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UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

NATIONAL ASSOCIATION OF WHEAT GROWERS; NATIONAL CORN GROWERS ASSOCIATION; UNITED STATES DURUM GROWERS ASSOCIATION; WESTERN PLANT HEALTH ASSOCIATION; MISSOURI FARM BUREAU; IOWA SOYBEAN ASSOCIATION; SOUTH DAKOTA AGRI-BUSINESS ASSOCIATION; NORTH DAKOTA GRAIN GROWERS ASSOCIATION; MISSOURI CHAMBER OF COMMERCE AND INDUSTRY; MONSANTO COMPANY; ASSOCIATED INDUSTRIES OF MISSOURI; AGRIBUSINESS ASSOCIATION OF IOWA; CROPLIFE AMERICA; AND AGRICULTURAL RETAILERS ASSOCIATION,

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.

Civil Action No. 2:17-cv-02401-WBS-EFB

PLAINTIFFS' NOTICE OF MOTION AND MOTION FOR PRELIMINARY INJUNCTION

[Declarations of Joel Brinkmeyer, David Heering, Blake Hurst, Blake Inman, Mark Jackson, Greg Kessel, Mark Martinson, Ray McCarty, Dan Mehan, Chris Novak, Renee Pinel, Andrew Prins, Gordon Stoner, Dan Wogsland, and Kathy Zander filed and [Proposed] Order lodged concurrently herewith]

Hearing: Feb. 20, 2018
Time: 1:30 p.m.
Ctrm: 5

The Honorable William B. Shubb

Case Filed: Nov. 15, 2017

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that on Tuesday, February 20, 2018, at 1:30 p.m., or as soon thereafter as counsel may be heard in Courtroom 5 of the above titled Court, located in the United States Courthouse at 501 I Street, Sacramento, CA 95814, before the Honorable William B. Shubb, Plaintiffs will and hereby do move the Court to enter a preliminary injunction, enjoining Defendants and their officers, employees, or agents, and all those in privity with those entities or individuals, from listing, under § 25249.8 of California's Safe Drinking Water and Toxic Enforcement Act of 1986 (more commonly known as Proposition 65), glyphosate as a chemical known to the State of California to cause cancer, or enforcing or threatening to enforce Proposition 65 or any of its implementing regulations with regard to glyphosate, including the requirement that any "person in the course of doing business" provide a "clear and reasonable warning" before "expos[ing] any individual to" glyphosate. Cal. Health & Safety Code. § 25249.6.

This Motion is made on the grounds stated in the Memorandum of Points and Authorities filed herewith. The listing of the herbicide glyphosate as a "chemical known to the State to cause cancer" under Proposition 65 and its attendant warning requirement coerce Plaintiffs to provide a cancer "warning" with which they vehemently disagree and that is contrary to the nearly unanimous worldwide scientific consensus that glyphosate does *not* pose any risk of cancer. As explained in detail in Plaintiffs' Memorandum, the warning requirement violates the First Amendment to the United States Constitution's protections

against compelled speech. Plaintiffs urgently need this Court's help to prevent California from infringing those freedoms, the loss of which, "for even minimal periods of time, unquestionably constitutes irreparable injury." *Valle Del Sol Inc. v. Whiting*, 709 F.3d 808, 828 (9th Cir. 2013). If the warning is allowed to go into effect, Plaintiffs also face reputational, competitive, and economic harms for which they cannot be compensated. Plaintiffs need relief sufficiently in advance of California's upcoming deadline on July 7, 2018 for implementing the Proposition 65 warning to mitigate or avoid these irreparable harms, which have already begun and span across U.S. agriculture.

In support of its Motion, Plaintiffs rely on the accompanying Memorandum of Points and Authorities; the Declarations of Joel Brinkmeyer, David Heering, Blake Hurst, Blake Inman, Mark Jackson, Greg Kessel, Mark Martinson, Ray McCarty, Dan Mehan, Chris Novak, Renee Pinel, Andrew Prins, Gordon Stoner, Dan Wogsland, and Kathy Zander, and the Exhibits attached thereto; such oral argument that may be properly presented at or before the time of the hearing; and upon any other matter the Court deems proper.

Plaintiffs anticipate that hearing of this Motion will require 1 hour. Plaintiffs do not anticipate calling live witnesses.

Dated: December 6, 2017

Respectfully submitted,

/s/ Philip J. Perry

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Plaintiffs,

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.

Civil Action No. 2:17-cv-02401-WBS-EFB

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

Hearing: Feb. 20, 2018
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The Honorable William B. Shubb

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INTRODUCTION

This case presents a simple question: Can a State force private parties to defame their own products by compelling them to provide a cancer warning with which they vehemently disagree and that is contrary to the nearly unanimous worldwide scientific consensus? Under bedrock First Amendment principles, the answer is no.

The Supreme Court held in *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626 (1985), that the government may sometimes require commercial speakers to disclose certain information about their products—but because the First Amendment bars the government from conscripting its citizens to proclaim the government's subjective views, any such disclosure must be, at a minimum, "purely factual and uncontroversial." *Id.* at 651. Most common disclosures fit that mold, informing consumers of indisputable facts, such as ingredient lists, calorie counts, country of origin, and universally acknowledged health risks. The compelled speech at issue in this case is nothing like those. Under threat of steep civil penalties and bounty hunter lawsuits, California is requiring that every product sold in-state that exposes consumers to the herbicide glyphosate be accompanied by a warning that glyphosate is "known to the State of California to cause cancer"—even though California's own scientists, the Environmental Protection Agency (EPA), and regulators around the world have declared otherwise. This requirement fails the *Zauderer* test and is plainly unconstitutional.

Plaintiffs are a nationwide coalition of agricultural producers and business entities, and together they represent a substantial segment of U.S. agriculture. Glyphosate is a critical tool in modern American agriculture, approved by the federal government for use in more than 250 agricultural crop applications in all 50 States. Plaintiffs use, sell, manufacture, grow, and rely upon products containing glyphosate or to which glyphosate is applied. Because of its longstanding and widespread use, glyphosate has been subject to rigorous scientific scrutiny by the federal government and regulators worldwide for decades. It is widely regarded as one of the safest herbicides ever developed, and the overwhelming scientific consensus is that it does *not* pose any risk of cancer. EPA has so concluded, numerous foreign regulators have so concluded, and, indeed, even California—through its regulatory arm, the Office of Environmental Health Hazard Assessment (OEHHA)—has twice reached the same conclusion.

One foreign entity in Lyon, France, the highly controversial International Agency for Research on Cancer (IARC) disagrees; IARC has concluded, based on admittedly "limited evidence in humans," that glyphosate is "*probably* carcinogenic." But, under California's Safe Drinking Water and Toxic Enforcement Act of 1986 (more commonly known as Proposition 65), the overwhelming scientific consensus that IARC is mistaken is irrelevant. By law, IARC's extreme outlier determination triggered an automatic requirement that OEHHA list glyphosate as a chemical "known to the state to cause cancer." CAL. HEALTH & SAFETY CODE § 25249.8(a) & CAL. LABOR CODE § 6382(b)(1) (IARC triggering mechanism). This

listing, in turn, triggers a requirement that any "person" exposing "any individual" to glyphosate must provide a warning that the product contains a chemical "known to the State of California to cause cancer." CAL. HEALTH & SAFETY CODE § 25249.6 (requiring warning); CAL. CODE REGS. tit. 27, §§ 25603.2(a), 25603.3 (providing for content of warning). Plaintiffs respectfully ask this Court to enjoin that warning requirement pending its final judgment in this case.

Plaintiffs are not asking this Court to decide whether IARC's outlier view or, instead, Plaintiffs' and the scientific consensus, is correct on the science. The Court does not need to resolve that question to decide this case. It is firmly established under the First Amendment that California cannot compel Plaintiffs to broadcast a warning that is—at best—factually controversial, and is also literally false on its face (because *California* does *not* "know" that glyphosate causes cancer; indeed, its own expert regulator has concluded otherwise). That legal conclusion is compelled by years of Supreme Court and Ninth Circuit precedent, including the Ninth Circuit's recent decision in *Am. Beverage Ass'n v. City and County of San Francisco*, 871 F.3d 884 (9th Cir. 2017) ("ABA"). There, San Francisco sought to compel a warning about the purported contribution of beverages with added sugar to obesity, diabetes, and tooth decay. *Id.* at 888. Because this statement "convey[ed] [a] message" that was "contrary to statements by the FDA," the Court of Appeals found the compelled warning deceptive, misleading, and (at a minimum) controversial, and held that the warning requirement could not be sustained under *Zauderer*. *Id.*

at 895. The same analysis applies even more clearly here, where not just EPA but an overwhelming majority of government regulators and other experts have found that glyphosate is *not* carcinogenic and have flatly rejected IARC's contrary conclusion.

Plaintiffs believe the legal merit of their First Amendment claim is indisputable and obvious on the face of the attached documents without any need for discovery, and thus the claim is appropriate for expedited judicial resolution. Plaintiffs urgently need this Court's protection, moreover, to prevent California from infringing their First Amendment freedoms, the loss of which, "for even minimal periods of time, unquestionably constitutes irreparable injury." *Valle Del Sol Inc. v. Whiting*, 709 F.3d 808, 828 (9th Cir. 2013) (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976)). If the warning requirement is allowed to go into effect, Plaintiffs face reputational, competitive, and economic harms for which they cannot be compensated. Plaintiffs need relief sufficiently in advance of California's upcoming July 7, 2018, deadline for implementing the Proposition 65 warning to mitigate or avoid these irreparable harms, which have already begun and span across U.S. agriculture. Because Plaintiffs are likely to succeed on the merits of their First Amendment claim and the equitable factors tip sharply in their favor, the Court should preliminarily enjoin the listing of glyphosate under Proposition 65 and the application of its attendant warning requirement pending a final judgment in this case, and set a schedule for expedited final resolution of the case.

BACKGROUND

A. Glyphosate And Its Federal Regulation

Glyphosate is a broad-spectrum herbicide that is used to control weeds in agricultural, residential, aquatic, and other settings. Since its introduction in 1974, glyphosate has become the world's most widely used herbicide because it is effective, economical, and "environmentally benign." *See* Declaration of Andrew D. Prins (Prins Decl.), Exh. A (USDA, EIB No. 124, Pesticide Use in U.S. Agriculture: 21 Selected Crops, 1960-2008 at 21 (May 2014)). It is the active ingredient in many commercial products that are marketed by multiple businesses under a number of trade names, including Roundup®, and is registered for use in over 160 countries. Declaration Of David C. Heering, Monsanto Company ¶¶ 8, 9, 31-33, 52.

Glyphosate is approved for use in more than 250 agricultural crop applications in the United States. *Id.* at ¶¶ 13, 24. In California, for instance, it is used for, among other things, cultivation of almond, citrus, and cotton. Heering Decl., Monsanto ¶ 24. Elsewhere in the United States, glyphosate is used on canola and on a high percentage of critical crops such as corn, cotton, and soybean. *Id.* at ¶¶ 13, 23, 24; *see also, e.g.*, Prins Decl., Exh. B (Michael Livingston et al., *Economic Returns to Herbicide Resistance Management in the Short and Long Run: The Role of Neighbor Effects,* Weed Sci., 2016 Special Issue, at 595 ("The percentage of acres treated with glyphosate rose from 1 to 77% for corn from 1996 to 2014, from 13 to 99% for cotton from 1996 to 2010, and from 25 to 98% for soybean from 1996 to

2012.")). It is also widely used in Canada, including for cultivation of oats and wheat. Heering Decl., Monsanto ¶ 13.

Glyphosate-based herbicides are also widely used by government agencies to control vegetation in rights of way, in aquatic environments, in garden settings, and to reduce the risk associated with rapid-spreading wildfire. *Id.* at ¶ 16. These widespread uses are attributable to glyphosate's well-recognized benefits over other cultivation and weed-suppression techniques. *See, e.g., id.* at ¶¶ 15, 17; Prins Decl., Exh. C (Stephen O. Duke & Stephen B. Powles, *Glyphosate: A Once-in-a-Century Herbicide*, 64 Pest Mgmt. Sci. 319, 322 (2008)); *see also, e.g.*, Declaration Of Blake Hurst, Missouri Farm Bureau ¶ 5 ("Glyphosate is an integral tool because it enables farmers to engage in no-till farming, a conservation tilling tactic that reduces soil erosion, is widely accepted to be better for the environment, and reduces the labor involved in farming practices."); Declaration Of Chris Novak, National Corn Growers Association ¶ 4; Declaration Of Dan Mehan, Missouri Chamber of Commerce and Industry ¶ 6; Declaration Of Dan Wogsland, North Dakota Grain Growers Association ¶¶ 5-9; Declaration Of Gordon Stoner, National Association of Wheat Growers ¶¶ 6-9; Declaration Of Greg Kessel, North Dakota Grain Growers Association ¶ 4; Declaration Of Kathleen Zander, South Dakota Agri-Business Association ¶ 8; Declaration Of Mark Jackson, Iowa Soybean Association ¶¶ 4-10; Declaration Of Mark Martinson, United States Durum Growers Association ¶¶ 5-8.

As an herbicide, glyphosate is subject to comprehensive federal regulation. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), all commercial herbicides must be

"registered" with the EPA. 7 U.S.C. § 136a. Before EPA grants a registration, it must determine that the herbicide will not cause "unreasonable adverse effects on the environment" or "human dietary risk." *Id.* §§ 136(bb), 136a. Among other things, EPA's review includes an evaluation of whether the herbicide is potentially carcinogenic. *See, e.g.*, Prins Decl., Exh. D (U.S. EPA, EPA/630/P-03/001F, *Guidelines for Carcinogen Risk Assessment* (Mar. 2005)). The Federal Food, Drug, and Cosmetic Act (FDCA), in turn, regulates the presence of herbicides on food products. 21 U.S.C. §§ 342(a), 331(b). Under the FDCA, EPA is charged with evaluating the human health impact of the presence of the herbicide's residue, including its potential carcinogenicity. *Id.* § 346a(b)(2)(A). After concluding that "there is a reasonable certainty that no harm will result," 21 U.S.C. § 346a(b)(2)(A)(ii), EPA has allowed the presence of glyphosate residues on all relevant United States crops and food inputs. 40 C.F.R. § 180.364.

B. The International Scientific Consensus That Glyphosate Does Not Cause Cancer, And IARC's Contrary Outlier View

Because of its immense popularity and widespread use, glyphosate is one of, if not the most, studied herbicides in the world. It has been recognized as a safe herbicide for over 40 years by EPA, regulators worldwide, and even California's own expert regulator.

The overwhelming scientific consensus is that glyphosate does not cause cancer. EPA has repeatedly reached and re-affirmed this conclusion. For example, when it approved a

renewal of glyphosate's registration under FIFRA, EPA reported as follows:

> Several chronic toxicity/carcinogenicity studies . . . resulted in no effects based on the parameters examined, or resulted in findings that glyphosate was not carcinogenic in the study. In June 1991, EPA classified glyphosate as a Group 3 oncogen——one that shows evidence of non-carcinogenicity for humans——based on the lack of convincing evidence of carcinogenicity in adequate studies.

See Prins Decl., Exh. E (U.S. EPA, EPA-738-F-93-011, Registration Eligibility Decision (R.E.D.) Facts: Glyphosate Sept. 1993). More recently, "[i]n 2014, EPA reviewed more than 55 epidemiological studies conducted on the possible cancer and non-cancer effects of glyphosate. [Its] review concluded that 'this body of research does not provide evidence to show that glyphosate causes cancer.'" *See* Prins Decl., Exh. F (Eric Sfiligoj, *EPA Plans Response to IARC Glyphosate Finding…But Not Just Yet*, CropLife, Apr. 6, 2015 (quoting Carissa Cyran, Chemical Review Manager for the EPA Office of Pesticide Programs), http://www.croplife.com/editorial/epa-plans-response-to-iarc-glyphosate-finding-but-not-just-yet/).

California's own OEHHA has been materially in agreement with EPA. In 1997 and 2007, OEHHA conducted risk assessments for glyphosate in drinking water in order to set public health goals, including an evaluation of glyphosate's potential carcinogenicity. *See* Prins Decl., Exh. G (OEHHA, Public Health Goal for Glyphosate in Drinking Water (Dec. 1997)); Prins Decl., Exh. H (OEHHA, Public Health Goal for Glyphosate (June 2007)). It reported as follows:

> Three carcinogenicity studies [were] conducted, two in rats and one in mice, and all [we]re considered to be negative. *In vitro* and *in vivo* genotoxicity tests [we]re generally negative. There [we]re a few reports of increased sister chromatid exchange in human and bovine lymphocytes at high concentrations *in vitro*, which could be secondary to oxidative stress, and effects on mouse bone marrow after very large intraperitoneal doses. Based on the weight of the evidence, glyphosate [wa]s judged *unlikely to pose a cancer hazard to humans*."

See Prins Decl., Exh. H (OEHHA, Public Health Goal for Glyphosate (June 2007), at 1 (emphasis added)); *see also* Prins Decl., Exh. G (OEHHA, Public Health Goal for Glyphosate in Drinking Water (Dec. 1997)) ("Glyphosate is a Group E carcinogen (evidence of no carcinogenic effects).").

The global community has long been in accord. The European Commission's Health and Consumer Protection Directorate-General has concluded glyphosate presents "[n]o evidence of carcinogenicity." *See* Prins Decl., Exh. I (Health & Consumer Prot. Directorate-Gen., European Commission, Review Report for the Active Substance Glyphosate, 6511/VI/99-final, at 12 (Jan. 21, 2002)). Multiple divisions of the World Health Organization ("WHO") have reached the same conclusion. *See* Prins Decl., Exh. J (WHO, WHO/SDE/WSH/03.04/97, Glyphosate and AMPA in Drinking water: Background Document for Development of WHO Guidelines for Drinking-water Quality at 5 (rev. June 2005) ("[n]o effect on survival" in glyphosate "carcinogenicity study")); Prins Decl., Exh. K (Int'l Programme on Chemical Safety, Environmental Health Criteria 159: Glyphosate at 15 (1994) ("The available studies do not indicate that technical glyphosate is mutagenic, carcinogenic or teratogenic.")). Germany's lead regulator—BfR—has found the

same. *See* Prins Decl., Exh. L (Eur. Comm'n, Renewal Assessment Report: Glyphosate, Volume 1, at 35 (rev. Mar. 31, 2015) (glyphosate is "unlikely to pose a carcinogenic risk in humans")); *id.* at 36 ("In epidemiological studies in humans, there was *no evidence* of carcinogenicity" (emphasis added)).

IARC is the *sole* exception to this global consensus. IARC is an international organization based in Lyon, France. *See Johns Manville v. W.C.A.B.*, No. B179922, 2005 WL 1655858, at *4 n.8 (Cal. Ct. App. July 15, 2005). It is not a regulator, but is instead an agency within the WHO that prepares so-called informational "Monographs" regarding the possibility that a variety of "agents" (*e.g.*, chemicals, complex mixtures, occupational exposures, and personal habits) may be carcinogenic. The organization is perhaps best 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. *See, e.g.*, Prins Decl., Exh. M (Akshat Rathi & Gideon Lichfield, *Why it Sometimes Seems Like Everything Causes Cancer*, Quartz, June 23, 2016 ("[O]f all the things the IARC has looked at, there is just *one* it is pretty sure *doesn't* cause cancer." (emphases added)), https://qz.com/708925/why-it-sometimes-seems-like-everything-causes-cancer/).

In March 2015, IARC released a Monograph concluding, despite the global consensus otherwise, that "[g]lyphosate is *probably carcinogenic to humans*." Prins Decl., Exh. N (Int'l Agency for Research on Cancer (IARC), WHO, Some Organophosphate Insecticides and Herbicides, IARC Monographs Volume 112, at 398 (2017)

[hereinafter IARC Monograph 112] (emphasis in original)). IARC came to that conclusion based on what it conceded was "*limited evidence* in humans for the carcinogenicity of glyphosate," and it seems to have based its conclusion primarily on its (again outlier) interpretation of a limited subset of studies on "experimental animals" and "mechanistic" data. *Id.* (emphasis in original).

Many of IARC's pronouncements have provoked substantial backlash among the scientific and public health communities, and that has been especially true with IARC's 2015 glyphosate classification. Immediately after IARC published its Monograph, EPA's Deputy Director for Pesticide Programs testified before the U.S. Senate Committee on Agriculture, Nutrition and Forestry to reaffirm EPA's long-standing non-carcinogenic evaluation. *See* Prins Decl., Exh. O (*Agriculture Biotechnology: A Look at Federal Regulation and Stakeholder Perspectives: Before the S. Comm. on Agric., Nutrition, & Forestry*, 114 Cong. 261, 6-7 (2015) (statement of William Jordan, Deputy Dir., Office of Pesticide Programs, EPA)). Others at that hearing, such as the Chief Physician at MassGeneral's Hospital for Children, observed that IARC's conclusion was "not supported by the data" and "flies in the face of comprehensive assessments from multiple agencies globally." *Id.* at 43. The following year, EPA's Office of Pesticides Program issued a 227-page glyphosate issue paper that concluded based upon "an extensive database … for evaluating the carcinogenic potential of glyphosate, including 23 epidemiological studies, 15 animal carcinogenicity studies, and nearly 90 genotoxicity studies" that the available data "do not

support a carcinogenic process for glyphosate." *See* Prins Decl., Exh. P (U.S. EPA, Glyphosate Issue Paper: Evaluation of Carcinogenic Potential (Sept. 12, 2016)).

Global regulators, from Germany, to Canada, to Australia, to New Zealand, to Japan, to South Korea, to the European Chemicals Agency, have likewise rejected IARC's conclusion. *See, e.g.*, Prins Decl., Exh. Q (Fed. Inst. for Risk Assessment (BfR), BfR Communication No. 007/2015, Does Glyphosate Cause Cancer? (Mar. 23, 2015) (German regulator considering and explicitly rejecting IARC's bases for its carcinogenic conclusion); *see also infra* at 28-30 (discussing these post-IARC conclusions in more detail). In the most recent study of glyphosate, the Agricultural Health Study——sponsored by the U.S. National Institutes of Health, National Cancer Institute, and the National Institute of Environmental Health Science——analyzed health effects in over 54,000 pesticide applicators over the course of three decades and confirmed there is "no evidence of any association between glyphosate use and risk of any" cancer. *See* Prins Decl., Exh. R (Gabriella Andreotti et al., *Glyphosate Use and Cancer Incidence in the Agricultural Health Study*, 110 JNCI: Journal of the National Cancer Institute 5 (Nov. 9, 2017)).

Not only has IARC's controversial glyphosate conclusion been widely rejected; its review process procedures have been widely criticized. There are reports that IARC's scientists purposely withheld key data from the IARC team addressing glyphosate, *see* Prins Decl., Exh. S (Kate Kelland, *The WHO's Cancer Agency Left in the Dark Over Glyphosate Evidence*, Reuters, June 14, 2017), and that some of its team promptly signed on with plaintiffs'

attorneys bringing claims by cancer victims against glyphosate manufacturers, *see* Prins Decl., Exh. T (Ben Webster, *Weedkiller Scientist was Paid £120,000 by Cancer Lawyers,* The Times, Oct. 18, 2017, https://www.thetimes.co.uk/article/weedkiller-scientist-was-paid-120-000-by-cancer-lawyers-v0qggbrk6). In light of these revelations and others, many questions have been raised about the reliability of IARC's review process, *see* Prins Decl., Exh. U (Kiera Butler, *A Scientist Didn't Disclose Important Data – and Let Everyone Believe a Popular Weedkiller Causes Cancer*, Mother Jones, June 15, 2017, http://www.motherjones.com/environment/2017/06/monsanto-roundup-glyphosate-cancer-who/), *including* by OEHHA, *see* Prins Decl., Exh. V (Letter from Joan E. Denton, Director, OEHHA, to Dr. Paul Kleihues, Director, IARC, 2 (Feb. 7, 2002)).

C. The Proposition 65 Scheme

California's Proposition 65 prohibits businesses from exposing California residents to chemicals known to the State to cause cancer without providing required warnings. CAL. HEALTH & SAFETY CODE § 25249.6. OEHHA is required to maintain "a list of those chemicals known to the state to cause cancer." *Id.* § 25249.8(a). Within twelve months after a chemical is listed, the statute requires that any "person in the course of doing business" provide a "clear and reasonable warning" before "expos[ing] any individual to" the listed chemical. *Id.* §§ 25249.6; 25249.10(b). Although Proposition 65 does not define precisely what text suffices to convey a "clear and reasonable warning," OEHHA's regulations have for decades provided what the cancer warning should convey: "WARNING: This

product contains a chemical known to the State of California to cause cancer." CAL. CODE REGS. tit. 27, § 25603.2. No matter what words are used, "[t]he message must clearly communicate that the chemical in question is known to the state to cause cancer." *Id.* § 25601.

Proposition 65 provides that, in addition to other substances, OEHHA's "list shall include at a minimum those substances identified by reference in Labor Code Section 6382(b)(1)." CAL. HEALTH & SAFETY CODE § 25249.8(a). Section 6382(b)(1) of the California Labor Code in turn references "[s]ubstances listed as human or animal carcinogens by [IARC]." According to OEHHA, once IARC finds a chemical to be potentially carcinogenic with sufficient evidence of carcinogenicity in experimental animals, the agency's listing task is "ministerial"—it publishes a "Notice of Intent to List" and provides a 30-day comment period during which interested parties may claim the chemical in question "has *not* been identified by reference in Labor Code section 6382(b)(1)." CAL. CODE REGS. tit. 27, § 25904(c) (emphasis added). But OEHHA will "not consider comments related to the underlying scientific basis for classification." *Id.* In other words, OEHHA will consider whether it has identified the wrong chemical, or IARC did not identify that chemical, but it will *not* consider whether IARC got its assessment wrong.

Proposition 65 has a multi-faceted enforcement scheme. The statute imposes penalties up to $2,500 *per day* for *each* failure to provide an adequate warning, and provides for recovery of attorneys' fees. CAL. HEALTH & SAFETY CODE § 25249.7(b); CAL. CODE

REGS. tit. 11, § 3201. In addition to these penalties, the statute also provides that any person who "*threatens* to violate"—that is, "create[s] a condition in which there is a substantial probability that a violation will occur"—may be "enjoined in any court of competent jurisdiction." CAL. HEALTH & SAFETY CODE §§ 25249.7(a), 25249.11(e) (emphasis added). Claims may be brought by the Attorney General, a district attorney, or a variety of local government attorneys. *Id.* § 25249.7(c). In addition, *any person* (even someone who has not been injured) may bring a private enforcement action on behalf of the pubic. Such a private plaintiff—colloquially known as a "bounty hunter"—may recover up to a quarter of the civil penalties. CAL. CODE REGS. tit. 11, § 3203(b), (d). Accordingly, private litigation under Proposition 65 is a "lucrative" business. *See* James T. O'Reilly, *Stop the World, We Want Our Own Labels: Treaties, State Voter Initiative Laws, and Federal Pre-Emption*, 18 U. Pa. J. Int'l Econ. L. 617, 635 (1997).

Because *any* exposure to *any* listed chemical sold without the mandated warning may trigger civil penalties, there has been wide-scale abuse of the Proposition 65 regime through bounty-hunter plaintiff "strike suits." In the words of Governor Brown, the law has been abused by "unscrupulous lawyers driven by profit rather than public health." *See* Prins Decl., Exh. W (Press Release, Governor Brown Proposes to Reform Proposition 65 (May 7, 2013).[1] For example, one bounty hunter plaintiff successfully

[1] *See also e.g.*, Prins Decl., Exh. X (Anthony T. Caso, *Bounty Hunters and the Public Interest—A Study of California Proposition 65*, Engage, Mar. 2012, at 30, 31 (describing case in which "law firm created an 'astroturf' environmental group to be

sued Whole Foods for "selling *firewood*" without the warning label. *Consumer Cause, Inc. v. Mrs. Gooch's Nat. Food Markets, Inc.*, 127 Cal. App. 4th 387, 392 (Cal. Ct. App. 2005) (emphasis added). As California judges have noted, the Proposition 65 framework allows even frivolous suits to result in "judicial extortion" that forces defendants to settle to avoid legal fees and the costs of proving that they are not in violation of the Act. *Consumer Cause, Inc. v. SmileCare*, 91 Cal. App. 4th 454, 477-79 (Cal. Ct. App. 2001) (Vogel, J., dissenting); *see also Consumer Def. Grp. v. Rental Hous. Indust. Members*, 137 Cal. App. 4th 1185, 1216 (Cal. Ct. App. 2006) (strike suits are "intended to frighten all but the most hardy of targets (certainly any small, ma and pa business)[] into a quick settlement").

The reason for this widespread abuse is straightforward—it is "absurdly easy" to initiate Proposition 65 litigation. *Id.* at 1215. The principal check against frivolous lawsuits is that private parties must file a "certificate of merit" indicating a legitimate basis for their claim. CAL. HEALTH & SAFETY CODE § 25249.7(d)(1). But this requirement is trivial to satisfy. In the words of one of California's own appellate courts, a bounty hunter need only "go on the internet and find some common objects

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a plaintiff in Proposition 65 litigation," which group "consisted of partners from the law firm" and which "sent out hundreds of demand letters charging businesses with failure to provide warnings" and "extort[ing] payments of attorney fees or contributions to the front group")); Prins Decl., Exh. Y (Leeton Lee, *Nailed by a Bounty Hunter—A California Prop 65 Violation Can Cost Your Company*, PPB Magazine, Jan. 24, 2013, https://web.archive.org/web/20130616164651/http://pubs.ppai.org/2013/01/nailed-by-a-bounty-hunter-a-california-prop-65-violation-can-cost-your-company/ (documenting Proposition 65 bounty hunter suits)).

(e.g., furniture, paper, carpeting) which may 'contain' a substance on the regulatory carcinogen list. . . . [A] common place item, like a chair, doesn't have to contain any significant amount either, even a few molecules will do. Next, [the bounty hunter] call[s] up a local chemistry professor who will tell [him] that, at least in sufficient quantities, substances in those common objects will cause cancer, and are in fact on the list. . . . This phone call to your friendly professor will allow you to file the certificate of merit." *Consumer Def. Grp.*, 137 Cal. App. 4th at 1215.

Once a suit is initiated, the burden is then on the Proposition 65 defendant to establish that "the exposure"—to the extent there is any—"poses no significant risk assuming lifetime exposure at the level in question." CAL. HEALTH & SAFETY CODE § 25249.10(c). In some instances, OEHHA will predetermine the exposure threshold for particular listed substances in a determination called a "No Significant Risk Level" (NSRL), commonly referred to as a "safe harbor." But this safe harbor does not eliminate the prospect of strike suits. Proof that a defendant's product fits within the safe harbor is an "affirmative defense," *DiPirro v. Bondo Corp.*, 153 Cal. App. 4th 150, 185 (Cal. Ct. App. 2007); CAL. HEALTH & SAFETY CODE § 25249.10(c), and a bounty hunter literally "need not make *any showing at all*" regarding its applicability or lack thereof before filing suit. *Consumer Cause*, 91 Cal. App. 4th at 469 (emphasis added). Establishing the defense, in contrast, is very costly for the defendant, usually requiring detailed scientific analyses, possibly of multiple products. Litigating lifetime

exposure or even the safe harbor is generally extremely expensive and often drags on to trial. *See, e.g., Envtl. Law Found. v. Beech-Nut Nutrition Corp.*, 235 Cal. App. 4th 307, 314 (Cal. Ct. App. 2015) (safe harbor defense litigated at trial). Faced with such daunting litigation fees and the costs of commissioning an expert assessment, most parties logically "[s]ettle with the plaintiff," "[s]ave the cost of the assessment," "[s]ave the legal fees," and "[g]et rid of the case." *Consumer Cause*, 91 Cal. App. 4th at 478 (Vogel, J., dissenting). In other words, they succumb to "judicial extortion" and adopt a Proposition 65 warning regardless of their opposition. *Id.*

D. OEHHA's Glyphosate Listing And Its Significant Effects

On July 7, 2017, despite the overwhelming contrary views of the U.S. government, the international regulatory community, and even OEHHA itself that glyphosate is not carcinogenic, OEHHA listed glyphosate under Proposition 65 as a chemical "known to the state to cause cancer." *See* Prins Decl., Exh Z (OEHHA, *Glyphosate Listed Effective July 7, 2017, as Known to the State of California to Cause Cancer* (June 26, 2017), https://oehha.ca.gov/proposition-65/crnr/glyphosate-listed-effective-july-7-2017-known-state-california-cause-cancer). OEHHA made this listing mechanically—without conducting any of its own scientific analysis—based only on the fact that IARC had issued a monograph concluding that glyphosate is "probably" carcinogenic to humans. OEHHA refused to consider comments critiquing IARC's process and conclusion, and disclaimed any ability to address the underlying scientific dispute or reassess "the weight or quality of the evidence considered by IARC." *See*

Prins Decl., Exh. AA (OEHHA, *Notice of Intent to List: Tetrachlorvinphos, Parathion, Malathion, Glyphosate* (Sept. 4, 2015), https://oehha.ca.gov/proposition-65/crnr/notice-intent-list-tetrachlorvinphos-parathion-malathion-glyphosate).

As a result of OEHHA's listing, as of July 2018 any seller or manufacturer of a product sold in California that could expose a consumer to glyphosate must either provide a "clear and conspicuous" warning conveying that the product contains a chemical "known to the state of California to cause cancer," or prepare to defend against a costly enforcement action or strike suit. Past Proposition 65 litigants are already threatening new strike suits regarding glyphosate. *See* Heering Decl., Monsanto ¶ 42; Prins Decl., Exh. BB (Joseph Perrone, Ph.D., *Advocacy Groups Have Ulterior Motive in Wanting Weedkiller Banned*, The Modesto Bee, June 21, 2017, http://www.modbee.com/opinion/state-issues/article157416894.html (describing how "environmental groups cheered" at the glyphosate listing because it will be "a boon to their pocketbook")). This is consistent with past experience—Proposition 65 litigants routinely threaten litigation *within days* of the active warning date. *See* Prins Decl. ¶ 4. OEHHA has not yet established an NSRL for glyphosate, *see id.* at ¶ 2, but even if it does so, for the reasons discussed above (including that it would function only as an affirmative defense), that will not remove the threat of enforcement. *See supra* at 17-18.

Unless it is enjoined, the glyphosate listing and its associated warning requirement will have severe adverse impacts on Plaintiffs. For manufacturers and retailers of glyphosate,

the listing and the attendant warning requirement will broadly "stigmatiz[e]" these entities' products and reputations. *Baxter Healthcare Corp. v. Denton* 120 Cal. App. 4th 333, 344 (Cal. Ct. App. 2004); *see also* Heering Decl., Monsanto ¶¶ 45, 51-54. Members of Plaintiff Western Plant Health Association—which sell glyphosate in California—have *already* lost sales due to the Proposition 65 listing—even though the warning requirement is not yet in effect. Declaration of Renee Pinel, Western Plant Health Association ¶ 14. Similarly, Plaintiff Monsanto Company manufactures glyphosate and supplies glyphosate to public and private entities (including consumers) in California. Heering Decl., Monsanto ¶¶ 29-33. Major retailers in California already have informed Monsanto that they will not carry glyphosate-based products without a Proposition 65 warning and that they will begin removing those products without a warning from their shelves and inventory well before the warning requirement goes into effect. *Id.* at ¶ 35. This is true even if an NSRL is ultimately adopted. *Id.* at ¶ 36; *see also* Am. Complaint ¶¶ 79, 85, 86.

Until and unless the warning requirement is enjoined, therefore, Plaintiffs (and their members) will be faced with a "Hobson's choice," *Baxter Healthcare Corp.* 120 Cal. App. 4th at 344—either communicate to consumers a disparaging health warning about glyphosate products that is contrary to every regulatory finding of glyphosate's safety, or face the significant risk of an enforcement action or strike suit under Proposition 65 for failing to do so. Heering Decl., Monsanto ¶¶ 40-44; Pinel Decl., Western Plant Health Association ¶ 15; Declaration Of Joel

Brinkmeyer, Agribusiness Association of Iowa ¶¶ 8-10. Decisions about labeling on products must be made imminently. Heering Decl., Monsanto ¶ 38.

Even if OEHHA ultimately establishes an NSRL, Plaintiffs will still be injured because they will be forced to choose between providing the warning, or undertaking costly assessments to demonstrate that exposures to glyphosate from their products will fall below the NSRL (an undertaking that would still not prevent a subsequent enforcement action or strike suit). Heering Decl., Monsanto ¶¶ 40, 41, 44; Pinel Decl., Western Plant Health Association ¶ 16.

For entities that sell finished food products into California that are made using glyphosate-treated crops—like members of Plaintiffs Missouri Chamber of Commerce and Industry and Associated Industries of Missouri—the listing will have similar effects. *See, e.g.*, Jackson Decl., Iowa Soybean ¶¶ 14-19; Mehan Decl., Missouri Chamber ¶¶ 9-12; Declaration Of Ray McCarty, Associated Industries of Missouri ¶¶ 10-12. Members of these Plaintiffs will face an imminent choice between (1) providing a disparaging glyphosate warning for their products that is contrary to the worldwide scientific consensus, which likely will diminish demand for those products; (2) engaging in costly efforts to demonstrate that any exposures to glyphosate residues on their products will fall below any established NSRL or requiring their suppliers to undertake those efforts, and even so still facing the likely prospect of expensive enforcement actions; or (3) halting the use of glyphosate-treated crops as inputs. *See* Mehan Decl., Missouri Chamber ¶¶ 10-11; Stoner

Decl., Nat'l Assoc. Wheat Growers ¶¶ 11-14; Brinkmeyer Decl., Iowa Agribusiness ¶ 10; Zander Decl., S.D. Agri-Business ¶¶ 8-11; Jackson Decl., Iowa Soybean ¶¶ 17-18; Martinson Decl., U.S. Durum Growers ¶¶ 13-17; McCarty Decl., Assoc. Indus. of Missouri ¶¶ 8-13.

The pressures on these Plaintiffs will then have ripple effects on farmers upstream: With the threat of enforcement under Proposition 65 looming, many grain handlers and finished food producers will demand that farmers providing inputs either cease using glyphosate on their crops or certify that their crops do not contain glyphosate residues beyond particular levels, which will require expensive testing or segregation of glyphosate-treated crops from non-glyphosate-treated crops—each an undesirable option that will require modifications to business practices around the country and that carries considerable expense. *See, e.g.*, Hurst Decl., Missouri Farm Bureau ¶¶ 12-14; Declaration Of Blake Inman, United States Durum Growers Association ¶¶ 12-15; Mehan Decl., Missouri Chamber ¶¶ 10-11; Stoner Decl., Nat'l Assoc. Wheat Growers ¶¶ 14-15; Kessel Decl., N.D. Grain Growers ¶¶ 8-10; Jackson Decl., Iowa Soybean ¶ 18; McCarty Decl., Assoc. Indus. of Missouri ¶¶ 11-13. This will dramatically affect the practices of farmers across the country, including members of Plaintiffs National Association of Wheat Growers, National Corn Growers Association, United States Durum Growers Association, Missouri Farm Bureau, Iowa Soybean Association, North Dakota Grain Growers Association, and Missouri Chamber of Commerce and Industry.

ARGUMENT

Plaintiffs ask this Court to preliminarily enjoin the listing of glyphosate under Proposition 65 and its attendant warning requirement to maintain their First Amendment right against being compelled to disparage their own products with factually controversial and literally false warnings with which they vehemently disagree. "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 v. NRDC*, 555 U.S. 7, 20 (2008). "[I]n the First Amendment context, the moving party bears the initial burden of making a colorable claim that its First Amendment rights have been infringed, or are threatened with infringement, at which point the burden shifts to the government to justify the restriction" on speech and demonstrate that the plaintiff is unlikely to succeed on the merits. *Thalheimer v. City of San Diego*, 645 F.3d 1109, 1116 (9th Cir. 2011). This Court should grant equitable relief here because Plaintiffs amply meet the "colorable" standard—the compelled glyphosate warning clearly violates the First Amendment—and the remaining factors all weigh heavily in Plaintiffs' favor.

I. PLAINTIFFS ARE LIKELY TO SUCCEED ON THEIR CLAIM THAT THE COMPELLED GLYPHOSATE WARNING VIOLATES THE FIRST AMENDMENT

In general, the First Amendment forbids regulations compelling speech to the same extent that it forbids regulations restricting speech. *See, e.g., Hurley v. Irish-American Gay,*

Lesbian and Bisexual Grp. of Boston, 515 U.S. 557, 573 (1995) ("[O]ne important manifestation of the principle of free speech is that one who chooses to speak may also decide what not to say." (quotations omitted)). And regulations of non-misleading commercial speech are, in general, subject at least to intermediate scrutiny, under which the government must show its regulation directly advances a substantial government interest and is no more "extensive than is necessary to serve that interest." *Cent. Hudson Gas & Elec. Co. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557, 566 (1980).

In *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, the Supreme Court recognized a narrow exception to this intermediate scrutiny. Because businesses have only a "minimal" interest in "*not* providing any particular factual information," *Zauderer* held that the government may 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." 471 U.S. at 651 (emphasis in original) (upholding rule requiring lawyer to disclose on advertisements that in contingency cases client would still be liable for costs). It is the government's burden to demonstrate that all these requirements are satisfied. *ABA*, 871 F.3d at 895 ("[T]he government must carry the burden of demonstrating that its disclosure requirement is purely factual and uncontroversial [and] not unduly burdensome."). Defendants will not be able to satisfy that burden in this case.

Because the glyphosate warning is not purely factual and uncontroversial, it cannot be upheld under *Zauderer*. Nor could it conceivably be upheld under the more demanding *Central Hudson* standard.

A. The Compelled Glyphosate Warning Will Fail Under *Zauderer* Because It Is Not "Purely Factual and Uncontroversial"

The First Amendment prohibits the government from forcing its citizens to repeat the government's—or any third party's—subjective opinion. *See Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n of Cal.*, 475 U.S. 1, 13-14 (1986) (plurality op.); *Video Software Dealers Ass'n v. Schwarzenegger*, 556 F.3d 950, 965-67 (9th Cir. 2009) (invalidating subjective "labeling requirement" for "violent" video games). The *Zauderer* exception is therefore necessarily limited to compelled disclosure of factual information, the accuracy of which cannot be reasonably disputed. *CTIA-The Wireless Ass'n v. City of Berkeley*, 854 F.3d 1105, 1117 (9th Cir. 2017) ("[U]ncontroversial in [the *Zauderer*] context refers to the factual accuracy of the compelled disclosure."); *ABA*, 871 F.3d at 892 n.5 ("As we have clarified, the term 'uncontroversial' in this context refers to the factual accuracy of the compelled disclosure."); *see also Nat'l Ass'n of Mfrs. v. SEC*, 800 F.3d 518, 529 (D.C. Cir. 2015) ("A controversy, the dictionaries tell us, is a dispute, especially a public one."). For example, the government can compel the disclosure of a product's country of origin, *Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18, 27 (D.C. Cir. 2014); whether a product contains mercury, *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d

104, 107 (2d Cir. 2001); the costs a client is liable to pay, *Zauderer*, 471 U.S. at 650; and what contents are included in a package of services offered, *Milavetz, Gallop & Milavetz, P.A., v. United States*, 559 U.S. 229, 232 (2010)——all facts that can be reasonably and definitively ascertained.

By contrast, the government cannot compel disclosure of purported "facts" over which there is significant room for disagreement. Thus, in *CTIA-Wireless Ass'n v. City & County of San Francisco*, the Ninth Circuit affirmed a preliminary injunction of a requirement that cell phone dealers inform consumers about health risks from the phones' radiofrequency energy emissions. 494 F. App'x 752, 753 (9th Cir. 2012). The warning contained suggestions as to "what consumers should do" to avoid exposure——language that "*could* . . . be interpreted by consumers as expressing San Francisco's opinion that using cell phones is dangerous." *Id.* at 753 (emphasis added). Such an impression would have conflicted with the Federal Communications Commission's "established limits," within which radiofrequency energy exposure is safe, and would have waded directly into an ongoing "debate in the scientific community about the health effects of cell phones." *Id.* at 753-54.[2]

[2] By contrast, the Ninth Circuit held that the City of Berkeley *was* permitted to require disclosure that "[i]f you carry or use your phone" in certain areas close to your body, "you may exceed the federal guidelines for exposure to R[adio]F[requency] radiation." *CTIA-The Wireless Ass'n v. City of Berkeley, California*, 854 F.3d 1105, 1111 (9th Cir. 2017). That warning largely mirrored FCC disclosure requirements that CTIA did not challenge. The Ninth Circuit upheld that warning requirement because it was "literally true" and not "misleading." *Id.* at 1119-20.

Similarly, the City of San Francisco recently enacted an ordinance requiring that most advertisements for sugar sweetened beverages ("SSBs") contain the following: "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." *ABA*, 871 F.3d at 888. The district court denied a preliminary injunction principally because it concluded that there was "no real dispute as to the literal accuracy of the required warning" (*i.e.*, no dispute that added sugar contributes to tooth decay, diabetes, and obesity). *Am. Beverage Ass'n v. City and County of San Francisco*, 187 F. Supp. 3d 1123, 1139 (N.D. Cal. 2016). The Ninth Circuit disagreed and reversed. It held that the "factual accuracy of the warning was, at a minimum, controversial" because "when consumed as part of a diet that balances caloric intake with energy output, consuming beverages with added sugar *does not* contribute to obesity or diabetes." *ABA*, 871 F.3d at 895 (emphasis added); *see also id.* (quoting FDA promulgations in conflict with San Francisco's warning). As a result, San Francisco was effectively compelling the plaintiffs "to convey San Francisco's disputed policy views." *Id.* at 896.

Sometimes, "determining whether a disclosure is 'uncontroversial' may be difficult." *Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18, 34 (D.C. Cir. 2014) (en banc) (Kavanaugh, J., concurring in the judgment). That is not so for California's glyphosate warning. The accuracy of this compelled warning is *indisputably* controversial. Attached as Appendix 1 is a chart comparing the relevant conclusions of U.S. and other national regulators and authoritative bodies with California's

warning requirement. For example, the chief U.S. glyphosate regulator——EPA——does not agree that glyphosate causes cancer. *See supra* at 7-8. Even *California's own expert regulator* has twice found that glyphosate does not cause cancer. *See supra* at 8-9.

Indeed, regulators around the world specifically rejected IARC's conclusion *after* it was rendered and after reviewing much of the same evidence as IARC. For example, Germany's BfR concluded, despite IARC's contrary designation, that it continued to assess "glyphosate as non-carcinogenic." *See* Prins Decl., Exh. Q (BfR, Does Glyphosate Cause Cancer?). BfR noted that it "ha[d] compiled the most comprehensive toxicological database, presumably worldwide, for glyphosate" and that "the entire database"——rather than IARC's "more or less arbitrary selection of studies"——supported the non-carcinogenic conclusion. *Id.* The European Union's European Food Safety Authority (EFSA) likewise rebutted IARC's unfounded classification and set forth several similar reasons as BfR for its disagreement. *See* Prins Decl., Exh. CC (Eur. Food Safety Auth. (EFSA), Peer Review of the Pesticide Risk Assessment of the Active Substance Glyphosate, DOI 10.2903/j.efsa.2015.4302, at 11 (Nov. 12, 2015)). And, remarkably, although IARC is part of the WHO, a separate component of the WHO concluded in a 2016 review, after the IARC classification, that "glyphosate is *unlikely* to pose a carcinogenic risk to humans." *See* Prins Decl., Exh. DD (Food & Agric. Org. of the U.N. (FAO) and WHO, Joint FAO/WHO Meeting on Pesticide Residues: Summary Report (May 16, 2016)). At risk of belaboring the point, regulators from Canada, the European

Chemicals Agency, Australia, New Zealand, Japan, and South Korea also agree with the non-carcinogenic consensus, including in very recent analyses. *See* Prins Decl., Exh. EE (Pest Mgmt. Regulatory Agency, Health Canada, RVD2017-01, Re-evaluation Decision: Glyphosate (Apr. 28, 2017), at 1 ("Glyphosate is not genotoxic and is unlikely to pose a human cancer risk.")); Prins Decl., Exh. FF (Eur. Chems. Agency (ECHA) Press Release ECHA/PR/17/06, Glyphosate Not Classified as a Carcinogen by ECHA (Mar. 15, 2017) (March 2017 conclusion that "the available scientific evidence did not meet the criteria to classify glyphosate as a carcinogen, as a mutagen or as a toxic for reproduction.")); Prins Decl., Exh. GG (Austl. Pesticides & Veterinary Meds. Auth., Regulatory Position: Consideration of the Evidence for a Formal Reconsideration of Glyphosate, 11 (Sept. 2016) ("Following the assessment of the 19 studies relevant to the IARC carcinogenicity classification of glyphosate . . . [we] concluded that there did not appear to be any new information to indicate that glyphosate poses a carcinogenic or genotoxic risk to humans.")); Prins Decl., Exh. HH (Envtl. Prot. Auth., Gov't of N.Z., Review of the Evidence Relating to Glyphosate and Carcinogenicity, at 16 (August 2016) ("[G]lyphosate is unlikely to be genotoxic or carcinogenic.")); Prins Decl., Exh. II (Food Safety Commission of Japan, Risk Assessment Report: Pesticides, Glyphosate Summary (September 2016)); Heering Decl., Monsanto, Exh. K (Rural Development Administration (Korea), Assessment of the Safety of Pesticides Containing Glyphosate and Diazinon (Mar. 10, 2017)); *see also* Prins Decl., Exh. R (*Glyphosate Use and Cancer Incidence in the Agricultural Health Study*) (the most recent study of

glyphosate, sponsored by the U.S. National Institutes of Health, National Cancer Institute, and the National Institute of Environmental Health Science, confirming that there is "no evidence of any association between glyphosate use and risk of any" cancer).

The Ninth Circuit's decision in *ABA* confirms that the accuracy of California's compelled glyphosate warning is impermissibly controversial. In *ABA*, the warning's conflict with the view of FDA was ample to establish controversy. 871 F.3d at 895 ("conclud[ing] that the factual accuracy of the warning is, at a minimum, controversial" because it "is contrary to statements by the FDA"). Here, the chorus of dissent is far louder.

The compelled glyphosate warning also is not "purely factual and uncontroversial" for the *independent* reason that it is false and misleading to say that glyphosate is "known" to California to "cause" cancer. *See ABA*, 871 F.3d at 893. The ordinary meaning of the word "knows" includes "to apprehend with certitude as true, factual, sure, or valid." *Webster's Third New International Dictionary* (1986 ed.). California emphatically has no such "certitude" of glyphosate's carcinogenicity. To the contrary, California has previously stated that it *knows* the opposite, *see* Prins Decl., Exh. G (OEHHA 1997) (OEHHA conclusion that glyphosate is "unlikely to pose a cancer hazard to humans"), and it has never revisited that conclusion. And because California affirmatively disclaims the ability under its law to independently evaluate IARC's conclusions, it strains credulity and linguistics to say that California "knows" what IARC claims

to know. *See* Prins Decl., Exh. Z (OEHHA, *Notice of Intent to List*) (confirming "ministerial" nature of Proposition 65 listing based on IARC's conclusion).

In addition to the fact that California cannot be said to "know" something that (i) its own expert scientific agency disagrees with, (ii) is based on nothing more than an analysis conducted by a non-regulatory entity (iii) that California admits it is legally constrained from questioning, the compelled glyphosate warning is *also* misleading because even *IARC* has not concluded that glyphosate is "known to cause" cancer in humans (which is the obvious import of an unqualified cancer warning placed on products intended for purchase by humans). The most IARC has concluded, based on admittedly "limited evidence in humans," is that glyphosate is "probably carcinogenic" to humans. IARC Monograph 112 at 398 (emphasis omitted). Indeed, IARC specifically chose not to categorize glyphosate as a chemical that "is carcinogenic in humans" or for which there is "sufficient evidence of carcinogenicity in humans." *Id.* at 30 (emphasis omitted). Thus, the warning is misleading in a second respect because it overstates even IARC's conclusion and thereby compels a statement about glyphosate that no entity anywhere has ever concluded is true.

Because California will not be able to establish that the compelled glyphosate warning is purely factual and uncontroversial, it will fail review under *Zauderer*.

B. The Compelled Glyphosate Warning Will Be Found To Violate The First Amendment

To Plaintiffs' knowledge, no court has ever upheld under the First Amendment a regulation compelling a disclosure or warning that fails *Zauderer*'s "purely factual and uncontroversial" standard. That is unsurprising, because it is bedrock First Amendment law that the government cannot mandate allegiance to its subjective or disputed opinions. *See Video Software Dealers*, 556 F.3d at 965-66; *ABA*, 871 F.3d at 898 n.12. But regardless of whether such regulations are per se unlawful or instead subject to an intermediate scrutiny that precious few if any can satisfy, the compelled warning in this case—which is not merely disputable, but contrary to the views of the overwhelming majority of government regulators and scientific experts worldwide and also literally false and misleading—cannot survive constitutional review.

Under *Central Hudson's* intermediate scrutiny, the burden is on the government to justify its speech mandate. *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 505 (1996). And California cannot possibly satisfy that burden here. *Central Hudson* requires that the government show a "substantial" government interest that its regulation "directly" advances through burdens on speech no more "extensive than [] necessary to serve that interest." *Id.* at 566; *see also Cal-Almond, Inc. v. U.S. Dep't of Agric.*, 14 F.3d 429, 437 (9th Cir. 1993). As relevant here, Proposition 65's stated purpose is to "inform[] [Californians] about exposures to chemicals that cause cancer . . . ." *See Cal. Chamber of Com. v. Brown*, 196 Cal. App. 4th 233, 258 (Cal. Ct.

App. 2011). Assuming California's interest in so informing consumers is substantial, the compelled glyphosate warning would fail intermediate scrutiny for two independent reasons: it neither (1) materially advances that interest nor (2) is sufficiently tailored to serving it.

First, California cannot show that the warning materially advances its interest in informing consumers about cancer risks because California has conducted no analysis showing that this outlier warning informs consumers about a genuine cancer risk. *See Cal-Almond*, 14 F.3d at 438 (no direct advancement where government admits it has not conducted its own analysis). California admits that it is precluded from conducting such an analysis by its own statutes, which required that it list glyphosate under Proposition 65 automatically once IARC made its determination. *See* Prins Decl., Exh. Z (OEHHA, *Notice of Intent to List*). But California cannot evade its burden to prove material advancement in this case by complaining that it was required by its own laws to accept IARC's conclusions as definitive and ignore the larger body of scientific evidence about glyphosate.

By law, moreover, the Proposition 65 warning "must clearly communicate that the chemical in question is *known* to the state to *cause* cancer." CAL. CODE REGS. tit. 27, § 25601 (emphasis added). But as discussed earlier, that specific message is false and misleading both because California knows no such thing and because even IARC's monograph stops short of making any definitive conclusion about causation in humans. Even a simple comparison of IARC's conclusions and the compelled warning shows

that the Proposition 65 warning is literally false or at the least highly misleading on its face. *Compare* IARC Monograph 112 at 398 ("There is *limited evidence* in humans for the carcinogenicity of glyphosate … Glyphosate is *probably carcinogenic to humans*.") and *id.* at 27 (stating that "[l]imited evidence of carcinogenicity" means that "chance, bias or confounding could not be ruled out with reasonable confidence") *with* CAL. CODE REGS. tit. 27, § 25601 (providing that the "[t]he message must clearly communicate that the chemical in question is known to the state to cause cancer") *and id.* § 25603.2(a) (providing safe harbor only when the message "include[s] the following language: … 'WARNING: This product contains a chemical known to the State of California to cause cancer.'"). Compelling a false or misleading warning does not advance any legitimate government interest. *See, e.g.*, *Video Software Dealers*, 556 F.3d at 967 ("[T]he State *has no* legitimate reason to force retailers to affix false information on their products."); *Entm't Software Ass'n v. Hatch*, 443 F. Supp. 2d 1065, 1072 (D. Minn. 2006) ("A state's requirement that a business post a false statement serves no legitimate government interest.").

Indeed, not only does the glyphosate warning fail to materially advance California's interest in informing Californians about exposure to carcinogenic substances, it actively *undermines* that interest. Mandating warnings without an adequate basis contributes to *over*warning——a real-life version of the Boy Who Cried Wolf——which causes consumers to tune warnings out entirely, even when they are well-founded and important. *See, e.g., Johnson v. Am. Standard, Inc.*, 43 Cal. 4th 56, 70

(2008) (overwarning "invite[s] mass consumer disregard and ultimate contempt for the warning process"); *Dowhal v. SmithKline Beecham Consumer Healthcare*, 32 Cal. 4th 910, 932 (2004) ("problems of overwarning are exacerbated" where, as here, "warnings must be given even as to very remote risks"); *Thompson v. County of Alameda*, 27 Cal. 3d 741, 755 (1980) (noting that "by reason of their sheer volume," insignificant warnings "would add little to the effective protection of the public"); *see also Gaeta v. Perrigo Pharms.*, 562 F. Supp. 2d 1091, 1097 (N.D. Cal. 2008) (noting that overwarning can "have a *negative* effect on . . . public health"); *Mason v. SmithKline Beecham Corp.*, 596 F.3d 387, 392 (7th Cir. 2010) (concluding that overwarning "can deter potentially beneficial uses of [the substance] by making it seem riskier than warranted and can dilute the effectiveness of valid warnings").

Second, the compelled glyphosate warning independently fails intermediate scrutiny because it is not narrowly tailored. California has not explored any less restrictive alternatives to communicate any concerns about glyphosate, even though several obvious alternatives exist. *See Valle Del Sol*, 709 F.3d at 826 (holding that a speech restriction is overinclusive where it "restricted more speech than necessary"). For one, California could itself inform the public about IARC's conclusion, and truthfully explain how that conclusion differs from the conclusions of EPA and regulators worldwide. *See Linkmark Assocs., Inc. v. Willingboro*, 431 U.S. 86, 97 (1977) (government could have used alternative of speaking itself to give "widespread publicity" to issue); *Sorrell v. IMS Health*, 564 U.S.

552, 578 (2011) ("The State can express [its] view through its own speech."); *Evergreen Ass'n v. City of N.Y.*, 740 F.3d 233, 250-51 (2d Cir. 2014) (city could have communicated message through its own advertisements). And, of course, rather than mandating a warning that California "knows" glyphosate "causes" cancer, California might consider a very different disclosure—*e.g.*, "California is aware of one report suggesting that glyphosate caused cancer in certain experimental animals. But many other reports disagree, including those conducted by U.S. and international regulators." Defendants cannot demonstrate why these or other less restrictive alternatives would not address the State's interests.

II. THE REMAINING EQUITABLE FACTORS WEIGH HEAVILY IN PLAINTIFFS' FAVOR

Plaintiffs easily satisfy the remaining elements for preliminary equitable relief: they are "likely to suffer irreparable harm in the absence of preliminary relief"; "the balance of equities tips in [their] favor"; and "an injunction is in the public interest." *Winter*, 555 U.S. at 20.

Plaintiffs' demonstrated likelihood of success satisfies the "likely to suffer irreparable injury" requirement. Absent an injunction, Plaintiffs will be unlawfully coerced by the threat of litigation and penalties to abandon their First Amendment rights and disseminate a factually controversial and literally false and misleading warning with which they vehemently disagree. "[T]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." *Valle Del Sol*, 709 F.3d at 828 (quoting *Elrod v. Burns*, 427 U.S. 347,

373 (1976). It is accordingly "relatively easy" to establish this factor in a First Amendment case," *CTIA-The Wireless Ass'n* 854 F.3d at 1123; plaintiffs "*need only* demonstrate the existence of a colorable First Amendment claim," *Brown v. California Dep't of Transp.*, 321 F.3d 1217, 1225 (9th Cir. 2003) (emphasis added). Plaintiffs here have done that in spades. *See supra* at 24-36.

In addition to the threatened constitutional injury, the compelled warning requirement will cause several additional forms of significant and/or intangible injuries that constitute irreparable harms:

- The compelled glyphosate warning will damage the reputation and goodwill associated with Plaintiffs (and their members) and their products by misleading consumers and branding their products as cancer-causing killers. Heering Decl., Monsanto ¶¶ 39, 45, 52-54; Inman Decl., U.S. Durum Growers ¶¶ 10-11; Novak Decl., Nat'l Corn Growers Ass'n ¶ 7; Kessel Decl., N.D. Grain Growers ¶ 11; Brinkmeyer Decl., Iowa Agribusiness ¶¶ 9, 15; Zander Decl., S.D. Agri-Business ¶¶ 8-10; Pinel Decl., Western Plant Health Association ¶ 17; Jackson Decl., Iowa Soybean ¶ 13; Martinson Decl., U.S. Durum Growers ¶¶ 18-19; McCarty Decl., Assoc. Indus. of Missouri ¶¶ 8-10; *see Life Alert Emergency Response, Inc. v. LifeWatch, Inc.*, 601 F. App'x 469, 474 (9th Cir. 2015) (threat to "reputation and goodwill . . . constitutes irreparable harm"); *see also Rent-A-Ctr., Inc. v. Canyon Television & Appliance Rental, Inc.*, 944 F.2d 597, 603

(9th Cir. 1991) (same); *Gerling Glob. Reinsurance Corp. of Am. v. Quackenbush*, Nos. Civ. S-00-0506WBSJFM, Civ. S-00-0613WBSJFM, CIV S-00-0779WBSJFM, Civ.S-00-0875WBSJFM, 2000 WL 777978, at *13 (E.D. Cal. June 9, 2000) (Shubb, J.) (irreparable harm where defendant's actions "suggest" plaintiff's services are unsavory).

- This reputational disparagement will put Plaintiffs at a significant competitive disadvantage. Hurst Decl., Missouri Farm Bureau ¶¶ 19-21; Inman Decl., U.S. Durum Growers ¶¶ 10-11, 17; Wogsland Decl., N.D. Grain Growers ¶¶ 13, 17-18; Stoner Decl., Nat'l Assoc. Wheat Growers ¶¶ 10, 16; Brinkmeyer Decl., Iowa Agribusiness ¶¶ 15-16; Zander Decl., S.D. Agri-Business ¶¶ 8, 13; Jackson Decl., Iowa Soybean ¶¶ 13, 19; McCarty Decl., Assoc. Indus. of Missouri ¶¶ 8-10, 14; *see also, e.g.*, *Int'l Franchise Ass'n v. City of Seattle*, 803 F.3d 389, 411 (9th Cir. 2015) ("A rule putting plaintiffs at a competitive disadvantage constitutes irreparable harm.").
- The glyphosate listing and warning requirement have already caused some Plaintiffs to lose customers and will certainly cause loss of prospective customers. Pinel Decl., Western Plant Health Association, ¶ 14; Heering Decl., Monsanto ¶¶ 35, 36, 39, 46-52; *Stuhlbarg Int'l Sales Co. v. John D. Brush & Co.*, 240 F.3d 832, 841 (9th Cir. 2001) ("Evidence of threatened loss of prospective customers or goodwill certainly

supports a finding of the possibility of irreparable harm."); *Design Furnishings, Inc. v. Zen Path LLC*, No. CIV. 2:10-02765 WBS GGH, 2010 WL 4321568, at *4 (E.D. Cal. Oct. 21, 2010) (Shubb, J.) (irreparable harm where defendant's actions "cause plaintiff to lose prospective customers").

- The warning requirement has already caused major glyphosate retailers to determine that they will not carry glyphosate-based products without a warning on the products' labels with which Plaintiffs vehemently disagree. Pinel Decl., Western Plant Health Association ¶¶ 14-15; Heering Decl., Monsanto ¶ 35. This is true even if an NSRL is ultimately adopted. Pinel Decl., Western Plant Health Association ¶ 16; Heering Decl., Monsanto ¶ 36. Accordingly, major retailers will remove Plaintiffs' unlabeled glyphosate-based products from store shelves and inventory well in advance of the effective date of the warning requirement. Heering Decl., Monsanto ¶ 38; *see De Simone v. VSL Pharmaceuticals, Inc.*, 133 F. Supp. 3d 776, 799 (D. Md. 2015) ("irreparable harm" from pulling products "off the shelves"). Likewise, the warning requirement threatens to impose operational burdens on major retailers, further impairing Plaintiffs' reputations and goodwill. *See, e.g.*, Heering Decl., Monsanto ¶ 39.
- The warning requirement threatens to force changes throughout the food, agricultural, and herbicide

industries by imposing (at a minimum) extensive and wholly unnecessary testing requirements, and disruption to and segregation of supply chains. *See, e.g.*, Hurst Decl., Missouri Farm Bureau ¶¶ 12-15; Inman Decl., U.S. Durum Growers ¶¶ 12-15; Novak Decl., Nat'l Corn Growers Ass'n ¶¶ 9-10; Wogsland Decl., N.D. Grain Growers ¶¶ 13-16; Stoner Decl., Nat'l Assoc. Wheat Growers ¶¶ 11-14; Kessel Decl., N.D. Grain Growers ¶¶ 7-10; Brinkmeyer Decl., Iowa Agribusiness ¶ 13; Jackson Decl., Iowa Soybean ¶¶ 14-18; Martinson Decl., U.S. Durum Growers ¶¶ 13-15, 17; McCarty Decl., Assoc. Indus. of Missouri ¶¶ 9, 11-13; Heering Decl., Monsanto ¶¶ 37, 39-41. It also threatens to cause burdensome operational changes in the retail setting, which will further impair the goodwill of Plaintiffs and their relationships with suppliers and retailers. *Id.* at ¶ 39.

- If Plaintiffs who farm using glyphosate are forced to cease using glyphosate by suppliers, this will result in significant disruption to their longstanding business practices. *See, e.g.*, Hurst Decl., Missouri Farm Bureau ¶¶ 5-7, 15-17; Wogsland Decl., N.D. Grain Growers ¶¶ 13-16; Stoner Decl., Nat'l Assoc. Wheat Growers ¶¶ 7-9, 14-15; Kessel Decl., N.D. Grain Growers ¶¶ 3, 7-10; Jackson Decl., Iowa Soybean ¶¶ 4-10, 16-18. *See Am. Trucking Ass'ns, Inc. v. City of Los Angeles*, 559 F.3d 1046, 1058 (9th Cir. 2009)

(forcing a "change [in] the whole nature of [plaintiff's] business" constitutes irreparable harm). Moreover, to the extent any of these injuries could be deemed financial in nature, they are not reparable as a matter of law because California's sovereign immunity precludes them from being remedied by money damages. *See California Pharmacists Ass'n v. Maxwell-Jolly*, 563 F.3d 847, 852 (9th Cir. 2009) (finding irreparable harm due to economic loss where sovereign immunity prevents recovery of money damages); *Pac. Merch. Shipping Ass'n v. Cackette*, No. CIV. S-06-2791 WBS KJM, 2007 WL 2914961, at *3 (E.D. Cal. Oct. 5, 2007) (Shubb, J.) ("irreparable harm" from "complying with regulations" where "Eleventh Amendment" prohibits recovery); *North East Medical Servs., Inc. v. Cal. Dep't of Health Care Servs.*, 712 F.3d 461, 466 (9th Cir. 2013) (California has immunity from "monetary damages").

The final two factors——the balance of equities and public interest——"merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). These factors also strongly support immediate relief. The courts have "consistently recognized the significant public interest in upholding First Amendment principles." *Doe v. Harris*, 772 F.3d 563, 583 (9th Cir. 2014). And neither the public nor the government "has [any] legitimate interest in enforcing an unconstitutional" law. *KH Outdoor, LLC v. City of Trussville*, 458 F.3d 1261, 1272 (11th Cir. 2006). The compelled warning is not yet in effect, so an injunction would merely preserve the status quo. As noted, moreover, *federal* regulators already account for pesticide residues, including *inter alia* their presence in foods. *See*

supra at 5-7. The public interest in health, therefore, is already protected. *See Am. Meat Inst. v. Ball*, 550 F. Supp. 285, 294 (W.D. Mich. 1982) (state warning "does not further any legitimate state interest" where it conflicts with federal standards and invites consumer confusion), *aff'd sub nom. Am. Meat Inst. v. Pridgeon*, 724 F.2d 45 (6th Cir. 1984); *Kraft Foods N. Am. Inc. v. Rockland County*, No. 01 Civ. 6980(WHP), 2003 WL 554796, at *10 (S.D.N.Y. Feb. 26, 2003) ("[The] County imposes a [food labeling] standard that is impermissibly different from the federal regulations . . . . Thus, [the] County fails to establish a legitimate state purpose."). Enforcement of California's glyphosate warning will not make the public more safe—to the contrary, it will affirmatively harm the public by exacerbating the problem of rampant overwarning which undermines and diminishes the utility and effect of those warnings that are actually justified. *See supra* at 35.

CONCLUSION

For the foregoing reasons, the requested preliminary injunction should issue.

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Respectfully submitted,

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