No. 20-16758

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

XAVIER BECERRA, IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL OF THE STATE OF CALIFORNIA, ET AL.,

Defendants-Appellants,

v.

NATIONAL ASSOCIATION OF WHEAT GROWERS, ET AL.,

Plaintiffs-Appellees.

On Appeal from the U.S. District Court for the Eastern District of California, No. 2:17-cv-02401-WBS-EFB (Hon. William B. Shubb)

AMICUS BRIEF OF NATURAL RESOURCES DEFENSE COUNCIL, UNITED STEELWORKERS, ALLIANCE OF NURSES FOR HEALTHY ENVIRONMENTS, AS YOU SOW, CALIFORNIANS FOR PESTICIDE REFORM, CENTER FOR FOOD SAFETY, CLEAN WATER ACTION, ENVIRONMENTAL LAW FOUNDATION, PESTICIDE ACTION NETWORK NORTH AMERICA, AND SAN FRANCISCO BAY PHYSICIANS FOR SOCIAL RESPONSIBILITY URGING REVERSAL IN SUPPORT OF DEFENDANTS-APPELLANTS

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CORPORATE DISCLOSURE STATEMENT

Amici Natural Resources Defense Council, United Steelworkers, Alliance of Nurses for Healthy Environments, As You Sow, Californians for Pesticide Reform, Center for Food Safety, Clean Water Action, Environmental Law Foundation, Pesticide Action Network North America, and San Francisco Bay Physicians for Social Responsibility are nonprofit corporations with no parent corporation and no outstanding stock shares or other securities in the hands of the public. Amici do not have any parent, subsidiary, or affiliate that has issued stock shares or other securities to the public. No publicly held corporation owns any stock in amici.

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INTRODUCTION

Chemical hazard evaluations are often based on evolving scientific knowledge. Epidemiological studies, for example, are complex—many diseases have long latency periods, and we are exposed to a cocktail of chemicals from myriad sources in our daily lives. Industry groups have leveraged the uncertainty inherent in most risk assessments to undermine laws intended to inform and protect the public. The much-delayed regulation of secondhand smoke, asbestos, and lead in gasoline are prime examples of government action lagging behind science, at industry's urging and to the detriment of our health.

California's voters passed Proposition 65—one of the nation's most important right-to-know laws—to protect themselves from unwanted exposure to hazardous chemicals that can cause cancer or reproductive harm. The list of chemicals subject to Proposition 65's warning requirements is based on highly technical determinations by expert agencies established to evaluate such hazards. One of these groups, identified in California's regulations as an authoritative scientific body, is the World Health Organization's International Agency for Research on Cancer. That agency has classified glyphosate—the active ingredient

in Monsanto Company's popular weed killer, Roundup—as "probably carcinogenic to humans" based on a robust synthesis of publicly available information, including published reports, peer-reviewed studies, and government data. The finding prompted California to add glyphosate to the Proposition 65 list.

Monsanto and a consortium of agribusiness groups (collectively, "Monsanto" or "Plaintiffs") contend that the Proposition 65 warning requirement compels false and misleading speech because there is not yet consensus on the exposure levels at which glyphosate may cause cancer. Whether a science agency's finding is so unsound as to be counterfactual is not, however, an inquiry that should be made in a First Amendment context and without a full evidentiary record. Plaintiffs' theory, if adopted, would magnify incentives for industry to sponsor contrary studies and generate doubt among regulatory bodies in order to undercut regulations. It would also open the doors for judicial scrutiny of a wide array of regulations any time a regulated entity can point to dissenting scientific views. Such a result is neither wise nor constitutionally required.

AMICI CURIAE'S IDENTITY AND INTEREST IN THE CASE

Amici represent the interests of health practitioners, environmental and labor organizations, and consumer and shareholder advocacy groups. They work to address health harms caused by exposure to toxic substances and support right-to-know laws, including product labeling regulations, that enable workers and consumers to better protect themselves from unwanted exposure to harmful chemicals. Amici submit this brief to provide context on regulatory agencies' processes for assessing health risks and to illustrate how Plaintiffs' invitation to constitutionalize complex and technical risk-assessment processes will destabilize myriad warning laws and undercut states' ability to protect health and the environment.[1]

Environmental and public health amici Natural Resources Defense Council, Inc. (NRDC), Center for Food Safety, Clean Water Action, and Environmental Law Foundation are nonprofit groups that have worked for decades on behalf of themselves and their nationwide

[1] All parties have consented to the filing of this brief. This brief was not authored in whole or part by counsel for a party. No party or counsel for a party, and no person other than the amici curiae or their counsel, contributed money intended to fund the preparation or submission of this brief.

memberships, including members in California, to reform outdated chemical-safety laws and urge federal and state agencies to act on the latest science in regulating dangerous chemicals that harm health and the environment. This includes reducing exposure to harmful additives like flame retardants in furniture, PFAS in food packaging, and phthalates in children's toys, and strengthening our clean water laws to stop pollution at its source. Amici have pushed for passage and continued enforcement of labeling and disclosure requirements, including Proposition 65, that empower consumers to choose products that are better for their health and the environment.[2]

Worker advocacy group United Steelworkers (USW) is an international labor organization and the authorized collective bargaining representative for approximately 850,000 North American workers, including a majority of unionized workers in the chemical,

[2] *See, e.g.*, NRDC, Petition for Listing of 18 Chemicals Pursuant to Authoritative Bodies Mechanism of Safe Drinking Water and Toxic Enforcement Act of 1986 (July 6, 2006), https://oehha.ca.gov/media/downloads/proposition-65/proposition-65/nrdctooehha070606.pdf (identifying chemicals that the National Institute for Occupational Safety and Health determined cause reproductive toxicity); *People ex rel. Lungren v. Superior Court*, 926 P.2d 1042 (Cal. 1996) (landmark Proposition 65 case led by Environmental Law Foundation).

petroleum, rubber, paper, metals, mineral mining (other than coal), and general manufacturing industries. USW represents approximately 40,000 members in California, in industries including healthcare, manufacturing, education, and service. The organization's members include workers who are exposed to chemicals in products, both in the workplace and in their non-work activities. USW advocates for right-to-know laws, which provide workers with information to assess the hazards of chemicals in consumer and other products.

Healthcare professional organizations Alliance of Nurses for Healthy Environments (ANHE) and San Francisco Bay Physicians for Social Responsibility (SF Bay Physicians) are nonprofit education and advocacy organizations that draw on the expertise of health professionals to promote policies to protect human and environmental health. ANHE is a public health organization that seeks to protect people from exposure to toxins in the environment through public education, partnering with nurse researchers, and working at the local, state, and federal levels to establish and reform chemical safety laws. ANHE is concerned about the links between chemical exposure and cancers, reproductive and developmental diseases, and other chronic

ailments like asthma, diabetes, and cardiovascular disease. SF Bay Physicians similarly organizes physicians and other healthcare professionals to promote policies that protect human and environmental health on matters ranging from climate change to gun violence to toxic chemicals. Both groups support right-to-know laws that enable people to better understand and limit exposure to toxic chemicals in their everyday lives.

Toxics policy reform advocates Californians for Pesticide Reform (CPR) and Pesticide Action Network North America (PANNA) are, respectively, statewide and nationwide coalitions of organizations working to fundamentally shift the way hazardous pesticides are used. CPR builds leadership in communities living on the front lines of pesticide exposure, and has led successful campaigns to eliminate the use of glyphosate and other harmful synthetic pesticides from schools, parks, and other public lands in California. PANNA's network of organizations likewise supports Proposition 65 as part of its work defending communities most at risk of exposure to hazardous pesticides, including farmworkers, family farmers, and children living in agricultural communities.

Shareholder advocacy group As You Sow was founded in 1992 to promote environmental and social corporate responsibility through business collaboration, coalition building, and innovative legal strategies. Among its other advocacy strategies, As You Sow works to lower consumer and occupational exposures to toxics by bringing manufacturers and industries into compliance with Proposition 65.

BACKGROUND

A. Regulation in the context of evolving scientific knowledge

Courts have long recognized that regulators must sometimes act based on the available scientific information because a wait-and-see approach can imperil health and the environment. In a seminal opinion reviewing limits on lead in gasoline, the D.C. Circuit acknowledged that "[q]uestions involving the environment are particularly prone to uncertainty," and "speculation, conflicts in evidence, and theoretical extrapolation typify" regulatory actions in this realm. *Ethyl Corp. v. EPA*, 541 F.2d 1, 24 (D.C. Cir. 1976). "[S]tatutes and common sense demand regulatory action to prevent harm, even if the regulator is less than certain that harm is otherwise inevitable." *Id.* at 25; *accord United Steelworkers of Am. v. Marshall*, 647 F.2d 1189, 1252 (D.C. Cir. 1980)

(noting, in review of workplace lead limits, that Congress intended agency "to act firmly even in the face of medical uncertainty, not to be paralyzed by debate surrounding diverse medical opinions" (quotation marks omitted)).

This Court has similarly accorded leeway to agencies, allowing actions that "risk[] error on the side of overprotection rather than underprotection" in limiting occupational exposure to toxins, *ASARCO, Inc. v. Occupational Safety & Health Admin.*, 746 F.2d 483, 490 (9th Cir. 1984) (denying industry challenge to arsenic regulations) (quotation marks omitted), and in preserving ecologically sensitive areas of the ocean, *NRDC v. Pritzker*, 828 F.3d 1125, 1138 (9th Cir. 2016) (noting incomplete "state of the science" and "data-poor areas" of the world's oceans).

In the realm of consumer product regulations, cigarette warnings and related commercial restrictions are examples of laws issued even when the danger of smoking had "not [been] established beyond all doubt" (doubt largely sown by the tobacco industry, *see infra* p. 28). *Banzhaf v. FCC*, 405 F.2d 1082, 1097 (D.C. Cir. 1968) (upholding advertising restrictions). When the link between smoking and lung

disease was emerging in the 1960s, the federal government required tobacco companies to include a statement on cigarette packs that smoking is hazardous to health. *See* Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, § 4, 79 Stat. 282, 283 (1965).

Courts have also upheld food labeling rules even when the science is unsettled or the benefit of labeling is disputed. In reviewing a state disclosure rule for genetically modified ingredients, a district court acknowledged "conflicting studies assessing the health consequences" of such food and dismissed industry plaintiffs' concern that the required label would carry a negative connotation. *Grocery Mfrs. Ass'n v. Sorrell*, 102 F. Supp. 3d 583, 597-98 (D. Vt. 2015); *see id.* at 625 (holding that requirement was not "viewpoint discrimination" even though it "reflects the State's preference for a legislative outcome"). And in a challenge to a city rule requiring calorie information on menus, the Second Circuit rejected restaurant plaintiffs' argument that they "do not believe that disclosing calorie information would reduce obesity, and would prefer to provide complete nutrition information" instead of calorie listings. *N.Y. State Rest. Ass'n v. N.Y.C. Bd. of Health*, 556 F.3d 114, 131-34 (2d Cir. 2009) (rejecting First Amendment claims).

B. Proposition 65 and glyphosate

Consistent with the traditional rule that states have "great latitude under their police powers to legislate as to the protection of the . . . health . . . of all persons," *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996) (quotation marks omitted), California voters approved Proposition 65 to warn the public of health risks posed by products they use or to which they may be otherwise exposed. Proposition 65 requires the Governor of California to publish a list of chemicals known to the State to cause cancer. Cal. Health & Safety Code § 25249.8. As further explained below, the inclusion of chemicals on the list is a two-step process in which the State first determines if a chemical causes harm (the hazard identification step). *See* Cal. Code Regs. tit. 27, § 25904 (b)(2), (3). If so, the State then identifies the circumstances in which harm is expected, including assessing levels of chemical exposure at which harm may occur (the risk characterization step). *See id.* § 25705; Cal. Health & Safety Code § 25249.10(c).

A chemical is "known to the state to cause cancer" if it is recognized as a carcinogen by specified expert entities or identified on certain lists—including, as relevant here, lists under California Labor

Code section 6382(b)(1). *See* Cal. Health & Safety Code § 25249.8(a) (incorporating labor code provision). The Labor Code provision, in turn, incorporates chemicals identified by IARC as human or animal carcinogens. Cal. Labor Code § 6382(b)(1); *see also* Cal. Code Regs. tit. 27, § 25306(m)(1). IARC is a highly respected intergovernmental research arm of the United Nation's World Health Organization, tasked with making carcinogen hazard assessments. *See* World Health Organization, IARC Monographs on the Evaluations of Carcinogenic Risks to Humans: Preamble 1 (2006).[3] Federal and state regulators routinely refer to IARC's independent assessments and recognize the agency as one of the world's leading authorities on carcinogen analysis. *See, e.g.*, Occupational Safety and Health Administration, Occupational Exposure to Beryllium, 82 Fed. Reg. 2470, 2540 (Jan. 9, 2017) (citing IARC's findings on lung cancer); *Cal. Chamber of Commerce v. Brown*, 126 Cal. Rptr. 3d. 214, 236 (Ct. App. 2011) (noting that IARC was one of "several well-recognized sources to which manufacturers already routinely referred to obtain hazard information"); *see also* 6-ER-1231 –

[3] http://monographs.iarc.fr/ENG/Preamble/CurrentPreamble.pdf

6-ER-1236 (listing dozens of state regulations that rely on IARC carcinogenicity findings).

If a product contains a Proposition 65-listed chemical, the business is generally required to give a "clear and reasonable warning" regarding that exposure. Cal. Health & Safety Code § 25249.6. Businesses may seek an exemption from the requirement by requesting a "safe use determination" from California's Office of Environmental Health Hazard Assessment, showing that the level of exposure poses "no significant risk" of cancer. *Id.* § 25249.10(c); *see* Cal. Code Regs. tit. 27, § 25705. For many of the listed chemicals, the State calculates an exposure level below which the risk is deemed not significant. Cal. Code Regs. tit. 27, § 25705. The State also provides guidelines to businesses on how to conduct quantitative risk assessments to determine whether a product causes an exposure that poses no significant risk. Cal. Health & Safety Code § 25249.10(c); Cal. Code Regs. tit. 27, §§ 25701(a), 25703, 25705, 25721.

Glyphosate is a broad-spectrum herbicide widely used in agriculture (including soybean, cotton, and oats), parks, home gardens, and residential landscapes. IARC determined in 2015 that glyphosate is

"probably carcinogenic" to humans based on: "limited evidence" of cancer in studies of real-world occupational exposures to formulated products; "sufficient evidence" from laboratory rodent studies; and, "strong evidence" that pure glyphosate and glyphosate-based products causes the kind of cell damage that is known to lead to cancer. IARC, Q&A on Glyphosate (2016)[4]; *see also* 6-ER-1126 (IARC Monograph).

Following IARC's finding, in July 2017, the Office of Environmental Health Hazard Assessment (OEHHA) placed glyphosate on the State's Proposition 65 list. Businesses were therefore required to include a warning label on glyphosate-containing products starting July 2018, unless they could show that the level of exposure from the product posed no significant risk of cancer. *See* Cal. Health & Safety Code §§ 25249.6, 25249.10. This requirement never went into effect, however, because of the ensuing litigation. *See infra* p. 16.

In April 2018, after providing public notice and opportunity to comment, California finalized the No Significant Risk Level for glyphosate at 1100 micrograms/day. OEHHA, Amendment to Section

[4] https://www.iarc.fr/wp-content/uploads/2018/11/QA_Glyphosate.pdf

25705 No Significant Risk Level–Glyphosate (Apr. 10, 2018).[5] If a business can show that human exposures from its product are below that level, it is exempt from the labeling requirement. Cal. Health & Safety Code § 25249.10(c).

Since California's decision in 2017 to list glyphosate, the U.S. Agency for Toxic Substances and Disease Registry (ATSDR) released its final toxicological profile for glyphosate. The comprehensive report bolsters IARC's 2015 findings on the health effects of glyphosate exposure, including the link to blood cancers like non-Hodgkin's lymphoma. ATSDR, Toxicological Profile for Glyphosate 6 (Aug. 2020) ("Numerous studies reported risk ratios greater than one [indicating increased risk] for associations between glyphosate exposure and risk of non-Hodgkin's lymphoma or multiple myeloma . . . .").[6]

Not all agencies have reached identical conclusions, however. The Environmental Protection Agency's (EPA) Office of Pesticide Programs concluded that glyphosate is not carcinogenic at assumed low levels of exposure. EPA, Glyphosate Interim Registration Review Decision, Case

[5] https://oehha.ca.gov/media/downloads/crnr/glyphosateamendment041018.pdf
[6] https://www.atsdr.cdc.gov/ToxProfiles/tp214.pdf

Number 0178, at 10 (Jan. 2020) (hereafter "EPA Interim Review").[7] And the European Chemicals Agency noted "partly contradictory results" on the link between glyphosate and cancer, while acknowledging that "[e]pidemiological studies are of limited value for detecting the carcinogenic potential of an active substance in [pesticides] since humans are never exposed to a single compound alone." 7-ER-1554. California law permits a qualified warning label that acknowledges different agencies' findings and does not force a business to make an unqualified statement that the product is "known to cause cancer." *See* 9th Cir. Dkt. 18, Opening Br. of Appellant Xavier Becerra, Att'y Gen. of the State of Cal., at 41 (hereafter "Opening Br.").

C. District court proceedings

Monsanto sued the State in 2017, before the glyphosate warning requirement went into effect, claiming that the requirement violated its First Amendment rights against compelled speech. In the realm of commercial speech, "First Amendment interests implicated by disclosure requirements are substantially weaker than those at stake

[7] https://www.epa.gov/sites/production/files/2020-01/documents/glyphosate-interim-reg-review-decision-case-num-0178.pdf

when speech is actually suppressed." *Zauderer v. Off. of Disciplinary Couns. of the Sup. Ct. of Ohio*, 471 U.S. 626, 651 n.14 (1985). It is well settled that "the government may compel truthful disclosure in commercial speech" without running afoul of First Amendment concerns "as long as the compelled disclosure is 'reasonably related' to a substantial governmental interest," *CTIA-The Wireless Ass'n v. City of Berkeley*, 928 F.3d 832, 842 (9th Cir. 2019) (quoting *Zauderer*, 471 U.S. at 651), and "involves 'purely factual and uncontroversial information,'" *id.* (quoting *Nat'l Inst. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361, 2372 (2018)).

The district court granted Monsanto's motion for a preliminary injunction in February 2018, finding that the warning requirement was not "factually accurate" because some agencies have found "insufficient evidence that glyphosate causes cancer." 1-ER-53. In June 2020, the court granted summary judgment for Monsanto and permanently enjoined the glyphosate warning requirement. 1-ER-33 – 1-ER-34. In so ruling, the court brushed off the fact that OEHHA had set a No Significant Risk Level for glyphosate, and that Plaintiffs had not provided any evidence that they sell products that would expose

consumers at levels exceeding that threshold and therefore require a warning.

Even though the Proposition 65 listing is based on whether glyphosate is a cancer *hazard*—that is, whether the chemical has been shown to cause cancer at any dose, high or low—the district court's analysis focused on cancer *risk*—whether regulatory bodies have reached consensus on the precise levels of exposure, usage conditions, and pathways of exposure at which glyphosate will cause cancer. Because the lower court missed this critical distinction between hazard and risk assessment, *see infra* pp. 32-34, it wrongly concluded that the Proposition 65 warning is not "factual and uncontroversial" and thus not subject to the relaxed standard of *Zauderer*. 1-ER-23, 33. Instead, the district court improperly applied a stricter test under *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980), and concluded that the State failed to show that the glyphosate warning "directly advances the asserted government interest, [or] that it is not more extensive than necessary to achieve that interest." 1-ER-34.

The court ostensibly declined to "express an opinion as to the criticisms the parties lodge against the IARC on one hand, and the EPA on the other," 1-ER-26, but it discounted IARC's and ATSDR's hazard assessments: "[T]he fact that there have been additional studies suggesting a link between glyphosate and cancer, or the fact that there has been some criticism of the EPA's finding . . . does not establish that California knows that glyphosate causes cancer," 1-ER-26 – 1-ER-27.

The State appealed the decision. 9th Cir. Dkt. 1.

ARGUMENT

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

The court below concluded that no glyphosate warning label would be "purely factual and uncontroversial" because, in its view, the "heavy weight of authority stat[es] that glyphosate does not cause cancer." 1-ER-26-27.[8] Under the district court's reasoning, judges will be required

[8] The lower court found "the statement that glyphosate is 'known to the state of California to cause cancer' is misleading." 1-ER-23. But Proposition 65 does not require consensus—for instance, a chemical "is known to the state to cause cancer" if it is listed under the relevant Labor Code provision or if "*a* body considered to be authoritative by [the

to determine—without the benefit of a full scientific evidentiary record—when toxicology and epidemiology findings are certain enough to be "uncontroversial" and thus pass constitutional muster. This is not a workable legal standard.

A. Scientific knowledge is constantly evolving and thus subject to "controversy"

The state of the science is always evolving. These advances do not render previous understandings of chemical hazards mistaken—on the contrary, the development of more sensitive techniques has enabled scientists to identify adverse health effects at increasingly lower exposures of hazardous materials. *See, e.g.*, *Lead Indus. Ass'n v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir. 1980) ("[M]ore often than not the 'margins of safety' that are incorporated into air quality standards turn out to be very modest or nonexistent, as new information reveals adverse health effects at pollution levels once thought to be harmless." (citation omitted)). Science is not "static, and what is 'known' is necessarily defined by the state of the art at the time." *Cal. Chamber of*

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state's] experts has formally identified it as causing cancer or reproductive toxicity." *See* Cal. Health & Safety Code § 25249.8(a)-(b) (emphasis added); Opening Br. at 10 n.7.

Com., 126 Cal. Rptr. 3d at 233; *see also N. Am. Bldg. Trades Unions v. OSHA*, 878 F.3d 271, 291 (D.C. Cir. 2017) (per curiam) (noting that agency "is bound to confront inconsistency and uncertainty" in risk assessment). As renowned epidemiologist Austin Bradford Hill stated: "All scientific work is incomplete—whether it be observational or experimental," and may be "modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action that it appears to demand at a given time." Austin Bradford Hill, *The Environment and Disease: Association or Causation?* 58 *Proc. Royal Soc'y Med.* 295, 300 (May 1965).[9]

This is particularly true in protecting against health harms from chemical exposures. Environmental health science is a complex discipline. Exposure to a substance could injure one person but leave another unharmed because of differences in their genetics, age, and preexisting health conditions. *See* Nat'l Acads. of Scis., Eng'g & Med., Nat'l Rsch. Council, *Science and Decisions: Advancing Risk Assessment*

[9]https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1898525/pdf/procrsmed00196-0010.pdf

176 & n.a (2009) (listing numerous factors in health vulnerability).[10] It is nearly impossible to prove empirically a link between one chemical exposure and a discrete health harm because no human is exposed to only one toxin. Rather, we experience cumulative and synergistic effects from exposures to numerous substances in food packaging, drinking water, cosmetics, and household goods, among other sources. *See id.* at 146, 213 (noting "simultaneous exposure to multiple chemical and nonchemical stressors and other factors that could influence vulnerability"). And because ethical codes and laws prohibit direct human experimentation, it is often impossible to achieve absolute certainty on adverse effects of a chemical. *See, e.g.*, 40 C.F.R. §§ 26.203 (banning federally funded human dosing studies on children and pregnant or nursing women), 26.1203 (same for third-party intentional human dosing studies).

B. Judicial review of the soundness of an agency's scientific judgment does not fit well within a First Amendment framework

This Court should decline Plaintiffs' invitation to unnecessarily

[10] https://www.nap.edu/catalog/12209/science-and-decisions-advancing-risk-assessment

decide complex scientific questions under the guise of constitutional scrutiny. Judges are certainly capable of weighing expert evidence on these issues, and at times are appropriately called on to ensure that agencies follow the law and apply rigorous scientific methods. Here, however, Monsanto has not shown that it is even required to warn of glyphosate in its products, because the levels in those products may fall below the No Significant Risk Level threshold. Courts should not be forced to make judgments prematurely, via a First Amendment analysis, on which hazards are significant enough to merit warnings or disclosures. *See Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 116 (2d Cir. 2001) (observing that plaintiff's First Amendment theory subjects "long-established programs to searching scrutiny by unelected courts").

Constitutional claims are not like claims under statutes such as the Administrative Procedure Act (APA), 5 U.S.C. § 706, where the court reviews, on the basis of an administrative record, whether there is a rational connection between the facts found and the decision made. *See, e.g.*, *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); *N. Am. Bldg. Trades Unions*, 878 F.3d at 287 ("We lack the technical expertise to second-guess OSHA's

judgment when it 'review[ed] all sides of the issue and reasonably resolve[d] the matter.'" (alterations in original) (quoting *Pub. Citizen Health Rsch. Grp. v. Tyson*, 796 F.2d 1479, 1500 (D.C. Cir. 1986)). In an APA case, the court has the full evidentiary record of scientific and medical literature, and where there is uncertainty, the court is deferential in matters at the core of agency expertise. *See, e.g.*, *League of Wilderness Defs. Blue Mountains Biodiversity Project v. Allen*, 615 F.3d 1122, 1130 (9th Cir. 2010) ("[Judicial] deference is highest when reviewing . . . judgments involving the evaluation of complex scientific data within the agency's technical expertise."); *Amoco Oil Co. v. EPA*, 501 F.2d 722, 741 (D.C. Cir. 1974) (rejecting challenge to leaded gasoline rules and noting that when "regulations turn on choices of policy, on an assessment of risks, or on predictions dealing with matters on the frontiers of scientific knowledge, [courts] will demand adequate reasons and explanations, but not 'findings' of the sort familiar from the world of adjudication").

In contrast, the First Amendment inquiry that Monsanto urges here forces courts to second-guess agencies' interpretation of data and determine when an expert finding is so unsound as to render it

counterfactual under *Zauderer*. Judges will be asked to determine—without the benefit of a full scientific record—where a chemical fits on the spectrum of warnings that are "purely factual," 1-ER-33, or "subjective and stigmatizing," Dist. Dkt. 35, Br. of Amicus Curiae Chamber of Commerce of U.S. in Supp. of Pls.' Mot. for Prelim. Inj. 3. These are not the sorts of questions courts should be forced to resolve prematurely via a First Amendment analysis untethered to the full suite of scientific evidence.

What percentage of studies need to support an agency's finding to make a hazard assessment "purely factual and uncontroversial"?[11] How many of those studies can be based on cell or tissues tests and live animal experimentation, and how many must be based on observations in humans? And how many fatalities need to be linked to a chemical before a state is permitted to regulate the marketing of products containing that chemical? These may be easy calls at the extremes, but most risk assessment decisions will fall somewhere in between.

[11] The vagueness of such a standard is thrown into sharp relief by the fact that recently, even the results of a presidential election decided by a large electoral college margin have been deemed controversial.

Individual judges will assess risks differently, encouraging forum shopping and inconsistent judicial decisions on the risks posed by chemicals. And in another dimension to forum shopping, businesses may seek conclusions from health agencies in other states or countries on a chemical's purported safety as evidence that a Proposition 65 warning is "misleading." In effect, a business could use other states' science agency findings to veto California's decision, upending bedrock principles of federalism. *Cf. Rocky Mountain Farmers Union v. Corey*, 913 F.3d 940, 955 (9th Cir. 2019) (affirming state renewable fuels rule and noting that "autonomy in the regulation of economic and social affairs is central to our system" of federalism).

The policy implications of upholding the district court's ruling are far reaching. Constitutionalizing matters at the core of agencies' expertise opens to judicial scrutiny a wide range of federal and state regulations that require the disclosure of product and other commercial information. This includes requirements to post notification of workplace hazards, 29 C.F.R. § 1910.1200, disclosures in prescription-drugs advertising, 21 C.F.R. § 202.1, product labeling rules for chemicals in car air fresheners and household cleaning products, Cal.

Health & Safety Code §§ 108952, 108954, and disclosure of pesticide formulas, N.Y. Envtl. Conserv. Law § 33–0707. *See also, e.g.*, 21 U.S.C. § 343(q)(1) (nutritional labeling); 42 U.S.C. § 11023 (reporting of toxic chemical releases); 15 U.S.C. § 78*l* (securities disclosures); 15 U.S.C. § 1333 (cigarette labeling).

To be sure, there may be times when a court is properly asked to evaluate whether an agency reasonably determined that a particular product exposes consumers to chemicals at a level that requires a Proposition 65 warning, and what that warning must say. At that time, the court may need to evaluate the scientific evidence on toxicity and exposure to glyphosate. But that question is not before this Court, nor was it before the district court. Plaintiffs have not shown that they are even subject to Proposition 65's warning requirement, which does not apply if they show that the products cause glyphosate exposure below the No Significant Risk Level.

In short, First Amendment jurisprudence does not provide a principled way to measure the level of scientific certainty that distinguishes "uncontroversial" warning labels from "stigmatizing" ones. *Cf. Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 316 (1st Cir.

2005) (Boudin, C.J., and Dyk, J., opinion of the court with respect to First Amendment claim) (declining to apply "extensive First Amendment analysis" to "routine" public health regulation of pharmaceutical company disclosures). Wherever that line is drawn, though, there is enough scientific certainty in this case—where the world's most respected cancer research agency has determined that glyphosate is a probable human carcinogen—for the warning requirement to pass constitutional muster.

II. A First Amendment "controversy" standard creates perverse incentives to manufacture scientific doubt

Information gaps and disagreements are common when developing regulations based on highly technical analyses of hazards and risks. *See supra* pp. 9-11. The district court's reasoning may further encourage businesses unhappy with regulation to play on the complexity of these assessments. Industries with an economic interest in avoiding disclosures have more incentive to invest in trumpeting scientific disagreements or sponsoring contrary studies to manufacture controversy, evade product warning requirements, and force a race to the bottom, using one state agency's weaker regulation to undercut another state's more robust one. *Cf. In re Prempro Prods. Liab. Litig.*,

586 F.3d 547, 557 (8th Cir. 2009) (describing how, after National Institute of Health-sponsored study found cancer risks from hormone replacement therapy, industry attacked the study's methodology and tried to shift attention to other studies).

The magnification of scientific doubt to shape pro-industry policy is, unfortunately, nothing new. An extensive body of academic research ties climate-change denialism among policymakers to the fossil fuel industry's decades-long efforts to undermine climate science. *See, e.g.*, Naomi Oreskes & Erik M. Conway, *Merchants of Doubt: How a Handful of Scientists Obscured the Truth on Issues from Tobacco Smoke to Global Warming* (2010); David Michaels, *Doubt Is Their Product: How Industry's Assault on Science Threatens Your Health* (2008). And the tobacco industry has a well-documented history of sponsoring contrary science to influence regulations. *See United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 723, 761 (D.D.C. 2006) (describing tobacco companies' coordinated effort to discredit scientific consensus that secondhand smoke causes disease), *vacated in part on other grounds*, 566 F.3d 1095 (D.C. Cir. 2009). Monsanto itself has been associated with thousands of inadequate or falsified test results—including studies

of glyphosate-containing herbicides—that EPA later threw out. *See* Mary Thornton, *EPA Review Finds Flawed Tests Made By Research Firm*, Wash. Post, May 13, 1983.[12]

Companies would be further emboldened to pressure sympathetic agencies into making less health-protective findings in order to leverage that against another agency's stronger regulations. We need not look far for an example of this. Monsanto emails made public during court proceedings show that the corporation encouraged EPA to "kill" the toxicology review from ATSDR, *see supra* p. 14, which found an increased risk of blood cancers from glyphosate exposure. *See* Pls.' Mot. to Compel Dep. of Jess Rowland, at 102, *In re: Roundup Prods. Liab. Litig.*, No. 16-md-02741-VC (N.D. Cal. filed Mar. 14, 2017) (Monsanto's head of Regulatory Affairs stating "I doubt EPA . . . can kill [the report]; but it's good to know they are actually going to make the effort now to coordinate due to our pressing and their shared concern that ATSDR is inconsistent it its conclusions w[ith] EPA").[13]

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[12] https://www.washingtonpost.com/archive/politics/1983/05/13/epa-review-finds-flawed-tests-made-by-reasearch-firm/584839e8-8d68-4f2d-9797-decc25ecd18d/

[13] https://www.documentcloud.org/documents/3521387-Doc-189-Docs-Mentioning-EPA-Jess-Rowland.html

The lower court's ruling, if allowed to stand, will encourage businesses to double down on these strategies of funding contrary studies and manufacturing the appearance of disagreement to serve their financial interests.

III. The district court erred in discounting IARC's conclusion as an outlier opinion

Even if First Amendment scrutiny were appropriate for a Proposition 65 warning requirement, the district court clearly erred in dismissing IARC's finding. Indeed, the court's attempt to weigh various glyphosate studies, *see* 1-ER-25, shows how the First Amendment framework is ill-suited to resolving disputes at the core of agencies' specialized technical competence. The court decided that a Proposition 65 warning for glyphosate was not "factual and uncontroversial," because while IARC had found it was a likely human carcinogen, EPA and other regulatory groups made different findings. *Id.* But those findings were *in response to a different inquiry*. The district court misinterpreted Proposition 65's hazard finding and ignored the critical difference between IARC's conclusion and that of other agencies.

A. Understanding risk assessment

Understanding the source of the district court's confusion requires a basic working knowledge of risk assessment. Risk assessment uses available data "to define the health effects of exposure of individuals or populations to hazardous materials and situations," and looks at potential risks under specified conditions. *See* Nat'l Acads. of Scis., Eng'g & Med., Nat'l Rsch. Council, *Risk Assessment in the Federal Government: Managing the Process* 3 (1983).[14] The risk assessment process involves several steps. The first step of "hazard identification" determines "whether a particular chemical is or is not causally linked to particular health effects." *Id.* Subsequent steps evaluate how certain levels of exposure affect the health outcome—called the "dose-response assessment"—and how much exposure occurs in various settings—known as "exposure assessment." From this information, scientific agencies determine the nature and magnitude of human risk—the "risk characterization." *Id.*; Nat'l Acads. of Scis., Eng'g & Med., Nat'l Rsch. Council, *Science and Judgment in Risk Assessment* 4-5 (1994).[15]

[14] https://www.nap.edu/download/366
[15] https://www.nap.edu/catalog/2125/science-and-judgment-in-risk-assessment

Regulatory agencies have a range of tools to address different levels and types of health risks. The federal Toxic Substances Control Act, for example, authorizes EPA to issue regulations to eliminate "unreasonable risk" to health and the environment posed by certain chemicals. *See* 15 U.S.C. § 2605(a). EPA may, in some circumstances, ban the chemical. *Id.* § 2605(a)(1). In other circumstances, it may require "clear and adequate" warnings that allow consumers to choose whether to be exposed to that substance. *Id.* § 2605(a)(3).

Proposition 65 operates somewhat similarly. Chemicals that are determined to pose a hazard are listed by the State; but if the level of exposure from a product containing that chemical does not pose a significant risk of cancer or reproductive harm, no warning is required. *See* Cal. Health & Safety Code §§ 25249.6, 25249.10(c). In other words, whether a listed chemical requires a warning depends on whether a business shows its product would expose consumers to only insignificant levels of that chemical. *See supra* p. 12.

B. EPA's findings on glyphosate do not conflict with IARC's

The district court conflated the various steps of the risk assessment process in interpreting EPA's review of glyphosate in

pesticides as a general conclusion that glyphosate is "not a cancer risk." *See* 1-ER-25 (citing EPA, Office of Pesticide Programs, Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential 144 (Dec. 12, 2017) (hereafter "Glyphosate Issue Paper")).[16] But EPA's statement is not a pure hazard assessment. That is, EPA did *not* find that glyphosate is not carcinogenic to humans at sufficiently high exposures. The agency's analysis excluded findings of increased tumors and other negative health effects because they occurred at doses that EPA thought was unlikely to occur. *See* Glyphosate Issue Paper, at 136.

That finding is distinct from a Proposition 65 listing decision, which is a hazard identification that asks whether glyphosate is a human carcinogen. That identification—which IARC performed and ATSDR recently confirmed—*precedes* a risk assessment. *See supra* pp. 13-14. The subsequent risk assessment sets the "safe harbor" level of exposure below which the chemical does not present a significant risk—and for glyphosate, California set that level at 1100 micrograms/day, *see supra* p. 13.

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[16] https://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=534487

For this reason, EPA's statement that glyphosate is "not likely to be carcinogenic" *at the 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 if it can show that EPA's prediction was right—i.e., that actual exposures from the product do not pose a significant risk of cancer.

EPA's "no risk" finding is also not as clear cut as it appears.[17] The agency's Interim Registration Review addresses cancer risk in a perfunctory way and refers to the agency's Draft Human Health Risk Assessment and the Final Report of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel. *See* EPA Interim Review at 5; *see also id.* at 10 (referring to human health harms from "current registered uses of glyphosate"). That Draft Human Health Risk Assessment in turn relies on the agency's Glyphosate Issue Paper, a draft of which was reviewed by the Scientific Advisory Panel.

[17] Amici Center for Food Safety, NRDC, and PANNA have challenged EPA's Interim Registration Review for glyphosate in petitions for review that are currently before this Court, including EPA's "no risk" cancer finding. *See Rural Coal. v. EPA*, No. 20-70801 (9th Cir. filed Mar. 20, 2020); *NRDC v. EPA*, No. 20-70787 (9th Cir. filed Mar. 20, 2020).

The Issue Paper makes clear that EPA excluded studies showing incidences of tumors in high dose experiments. Glyphosate Issue Paper, at 142 (noting some evidence of "increased tumor incidences in various studies at the highest doses tested").

The Scientific Advisory Panel's final report provides important context for and insight into EPA's "no risk" determination. *See* EPA, *Final Report of the Dec. 13-16, 2016, FIFRA SAP Meeting* (hereafter "Science Panel Report").[18] Members of the Panel criticized EPA for "not considering tumor responses at doses exceeding 1,000/mg/kg/day"—a methodology that is "not consistent with either EPA (2005) *Cancer Guidelines* or standard ways in which bioassay [laboratory rodent tests] results are typically interpreted." Science Panel Report, at 74.

The report also points out a "critical data-gap": The studies reviewed were of low-level exposures of farmers applying herbicide, but do not look at "potentially more highly exposed workers, such as those who manufacture, formulate or are involved in the wholesale handling or selling of glyphosate." Science Panel Report, at 15, 20-21. And the

[18] https://www.epa.gov/sites/production/files/2017-03/documents/december_13-16_2016_final_report_03162017.pdf

low-exposure assumptions for farmworkers may be faulty because they "do not adequately capture possibly much higher exposures cohort members likely experienced after the introduction of transgenic crops in 1995." *Id.* at 32; *see* U.S. Geological Survey, *Estimated Annual Agricultural Pesticide Use: Pesticide Use Maps—Glyphosate* (last modified June 18, 2020) (graph showing approximately 25 million pounds of glyphosate used in 1995 compared to 270)[19]; *cf.* Patricia Cohen, *Roundup Maker to Pay $10 Billion to Settle Cancer Suits*, N.Y. Times, June 24, 2020 (summarizing 2018 jury award of $289 million to a school groundskeeper "after concluding that glyphosate caused his cancer").[20]

Finally, internal EPA emails also show that "ORD's [Office of Research and Development] epidemiologists agree with IARC that there is 'limited evidence' of carcinogenicity in humans," a finding that "would rule out" the EPA categorization of "[n]ot likely to be carcinogenic." Dist. Dkt. 138-16, Zuckerman Decl., Ex. PP, at 1763. The "[b]ottom line"

[19] https://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2017&map=GLYPHOSATE&hilo=L&disp=Glyphosate

[20] https://www.nytimes.com/2020/06/24/business/roundup-settlement-lawsuits.html

is that "ORD scientists . . . would be split between '[l]ikely to be carcinogenic' and '[s]uggestive evidence.'" *Id.* at 1764.

In sum, the district court missed the fundamental distinction between IARC's hazard finding and EPA Office of Pesticide Programs' low-dose risk assessment, and compounded its error by failing to grapple with the nuances of EPA's analysis. *See also* IARC, Q&A on Glyphosate 3 ("Many regulatory agencies rely primarily on industry data from toxicological studies that are not available in the public domain. In contrast, IARC systematically assembles and evaluates all relevant evidence available in the public domain for independent scientific review."). These critical errors underscore why courts should not be second-guessing complex scientific determinations via a First Amendment analysis. Agencies like the Office of Environmental Health Hazard Assessment and IARC 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. USDA*, 415 F.3d 1078, 1093 (9th Cir. 2005) (finding deference to agency judgment is "especially appropriate" where an agency decision "involves a high level of technical expertise").

If these highly complex and technical decisions are to be reviewed, it is best done with the benefit of a scientific evidentiary record and not shoehorned into the framework of a "factual and uncontroversial" First Amendment test.

CONCLUSION

Health and safety requirements are often issued before regulators have absolute certainty on risks. Such regulatory measures, which include product testing requirements, disclosure obligations, and bans, reflect complex policy decisions in assessing risks and choosing how to protect the public in the face of evolving scientific knowledge.

Whether an expert agency's finding is robust enough to support a regulation is a scientific question, not a constitutional one. This Court should reverse the lower court's decision and reject Monsanto's invitation to apply a First Amendment inquiry to matters at the core of health regulatory agencies' expertise.

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Respectfully submitted,

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