Monsanto") has abandoned its First Amendment claim in that forum, and joined forces with various agricultural trade associations and business entities (collectively, "Plaintiffs") to shop that same claim before this Court. This Court should follow the lead of the California superior court, as well as that of the Fifth District Court of Appeal and the California Supreme Court, both of whom declined Monsanto's request for a stay. As the superior court correctly found in dismissing this claim on the pleadings, Monsanto's claim is unripe and speculative. Whether a warning will ultimately be required post-July 2018 for any of Plaintiffs' products or uses requires assessment of exposure levels on which Plaintiffs have provided no evidence. In addition, contrary to Plaintiffs' representations, Proposition 65 does not dictate the text of the warning, which the regulated entity may propose to tailor to its individual situation. Thus, the Court has no concrete warning language to review, nor any information on the means that will be used to give the warning. *A fortiori*, such an unripe claim does not carry the urgency required for a preliminary injunction.

Even if this Court were to find Plaintiffs' claim were ripe, this Court should deny the motion for preliminary injunction, because Plaintiffs have not met any of the required four factors. Plaintiffs are not likely to succeed on the merits of their claims. Critically, Plaintiffs fail to acknowledge that OEHHA's listing of glyphosate does not constitute Plaintiffs' speech, but government speech, which cannot form the basis for their First Amendment claim. As to the Proposition 65 warnings, which may or may not apply to Plaintiffs' products or uses of glyphosate, and none of which have actually been written, Plaintiffs cannot demonstrate they are likely to prevail under either the *Central Hudson* or *Zauderer* tests. Contrary to Plaintiffs' gross misrepresentations, Proposition 65:

- advances a substantial government interest in providing Californians with information on exposure to chemicals identified as carcinogens;

- is no more extensive than necessary, because it exempts from any warning requirement those products or uses that do not result in a *significant* risk of cancer assuming lifetime exposure, a determination that will be facilitated by OEHHA's soon to be completed determination of safe harbor levels of exposure (not, as Plaintiffs misrepresent, requiring every manufacturer of product containing a scintilla of a listed chemical to post a warning); and
- provides a reasonable fit to the government's interest by allowing the regulated community to draft customized warnings tailored to their situation (contrary to the two cases most heavily relied on by Plaintiffs—*American Beverage Association* and *CTIA-The Wireless Association*—where the text of the mandatory warning was fixed by the government).

Nor should this Court be swayed by Plaintiffs' smear campaign against the International Agency for Research on Cancer ("IARC"). IARC is the cancer research arm of the United Nations World Health Organization, and California and eighteen other states have relied on its Monographs for decades. Indeed, the specific Proposition 65 listing method that Plaintiffs assail here has been applied in three decisions of California courts of appeal. Because Plaintiffs cannot show they are likely to prevail on the merits, their assertion of irreparable harm from infringement of their First Amendment rights fails as well. Plaintiffs' claims of irreparable harm are woefully insufficient, either because they rest on costs of compliance with regulation, stem from government speech—*i.e.*, the listing of glyphosate—or because they are built upon multiple layers of speculation. Finally, the equities and the public interest weigh heavily in favor of the State of California being allowed to continue to implement and enforce its laws. An injunction against the Attorney General's enforcement of the warning requirement would harm the State by undercutting a reasonable regulatory process adopted by California's voters to assure that its citizens are warned of significant cancer risks.

For all of these reasons, as discussed in more detail below, Defendants Dr. Lauren Zeise, Director of the Office of Environmental Health Hazard Assessment, and Xavier Becerra,

Attorney General of the State of California (jointly, "State Parties") respectfully request that this Court deny Plaintiffs' motion for a preliminary injunction.

BACKGROUND

I. STATUTORY AND REGULATORY BACKGROUND: PROPOSITION 65

A. Listing of Chemicals Under Proposition 65.

In 1986, in response to public concern 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), the California voters adopted Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986, Cal. Health & Safety Code §§ 25249.5 –25249.14,[1] which requires the Governor to publish a "list of those chemicals known to the state to cause cancer or reproductive toxicity within the meaning of this chapter," § 25249.8(a), and requires businesses to warn Californians before exposing them to listed chemicals.[2] § 25249.6. Consistent with their distrust of state agencies, the voters wanted to be informed when they were exposed to chemicals that had been identified by certain outside entities as causing cancer. *See* § 25249.8(a); Cal. Lab. Code §§ 6382(b)(1), (d). Among those outside entities was IARC, an "'organization[] of the most highly regarded national and international scientists.'" *Deukmejian*, 212 Cal. App. 3d at 436 (quoting the Ballot Pamphlet for Proposition 65, at 54).[3]

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

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

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

[3] A copy of the Ballot Pamphlet for Proposition 65 is attached as Exhibit A to the Declaration of Laura J. Zuckerman ("Zuckerman Decl.").

Under the listing mechanism at issue here, the Labor Code listing mechanism of section 25249.8(a), OEHHA must list "at a minimum those substances identified by reference in Labor Code section 6382(b)(1)," a provision of the California Labor Code concerned with workplace hazards. Section 6382(b)(1), in turn, identifies "[s]ubstances listed as human or animal carcinogens by the International Agency for Research on Cancer (IARC)." At a minimum, therefore, under the Labor Code listing mechanism OEHHA must include substances that the IARC has listed as a human or animal carcinogen. *Deukmejian*, 212 Cal. App. 3d at 437. Thus, under this mechanism, OEHHA lists chemicals that IARC has classified as carcinogenic to humans (Group 1), probably carcinogenic to humans (Group 2A), or possibly carcinogenic to humans (Group 2B). 27CCR, § 25904(b).

For Group 2A and Group 2B chemicals, there is an additional requirement for listing under the Labor Code mechanism. There must be "sufficient evidence of carcinogenicity in experimental animals." 27CCR, § 25904(b)(2), (b)(3). Before placing a Group 2A chemical like glyphosate on the list, OEHHA must review the IARC determination to ascertain that IARC found sufficient evidence of carcinogenicity in experimental animals. *See Styrene Info. and Research Ctr. v. Office of Envtl. Health Hazard Assessment*, 210 Cal. App. 4th 1082, 1101 (Cal. Ct. App. 2012) (rejecting listing of a Group 2B chemical under the Labor Code listing mechanism for which there was not sufficient evidence of carcinogenicity in humans or animals). If the chemical meets the criteria for listing, OEHHA must list it. *California Chamber of Commerce v. Brown*, 196 Cal. App. 4th 233, 260 (Cal. Ct. App. 2011); 27CCR, § 25904(b).

The voters chose this approach of including chemicals shown through experiments to cause cancer in animals, even if there is not yet evidence of cancer in humans, for a good reason: "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)).[4] Listings thus take into account the *hazard* posed by the chemical – that it has been shown to cause cancer. As will be discussed below, under Proposition 65 the level of *risk* is a factor in determining whether the warning requirement applies in a particular case.

B. The Warning Requirement.

The warning requirement is narrower than the listing requirement. As discussed below, while the listing requirement applies to the chemical and its capacity to cause cancer at any level of exposure, the warning requirement applies only to certain anticipated exposures. *See Exxon Mobil Corp. v. Office of Envtl. Health Hazard Assessment*, 169 Cal. App. 4th 1264, 1291-92 (Cal. Ct. App. 2009) (level of exposure and risk/concern for humans are separate from the listing analysis). Twelve months after a chemical is listed, any business with ten or more employees must provide a clear and reasonable warning if it "knowingly and intentionally expose[s] any individual to a chemical known to the state to cause cancer or reproductive toxicity . . . ." §§ 25249.6, 25249.10(b). A business can cure a violation of § 25249.6 (the "warning requirement") either by discontinuing the exposure, or by providing a warning to those exposed.

A business need not provide a warning for a listed carcinogen if it can show that the exposure it causes "poses no significant risk assuming lifetime exposure at the level in question." § 25249.10(c); *DiPirro v. Bondo Corp.*, 153 Cal. App. 4th 150, 188 (Cal. Ct. App. 2007). This "no significant risk" level ("NSRL") is defined as an exposure that results in no more than "one excess case of cancer in an exposed population of 100,000, assuming lifetime exposure at the level in question."[5] 27CCR, § 25703(b). In short, if a business shows that the exposure it causes will cause *no more than one excess cancer* per 100,000 exposed individuals, it need not warn.[6]

[4] This parallels federal agency understanding of the meaning of "carcinogen." *See, e.g.*, 29 C.F.R. § 1910.1200, Appendix 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.")

[5] *See* Glossary attached as Exhibit A.

[6] The no significant risk level is much less strict than the "1 in 1,000,000 risk" level standard used by many regulatory agencies. *See Ingredient Communication Council v. Lungren*, 2 Cal. App. 4th 1480, 1494, n.8 (Cal. Ct. App. 1992) ("The threshold risk under Proposition 65 is not especially low compared to other epidemiological standards commonly used by regulatory bodies.")

For many chemicals, OEHHA has adopted an NSRL by regulation, commonly called a "safe harbor" level. *See* 27CCR, § 25705. The safe-harbor level represents the level of exposure to a particular chemical that does not require a warning under Proposition 65. OEHHA has proposed a safe harbor level for glyphosate of 1,100 micrograms per day ("µg/day").[7] This rulemaking process is expected to conclude between March 1 and May 31, 2018 and thus will be effective no later than July 1, 2018, before the warning requirement takes effect. *See* Declaration of Mario Fernandez ("Fernandez Decl."), ¶ 9. Businesses do not need to provide a warning for exposures shown to be below the safe harbor level. 27CCR, § 25705(a).

Proposition 65 does not dictate the contents of the warning. It merely requires that the warning be "clear and reasonable." § 25249.6. OEHHA has adopted "safe harbor" warnings deemed to meet that standard. 27CCR, §§ 25601 – 25607.33; *see also Environmental Law Found. v. Wykle Research, Inc.*, 134 Cal. App. 4th 60, 66 (Cal. Ct. App. 2005). The current safe harbor language for consumer product exposures, in effect through August 2018, states: "WARNING: This product contains a chemical known to the state of California to cause cancer." 27CCR, § 25303.2(a)(1). OEHHA's new safe harbor warning language, effective August 30, 2018, has the potential to provide more context via the new warning website (www.P65Warnings.ca.gov):

> For signs, labels, and shelf tags:
>
> (1) A symbol consisting of a black exclamation point in a yellow equilateral triangle with a bold black outline. Where the sign, label or shelf tag for the product is not printed using the color yellow, the symbol may be printed in black and white. The symbol shall be placed to the left of the text of the warning, in a size no smaller than the height of the word "WARNING".
>
> (2) The word "**WARNING:**" in all capital letters and bold print, and:
>
> (A) For exposures to listed carcinogens, the words, "This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.
>
> *See* 27CCR, § 25603(a).

[7] Zuckerman Decl., Exh. B (OEHHA, Notice of Proposed Rulemaking, Title 27, California Code of Regulations, Amendment to Section 25705, Specific Regulatory Levels Posing No Significant Risk: Glyphosate (April 7, 2017)). A microgram is a millionth of a gram.

For on-product labels the following option is available:

WARNING: Cancer - www.P65Warnings.ca.gov.

27CCR, §25603(b)(2)(A).

Use of either the current or recently-adopted safe harbor warnings is optional. A business may use any other warning method or content that is clear and reasonable, § 25249.6; 27CCR, § 25601, § 25249.6; 27CCR, § 25601, and a court may approve a more nuanced warning that it deems appropriate. The Attorney General's regulations provide guidance on what language is and is not permitted in warnings other than the safe-harbor warning:

> Certain phrases or statements in warnings are not clear and reasonable, such as (1) use of the adverb "may" to modify whether the chemical causes cancer or reproductive toxicity (as distinguished from use of "may" to modify whether the product itself causes cancer or reproductive toxicity; (2) additional words or phrases that contradict or obfuscate otherwise acceptable warning language.

Cal. Code Regs. tit. 11, § 3202(b). Moreover, the Attorney General's regulations permit the words "the state of California" to be deleted from the safe-harbor language. *Id*. Whether a non-safe-harbor warning is clear and reasonable is determined on a case-by-case basis. *Ingredient Commc'n Council*, 2 Cal. App. 4th at 1480, 1492 (Cal. Ct. App. 1992).

In recognition of this flexibility, businesses and enforcers have created, and courts have upheld, a variety of alternative and more nuanced warnings, including the examples below.

Warning for acrylamide in food products:

Acrylamide is recognized as a carcinogen by the U.S. Environmental Protection Agency ("EPA"), and acrylamide levels increase markedly if starchy foods are overcooked.[8] The

[8] Plaintiffs claim, erroneously, that IARC concluded that "food exposed to 'high temperatures' (i.e., French fries) are probably or possibly carcinogenic." Mot. at 10. IARC reached no such conclusion. However, the carcinogenicity of acrylamide, a chemical created when starchy foods like French fries are cooked at high temperatures has been recognized by numerous agencies. *See* United States Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Guidance for Industry – Acrylamide in Foods (March 2016), available at https://www.fda.gov/downloads/food/ucm374534.pdf (last visited January 21, 2018).

As the American Cancer Society notes:

following warning was negotiated by the parties in a settlement with the Attorney General to include these chemical-specific facts, and to place the cancer risk in context:

> 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 cancer. This chemical is not added to our foods, but is created when certain foods are browned. Other foods sold here, such as hamburger buns, biscuits, croissants, and coffee also contain acrylamide, but generally in lower concentrations than fried potatoes. Your personal cancer risk is affected by a wide variety of factors. The FDA has not advised people to stop eating baked or fried potatoes. For more information see www.fda.gov.[9]
>
> Similarly-nuanced warnings have been created for mercury (a reproductive toxicant) in fish.

The warning below was used in an Attorney General settlement and approved by the court.

> Warning for mercury in fresh or frozen fish:
>
> Nearly all fish and shellfish contain some amount of mercury and related compounds, chemicals known to the State of California to cause cancer, and birth defects or other reproductive harm. Certain fish contain higher levels than others.
>
> Pregnant and nursing women, women who may become pregnant, and young children should not eat the following fish:
>
> Swordfish Shark King Mackerel Tilefish
>
> They should also limit their consumption of other fish, including tuna.
>
> Fish and shellfish are an important part of a healthy diet and a source of essential nutrients. However, the federal Food and Drug Administration ("FDA") and the U.S. Environmental Protection Agency ("EPA") advise pregnant and nursing women,

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> In its most recent Report on Carcinogens (2014), the [National Toxicology Program] has classified acrylamide as "reasonably anticipated to be a human carcinogen" based on the studies in lab animals.
> The US Environmental Protection Agency (EPA) . . . classifies acrylamide as "likely to be carcinogenic to humans" based on studies in lab animals.

American Cancer Society, Acrylamide and Cancer, https://www.cancer.org/cancer/cancer-causes/acrylamide.html (last visited January 21, 2018). This is consistent with IARC's conclusion that acrylamide is "probably carcinogenic to humans." IARC, *Acrylamide*, in Monograph Volume 60: Some Industrial Chemicals (1994), available at http://monographs.iarc.fr/ENG/Monographs/vol60/mono60-16.pdf, at 425 (last visited January 21, 2018).

[9] Zuckerman Decl., Exh. C, Consent Judgment Between Plaintiffs People of the State of California, Council for Education and Research on Toxics, and Defendant Burger King Corporation, in *Council for Education and Research on Toxics v. McDonald's Corporation and Burger King Corporation*, No. BC280980 (Cal. Super. Ct. 2007), at 4.

> women who may become pregnant, and children to limit their weekly consumption of fish and to eat fish that are lower in mercury.
>
> The California Department of Health Services recommends that these individuals:
>
> Eat a variety of different types of fish;
>
> Eat smaller fish rather than older, larger fish;
>
> Begin following these guidelines one year before becoming pregnant.
>
> According to the FDA and EPA, fish or shellfish that tend to be lower in mercury include Pollock, shrimp, and scallops. Mercury levels in tuna vary. Tuna steaks and canned albacore tuna have higher levels of mercury than canned light tuna.
>
> For more information about the risks of mercury in fish and about the levels in various types of fish consult the following websites:
>
> U.S. Food and Drug Administration ("FDA") www.cfsan.fda.gov
>
> U.S. Environmental Protection Agency www.epa.gov/ost/fish
>
> Or call the FDA toll-free at 1-888-SAFEFOOD (1-888-723-3366).[10]

As these examples demonstrate, under the statute, businesses can use nuanced warning language, tailored to the product and the chemical, in lieu of safe harbor warnings.

C. Proposition 65 Enforcement.

Proposition 65 may be enforced by the Attorney General, by any district attorney, and by city attorneys in cities above a certain size. § 25249.7(c). OEHHA does not enforce the statute. *Baxter Healthcare Corp. v. Denton*, 120 Cal. App. 4th 333, 346 (Cal. Ct. App. 2004). Private citizens may also enforce the statute "in the public interest," with certain restrictions. § 25249.7(d). To file an enforcement action, a private enforcer must first provide notice of the alleged violation ("60-day notice") to the public prosecutors and the alleged violator. § 25249.7(d)(1). If, after 60 days, no public prosecutor is diligently prosecuting the violation, then the private enforcer may file suit. *Id.*

To minimize the filing of frivolous private enforcement actions, the California Legislature amended Proposition 65 to require private enforcers to demonstrate a basis for their belief that an

[10] Zuckerman Decl., Exh. D., 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), at Exh. A.

action has merit before proceeding with private enforcement. *DiPirro v. American Isuzu Motors, Inc.*, 119 Cal. App. 4th 966, 970 (Cal. Ct. App. 2004). The private enforcer must submit a "certificate of merit" with each 60-day notice stating that the person executing the certificate has consulted with relevant experts who have reviewed "facts, studies, and other data regarding the exposure" at issue and that, based on that consultation, the noticing party believes "there is a reasonable and meritorious case for the private action." § 25249.7(d)(1). The noticing party must submit confidential factual information to the Attorney General "sufficient to establish the basis of the certificate of merit. . . ." *Id*. In 2017, the Legislature further amended the law to require that, if, after meeting and conferring with the noticing party, the Attorney General believes there is no merit to the 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.[11] §§ 25249.7(e)(1)(A), (g); *see also, e.g.*, letters attached as Exhibits E and F to the Zuckerman Decl.

A business that has not received a 60-day notice but which is concerned about possible liability may 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. Fernandez Decl., ¶ 11.

[11] The cases cited in support of Plaintiffs' claim that the certificate of merit requirement is "trivial to satisfy" all pre-date this recent statutory change. Mot. 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 to provide detailed exposure scenarios in cases involving non-food products.

II. IARC AND ITS CLASSIFICATION OF GLYPHOSATE AS "PROBABLY CARCINOGENIC TO HUMANS"

A. The International Agency for Research on Cancer and the Monograph Process

IARC was founded in 1965 as the cancer research arm of the United Nations World Health Organization, and exists to "promote international collaboration in cancer research."[12] The United States was a founding member of IARC and remains a member.[13]

IARC publishes, in the form of "Monographs," "critical reviews and evaluations of evidence on the carcinogenicity of a wide range of human exposures."[14] Monographs are prepared by a "Working Group" of international scientific experts without conflicts of interest.[15] Each Working Group works to determine whether a chemical should be categorized as Group 1 (carcinogenic to humans), Group 2A (probably carcinogenic to humans), Group 2B (possibly carcinogenic to humans), Group 3 (not classifiable as to its carcinogenicity to humans), or Group 4 (probably not carcinogenic to humans).[16] Once the Monograph is published, IARC encourages readers to "communicate any errors," and specifically requests information from "[a]nyone who is aware of published data that may alter the evaluation of the carcinogenic risk of an agent to humans."[17] To the State Parties' knowledge, Monsanto has never requested such re-evaluation.

B. Reliance on IARC by Government Entities

Federal and state entities consider IARC an authoritative source for identifying carcinogens.[18] For example, the U.S. Department of Health and Human Services notes that IARC

[12] Zuckerman Decl., Exh. G, IARC, Statute Rules and Regulations, Fourteenth Edition (May 2014), at 5-6.

[13] *Id*. at 27.

[14] Zuckerman Decl., Exh. H, IARC, Preamble to Monograph Volume 112: Some Organophosphate Insecticides and Herbicides (2017) ("Monograph 112"), at 10.

[15] *Id*. at 12; *see also* Zuckerman Decl., Exh. I, IARC and World Health Organization, Declaration of Interests for IARC/World Health Organization Experts.

[16] Zuckerman Decl., Exh. H, *Preamble* to Monograph-112 ("Preamble"), at 30-31; *see also Styrene Info. And Research Ctr.*, 210 Cal. App. 4th 1082, 1090-91 (Cal. Ct. App. 2012).

[17] Zuckerman Decl., Exh. J, IARC, *Note to Readers* from Monograph 112 (2017). IARC routinely publishes corrections to its Monographs. *See, e.g.*, Zuckerman Decl., Exh. K, IARC *Corrigenda* to Monograph 112 (updated 20 September 2016).

[18] Plaintiffs' suggestion that IARC is known for its "fringe conclusions that substances like coffee, aloe vera, pickled vegetables, and food exposed to 'high temperatures' (i.e., French fries) are probably or possibly carcinogenic," Mot. at 10, is inaccurate, and displays their cavalier approach to the very serious issue of cancer risk. For example, IARC was not on the "fringe" in

"Monograph volumes are considered critical references that inform health policy and cancer research worldwide about carcinogenic risks to reduce cancer globally."[19]

The Federal Occupational Safety and Health Administration relies on IARC as a source for determining the carcinogenicity of chemicals for purposes of warning employees about exposure. 29 C.F.R., § 1910.1200 Appendix F. And regulations promulgated under the Toxic Substances Control Act identify a chemical as a known or potential carcinogen if IARC classifies it as Group 1, 2A, or 2B – essentially the same criterion that requires listing of a chemical under the Labor Code listing mechanism. 40 C.F.R., § 707.60(c)(2)(ii).

It is not just federal agencies that rely on IARC. Besides Proposition 65, other California statutes rely on IARC findings: Cal. Penal Code § 374.8(c)(2)(D), involving the illegal deposition of hazardous substances; Cal. Educ. Code § 32062(a) and (b), addressing toxic art

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any of the following conclusions:

- Aloe Vera. A two-year study by the U.S. National Toxicology Program of oral consumption of non-decolorized whole leaf extract of aloe vera "found clear evidence of carcinogenic activity in male and female rats, based on tumors of the large intestine." https://nccih.nih.gov/health/aloevera (last accessed January 21, 2018). This is consistent with IARC's conclusion that whole leaf aloe vera was "possibly carcinogenic to humans." https://monographs.iarc.fr/ENG/Monographs/vol108/mono108-01.pdf., at 67. (This whole leaf non-decolorized aloe vera is *not* the aloe vera product that is commonly sold in the United States.)

- Pickled Vegetables. An analysis published by the British Journal of Cancer with funding from the U.S. National Institutes of Health concluded: "Our results suggest a potential two-fold increased risk of oesophageal cancer associated with the intake of pickled vegetables." https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2778505 (last accessed January 21, 2018). This is consistent with IARC's conclusion that traditional Asian pickled vegetables are "possibly carcinogenic to humans." http://monographs.iarc.fr/ENG/Monographs/vol56/mono56-7.pdf, at 109.

- French fries. *See* note 8, *supra*.

- Coffee. IARC initially classified coffee as possibly carcinogenic to humans in 1991. IARC, *Coffee*, in Monograph Volume 51: Coffee, Tea, Mate, Methylxanthines and Methylglyoxal (1991), at 174. In 2016, based on its review of more than 1,000 studies in humans and animals, IARC updated its classification of coffee, finding that it "was not classifiable as to its carcinogenicity to humans." IARC, Press Release Number 244: IARC Monographs evaluate drinking coffee, mate, and very hot beverages (June 15, 2016), available at https://www.iarc.fr/en/media-centre/pr/2016/pdfs/pr244_E.pdf.

[19] *See* United States Department of Health and Human Services, Limited Competition: IARC Monographs Program (UOI), available at http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-14-503.html (last visited January 21, 2018).

supplies in schools; and the California Safe Cosmetics Act of 2005, Cal. Health & Safety Code § 111791.5(b)(2). Many other States rely on IARC's evaluations to create lists of hazardous chemicals and identify carcinogens for other public health purposes, including Alaska, Connecticut, Illinois, Indiana, Louisiana, Massachusetts, Missouri, Nevada, New Hampshire, New Jersey, Oregon, Pennsylvania, Rhode Island, Tennessee, Texas, Vermont, Virginia, and Washington.[20] Even businesses rely on IARC's published monographs to argue that certain chemicals should not be considered carcinogens. *See, e.g., Baxter Healthcare Corp.*, 120 Cal. App. 4th at 351 (healthcare company and court relied on IARC classifications to conclude that a chemical was not a human carcinogen).

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

In March 2015, IARC convened a Working Group of internationally recognized scientific experts to review the evidence for the carcinogenicity of glyphosate.[21] These experts included representatives from the U.S. National Cancer Institute, the U.S. Environmental Protection Agency, the U.S. National Institute of Environmental Health, and the California Environmental Protection Agency; professors of veterinary medicine form Texas A&M and Mississippi State University; and experts from Australia, Canada, Chile, France, Finland, Italy, New Zealand, and the Netherlands.[22] IARC reviewed both human and animal studies, noting that "it is biologically plausible that agents for which there is sufficient evidence of carcinogenicity in experimental animals . . . also present a cancer hazard to humans."[23] IARC examined three types of evidence: studies in humans, studies in animals, and other relevant data.[24] Consistent with the principle that

[20] For example, Pennsylvania creates a hazardous substance list that includes all substances listed by IARC as having "sufficient evidence of carcinogenicity in animals." Penn. Statutes, tit. 35, § 7303(a)(6); Penn. Admin. Code, tit. 34, § 323.5(a)(6). New Jersey's "Right to Know Hazardous Substance List" must be updated based on the IARC Monograph Supplements. N.J. Admin. Code, tit. 8:59-9.3, subd. (b)(7). Rhode Island requires employers to maintain a hazardous and/or toxic chemical lists that include chemicals listed as carcinogens by IARC. R.I. Gen. Laws, tit. 28, § 28-21-2(13), (13). Massachusetts creates a list of toxic or hazardous substances which includes substances found to have sufficient evidence of carcinogenicity in animals as indicated in the IARC Monographs. Mass. Reg., tit. 105, § 670.010(b)(1); *see also* Zuckerman Decl., Exh. L, Table of Reliance on IARC by Other States.

[21] Zuckerman Decl., Exh. M, IARC *Cover*, Monograph 112.

[22] Zuckerman Decl., Exh. N, IARC *List of Participants*, Monograph 112.

[23] Zuckerman Decl., Exh. H, Preamble, at 20.

[24] Zuckerman Decl., Exh. O, IARC *Glyphosate*, from Monograph 112.

"science has never been static, and what is 'known' is necessarily defined by the state of the art at the time," *California Chamber of Commerce v. Brown*, 196 Cal. App. 4th 233, 259 (Cal. Ct. App. 2011), IARC then classified glyphosate as "probably carcinogenic to humans (Group 2A)," its second highest classification, based on sufficient evidence in animals and limited evidence in humans (positive association for non-Hodgkins lymphoma).[25] *Id*. at 142-43. IARC noted that the mechanistic and other relevant data also supported the Group 2A classification.[26]

III. THE LISTING OF GLYPHOSATE AND THE STATE COURT LITIGATION

Following the IARC classification, OEHHA issued a Notice of Intent to List Glyphosate in November 2015.[27] The notice stated OEHHA's preliminary determination that, based on IARC's March 2015 classification of glyphosate as "probably carcinogenic to humans" (Group 2A), and

[25] Zuckerman Decl., Exh. O, IARC *Glyphosate*, from Monograph 112, at 78.

[26] *Id*. In an attempt to support their claim that glyphosate should be de-listed, Plaintiffs seek to undermine the listing's validity by suggesting that the integrity of the IARC classification process for glyphosate was compromised, and infected with bias. Mot. at 12. As explained in detail in the attached January 11, 2018 response from Christopher Wild, Ph.D., IARC Director, to members of Congress, these allegations are unfounded. Citing an article about Dr. Aaron Blair, Plaintiffs claim IARC scientists withheld key data from those evaluating glyphosate. Mot. at 12. But the data was from an unpublished study, and Dr. Blair's deposition testimony confirmed that it would not have changed his opinion about the carcinogenicity of glyphosate. Zuckerman Decl., Exhibit P, Christopher Wild, IARC Director, Letter to Congressmen Smith, Biggs, and Lucas (Jan. 11, 2018), at 3. In addition, Plaintiffs note that a 2017 update from the ongoing Agricultural Health Study reported that glyphosate was not statistically significantly associated with cancer. Mot. at 12; *see* https://www.ncbi.nlm.nih.gov/pubmed/29136183 (last visited January 21, 2018). However, an earlier peer-reviewed publication from the ongoing Agricultural Health Study, which reached the same conclusion as the later study, *was* taken into account by the Working Group, but "did not outweigh the positive associations found in other epidemiological studies." Zuckerman Decl., Exhibit P, at 2. Further, the latest update to the Agricultural Health Study shows an increased leukemia risk with glyphosate exposure, further supporting IARC's determination. *Id*. Finally, by highlighting Dr. Christopher Portier's work for attorneys representing cancer victims in their suits against glyphosate manufacturers, Plaintiffs imply that the Working Group process was biased. Mot. at 13. However, as the IARC letter explains, (1) IARC has no evidence of any contractual relationship between Dr. Portier and plaintiffs' attorneys at the time glyphosate was reviewed, (2) Dr. Portier was not a member of the Working Group for glyphosate, only an Invited Specialist, and thus did not assess and evaluate the data, and (3) none of the Working Group members or other meeting participants suggested Dr. Portier had any undue influence over the consensus glyphosate determination. Zuckerman Decl., Exhibit P, at 1-2. IARC's response to these allegations only serves to underscore the integrity of the Monograph process.

[27] Zuckerman Decl., Exh. Q, OEHHA, Notice of Intent to List Chemicals by the Labor Code Mechanism: Tetrachlorvinphos, Parathion, Malathion, Glyphosate (September 4, 2015); *see* https://oehha.ca.gov/media/downloads/crnr/090415noillcset27.pdf (last visited January 21, 2018).

pursuant to the Labor Code listing mechanism, glyphosate met the criteria for listing under Proposition 65.[28]

In January 2016, before OEHHA had made its final listing decision, Monsanto filed a complaint in Fresno County Superior Court seeking to block the listing of glyphosate. Monsanto challenged the Labor Code listing mechanism as unconstitutional on multiple grounds, including violations of the free speech provisions of the United States and California constitutions, procedural due process, the Guarantee Clause, and the unlawful delegation doctrine.[29] The trial court rejected each of Monsanto's claims based on the pleadings, held that Monsanto's First Amendment claim was not ripe, and entered judgment in favor of OEHHA.[30]

Monsanto filed a notice of appeal and petitioned the California Court of Appeal and the California Supreme Court to stay the listing of glyphosate pending the appeal's outcome. In its papers, Monsanto argued that it would suffer irreparable harm from the listing. Both courts denied the petition for stay, and OEHHA listed glyphosate on July 7, 2017.[31] In August, at Monsanto's request, the Court of Appeal ordered an expedited hearing schedule. Thereafter, Monsanto dropped the First Amendment claim in its reply brief on appeal, and, together with the

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[28] *Id*. at 2.

[29] Zuckerman Decl., Exh. R, Monsanto Company's First Amended Verified Petition for Writ of Mandate and Complaint for Preliminary and Permanent Injunctive and Declaratory Relief, *Monsanto Co. and California Citrus Mutual et al. v. OEHHA and Sierra Club et al; Center for Food Safety*, No 16CECG00183 (Fresno Super. Ct. Aug. 10, 2016).

[30] Zuckerman Decl., Exh. S, Stipulation and Order and Judgment, *Monsanto Co. and California Citrus Mutual et al. v. OEHHA and Sierra Club et al; Center for Food Safety*, No. 16CECG00183 (Fresno Super. Ct. March 20, 2017). Plaintiffs' Motion omits any reference to the state court proceedings.

[31] California Supreme Court, Monsanto Company v. OEHHA, Case No. S242595, Disposition (June 22, 2017), available at http://appellatecases.courtinfo.ca.gov/search/case/disposition.cfm?dist=0&doc_id=2205351&doc_no=S242595&request_token=NiIwLSIkXkw%2BW1BFSCMtXE9IQEw0UDxTJyI%2BUzNSICAgCg%3D%3D (last visited January 21, 2018), and California Fifth District Court of Appeal, Monsanto Company v. OEHHA, Case No. F075362, Order Denying Petition Filed (June 16, 2017), available at http://appellatecases.courtinfo.ca.gov/search/case/dockets.cfm?dist=5&doc_id=2186307&doc_no=F075362&request_token=NiIwLSIkXkw%2BW1BFSCMtWEtIMDg7UExbJCNOSzxTUCAgCg%3D%3D (last visited January 21, 2018); Zuckerman Decl, Exh. T, OEHHA Chemicals Known to the State to Cause Cancer or Reproductive Toxicity List (December 29, 2017).

agricultural trade association and business entity plaintiffs, filed this action alleging violations of the First Amendment, the Supremacy Clause, and substantive due process a short time later.[32]

Monsanto's state court appeal is fully briefed and the court has set oral argument for March 2018. A decision is expected within approximately ninety days of the date of the hearing, and may come sooner given the Court of Appeal's decision to grant calendar preference, so it is likely the ruling will issue by July 1, 2018, before the warning requirement goes into effect.

LEGAL STANDARD

"[T]he purpose of a preliminary injunction is to preserve the status quo between the parties pending a resolution of a case on the merits." *McCormack v. Hiedeman*, 694 F.3d 1004, 1019 (9th Cir. 2012). However, it is well established that "[i]njunctive relief is 'an extraordinary and drastic remedy, one that should not be granted unless the movant, by a clear showing, carries the burden of persuasion.'" *Nat'l Grange of the Order of Patrons of Husbandry v. Cal. State Grange*, 2016 WL 8730678, at *3 (E.D. Cal. Sept. 23, 2016) (quoting *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997)); *see also Winter v. NRDC, Inc.*, 555 U.S. 7, 22, 24 (2008) ("*Winter*") (citation omitted) ("injunctive relief [is] an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief").

A "plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter*, 555 U.S. at 20. Also, "'serious questions going to the merits' and a balance of hardships that tips sharply towards the plaintiff can support issuance of a preliminary injunction, so long as the plaintiff also shows that there is a likelihood of irreparable injury and that the injunction is in the public interest." *Alliance for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1135 (9th Cir. 2011). Balancing the equities in favor of an injunction is particularly difficult when a plaintiff seeks to enjoin a State from effectuating a statute. "[A]ny time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable

[32] Monsanto is only a party to the First Amendment claim in this case, not to the preemption and substantive due process claims. Plaintiffs' Amended Complaint for Declaratory and Injunctive Relief at 5, n.2.

injury." *Maryland v. King*, 567 U.S. 1301 (2012) (citation omitted); *see also Coal. For Econ. Equity v. Wilson*, 122 F.3d 718, 719 (9th Cir. 1997).

While a prohibitory injunction is an extraordinary remedy requiring the moving party to make a strong showing of necessity, it only "preserves the status quo." *Stanley v. University of S. Cal.*, 13 F.3d 1313, 1320 (9th Cir. 1994). In contrast, "[a] mandatory injunction 'goes well beyond simply maintaining the status quo *pendente lite* [and] is particularly disfavored.'" *Id.* (citation omitted); *see also Sassman v. Brown*, 73 F. Supp. 3d 1241, 1247 (E.D. Cal. 2014). "When a mandatory preliminary injunction is requested, the district court should deny such relief 'unless the facts and law clearly favor the moving party,'" *Stanley*, 13 F.3d at 1320, and mandatory injunctions "'are not granted unless extreme or very serious damage will result and are not issued in doubtful cases ….'" *Anderson v. United States*, 612 F.2d 1112, 1115 (9th Cir. 1979) (citation omitted).

ARGUMENT

Although Plaintiffs' brief blurs the distinction between the two types of injunctive relief sought, by seeking to enjoin (a) "the listing of glyphosate under Proposition 65," and (b) "the application of its attendant warning requirement pending a final judgment in this case," Mot. at 4, Plaintiffs seek both a mandatory injunction and a prohibitory injunction involving two very different types of speech. They seek to enjoin the *listing* of glyphosate (i.e., to require OEHHA to de-list the chemical) and to enjoin any *warning requirement* based on that listing. The distinction is critical, because whereas Plaintiffs' free-speech interests may be implicated in the future by the warning requirement, they are not implicated by OEHHA's listing of glyphosate, which is pure government speech.

I. PLAINTIFFS ARE NOT ENTITLED TO A MANDATORY INJUNCTION REQUIRING OEHHA TO DE-LIST GLYPHOSATE.

A. Plaintiffs Cannot Prevail on the Merits of Their Claim That OEHHA's Listing of Glyphosate Violated Their Free Speech Rights.

OEHHA listed glyphosate as a carcinogen on July 7, 2017. At the time this federal action was filed, glyphosate was on the Proposition 65 list. Thus, as a practical matter, it is no longer possible for this Court to enjoin the listing of glyphosate. *See, e.g., Owen v. City of Portland*, 236

F. Supp. 3d 1288, 1297 (D. Or. 2017) ("because the Ordinance has already taken effect, it is too late for a Court to direct the City not to allow the Ordinance to take effect.") What Monsanto appears to seek instead is a mandatory injunction requiring OEHHA to *de-list* glyphosate. The First Amendment provides no basis for such an injunction, as the listing involves government speech that does not implicate Plaintiffs' First Amendment interests. *See Pleasant Grove City, Utah v. Summum*, 555 U.S. 460, 467 (2009) ("The Free Speech Clause restricts government regulation of private speech; it does not regulate government speech.").

In *Pleasant Grove*, the Supreme Court held that a religious organization's free speech rights had not been violated by a city's denial of its request to put up a monument in a public park in which a Ten Commandments monument already stood. Although it found that the placement of a permanent monument in a public park was a form of speech, it was a form of government speech, and "therefore not subject to scrutiny under the Free Speech Clause." *Pleasant Grove*, 555 U.S. at 464. The Court cited a long line of cases in support of this proposition, including *Johanns v. Livestock Marketing Ass'n*, 544 U.S. 550, 553 (2005) ("the Government's own speech . . . is exempt from First Amendment scrutiny"); *Columbia Broad. Sys., Inc. v. Democratic Nat'l Comm.*, 412 U.S. 94, 139, n.7 (1973) (Stewart, J., concurring) ("Government is not restrained by the First Amendment from controlling its own expression"); *Rosenberger v. Rector and Visitors of Univ. of Va.*, 515 U.S. 819, 833 (1995) (government entity is "entitled to say what it wishes"). *Pleasant Grove*, 555 U.S. at 467.

There can be no doubt that OEHHA's July 7, 2017, placement of glyphosate on the Proposition 65 list of chemicals known to the State to cause cancer, *see* https://oehha.ca.gov/proposition-65/crnr/glyphosate-listed-effective-july-7-2017-known-state-california-cause-cancer (last visited January 20, 2018), as an action by a California executive branch agency, was government speech. *See, e.g., R.J. Reynolds Tobacco Co. v. Shewry*, 423 F.3d 906, 918 (9th Cir. 2005) (key issue is "the degree of governmental control over the message"). Plaintiffs have not alleged that OEHHA's listing of glyphosate has compelled them to engage in any type of speech (much less factually inaccurate speech), or indeed chilled their First Amendment rights in any way. Nor can they: their First Amendment claim rests solely on the

Proposition 65 warning requirement – specifically, on a theoretical requirement for a future Proposition 65 warning for glyphosate.

II. PLAINTIFFS ARE NOT ENTITLED TO A PRELIMINARY INJUNCTION PROHIBITING THE ATTORNEY GENERAL FROM ENFORCING THE WARNING REQUIREMENT.

Plaintiffs are not entitled to a preliminary injunction preventing enforcement of Proposition 65's warning requirement.[33] Their First Amendment claim is not ripe for adjudication, and even if it were, Plaintiffs do not meet the standard for a preliminary injunction.

A. The Matter is not Ripe for Adjudication Under Article III of the U.S. Constitution.

Plaintiffs' compelled-speech claim is unripe. Plaintiffs have not provided any evidence that they will be required to warn, or, if they are required to warn, what the language of their warning will be, which makes it impossible for the Court to determine whether there is any compelled speech that does not pass constitutional muster.

The role of the federal courts is "neither to issue advisory opinions nor to declare rights in hypothetical cases, but to adjudicate live cases or controversies consistent with the powers granted the judiciary in Article III of the Constitution." *Thomas v. Anchorage Equal Rights Comm'n*, 220 F.3d 1134, 1138 (9th Cir. 2000); *see also, e.g., Ray Charles Found. v. Robinson*, 795 F.3d 1109, 1116 (9th Cir. 2015) (ripeness goes to the court's subject matter jurisdiction to hear a case). The ripeness requirement "prevent[s] the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements…." *Abbott Lab. v. Gardner*, 387 U.S. 136, 148 (1967), *overruled on other grounds*, *Califano v. Sanders*, 430 U.S. 99 (1977).

The ripeness inquiry has both constitutional and prudential components. *Nat'l Park Hospitality Ass'n v. Dep't of Interior*, 538 U.S. 803, 808 (2003). For a claim to be ripe in the constitutional sense in a declaratory judgment case, "the facts alleged, under all the circumstances, [must] show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory

[33] It is not at all clear that all of the plaintiffs in this case other than Monsanto have standing to assert a First Amendment challenge to the Proposition 65 warning requirement. For purposes of this motion, however, defendants will assume *arguendo* that Plaintiffs all have standing to assert a First Amendment claim.

judgment." *Montana Env'l Info. Center v. Stone-Manning*, 766 F.3d 1184, 1188 (9th Cir. 2014) (citations and internal quotation marks omitted); *Colwell v. Dep't of Health and Human Serv.*, 558 F.3d 1112, 1123 (9th Cir. 2009) (dispute must "present concrete legal issues, presented in actual cases, not abstractions") (citations and internal quotation marks omitted). "[N]either the mere existence of a proscriptive statute nor a generalized threat of prosecution satisfies the 'case or controversy' requirement." *Thomas*, 220 F.3d at 1139. Courts may also decline to exercise jurisdiction based on prudential considerations. *Id.* at 1141. These prudential considerations are twofold: "'the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration.'" *Id*. (quoting *Abbott Lab.*, 387 U.S. at 149; *see also Portman v. County of Santa Clara*, 995 F.2d 898, 903 (9th Cir. 1993).

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

> The record before us is remarkably thin and sketchy, consisting only of a few conclusory affidavits. "*A concrete factual situation is necessary to delineate the boundaries of what conduct the government may or may not regulate*." *San Diego County Gun Rights Comm. v. Reno*, 98 F.3d 1121, 1132 (9th Cir. 1996)]. And yet, the landlords ask us to declare Alaska laws unconstitutional, in the absence of any identifiable tenants and with no concrete factual scenario that demonstrates how the laws, as applied, infringe their constitutional rights.

Id. (emphasis added); *see also American-Arab Anti-Discrimination Comm. v. Thornburgh*, 970 F.2d 501, 510-11 (9th Cir. 1992) (case "with many unknown facts" and a "sketchy record" is not fit for review). In short, courts should not decide "'constitutional questions in a vacuum.'" *American-Arab*, 970 F.2d at 511 (quoting *W.E.B. DuBois Clubs of America v. Clark*, 389 U.S. 309, 312 (1967)). This case raises the same concern.

1. Plaintiffs' First Amendment Claim is Unripe From Either a Constitutional or a Prudential Standpoint.

The facts alleged to support Plaintiffs' claims do not reveal a controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment, failing both the

constitutional and prudential tests for ripeness. The First Amendment claim related to enforcement of the warning requirement is devoid of the factual context necessary to make it fit for judicial resolution. It is not now known that any of Plaintiffs' products will require Proposition 65 warnings, and, even if such warnings will be required for some products, it is not known what they will say.

a. OEHHA's Proposed Safe Harbor Level Will Likely Exempt Many of Plaintiffs' Products from the Warning Requirement, and Plaintiffs Offer no Evidence to the Contrary.

OEHHA is now concluding a formal regulatory process to set a safe harbor NSRL – OEHHA's estimation of the exposure level that will pose a significant cancer risk. OEHHA began this rulemaking process even before glyphosate was listed, proposing a safe harbor level of 1,100 µg/day.[34] During the extended comment period, OEHHA received 1,310 comments, to which its legal staff and scientists are currently preparing responses. *See* Fernandez Decl., ¶¶ 4, 6, 8, 10. OEHHA estimates that the regulation will be complete and submitted to the Office of Administrative Law in February 2018, and that it will take effect before any warning requirement for glyphosate goes into effect. *Id.*, ¶ 9. One purpose of the proposed regulation is to relieve businesses of the requirement to provide warnings for glyphosate-containing products that do not pose a significant cancer risk.[35]

Plaintiffs argue that the proposed safe harbor NSRL won't be of any use to them. Mot. at 21. Plaintiffs' argument is both spurious and unsupported by any facts. Plaintiffs' papers are completely devoid of information regarding the glyphosate exposures that their products will

[34] Zuckerman Decl., Exh. B, OEHHA, Notice of Proposed Rulemaking, Title 27, California Code of Regulations, Amendment to Section 25705, Specific Regulatory Levels Posing No Significant Risk: Glyphosate (April 7, 2017). To put this regulatory NSRL in perspective, out of 311 chemicals for which OEHHA has set NSRLs, the proposed 1,100 microgram-per-day safe harbor NSRL for glyphosate would be the third highest. *See* Proposition 65 Safe Harbor Levels (May 17, 2017), available at https://oehha.ca.gov/proposition-65/general-info/current-proposition-65-no-significant-risk-levels-nsrls-maximum (last visited January 21, 2018).

[35] Importantly, however, while compliance with this safe-harbor serves as shield to liability, exposures above this level do not necessarily expose a company to liability. Any company may defend a failure-to-warn suit by showing that a different, higher NSRL should apply. § 25249.10(c); *see also* 27CCR, § 25701(a) ("Nothing in this article shall preclude a person from using evidence, standards, risk assessment methodologies, principles, assumptions or levels not described in this article to establish that a level of exposure to a listed chemical poses no significant risk.).

cause: the voluminous exhibits in support of their motion do not contain a single laboratory test for glyphosate residue in any food product, much less any analysis of which types of products might exceed the safe harbor NSRL and therefore might need to have warnings, or any evidence that the glyphosate concentrations in their products will even approach levels at which warnings could be required.

What information is publicly available on several dozen U.S. food products indicates that glyphosate exposure levels are below the proposed safe harbor level. For example, three environmental groups have reported results for 49 tests of consumer products that are available on the Internet. *It is doubtful that a single one of these products would require a warning if the 1,100 µg/day safe harbor level is adopted.* Specifically:

- Food Democracy Now and The Detox Project published a report in 2016, entitled "Glyphosate: Unsafe on Any Plate," which detailed their testing of 29 consumer food products. The product with the highest glyphosate concentration was Original Cheerios, at 1,125.3 ppb. A consumer would have to eat 977.52 grams of this product (2.16 pounds) per day in order to exceed the proposed safe harbor level. [36]
- The Alliance for Natural Health – USA issued a report, "Glyphosate Levels in Breakfast Foods: What is Safe?" in 2016, showing its testing of ten consumer products. Instant Oatmeal Strawberries and Cream had the highest glyphosate level, at 1,327.1 ppb. A consumer would need to eat 828.9 grams of this oatmeal (1.83 pounds) per day to suffer an exposure in excess of the proposed safe harbor level.[37]
- The Organic Consumers Association found glyphosate in ten samples of Ben & Jerry's Ice Cream at levels ranging from zero (0) to 1.74 ppb. At the highest of

[36] The report can be found at https://s3.amazonaws.com/media.fooddemocracynow.org/images/FDN_Glyphosate_FoodTesting_Report_p2016.pdf (last accessed January 21, 2018) and https://s3.amazonaws.com/media.fooddemocracynow.org/images/anresco_reports_food_testing_2016.pdf (last visited January 21, 2018). The calculation is as follows: 977.52 grams x 1.1253 µg/g/day = 1,100 µg/day. (1,125.3 ppb = 1.1253µg/g.)

[37] The report can be found at: http://www.anh-usa.org/wp-content/uploads/2016/04/ANHUSA-glyphosate-breakfast-study-FINAL.pdf (last accessed January 21, 2018.) The calculation is as follows: 828.9 grams x 1.3271 µg/g/day = 1,100 µg/day. (1.3271.1 ppb = 1.3271 µg/g).

those levels, a consumer would need to eat 632,183 grams (1,393.7 pounds) of this ice cream daily to exceed the proposed safe harbor level. [38]

Since an average consumer will not eat 2.16 pounds of Cheerios, or 1.83 pounds of Instant Oatmeal Strawberries and Cream, or 1,393.7 pounds of Ben & Jerry's ice cream per day, these products presumably would qualify for the exemption under the safe harbor NSRL and will not require a warning.[39]

In addition, while Plaintiffs assert, without any evidence *specific to this case*, that the "safe harbor NSRL does not eliminate the prospect of strike suits," Mot. at 17, the regulatory NSRL proposed for glyphosate would effectively eliminate the prospect of enforcement actions based on any of the 49 test results referenced above, and it would provide a strong disincentive to similar litigation. If any of the above-mentioned environmental groups wished to sue, for example, they would be required first to provide the Attorney General with a sixty-day notice and a certificate of merit supported by facts and studies that establish that there is a violation. § 25249.7(d)(1); Cal. Code Regs. tit. 11, §§ 3100, 3101, 3102; *see also* Background, Part I.C, *supra.* For chemicals in consumer products that are not part of the listed ingredients, the Attorney General usually looks for laboratory results to satisfy this requirement. On receiving the test results for any of the 49 products referenced above, the Attorney General would inform the noticing party that: (1) the laboratory results for these products establish that there is no violation of Proposition 65 because the exposure does not exceed the safe harbor NSRL, (2) the sixty-day notice based on those results should be withdrawn, and (3) any action based on those results would not be in the public interest and would not warrant civil penalties or an award of fees. In the unlikely event that the private enforcer refused to withdraw the notice, the Attorney General would inform all parties by a letter, posted on his public website, that there is no merit to the proposed action. *See* §§ 25249.7(e)(1)(A) and (g).

[38] *See* Ben & Jerry's statement: https://www.benjerry.com/about-us/media-center/glyphosate-statement (last accessed January 2, 2018), and the Report by the Organic Consumers Association: www.organicconsumers.org/press/ben-jerry's-ice-cream-tests-positive-roundup-herbicide-ingredient-glyphosate (last accessed January 21, 2018). The calculation is as follows: 632,183 grams x 0.00174 µg/g/day = 1,100 µg/day. (1.74 ppb = 0.00174 µg/g.)

[39] For consumer products, the term "average user" is defined at 27CCR, § 25721(d)(4), which references consumption data published by the U.S. Department of Agriculture.

b. There is No Evidence That Plaintiffs' Defenses Will Fail and Warnings Will be Required.

Even if exposures to glyphosate exceed the safe harbor NSRL that OEHHA likely will have established before the glyphosate warning requirement takes effect, Plaintiffs will have the opportunity to show that they do not cause a significant cancer risk, and that warnings are not required. This has not happened yet.

In contrast to the laws at issue in *Am. Beverage Ass'n v. City and County of San Francisco*, 871 F.3d 884 (9th Cir. 2017) ("*American Beverage*") and *CTIA-The Wireless Ass'n v. City of Berkeley, California*, 854 F.3d 1105 (9th Cir. 2017) ("*CTIA-Wireless*"), which provided businesses with no defenses to the applicable warning requirement (for sugar-sweetened beverages and cellphones, respectively), Proposition 65 allows Monsanto and other companies to establish that no warnings are required (even for glyphosate exposures of more than 1,100 µg/day) because their products do not pose a substantial cancer risk. *See Exxon Mobil v. Office of Envtl. Health Hazard Assessment,* 169 Cal. App. 4th 1264, 1291-92 (Cal. Ct. App. 2009) (holding that Exxon's argument that it was biologically impossible for a chemical to cause reproductive harm in humans would be properly heard during the second step of the Proposition 65 process, when Exxon could raise the defense that exposures to chemical did not exceed the Proposition 65 risk level.) That time has not come. It may be that Monsanto or other plaintiffs will succeed in showing that exposures to glyphosate from their products do not pose a significant cancer risk, but since this has not happened, and since there is no way for the Court to know whether or not it will happen, this case is not ripe.

c. There is No Evidence of What Any Warnings Will Say.

Even if it were clear that all of these Plaintiffs (or their members) had to provide warnings, the First Amendment challenge to the warning requirement would still be unfit for judicial decision. Because the statute and regulations require no set warning language and no single method of delivery, the Court has none of the information it needs on the content of any required warning to evaluate whether the compelled speech violates Plaintiffs' free speech rights under *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626 (1985), or

Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n, 447 U.S. 557 (1980). A warning need only be "clear and reasonable," 27CCR, § 25601, and there are different methods for delivering the warning (signs, shelf tags, electronic devices, labels, catalogs, Internet), not just placement of a label on the product. 27CCR, §§ 25603.1 (current regulation), 25602 (operative Aug. 30, 2018). A business's ability to select a method of delivery enables it to minimize the burden the warning might otherwise impose.[40]

Thus, while safe harbor warnings are available to facilitate providing clear and reasonable warnings, companies do not have to use the safe harbor warnings, nor are they required to utilize the *best* warning, as long as the warning they provide is "clear and reasonable." *Environmental Law Found.*, 134 Cal.App.4th at 66. As discussed above, businesses subject to Proposition 65's warning requirement can, and frequently do, tailor warnings to ensure that they are factually accurate and not misleading. *See* discussion above at 5-9. Without knowing what the glyphosate warning will be, the Court cannot decide the First Amendment issues presented by this motion.

By contrast, there was no ripeness issue in the recent Ninth Circuit compelled-speech cases Plaintiffs rely on so heavily. In both *American Beverage* and *CTIA-Wireless*, the statute in question mandated that the parties provide a *specific* warning, with no opportunity for defense or for variation. *See American Beverage*, 871 F.3d at 888 (warning language required to take up 20% of *companies' advertising space* for sugar-sweetened beverages and must state "WARNING Drinking beverages with added sugar(s) contributes to obesity, diabetes, and tooth decay. This is a message from the City and County of San Francisco"); *CTIA-Wireless*, 854 F.3d at 1111 (must provide notice to cell phone users that ". . . If you carry or use your phone in a pants or shirt pocket or tucked into a bra when the phone is ON and connected to a wireless network, you may exceed the federal guidelines for exposure to RF radiation. . . ."). In both those cases, because the plaintiffs were under an *immediate, absolute* obligation to provide the *specified* warnings in *all instances*, the free speech issues were ripe. In fact, in *American Beverage,* the court made clear that a warning with more context – like the ones that can be provided under Proposition 65 -

[40] For example, a business that sells products in States other than California may elect to use shelf signs for sales in California, rather than label all of its products.

would have passed muster under *Zauderer*. *See* 871 F.3d at 895. This makes clear how critical the content of the warning is to the court's determination of the First Amendment issue, and illustrates why this case is not ripe.

To rule on the First Amendment claim, this Court would have to assume that warnings are required, and speculate about what the warnings would say. The necessity of indulging these hypotheticals makes Plaintiffs' claims unfit for judicial resolution at this time. In light of the foregoing, it is not surprising that, when Monsanto raised an identical free speech claim in the state court action, the Superior Court concluded that it was premature:

> [B]ecause the adding of glyphosate as a "known carcinogen" to the Proposition 65 list does not necessarily require Monsanto to add a warning label to its products, the issue is not yet ripe for adjudication, and Monsanto has not stated a claim based on the alleged violation of its free speech rights.[41]

Judge Capetan's ruling is correct as to all the Plaintiffs here. Even if Plaintiffs cause exposures to glyphosate above the proposed safe harbor level in California, which is not at all certain, Proposition 65 warnings may never be required. Plaintiffs ask this Court to adjudicate their First Amendment claim based on conjecture, together with assumptions that may or may not prove true. Because federal courts are not to "declare rights in hypothetical cases," *Thomas*, 220 F.3d at 1138, or "entangle themselves in abstract disagreements," *Abbott Lab.*, 387 U.S. at 149, this request must be rejected.[42]

[41] Zuckerman Decl., Exh. S, Stipulation and Order and Judgment, No. 16CECG00183 (Fresno Super. Ct. March 20, 2017).

[42] To the extent Plaintiffs complain of regulatory uncertainty, they can avail themselves of the Safe Use Determination procedure set forth in the Proposition 65 regulations, 27CCR, § 25204, and seek a determination from OEHHA as to whether, in OEHHA's best judgment, they will be required to provide a warning. Since Plaintiffs are in the best position to know the composition of their own products and whether and how their customers will be exposed to glyphosate when they use these products or consume food treated with them, and since they are already required under federal law to control the amount of glyphosate residue on their products, 40 C.F.R.§ 280.364, availing themselves of the Safe Use Determination procedure does not impose a significant burden on them, and will provide guidance to govern their future behavior.

B. Plaintiffs Have Not Met the Standard for a Preliminary Injunction Against Attorney General Enforcement of the Warning Requirement.

Even if the matter were ripe, which it is not, a preliminary injunction prohibiting the Attorney General from enforcing the warning requirement should not issue in this case.[43] Plaintiffs will not succeed on the merits, they face no irreparable harm if the motion is denied, and any balancing of the equities and public interest weighs strongly against them.

1. Plaintiffs Will Not Succeed on the Merits.

Plaintiffs base their First Amendment argument with respect to the warning requirement on the unsupported claim that they will be required to provide warnings that describe glyphosate as a chemical "known to the state to cause cancer," a description they insist is false. Mot. at 30. They also claim that this warning requirement does not materially advance the State's interest in informing Californians about exposures to chemicals that cause cancer, and that it is not sufficiently tailored to serve that interest. Mot. at 33. As the following discussion will show, these arguments are wrong on the facts and the law.[44]

a. The Standard for Commercial Speech.

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

[43] Nor can a preliminary injunction be issued against Dr. Zeise to prohibit her from enforcing it. As Director of OEHHA, Dr. Zeise plays no role in enforcing Proposition 65. Any claims against Dr. Zeise are barred by sovereign immunity to the extent they seek to enjoin her from enforcing the warning requirement: because she does not enforce the statute, such claims do not fall within the *Ex parte Young* exception to the rule that the Eleventh Amendment bars a suit in federal court against state officials when, as here, "the state is the real, substantial party in interest." *Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 100-01 (1984); *Snoeck v. Brussa*, 153 F.3d 984, 986 (9th Cir. 1998).

[44] In making these arguments, Plaintiffs omit important facts. For example, Plaintiffs state that IARC classified glyphosate as "probably carcinogenic," based on "limited evidence in humans," without noting that IARC's 's classification was that glyphosate is "probably carcinogenic *to humans,*" and that IARC found there was "sufficient" evidence in animals and limited evidence in humans. This is an important omission, because *chemicals are routinely designated as carcinogens based on animal evidence*. *Baxter Healthcare Corp.,* 120 Cal. App. 4th at 369; 29 C.F.R. § 1910.1200, Appendix A.6.1. Plaintiffs also omitted to note IARC's conclusion that the mechanistic and other relevant scientific data supported the Group 2A classification.

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)); *see also Nat'l Elec. Mfrs. Ass'n v. Sorrell,* 272 F.3d 104, 113 (2d Cir. 2001) (quoting *Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 72 (2d Cir. 1996)) ("Commercial speech is subject to 'less stringent constitutional requirements' than are other forms of speech."). Under *Central Hudson*, regulations of non-misleading commercial speech must advance a substantial government interest and be no more extensive than is necessary to serve that interest, i.e., are subject to intermediate scrutiny.[45] *Id.*, 447 U.S. at 566.

In cases like this one, involving compelled commercial speech, the test is less stringent than the *Central Hudson* test. In *Zauderer,* the Supreme Court held that businesses have only a "minimal interest" in "not providing any particular factual information," and that the government may therefore compel the disclosure of "purely factual and uncontroversial information" about commercial products or services, so long as the compelled message is reasonably related to a substantial governmental interest and is neither "unjustified [n]or unduly burdensome."[46] *Zauderer*, 471 U.S. at 651. In this context, the term "uncontroversial" "refers to the factual accuracy of the compelled disclosure, not to its subjective impact on the audience," and therefore "*Zauderer* requires only that the information be 'purely factual.'" *CTIA-Wireless*, 854 F.3d at 1117. The Ninth Circuit has acknowledged, however, that a statement can be "literally true but nonetheless misleading and in that sense, untrue." *Id*. at 1119; *see also American Beverage*, 871 F.3d at 893 (statement meets *Zauderer* test if it provides accurate factual information and is not misleading.) For example, the warning at issue in *American Beverage* stated that "drinking

[45] In applying this analysis, the Supreme Court subsequently rejected the argument that state regulation of commercial speech should be subject to a "least-restrictive-means" standard and instead cautioned that substantial deference must be accorded to the States when reviewing any given restriction on commercial speech. *Fox*, 492 U.S. at 477-81. Specifically, Justice Scalia explained that the *Central Hudson* test requires a "'fit' between the legislature's ends and the means chosen to accomplish those ends, a fit that is not necessarily perfect, but reasonable . . ." *Id.* at 480 (citation and internal quotation marks omitted).

[46] While *Zauderer* involved a disclosure requirement in the legal advertising context, its holding has been applied in a case analogous to the present one, where a manufacturers' association challenged a state law that required businesses to disclose that mercury was present in their products and they should be recycled or disposed of as hazardous waste. *Sorrell,* 272 F.3d at 107.

beverages with added sugar(s) contributes to obesity, diabetes, and tooth decay." The Ninth Circuit found this warning misleading and therefore "controversial" in the *Zauderer* sense because it "conveys the message that sugar-sweetened beverages contribute to these health conditions regardless of the quantity consumed or other lifestyle choices," a conclusion flatly rejected by the U.S. Food and Drug Administration. *American Beverage*, 871 F.3d at 895-96. Yet the *American Beverage* court found that additional context, for example stating that the risk was caused by "overconsumption" of the beverages, would have made the warning not misleading. *Id.* at 895.

As discussed below, the Proposition 65 requirement at issue in this case satisfies the *Central Hudson* test because it advances a substantial government interest, and is no more extensive than is necessary to serve that interest. *Central Hudson,* 447 U.S. at 566. The warning requirement also satisfies the *Zauderer* test because it is "reasonably related to a substantial governmental interest," and there are safeguards to ensure that this requirement is not unduly burdensome and that any warning will be "purely factual." *CTIA-Wireless*, 854 F.3d at 1115-17.

b. The State Has a Substantial Interest in Providing Accurate Warnings to Persons Who Are Exposed to Significant Levels of Glyphosate.

The first question, under *Central Hudson* or *Zauderer,* is whether any warning requirement for glyphosate involves a substantial governmental interest. That substantial interest is manifestly present here. The State has a strong interest in protecting its citizens from cancer, which in 2013 was the State's second leading cause of death, claiming 57,504 lives.[47] Similarly, the State's voters, in enacting Proposition 65, stated that their objective was "[t]o be informed about exposures to chemicals that cause cancer," particularly in light of their mistrust that state government agencies will protect them from such risks. *AFL-CIO v. Deukmejian*, 212 Cal. App. 3d 425, 430-31 (Cal. Ct. App. 1989) (quoting the Preamble to Proposition 65 in the Ballot Pamphlet, at p. 53).

IARC is an international agency that has long been relied on by numerous States and the

[47] American Cancer Society: California Cancer Facts & Figures: 2017. https://www.cancer.org/content/dam/cancer-org/online-documents/en/pdf/reports/california-facts-figures-2017.pdf, at 2 (last accessed, January 21, 2018.)

United States government to evaluate cancer risks. In 2015, it assembled a Working Group of sixteen scientists, respected experts in their fields, to evaluate the potential carcinogenicity of glyphosate.[48] As noted above, these experts included members from multiple United States federal government agencies, as well as representatives from other countries, the State of California, and academia. *See* Background, Part II.C, *supra*. After reviewing the published literature on the carcinogenicity of glyphosate, these sixteen experts, *by consensus,* reached the conclusion that (1) there is limited evidence in humans for the carcinogenicity of glyphosate, with a positive association for non-Hodgkins lymphoma; (2) there is sufficient evidence of carcinogenicity in experimental animals; (3) glyphosate is probably carcinogenic to humans, and (4) the mechanistic and other relevant data support the classification of glyphosate as probably carcinogenic to humans (Group 2A).[49] The Working Group published a 92-page monograph that detailed the evidence and reasoning supporting this consensus.[50]

When a chemical has been identified as a carcinogen by a consensus of a group of the world's foremost scientific experts, the State has a strong interest in informing its citizens of their exposure, unless the business can show that the exposure does not pose a *significant cancer risk.* Since a warning requirement is a rational way to advance this interest, the first prong of the *Central Hudson* and *Zauderer* tests has been satisfied.

c. The Warning Requirement for Glyphosate is Tailored to the State's Interest.

The provisions governing the language of the Proposition 65 warnings, and the circumstances under which warnings must be given, ensure that any required warnings will meet the standards of *Central Hudson* and *Zauderer.*

[48] Zuckerman Decl., Exh. N, Monograph-112.

[49] Zuckerman Decl., Exh. O, IARC, *Glyphosate,* from Monograph-112 at 78. IARC's finding that there is sufficient evidence that glyphosate causes cancer in experimental animals is highly significant. As discussed in more detail at pp. 4-5, above, the "qualitative assessment of carcinogenic risks to humans ordinarily is based on data from experiments in animals." *Deukmejian*, 212 Cal.App.3d at 438, n.7.

[50] *Id*.

(1) The language of the warning can be tailored to the facts.

The Proposition 65 warning requirement is different from the warning requirements at issue in *American Beverage* and *CTIA-Wireless* in two crucial ways. First, in both those cases, warnings were mandatory, with no exceptions. In contrast, Proposition 65 provides businesses with a defense – specifically, the opportunity to show that they are exempt from the warning requirement because exposure levels from their products do not pose a significant cancer risk in humans. § 25249.10(c); 27CCR, § 25703(b). Accordingly, a business will not be required by a court to provide a warning unless the court has rejected its defense that the chemical in its products does not cause a significant cancer risk.[51]

Second, unlike the warnings at issue in both *American Beverage* and *CTIA-Wireless*, where businesses were required to provide uniform warnings specified by the government that could not be changed, the Proposition 65 warning requirement is flexible: the warning may be product-specific and contain contextual information necessary to ensure that it is truthful and not misleading. Provided the other requirements in the regulations (including the Attorney General's regulations) are complied with, the sole requirement is that the warning clearly and reasonably communicate that the consumer is being exposed to a chemical that is known to cause cancer within the meaning of Proposition 65.[52] *See* discussion at pp. 5-9, *supra*.

Further, this message can be conveyed in a multitude of ways. While usually including the terms "known to the state of California to cause cancer," which is used in the existing sections on "safe harbor" warnings in the regulations for food, 27CCR, § 25607.2, and other products, 27CCR, §§ 25607.3-25607.31, this language is not mandatory in all circumstances. It is not used in some of the safe harbor regulations due to take effect in August 2018.[53] Indeed, even if the

[51] In raising that defense, the business will not be bound by IARC's classification of glyphosate: it may present expert evidence and testimony regarding the issue whether glyphosate is a carcinogen if relevant to whether its products cause a significant cancer risk to exposed humans, so that the court may consider those arguments in deciding whether warnings are required, and, if so, in approving any alternate form of warning.

[52] 27CCR, § 25602; Cal. Code Regs. tit. 11, § 3202(b)

[53] For example, even the new safe harbor warning that does contain the "known to the state to cause cancer" language also contains the language "For more information go to www.P65Warnings.ca.gov," 27CCR, § 25603(a), where people can obtain more detailed information about the exposure. And an optional the safe harbor warning for product labels simply says, "**WARNING:** Cancer - www.P65Warnings.ca.gov." *Id*.

business elects to use the current safe harbor warning, the Attorney General's regulations specifically permit the words "state of California" to be omitted. Cal. Code Regs., tit. 11, § 3202(b). Thus, the linchpin of Plaintiffs' entire claim that they will be compelled to issue a false or misleading statement to the extent that they must say "glyphosate is '*known' to the state* to 'cause' cancer," rests on the faulty premise that the warning must say "known to the state." *See* Mot. at 30 (emphasis added); *see also id.*, at page 1, lines 23-26, page 3, lines 16-18, page 31, lines 4-5, page 33, lines 24-25. The acrylamide and fish warnings on pp. 7-9 above are just two examples of how warning language can be drafted to include necessary context and ensure accuracy. There may be similar options for a clear and reasonable Proposition 65 warnings for glyphosate exposures, all of which will be purely factual and not misleading as required by *Zauderer* and *CTIA-Wireless*.

Even in the unlikely event that a business wishing to provide a more nuanced warning were ordered by a court to use the current safe-harbor warning language that incorporates "known to the state of California to cause cancer" or ("known to cause cancer") in connection with a warning for glyphosate, the warning will be truthful and not misleading. Under the statute, use of this language simply means that glyphosate has been identified as a carcinogen by one of the relevant bodies, and has been listed accordingly.[54] As the IARC Monograph shows, glyphosate is known to cause cancer in animals, which, under the clear holding of *Deukmejian*, 212 Cal. App. 3d at 436, means it is known to cause cancer. This is consistent with principles of toxicology, pursuant to which chemicals are routinely identified as carcinogens based solely on animal

[54] Monsanto makes much of the fact that OEHHA's Pesticide and Toxicology Branch reached a different conclusion about the carcinogenicity of glyphosate in its now-outdated reviews, claiming that this proves that glyphosate is not "known to the state to cause cancer." Mot. at 30. This argument is spurious. Under Proposition 65, chemicals are "known" to the State to cause cancer when they have been listed as "known to the state to cause cancer . . . *within the meaning of this chapter*." § 25249.8(a) (emphasis added). In addition, because the Attorney General's regulations permit the use of the language "known to cause cancer" instead, Plaintiffs' argument that the State does not "know" glyphosate causes cancer, making the safe harbor warning misleading, Mot. at 3, is a red herring. *See* Cal. Code Regs. tit. 11, § 3302(b). Finally, the Pesticide and Toxicology Branch's findings are now outdated. IARC's Monograph relied on additional studies not considered by the Pesticide and Toxicology Branch in 1997 or 2007, and on new studies published between 2007 and 2015 that were not available at the time of those assessments. Zuckerman Decl., Exh. O, IARC, *Glyphosate*, from Monograph 112 (2017) at 79-92.

evidence, even if there exists insufficient human evidence. "The principle which 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*. at 438, n.7.

In sum, if a business is required by a court to provide a warning, it will be because (1) its product causes an exposure that exceeds the safe harbor NSRL *and* (2) the state court has rejected its defense that the glyphosate in the product does not cause a significant cancer risk.[55] Under those circumstances, the safe harbor warning will be truthful, as will a warning tailored to correspond with the evidence and to ensure that it is purely factual.

(2) Proposition 65 carefully distinguishes between harmful and harmless exposures to glyphosate.

In addition to the flexibility Proposition 65 provides with respect to warning language and placement, the requirements for when warnings are – and are not – required for glyphosate ensure a careful "fit" between the state's ends and means. *Fox*, 492 U.S. at 480. Plaintiffs are wrong when they say that "[e]very product sold in-state that exposes consumers to the herbicide glyphosate must be accompanied by a warning." Mot. at 1. Proposition 65 is, in fact, narrowly tailored to "distinguish[] . . . between 'the harmless and the harmful.'" *Fox*, 492 U.S. at 480 (citations omitted). Unlike in *American Beverage* and *CTIA-Wireless,* where warnings were mandatory and there was no defense to providing them, Plaintiffs will be under no obligation to warn if they can show that "the exposure [they cause] poses no significant risk assuming lifetime exposure at the level in question." § 25249.10(c); *DiPirro v. Bondo Corp.*, 153 Cal. App. 4th 150, 188 (Cal. Ct. App. 2007)

By regulation, OEHHA has set the default "No Significant Risk Level" at one excess human cancer per 100,000 exposed individuals, § 25249.10(c); 27CCR § 25703(b), which is much *less strict* than the "one in one million risk" standard used by many regulatory agencies.

[55] The requirement that a warning be provided therefore reflects both IARC's determination that glyphosate poses a cancer hazard that can be extrapolated to humans (based on sufficient evidence in animals, limited evidence in humans, and strong mechanistic evidence), and a court's rejection of the business's defense of no significant risk. *See* § 25249.10(c).

Ingredient Commc'n Council, 2 Cal. App. 4th 1480, 1494, n.8. Thus, although Plaintiffs insist that glyphosate poses no cancer risk—and that the evidence supports their position, Mot. at 7-12— Plaintiffs' burden to qualify for the NSRL is much lower. Plaintiffs need only show that glyphosate "does not pose a *significant risk* of causing cancer" in humans. *Baxter Healthcare Corp. v. Denton,* 120 Cal. App. 4th at 333, 369 (Cal. Ct. App. 2004) ("Baxter did not have to prove that DEHP definitively does not cause cancer, only that it does not pose a *significant risk* of causing cancer. This is an important distinction.") (emphasis in original).

Since Proposition 65 requires warnings only when the business cannot show that the exposure to glyphosate does not present a *significant* health risk, there is a proper 'fit' between the State's ends and means. In this case, as noted above, OEHHA is setting a safe-harbor risk level – which is OEHHA's calculation of the exposure level that will cause 1 excess cancer per 100,000 exposed individuals. The availability of this safe harbor level underscores the ways in which Proposition 65 draws a line between chemical exposures that cause a significant cancer risk and those that do not.

In light of these facts, the Proposition 65 warning requirement satisfies both the *Central Hudson* and the *Zauderer* tests. Under *Central Hudson,* a restriction on commercial speech must advance a substantial government interest and be no more extensive than is necessary to serve that interest. *Id*., 447 U.S. at 566. Specifically, there must be a "reasonable 'fit' between the government's ends and the means chosen to accomplish those ends – a fit that is not necessarily perfect, but reasonable. . . ." *Fox*, 492 U.S. at 480. Those requirements are met here.

First, the State's interest in providing information to its citizens in this case is extremely strong. The voters identified a respected international scientific agency to evaluate carcinogens; that agency conducted a robust analysis of glyphosate following its own established procedures; and the State listed glyphosate only after IARC's analysis resulted in consensus among the Working Group (sixteen scientists with expertise in the field, including several from U.S. universities and federal agencies) that glyphosate causes cancer in animals and is a probable human carcinogen. The State has a strong interest in informing Californians about products that expose them to this chemical.

Second, the warning requirement is no "more extensive than necessary," meaning that the proper "fit" is present. The statute provides businesses with a complete defense that exempts them from the warning requirement if their products do not cause a significant risk of cancer. It properly requires warnings from businesses whose products do cause a significant cancer risk. It is appropriate to place these requirements on these businesses, because they are in the best position to know how much glyphosate is in their products (*e.g.*, in the case of food) and how their products are likely to be used.

Finally, as shown above, the warning language is not written into the law or set in stone, and it can be tailored to "fit" both the chemical and the way the chemical is used, so long as it is clear and truthful, and the warning method is reasonable. 27CCR, § 25601. Both prongs of the *Central Hudson* test are therefore satisfied.

The Proposition 65 warning requirement also satisfies the more lenient *Zauderer* test, which requires that the warnings be reasonably related to a substantial governmental interest, and provide "purely factual" information. *CTIA-Wireless*, 854 F.3d at 1115, 1118 (citing *Zauderer*, 471 U.S. 651). As explained in the preceding paragraph, the warning requirement here meets the first of these requirements because the governmental interest is substantial and the warning requirement is reasonably related to advancing that interest. The requirement is justified because informing citizens about exposure to chemicals identified by expert agencies as causing cancer is a proper government function. It is not unduly burdensome because, unlike the ordinance at issue in *American Beverage*, which required warnings on advertisements, that, by their size, virtually swallowed up the businesses' own speech, and "effectively rul[ed] out" advertising in particular media, the warning here will have no such chilling effect on commercial speech. *See American Beverage*, 871 F.3d at 893 (quoting *Ibanez v. Florida Dept. of Business and Professional Regulation, Bd. of Accountancy*, 512 U.S. 136, 146 (1994)); *Zauderer*, 471 U.S. at 651. In fact, if a warning is necessary it can be given by labels, shelf signs, or other methods. 27CCR, §§ 25603.1 (current regulation), 25602 and 25607.1 (operative Aug. 30, 2018).

The warning will also be purely factual, for three reasons. First, there is no dispute that IARC found by consensus, based on review of public studies that had been made available for

independent scientific review, that there is sufficient evidence that glyphosate causes cancer in animals; that there is limited evidence of carcinogenicity in humans; that the mechanistic and other relevant data support the classification of glyphosate as probably carcinogenic to humans; and that glyphosate is probably carcinogenic to humans (Group 2A).[56] As is often the case, while there was limited human data, the animal and mechanistic data were sufficient to establish carcinogenicity. Second, warnings will only be required *if* the products cause an exposure to glyphosate in excess of the regulatory NSRL, and the business cannot show that its products do not cause a significant cancer risk to California consumers. Third, if warnings are required, they can be crafted to accurately and factually convey the specific risk from exposure to glyphosate for a specific product.

In sum, the potential enforcement of the Proposition 65 warning requirement for glyphosate will not violate Plaintiffs' free speech rights. Plaintiffs have failed to establish the most important of the *Winter* factors – likelihood of success on the merits.[57]

2. Plaintiffs Will Not Suffer Irreparable Harm in the Absence of Preliminary Relief.

Nearly as important as the weakness of Plaintiffs' First Amendment claim is the fact that Plaintiffs will suffer no harm, much less irreparable harm, if their request for a preliminary injunction is denied.[58] Plaintiffs allege that a preliminary injunction is necessary because they will suffer irreparable harm if glyphosate is not de-listed, and if the Attorney General is allowed to enforce the statute when the warning requirement goes into effect on July 7, 2018. Their argument, however, does not hold water.

Although the standard for establishing irreparable harm is somewhat relaxed in a First Amendment case, "the mere assertion of First Amendment rights does not automatically require a

[56] Zuckerman Decl., Exh. O, IARC, *Glyphosate*, from Monograph 112, at 78.

[57] Because Plaintiffs have failed to establish that they are likely to succeed on the merits, the Court need not consider the other preliminary-injunction factors. *See Garcia v. Google, Inc.*, 786 F.3d 733, 740 (9th Cir. 2015).

[58] The arguments set forth in this section and previous sections address Plaintiffs' argument that Proposition 65's *warning* requirement violates their commercial speech rights. As explained above, Plaintiffs cannot properly claim that the *listing* of glyphosate implicates their free speech rights, because that listing constitutes speech by the State of California.

finding of irreparable injury." *CTIA-Wireless*, 854 F.3d at 1123. Plaintiffs have alleged no chilling of their own speech, and courts distinguish between restrictions on speech (which the Proposition 65 warning requirement is not), where a presumption is appropriate, and a "rule or regulation that may only potentially affect speech," where the plaintiff must demonstrate the "injunction will prevent the feared deprivation of free speech rights." *See Bronx Household of Faith v. Bd. of Educ. of City of New York*, 331 F.3d 342, 349-50 (2d Cir. 2003). Here, Plaintiffs have not alleged, or provided any evidence to show, that they will ever expose Californians to amounts of glyphosate that exceed the proposed 1,100 µg/day safe harbor NSRL, much less any higher NSRL they may establish. (*See* discussion at pp. 21-24 above.) They are therefore seeking to enjoin a statute that "may only potentially affect [their] speech," and may not affect it at all. *See id*.

To the extent that Plaintiffs complain of the expense of testing their products to determine the level of glyphosate exposure they cause consumers, Plaintiffs or their suppliers are already under an obligation imposed by the federal government to ensure that the chemical residues in their products do not exceed the tolerances established for glyphosate, which shows that the prospect of monitoring these products for glyphosate will not be as unusual or burdensome as Plaintiffs suggest.[59] And since they are exposing California consumers to a pesticide that a respected international agency has deemed a carcinogen, they can hardly be heard to complain about the duty to determine the level at which the exposure occurs, and, if necessary, whether it causes a significant risk of cancer to exposed individuals, thus requiring a warning.

[59] Monsanto notes that the EPA has allowed the presence of glyphosate residues on crops and food. Mot. at 7. However, the EPA only allows the presence of glyphosate residues that fall below certain tolerances. 40 C.F.R. § 180.364. The EPA explains, "Before allowing the use of a pesticide on food crops, EPA sets a maximum legal residue limit (called a tolerance) for each treated food. The tolerance is the residue level that triggers enforcement action. That is, if residues are found above that level, the commodity will be subject to seizure by the government." https://www.epa.gov/safepestcontrol/food-and-pesticides#regulate (last accessed January 21, 2018.) The EPA tolerances for glyphosate are therefore meaningfully more stringent than the Proposition 65 requirement at issue here, which requires only a warning. Depending on the food product, the EPA tolerance levels may be more or less that the levels that would cause exposures that require such a warning under Proposition 65.

In addition, the economic harm Plaintiffs claim is highly speculative, as is any link between the warning requirement and the declines in sales and forced changes in business practices they claim have already occurred.[60] This category of harm is far more likely attributable to the original 2015 IARC carcinogenicity determination, the 2017 listing of glyphosate, which is government speech that Plaintiffs cannot use the First Amendment to enjoin, or to other factors, than it is to anticipated enforcement of the potential warning requirement. Moreover, these claims of harm are belied by the fact that more than 100 pesticides are listed by California pursuant to Proposition 65, and many are among the pesticides most widely used in California.[61] As the Ninth Circuit has held, "[s]peculative injury cannot be the basis for a finding of irreparable harm." *In re Excel Innovations, Inc.*, 502 F.3d 1086, 1098 (9th Cir. 2007) (citing *Goldie's Bookstore, Inc. v. Superior Court*, 739 F.2d 466, 472 (9th Cir. 1984)).

3. The Balance of Equities and the Public Interest Weighs Heavily Against a Preliminary Injunction.

"[A]ny time a State is enjoined by a Court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury." *New Motor Vehicle Bd. of Cal. v. Orrin W. Fox Co.*, 434 U.S. 1345, 1351 (1977) (Rehnquist, J., in chambers); *see also Clark v. Coye*, 60 F.3d 600, 603-04 (9th Cir. 1995) ("[d]ue to concerns of comity and federalism, the scope of federal injunctive relief against an agency of state government must always be narrowly tailored" and carefully scrutinized). Plaintiffs have to show that "the balance of equities tips in [their] favor, and that an injunction is in the public interest."[62] *Winter*, 555 U.S. at 20; *see*

[60] Monsanto's claims of economic harm are sharply undercut by its prediction, as reported in recent news articles, that higher generic prices for glyphosate would boost its business over the next year. *See, e.g.*, http://www.foxbusiness.com/features/2018/01/04/monsanto-expects-growth-from-flagship-herbicide-this-year-update.html (last visited January 21, 2018). And Monsanto's public filings do not evince any concern about the glyphosate listing, or the anticipated enforcement of the Proposition 65 warning requirement for glyphosate, on its future profitability.

[61] Compare the California Department of Pesticide Regulation's list of active ingredients in pesticides, http://www.cdpr.ca.gov/docs/label/actai.htm, and list of the top 100 pesticides used in California in 2015, http://www.cdpr.ca.gov/docs/pur/pur15rep/top_100_ais_lbs_2015.pdf, with the December 29, 2017 Proposition 65 list of chemicals, attached to the Zuckerman Declaration as Exhibit T, and available at http://oehha.ca.gov/proposition-65/proposition-65-list [all last visited January 21, 2018].) As an example, 1,3-Dichloropropene is on the Proposition 65 list, but was still the third most commonly-used pesticide in California in 2015.

[62] Where, as here, the government is a party, these two factors "merge." *Drakes Bay Oyster Co. v. Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014).

also Klein v. City of San Clemente, 584 F.3d 1196, 1201 (9th Cir. 2009) (movant has the burden of establishing the elements necessary to obtain injunctive relief).

Plaintiffs fail to show that the balance of equities, or the public interest, tips in their favor. To the contrary, these factors weigh in favor of denying the requested injunction. Having previously concluded that "'state government agencies had failed to provide them with adequate protection'" from hazardous chemicals, *Lungren,* 14 Cal. 4th at 306 (quoting Ballot Pamphlet at 53), California voters determined that they wanted to be informed when they were being exposed to chemicals classified by certain entities, including IARC, as cancer hazards. The voters wanted to receive this information even if other entities disagreed, and even if the science was not entirely settled. Since IARC has published a Monograph stating its formal conclusion that glyphosate causes cancer in animals and is a probable human carcinogen, the public interest in informing Californians of exposure to glyphosate is strong.

To protect this interest, the Proposition 65 process must be allowed to proceed. Once the warning requirement becomes effective in July 2018, private enforcers will do something that neither Monsanto, nor the other plaintiffs or their amici, admits to having done: test products for glyphosate content. Plaintiffs' papers suggest – without evidentiary support – that many food products will have glyphosate levels high enough to require warnings. It is possible that the testing by private enforcers will bear this out, but it is also possible that testing will show that

(1) the proposed safe harbor NSRL will exempt most, or even all, food products from the warning requirement; or

(2) if warnings are required on food, they will be required only for a small percentage of products that have high levels of glyphosate due to misuse of the pesticide, which can be corrected by proper use of the chemical.

Because Plaintiffs' motion is devoid of any information that would allow the Court to determine which of these scenarios is more likely, the Court is faced with an information vacuum. The preliminary injunction that Plaintiffs seek would make this information vacuum permanent: it would prevent the Proposition 65 process from casting light on the levels of, and the cancer risks from, the glyphosate that farmworkers and gardeners frequently use, and that may be present

in California's food supply. Californians' right to this knowledge, and the public interest in providing it to them, outweighs any equitable argument that Plaintiffs can put forward. Indeed, Plaintiffs are free to seek a re-evaluation of IARC's glyphosate classification; to dispute the science; to fund alternative scientific studies; or to follow the Proposition 65 process and show that glyphosate exposure from their products poses no significant risk to consumers – but they cannot enjoin the operation of the warning requirement based on the claim that its enforcement will violate their free speech rights. There can be no equitable argument in support of withholding truthful information from the public, if and when the statute requires the information be provided.

CONCLUSION

Plaintiffs have failed to establish that they are entitled to the extraordinary remedy of a preliminary injunction. For the reasons set forth above, the State Parties respectfully request that the Court deny Plaintiffs' motion.

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Respectfully submitted,

XAVIER BECERRA
Attorney General of California
SUSAN S. FIERING
Supervising Deputy Attorney General
DENNIS A. RAGEN
Deputy Attorney General
HEATHER LESLIE
Deputy Attorney General

/S/ LAURA J. ZUCKERMAN

LAURA J. ZUCKERMAN
Deputy Attorney General
Attorneys for Defendants Dr. Lauren Zeise, Director, Office of Environmental Health Hazard Assessment, and Xavier Becerra, Attorney General of the State of California

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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 goes 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)."