MICHAEL E. WALL (SBN 170238)
KAITLIN A. MORRISON, of counsel
Natural Resources Defense Council
111 Sutter Street, 21st Floor
San Francisco, CA 94104
Tel.: (415) 875-6100 / Fax: (415) 795-4799
mwall@nrdc.org

Counsel for Proposed Amici Curiae Natural Resources Defense Council, Inc., Sierra Club, and Center for Environmental Health

UNITED STATES DISTRICT COURT FOR THE

EASTERN DISTRICT OF CALIFORNIA

NATIONAL ASSOCIATION OF WHEAT GROWERS, et al., Plaintiffs, v. LAUREN ZEISE, et al., Defendants.	Case No. 2:17-cv-02401-WBS-EFB **NOTICE OF UNOPPOSED MOTION AND UNOPPOSED MOTION OF NATURAL RESOURCES DEFENSE COUNCIL, INC., ET AL., FOR LEAVE TO FILE AMICUS BRIEF IN SUPPORT OF DEFENDANTS AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION** Date: February 20, 2018 Time: 1:30 pm Judge: Hon. William B. Shubb

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that on February 20, 2018, at 1:30 p.m., or as soon thereafter as the matter may be heard, before the Honorable William B. Shubb, in Courtroom 5 of the U.S. District Court for the Eastern District of California, 501 I Street, Sacramento, CA 95814, proposed amici curiae Natural Resources Defense Council, Inc. (NRDC), Sierra Club, and Center for Environmental Health (CEH) (collectively, Proposed Amici) will and hereby do respectfully move for leave to file an amicus brief in support of Defendants.

Counsel for Proposed Amici conferred with counsel for the parties, who have consented to this motion, and to the motion being submitted on the papers pursuant to L.R. 230(g). This motion is timely pursuant to this Court's January 5, 2018, Order requiring any amicus brief in support of Defendants to be filed by January 26, 2018. *See* ECF No. 43. The grounds for this motion follow:

The proposed amicus brief, attached as Exhibit A to this motion, provides background on the science of risk assessment, to help the Court gain a clearer picture of the issues presented. The proposed brief argues that courts should not unnecessarily decide complex scientific issues under a First Amendment framework, without the necessary evidence before it, and before such a determination is warranted. It also argues that Proposition 65's requirement that businesses demonstrate that their products pose no significant risk of cancer does not offend the First Amendment or unconstitutionally burden businesses.

"Federal district courts possess the inherent authority to accept amicus briefs." *Padilla v. Beard*, No. 2:14-CV-1118 KJM CKD, 2017 WL 1364666, at *5 (E.D. Cal. Apr. 14, 2017) (citing *Jamul Action Comm. v. Stevens*, No. 13–01920, 2014 WL 3853148, at *5 (E.D. Cal. Aug. 5, 2014)). "District courts frequently welcome amicus briefs from non-parties . . . if the amicus has unique information or perspective that can help the court beyond the help that the lawyers from the parties are able to provide." *Nat'l Petrochemical & Refiners Ass'n v. Goldstene*, No. CVF10-163 LJO DLB, 2010 WL 2228471, at *1 (E.D. Cal. June 3, 2010).

Natural Resources Defense Council, Inc. (NRDC) is a nonprofit public-health and environmental organization with hundreds of thousands of members nationwide, including tens of thousands of members in California. NRDC works to protect human health and the environment, and to ensure its members and the public generally have information necessary to make informed decisions about whether and to what extent to expose themselves to toxic chemicals. Proposition 65 serves that interest.

Sierra Club is a national nonprofit organization of approximately 825,000 members, roughly 180,000 of whom live in California. The Sierra Club is dedicated to exploring, enjoying, and protecting the wild places of the earth; to practicing and promoting the responsible use of the earth's ecosystems and resources; to educating and encouraging humanity to protect and restore the quality of the natural and human environment; and to using all lawful means to carry out these objectives. The Sierra Club's concerns include ensuring that its members and the public are informed about the health and environmental risks associated with exposure to harmful chemicals, and that the public, Sierra Club members, and the environment are adequately protected from toxic substances. Sierra Club's particular interest in this case stems from its long history of advocacy to support laws, including Proposition 65, that protect public health and the environment from toxic chemicals.

Center for Environmental Health (CEH) is a nonprofit environmental health advocacy organization with tens of thousands of supporters nationwide, including thousands of supporters in California. CEH protects people from toxic chemicals by working with communities, consumers, workers, government, and the private sector to demand and support business practices that are safe for public health and the environment. Proposition 65 plays a significant role in CEH's work to further its mission.

For these reasons, Proposed Amici respectfully ask the Court to grant their unopposed motion for leave to file the proposed amicus brief.

January 26, 2018

Respectfully submitted,

/s/ Michael E. Wall
MICHAEL E. WALL (SBN 170238)
KAITLIN MORRISON, of counsel
Natural Resources Defense Council
111 Sutter Street, 21st Floor
San Francisco, CA 94104
Tel.: (415) 875-6100 / Fax: (415) 795-4799
mwall@nrdc.org

Counsel for Proposed Amici
Natural Resources Defense Council, Inc.,
Sierra Club, and Center for Environmental Health

MICHAEL E. WALL (SBN 170238)
KAITLIN A. MORRISON, of counsel
Natural Resources Defense Council
111 Sutter Street, 21st Floor
San Francisco, CA 94104
Tel.: (415) 875-6100 / Fax: (415) 795-4799
mwall@nrdc.org

Counsel for Proposed Amici Curiae Natural Resources Defense Council, Inc., Sierra Club, and Center for Environmental Health

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NATIONAL ASSOCIATION OF WHEAT GROWERS, et al., Plaintiffs, v. LAUREN ZEISE, et al., Defendants.	Case No. 2:17-cv-02401-WBS-EFB **[PROPOSED] BRIEF OF NATURAL RESOURCES DEFENSE COUNCIL, INC., ET AL., AS AMICUS CURIAE IN SUPPORT OF DEFENDANTS AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION** Date: February 20, 2018 Time: 1:30 pm Judge: Hon. William B. Shubb

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INTRODUCTION

Proposition 65's disclosure requirements result from highly technical hazard and risk determinations by expert science agencies established to evaluate those hazards. The International Agency for Research on Cancer (IARC), a respected and apolitical cancer-research agency, determined that glyphosate is carcinogenic. California's Office of Environmental Health Hazard Assessment (OEHHA), the state science agency charged with assessing hazards from carcinogens, is now in the process of finalizing its evaluation of what level of exposure to glyphosate poses no significant risk of cancer. While scientists may continue to wrestle with toxicity of glyphosate and the levels of exposures that pose a risk, these are not questions that the judiciary is routinely called upon to resolve. And they are not properly presented here.

This Court should reject Plaintiffs' invitation to overrule IARC and predetermine OEHHA's no-significant-risk evaluation under the guise of First Amendment scrutiny—and with no scientific record before it. Doing so would constitutionalize a complex and technical risk-assessment process, force the resolution of complex scientific questions in a First Amendment box, and destabilize myriad warning laws. And it would do so before OEHHA has completed the safe harbor process that will inform whether Plaintiffs, or any of them, need to give a warning. Resolving scientific questions about glyphosate may be necessary and appropriate in some future case. But the "idea that these thousands of routine regulations require an extensive First Amendment analysis is mistaken." *Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 316 (1st Cir. 2005) (Boudin, C.J., Dyk, J., concurring).

Chamber of Commerce et al.'s amicus brief goes yet further, positing a novel principle under which the First Amendment would restrict a state's power to require that businesses prove their products are safe. At least in this context, a business's testing of its own products is not speech. A business may not *want* to test its product to determine whether it poses a significant cancer risk. But the option to do so, to avoid warning that the product contains a carcinogen, does not implicate the First Amendment.

BACKGROUND

A. Risk assessment

Understanding how Proposition 65 works requires a working knowledge of the science of risk assessment. Risk assessment uses available data "to define the health effects of exposure of individuals or populations to hazardous materials and situations,"[1] and is "a systematic approach to organizing and analyzing scientific knowledge and information for . . . substances that might pose risks under specified conditions."[2] As explained by the National Research Council,[3] risk assessment typically "entails the evaluation of information on the hazardous properties of substances, on the extent of human exposure to them, and on the characterization of the resulting risk."[4]

The risk assessment process can be broken into several steps. The first step, known as "hazard identification," involves "determination of whether a particular chemical is or is not causally linked to particular health effects."[5] Later steps look at how the extent of exposure affects the occurrence of the health effects (called, "dose-response assessment"), how much

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[1] Nat'l Acad. of Sci., Eng'g & Med., Nat'l Research Council, *Risk Assessment in the Federal Government: Managing the Process* 3 (1983) [hereinafter *Risk Assessment*], https://www.nap.edu/download/366.

[2] Nat'l Acad. of Sci., Eng'g & Med., Nat'l Research Council, *Science and Judgment in Risk Assessment* 4 (1994) [hereinafter *Science in Risk Assessment*], https://www.nap.edu/catalog/2125/science-and-judgment-in-risk-assessment.

[3] The National Research Council was established by the National Academy of Science at the request of President Wilson, and its mandate was reaffirmed and broadened by Presidents Eisenhower and George H.W. Bush. *See* Exec. Ord. No. 12832, 58 Fed. Reg. 5905 (Jan. 22, 1993); Exec. Ord. No. 10668, 21 Fed. Reg. 3155 (May 12, 1956), http://cdn.loc.gov/service/ll/fedreg/fr021/fr021093/fr021093.pdf. The National Academy of Sciences was chartered by President Lincoln, and is composed of scientists elected by peers in recognition of distinguished achievement in their respective fields. *See generally* Nat'l Acad. of Sci., Eng'g & Med., *History of the National Academies* (last visited Jan. 16, 2018), http://www.nationalacademies.org/about/history/index.html.

[4] *Science in Risk Assessment*, *supra* note 2, at 4; *see also* Nat'l Acad. of Sci., Eng'g & Med., *Science and Decisions: Advancing Risk Assessment* 19 (2009) [hereinafter *Science and Decisions*], https://www.nap.edu/catalog/12209/science-and-decisions-advancing-riskassessment.

[5] *Risk Assessment*, *supra* note 1, at 3.

exposure occurs ("exposure assessment"), and by combining information from the earlier steps, the nature and magnitude of human risk ("risk characterization").[6] This multi-step risk-assessment process is woven into the fabric of a wide array of health and environmental protection statutes, informing risk-management choices.

At the federal level, for example, the Toxic Substances Control Act authorizes the U.S. Environmental Protection Agency (EPA) to promulgate regulations to eliminate "unreasonable risk" to health and the environment posed by certain chemical substances. *See* 15 U.S.C. § 2605(a). The EPA may entirely ban such a chemical in some circumstances. *Id.* § 2605(a)(1). Or, EPA might instead require "clear and adequate" warnings, *id.* § 2605(a)(3), that allow consumers to choose for themselves whether to be exposed to that substance. Proposition 65 is in some ways similar, although instead of allowing for a chemical to be banned, it prohibits the discharge of significant amounts of a chemical identified as a carcinogen to a source of drinking water, and requires a business to provide a warning that its product contains the carcinogen if the business cannot or will not show that exposure it causes poses no significant risk of cancer. Cal. Health & Safety Code §§ 25249.5, 25249.6, 25249.9, 25249.10.

B. Public-health decision making in the face of scientific uncertainty

Health and safety standards are often promulgated before the scientific community reaches consensus on risks. Such standards reflect a policy choice to protect the public in the face of uncertainty: If public health officials ignore or discount hazards while waiting for definitive science, then underprotection will likely result. *See Nat. Res. Def. Council v. Pritzker*, 828 F.3d 1125, 1138 (9th Cir. 2016).

To develop such standards, health officials synthesize the information that exists about a hazard, evaluate the risk, and develop corresponding safeguards. In the 1960s, for example, as the link between cigarettes and cancer was emerging, regulators required cigarette manufacturers to inform consumers on package labels "that cigarette smoking may be hazardous to health." Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, § 2, 79 Stat. 282, 282

[6] *Id.*; *Science in Risk Assessment*, *supra* note 2, at 4-5.

(1965). Opponents of such labeling, including some with a financial stake in the tobacco industry, opposed these disclosures on the basis that the state of science on the risks from tobacco was still too uncertain. *See Environmental Decisions*, *infra*, at 116. Health officials determined, however, that the tobacco industry's preferred wait-and-see approach would not sufficiently protect human health.

As the tobacco example illustrates, the science that informs regulatory decisions involves uncertainty.[7] Indeed, in environmental health science, some uncertainty is almost inevitable. *See Bitler v. A.O. Smith Corp.*, 400 F.3d 1227, 1235 (10th Cir. 2005) ("any scientific theory is subject to future refutation through further observation and testing"). There are many reasons for this: Information about environmental health risks is often incomplete. "[S]cience has never been static, and what is 'known' is necessarily defined by the state of the art at the time." *Cal. Chamber of Commerce v. Brown*, 126 Cal. Rptr. 3d 214, 233 (2011). Direct experimentation on humans may be unethical or illegal.[8] Exposure to a substance could harm one person but leave another unscathed, because of differences in genetics, age, health status, or other factors.[9] And individuals may face cumulative risks, from aggregate exposures to multiple agents or stressors, that may vary from person to person.[10]

However, uncertainty about the *extent* of a hazard does not mean there is no hazard. Health officials account for such uncertainties in many ways. When standards are extrapolated from animal studies or human evidence, possible differences between humans and animals, or among humans, may lead officials to set exposure standards well below the level that has been

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[7] Institute of Med., Nat'l Acad. of Sci., *Environmental Decisions in the Face of Uncertainty* 138-39 (2013) ("*Environmental Decisions*"), https://www.nap.edu/catalog/12568/environmental-decisions-in-the-face-ofuncertainty; U.S. Envtl. Prot. Agency, Office of Pesticide Programs, *Consideration of the FQPA Safety Factor and Other Uncertainty Factors in Cumulative Risk Assessment of Chemicals Sharing a Common Mechanism Of Toxicity* (Feb. 28 2002), https://www.epa.gov/sites/production/files/2015-07/documents/apps-10x-sf-for-cra.pdf.

[8] *See, e.g.*, 40 C.F.R. § 26.203 (banning certain federally-supported intentional human dosing studies on subjects who are pregnant, nursing, or a child); *id.* § 26.1203 (banning certain third-party intentional human dosing studies on children and pregnant or nursing women).

[9] *See Science and Decisions*, *supra* note 4, at 165.

[10] *See id.*; *see generally* U.S. Envtl. Prot. Agency, *supra* note 8, at 3.

proven to be unsafe. *See* Cal. Code Regs., tit. 27, § 25703(b); *see also Nat. Res. Def. Council v. U.S. EPA*, 735 F.3d 873, 884 (9th Cir. 2013) (describing exposure levels set by EPA at "1/1000th of the amount . . . that has been shown to produce no harmful effects in mice in laboratory studies."). Officials may also take other steps, short of setting enforceable exposure limits or product bans, such as requiring warnings to inform the public. Requiring a business to disclose that a chemical is hazardous, rather than banning the chemical to eliminate risk, allows members of the public to make their own choices about which exposures they find acceptable.

C. Proposition 65

California's Safe Drinking Water and Toxic Enforcement Act of 1986, Cal. Health & Safety Code § 25249.5 et seq.—popularly called "Proposition 65"—establishes a multi-step process to address concerns about hazardous chemicals: Initially, the State determines whether to "list" a chemical as "known to the state" to cause cancer or reproductive toxicity. *Id.* § 25249.8(a). This step encompasses the *hazard-identification* step of the risk assessment process described above—that is, the "determination of whether a particular chemical is or is not causally linked to particular health effects."[11]

At this stage, Proposition 65 directs 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." *Id.* § 25249.8(a). That a chemical is listed by the State as "known . . to cause cancer" does not mean that any particular exposure *will* cause cancer; it simply means that the State has identified the chemical as a carcinogen, based on the standards set forth in Proposition 65. Whether one agrees or disagrees with the State's listing is not, of course, a First Amendment concern, for the listing itself involves only the State's speech.

A chemical's listing under Proposition 65 triggers two additional provisions: First, a person may not knowingly discharge significant amounts of a listed chemical into a source of drinking water. *Id.* §§ 25249.5, 25249.9; *see Exxon Mobil Corp. v. Office of Envtl. Health Hazard Assessment*, 169 Cal. App. 4th 1264, 1268 (2009). This discharge prohibition is an

[11] *Risk Assessment*, *supra* note 1, at 3.

exercise of the State's traditional police powers, and like the listing itself, does not involve businesses' speech. *Cf. Rumsfeld v. Forum for Acad. & Inst. Rights, Inc.*, 547 U.S. 47, 65-66 (2006) (declining to extend First Amendment protection to conduct that was not "inherently expressive").

In addition, beginning one year after a chemical is listed by the State as known to cause cancer, businesses may not knowingly expose people to the chemical without giving a "clear and reasonable warning" regarding the exposure, unless the business can show that the exposure presents "no significant risk" of cancer. Cal. Health & Safety Code §§ 25249.6, 25249.10(b), (c). If a business can show that its product presents no significant risk, it need not give a warning.

The requirement that, in the first instance, businesses make this "no significant risk" showing with respect to their own products reflects that businesses usually have better access to information about their products than their customers do. But businesses are not left without help in evaluating whether a risk is sufficient to require a warning. OEHHA has promulgated detailed scientific guidelines on how to conduct quantitative risk assessments to determine whether a product causes an exposure that poses no significant risk. Cal. Code Regs., tit. 27, §§ 25701(a); 25703, 25721. And OEHHA itself determines No Significant Risk Levels on which businesses may rely in deciding whether to warn. *See id.* §§ 25701(b)(3)(A), 25705.

Last spring, for example, OEHHA proposed, sought public comment on, and held a public hearing on a No Significant Risk Level for glyphosate. When finalized, the glyphosate No Significant Risk Level will provide businesses with "a 'safe harbor' value that aids [them] in determining whether a warning is required for a given exposure."[12] A business that does not expose consumers above the No Significant Risk Level determined by OEHHA will not need to give any warning. A business that exposes individuals at levels that exceed that standard also

[12] *See* Office of Envtl. Health Hazard Assessment, *Initial Statement of Reasons: Glyphosate Proposition 65 Safe Harbors* 9, https://oehha.ca.gov/media/downloads/crnr/glyphosate032917isor.pdf.

will not need to give a warning, provided the business can show that its product does not present a significant risk of cancer to those exposed.

In short, OEHHA's decision to list a chemical is based on a determination that the chemical presents a *hazard*. That determination is separate from the question whether any particular consumer product causes exposures that pose a significant *risk* to human health. Chemicals that are determined under Proposition 65 to pose a hazard are listed by the State; but if exposure is not sufficient to pose a significant risk, no warning is required. Whether a listed chemical requires a warning therefore depends on whether the business can show that the levels of the chemical to which consumers would be exposed are not significant, or fall below the No Significant Risk Level that OEHHA determines.

D. OEHHA's listing of glyphosate as a carcinogen under Proposition 65

As a starting point, California's voters decided that the Proposition 65 list must include certain chemicals identified through a refence to longstanding warning requirements in the Labor Code, including "[a]ny substance . . . listed as human or animal carcinogens by the International Agency for Research on Cancer (IARC)." Cal. Lab. Code § 6382(a), (b)(1); *see Cal. Chamber of Commerce*, 126 Cal. Rptr. 3d at 218. In addition, "[a] chemical is known to the state to cause cancer" for purposes of updating the list "if a body considered to be authoritative by [the state's] experts has formally identified [the chemical] as causing cancer." Cal. Health & Safety Code § 25249.8(b). IARC has been identified by the State's experts as an authoritative body for identifying carcinogens. Cal. Code Regs., tit. 27, § 25306(m)(1).

IARC is a highly respected intergovernmental scientific agency within the World Health Organization of the United Nations, tasked with making carcinogen hazard assessments. *See, e.g.*, *Cal. Chamber of Commerce*, 126 Cal. Rptr. 3d at 236 (noting that IARC was one of "several well-recognized sources to which manufacturers already routinely referred to obtain hazard information."); Nat'l Acad. of Sci., Eng'g & Med., Nat'l Research Council, *Review of EPA's Draft IRIS Assessment of Formaldehyde* 160 (2011), https://www.nap.edu/download/13142 (describing IARC's "systematic approach[] to hazard identification" by "gathering and review of

all lines of evidence and classification of the strength of evidence in a uniform and hierarchic structure."). IARC is a scientific organization, not a policymaking body, and performs its analysis on carcinogenicity for the benefit of other international organizations and governments. *See* World Health Organization, International Agency for Cancer Research, IARC Monographs on the Evaluations of Carcinogenic Risks to Humans: Preamble 3 (2006), http://monographs.iarc.fr/ENG/Preamble/CurrentPreamble.pdf. Federal public health officials routinely refer to IARC's independent assessments, and recognize IARC as one of the world's leading authorities on carcinogen analysis.[13]

In March 2015, IARC determined that glyphosate is "probably carcinogenic to humans" based on sufficient evidence in animals and limited evidence in humans, including a positive association for non-Hodgkins lymphoma. IARC, *Monograph on Glyphosate* 78 (updated Aug. 11, 2016), http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-10.pdf. Because glyphosate was "listed as a human or animal carcinogen" by IARC, and thus by Cal. Lab. Code § 6382(b)(1), on July 7, 2017, OEHHA listed glyphosate as known to the State to cause cancer within the meaning of Proposition 65.

Although Plaintiffs point to the conclusions of other agencies as seemingly inconsistent with IARC's conclusion, those differences should not be overstated. For example, Plaintiffs note that EPA determined late last year that glyphosate is "not likely to be carcinogenic to humans." *See* U.S. Envtl. Prot. Agency, Office of Pesticide Programs, *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* 144 (Dec. 12, 2017), https://www.epa.gov/sites/production/files/2017-12/documents/revised_glyphosate_issue_paper_evaluation_of_carcinogenic_potential.pdf. What Plaintiffs fail to note, however, is that unlike IARC's

[13] Recently, for example, the Occupational Safety and Health Administration ("OSHA") cited IARC's monographs, alongside studies by the National Toxicology Program and other federal agencies, as a primary basis for its decision to tighten workplace exposure limits for silica. Occupational Exposure to Respirable Crystalline Silica, 81 Fed. Reg. 16,286 (Mar. 25, 2016). The EPA and Department of Transportation have also drawn on IARC's work to inform recent regulatory work, and described IARC as "a recognized international authority on the carcinogenic potential of chemicals and other agents." 80 Fed. Reg. 40,138, 40,424 (July 13, 2015).

determination, EPA's statement is not a pure hazard assessment. That is, EPA did not determine that glyphosate could not be carcinogenic to humans at sufficiently high exposures, but instead excluded from its analysis findings of increased tumor incidences at doses that EPA thought to be unlikely to occur. *See id.* at 136. But, under Proposition 65, the *listing* decision is a hazard identification—what IARC performed—and precedes an exposure assessment or full-blown risk assessment. For this reason, EPA's statement that glyphosate is "not likely to be carcinogenic" at exposure levels EPA expects is not inconsistent with IARC's hazard identification of glyphosate as a carcinogen. And under Proposition 65, a business will not be required to provide any warning at all if the business can show that EPA's prediction was right—i.e., that actual exposures do not pose a significant risk of cancer.

Although OEHHA has listed glyphosate, it has not yet completed its safe harbor process. OEHHA has *proposed* a No Significant Risk Level of 1100 micrograms per day (assuming lifetime exposure at that level, Cal. Health & Safety Code § 25249.10(c)), but that is not yet final. Office of Envtl. Health Hazard Assessment, *supra* note 13, at 1. This ongoing regulatory risk assessment, by a scientific agency set up to conduct the State's assessments of environmental hazards, will serve to distinguish "the harmless from the harmful," *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626, 646 (1985).

On July 7, 2018, twelve months after glyphosate was listed under Proposition 65, a business that chooses to knowingly and intentionally expose members of the public to significant amounts of that chemical—rather than, say, reformulating its product—must provide clear and reasonable warnings to those individuals, unless the business can show that the glyphosate exposure poses no significant risk of cancer, or another exception applies.[14] Cal. Health & Safety Code §§ 25249.6, 25249.10. No warning will be needed for products that cause exposures under the No Significant Risk Level that OEHHA determines.[15]

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[14] We do not understand Plaintiffs to have offered any evidence that they sell products that would expose any consumer at levels exceeding that threshold. *See* State Br. 20-21.

[15] Businesses may, for example, proactively seek an exemption by requesting a "safe use determination" from the agency. Cal. Code Regs. tit. 27, § 25204.

ARGUMENT

I. Courts should be wary of constitutionalizing scientific questions at the core of agencies' specialized technical competence, or deciding such questions unnecessarily

This Court should decline Plaintiffs' invitation to unnecessarily decide complex scientific questions under the guise of constitutional scrutiny. Plaintiffs' First Amendment challenge to OEHHA's listing of glyphosate as a carcinogen, based on IARC's hazard identification, ignores that OEHHA's *listing* involves only the State's speech, not Plaintiffs'. It is not even clear that Plaintiffs will have to provide warnings pursuant to that listing. OEHHA has not yet finalized its analysis of what level of glyphosate exposure poses no significant cancer risk. Thus, OEHHA has not yet resolved a highly-technical question that will inform whether any business, including any Plaintiff, needs to warn of glyphosate in its products. Courts should hesitate before unnecessarily deciding complex scientific issues when a science agency charged with doing so has not yet completed its work.

IARC made a hazard determination that glyphosate is a "probable human carcinogen"; OEHHA is now in the process of determining the level of glyphosate that poses "no significant risk," to help guide businesses that may be subject to the warning requirement. Second-guessing those determinations—one of which is not yet final—would require the Court to delve deeply into scientific data that is not before the Court. The First Amendment does not require courts to resolve such questions unnecessarily, and common sense plainly counsels against it.

A rule that forced courts to prematurely resolve complex scientific questions as part of a First Amendment analyses would lead the judiciary into taxing and treacherous ground. Judges would be forced to make policy judgments about which hazards are significant enough to merit

warnings or disclosures—subjecting "long-established programs to searching scrutiny by unelected courts." *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 116 (2d Cir. 2001). But determining what level of exposure would cause a significant cancer risk is not at the center of what the judicial branch typically does. Agencies like OEHHA were set up to make such decisions, and the judicial branch generally shares none of the risk-assessment resources of these agencies. *Cf. Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. U.S. Dep't of Agric.*, 415 F.3d 1078, 1093 (9th Cir. 2005) (finding that deference to agency judgment is especially appropriate where an agency decision involves a high level of technical expertise).

The consequences of constitutionalizing such questions would be quite troubling. Plaintiffs unhappy with science agency evaluations would play on the complexity of risk assessment to conflate hazard identification with risk characterization. Those with an economic interest in avoiding disclosures would trumpet any scientific disagreement—and in science, there is almost always room for disagreement—or even manufacture the appearance of disagreement to serve their financial interests.[16] *See In re Prempro Prods. Liab. Litig.*, 586 F.3d 547, 557 (8th Cir. 2009) (describing how, after National Institute of Health-sponsored study found the cancer risk of hormone replacement therapy to have been underestimated, a company tried to "'shift attention to other cancers;' characterize the study as 'just one more paper;' and highlight flaws in the study's methodology"). And individual judges might assess risks differently, encouraging

[16] Indeed, there have been reports of behind-the-scenes attempts by industry, including one of Plaintiffs, to influence some of the very government assessments of glyphosate that are now cited as evidence of scientific uncertainty. *See* Peter Waldman et al., *Monsanto Was Its Own Ghostwriter for Some Safety Reviews*, Bloomberg (Aug. 9, 2017), https://www.bloomberg.com/news/articles/2017-08-09/monsanto-was-its-own-ghostwriter-for-some-safety-reviews; Simon Marks, *Monsanto Attempts Takedown Of Agency Linking Its Weedkiller To Cancer*, Politico (Aug. 17, 2017), https://www.politico.eu/article/monsanto-roundup-attempts-takedown-of-iarc-who-linking-its-weedkiller-to-cancer; *see also* Nathan Donley, *Don't let EPA and Monsanto hide the truth on Roundup*, Sacramento Bee (Jan. 16, 2018), http://www.sacbee.com/opinion/op-ed/soapbox/article194490339.html.

forum shopping and inconsistent judicial decisions regarding science and the risks posed by chemicals.

Judges are certainly capable of weighing expert evidence on these issues, and at times are appropriately called upon to ensure that agencies follow the law and apply rigorous scientific methods. But for courts to decide such questions prematurely, in a facial constitutional challenged to warnings that Plaintiffs may never have to give, would invite mischief. Constitutional claims are not like claims under the Administrative Procedure Act, where the courts conduct their review on an administrative record and overturn agency action if it is arbitrary and capricious. *See, e.g.*, *Lands Council v. Powell*, 395 F.3d 1019, 1026-28 (9th Cir. 2005). Plaintiffs here ask the Court to determine, via a First Amendment analysis untethered to the scientific evidence, that the IARC determination was so scientifically unsound as to be counterfactual under *Zauderer*. It should not be the day-to-day business of courts to determine what scientific facts are "uncontroversial" in the First Amendment context, particularly where, as here, the crucial facts—including the large body of scientific evidence regarding the toxicology of glyphosate, and the human and animal studies that support IARC's analysis and that will inform OEHHA's calculation of a No Significant Risk Level—are not before the Court. To the extent that Plaintiffs ask the Court to second-guess IARC's underlying finding of a hazard without a scientific evidentiary record, this Court should decline.

There may be a time when a court is properly asked to evaluate whether a particular product exposes consumers to glyphosate at a level that requires a warning under Proposition 65, and what that warning must say. At that time, the court may need to evaluate the scientific evidence on toxicity and exposure to glyphosate. This is not that time, for no such warning claim is yet ripe. The law does not require "extensive First Amendment analysis" for "routine regulations." *Pharm. Care Mgmt. Ass'n*, 429 F.3d at 316 (Boudin, M., Dyk, T., concurring). It certainly does not require this Court, in this case, to resolve scientific uncertainties about glyphosate without the evidence necessary—and in advance of the need—to do so.

II. Proposition 65's requirement that businesses demonstrate that their products pose no significant risk of cancer does not offend the First Amendment

A. The First Amendment framework applied to Proposition 65

Commercial speech "occurs in an area traditionally subject to government regulation," and is therefore "accord[ed] a lesser protection . . . than . . . other constitutionally guaranteed expression." *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N. Y.*, 447 U.S. 557, 562-63 (1980). This already-reduced protection for commercial speech is relaxed further where the government, rather than suppressing commercial speech, compels a disclosure. "First Amendment interests implicated by disclosure requirements are substantially weaker than those at stake when speech is actually suppressed." *Zauderer*, 471 U.S. at 651 n.14; *see also Rubin v. Coors Brewing Co.*, 514 U.S. 476, 481 (1995) (labeling content constitutes commercial speech). "Because the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides, [a speaker's] constitutionally protected interest in *not* providing any particular factual information in his advertising is minimal." *Zauderer*, 471 U.S. at 651 (citation omitted).

Under well-settled law, "the government may compel truthful disclosure in commercial speech as long as the compelled disclosure is 'reasonably related' to a substantial governmental interest." *CTIA-The Wireless Ass'n v. City of Berkeley*, 854 F.3d 1105, 1118 (9th Cir. 2017). That is all Proposition 65 requires: a "clear and reasonable" warning that the chemical has been identified by the State as a carcinogen within the meaning of Proposition 65. Cal. Health & Safety Code § 25249.6.

A compliant warning that is factually true is plainly possible; indeed, Plaintiffs themselves propose a disclosure they appear to claim would meet that standard.[17] And a clear

[17] *See* Pls.' Br. in Supp. of Prelim. Inj. 36. While the exact wording of a compliant warning is fact-specific and not properly presented in this facial challenge, a court might consider a disclosure like: "This product contains a chemical that is deemed a carcinogen under California law because it has been determined to by the International Agency for Research on Cancer to be a probable human carcinogen. No determination has been made that exposure to this product will cause cancer." Plaintiffs' critique of safe-harbor warning language, *see id.* 13-14, is misplaced,

and reasonable warning would obviously be reasonably related to the State's substantial interest in public health and consumer welfare, requiring a warning only on products that have not been proven to expose consumers to amounts of glyphosate that do not pose a significant risk of cancer. The scientific question of what *level* of exposure makes the cancer risks insignificant will be addressed in OEHHA's determination of a No Significant Risk Level, and could be further addressed by the businesses regulated under Proposition 65. Those businesses have a full opportunity to show that even an exposure above OEHHA's No Significant Risk Level in fact poses no significant risk. But these questions are not properly decided now, before OEHHA makes its determination, in this facial First Amendment attack.

B. The safe-harbor framework does not offend the First Amendment

Contrary to the views of amicus Chamber of Commerce ("Chamber"), Proposition 65's framework—in which businesses have the burden to evaluate their own product's safety—does not "unconstitutionally burden[] businesses with a constrained choice." *Contra* Chamber of Commerce Amicus Br. ("Chamber Br.") 13-21. Any commercial speech ultimately compelled by Proposition 65 must pass *Zauderer* review. That is, the disclosure must be a factual and uncontroversial statement that is reasonably related to the State's substantial interest in public health. *See CTIA*, 854 F.3d at 1118.

Proposition 65's safe-harbor mechanism does not alter this standard. That California has effectively required businesses to test their products for safety before selling them without a warning is no more a First Amendment issue than a requirement that a drug manufacturer test and obtain regulatory approval for its products before marketing them. Such a testing requirement is well within the State's powers.

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since Proposition 65 does not require that language, *see* State Br. 6-9. Regulations that become effective in August 2018 limit the context that may be given for a warning to qualify as a safe-harbor warning. See Cal. Code Regs. tit. 27, § 25601(e). It is important to note this applies only to safe harbor warnings, and should not be "construed to preclude a person from providing a warning using content or methods other than those specified" so long as the warning is clear and reasonable. *See id.* § 25600(f).

1. Proposition 65 does not "invert" First Amendment burdens

The Chamber cites not a single case to support its theory that businesses' decisions to test their products before selling them without a warning inverts the First Amendment burden. No business has a First Amendment right to sell a product in California without testing it. And any burden placed on a business to test its products for glyphosate, and evaluate the risks those products pose, is distinguishable from the State's burden to justify its disclosure requirement. A product-testing requirement is a run-of-the-mill business regulation, not a speech restriction.

Businesses that wish to sell glyphosate-containing products in California need to give a warning only if they (a) choose to sell a product that exceeds the safe harbor level and (b) are not otherwise able to show that the product they are selling poses no significant risk of cancer. In this context, placing the initial burden of showing that a product poses no significant risk on the business makes sense: the business is best-positioned to measure the quantity of a substance in its products, and, consequently, whether it meets the safe harbor level. If there is no significant risk, no warning need be given. If a business chooses not to test its own products, and continues to sell the products without a warning, prospective private enforcers of Proposition 65 may test the product to determine if the lawsuit would be meritorious. Before bringing an action, the prospective enforcer is required to submit a certificate of merit to the Attorney General affirming that "one or more persons with relevant and appropriate experience or expertise who has reviewed facts, studies, or other data regarding the exposure to the listed chemical . . . believes there is a reasonable and meritorious case for the private action." Cal. Health & Safety Code § 25249.7(d)(1); *see* State Br. 23.

Product testing is *conduct*. To be sure, the First Amendment protects some forms of conduct as "'symbolic speech,'" but only "conduct that is inherently expressive." *Rumsfeld*, 547 U.S. at 65-66. Testing to evaluate a product's carcinogenicity is not "intended to be communicative" and would not "reasonably be understood by the viewer to be communicative." *Clark v. Cmty. for Creative Non-Violence*, 468 U.S. 288, 294 (1984). The Chamber's complaint that Proposition 65 obliges its members to test their products is thus beside the point, for if

Proposition 65 is viewed as imposing a testing requirement, that requirement "affects what [businesses] must *do* . . . not what they may or may not *say*." *Rumsfeld*, 547 U.S. at 60. Businesses need not say anything after testing the product—if the product presents no significant risks. Plaintiffs may not want to test their products, or to warn of any significant risks that they find. But requiring a business to conduct such a test does not violate the First Amendment. Giving the business the option to test, to show that its product does not present a significant cancer risk, does not either.

Any burden that Proposition 65 places on businesses to test their products is not a First Amendment burden. If the testing reveals an exposure (a) above the safe harbor and (b) that the business cannot show to be safe, then the business may need to make a factual disclosure reasonably related to a substantial government interest. Such a warning could be subject to *Zauderer* review. But nothing about Proposition 65's safe-harbor changes *Zauderer*. To the contrary, that safe harbor helps to ensure that any disclosure that Proposition 65 compels is "reasonably related" to the State's substantial interest in public health. Products shown not to pose significant risks need not carry a warning.

2. Proposition 65 does not unconstitutionally burden businesses

Plaintiffs have not yet been compelled to speak. The warning requirement for glyphosate goes into effect in July, and it remains unclear to what extent any particular Plaintiff will be required to provide a warning at all. Plaintiffs' claims are, therefore, unripe. *See* State Br. 19-26.

The Chamber asks the Court to decide this unripe claim anyway, by characterizing Proposition 65's framework as unconstitutionally burdening businesses. The strained logic of the Chamber's argument seems to be that: (1) the warning requirement does not really apply because glyphosate is safe, but (2) proving that will be expensive, and so (3) businesses will be forced either to give warnings, or face lawsuits. This may be a "constrained choice," but it is not an unconstitutional one.

It should go without saying that the First Amendment does not bar a state from requiring businesses to test products sold in the state for safety. A state generally has the "ability under its

police powers to enact laws or ordinances to further the health and safety of its citizens." *Chamber of Commerce of U.S. v. Bragdon*, 64 F.3d 497, 503 (9th Cir. 1995); *see also Barnes v. Glen Theatre, Inc.*, 501 U.S. 560, 569 (1991) (recognizing that state police power extends to protection of "public health, safety, and morals."). "States are accorded wide latitude in the regulation of their local economies under their police powers, and rational distinctions may be made with substantially less than mathematical exactitude." *Merrifield v. Lockyer*, 547 F.3d 978, 989 (9th Cir. 2008) (quoting *City of New Orleans v. Dukes*, 427 U.S. 297, 303 (1976) (emphasis removed).

A law explicitly requiring businesses to test and evaluate the carcinogenicity of glyphosate-containing products—or even banning those products entirely—would not implicate the First Amendment. If such a law is constitutionally permissible—and it is—then allowing businesses the choice to provide a factually accurate warning rather than test is, too. As the Supreme Court explained in an analogous context, a condition on a government privilege "cannot be unconstitutional if it could be constitutionally imposed directly." *Rumsfeld*, 547 U.S. at 59–60.

There is no constitutional significance to "how cheaply and easily enforcement actions may be initiated by plaintiffs," either. Chamber Br. 18. The risk of civil lawsuits for a failure to warn is not new; it is inherent in the common law of tort. *See Davis v. Wyeth Labs., Inc.*, 399 F.2d 121, 128 (9th Cir. 1968) (warnings must be given in certain cases "to prevent a product from being unreasonably dangerous"); Restatement (Third) of Torts: Prod. Liab. § 2(c) (1998). In fact, Monsanto is currently being sued over the dangerousness of its products, independent of any Proposition 65 warning requirement that may ultimately become effective. *See* Complaint, *Pennie v. Monsanto*, No. RG17853420, filed March 17, 2017 (Alameda Sup. Ct. Mar. 17, 2017) (alleging, *inter alia*, design defect, failure to warn, and negligence); *Hardeman v. Monsanto Co.*, 216 F. Supp. 3d 1037, 1040 (N.D. Cal. 2016) (denying Monsanto's motion to dismiss in failure-to-warn case regarding Monsanto product Roundup, which contains glyphosate). If the First Amendment implicated the ease of bringing such a suit, then many procedural requirements

attendant to state tort law—ranging from filing fees to the admissibility standards for expert evidence—would suddenly require constitutional scrutiny. That is not the law.

A company's decision to warn rather than face possible (albeit, the Chamber contends, unmeritorious) private litigation, is a *business* decision; it is not a state-compelled speech requirement. The State, through Proposition 65, does not require a warning if a product is proven to not pose a significant risk of cancer. *See* Cal. Health & Safety Code § 25249.10(c) ("Section 25249.6 shall not apply to … [a]n exposure for which the person responsible can show that the exposure poses no significant risk."). The possibility that providing a warning may sometimes be cheaper than proving that a product poses no significant risk may be a possible policy critique of the expense of litigation. But it is not a First Amendment harm that can be laid at the feet of OEHHA.

CONCLUSION

This Court should deny Plaintiffs' motion for a preliminary injunction.

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Respectfully submitted,

/s/ Michael E. Wall

MICHAEL E. WALL (SBN 170238)
KAITLIN A. MORRISON, of counsel
Natural Resources Defense Council
111 Sutter Street, 21st Floor
San Francisco, CA 94104
Tel.: (415) 875-6100 / Fax: (415) 795-4799
mwall@nrdc.org

Counsel for Proposed Amici
Natural Resources Defense Council, Inc., Sierra Club, and Center for Environmental Health