No. 20-16758

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NATIONAL ASSOCIATION OF WHEAT GROWERS, ET AL.,
Plaintiffs-Appellees,

v.

ROB BONTA,* ATTORNEY GENERAL OF CALIFORNIA, ET AL.,
Defendants-Appellants.

On Appeal from the United States District Court for the
Eastern District of California, Case No. 2:17-cv-02401-WBS-EFB
Honorable William B. Shubb

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* Following Defendant Xavier Becerra's confirmation as HHS Secretary, Rob Bonta was confirmed as the Attorney General of California on April 22, 2021. *See* Fed. R. App. P. 43(c).

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Defendants-Appellees make the following disclosures.

Defendants-Appellees National Association of Wheat Growers, National Corn Growers Association, U.S. Durum Growers Association, Missouri Farm Bureau Federation, Iowa Soybean Association, South Dakota Agri-Business Association, North Dakota Grain Growers Association, Missouri Chamber of Commerce and Industry, Agribusiness Association of Iowa, Associated Industries of Missouri, CropLife America, Western Plant Health Association, and Agricultural Retailers Association have no parent corporations and no publicly held corporations own 10% or more of any of these Defendants-Appellees' stock.

Defendant-Appellee Monsanto Company is an indirect, wholly owned subsidiary of Bayer AG. Bayer AG is a publicly held corporation. No other publicly held corporation owns 10% or more of Monsanto Company's stock.

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INTRODUCTION

This case concerns a new compelled warning for glyphosate, the most widely used herbicide in the world, and one of the most thoroughly studied. Glyphosate has been subject to decades of examination by regulators worldwide. *Every* expert national regulator to have assessed the safety of glyphosate—including the United States EPA and regulators in Europe, Canada, Australia, New Zealand, Japan, and South Korea—has concluded that glyphosate does *not* cause cancer. And the only times it considered that question, California's own Office of Environmental Health Hazard Assessment (OEHHA) came to the same conclusion. Yet, because a single entity, the International Agency for Research on Cancer (IARC), concluded that glyphosate probably is capable of causing cancer (at unspecified exposure levels), California's Proposition 65 requires that every product containing even small amounts of glyphosate display a warning telling consumers that glyphosate is a chemical "known to the state of California to cause cancer."

Laws that compel speech, just like laws that restrict speech, are presumptively unconstitutional, and are ordinarily subject to at least intermediate scrutiny. *See Nat'l Inst. of Family & Life Advocates v. Becerra* (*NIFLA*), 138 S. Ct. 2361, 2371 (2018). The Supreme Court has articulated a narrow exception, permitting more streamlined review of certain compelled commercial disclosures under the standard articulated in *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of*

Ohio, 471 U.S. 626, 651 (1985)—but that standard applies only where the disclosure consists of "purely factual and uncontroversial" information, such as ingredient lists, calorie counts, country-of-origin designations, and well-established health risks. The compelled warning requirement at issue in this case is nothing like that.

The problem here is that the compelled Proposition 65 warning would convey the message that it is an established fact that glyphosate causes cancer when, in actuality, the vast weight of scientific authority is to the contrary. Plaintiffs, a broad coalition of agricultural and farming associations and businesses, filed suit to enjoin enforcement of Proposition 65's warning requirement as applied to glyphosate. In granting their motion for summary judgment, the district court held that this compelled warning would be false or, at a minimum, deeply misleading, and that compelling it violates the First Amendment.

On appeal, the Attorney General no longer defends the lawfulness of the standard Proposition 65 warning as applied to glyphosate. Instead, he champions a supposed "alternative" warning (the "Alternative Warning") that he proposed in summary judgment briefing below. This Alternative Warning would acknowledge that IARC's finding is the basis of the "known to cause cancer" language and would note EPA's disagreement with IARC. According to the Attorney General, the availability of this alternative warning rescues Proposition 65's application to

glyphosate from its constitutional flaws. The district court rightly rejected this argument as well.

The Attorney General's reliance on the Alternative Warning is misplaced because it adds qualifying language that is both irrelevant to the constitutional analysis and noncompliant with Proposition 65. The Attorney General's own brief concedes that what California law requires is a "'clear and reasonable'" warning that a chemical is "'known to the state to cause cancer' or 'words to that effect.'" Br. 13 (alteration omitted) (quoting Cal. Health & Safety Code § 25249.6 and *Dowhal v. SmithKline-Beecham Consumer Healthcare*, 32 Cal. 4th 910, 918 (2004)). And it is *that* message—the speech that state law *compels*; not whatever additional explanatory statements state law might *allow*—that is the proper focus of the First Amendment analysis. In addition, the Alternative Warning is not actually an available option because—under controlling California precedent and per the Attorney General's own regulations—Proposition 65 forbids the addition of any language that would undermine the certitude of the core required warning. For both of these reasons, the district court's judgment can and should be affirmed without any need for this Court to consider whether compelling the Alternative Warning also would violate the First Amendment. But if the Court reaches that question, it should affirm on that basis, too.

Like the core Proposition 65 warning, the Alternative Warning is both misleading and controversial. The Alternative Warning (1) retains the core statement that glyphosate is "known to cause cancer," (2) tells consumers that California reached this conclusion because the weighty-sounding "International Agency for Research on Cancer has classified it as a carcinogen," and (3) only briefly notes at the tail end (if consumers read that far) that EPA believes glyphosate is not likely carcinogenic. Thus, the Alternative Warning would convey to reasonable consumers that the weight of authority is that glyphosate causes cancer or, at best, that authoritative bodies are split equally on that question—and both of those messages are false. Moreover, the Alternative Warning would unquestionably require Plaintiffs to wade into a scientific controversy and present viewpoints with which they strongly disagree, which independently renders it ineligible for review under the *Zauderer* standard.

The Alternative Warning would therefore be evaluated under the intermediate scrutiny standard of *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980)—and as the district court held, the Attorney General failed to prove that it could survive either element of that test. First, compelling the Alternative Warning would not directly advance a substantial state interest. As this Court has previously recognized, the State has no legitimate interest, much less a substantial interest, in misleading consumers. In addition, the interest

the Attorney General now invokes—informing consumers whenever one of a handful of entities determines that a chemical probably causes cancer, even if most authorities disagree—was explicitly *disclaimed* in the Proposition 65 ballot summary, which told the voters who enacted the statute that it would require businesses to warn consumers about "chemicals that are scientifically known[,] not merely suspected, but known[] to cause cancer." 2-ER-121. Second, as applied to glyphosate, compelling a Proposition 65 warning burdens First Amendment freedoms more than necessary to advance the State's purported interests. As the district court concluded, to the extent the State wishes to inform consumers about IARC's views about glyphosate, the Attorney General did not meet his burden to show that the State could not advance that interest, without burdening private speech, by providing consumers that information itself. Indeed, the Attorney General introduced no evidence whatsoever on that score—a failure that, by itself, is fatal.

The Attorney General and his amici protest that unless this Court overturns the district court's narrow and well-reasoned decision, the sky will fall and all of this Nation's health and safety warnings will be at risk. They insist, in particular, that governments will never be able to require warnings over which there is any "scientific disagreement," Br. 58, and will be unable to warn the public of emerging health risks. That is nonsense. Despite the Attorney General's efforts to cast his appeal in apocalyptic terms, he lost this case for more prosaic reasons. The district

court followed established precedent to enjoin a warning requirement that is inconsistent with the overwhelming weight of scientific authority. Its decision casts no doubt on the government's ability to require warnings about established risks to health and safety. And it equally casts no doubt on the government's ability to require warnings about serious emerging risks; such warning mandates are permissible where (unlike here) the State can demonstrate that the warnings are not misleading, that the State cannot effectively disseminate the warnings itself, and that the warning mandates satisfy the other requirements of intermediate scrutiny.

This Court should affirm the decision of the district court.

STATEMENT OF THE ISSUES

Whether, in light of the consensus among EPA and other national regulators that glyphosate is not a human carcinogen, the district court correctly held that the First Amendment bars California from compelling Plaintiffs to provide a Proposition 65 cancer warning for products containing glyphosate.

STATEMENT OF ADDENDUM

Pertinent constitutional provisions, statutes, and rules are set forth in the Addendum.

STATEMENT OF JURISDICTION

Plaintiffs concur that the district court had and this Court has jurisdiction, and that this appeal was timely filed, as stated by the Attorney General.

STATEMENT OF THE CASE

A. Glyphosate Is Approved In the United States As A Pesticide, Including For Use On Crops And Food Inputs

Glyphosate is an herbicide used to control weeds in agricultural, residential, and other settings. SER237-40 (¶¶ 6-17). It is the world's most widely used herbicide. *See* SER237; SER277. Glyphosate serves as the active ingredient in many commercial products, including most Roundup® products, and has been registered for use in over 160 countries. SER237, 245, 259 (¶¶ 8, 9, 31-32, 67).

In the United States, glyphosate is approved for use in more than 250 agricultural crop applications. SER239, 244-45 (¶¶ 13, 30-31); *see also, e.g.*, SER318-19. Glyphosate-based herbicides are also widely used in garden settings, by government agencies to control vegetation in aquatic environments, and to reduce wildfire risk. SER240 (¶ 16). Glyphosate is broadly used because of its well-recognized benefits over other weed-suppression techniques, including its lesser environmental impacts.[1]

Glyphosate is subject to comprehensive federal regulation. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), commercial herbicides such as glyphosate must be registered with EPA. 7 U.S.C. § 136a. Before EPA can grant

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[1] *See, e.g.*, SER239-40 (¶¶ 15, 17); SER282; SER1021-22 (¶¶ 5-7); SER1062 (¶ 6); SER1091-92 (¶¶ 5-9); SER1079-80 (¶¶ 7-10); SER1031-33 (¶¶ 6-12); SER1042-43 (¶¶ 5-8).

registration, it must conclude that the herbicide will not cause "any unreasonable risk to man or the environment" or "human dietary risk." *Id.* § 136(bb); *see id.* § 136a(c)(5)(C)-(D). This review includes a mandatory evaluation of whether the herbicide is potentially carcinogenic. *See, e.g.*, SER292-313. The Federal Food, Drug, and Cosmetic Act (FDCA) then regulates the presence of registered herbicides on food products. 21 U.S.C. §§ 342(a), 331(b), 346a. Under the FDCA, EPA is charged with evaluating the human health impact of the presence of the herbicide's food residue, including potential carcinogenicity. *Id.* § 346a(b)(2)(A).

B. The International Scientific Consensus That Glyphosate Does Not Cause Cancer

Because of its immense popularity, glyphosate is one of the most studied herbicides in the world. Regulators worldwide, including EPA, have recognized for decades that glyphosate is safe when used as directed, and have uniformly concluded that glyphosate poses no risk of cancer.

EPA has repeatedly reached and re-affirmed this conclusion. "In June 1991, EPA classified glyphosate as a Group E oncogene—one that shows evidence of non-carcinogenicity for humans—based on the lack of convincing evidence of carcinogenicity in adequate studies." SER335. In 1993, when it renewed glyphosate's FIFRA registration, EPA credited "[s]everal chronic toxicity/carcinogenicity studies ... finding[] that glyphosate was not carcinogenic." *Id.* More recently, in 2014, "EPA reviewed more than 55 epidemiological studies"

and "'concluded that this body of research does not provide evidence to show that glyphosate causes cancer.'" SER343 (citation omitted). In late 2017, EPA issued a comprehensive evaluation of glyphosate, and again determined that glyphosate is "not likely to be carcinogenic to humans" and that "the weight-of-evidence clearly do not support the descriptors 'carcinogenic to humans' and 'likely to be carcinogenic to humans' at this time." SER905, 910. And in April 2019, EPA issued another evaluation, once again reaffirming that "glyphosate is 'not likely to be carcinogenic to humans.'" 7-ER-1412-13. For several decades, EPA also has concluded that "there is a reasonable certainty that no harm will result" from glyphosate food residues, 21 U.S.C. § 346a(b)(2)(A)(ii), and allowed the presence of glyphosate residues on all relevant United States crops and food inputs. 40 C.F.R. § 180.364; *see* 78 Fed. Reg. 60,707 (2013).

The only evaluations ever done by California's own expert regulator, OEHHA, agreed with EPA. In 1997 and 2007, OEHHA evaluated glyphosate's potential carcinogenicity. *See* SER359; SER372. After reviewing studies, OEHHA found that "glyphosate [wa]s judged *unlikely to pose a cancer hazard to humans*." SER372 (emphasis added); *see also* SER359 (finding "evidence of no carcinogenic effects"). OEHHA has never re-evaluated or modified that determination.

The global community has long been in accord. The EU's European Chemicals Agency concluded "the available scientific evidence did not meet the

criteria to classify glyphosate as a carcinogen, as a mutagen or as toxic for reproduction." SER750. The European Commission's Health and Consumer Protection Directorate-General concluded that glyphosate presents "[n]o evidence of carcinogenicity." SER414. A division of the World Health Organization ("WHO") reached the same conclusion. *See* SER463. And global regulators, from the European Union to Canada, Australia, New Zealand, Japan, and South Korea have also concluded that glyphosate is unlikely to pose any cancer hazard or risk.[2]

C. IARC's Contrary View, And The Global Repudiation Of That View

IARC disagrees with this worldwide consensus. IARC is not a regulator. It is an agency within the WHO, located in Lyon, France, that forms *ad hoc* panels to prepare "Monographs" regarding the possibility that a variety of "agents" (*e.g.*, chemicals, and/or lifestyle factors) may be carcinogenic. IARC purports to evaluate only "cancer hazards"—that is, whether a substance "is capable of causing cancer under *some* circumstances" and at *some* level of exposure. *In re Roundup Prods.*

[2] *See*, *e.g.*, SER466 (European Commission concluding in 2015 that glyphosate is "unlikely to pose a carcinogenic risk in humans"); SER704-05 (German agency, 2015); SER738; 9-ER-1861 (Food & Agric. Org. of U.N. & WHO, finding that "glyphosate is unlikely to pose a carcinogenic risk to humans")); SER741 (Canadian agency concluding "Glyphosate is not genotoxic and is unlikely to pose a human cancer risk," 2017); 8-ER-1787 (Australian agency concluding "exposure to glyphosate does not pose a carcinogenic or genotoxic risk to humans," 2017); 8-ER-1757 (New Zealand agency concluding "glyphosate is unlikely to be genotoxic or carcinogenic to humans," 2016); SER754-55 (Food Safety Commission of Japan); SER1003 (Korean agency, 2017).

Liab. Litig., 390 F. Supp. 3d 1102, 1113-14 (N.D. Cal. 2019) (emphasis added). IARC recognizes that this is only the "'first step in carcinogen risk assessment,'" and IARC does not undertake the second necessary step—determining the cancer "risk" that captures the "'carcinogenic effects expected from exposure'" at a particular level. *Id.* at 1114 (quoting IARC Monograph).

In March 2015, IARC released a Monograph concluding that "[g]lyphosate is *probably carcinogenic to humans*." 6-ER-1141. IARC reached that conclusion based on what it conceded was "*limited evidence* in humans for the carcinogenicity of glyphosate," (*i.e.*, "chance, bias, or confounding could not be ruled out with reasonable confidence"). 4-ER-764; 6-ER-1141. IARC relied primarily on its interpretation of a limited set of studies on "experimental animals" and "mechanistic" data and, again, did not opine that glyphosate would in fact cause cancer at any particular exposure level (much less a realistic one). Instead, IARC left the question "whether the substance currently presents a meaningful risk to human health" to "other public health entities." *In re Roundup*, 390 F. Supp. 3d at 1108.

IARC's 2015 glyphosate classification provoked substantial backlash in the scientific and public health communities. One FDA official testified before the Senate to reaffirm the long-standing evaluation that glyphosate does not cause cancer. *See* SER469-70. Others, such as the Chief Physician at MassGeneral

Hospital for Children, testified that IARC's conclusion was "not supported by the data" and "flies in the face of comprehensive assessments from multiple agencies globally." SER472.

The following year, EPA issued a 227-page glyphosate issue paper that concluded based upon "an extensive database … for evaluating the carcinogenic potential of glyphosate, including 23 epidemiological studies, 15 animal carcinogenicity studies, and nearly 90 genotoxicity studies" that the available data "do no[t] support a carcinogenic process for glyphosate." SER615. EPA confirmed again in December 2017 that glyphosate is "not likely to be carcinogenic to humans." SER905, 910. And in April 2019, another EPA review reaffirmed that "glyphosate is 'not likely to be carcinogenic to humans.'" 7-ER-1412-13, 1424-25; *see also* SER985-86. In that review, EPA observed that its "cancer evaluation is more robust than IARC's" because IARC only considers publicly available scientific literature, and IARC thus considered barely half of the animal carcinogenicity studies that EPA considered. 7-ER-1412.

In an August 2019 letter, EPA reiterated that it "disagrees with IARC's assessment of glyphosate," and that EPA would therefore not approve herbicide labels bearing the Proposition 65 cancer warning, which would be "false and misleading" and render a product "misbranded" under FIFRA. SER315. Most

recently, in January 2020, EPA conclusively reaffirmed that "glyphosate is not likely to be carcinogenic to humans." SER23.

Other nations' regulators have similarly rejected IARC's conclusions. Canada's Pest Management Regulatory Agency, for instance, explicitly rejected IARC's findings, emphasizing that it had "assessed a much larger and more relevant body of scientific information than was considered" by IARC. SER742-48; *see also* 8-ER-1786-87 (Australian regulator reviewing IARC's assessment and concluding that "the scientific weight-of-evidence indicates that … exposure to glyphosate does not pose a carcinogenic or genotoxic risk to humans"); 8-ER-1743, 1757 (New Zealand reaffirming that "glyphosate is unlikely to be genotoxic or carcinogenic to humans"); SER704-05 (German regulator questioning IARC's conclusions); *supra* n.2.[3]

One of the most extensive epidemiological studies ever conducted of glyphosate also refutes IARC's conclusions. The 2018 Agricultural Health Study—sponsored by the U.S. National Institutes of Health, National Cancer Institute, and

[3] *Amicus curiae* National Black Farmers Association relies (at 8) on a webpage authored by counsel for plaintiffs in glyphosate personal injury suits, which purportedly identifies countries and localities that have banned or restricted glyphosate or intend to. Reference to that website shows these claims to be exaggerated and misleading. *See* Baum Hedlund, *Where Is Glyphosate Banned?*, https://www.baumhedlundlaw.com/toxic-tort-law/monsanto-roundup-lawsuit/where-is-glyphosate-banned-/ (Apr. 2021) (in Austria and Switzerland, for example, proposals to ban glyphosate were *rejected*).

the National Institute of Environmental Health Science—tracked health effects in over 54,000 pesticide applicators over the course of three decades. Analysis of that data confirmed there is "no evidence of an association between glyphosate use" and cancer. SER713. While EPA considered this study, IARC did not. 7-ER-1412, 1424; *see also* 6-ER-1142-55.

Despite this overwhelming scientific consensus, juries in three California tort cases returned verdicts against Monsanto in favor of plaintiffs with cancer, after being informed of IARC's determination. *See Hardeman v. Monsanto Co. (In re Roundup Prods. Liab. Litig.)*, 385 F. Supp. 3d 1042, 1044 (N.D. Cal. 2019). The district court overseeing the multi-district litigation in which the federal tort claims have been consolidated found it a "close question" whether the plaintiffs could even admit IARC's conclusion into evidence, as "[t]he evidence, viewed in its totality, seems too equivocal to support any firm conclusion that glyphosate causes" cancer. *In re Roundup*, 390 F. Supp. 3d at 1109, 1151; *see also id.* at 1108-09 ("[T]he largest and most recent [studies] suggest there is no link at all."). Although the district court permitted the plaintiffs to introduce the fact of IARC's glyphosate classification, SER51, and permitted Monsanto to advise the jury of EPA's contrary conclusion, it excluded as "cumulative" *all* findings of foreign regulators that glyphosate is non-

carcinogenic. *Id*.; SER64 n.5.[4] Monsanto's appeals in the one federal case and one of the two state court cases on which the Attorney General relies remain pending.

D. Proposition 65

California's Proposition 65 requires OEHHA to list as "known to cause cancer" all substances identified as human or animal carcinogens by any one of several entities, including IARC and EPA. Cal. Health & Safety Code § 25249.8(a); Cal. Labor Code § 6382(b)(1). Once such an agency finds that a chemical is potentially carcinogenic to humans, OEHHA *must* list the chemical, regardless of whether the cancer finding is an outlier and regardless of whether other agencies that Proposition 65 considers authoritative—or California's own regulators—disagree with it. Cal. Code Regs. tit. 27, § 25904(c).

[4] The two state court verdicts the Attorney General identifies (at 38-39) suffered from similar flaws. In *Johnson v. Monsanto*, the jury was also prevented from hearing of the consensus of expert regulators, as the trial court excluded the findings of all foreign regulators and most EPA reports as hearsay. Appellant's Opening Br. 68-69, 266 Cal. Rptr. 3d 111 (Ct. App. 2020) (No. A155940, A156706), 2019 WL 1871152. Moreover, the *Johnson* plaintiff's claim that his cancer was caused by glyphosate was "based on the testimony of" only *one* expert—Dr. Nabhan. SER224-25. That same expert was excluded on *Daubert* grounds by the federal district court at the general causation stage because the doctor "all but admitted that he reached his conclusion regarding glyphosate upon reading the IARC report, and that contrary new evidence was unlikely to shake his faith in IARC's conclusion." *In re Roundup*, 390 F. Supp. 3d at 1148. Dr. Nabhan also appeared in the second state court case, *Pilliod v. Monsanto*, but in that case he *expressly admitted* "that reasonable people can disagree on whether glyphosate causes NHL." 10-ER-2218.

After a chemical is listed, Proposition 65 requires that any "person in the course of doing business" provide a "clear and reasonable warning" before "expos[ing] any individual to" the listed chemical. Cal. Health & Safety Code § 25249.6. The Attorney General concedes that this warning must convey that the chemical "is 'known to the state to cause cancer[,]' or 'words to that effect.'" Br. 12 (alteration in original) (quoting Cal. Health & Safety Code § 25249.6 and *Dowhal*, 32 Cal. 4th at 918).

The only forms of warning that comply with that statutory requirement as a matter of law are OEHHA's core "safe harbor" warnings. Under OEHHA's regulations, Plaintiffs can shield themselves from threat of enforcement only if they adopt one of these two warnings:

⚠ **WARNING:** This product can expose you to chemicals including glyphosate, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

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

Cal. Code Regs. tit. 27, § 25603(a), (b); SER248-49 (¶ 42).

A business that departs from this safe harbor language risks a judicial finding that its warning does not clearly convey the required message. SER1011-15 (¶¶13-21).

Proposition 65 imposes penalties on businesses of up to $2,500 *per day* for *each* failure to provide the required warning. Cal. Health & Safety Code

§ 25249.7(b); *see also id.* §§ 25249.7(a), 25249.11(e) (authorizing injunctive relief). Claims may be brought by the Attorney General, a district attorney, or local government attorneys. *Id.* § 25249.7(c).

In addition, *any person* (even if they have not been injured) may bring a private enforcement action on behalf of the public interest. *Id.* § 25249.7(d). Such a private plaintiff—colloquially known as a "bounty hunter"—is entitled to a quarter of the civil penalties, plus attorneys' fees. Cal. Code Regs. tit. 11, §§ 3203(b), (d), 3201. There has been wide-scale and widely acknowledged abuse of the Proposition 65 regime through such bounty-hunter "strike suits." In the words of then-Governor Jerry Brown, the law has been abused by "unscrupulous lawyers driven by profit rather than public health." *See* SER716; *see also, e.g.*, SER718-19; SER728-29 (discussing bounty-hunter suits). For example, one plaintiff successfully sued Whole Foods for "selling firewood" without a warning. *Consumer Cause, Inc. v. Mrs. Gooch's Nat. Food Mkts., Inc.*, 127 Cal. App. 4th 387, 392 (2005). As California judges have noted, Proposition 65 allows even frivolous suits to result in "judicial extortion," forcing defendants to settle. *Consumer Cause, Inc. v. SmileCare*, 91 Cal. App. 4th 454, 477-79 (2001) (Vogel, J., dissenting); *see also Consumer Def. Grp. v. Rental Hous. Indus. Members*, 137 Cal. App. 4th 1185, 1216 (2006) (strike suits are "intended to frighten all but the most hardy of targets (certainly any small, ma and pa business) into a quick[] settlement").

The reason for this widespread abuse is straightforward—it is "absurdly easy" to initiate Proposition 65 litigation. *Consumer Def. Grp.*, 137 Cal. App. 4th. at 1215. Private parties must file a "certificate of merit" indicating a legitimate basis for their claim, Cal. Health & Safety Code § 25249.7(d)(1), but all that is required to satisfy that requirement is to identify any object that contains "a few molecules" of a listed substance, and obtain an expert's confirmation "that, at least *in sufficient quantities*, substances in those common objects will cause cancer, and are in fact on the list." 137 Cal. App. 4th at 1215. Additionally, although the California Attorney General may send "a letter" to a Proposition 65 plaintiff "stating the Attorney General believes there is no merit to the action," Cal. Health & Safety Code § 25249.7(e)(1)(A), that letter has no legal force, and private bounty hunters are free to ignore it—as they have done in past cases. *See* SER1009-11 (¶¶ 10-12).

This scheme presumes that any amount of the listed chemical in a product poses an actual cancer risk, and places the burden on the defendant to establish as an affirmative defense that the chemical "poses no significant risk assuming lifetime exposure at the level in question." Cal. Health & Safety Code § 25249.10(c). OEHHA may streamline this process by predetermining a "No Significant Risk Level" (NSRL) for a listed substance, but to establish this affirmative defense, the defendant still must prove that average exposure from its products will fall below the NSRL, *id.*; *DiPirro v. Bondo Corp.*, 153 Cal. App. 4th 150, 185 (2007), whereas

a bounty hunter "need not make *any showing at all*" that exposure will exceed the safe harbor before filing suit, *Consumer Cause*, 91 Cal. App. 4th at 469 (emphasis added) (citation omitted). Establishment of the affirmative defense, through the NSRL or otherwise, is a question of fact reliant on complex testing, scientific analyses, consumption surveys, and expert testimony—an expensive process that, for those few defendants obstinate enough to resist settlement, often drags on to trial. *See, e.g.*, *Envtl. Law Found. v. Beech-Nut Nutrition Corp.*, 235 Cal. App. 4th 307, 314 (2015) (safe harbor defense litigated at trial); *see also* SER1010-13 (¶¶11-17) (suit against McDonalds maintained for six years, even after Attorney General determined that exposure fell below NSRL); *Sciortino v. Pepsico, Inc*., 108 F. Supp. 3d 780, 786 (N.D. Cal. 2015) (bounty-hunter suit notwithstanding safe harbor NSRL). Faced with daunting litigation fees, the costs of expert assessments, and the risk of catastrophic statutory damages, most defendants logically "[s]ettle with the plaintiff," "[s]ave the cost of the assessment," "[s]ave the legal fees," and "[g]et rid of the case." *Consumer Cause*, 91 Cal. App. 4th at 478 (Vogel, J., dissenting).

E. OEHHA's Glyphosate Listing And NSRL

As a result of IARC's probable-carcinogen finding, on July 7, 2017, OEHHA listed glyphosate under Proposition 65. *See* SER732. Consistent with the automatic, "ministerial" nature of this listing, OEHHA refused to consider comments critiquing IARC's process and conclusion, and disclaimed any ability to address whether

glyphosate actually causes cancer or reassess "the weight or quality of the evidence considered by IARC." 6-ER-1256.

A year later (and six months after Plaintiffs filed this suit), on April 6, 2018, OEHHA established a safe harbor NSRL of 1100 micrograms per day for glyphosate. *See* 6-ER-1366; SER996; 6-ER-1262-1309.

F. Procedural History

Plaintiffs are a nationwide coalition of agricultural producers and business entities who manufacture and sell glyphosate products, and use glyphosate in their agricultural operations. They collectively represent a substantial segment of U.S. agriculture.

Plaintiffs filed this suit on November 15, 2017, bringing claims under the First Amendment, the Supremacy Clause, and the Due Process Clause, seeking declaratory and injunctive relief. *See* 11-ER-2296-330; 11-ER-2331-66. Plaintiffs asserted that despite the NSRL, Proposition 65's glyphosate warning requirement would have serious impacts on Plaintiffs and their members, forcing them either to communicate a disparaging health warning with which they disagree or to undertake continual tests of their products to determine whether glyphosate exposures from those products will fall below the NSRL—and incur the substantial risks of defending against enforcement actions. SER248-50, 254-55 (¶¶ 41-45, 55-56); SER1071-72 (¶¶ 13-16); SER1053-54 (¶¶ 9-10, 22); SER1063 (¶¶ 10-11). Shortly

thereafter, Plaintiffs moved for a preliminary injunction based solely on their First Amendment claim. *See* SER1181-1230. After briefing and oral argument, the district court granted that preliminary injunction. *See* 1-ER-57-58.

The district court first rejected the Attorney General's argument that this case was unripe because glyphosate exposures from Plaintiffs' pesticides and food products are highly unlikely to exceed the (then-proposed) NSRL. The court explained that bounty hunters "have brought enforcement actions for various chemicals notwithstanding a defense of compliance with the safe harbor level for those chemicals," and absent an injunction Plaintiffs would furthermore "be required to test their products to determine whether their products exceeded the safe harbor level, incurring the attendant costs, which in itself is a cognizable injury." 1-ER-45, 47.[5] Turning to the merits, the district court held that Plaintiffs were likely to succeed on their First Amendment claim because the warning that glyphosate is "known to the state of California to cause cancer" is "factually inaccurate and controversial" in light of "the heavy weight of evidence in the record that glyphosate is not in fact known to cause cancer." 1-ER-54, 55, 57. Notably, at the preliminary injunction hearing, the Attorney General *rejected* the possibility of an alternative

[5] The Attorney General no longer argues that this case is unripe. *See* Br. 28 (stating that warnings are "more likely to be required for occupational or other uses of glyphosate-based weedkillers").

Proposition 65 warning that would provide even a slightly more balanced description of the science, because that would impermissibly "dilute" the required core "safe harbor" warnings. SER1170 (51:3-7); *see also* SER1166-67 (47:16-19, 47:20-48:11).

Shortly thereafter, the Attorney General moved for reconsideration. This time, he proffered two alternative warnings that provided the additional context he had previously argued was noncompliant with Proposition 65. SER1108, 1115. The district court was unconvinced. It observed that it "appears that a warning properly characterizing the debate as to glyphosate's carcinogenicity would not comply with Proposition 65," 1-ER-67 n.7, and in any event the first proposed alternative warning was "not significantly different" from the already-rejected safe harbor warning, and the second one misleadingly "convey[ed] the message that there is equal weight of authority for and against the proposition that glyphosate causes cancer." 1-ER-63-64, 67.

The parties then filed cross motions for summary judgment. It was at that point—over two years after Plaintiffs filed this suit, and over a year after the warning requirement would have taken effect (but for the preliminary injunction)—that the Attorney General advanced his "warning option 3"—the Alternative Warning—that he now defends on appeal. It reads as follows:

> WARNING: This product can expose you to glyphosate. The State of California has determined that glyphosate is known to cause cancer

> under Proposition 65 because the International Agency for Research on Cancer has classified it as a carcinogen, concluding that there is sufficient evidence of carcinogenicity from studies in experimental animals and limited evidence in humans, and that it is probably carcinogenic to humans. The EPA has concluded that glyphosate is not likely to be carcinogenic to humans. For more information about glyphosate and Proposition 65, see www.P65warnings.ca.gov.

SER191; *see also* Br. 41.

The district court granted summary judgment in Plaintiffs' favor. The court concluded that "the most obvious reading of the Proposition 65 cancer warning"—that glyphosate is "known to the state of California to cause cancer"—"is that exposure to glyphosate in fact causes cancer." 1-ER-23–24 (citations omitted). And that message would be "misleading" to the "ordinary consumer," and thus ineligible for review under the *Zauderer* standard, since "[e]very regulator of which the court is aware, with the sole exception of the IARC, has found that glyphosate does not cause cancer or that there is insufficient evidence to show that it does." *Id.*

The district court also expressed serious concern with the Attorney General's continually shifting "alternative warnings." 1-ER-28. The court could not "condone the state's approach," in which having previously "rejected multiple alternative warnings" because they would impermissibly "'dilute'" the warning, the Attorney General "repeatedly propose[d] iterations of alternative warnings that the state would never allow under normal circumstances, absent this lawsuit." 1-ER-28–29 (citation omitted). The court remained skeptical that any of the three proposed

options complied with Proposition 65's requirements, but held that even if any were compliant with Proposition 65, they all violated the First Amendment. The court explained that none of the alternative warnings were eligible for streamlined review under *Zauderer* because, like the core Proposition 65 warning, they would all "mislead[]" consumers by communicating that glyphosate *in fact* causes cancer, and warnings "2" and "3" would also misleadingly "convey[] the message that there is equal weight of authority for and against the proposition that glyphosate causes cancer." 1-ER-29-31.

Finally, the district court held that the Attorney General could not meet his burden to show that any of the warnings could survive intermediate scrutiny under *Central Hudson*, because such "misleading statements about glyphosate's carcinogenicity" do not sufficiently advance California's articulated interest in informing consumers "'about exposures to chemicals that cause cancer.'" 1-ER-34 (citation omitted). The district court also found that the warning requirement failed narrow tailoring because California had other "options available to inform consumers of its determination that glyphosate is a carcinogen, without burdening the free speech of businesses," *e.g.*, by conveying its views about glyphosate through its own speech. *Id.*

The district court thus entered summary judgment in Plaintiffs' favor on their First Amendment claim, dismissed Plaintiffs' remaining claims without prejudice,

denied the Attorney General's cross-motion for summary judgment, and permanently enjoined the Attorney General and all persons in privity with him from enforcing Proposition 65's warning requirement for glyphosate. 1-ER-37-38. On September 9, 2020, the Attorney General filed a notice of appeal. 11-ER-2367-71.

SUMMARY OF THE ARGUMENT

Under the First Amendment, laws compelling private speech are presumptively unconstitutional, and the government bears the burden of justifying them. The district court correctly concluded that the Attorney General failed to satisfy that burden here.

For decades, national regulators worldwide have reaffirmed that glyphosate does *not* cause cancer. California's Proposition 65 nonetheless compels Plaintiffs to state that glyphosate is "known to the state of California to cause cancer," based on the outlier conclusion of a single international body that glyphosate probably causes cancer at some unknown measure of exposure. The district court held that this core "safe harbor" warning would convey the message that it is a known fact that glyphosate causes cancer—a message that is false and misleading, and at a minimum deeply controversial. The Attorney General does not contest that holding.

Instead, the Attorney General defends the constitutionality of a purported Alternative Warning that he first proposed on summary judgment, which adds limited additional context to the core warning. This Court can and should affirm

without addressing the constitutionality of this Alternative Warning, for two reasons. First, the proper focus of the First Amendment analysis is the speech that the government is seeking to *compel*—here, the core Proposition 65 warning—not whatever additional text the government might *permit* the speaker to append. Because the speech compelled is false and misleading, that ought to be the end of the inquiry. Second, the Alternative Warning is not an available alternative in any event because it would not comply with Proposition 65.

But even if the Alternative Warning were relevant to the First Amendment analysis and compliant with Proposition 65, it could not constitutionally be compelled. The Alternative Warning is not "purely factual" within the meaning of *Zauderer* because it continues to convey the misleading message that glyphosate probably causes cancer, or at minimum the misleading message that there is equal weight of support for and against the proposition that glyphosate causes cancer. The Alternative Warning is also not "uncontroversial" under *Zauderer* because it forces Plaintiffs to propagate a debate over glyphosate's carcinogenicity.

The Alternative Warning must therefore be evaluated under *Central Hudson*'s heightened scrutiny–and the district court correctly held that it cannot survive that scrutiny. Indeed, it fails at the threshold because the State has no legitimate interest, much less a substantial one, in forcing private parties to convey a misleading warning. But even if the Alternative Warning were not misleading, its conveyance

would not directly advance a substantial state interest. The Attorney General suggests that compelling this warning serves California residents' interest in being told of the findings of *any* of several organizations that a substance probably causes cancer—regardless of whether other organizations disagree. To the extent that could in theory qualify as a substantial interest, it is not the interest that Proposition 65 was enacted to serve. The Proposition 65 ballot summary assured voters that the law would address "chemicals that are scientifically known[,] not merely suspected, but known[] to cause cancer." 2-ER-121. The Alternative Warning is also more burdensome than necessary to advance the asserted informational interest. The Attorney General, who bears the burden of proof, provided no evidence whatsoever that the State could not serve its asserted interest through its own advertising campaign.

STANDARD OF REVIEW

This Court reviews *de novo* a district court's grant of summary judgment. *See Stevens v. CoreLogic, Inc.*, 899 F.3d 666, 672 (9th Cir. 2018).

ARGUMENT

A government seeking to regulate private speech has the burden to establish that those regulations are constitutional. *See Doe v. Harris*, 772 F.3d 563, 570 (9th Cir. 2014). The Attorney General must thus establish that the *Zauderer* standard of review applies. *See NIFLA*, 138 S. Ct. at 2377; *Am. Beverage Ass'n v. City & Cnty.*

of San Francisco (*ABA I*), 871 F.3d 884, 895 (9th Cir. 2017) ("The government must carry the burden of demonstrating that its disclosure requirement is purely factual and uncontroversial."), *on reh'g en banc*, 916 F.3d 749 (9th Cir. 2019); *see also Ibanez v. Fla. Dep't of Bus. & Pro. Reg.*, 512 U.S. 136, 142 n.7 (1994). And should he fail to do so, the Attorney General then must prove that the warning satisfies intermediate scrutiny under *Central Hudson*. *See CTIA – The Wireless Ass'n v. City of Berkeley*, 928 F.3d 832, 842 (9th Cir). Because the Attorney General failed to present evidence sufficient to establish either that the warning requirement at issue is eligible for review under the *Zauderer* standard or that it satisfies intermediate scrutiny, the district court correctly granted summary judgment in Plaintiffs' favor.

I. THE ATTORNEY GENERAL DOES NOT CONTEST THE DISTRICT COURT'S HOLDING THAT THE CORE PROPOSITION 65 WARNING VIOLATES THE FIRST AMENDMENT AS APPLIED TO GLYPHOSATE

As the district court explained, a reasonable consumer, reading the core required warning that glyphosate is "known to the state of California to cause cancer," would understand "that exposure to glyphosate in fact causes cancer." 1-ER-23-24 (citations omitted). And a reasonable consumer would not understand a substance to be "'known to cause cancer' where only one health organization had found that the substance in question causes cancer and virtually all other government agencies and health organizations … had found there was no evidence that it caused

cancer." 1-ER-24 (citation omitted). Accordingly, Proposition 65's core warning "is false and misleading when used for glyphosate." 1-ER-23.

That commonsense holding is plainly correct, and the Attorney General's opening brief does not contest it. For the reasons explained below, *infra*, at 29-38, that uncontested holding provides a sufficient basis for affirming the district court's judgment.

II. THE ATTORNEY GENERAL'S ALTERNATIVE WARNING IS A RED HERRING

Rather than defend the constitutionality of the only glyphosate warning required by Proposition 65, the Attorney General attempts to evade that issue by arguing that the Alternative Warning he devised in the course of this litigation is constitutionally permissible. As we explain below, *infra*, at 39-67, that argument is incorrect. But this Court need not reach that issue, for two reasons. First, what matters under the First Amendment is the language that Proposition 65 *compels*—not any additional qualifying language that Proposition 65 purportedly *permits*. And second, a warning containing this additional qualifying language would not comply with Proposition 65 regardless.

A. The Proper Focus Of The First Amendment Inquiry Is The Core Warning Compelled By Proposition 65

As the Attorney General acknowledges, the only speech that Proposition 65 *compels* is that glyphosate is "'known to the state to cause cancer,'" or "'words to

that effect.'" Br. 13 (quoting Cal. Health & Safety Code § 25249.6 and *Dowhal*, 32 Cal. 4th at 918). The supplemental text proffered by the Attorney General in the Alternative Warning is not required by the statute; it is, at best, clarifying language that Proposition 65 might *permit* a speaker to append.

But the scrutiny afforded a compelled speech requirement, and its lawfulness, depends on the text that the government forces the speaker to convey, not on whatever further text the government may allow the speaker to add to prevent listeners from being misled. This is necessarily so because the First Amendment harm arises from being forced to convey speech with which one disagrees, and that harm is not cured by allowing the speaker in the next breath to correct or disavow the misstatement they were compelled to make. To the contrary, it is well established "[t]hat kind of forced response is antithetical to the free discussion that the First Amendment seeks to foster." *Pac. Gas & Elec. Co. v. Public Utilities Comm'n of Cal.*, 475 U.S. 1, 16 (1986). As the Supreme Court has explained, a statute causes First Amendment harm where it forces a speaker "to tailor its speech to an opponent's agenda," and "respond to … arguments where the [speaker] might prefer to be silent." *Id.* at 10.

Neither the Supreme Court nor this Court—nor to our knowledge, any court—has *ever* suggested that the government may compel a misleading statement so long as it permits the speaker to simultaneously rebut that statement. To be sure, this

Court explained in *CTIA* that it was a virtue that the subject ordinance "allow[ed] a cell phone retailers to add to [a] compelled disclosure" if they were "concerned" that a term was inflammatory and misleading. 928 F.3d at 848. But this Court did *not* hold that the government can compel an otherwise misleading disclosure so long as the speakers are then permitted to append their own corrective text. To the contrary, the Court noted retailers' ability to add further text *only after* concluding that the compelled disclosure, as mandated, was *not* in fact misleading. *Id.* at 847-48. The same was true in *Milavetz, Gallop & Milavetz, P.A. v. United States*, where the Supreme Court found that "[o]ther information" that a speaker "must or may include in its advertisements ... provides additional assurance that consumers will not misunderstand the term"—but *only after* determining that the compelled statements themselves were not misleading. 559 U.S. 229, 251-52 (2010).

If the law were otherwise, governments could compel all manner of false, misleading, or one-sided statements so long as speakers were then allowed to disavow or rebut the falsities or provide necessary context. That cannot be right. If a state or municipality *compelled* vaccine manufacturers to warn that a "vaccine is known by the state to cause autism" whenever any of several named anti-vaccine organizations so concluded, that compelled warning would properly be understood to violate the First Amendment—even if manufacturers were *permitted* to append additional text documenting the overwhelming weight of authority that the vaccine

does not case autism. So too here, and for that reason this Court need not consider the Attorney General's additional proposed warning text in evaluating whether the compelled Proposition 65 warning violates the First Amendment.

B. California's Warning Does Not Comply With Proposition 65

This Court need not address the Alternative Warning for an additional reason: the Alternative Warning would not comply with Proposition 65. The Attorney General argues otherwise out of desperation. As the district court recognized, the Attorney General "would never allow" a warning such as this one "under normal circumstances, absent this lawsuit." 1-ER-29. And rightly not. This made-for-litigation warning is flatly inconsistent with California precedent, and OEHHA's and the Attorney General's own regulations. Proposition 65's application to glyphosate cannot be salvaged by jettisoning settled state law establishing the overall message that must be conveyed under the statute, and adopting instead a hollowed-out interpretation that would leave courts and businesses guessing what warning is lawful in the circumstances of each case.

1. Proposition 65 requires a warning that the chemical at issue causes cancer

The California Supreme Court has held that Proposition 65 requires a warning conveying that the "'product contains [chemical], a chemical known to the state of California to cause [cancer],' or words to that effect." *Dowhal*, 32 Cal. 4th at 918. As the district court recognized, such a warning conveys that it is a fact that the

chemical causes cancer. 1-ER-23. A warning that sends an equivocal message—that the chemical may or may not be a carcinogen—would not satisfy that requirement. *See* 1-ER-28–29. OEHHA's regulations accordingly make clear that a warning "may contain information that is supplemental to the content required … only to the extent that it identifies the source of the exposure or provides information on how to avoid or reduce exposure to the identified chemical or chemicals." Cal. Code Regs. tit. 27, § 25601(e).

Outside the context of this litigation, the Attorney General agrees strongly with that conclusion. The Attorney General's own regulations regarding permissible Proposition 65 settlements flatly prohibit use of diluting and qualifying language. They specify that the use of "additional words or phrases that contradict or obfuscate otherwise acceptable warning language" will prevent a warning from being "clear and reasonable" as required by the statute. Cal. Code Regs. tit. 11, § 3202(b); *see also People ex rel. Lockyer v. Tri-Union Seafoods*, No. CGC-01-402975, 2006 WL 1544384, at *61 (Cal. Super. Ct. May 11, 2006) (concluding that language that "dilutes the actual warning" is non-compliant, citing Attorney General's regulation), *aff'd*, 171 Cal. App. 4th 1549 (2009). And in keeping with that principle, the Attorney General's regulation specifically prohibits businesses even from "us[ing] ... the adverb 'may' to modify whether the chemical causes cancer." Cal. Code Regs.

tit. 11, § 3202(b).[6] If Proposition 65 forbids a warning stating that glyphosate "may" cause cancer, it necessarily forbids the use of language that would call glyphosate's carcinogenicity into even greater doubt, as the Alternative Warning would do by informing consumers that EPA believes glyphosate does *not* cause cancer. In fact, the Attorney General made precisely this point when he initially told the district court that Proposition 65 would not permit text informing consumers of an authoritative agency's contrary view, before reversing his position and offering the Alternative Warning. SER1167-70 (48:15-51:7) (arguing that disclosing contrary findings would impermissibly "dilute[] the warning"); 1-ER-28.

Likewise, the Alternative Warning recounts that IARC found "sufficient evidence" of carcinogenicity only in animals, concluded that there was only "limited evidence" of carcinogenicity in humans, and made only a finding of probable (not certain) carcinogenicity. Br. 41. While Plaintiffs agree those are steps in the direction of accuracy, this explanatory text also dilutes the core required message and thereby renders the Alternative Warning incompatible with the statute—once again, something the Attorney General previously recognized. SER1166 (47:16-19) (rejecting proposed warning "because talking about it being a carcinogen in animals

[6] A business is permitted to explain that its product "may" cause cancer if used in certain ways, but will not cause cancer if used in other ways, but it is forbidden to qualify the carcinogenicity of the underlying chemical itself by indicating that it "may" or may not cause cancer. Cal. Code Regs. tit. 11, § 3202(b).

tends to dilute the warning"); *see* SER1167; SER1117. That same problem would also doom any further litigation-inspired alternatives the Attorney General might propose: As the district court observed, "any glyphosate warning which does not compel a business to make misleading statements about glyphosate's carcinogenicity would likely violate the Attorney General's own guidelines for approval of Proposition 65 enforcement action settlements." 1-ER-28.[7]

2. The Attorney General cannot evade these established standards

This Court should reject the Attorney General's attempts to evade California precedent, OEHHA's implementing regulations, and his own regulations by pointing to judicial settlements permitting the use of plainly distinguishable "additional clarifying" information in a warning. Br. 14-15. None of the supplemental information in those warnings contradicted, obfuscated, or diluted the central Proposition 65 message that the substance at issue causes cancer.

For instance, the Attorney General settled litigation with makers of potato chips with an agreed-upon warning that the chemical acrylamide "is not added to

[7] That is not to say that California is barred from enforcing Proposition 65's warning requirement whenever outlier groups disagree with scientific consensus, nor that governments are categorically prohibited from requiring warnings in circumstances where science is still evolving. It means only that Proposition 65's unequivocal warning requirement is not suited to circumstances where there is a genuine and well-founded scientific disagreement about the carcinogenicity of the substance at issue.

these foods but is created when these and certain other foods are browned" and that "FDA has not advised people to stop eating potato crisps and/or potato chips [] or any foods containing acrylamide as a result of cooking." Br. 15 (alteration in original) (quoting 4-ER-672). But that language does not in any way qualify or dilute the core message that acrylamide is known to cause cancer. In the district court, the Attorney General also touted a Proposition 65 settlement warning applicable to mercury in fish, which includes language stating that "[f]ish and shellfish are an important part of a healthy diet and a source of essential nutrients." 3-ER-633. But again, that supplemental language says nothing to cast doubt on the core message that mercury causes developmental harm.[8]

The Attorney General also finds no support in the statutory text. He claims that businesses may add language so long as "the circumstances warrant" because Proposition 65 merely requires that a warning be "clear and reasonable." Br. 15. But the statutory terms "clear" and "reasonable" do not give companies license to convey something less than certainty about carcinogenic risk. To the contrary, as

[8] Below, the Attorney General also argued that the district court should ignore his regulation because it merely "provides guidelines that the Attorney General will consider in his review of Proposition 65 settlements." SER210. The Attorney General does not press that argument here, and for good reason: The regulation unquestionably reflects the Attorney General's considered interpretation of what the *statute* requires. *See Tri-Union*, 2006 WL 1544384, at *61 (citing regulation as authority on statute).

OEHHA has explained, the requirement of a "clear" warning means only that a company must "clearly communicate[] that the chemical in question is known to the State of California to cause cancer." SER120. And the word "reasonable" governs only "the method employed to *transmit* the message" (*i.e.*, the method must be "reasonably calculated to make the warning message available to the individual prior to exposure"). *Id.* (emphasis added). These terms *constrain* a company's leeway to experiment with the warning—they do not, as the Attorney General argues, authorize a company to dilute the warning.

3. If Proposition 65's warning requirement were as indeterminate as the Attorney General now contends, it would be unconstitutional for other reasons

Acceptance of the Attorney General's litigating position that Proposition 65 merely requires whatever warning is "clear and reasonable" under the circumstances, as determined "case-by-case" in enforcement proceedings, Br. 14, would create debilitating uncertainties and potential liability for regulated businesses. Whether the Attorney General would himself agree that any particular divergence from safe harbor language was permissible would be anybody's guess, and despite the Attorney General's suggestions to the contrary, he has no tools to prevent bounty-hunter suits in which state courts, themselves acting without guidance, would decide *ex post* what warning was required. The scheme the Attorney General envisions is neither workable nor constitutional. As one district

court recently held—noting that the use of non-safe-harbor warnings is expensive, deeply risky, and almost never undertaken—"[i]f the seas beyond the safe harbor are so perilous that no one risks a voyage, then the State has either compelled speech that it is not purely factual, or its regulations impose an undue burden." *Cal. Chamber of Com. v. Becerra*, No. 2:19-cv-02019-KJM-EFB, 2021 WL 1193829, at *14 (E.D. Cal. Mar. 30, 2021).

This dilemma highlights a further constitutional infirmity in the Attorney General's position. Although Plaintiffs believe that Proposition 65's warning requirement is perfectly clear—*see Dowhal*, 32 Cal. 4th at 918—if as the Attorney General argues, the requirements of Proposition 65 were infinitely malleable, they would also necessarily be unconstitutionally vague. Imposing serious penalties based on a disclosure law that fails to "specify precisely what disclosures [are] required" would, as the Supreme Court has explained, "raise significant due process concerns." *Zauderer*, 471 U.S. at 653 n.15; *see also Cal. Teachers Ass'n v. State Bd. of Educ.*, 271 F.3d 1141, 1150 (9th Cir. 2001) ("When First Amendment freedoms are at stake, courts apply the vagueness analysis more strictly, requiring statutes to provide a greater degree of specificity and clarity than would be necessary under ordinary due process principles."); *Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 793-94 (1988) (Supreme Court "could not agree to a measure that requires the speaker to prove 'reasonableness' case by case based upon what is

at best a loose interference that the fee might be too high," as such a burden-shifting framework operated in "direct contravention of the First Amendment's dictates"). Simply put, the government cannot constitutionally put the onus on businesses to divine the message that must be conveyed to both avoid liability and refrain from falsely slandering their own products.

III. THE ATTORNEY GENERAL'S ALTERNATIVE WARNING ALSO VIOLATES THE FIRST AMENDMENT

A. The Alternative Warning Is Not Eligible For Review Under *Zauderer*

1. The *Zauderer* standard of review applies only to purely factual and uncontroversial warnings

To qualify for review under the *Zauderer* standard, the government must show that it is compelling disclosure of only "purely factual and uncontroversial information." *NIFLA*, 138 S. Ct. at 2372 (quoting *Zauderer*, 471 U.S. at 651).[9] In other words, this standard applies *only* when the government establishes that the compelled disclosure constitutes "straightforward, evenhanded, and readily understood" information—for instance, the product's ingredients, nutritional content, or geographic origin. *Am. Meat Inst. v. U.S. Dep't of Agric.* (*AMI*), 760

[9] The only compelled disclosures that the Supreme Court has upheld under *Zauderer* are those mandated to prevent consumer deception. Although this Court has held that disclosures compelled to advance other interests can also be eligible for review under *Zauderer*, Plaintiffs disagree and preserve their argument for further review.

F.3d 18, 34 (D.C. Cir. 2014) (en banc) (Kavanaugh, J., concurring in the judgment); *see id.* ("[T]he Government must show that the disclosure is purely factual, uncontroversial, not unduly burdensome, and reasonably related to the Government's interest."); *see also id.* (noting agreement with majority on that point).

Obviously, to be "purely factual," the disclosure must "'provide[] accurate factual information.'" *ABA I*, 871 F.3d at 893 (citation omitted). But even a compelled statement that is "literally true" cannot be considered purely factual if it is "misleading and, in that sense, untrue." *CTIA*, 928 F.3d at 847. *NIFLA* confirmed, moreover, that the disclosure must be both "purely factual" *and* "uncontroversial." 138 S. Ct. at 2372 (citation omitted). Thus, a disclosure cannot be one-sided, *see AMI*, 760 F.3d at 22, 27; incomplete, *see id.* at 27; or subject to misinterpretation, *see R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1216-17 (D.C. Cir. 2012), *overruled in part on other grounds by AMI*, 760 F.3d at 22-23. A "disputed" message as to which there is no scientific consensus also does not qualify as factual and uncontroversial. *ABA I*, 871 F.3d at 895-96.

In determining whether a warning is purely factual and uncontroversial, what matters is the message that consumers will understand the warning to convey. *See, e.g.*, *CTIA*, 928 F.3d at 846-48. Just as in the analogous context of false advertising, this need not mean that a statement will mislead *all* consumers, but instead that it will *tend* to mislead—or, put differently, that it could mislead a reasonable

consumer. *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 287 (D.C. Cir. 2019) ("In evaluating regulation of commercial speech to prevent misleading claims" in the analogous false advertising context, courts "look to whether 'consumers acting reasonably under the circumstances' would understand a product claim to contain a false message.") (citation omitted)); *cf. Zauderer*, 471 U.S. at 652-53 ("When the possibility of deception is as self-evident as it is in this case, we need not require the State to 'conduct a survey of the … public before it [may] determine that the [advertisement] had a *tendency to mislead*.'" (alterations in original) (citation omitted) (emphasis added)).[10] Finally, in considering whether compelled speech is misleading, courts must consider how that speech would be understood "not just [by] those with sophisticated levels of health literacy," but by "unsophisticated consumers" as well. *Am. Beverage Ass'n v. City & Cnty. of San Francisco (ABA II)*, 916 F.3d 749, 766 (9th Cir. 2019) (Christen, J., concurring in part and in the judgment).

[10] In the false advertising context, it is sufficient to show that a significant minority of consumers would be misled by a statement. *See POM Wonderful, LLC v. FTC*, 777 F.3d 478, 490 (D.C. Cir. 2015); *see also ECM BioFilms, Inc. v. FTC*, 851 F.3d 599, 610-11 (6th Cir. 2017). The same standard should be applied in the compelled speech context, as the government should not be able to force a business to convey a denigrating statement about its products that would be punishable as false advertising if made voluntarily about its products by a competitor.

2. The district court correctly held that the Alternative Warning is ineligible for review under the *Zauderer* standard because it is misleading and, at a minimum, controversial

The Alternative Warning is both false and misleading, and at a minimum forces Plaintiffs to convey viewpoints about which there is vigorous and well-founded scientific disagreement. For those reasons, as the district court held, the warning is not "purely factual and uncontroversial" and is ineligible for review under the *Zauderer* standard.

a. The Alternative Warning is misleading

As the district court concluded, the Alternative Warning is misleading because it "states that glyphosate is known to cause cancer and conveys the message that there is equal weight for and against the authority that glyphosate causes cancer, when the weight of evidence is that glyphosate does not cause cancer." 1-ER-31. That conclusion was correct.

The Alternative Warning fails to cure the central flaw in the safe harbor Proposition 65 warnings: It retains (as it must, by law) the statement that "glyphosate is known to cause cancer." Br. 41. Knowledge means a perception of truth. *See Know*, Merriam-Webster's Collegiate Dictionary (10th ed. 1993). And "cause" means a "reason for an action or condition." *Cause*, Merriam-Webster's Collegiate Dictionary (10th ed. 1993). To state that glyphosate is "known" by California to "cause" cancer thus conveys that it is a known fact that glyphosate

causes cancer, and in light of the overwhelming consensus to the contrary, that message is inaccurate and misleading. As the district court explained, even if it were "literally true that California technically 'knows' that glyphosate causes cancer as the State has defined that term in [Proposition 65] and regulations, the required warning would nonetheless be misleading to the ordinary consumer" because "'the most obvious reading of the Proposition 65 cancer warning is that exposure to glyphosate in fact causes cancer.'" 1-ER-23–24 (citation omitted).

This message is misleading because, in reality, the heavy weight of authority is that glyphosate does *not* cause cancer—as the EPA, and the expert regulators of Canada, Australia, Germany, the EU, New Zealand, Japan, South Korea, and even California's OEHHA have determined. *See supra,* at 9-10. Indeed, EPA has gone so far as to state that a product labeled with the statement that glyphosate is known to cause cancer would be *mislabeled* under FIFRA. *Supra*, at 12.

The Attorney General attempts to muddy the waters by questioning (at 31) "the methodology and conclusions of two of the[se] agencies: [the European Food Safety Authority (EFSA)] and EPA." He points to a letter ostensibly authored by "[n]inety-four independent scientists" critiquing the findings of the European Food Safety Authority. *Id.* But that letter was drafted by a *single* individual, Christopher Portier, who was at the time a paid plaintiffs' consultant in the glyphosate personal injury litigation and solicited the letter's other signatories without disclosing to them

his financial stake in the issue—and regardless, EFSA later considered and addressed the letter's criticisms. *See* SER84, 87; SER106. The Attorney General's attacks on EPA's process have similarly been addressed and rejected by EPA, and in any event do nothing to establish that glyphosate is "known" to cause cancer. *See supra,* at 12-13. And the Attorney General does not even attempt to take on the many other regulators, from Germany to Canada to New Zealand, who agree that glyphosate does not cause cancer in humans.[11]

Finally, the Attorney General's citation of a handful of jury verdicts in personal-injury cases does not come close to satisfying his burden to prove that a "known to cause cancer" warning for glyphosate is "purely factual and uncontroversial." Br. 40-43 (citations omitted). As discussed *supra*, at 14-15, these personal-injury verdicts—most of which remain pending on appeal—do not mean that it is an established fact that glyphosate causes cancer, especially given the

[11] The Attorney General and his amici also cast aspersions on the integrity of industry-funded research. Br. 33; Amicus Natural Resources Defense Council Br. 27-29, 37-38. But the notion that Plaintiffs "manufactured" a factual controversy from whole cloth is entirely ungrounded and refuted by the independent analyses undertaken by numerous national regulatory agencies. *See Hardeman v. Monsanto Co. (In re Roundup Prods. Liab. Litig.)*, 385 F. Supp. 3d 1042, 1047 (N.D. Cal. 2019) (finding "[plaintiff] did not present evidence that Monsanto hid evidence from the EPA or, alternatively, that it had managed to capture the EPA"); *see also* SER5 (EPA noting similar charges "did not result in changes to the agency's risk assessment").

contrary consensus of expert regulators who have intensively studied the issue. *See* 1-ER-27.[12]

The Attorney General protests, however, that even if the first stanza of the warning is misleading, each individual statement within the Alternative Warning is literally true and its additional qualifying text renders the overall warning non-misleading. To the extent the Attorney General is arguing that compelled speech need only be literally true to qualify for *Zauderer* review, this Court in *CTIA* squarely held that a "literally true" statement is "untrue" if it is "nonetheless misleading." *CTIA,* 928 F.3d at 847. And here, the additional text in the Alternative Warning, at absolute best, renders the warning's initial line literally true only in a hyper-technical way that no ordinary consumer would understand. It also compounds the problems by introducing further messages that also mislead. To take the text in order:

First, the Attorney General cannot rescue the Alternative Warning by specifying that "glyphosate is known to cause cancer *under Proposition 65*." Br. 41 (emphasis added). A clever lawyer might perhaps recognize that this language alludes to the statutory definition of "known to cause cancer" under a law known as

[12] The preliminary settlement in the federal multidistrict litigation cited by the Attorney General also provides no support for the Attorney General's position. Br. 73 & n.97. That a company faced with thousands of lawsuits should choose to settle those cases without admission of fault rather than risk the costs and risks of unending jury trials hardly establishes that glyphosate is known to cause cancer.

Proposition 65, and so conclude that the phrase *does not* in fact convey the ordinary English meaning of its text. But as the district court explained, "[o]rdinary consumers do not interpret warnings in accordance with a complex web of statutes, regulations, and court decisions, and the most obvious reading of the Proposition 65 cancer warning is that exposure to glyphosate in fact causes cancer." 1-ER-24; *cf. ABA II*, 916 F.3d at 766 (Christen, J., concurring in part and concurring in the judgment) (City's "contention that a reasonable person would understand San Francisco's intended message [was] in tension with the goal of having a public health message understood by the maximum number of consumers, not just those with sophisticated levels of health literacy"). The government cannot compel false speech by defining words to mean something other than what they convey in plain English. *See Nat'l Ass'n of Mfrs. v. SEC*, 800 F.3d 518, 529-30 (D.C. Cir. 2015) (rejecting government's argument that a warning accurately described a product as not "conflict free" as that term was defined in the relevant statute, because if that argument were accepted "there would be no end to the government's ability to skew public debate by forcing companies to use the government's preferred language"); *id.* at 540 (Srinivasan, J., dissenting) (acknowledging that government does not have "carte blanche to compel commercial speakers to voice any prescribed set of words as long as the words are defined by statute or regulation").

Second, it makes no difference that the Alternative Warning adds that California knows that glyphosate causes cancer under Proposition 65 "*because the International Agency for Research on Cancer has classified it as a carcinogen*." Br. 41 (emphasis added). The clear import of the sentence remains that California "knows" that glyphosate "causes" cancer *because it causes cancer*. If anything, this language reinforces the gravity of the misleading message by referencing a finding of carcinogenicity by an entity whose name suggests authoritative scientific expertise. True, the statement goes on to explain the basis for IARC's classification, and to note that its actual finding was that glyphosate is "probably carcinogenic to humans." But even then, it misleads because it fails to acknowledge that IARC made only a "hazard" finding, not a finding that glyphosate entails an actual "risk" of cancer to humans at real-world exposure levels. *See supra*, at 10-11.

This risk-hazard distinction—much emphasized by the Attorney General, *see* Br. 28-31—underscores an additional way in which both the safe harbor warnings and the Alternative Warning are misleading. As the Attorney General concedes, IARC made *only* a "hazard" finding—that is, that at *some* theoretical level of exposure, glyphosate is probably capable of causing cancer. Br. 30. IARC did not, however, evaluate "risk"—that is, whether there is any "likelihood cancer will occur" at realistic exposure levels. *Id.* (quoting *Monsanto Co. v. OEHHA,* 22 Cal.

App. 5th 534, 541 (2018)); Br. 31 (acknowledging IARC "does not purport to address whether glyphosate presents a cancer risk at typical exposure levels").[13]

The core Proposition 65 warning and the Alternative Warning, however, are *risk* warnings: any reasonable consumer would interpret those warnings to indicate that glyphosate poses a cancer risk in the real world, *i.e.*, *at levels to which they might plausibly be exposed*. *See Cal. Chamber of Com.*, 2021 WL 1193829, at *13 ("People who read the safe harbor warning will probably believe that [the product] increases their personal risk of cancer."). After all, why would the government require a business to warn that a substance is "known" to cause cancer, if it presents no actual risk?

At times, the Attorney General appears to imply that although *IARC* never conducted a risk assessment, California's OEHHA later conducted one as part of the NSRL process and concluded that glyphosate in fact poses a risk of cancer. *See, e.g.*, Br. 25-27. But OEHHA made no independent finding of cancer hazard or risk. When considering the NSRL, OEHHA steadfastly refused to evaluate the validity of "IARC's scientific conclusions" regarding cancer hazard, explaining that comments

[13] Numerous national-level regulators, including EPA, the European Chemical Agency, the European Food Safety Authority, and the New Zealand Environmental Protection Agency, have concluded that glyphosate does not pose even a cancer *hazard*—as the Attorney General concedes. *See supra*, at 8-14; Br. 28-29, 31. No governmental regulator has ever found that glyphosate *does* pose a hazard.

addressing that issue were "not directed to the subject of this rulemaking." 6-ER-1263–64; *see* 6-ER-1263 (contrary "conclusions of other international regulatory or scientific bodies" outside scope of rulemaking). Indeed, to the extent OEHHA ever evaluated the hazard question, it expressly found in 1997 and 2007 that glyphosate does not cause cancer—findings that it has never disavowed. *See* SER359; SER372

In the NSRL process, OEHHA did determine that there is *no* significant risk *below* the NSRL, Cal. Code Regs. tit. 27, § 25701(b)(3)(A), but it never determined that there *is* any risk *above* the NSRL. *See Baxter Healthcare Corp. v. Denton*, 120 Cal. App. 4th 333, 358 (2004) (An "NSRL is only a determination that an exposure below the level is not a significant risk. In OEHHA's words, its establishment of a NSRL 'expressly is not a determination that any level above the NSRL poses a significant risk.'"); *see also* Cal. Code of Regs. tit. 27, § 25701(d). By law, moreover, when developing the NSRL OEHHA felt constrained to rely on the same narrow set of studies that IARC itself considered, and further considered itself bound to rely on the *single* study (among the eight that IARC relied on) that produced the most conservative (*i.e.*, sensitive) results. 6-ER-1269–71. OEHHA therefore merely identified a single mouse study on which IARC relied as the "most sensitive study deemed to be of sufficient quality," Cal. Code Regs. tit. 27, § 25703(a)(3), and derived the NSRL for glyphosate based on data in that one study. *See* 6-ER-1267–

68 & n.24.[14] OEHHA did not weigh these studies against others to determine whether, in fact, glyphosate poses an actual cancer risk at a plausible level of exposure. *See* 6-ER-1280–81.

Third, the Alternative Warning's next sentence, mentioning that "EPA has concluded that glyphosate is not likely to be carcinogenic to humans," Br. 41, does not come close to balancing the scales. As an initial matter, the Alternative Warning buries the lede by noting EPA's contrary view only at the tail end of a detailed cancer warning. And it compounds that problem by describing EPA's conclusion with the tentative-sounding "is not likely to be carcinogenic to humans."[15] Juxtaposed against the leading, more detailed, and far more forceful language warning that glyphosate is "known to cause cancer" and that IARC "has classified it as a carcinogen," this perfunctory 14-word acknowledgement of EPA's position at the bottom of the Alternative Warning is not designed or likely to create an evenhanded

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[14] In 2004, the WHO's International Programme on Chemical Safety and the United Nation's Food and Agriculture Organization reviewed that same mouse study, concluding that it did *not* support carcinogenicity, and "produced no signs of carcinogenic potential at any dose." SER1001.

[15] "Not likely to be carcinogenic" is the lowest classification that EPA applies to any substance; it is used only when the "available data are considered robust for deciding that there is no basis for human hazard concern." EPA, *Evaluating Pesticides for Carcinogenic Potential*, https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/evaluating-pesticides-carcinogenic-potential (visited May 12, 2021).

impression. Indeed, one legitimately wonders how many consumers would reach the end of this nearly 100-word warning to learn of EPA's findings.

In addition to these problems, by mentioning only EPA's contrary finding—and omitting the fact that EPA explicitly considered and rejected IARC's conclusion after reviewing a far broader scope of scientific studies, *see supra,* at 12-13, and that a host of national regulators unanimously agree with EPA that glyphosate does not cause cancer—the warning adds yet another layer of deception because it "conveys the message that there is equal weight for and against the authority that glyphosate causes cancer, when the weight of evidence is that glyphosate does not cause cancer." 1-ER-31; *see also Amidon v. Student Ass'n of SUNY*, 508 F.3d 94, 101 (2d Cir. 2007) (holding that the amount of space "allocated to a [controversial view], whether a lot or a little, can skew [the] debate on issues" unconstitutionally); *AMI*, 760 F.3d at 27 (compelled disclosure is controversial if it is "one-sided [and] incomplete").[16] Worse still, by listing California *and* IARC on one side of the scale and only EPA on the other, the Alternative Warning conveys the misleading impression that EPA's view is the minority one.

[16] Indeed, the jury verdicts on which the Attorney General relies highlight the risk that ordinary consumers, when presented with information conveying that IARC has determined that glyphosate causes cancer while EPA has determined the opposite—and not being told of the worldwide scientific consensus favoring EPA's view—will erroneously conclude that glyphosate causes cancer.

The Attorney General argues that he has reasonably excluded from the Alternative Warning mention of the other national regulators that agree with EPA because those agencies are not considered "authoritative" *under Proposition 65 itself*. Br. 57. But California cannot by statute limit what evidence is relevant under the First Amendment. Regardless of what agencies California has chosen as triggers for Proposition 65's warning requirement, the Alternative Warning's omission of the worldwide regulatory consensus that glyphosate does not cause cancer renders its summary of the science misleading.[17]

The Attorney General faults Plaintiffs for "provid[ing] no evidence that the average Californian would consider the warning misleading" and argues that "no evidence presented to the district court supported the court's view that the typical Californian would assume the warning to suggest the existence of a scientific consensus regarding glyphosate's carcinogenicity." Br. 53, 62. But that puts things backwards. It was the *Attorney General* who had the burden under the First Amendment to produce evidence to justify California's compelled speech requirement. *Supra,* at 27-28. The Attorney General could have attempted to carry that burden by running a survey to test whether the Alternative Warning would

[17] The Attorney General suggests that recognizing this overwhelming consensus would represent "a 'count-the-noses' approach." Br. 63. But it is not counting noses to believe it material that *all* national regulators to have independently examined glyphosate have concluded it does not cause cancer in humans.

convey the nuanced, even-handed message he claims. That is the way the party with the burden of proof ordinarily seeks to establish how consumers understand contested speech. *See*, *e.g.*, *Rice v. Fox Broad. Co.*, 330 F.3d 1170, 1182 n.8 (9th Cir. 2003) (holding that plaintiff with burden of proof in false advertising case must "prove that defendants' statements are misleading to a reasonable consumer" to withstand summary judgment, and must "demonstrate by extrinsic evidence, such as consumer survey evidence, that the challenged statements tend to mislead consumers"). But the Attorney General introduced no survey evidence, or any other evidence, to carry his burden.

b. At a minimum, the Alternative Warning is "controversial"

Although the district court did not need to reach the issue, the Alternative Warning is also ineligible for review under *Zauderer* because, at a bare minimum, it conveys highly controversial, fiercely contested opinions. Statements within the Alternative Warning are "controversial" in the sense that they are subject to "disagree[ment]" regarding "the truth of the facts required to be disclosed." *AMI*, 760 F.3d at 27.

A "disputed" message as to which there is fierce disagreement cannot be deemed "uncontroversial." *ABA I*, 871 F.3d at 895-96. That is, the government cannot under *Zauderer* compel disclosure of purported "facts" over which there is significant room for disagreement, either directly ("Controversial Fact X is true") or

indirectly ("The Government has concluded that Controversial Fact X is true."). *See Nat'l Ass'n of Mfrs.*, 800 F.3d at 537 (Srinivasan, J., dissenting) (conceding that, under *Zauderer*, "the government cannot attempt to prescribe, under the guise of requiring disclosure of 'purely factual' information, … '*matters of opinion*.'" (citation omitted)).

The Alternative Warning also flunks this requirement. The Alternative Warning conveys IARC's opinion that glyphosate is a probable human carcinogen, an outlier view that has been rejected by EPA and a host of other national regulators. The Alternative Warning also conveys the message that California believes IARC is right and EPA is wrong on this question. Because the Alternative Warning would require Plaintiffs to convey IARC's and California's highly controversial opinions, it bears no resemblance to the sorts of "purely factual and uncontroversial" statements that are eligible for review under the *Zauderer* standard.

The Attorney General argues that the Alternative Warning merely "presents in summary form the findings" of EPA and IARC, and asserts that there is nothing controversial in evenhandedly disclosing the views of both authorities and noting disagreement. Br. 57. That is wrong, for several reasons. First, the Alternative Warning still forces Plaintiffs to convey IARC's controversial carcinogenicity finding, even if it then allows them to add that EPA disagrees. Second, for all the

reasons discussed above, the warning is not evenhanded; it places a heavy thumb on the scale in favor of the view that glyphosate causes cancer. *Supra,* at 42-51.

Third, even if the Alternative Warning accurately framed IARC's view, forcing a private party to wade publicly into a heated controversy and broadcast a summary of the competing views, including government opinions with which the speaker strongly disagrees, is a far cry from the unremarkable disclosure laws that are reviewed under *Zauderer.* *Zauderer* provides a streamlined standard of review for the compelled disclosure only of simple facts whose accuracy is not controversial—such as calorie counts, country-of-origin designations, ingredient listings, that an entity is a "debt relief agency" providing particular services, whether a product contains mercury, or that a litigant may have to pay court costs. *See, e.g.*, *Milavetz*, 559 U.S. at 249-50; *Loan Payment Admin. LLC v. Hubanks*, 821 F. App'x 687, 689 (9th Cir. 2020); *Nat'l Elec. Mfts. Ass'n v. Sorrell*, 272 F.3d 104, 107 (2d Cir. 2001); *AMI*, 760 F.3d at 27; *New York State Rest. Ass'n v. New York City Bd. of Health*, 556 F.3d 114, 131-32 (2d Cir. 2009); *Zauderer*, 471 U.S. at 650-51. But compelling private parties to summarize and convey conflicting views (including views with which the speaker strongly disagrees) is qualitatively different, and intrudes more profoundly into their First Amendment freedoms. There may be exceptional circumstances where the government can lawfully compel such disclosures, but at a minimum such a law must satisfy heightened scrutiny.

This Court's decision in *CTIA,* 928 F.3d 832, is not to the contrary. To begin with, as the district court recognized (1-ER-31-32), the facts there could not be less like those in this case. Berkeley's compelled disclosure merely "require[d] cell phone retailers to disclose, in summary form, the information to consumers that the FCC already requires cell phone manufacturers to disclose." 928 F.3d at 841. This case involves the opposite circumstance: EPA has made clear its view that Proposition 65's cancer warning for glyphosate would be false and misleading. *See supra*, at 12.

The Attorney General argues that this Court found that Berkeley's compelled disclosure went further than that and conveyed that cellphone radiation poses health risks, and yet the Court held "the existence of a scientific disagreement d[id] not create a 'controversy' within the meaning of the First Amendment." Br. 44. But that is not a faithful reading of the case: In so arguing, the Attorney General embraces a view of Berkeley's required disclosure that the majority opinion *rejected* (and the dissent embraced). Key to *CTIA*'s holding was the majority's conclusion that the text did not take a stand on that "inflammatory" issue, and merely repeated the federal government's advice as to how to avoid overexposure to RF radiation without suggesting that failure to take those measures would be dangerous. As the majority opinion explained, it was only "*[b]ecause* [the Court had] determined that the disclosure is factual and not misleading," that it rejected "CTIA's argument that

the disclosure is controversial" within the meaning of *Zauderer*. *CTIA*, 928 F.3d at 848 (emphasis added). And it was on that ground that the Court concluded that having to convey the FCC's advice about how to assure safety in the use of cell phones did not require a retailer to take sides in the wider debate about cell phone safety. *Id.* at 846-48. Not so here, where Proposition 65 would force Plaintiffs to state that a chemical in their products is known to cause cancer.[18] Nothing in *CTIA* suggests that a warning of this sort is suitable for streamlined review under *Zauderer*.

3. The Attorney General's other efforts to evade heightened scrutiny are meritless

The Attorney General advances a number of additional arguments why, in his view, the Alternative Warning should not be subject to heightened First Amendment scrutiny. None are persuasive. First, the Attorney General attacks a straw man by arguing that the First Amendment "does not prohibit compelled disclosures relating to any topic over which there exists some scientific disagreement." Br. 58. But as noted above, this case does not present the question of how much acceptance a scientific position must enjoy before it becomes a fact that the government can

[18] As the district court pointed out, the warning here is far more similar to the original cell phone warning required in a related case, which would have required businesses to state that "THE WORLD HEALTH ORGANIZATION HAS CLASSIFIED RF ENERGY AS A POSSIBLE CARCINOGEN"—and which this Court struck down in an unpublished memorandum. 1-ER-32 (quoting *CTIA – The Wireless Ass'n v. City & Cnty. of San Francisco*, 827 F. Supp. 2d 1054, 1058 (N.D. Cal. 2011), *aff'd*, 494 F. App'x 752 (9th Cir. 2012)).

compel private parties to disseminate. This is not a circumstance in which the compelled statement is the consensus view, with only fringe "scientific disagreement" on the other side of the debate. It is the opposite: The vast weight of authority *disagrees* with the proposition that glyphosate causes cancer. *See supra*, at 8-14.

The Attorney General attacks a different straw man when he asserts (at 59) that the district court's reasoning would necessarily doom any compelled warning regarding emerging risks about which there is not yet a scientific consensus. A law compelling such a warning might well satisfy heightened scrutiny—indeed, that is likely true of early warnings regarding the danger of cigarettes. *Zauderer*, however, is not the appropriate standard of review for such warnings. And, of course, nothing prevents California from using its own speech to warn consumers about any substance that it believes to pose an emerging risk.

The Attorney General also argues (at 64-67) that the Alternative Warning must be considered factual and uncontroversial because it conveys information that is similar to that provided by several federal agencies. This argument is misleading. *None* of those agencies has concluded or required businesses to state that glyphosate causes or is known to cause cancer. The fact that some agencies, *in their own factsheets*, include IARC's conclusion regarding glyphosate (along with the contrary findings from regulators around the world) has no bearing on this First Amendment

analysis. *See Johanns v. Livestock Mktg. Ass'n*, 544 U.S. 550, 553 (2005) ("[T]he Government's own speech … is exempt from First Amendment scrutiny."). That OSHA requires businesses to offer Safety Data Sheets that include information on IARC's glyphosate determination (Br. 20-21) is also beside the point: Monsanto's Safety Data Sheet for its glyphosate product states that the product is *not* "carcinogenic in rats or mice," and that IARC's "classification as a carcinogen is not warranted." 6-ER-1243. That contradictory language is presumably why the Attorney General is careful to note that he has not "assessed whether Monsanto's Safety Data Sheet" would comply with Proposition 65. Br. 21 n.24; *see* Br. 65 n.89.

The Attorney General's reliance on Monsanto's agreement, in the proposed settlement of federal multidistrict litigation, to request permission from EPA to include on its pesticide labeling an Internet link to a website setting forth publicly available science on glyphosate, including the detailed reviews of worldwide regulators,[19] is equally unavailing. Br. 73. Contrary to the Attorney General's suggestion, that proposed disclosure—which would be voluntary and involve no Plaintiffs aside from Monsanto—bears no meaningful resemblance to the Alternative Warning. Most obviously, it would not require Monsanto to suggest that

[19] *See* Settlement Agreement, art. IX, attached to Mot. for Prelim. Approval of Proposed Class Settlement, *In re Roundup Prods. Liab. Litig.*, Case No. 3:16-md-02741 (N.D. Cal. Feb. 3, 2021), https://www.lieffcabraser.com/pdf/Class_Plan_Documents.pdf.

glyphosate is known to cause cancer. Instead, it would simply and without comment point to the science, which overwhelmingly concludes the opposite.

The Attorney General, finally, seeks refuge in *NIFLA*'s statement that the Court did "not question the legality of health and safety warnings long considered permissible, or purely factual and uncontroversial disclosures about commercial products." 138 S. Ct. at 2376. But faithfully applying *Zauderer*'s "purely factual and uncontroversial" standard does not threaten "health and safety warnings long considered permissible." *See id.* at 2380-81 (Breyer, J., dissenting) (citing, e.g., Cal. Veh. Code Ann. § 27363.5 (requiring hospitals to tell parents about child seat belts); N.Y.C. Rules & Regs., tit. 1, § 27-01 (requiring signs by elevators showing stair locations); San Francisco Dep't of Health, Director's Rules & Regs., Garbage & Refuse (July 8, 2010), https://www.sfdph.org/dph/files/EHSdocs/SolidWaste/RefuseService.pdf (requiring property owners to inform tenants about garbage disposal procedures)); *see also New York Rest. Ass'n*, 556 F.3d at 131-34 (upholding requirement to post calorie counts); *Sorrell*, 272 F.3d at 107 (upholding requirement to disclose that products contain mercury). The Alternative Warning is decidedly unlike those longstanding health and safety warnings, because it conveys a view that is contrary to the established consensus of every national regulator to study the question.

To the extent the Attorney General simply believes that compelled health warnings should be given greater leeway, and not be subject to rigorous standards of accuracy and evenhandedness, his quarrel is with the Constitution itself. As the Supreme Court recently emphasized, "'[p]recision ... must be the touchstone' when it comes to regulations of speech." *NIFLA*, 138 S. Ct. at 2376 (citation omitted). "Insisting that compelled speech be purely factual may seem persnickety, but there are significant constitutional implications whenever the government seeks to control our speech." *ABA II*, 916 F.3d at 767 (Christen, J., concurring in part and concurring in the judgment). Accordingly, when "the government takes the momentous step of mandating that its message be delivered by private parties, it is exceptionally important that the compelled speech be purely factual." *Id.* The Alternative Warning fails that test.

B. The Alternative Warning Fails *Central Hudson* Review

Because the Alternative Warning does not qualify for *Zauderer* review, it is subject to heightened scrutiny under *Central Hudson*. To meet that standard, the Attorney General must show a "substantial" government interest that its regulation "directly" advances through burdens on speech no more "extensive than ... necessary to serve that interest." *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566 (1980).

1. Requiring Plaintiffs to convey the Alternative Warning would not advance a substantial government interest

The Attorney General cannot carry his burden to show that the Alternative Warning directly advances a substantial governmental interest.

First, and fundamentally, California has "no legitimate reason to force retailers to affix false information on their products." *Video Software Dealers Ass'n v. Schwarzenegger*, 556 F.3d 950, 967 (9th Cir. 2009), *aff'd sub nom. Brown v. Ent. Merchs. Ass'n*, 564 U.S. 786 (2011); *see also ABA I*, 871 F.3d at 898 n.12; *CTIA*, 928 F.3d at 854 (9th Cir.) (Friedland, J., dissenting in part) ("The First Amendment clearly does not permit the government to force businesses to make false or misleading statements about their products."); *Nat'l Ass'n of Mfrs.*, 800 F.3d at 539 (Srinivisan, J., dissenting) (misleading disclosure would "run into a more basic First Amendment problem still"). Plaintiffs are aware of no case in which a court has upheld a compelled warning under intermediate scrutiny after finding that the warning was false or misleading.

Second, even ignoring its misleading nature, the Alternative Warning does not advance an interest that California voters intended to further when they enacted Proposition 65. California unquestionably has a substantial interest in informing consumers about those products that pose an *actual* risk of cancer. And Proposition 65 unquestionably was enacted to advance that substantial interest. In enacting the law, California voters relied on the ballot summary, which explained that

Proposition 65 would require "businesses to warn people before knowingly and intentionally exposing them to chemicals *that cause cancer*." 2-ER-119 (emphasis added).

But applying Proposition 65's warning requirement to glyphosate does not advance *that* interest. No authoritative body—not IARC, not OEHHA, and none of the many national regulators that have looked at this issue—has *ever* concluded that glyphosate poses a genuine cancer risk to humans. *See, e.g.*, SER23 ("EPA has thoroughly evaluated potential human health risk associated with exposure to glyphosate and determined that there are no risks to human health from the current registered uses of glyphosate and that glyphosate is not likely to be carcinogenic to humans."). For that reason, compelling a cancer warning for glyphosate would, if anything, hinder the interest that Proposition 65 was meant to serve: "Psychological and other social science research suggests that overuse may cause people to pay less attention to warnings generally" and negatively affect "'the believability and credibility of warnings,'" undermining the statutory interest in informing consumers about actual cancer risks. *See CTIA,* 928 F.3d at 854-55 (Friedland, J., dissenting in part) (citing academic studies); *see also Nicolle-Wagner v. Deukmejian*, 230 Cal. App. 3d 652, 661 (1991) (upholding OEHHA regulation that reduced "'unnecessary warnings, which could distract the public from other important warnings on consumer products'" (quoting OEHHA's Statement of Reasons)).

The Attorney General disputes none of that. He argues that compelling the Alternative Warning would advance a different interest: informing California residents whenever any of several enumerated "governmental and non-governmental organizations" concludes that a substance probably causes cancer, even if that is an outlier view. Br. 68-69. This argument fails for a different reason. To the extent that informing consumers about substances that *might* cause cancer at some exposure level to which consumers may never be subject in real life could ever qualify as a substantial government interest, it was not an interest that Proposition 65 was enacted to serve. To the contrary, the Proposition 65 ballot summary *expressly disclaimed* that interest. It assured voters that the law would address "chemicals that are scientifically known[,] not merely suspected, but known[] to cause cancer." 2-ER-121. Despite the Attorney General's insistence that the statute's structure creates the possibility that it might require warnings in circumstances like these where authoritative organizations disagree about a chemical's carcinogenicity, Br. 69, the Attorney General cannot satisfy his burden under the direct-advancement requirement by relying on an asserted interest that the ballot summary explicitly disclaimed. *See, e.g.*, *United States v. Virginia*, 518 U.S. 515, 533, 535-36 (1996) (holding, under equal-protection intermediate scrutiny, that "justification must be genuine, not hypothesized or invented *post hoc* in response to

litigation"); *R.J. Reynolds*, 696 F.3d at 1218 (applying *Central Hudson* to scrutinize statute and administrative record to ascertain "primary objective" of rule).

2. Compelling the Alternative Warning would burden more speech than necessary

In *NIFLA*, the Supreme Court held that California's compelled licensed-clinic disclosure was more speech-restrictive than necessary, and thus flunked intermediate scrutiny, because "California could inform" its citizens about state-funded family planning services itself "'without burdening a speaker with unwanted speech'"—and the Attorney General had provided no meaningful evidence "that an advertising campaign [was] not a sufficient alternative" to compelled speech. *NIFLA*, 138 S. Ct. at 2376 (citation omitted). The application of Proposition 65's warning requirement to glyphosate fails for the very same reason. To the extent that California wishes to inform residents about IARC's outlier view on glyphosate, the Attorney General has failed to show that the State could not accomplish that goal through its own "advertising campaigns or posting information on the Internet." 1-ER-34.

The Attorney General protests (at 74-75) that OEHHA already "provides information about glyphosate" on its own website and on the Proposition 65 website. But the State's belief that its existing speech is insufficient does not establish that the State cannot effectively communicate the information at issue. In *NIFLA*, California similarly "argue[d] that it ha[d] *already tried* an advertising campaign"—

—yet the Supreme Court held that even a "'tepid response'" to that campaign "d[id] not prove that an advertising campaign is not a sufficient alternative." 138 S. Ct. at 2376 (emphasis added). Here, the Attorney General has given no reason that the State could not take further steps to inform the public beyond posting on a website, has not indicated that it has so much as tried an advertising campaign, and points to no evidence that its own speech is so inadequate that it is entitled to "co-opt [Plaintiffs] to deliver its message for it." *Id.*

That failure is particularly glaring in this case, because the Attorney General has assured the Court that "exposures to glyphosate in food products would fall below the NSRL, and thus would not require warnings." Br. 70. That leaves only the State's interest in warning consumers of glyphosate-based pesticides for lawn-and-garden or occupational use. *See, e.g.*, Br. 28 ("The practical effect of the NSRL is that [warnings] are more likely to be required for occupational or other use of glyphosate-based weedkillers …."); Br. 70 n.94. But as the presence of glyphosate in pesticide products is disclosed on the face of their labels, *see, e.g.*, 40 C.F.R. § 156.10(g), if California wishes to warn pesticide consumers about IARC's findings, the Attorney General suggests no reason why it could not do that effectively through a publicity campaign of its own. *See, e.g.*, *ABA II*, 916 F.3d at 757.

Finally, even if the Attorney General could demonstrate that California has a substantial interest in informing consumers accurately about the opposing scientific viewpoints on glyphosate, and that California for some reason cannot disseminate that information itself, requiring a Proposition 65-style warning is not tailored to that end. If the State wished to advance that interest, it could amend Proposition 65 to require an even-handed summary of the science that does not misleadingly suggest that glyphosate is "known" to cause cancer, and does not exclude mention of the vast weight of authority against IARC's view. Such an approach would still fail intermediate scrutiny because no regulator—and not even IARC—has concluded that glyphosate poses an actual risk of cancer, but it undoubtedly would impose a *lesser* First Amendment burden on private speakers than the current warning requirement.

Because neither the core Proposition 65 warning nor the Alternative Warning directly advances a substantial governmental interest as applied to glyphosate, much less in a manner no more extensive than necessary to serve that interest, the application of Proposition 65's warning requirement to glyphosate fails both elements of the *Central Hudson* test and violates the First Amendment.

CONCLUSION

For these reasons, this Court should affirm.

Dated: May 12, 2021

Respectfully submitted,

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UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Form 8. Certificate of Compliance for Briefs

9th Cir. Case Number 20-16758

I am an attorney for Appellees Monsanto Company and CropLife America.

This brief contains 15,669 words, excluding the items exempted by Fed. R. App. P. 32(f).

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Signature /s/ Richard P. Bress **Date** May 12, 2021

ADDENDUM

Pursuant to 9th Cir. R. 28-2.7

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U.S. Const. amend. I

Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.

Cal. Health & Safety Code § 25249.6

§ 25249.6. Required Warning Before Exposure to Chemicals Known to Cause Cancer or Reproductive Toxicity

No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in Section 25249.10.

Cal. Health & Safety Code § 25249.8

§ 25249.8. List of Chemicals Known to Cause Cancer or Reproductive Toxicity

(a) On or before March 1, 1987, the Governor shall cause to be published a list of those chemicals known to the state to cause cancer or reproductive toxicity within the meaning of this chapter, and he shall cause such list to be revised and republished in light of additional knowledge at least once per year thereafter. Such list shall include at a minimum those substances identified by reference in Labor Code Section 6382(b)(1) and those substances identified additionally by reference in Labor Code Section 6382(d).

(b) A chemical is known to the state to cause cancer or reproductive toxicity within the meaning of this chapter if in the opinion of the state's qualified experts it has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity, or if a body considered to be authoritative by such experts has formally identified it as causing cancer or reproductive toxicity, or if an agency of the state or federal government has formally required it to be labeled or identified as causing cancer or reproductive toxicity.

(c) On or before January 1, 1989, and at least once per year thereafter, the Governor shall cause to be published a separate list of those chemicals that at the time of publication are required by state or federal law to have been tested for potential to cause cancer or reproductive toxicity but that the state's qualified experts have not found to have been adequately tested as required.

(d) The Governor shall identify and consult with the state's qualified experts as necessary to carry out his duties under this section.

(e) In carrying out the duties of the Governor under this section, the Governor and his designates shall not be considered to be adopting or amending a regulation within the meaning of the Administrative Procedure Act as defined in Government Code Section 11370.

Cal. Health & Safety Code § 25249.10(c)

§ 25249.10. Exemptions from Warning Requirement

Section 25249.6 shall not apply to any of the following:

* * *

(c) An exposure for which the person responsible can show that the exposure poses no significant risk assuming lifetime exposure at the level in question for substances known to the state to cause cancer, and that the exposure will have no observable effect assuming exposure at one thousand (1,000) times the level in question for substances known to the state to cause reproductive toxicity, based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of such chemical pursuant to subdivision (a) of Section 25249.8. In any action brought to enforce Section 25249.6, the burden of showing that an exposure meets the criteria of this subdivision shall be on the defendant.

Cal. Code Regs. tit. 11, § 3202(b)

§ 3202. Clear and Reasonable Warnings.

Health and Safety Code section 25249.7(f)(4)(A) requires that, in order to approve a settlement, the court must find that "Any warning that is required by the settlement complies with" the clear and reasonable warning requirement of Proposition 65. This guideline provides additional information concerning the Attorney General's interpretation of the statute and existing regulations governing clear and reasonable warnings and factors that will be considered in his review of settlements. Nothing in this guideline shall be construed to authorize any warning that does not comply with the statute and regulations, or to preclude any warning that complies with the statute and regulations or to conflict with regulations adopted by the Office of Environmental Health Hazard Assessment. This guideline is intended to address some of the types of warnings commonly found in settlements, not to provide comprehensive standards.

* * *

(b) Warning language. Where the settling parties agree to language other than the "safe harbor" language set forth in the governing regulations (22 CCR § 12601(b)) the warning language should be analyzed to determine whether it is clear and reasonable. Certain phrases or statements in warnings are not clear and reasonable, such as (1) use of the adverb "may" to modify whether the chemical causes cancer or reproductive toxicity (as distinguished from use of "may" to modify whether the product itself causes cancer or reproductive toxicity); (2) additional words or phrases that contradict or obfuscate otherwise acceptable warning language. Certain other deviations from the safe-harbor warnings are generally clear and reasonable, such as (1) Using the language "Using this product will expose you to a chemical . . ." in lieu of "This product contains a chemical . . ."; or (2) deleting the reference to "the state of California" from the safe-harbor language.

* * *

Cal. Code Regs. tit. 27, § 25601

§ 25601. Safe Harbor Clear and Reasonable Warnings – Methods and Content.

(a) A warning is "clear and reasonable" within the meaning of Section 25249.6 of the Act if the warning complies with all applicable requirements of this article.

(b) Except as provided in Section 25603(c), a warning meets the requirements of this subarticle if the name of one or more of the listed chemicals in the consumer product or affected area for which the warning is being provided is included in the text of the warning. Where a warning is being provided for more than one endpoint (cancer and reproductive toxicity) the warning must include the name of one or more chemicals for each endpoint, unless the named chemical is listed as known to cause both cancer and reproductive toxicity and has been so identified in the warning.

(c) Consumer product exposure warnings must be prominently displayed on a label, labeling, or sign, and must be displayed with such conspicuousness as compared with other words, statements, designs or devices on the label, labeling, or sign, as to render the warning likely to be seen, read, and understood by an ordinary individual under customary conditions of purchase or use.

(d) Environmental exposure warnings must be provided in a conspicuous manner and under such conditions as to make the warning likely to be seen, read, and understood by an ordinary individual in the course of normal daily activity.

(e) The warning content may contain information that is supplemental to the content required by this subarticle only to the extent that it identifies the source of the exposure or provides information on how to avoid or reduce exposure to the identified chemical or chemicals. Such supplemental information is not a substitute for the warning content required by this subarticle.

Cal. Code Regs. tit. 27, § 25603

§ 25603. Consumer Product Exposure Warnings - Content.

(a) Unless otherwise specified in Section 25607.1 et seq., a warning meets the requirements of this subarticle if it is provided using one or more of the methods required in Section 25602 and includes all the following elements:

(1) A symbol consisting of a black exclamation point in a yellow equilateral triangle with a bold black outline. Where the sign, label or shelf tag for the product is not printed using the color yellow, the symbol may be printed in black and white. The symbol shall be placed to the left of the text of the warning, in a size no smaller than the height of the word "WARNING".

(2) The word "**WARNING**:" in all capital letters and bold print, and:

(A) For exposures to listed carcinogens, the words, "This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov."

(B) For exposures to listed reproductive toxicants, the words, "This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov."

(C) For exposures to both listed carcinogens and reproductive toxicants, the words, "This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer, and [name of one or more chemicals], which is [are] known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov."

(D) For exposures to a chemical that is listed as both a carcinogen and a reproductive toxicant, the words, "This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov."

(E) Where a warning is being provided for an exposure to a single chemical the words "chemicals including" may be deleted from the warning content set out in subsections (A), (B) and (D).

(b) A short-form warning may be provided on the product label using all the following elements:

(1) The symbol required in subsection (a)(1).

(2) The word "**WARNING**:" in all capital letters, in bold print.

(A) For exposures to listed carcinogens, the words, "Cancer - www.P65Warnings.ca.gov."

(B) For exposures to listed reproductive toxicants, the words, "Reproductive Harm - www.P65Warnings.ca.gov."

(C) For exposures to both listed carcinogens and reproductive toxicants, the words, "Cancer and Reproductive Harm - www.P65Warnings.ca.gov."

(c) A person providing a short-form warning on the product label pursuant to subsection (b) is not required to include within the text of the warning the name or names of a listed chemical.

(d) Notwithstanding subsection (a)(2) or (b)(2), where a warning for a consumer product exposure or occupational exposure from use of a pesticide is provided on a product label, and the pesticide label is regulated by the United States Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act, Title 40 Code of Federal Regulations, Part 156; and by the California Department of Pesticide Regulation under Food and Agricultural Code section 14005, and Cal. Code of Regs., title 3, section 6242; the word "**ATTENTION**" or "**NOTICE**" in capital letters and bold type may be substituted for the word "**WARNING**".

Cal. Code Regs., tit. 27 § 25701

§ 25701. General.

(a) The determination of whether a level of exposure to a chemical known to the state to cause cancer poses no significant risk for purposes of Section 25249.10(c) of the Act shall be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of the chemical as known to the state to cause cancer. Nothing in this article shall preclude a person from using evidence, standards, risk assessment methodologies, principles, assumptions or levels not described in this article to establish that a level of exposure to a listed chemical poses no significant risk.

(b) A level of exposure to a listed chemical, assuming daily exposure at that level, shall be deemed to pose no significant risk provided that the level is determined:

(1) By means of a quantitative risk assessment that meets the standards described in Section 25703;

(2) By application of Section 25707 (Routes of Exposure); or

(3) By one of the following, as applicable:

(A) If a specific regulatory level has been established for the chemical in question in Section 25705, by application of that level.

(B) If no specific level is established for the chemical in question in Section 25705, by application of Section 25709 (Exposure to Trace Elements) or 25711 (Levels Based on State or Federal Standards) unless otherwise provided.

* * *

Cal. Code Regs. tit. 27, § 25703

§ 25703. Quantitative Risk Assessment.

(a) A quantitative risk assessment which conforms to this section shall be deemed to determine the level of exposure to a listed chemical which, assuming daily exposure at that level, poses no significant risk. The assessment shall be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for listing the chemical as known to the state to cause cancer. In the absence of principles or assumptions scientifically more appropriate, based upon the available data, the following default principles and assumptions shall apply in any such assessment:

(1) Animal bioassay studies for quantitative risk assessment shall meet generally accepted scientific principles, including the thoroughness of experimental protocol, the degree to which dosing resembles the expected manner of human exposure, the temporal exposure pattern, the duration of study, the purity of test material, the number and size of exposed groups, the route of exposure, and the extent of tumor occurrence.

(2) The quality and suitability of available epidemiologic data shall be appraised to determine whether the study is appropriate as the basis of a quantitative risk assessment, considering such factors as the selection of the exposed and reference groups, reliable ascertainment of exposure, and completeness of follow-up. Biases and confounding factors shall be identified and quantified.

(3) Risk analysis shall be based on the most sensitive study deemed to be of sufficient quality.

(4) The results obtained for the most sensitive study deemed to be of sufficient quality shall be applicable to all routes of exposure for which the results are relevant.

(5) The absence of a carcinogenic threshold dose shall be assumed and no-threshold models shall be utilized. A linearized multistage model for extrapolation from high to low doses, with the upper 95 percent confidence limit of the linear term expressing the upper bound of potency shall be utilized. Time-to-tumor models may be appropriate where data are available on the time of appearance of individual tumors, and particularly when survival is poor due to competing toxicity.

(6) Human cancer potency shall be derived from data on human or animal cancer potency. Potency shall be expressed in reciprocal milligrams of

chemical per kilogram of bodyweight per day. Interspecies conversion of animal cancer potency to human cancer potency shall be determined by multiplying by a scaling factor equivalent to the ratio of human to animal bodyweight, taken to the one-fourth power.

(7) When available data are of such quality that physiologic, pharmacokinetic and metabolic considerations can be taken into account with confidence, they may be used in the risk assessment for inter-species, inter-dose, and inter-route extrapolations.

(8) When the cancer risk applies to the general population, human body weight of 70 kilograms shall be assumed. When the cancer risk applies to a certain subpopulation, the following assumptions shall be made, as appropriate:

Subpopulation	*Kilograms of Body Weight*
Man (18+ years of age)	70
Woman (18+ years of age)	58
Woman with conceptus	58
Adolescent (11-18 years of age)	40
Child (2-10 years of age)	20
Infant (0-2 years of age)	10

(b) For chemicals assessed in accordance with this section, the risk level which represents no significant risk shall be one which is calculated to result in one excess case of cancer in an exposed population of 100,000, assuming lifetime exposure at the level in question, except where sound considerations of public health support an alternative level, as, for example:

(1) where chemicals in food are produced by cooking necessary to render the food palatable or to avoid microbiological contamination; or

(2) where chlorine disinfection in compliance with all applicable state and federal safety standards is necessary to comply with sanitation requirements; or

(3) where a clean-up and resulting discharge is ordered and supervised by an appropriate governmental agency or court of competent jurisdiction.

Cal. Code Regs. tit. 27, § 25904

§ 25904. Chemical Listings by Reference to California Labor Code Section 6382(b)(1).

* * *

(c) At least 45 days prior to adding a chemical or substance that meets the criteria established in subsections (a) and (b) to the list, the lead agency shall publish a notice of intent to list the chemical or substance and provide a 30 day public comment period on whether or not the chemical or substance has been identified by reference in Labor Code section 6382(b)(1). Comment is restricted to whether the identification of the chemical or substance meets the requirements of this section. The lead agency shall not consider comments related to the underlying scientific basis for classification of a chemical by IARC as causing cancer.

Cal. Labor Code § 6382

§ 6382. Preparation and amendment of list; procedure; review

The director shall prepare and amend the list of hazardous substances according to the following procedure:

* * *

(b) The listings referred to in subdivision (a) are as follows:

(1) Substances listed as human or animal carcinogens by the International Agency for Research on Cancer (IARC).

(2) Those substances designated by the Environmental Protection Agency pursuant to Section 307 (33 U.S.C. Sec. 1317) and Section 311 (33 U.S.C. Sec. 1321) of the federal Clean Water Act of 1977 (33 U.S.C. Sec. 1251 et seq.) or as hazardous air pollutants pursuant to Section 112 of the federal Clean Air Act, as amended (42 U.S.C. Sec. 7412) which have known, adverse human health risks.

(3) Substances listed by the Occupational Safety and Health Standards Board as an airborne chemical contaminant pursuant to Section 142.3.

(4) Those substances designated by the Director of Pesticide Regulation as restricted materials pursuant to Section 14004.5 of the Food and Agricultural Code which have known, adverse human health risks.

(5) Substances for which an information alert has been issued by the repository of current data established pursuant to Section 147.2.

* * *