No. 20-16758

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

XAVIER BECERRA, ATTORNEY GENERAL OF CALIFORNIA, et al.,
Defendants/Appellants,

v.

NATIONAL ASSOCIATION OF WHEAT GROWERS, et al.,
Plaintiffs/Appellees.

On Appeal from the United States District Court
for the Eastern District of California

Nos. 2:17-cv-02401-WBS-EFB
(Hon. William B. Shubb)

OPENING BRIEF OF APPELLANT XAVIER BECERRA, ATTORNEY GENERAL OF THE STATE OF CALIFORNIA

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INTRODUCTION

Nearly thirty-five years ago, Californians voted overwhelmingly for Proposition 65, a groundbreaking initiative that requires businesses to warn individuals when they expose them to chemicals identified as carcinogens by certain expert agencies, including the International Agency for Research on Cancer (IARC), "a recognized international authority on the carcinogenic potential of chemicals and other agents[.]" 80 Fed. Reg. 40,138, 40,424 (July 13, 2015). This case challenges Proposition 65's ability to mandate such warnings for the chemical glyphosate, the active ingredient in Monsanto Company's popular herbicide, Roundup.[1]

IARC identified glyphosate as a carcinogen in 2015. In response to this identification, California's Office of Environmental Health Hazard Assessment (OEHHA), the lead agency for Proposition 65, placed glyphosate on the State's list of carcinogens in 2017, a listing that survived a constitutional challenge and, notwithstanding Monsanto's documented efforts to discredit IARC, was upheld by a California court of appeal in

[1] An herbicide is a category of pesticide used primarily for weed control. *See, e.g.*, https://www.epa.gov/ingredients-used-pesticide-products/types-pesticide-ingredients. The terms "herbicide" and "pesticide" will be used interchangeably throughout this brief to describe Roundup and other glyphosate-based herbicides.

2018. As a result of the listing, Proposition 65 requires businesses whose products expose Californians to high levels of glyphosate to provide a clear and reasonable warning that the chemical is a carcinogen.

Plaintiffs and Appellees Monsanto and a consortium of agricultural associations and business groups argued to the district court that any compelled disclosure of IARC's carcinogenicity determination would violate their First Amendment rights because several other organizations, including the United States Environmental Protection Agency (EPA), have stated that glyphosate is not a carcinogen. In effect, plaintiffs argued below that the First Amendment empowered them to expose consumers and workers even to high levels of glyphosate without warning them that IARC has found glyphosate to be a carcinogen – information those individuals could have used to protect themselves from exposure. This position is unfounded, and the district court erred by adopting it.

The purpose of First Amendment protection for commercial speech is to ensure that consumers have information to enable informed decisions in the marketplace. *See Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 651 (1985) (noting that First Amendment protection for commercial speech is "justified principally by the value to

consumers of the information such speech provides"); *see also Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc*., 425 U.S. 748, 756 (1976) (freedom of speech necessarily protects the right to receive information and ideas).

Here, an expert scientific agency has determined that glyphosate is a carcinogen. This is information that consumers, workers, and commercial users might well find useful when deciding whether to use glyphosate-based herbicides, and, if so, how to safeguard their health when using them. Nothing in the First Amendment or this Court's precedents requires a consensus of scientific judgment – which may take decades to develop – before the State may require a business to provide that vital information to those being exposed to glyphosate.

Under this Court's controlling decision in *CTIA-The Wireless Ass'n v. City of Berkeley*, 928 F.3d 832 (9th Cir. 2019), *cert. denied*, 140 S. Ct. 658 (2019) (*CTIA II*), Proposition 65's warning requirement for glyphosate is clearly constitutional. The district court's conclusion that there could be no warning that complied with the statute and with the First Amendment, which led the court to enjoin all enforcement, was in error. Defendant and Appellant Xavier Becerra, the Attorney General of California (Attorney General), has proposed one such warning: a detailed, purely factual, and

uncontroversial statement providing information about both IARC's determination and EPA's finding, a warning that is neither unjustified nor unduly burdensome, and that serves a substantial state interest. The Attorney General's proposed warning not only complies with Supreme Court and Ninth Circuit case law, but also advances one of the core purposes of the First Amendment, as well as of Proposition 65 – to foster the dissemination of accurate information that, in this case, serves to protect public health and safety.

Because the Attorney General's proposed Proposition 65 warning complies with the First Amendment, the Attorney General respectfully requests that the Court reverse the district court's order, vacate the judgment, and instruct the district court to enter judgment for the Attorney General.

JURISDICTIONAL STATEMENT

The district court had jurisdiction pursuant to 28 U.S.C. § 1331 (action arising under the United States Constitution).

On June 22, 2020, the district court granted the Plaintiffs' motion for summary judgment, and denied the Attorney General's cross-motion for summary judgment. 1-ER-5 at 36-37. The district court entered a final judgment disposing of the claims of all parties in the case on August 11, 2020. 1-ER-2. On September 9, 2020, the Attorney General timely appealed. 11-ER-2367.

This Court has appellate jurisdiction pursuant to 28 U.S.C. § 1291.

STATEMENT OF ISSUE PRESENTED

Whether, in the absence of scientific consensus, the First Amendment prohibits California's Proposition 65 from requiring a business to warn Californians before it exposes them to significant amounts of glyphosate, a chemical that the International Agency for Research on Cancer, a worldwide leader in cancer research, has determined causes cancer in animals and is probably carcinogenic to humans.

STATUTORY ADDENDUM

Pertinent statutes and regulations are set forth in an addendum to this brief.

STATEMENT OF THE CASE

In this section, the Attorney General provides the statutory and regulatory background underlying this case, the facts necessary to decide the question presented, and the case's procedural history.

I. STATUTORY AND REGULATORY BACKGROUND

The Safe Drinking Water and Toxic Enforcement Act, better known as Proposition 65, was enacted by initiative in 1986. The law requires the Governor of California to publish a "list of those chemicals known to the state to cause cancer or reproductive toxicity within the meaning of this chapter."[2] Cal. Health & Safety Code § 25249.8(a). It requires businesses to give warnings before exposing people to these chemicals.

Proposition 65 passed in response to voters' concerns that "'hazardous chemicals pose a serious potential threat to their health and well-being, [and] that state government agencies have failed to provide them with adequate protection . . . .'" *AFL-CIO v. Deukmejian*, 212 Cal. App. 3d 425, 430 (Cal. Ct. App. 1989) (quoting the Ballot Pamphlet for Proposition 65) (*Deukmejian*). Perhaps anticipating efforts by industry to influence

[2] The publication of the Proposition 65 list has been delegated by the Governor to the Office of Environmental Health Hazard Assessment (OEHHA), the current lead agency for implementation of the statute. *See* Cal. Health & Safety Code § 25249.12(a).

government regulators, Proposition 65 spells out certain explicit requirements. One is that businesses must inform people when they expose them to chemicals that have been identified by certain expert organizations – including IARC – as causing cancer. Cal. Health & Safety Code § 25249.8(a); Cal. Lab. Code §§ 6382(b)(1), (d). The proponents made this explicit in the ballot pamphlet:

> At a minimum, the Governor must include [in the Proposition 65 list] the chemicals already listed as known carcinogens by two organizations of the most highly regarded national and international scientists: the U.S.'s National Toxicology Program and the U.N.'s *International Agency for Research on Cancer*. (Emphasis added.)[3]

The voters could not have been more clear. They wanted to be warned about exposures to chemicals that IARC had classified as carcinogens, "***regardless of whether other identified listing agencies or processes agree***." *Monsanto v. Office of Environmental Health Hazard Assessment*, 22 Cal. App. 5th 534, 559 (Cal. Ct. App. 2018) (emphasis added) (*Monsanto v. OEHHA*). They did not require scientific agreement or consensus.

While the statute has been subject to criticism, it has had major successes over the years, and has been highly effective in providing

[3] 2-ER-120; *Legislature v. Deukmejian*, 34 Cal. 3d 658, 673 (Cal. 1983) ("Ballot summaries and arguments may be considered when determining the voters' intent and understanding of a ballot measure.").

information to consumers and in encouraging businesses to remove toxic chemicals from their products so that they do not need to provide a warning. These successes have included reducing high levels of lead and other hazardous substances in an array of products, including candy, children's jewelry, soda bottles, children's toys, artificial turf, dietary supplements, hair-straightening products, and children's bedding, as well as emissions of cancer-causing chemicals from chrome plating and asphalt roofing operations.[4]

A. The Listing Mechanisms

Proposition 65 provides four separate mechanisms for listing chemicals. Cal. Health & Safety Code §§ 25249.8(a), (b). Under the listing mechanism applicable here, the "Labor Code listing mechanism" of California Health and Safety Code section 25249.8(a), OEHHA is required to list "at a minimum those substances identified by reference in [California] Labor Code section 6382(b)(1)," which identifies "[s]ubstances listed as

[4] 2-ER-127 (Mexican-style candy), 2-ER-187 (ginger candy), 2-ER-230 (cola), 2-ER-318 (artificial turf), 3-ER-348 (jewelry); 3-ER-378 (toys); 3-ER-400 (children's furniture); 3-ER-415 at 428 (dietary supplements); 3-ER-462 (hair-straightening products); 3-ER-505 (hexavalent chromium from plating emissions); 3-ER-523 (asphalt emissions); 3-ER-552 (diesel emissions).

human or animal carcinogens by" IARC.[5] Cal. Health & Safety Code § 25249.8(a) (emphasis added); Cal. Labor Code § 6382(b)(1).

As the *Deukmejian* court explained, the relevant question for determining whether a chemical should be placed on the Proposition 65 list of carcinogens is not whether a chemical is probably carcinogenic *to humans,* but "whether it is in fact a known carcinogen . . . ." *Deukmejian*, 212 Cal. App. 3d at 437. Accordingly, the list must include chemicals for which there is sufficient evidence that exposure causes cancer in animals (e.g., "known carcinogens"), even if there is insufficient evidence that it causes cancer in humans. *Id.*; *Western Crop Protection Ass'n v. Davis*, 80 Cal. App. 4th 741, 749 (Cal. Ct. App. 2000); *Am. Chemistry Council v. Office of Environmental Health Hazard Assessment,* 55 Cal. App. 5th 1113, 1142 (Cal. Ct. App. 2020).

The statute takes this approach for sound scientific reasons: the principle of animal-to-human extrapolation in the context of carcinogenesis is well-established, and has been accepted by virtually all health and

[5] The other three listing mechanisms are the "authoritative body" listing mechanism, the "state's qualified experts" listing mechanism, and the "formally required to be labeled" listing mechanism. Cal. Health & Safety Code § 25249.8(b).

regulatory agencies. *See Deukmejian*, 212 Cal. App. 3d at 438 n.7 (citing Report, Office of Science and Technology Policy, 50 Fed. Reg. 10375 (Mar. 14, 1985)). "It is unethical to test humans, and because of the 20-30 year latency period of many human cancers, epidemiological studies[6] do not adequately warn humans and protect them from the risk of exposure to new carcinogens." *Id*. Indeed, "for recognized human carcinogens, the first evidence of carcinogenicity frequently is found in test animals; only afterwards are cancer effects looked for, and found, in humans." *Id.*

Chemicals thus are included on the list of "known" carcinogens if IARC – or one of the other authoritative bodies under Proposition 65[7] – has

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[6] "Epidemiological studies measure the risk of illness or death in an exposed population compared to that risk in an identical, unexposed population (for example, a population the same age, sex, race, and social status as the exposed population)." https://toxtutor.nlm.nih.gov/05-003.html#:~:text=Epidemiological%20studies%20measure%20the%20risk,status%20as%20the%20exposed%20population.

[7] In addition to IARC's statutory role under the Labor Code listing mechanism pursuant to which glyphosate was listed, Cal. Health & Safety Code section 25249.8(a), IARC has been identified in the regulations as one of five "authoritative bodies" for purposes of listing carcinogens under a different Proposition 65 listing mechanism. Cal. Health & Saf. Code § 25249.8(b) ("a chemical is known to the state to cause cancer . . . within the meaning of this chapter if . . . a body considered to be authoritative by [the state's qualified experts] has formally identified it as causing cancer . . ."). The five bodies considered to be authoritative by the "state's qualified experts," who are appointed by the Governor, are IARC, the National

classified them as probable or possible human carcinogens, provided there is sufficient evidence that exposure causes cancer in animals. *Deukmejian*, 212 Cal. App. 3d at 437; *see also Styrene Information & Research Center v. Office of Environmental Health Hazard Assessment,* 210 Cal. App. 4th 1082, 1094-95 (Cal. Ct. App. 2012) (OEHHA must list chemicals that IARC has classified as probably carcinogenic to humans or possibly carcinogenic to humans, but only if IARC has found "sufficient evidence of carcinogenicity in experimental animals"); Cal. Code Regs. tit. 27, §§ 25904 (b)(2), (3). Indeed, because IARC does not use the term "known carcinogen," for purposes of interpreting IARC monographs under California law, "sufficient evidence" of carcinogenicity is considered equivalent to "known" carcinogenicity. *See Deukmejian*, 212 Cal. App. 3d at 434 n.3.

B. The Warning Requirement

A business with ten or more employees must provide a clear and reasonable warning before it "knowingly and intentionally expose[s] any individual [in California] to a chemical known to the state to cause cancer or reproductive toxicity . . . ." Cal. Health & Safety Code §§ 25249.6,

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Institute for Occupational Safety and Health (NIOSH), the National Toxicology Program (NTP), EPA, and the U.S. Food and Drug Administration (FDA). Cal. Code Regs. tit. 27, § 25306(m).

25249.10(b). A business need not provide a warning for an exposure to a listed carcinogen if it can show that the exposure it causes "poses no significant risk assuming lifetime exposure at the level in question." Cal. Health & Safety Code § 25249.10(c).

1. The "Safe Harbor" No Significant Risk Level

The "no significant risk" level (NSRL) below which a company does not need to provide a Proposition 65 warning is defined as an exposure level that results in no more than "one excess case of cancer in an exposed population of 100,000, assuming lifetime exposure at the level in question." Cal. Code Regs. tit. 27, § 25703(b).[8] For many chemicals, OEHHA has adopted a specific NSRL by regulation, commonly called a "safe harbor" NSRL. *See* Cal. Code Regs. tit. 27, § 25705. Rather than rely on the safe harbor NSRL, businesses can instead hire an expert and seek to demonstrate that a higher NSRL should apply, by proving that a "lifetime exposure" at a

[8] The 1/100,000 risk level is less strict from the perspective of businesses (i.e., less protective of consumers) than the risk levels employed by other regulatory agencies. *Ingredient Communication Council v. Lungren*, 2 Cal. App. 4th 1480, 1494 n.8 (Cal. Ct. App. 1992) ("The threshold risk under Proposition 65 is not especially low compared to other epidemiological standards commonly used by regulatory bodies.")

higher exposure level poses "no significant risk." Cal. Health & Safety Code § 25249.10(c).

2. Warning Language

Proposition 65 does not dictate the contents of the warning, where one is required, as long as it is "clear and reasonable" in conveying that the chemical is "known to the state to cause cancer[,]" or "words to that effect." Cal. Health & Safety Code § 25249.6; *see Dowhal v. SmithKline-Beecham Consumer Healthcare*, 32 Cal. 4th 910, 918 (Cal. 2004). The statute specifically provides that a chemical is "known to the State to cause cancer" if it meets the criteria for listing. Cal. Health & Safety Code §§ 25249.8(a), (b).

OEHHA has adopted "safe harbor" warning methods and content deemed to be "clear and reasonable" for purposes of statutory compliance.[9] Cal. Code Regs. tit. 27, §§ 25601-25607.33; *see also Environmental Law Found. v. Wykle Research, Inc.*, 134 Cal. App. 4th 60, 66 (Cal. Ct. App. 2005). Most, but not all, of these safe harbor warnings, which include

[9] OEHHA's "safe harbor" warning regulations provide sample message content and warning methods for consumer product, occupational, and environmental exposure warnings that OEHHA has deemed "clear and reasonable" under the Act.

warnings for a number of specific chemical exposures, use the phrase, "known to the State of California to cause cancer."[10] Exceptions are the safe harbor warning for alcoholic beverages, Cal. Code Regs. tit. 27, § 25607.4 ("Drinking distilled spirits, beer, coolers, wine and other alcoholic beverages may increase cancer risk, and, during pregnancy, can cause birth defects"), and a short-form cancer warning for consumer products that states only, "**WARNING:** Cancer – www.P65Warnings.ca.gov." *Id.*, § 25603(b)(2).

As with the "safe harbor" NSRL, use of the safe harbor warning is *optional*. A business may use any other warning method or content that is clear and reasonable. Cal. Health & Safety Code § 25249.6; Cal. Code Regs. tit. 27, § 25601. Whether a non-safe-harbor warning is clear and reasonable is determined on a case-by-case basis. *Ingredient Commc'n Council v. Lungren*, 2 Cal. App. 4th 1480, 1491-92, 1494-95 (Cal. Ct. App. 1992).

In certain circumstances, it is reasonable to provide additional factual context in the text of the warning. Indeed, California courts have approved several Proposition 65 consent judgments in actions brought by the Attorney

[10] *See, e.g.*, Cal. Code Regs. tit. 27, §§ 25603, 25605, 25607.2, 25607.6, 25607.9, 25607.11, 25607.13, 25607.15, 25607.17, 25607.19, 25607.21, 25607.23, 25607.25, 25607.27, 25607.29, 25607.33.

General in which the proposed warnings departed from the standardized safe harbor warning language and provided additional information to help clarify the risks of the exposures involved.[11] One such example, negotiated by the parties in a suit brought by the Attorney General for failure to warn consumers about exposures to acrylamide in potato chips and French fries, is as follows:

> WARNING
>
> Cooked potatoes that have been browned, such as potato crisps and/or potato chips [] contain acrylamide, a substance identified as causing cancer under California's Proposition 65. []
>
> Acrylamide is not added to these foods but is created when these and certain other foods are browned.
>
> The FDA has not advised people to stop eating potato crisps and/or potato chips [] or any foods containing acrylamide as a result of cooking. For more information, see www.fda.gov.[12]

Thus, if the circumstances warrant, a business can tailor its warning to include additional clarifying information and still comply with the warning requirements of Proposition 65.

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[11] 3-ER-617 at 633; 4-ER-635 at 639-640.

[12] 4-ER-662 at 672.

3. Proposition 65 Enforcement

Proposition 65 may be enforced by the Attorney General, by any district attorney, and by certain city attorneys. Cal. Health & Safety Code § 25249.7(c). Private citizens may also enforce the statute "in the public interest," with certain restrictions. Cal. Health & Safety Code § 25249.7(d). OEHHA, the lead agency for statutory implementation, compiles the Proposition 65 list and issues regulations, but has no enforcement authority. *See* Cal. Health & Safety Code §§ 25249.7(c), (d); *Baxter Healthcare Corp. v. Denton*, 120 Cal. App. 4th 333, 346 (2004).

The Attorney General is the lead public enforcer of the statute, and exercises oversight authority over private enforcement. A private enforcer must first provide notice of the alleged violation to the public prosecutors, including the Attorney General, and to the alleged violator, before filing an enforcement action. Cal. Health & Safety Code § 25249.7(d)(1). If, after 60 days, no public prosecutor is diligently prosecuting the violation, the private enforcer may file suit. *Id.*

Under the statute, each private enforcer must submit to the Attorney General a "certificate of merit" with the 60-day notice stating that the person executing the certificate has consulted with an expert, and based on the

consultation believes "there is a reasonable and meritorious case for the private action." Cal. Health & Safety Code § 25249.7(d)(1). The noticing party must submit confidential, factual information to the Attorney General "sufficient to establish the basis of the certificate of merit . . . ." *Id*. For allegations of exposure to glyphosate residues in food, the private enforcer will need to conduct laboratory testing of food products and estimate daily consumption to demonstrate that the exposure levels are not below the NSRL. For non-food products, private enforcers will be required to provide reasonable exposure scenarios. If the Attorney General concludes there is no merit to a 60-day notice, he is required by law to send a letter to the noticing party and the alleged violator that so states, and post it on the Attorney General's website. Cal. Health & Safety Code §§ 25249.7(e)(1)(A), (g).

II. FACTUAL BACKGROUND

A. The International Agency for Research on Cancer

As discussed above, Proposition 65 requires businesses to warn people before exposing them to a chemical that the International Agency for Research on Cancer has identified as a carcinogen.

IARC was founded in 1965 as the cancer research arm of the United Nations World Health Organization and exists to "promote international

collaboration in cancer research."[13] IARC is recognized in the scientific and academic communities as "usually the main arbiter of what a cancer-causing agent is." *See Johnson v. Monsanto Company*, 52 Cal. App. 5th 434, 440 (Cal. Ct. App. 2020). Importantly, IARC reviews only those agents for which there is already some evidence or suspicion of carcinogenicity.[14] IARC evaluates these potential carcinogens by publishing Monographs, which are "critical reviews and evaluations of evidence on the carcinogenicity of a wide range of human exposures."[15]

Each IARC Monograph is prepared by a "Working Group" of international scientific experts specifically selected for their expertise, and to avoid conflicts of interest.[16] Each Working Group reviews the available evidence from cancer studies in humans and animals, as well as studies on mechanisms of carcinogenesis relating to the chemical to be evaluated.[17] The Working Group then classifies the chemical being evaluated either as Group 1 (carcinogenic to humans), Group 2A (probably carcinogenic to

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[13] 4-ER-699 at 704-705.
[14] *Id.*; 4-ER-727 at 748; 6-ER-1199 at 1205.
[15] 4-ER-727 at 747.
[16] 4-ER-727 at 747, 749.
[17] 4-ER-727 at 749.

humans), Group 2B (possibly carcinogenic to humans), or Group 3 (not classifiable as to its carcinogenicity to humans).[18] As of November 27, 2020, approximately 11.8% of the agents that IARC has evaluated through the Monograph program have been classified as "carcinogenic to humans," 8.7% as "probably carcinogenic" to humans – the same category as glyphosate – and the remaining 79.4% as "possibly carcinogenic to humans" or "not classifiable as to [their] carcinogenicity to humans."[19]

B. Reliance on IARC by U.S. Federal and State Government Entities

IARC is widely trusted by federal agencies and states, which rely on IARC as an authoritative source for carcinogen identification.[20] For

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[18] 4-ER-727 at 767-768; *see also Styrene*, 210 Cal. App. 4th at 1090-91. The IARC Preamble was amended in January 2019 to eliminate Group 4, and chemicals are now classified as either Group 1, Group 2A, Group 2B, or Group 3 agents. *See* Samet, J. M., *et al*., *The IARC Monographs: Updated Procedures for Modern and Transparent Evidence Synthesis in Cancer Hazard Identification*, JNCI J. National Cancer Inst. (2020) 112(1), at 35, available at https://academic.oup.com/jnci/article/112/1/30/5566248. The Working Group classified glyphosate as a Group 2A chemical (probably carcinogenic to humans).

[19] *See* https://monographs.iarc.fr/agents-classified-by-the-iarc/. For a full list of the agents classified by IARC as of December 2020, *see* https://monographs.iarc.fr/list-of-classifications/.

[20] Non-governmental health organizations like The American Cancer Society, to give one example, also consider IARC a respected authority on carcinogen identification. *See* IARC and NTP lists of "Known and Probable

example, the U.S. Department of Health and Human Services notes that IARC "Monograph volumes are considered critical references that inform health policy and cancer research worldwide about carcinogenic risks to reduce cancer globally."[21] Many federal and state statutes and regulations rely on IARC's classifications in order to identify carcinogens for binding regulatory purposes.[22] With respect to occupational warnings for carcinogens, the Occupational Safety and Health Administration (OSHA)

Human Carcinogens" at https://www.cancer.org/cancer/cancer-causes/general-info/known-and-probable-human-carcinogens.html ("In general, the American Cancer Society does not determine if something causes cancer (that is, if it is a carcinogen). Instead, we rely on the determinations of other respected agencies, such as the International Agency for Research on Cancer (IARC) and the US National Toxicology Program (NTP)").

[21] *See* 6-ER-1210 at 1212.

[22] These include regulations promulgated under the Toxic Substances Control Act, 15 U.S.C. § 2601 *et seq*., 40 C.F.R. § 707.60(c)(2)(ii); Cal. Penal Code § 374.8(c)(2)(D), involving the illegal deposit of hazardous substances; Cal. Educ. Code §§ 32062(a) and (b), addressing toxic art supplies in schools; the California Safe Cosmetics Act of 2005, Cal. Health & Safety Code § 111791.5(b)(2), and Cal. Labor Code § 6382(b)(1). Alaska, Connecticut, Illinois, Indiana, Louisiana, Massachusetts, Missouri, Nevada, New Hampshire, New Jersey, Oregon, Pennsylvania, Rhode Island, Tennessee, Texas, Vermont, Virginia, and Washington rely on IARC's evaluations to create lists of hazardous chemicals and identify carcinogens for other public health purposes. 6-ER-1231.

Hazard Communication Standard specifically mandates that workers receive the following warnings by means of Safety Data Sheets:

> Whether the hazardous chemical . . . has been found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs (latest edition), or by OSHA.

29 C.F.R. § 1910.1200, App. D.

Manufacturers, including Monsanto, have therefore included the 2015 IARC carcinogenicity finding for glyphosate on Safety Data Sheets for certain of their products.[23] Pursuant to OEHHA's regulations, where these Safety Data Sheets list the IARC determination in a manner that fully complies with the warning and labeling requirements of the OSHA regulations, no separate Proposition 65 warning need be provided at all, as the SDS warning is deemed to suffice.[24] Cal. Code Regs. tit. 27, § 25606. *See infra* at 63, 69.

Governmental agencies also rely on IARC's determination that a chemical is *not* classifiable as a carcinogen. OEHHA did this in 2001 when it removed saccharin from the Proposition 65 list, and more recently in 2019,

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[23] *See, e.g.*, 6-ER-1237 at 1243; *see infra* at 63 n.89.

[24] Because enforcement of the warning requirement for glyphosate has been enjoined since 2018, neither the Attorney General nor OEHHA has assessed whether Monsanto's Safety Data Sheets suffice for these purposes.

when it promulgated a regulation to establish that warnings are not required for chemicals in coffee created by roasting or brewing.[25]

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

In March 2015, IARC convened a Working Group of internationally-recognized scientific experts to review the evidence for the carcinogenicity of five herbicides, including glyphosate.[26] The group included scientists from four state and federal agencies, including the National Center for Computational Toxicology at EPA; three U.S. universities; and experts from eight other countries. The Working Group included an observer from Monsanto.[27]

IARC's Working Group examined studies in humans and animals, as well as mechanistic data (e.g., data indicating whether the biological mechanisms through which the chemical acts to cause cancer in animals also operate in humans).[28] On March 20, 2015, IARC classified glyphosate as

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[25] *See* 6-ER-1249; 6-ER-1252; *see also* Cal. Code Regs. tit. 27, § 25704.

[26] 4-ER-727 at 729-772; 5-ER-1061-6-ER-1155.

[27] 4-ER-727 at 740-742, 743, n.11 (observer from Monsanto).

[28] 4-ER-727 at 5-ER-1072-1091 (cancer in humans); 1091-1102 (cancer in experimental animals); 5-ER-1102-6-ER-1136 (mechanistic data).

"probably carcinogenic to humans (Group 2A)," its second highest classification, based on "sufficient evidence" that it causes cancer in animals, and "limited evidence" in humans.[29] Notably, the Monograph, which was published on July 29, 2015, cited evidence of a positive association in humans between exposures to glyphosate and non-Hodgkin's lymphoma, as observed in studies of humans in different geographic regions (the U.S., Canada, and Sweden).[30] Additionally, the Monograph stated that the mechanistic data provide strong evidence that glyphosate can operate through two key characteristics of known human carcinogens, genotoxicity and oxidative stress, and that these effects of glyphosate can operate in humans.[31] The 78-page Monograph represented the consensus findings of the 17-member Working Group. [32]

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[29] 4-ER-727 at 6-ER-1141-1142; 4-ER-727 at 767-768.

[30] 4-ER-727 at 6-ER-1138 and 6-ER-1141; https://www.iarc.who.int/news-events/glyphosate-monograph-now-available/ (notice of publication of Monograph)

[31] 4-ER-727 at 6-ER 1139-1141. The term "genotoxic" means "damaging to genetic material," https://www.merriam-webster.com/medical/genotoxic, and the term "oxidative stress" refers to "physiological stress on the body that is caused by the cumulative damage done by free radicals inadequately neutralized by antioxidants and that is held to be associated with aging," https://www.merriam-webster.com/medical/oxidative%20stress.

[32] 4-ER-727 at 740-742, 6-ER-1200 at 1201-1202.

D. OEHHA's Placement of Glyphosate on the Proposition 65 List.

In September 2015, OEHHA issued a notice of its intention to add glyphosate to the Proposition 65 list of carcinogens based on IARC's carcinogenicity determination.[33] Subsequently, Monsanto sued OEHHA in California state court, claiming that OEHHA's proposed inclusion of glyphosate on the list violated the California and United States Constitutions. The superior court rejected these claims in full. *See Monsanto Company v. Office of Environmental Health Hazard Assessment*, No. 16CECG00183, 2017 WL 3784247 (Fresno County Superior Court, March 10, 2017). The court of appeal unanimously affirmed. *Monsanto v. OEHHA*, 22 Cal. App. 5th 534.

At the heart of the challenge was Monsanto's claim that IARC was a foreign agency, with no accountability to California citizens, and that Proposition 65 could not constitutionally rely on IARC's determinations. *Monsanto v. OEHHA*, 22 Cal. App. 5th at 540, 548. The trial court and court of appeal both rejected this contention, with the court of appeal

[33] 6-ER-1255.

concluding that Proposition 65 reasonably relies on IARC to perform its carcinogen identification function:

> [IARC] is an international agency created specifically to scientifically investigate potentially carcinogenic compounds. Its reputation and authority on the world stage—and relatedly its funding—is dependent, in part, on its work being accepted as scientifically sound.

Id. at 559.

OEHHA placed glyphosate on the Proposition 65 list on July 7, 2017.[34] In the Notice of Intent to List, OEHHA explained that IARC had concluded that there was "sufficient evidence of carcinogenicity in experimental animals" and "'limited evidence' in humans."[35]

E. OEHHA's Establishment of a No Significant Risk Level for Glyphosate.

Shortly before placing glyphosate on the Proposition 65 list, OEHHA initiated a rulemaking process to set a "no significant risk level" (NSRL), or "safe harbor" daily exposure level, for the chemical.[36] In a 48-page analysis

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[34] https://oehha.ca.gov/proposition-65/crnr/glyphosate-listed-effective-july-7-2017-known-state-california-cause-cancer.

[35] 6-ER-1255 at 1255-1256.

[36] As indicated above, a "safe harbor" daily exposure level, or NSRL, is set by regulation and represents a level of exposure below which no warning is required. OEHHA's proposed rulemaking, the Initial Statement of Reasons, and the Final Statement of Reasons (FSOR) are available at https://oehha.ca.gov/proposition-65/crnr/amendment-section-25705-no-significant-risk-level-glyphosate-april-10-2018. The FSOR is at 6-ER-1262.

in its Final Statement of Reasons, OEHHA considered the scientific studies relied on by IARC, as well as studies and contentions submitted by commenters, including Monsanto, arguing that glyphosate poses no cancer risk at all. In conducting this review, OEHHA concluded that the studies on which IARC relied provided sufficient evidence of carcinogenicity in animals.[37] OEHHA took particular note of the fact that IARC identified a significant increase in a particular type of malignant kidney tumor that is rare in the strain of mice being studied, which is a strong indication of carcinogenicity. "OEHHA agree[d] with IARC's determination that these tumor findings are treatment-related and demonstrate[d] statistically significant dose-response relationships."[38]

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[37] OEHHA's Pesticide and Environmental Toxicology Branch reached a different conclusion about the carcinogenicity of glyphosate in now-outdated reviews from 1997 and 2007. Neither of these reviews considered studies published between 2007 and 2015, which were not available to the Pesticide and Environmental Toxicology Branch. *See* OEHHA's Response to Comments Concerning the Notice of Intent to List Glyphosate as Causing Cancer under Proposition 65, at 10, available at https://oehha.ca.gov/media/downloads/crnr/0317responsetocomments.pdf.

[38] 6-ER-1262 at 1268. An increase in the incidence of tumors observed in an animal cancer study is said to be "treatment related" when the increase is causally associated with exposure to the test substance. 4-ER-727 at 759. A "dose-response relationship" is an increased incidence of tumors (at a particular site or type) with increasing levels of exposure to the test substance. *Id*. A dose-response relationship strengthens the inference of a

OEHHA also agreed with IARC's determination that there is strong evidence that glyphosate causes genotoxicity and oxidative stress, and that these effects can operate in humans.[39] Genotoxicity and oxidative stress are two of the ten key characteristics of carcinogens.[40] OEHHA then calculated the NSRL by performing "a standard dose-response assessment" using the results of "the most sensitive scientific study of sufficient quality," as required by the governing regulation.[41] Based on this study, OEHHA adopted a safe-harbor NSRL of 1,100 micrograms per day (µg/day) for glyphosate.[42]

F. There Is No Evidence in the Record that Glyphosate Warnings Would Be Required for Food Products.

The impact of this NSRL is significant. Dr. Brian Lee, an experienced toxicologist specializing in hazard evaluations and regulatory compliance matters, surveyed publicly-available test results for glyphosate residue in food products, and concluded that, based on the NSRL, none of the food products for which testing was available would require a Proposition 65

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causal relationship between the exposure and the development of tumors. *Id*.

[39] 6-ER-1262 at 1284.
[40] 6-ER-1355 at 1356-1357.
[41] 6-ER-1262 at 1293; *see also* Cal. Code Regs. tit. 27, § 25703(a).
[42] 6-ER-1262; 6-ER-1366.

warning.[43] He further concluded that the levels in many food products were so low that a significant amount of testing would not likely be necessary.[44] Indeed, although it is always possible that there could be foods with extremely high glyphosate levels, there is no evidence in the record that any food products sold in California contain glyphosate at levels that would expose consumers to more than 1,100 micrograms per day.

Thus, to the extent warnings for glyphosate are required by the statute, the evidence in the record reveals that the practical effect of the NSRL is that they are more likely to be required for occupational or other use of glyphosate-based weedkillers, not for food products.

G. EPA's and Other Regulatory Agencies' Conclusions

IARC's scientific conclusion that glyphosate is a cancer hazard is not shared by all regulatory bodies. Most notably, EPA has stated that glyphosate is "not likely to be carcinogenic to humans," though its full statement appears to conflate assessments of *hazard* – whether the chemical causes cancer at any exposure level – with the *risk* of cancer at expected

[43] 6-ER-1368 at 1370-1376.
[44] 6-ER-1368 at 1370-1371.

exposure levels.[45] Regulatory agencies in other countries have also concluded that there is insufficient evidence that glyphosate causes cancer, either at all (i.e., it is not a cancer hazard),[46] or that, even if glyphosate poses a hazard, it does not pose a risk to humans at the levels to which humans are typically exposed (i.e., it does not present a cancer risk at those exposure levels).[47]

There are several explanations for the different conclusions reached by IARC and the other agencies. In the first place, to put the agencies' findings in context, it is important to understand the distinction between cancer

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[45] Glyphosate Interim Registration Review Decision (January 2020), available at https://www.epa.gov/sites/production/files/2020-01/documents/glyphosate-interim-reg-review-decision-case-num-0178.pdf, at 10 ("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"). In August 2019, EPA referenced an earlier "not likely to be carcinogenic to humans" finding in a letter specifically addressing Proposition 65 warnings for glyphosate. 7-ER-1406 at 1412, 1422, 1424-1430. The three other authoritative bodies under the statute and regulations (NIOSH, NTP, and the FDA) have reached no conclusions about the carcinogenicity of glyphosate.

[46] These agencies include the European Chemical Agency [ECHA], 7-ER-1462 at 1559, the European Food Safety Authority [EFSA], 8-ER-1634, and the New Zealand Environmental Protection Agency, 8-ER-1742 at 1757.

[47] These agencies include Health Canada, 8-ER-1762 at 1764, the Australian Pesticides and Veterinary Medicines Authority, 8-ER-1779 at 1787, and the Food and Agricultural Organization and the World Health Organization Joint Meeting on Pesticide Residues, 9-ER-1826 at 1861.

hazard and cancer risk. "A cancer 'hazard' is an agent that is capable of causing cancer under some circumstances, while a cancer 'risk' is an estimate of the carcinogenic effects expected from exposure to a cancer hazard."[48] In the context of Proposition 65, the listing decision reflects the identification of a cancer hazard, while the "no significant risk" defense is based on the level of risk posed by a particular exposure. *Am. Chemistry Council*, 55 Cal. App. 5th at 1141-42. For their part, IARC Monographs address only whether an agent like glyphosate presents a cancer hazard; the Monograph does not evaluate the level of risk such a hazard poses for each agent. *See In re Roundup Products Liability Litigation*, 390 F. Supp. 3d 1102, 1113–1114 (N.D. Cal. 2018) (IARC classification process, which identifies cancer hazards, is only the "first step in carcinogen risk assessment") (citations omitted); *see also Monsanto v. OEHHA*, 22 Cal. App. 5th at 541 ("monographs review whether an agent is capable of causing cancer but do not consider the likelihood cancer will occur").

As noted above, of the seven regulatory agencies listed *supra* at 28-29, four have diverged from IARC's conclusion about glyphosate's status as a

[48] 4-ER-727 at 747; 6-ER-1200 at 1207-1208.

cancer hazard.[49] EPA is the only one of these agencies that is an authoritative body under Proposition 65.[50] The analyses of the three other regulatory agencies, by contrast, address the level of risk to humans, and thus do not necessarily conflict with the IARC determination – which does not purport to address whether glyphosate presents a cancer risk at typical exposure levels.[51]

Moreover, serious questions have been raised about the methodology and conclusions of two of the agencies (EFSA and EPA) that determined that glyphosate does not pose a cancer hazard. Ninety-four independent scientists, including scholars and researchers from universities and scientific and cancer research institutions in many countries, concluded that EFSA's analysis of glyphosate contained serious flaws, and that the "most appropriate and scientifically based evaluation of the cancers reported in humans and laboratory animals as well as supportive mechanistic data is that

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[49] *See* Toxicological Profile for Glyphosate, August 2020, available at https://www.atsdr.cdc.gov/toxprofiles/tp214.pdf, at 126-27, Table 2-13 (Carcinogenicity Classification).

[50] *Supra* note 7.

[51] *See* Toxicological Profile for Glyphosate, August 2020, available at https://www.atsdr.cdc.gov/toxprofiles/tp214.pdf, Table 2-13 (Carcinogenicity Classification).

glyphosate is a *probable human carcinogen*."[52] EPA's own Science Advisory Panel concluded that, overall, "the EPA evaluation does not appear to follow the EPA 2005 cancer guidelines in several ways, notably for use of historical control data and statistical testing requirements."[53] Academic scholars, including three members of the EPA Science Advisory Panel that evaluated glyphosate, published a meta-analysis[54] of the human cancer epidemiology studies of glyphosate exposure and non-Hodgkin's lymphoma (NHL), and concluded that there is a "compelling link between exposures to [glyphosate-based herbicides] and increased risk for NHL."[55] This article

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[52] 9-ER-1950 at 1952 (emphasis in original).

[53] 9-ER-1955 at 1975.

[54] A meta-analysis is "a quantitative statistical analysis of several separate but similar experiments or studies [performed] in order to test the pooled data for statistical significance," https://www.merriam-webster.com/dictionary/meta-analysis.

[55] Zhang, L., Rana, I., Taioli, E., Shaffer, R., & Sheppard, L. (2019), *Exposure to Glyphosate-Based Herbicides and Risk for Non-Hodgkin Lymphoma: A Meta-Analysis and Supporting Evidence*, Mutation Research/Reviews in Mutation Research. 781. 10.1016/j.mrrev.2019.02.001, at 186, 196, 204, available at https://www.researchgate.net/publication/331019508_Exposure_to_Glyphosate-Based_Herbicides_and_Risk_for_Non-Hodgkin_Lymphoma_A_Meta-Analysis_and_Supporting_Evidence; 9-ER-1956 at 1963-1964 (listing three of the authors of the meta-analysis [Sheppard, Taioli and Zhang] as Science Review Board Members for EPA's Evaluation of the Carcinogenic Potential for Glyphosate). EPA itself has disagreed with this analysis. US EPA - *Glyphosate: Epidemiology Review of Zhang et al. (2019) and Leon et al.*

found that, using the highest exposure levels in each study, the risk of non-Hodgkin's lymphoma was increased by 41%.[56]

Other publications highlight flaws in EPA's analysis, including the following: (1) EPA relied substantially on unpublished studies commissioned by registrants like Monsanto (99% of which were negative), while IARC is required to base its review on data from reports published in the openly-available scientific literature, which are peer-reviewed, and data from publicly-available government agency reports (70% of which were positive); IARC did not review unpublished research and data sponsored and produced by Monsanto that was not peer reviewed;[57] (2) EPA focused on studies of glyphosate in its pure form, while IARC considered studies of exposures to glyphosate as it is actually used, i.e., mixed together with chemical surfactants that ensure that glyphosate penetrates plant surfaces (and thus also more easily enters human cells);[58] and (3) EPA's analysis

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(2019) publications for Response to Comments on the Proposed Interim Decision, available at https://www.epa.gov/sites/production/files/2020-01/documents/glyphosate-epidemiological-review-zhang-leon-proposed-interim-decision.pdf.

[56] Zhang *et al*., *supra* n.55, at 186, 196.

[57] 4-ER-727 at 749; 9-ER-2058. Dr. Charles Benbrook, who authored the article at 9-ER-2058, served as an expert witness for the private plaintiffs in the litigation against Monsanto discussed *infra* at 34-38.

[58] 9-ER-2058 at 2058, 2060-2065.

focused on the typically lower exposures from food consumption, while IARC's assessment also considered the higher exposures experienced by people who frequently apply large amounts of glyphosate-based herbicides.[59] EPA's analysis of glyphosate has also been criticized by scientists who contend it relied on invalid studies and improper statistical analysis;[60] improperly rejected a study showing a strong link between glyphosate and tumors;[61] and relied too heavily on studies of bacteria, which resulted in understating glyphosate's genotoxicity.[62]

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[59] 9-ER-2058 at 2059-2060, 2065-2066. Dr. Benbrook notes, "The EPA's . . . evaluation of glyphosate carcinogenicity is largely focused on typical, expected dietary exposures facing the general public." 9-ER-2068 at 2065. In contrast, the IARC Working Group studies "reflect high-end, real-world human-exposure scenarios more closely than any other category of study." 9-ER-2058 at 2066. Given the differences between IARC's and EPA's approaches, the agencies' conclusions may not conflict as much they may initially appear to do.

[60] 9-ER-2075 at 2081-2084, 2085-2103; Portier, *A comprehensive analysis of the animal carcinogenicity data for glyphosate from chronic exposure rodent carcinogenicity studies*, Environmental Health (2020) 19:18, at 4, 13, available at https://doi.org/10.1186/s12940-020-00574-1. Dr. Portier served as an expert witness for the private plaintiffs in the litigation against Monsanto discussed *infra* at 34-38.

[61] 9-ER-2075 at 2104-2111.

[62] 9-ER-2058 at 2062, 2066.

H. Recent Court Rulings and Jury Verdicts

It is also noteworthy that juries in three personal injury cases that have gone to trial over allegations that exposure to glyphosate-based pesticides caused cancer have concluded that glyphosate was a substantial factor in causing the plaintiffs' cancer. *Johnson v. Monsanto Company*, 52 Cal. App. 5th 434 (Cal. Ct. App. 2020); *In Re Roundup Prods. Liab. Litig*., (*Hardeman v. Monsanto Co*.), 385 F. Supp. 3d 1042 (N.D. Cal. 2019); *Pilliod v. Monsanto Co*., Alameda County Superior Court Case No. RG17862702, 10-ER-2168 at 2172. In all three cases, the juries awarded damages and punitive damages for plaintiffs.[63]

In *Johnson v. Monsanto Company*, a California jury determined that Dewayne Johnson contracted non-Hodgkin's lymphoma as a result of using large amounts of glyphosate-based herbicides in connection with his job as a groundskeeper and pesticide manager.[64] Mr. Johnson twice specifically

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[63] For an analysis of why these juries disagreed with EPA's findings, *see* Benbrook, *Shining a Light on Glyphosate-Based Herbicide Hazard, Exposures and Risk: Role of Non-Hodgkin Lymphoma Litigation in the USA, European Journal of Risk Regulation*, 11 (2020), at 498-519, available at https://www.cambridge.org/core/journals/european-journal-of-risk-regulation/article/shining-a-light-on-glyphosatebased-herbicide-hazard-exposures-and-risk-role-of-nonhodgkin-lymphoma-litigation-in-the-usa/DAB656565EFD8F07DE241C33EFCCDBD1.

[64] 10-ER-2119 at 2132; 10-ER-2155 at 2157-2160.

sought information about links between glyphosate and cancer, but Monsanto did not return his calls.[65] After considering the expert scientific evidence presented at trial, the jury rejected EPA's conclusion that glyphosate was not likely to be a carcinogen; indeed, the court of appeal subsequently noted that Mr. Johnson presented "abundant" evidence that glyphosate caused his cancer.[66] Specifically, in ruling in Mr. Johnson's favor, the jury – after being informed of EPA's conclusion that glyphosate was not a carcinogen – found that the cancer risks from Roundup and Ranger Pro were "known or knowable;" that Monsanto failed to adequately warn of these risks; and that the lack of a sufficient warning was a substantial factor in causing harm to Mr. Johnson.[67] In affirming the judgment, the court of appeal rejected Monsanto's argument that IARC's

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[65] 10-ER-2135, at 2137-2138, 2140-2141; 10-ER-2151 at 2152; 10-ER-2119 at 2122; 10-ER-2151 at 2153.

[66] 10-ER-2155 at 2157-2160; *Johnson v. Monsanto Company* slip opinion, https://www.courts.ca.gov/opinions/archive/A155940M.PDF, at 29 ("In our view, Johnson presented abundant—and certainly substantial—evidence that glyphosate, together with the other ingredients in Roundup products, caused his cancer.").

[67] 10-ER-2155 at 2157-2158. The court of appeal held that "Monsanto was liable on the failure-to-warn claims because substantial evidence was presented that Roundup's risks were 'known or knowable' to Monsanto." *Johnson v. Monsanto Company* slip opinion, https://www.courts.ca.gov/opinions/archive/A155940M.PDF, at 15-20.

Monograph represented a minority view, emphasizing instead "the strength of the Monograph."[68]

In *Hardeman v. Monsanto Co.*, the jury found that the Monsanto product Roundup, which contains glyphosate as its active ingredient, was a substantial factor in causing Edwin Hardeman's non-Hodgkin's lymphoma,[69] and that "Monsanto was negligent by not using reasonable care to warn about Roundup's [non-Hodgkin's lymphoma] risk."[70]

In *Pilliod v. Monsanto Co.,* the jury found that Roundup's design, and Monsanto's failure to adequately warn, were substantial factors in causing Alva and Alberta Pilliod to develop cancer.[71]

Each of the three juries awarded significant punitive damages, partly because they found Monsanto improperly attempted to influence regulators to conclude that glyphosate is not a carcinogen. In *Hardeman,* the court held that it was reasonable for the jury to conclude that Monsanto engaged in "'despicable conduct . . . with a willful and conscious disregard of the rights

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[68] *Id.* at 18, 20.

[69] 10-ER-2163.

[70] 10-ER-2165. Monsanto appealed the judgment to this Court. The case was argued and submitted on October 23, 2020. *Hardeman v. Monsanto Co.*, Ninth Circuit Case No. 19-16253.

[71] 10-ER-2168 at 2173-2177, 2179-2180, 2187-2188. The jury also found that the risks from Roundup were "known or knowable." *Id.* at 2173-2176.

or safety of others'. . . because the evidence easily supported a conclusion that Monsanto was more concerned with tamping down safety inquiries and manipulating public opinion than it was with ensuring its product is safe." *In re Roundup Prods. Liab. Litig*. 385 F. Supp. 3d 1042, 1046 (N.D. Cal. 2019).

In *Pilliod,* Judge Smith found that:

> Monsanto conducted initial studies about glyphosate but decided to not look further when there were indications that glyphosate might cause cancers. Monsanto retained Dr. Parry as a consultant to investigate glyphosate, but then engaged in a campaign to discredit him when it disagreed with what his research indicated. Monsanto worked to publish articles that it had ghostwritten. Monsanto made an aggressive attempt to discredit the IARC decision.[72]

Judge Smith concluded, "Monsanto's efforts to impede, discourage, or distort the scientific inquiry about glyphosate support a jury finding that it could not reasonably rely on the EPA's regulatory action or inaction that was based on that science."[73]

And in *Johnson,* the court of appeal commented that the record contained sufficient evidence to conclude that "Monsanto acted with a

[72] 10-ER-2200 at 2216.
[73] 10-ER-2200 at 2218.

willful and conscious disregard of others' safety." *Johnson v. Monsanto Company,* 52 Cal. App. 5th at 459.[74]

III. PROCEDURAL HISTORY

A. Preliminary Injunction

Monsanto and 13 agricultural and business groups initiated this lawsuit against Lauren Zeise, Ph.D., OEHHA's director, and the Attorney General in November 2017.[75] The amended complaint sought a declaration that both the listing of glyphosate and the Proposition 65 warning requirement as applied to glyphosate were unconstitutional, inter alia, on First Amendment grounds. 11-ER-2330 at 2361. Plaintiffs also sought an injunction invalidating the listing and barring all enforcement of the warning requirement for exposures to glyphosate. *Id.*

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[74] In ruling on a pre-trial motion in *Johnson,* Judge Karnow reached a similar conclusion:

> The internal correspondence noted by Johnson could support a jury finding that Monsanto has long been aware of the risk that its glyphosate-based herbicides are carcinogenic . . . and more dangerous than glyphosate in isolation, but has continuously sought to influence the scientific literature to prevent its internal concerns from reaching the public sphere and to bolster its defenses in products liability actions.

10-ER-2227 at 2271.

[75] Dr. Lauren Zeise, OEHHA's director, who was sued in her official capacity, was dismissed by stipulation, leaving the Attorney General the sole remaining defendant. *National Association of Wheat Growers et al. v. Zeise et al.*, 2:17-cv-2401-WBS-EFB, Dkt No. 93.

On February 26, 2018, the district court declined to enjoin the listing of glyphosate, finding that plaintiffs had not shown a likelihood of success on the merits of their claim that the inclusion of glyphosate on the Proposition 65 list violated the First Amendment. 1-ER-39 at 49. The court explained that because the listing was government speech, the First Amendment did not apply. *Id*.

At the same time, the court held that plaintiffs had shown a likelihood of success on their claim that a warning requirement for glyphosate violated the First Amendment, and that the other preliminary injunction factors weighed in plaintiffs' favor. 1-ER-39 at 50-57. The court therefore enjoined enforcement of the warning requirement. 1-ER-39 at 57-58. The Attorney General moved for reconsideration, which the court denied. 1-ER-59 at 67-68.

B. Summary Judgment

In 2019, the parties cross-moved for summary judgment. On June 22, 2020, the district court granted plaintiffs' motion for summary judgment and denied the Attorney General's motion. 1-ER-5 at 37-38. The court found that Proposition 65's warning requirement could not be applied to

glyphosate in a manner consistent with the First Amendment's restrictions on compelled speech. *See* 1-ER-5 at 30-32.

In so holding, the court rejected the nuanced warning offered by the Attorney General:

> "**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."

In reaching this conclusion, the court considered whether a warning for glyphosate should be subject to the lenient scrutiny applicable to compelled commercial speech that is "purely factual and uncontroversial," *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 651 (1985). 1-ER-5 at 18-20. The court determined that the *Zauderer* standard was inapplicable because any warning that complied with Proposition 65's "clear and reasonable" requirement would be misleading, and thus it would not be "purely factual and uncontroversial." 1-ER-5 at 23-33.

In reaching its holding, the district court placed great emphasis on the fact that the regulatory safe harbor language required a warning that a chemical is "known to the state of California to cause cancer." 1-ER-5 at

23. The district court discounted the express statement in the Attorney General's proposed non-safe-harbor warning that California has determined that glyphosate is a carcinogen "pursuant to Proposition 65," as well as the provisions of the statute that define when a chemical is "known to the State" to cause cancer. 1-ER-5 at 23-24. It also discounted the proposed warning's explanation that California has identified glyphosate as a carcinogen based on the determination by IARC that there is sufficient evidence of carcinogenicity from animal studies and that glyphosate is probably carcinogenic to humans. 1-ER-5 at 31. Instead, notwithstanding IARC's determination, given the disagreement among regulators, the district court reasoned that a warning stating that California "know[s]" that glyphosate causes cancer would be misleading to the ordinary consumer.[76] 1-ER-5 at 23-24. The court did not specifically consider any of the scientific evidence, but rather emphasized the number of agencies that diverged from IARC's conclusion. 1-ER-5 at 23-26. The court allowed that "there need

[76] The court did not specifically rule on whether the alternative warnings the Attorney General proposed would comply with Proposition 65, as it considered them misleading. The district court focused primarily on analyzing the language of the non-mandatory safe harbor warning because of the protection it provided from suits by private enforcers. 1-ER-5 at 23-27.

not be a complete consensus among the scientific community before a warning may be required," but ultimately held that California could not compel companies to disclose the findings of one agency when others disagree. 1-ER-5 at 33.

Next, having determined that the warning was not "purely factual and uncontroversial," the court applied intermediate scrutiny under *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557 (1980). 1-ER-5 at 33-35. It concluded that the State had not shown that Proposition 65's warning requirement, as applied to glyphosate, directly advanced the State's interest in informing the public about exposures to chemicals that cause cancer, and that it therefore failed the *Central Hudson* test. 1-ER-5 at 33-35.

The court entered judgment for plaintiffs on August 11, 2020. 1-ER-2. This appeal followed.

SUMMARY OF ARGUMENT

The District Court erred in holding that there was no possible Proposition 65 warning for glyphosate that satisfies the First Amendment's relaxed criteria for compelled commercial speech. Under the Supreme Court's and this Court's precedents, disclosure mandates are subject to reduced scrutiny, and must be upheld "if the information in the disclosure is

reasonably related to a substantial government interest and is purely factual and uncontroversial." *CTIA II*, 928 F.3d at 845 (citing *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985)).

The warning the Attorney General offered to the district court, and that he offers again here, *infra* at 49, meets this standard.

The warning is "purely factual," informing Californians of the carcinogenicity determination of the United Nations' International Agency for Research on Cancer, a worldwide leader in cancer research, regarding the active ingredient in a pesticide. Under *CTIA II*, the existence of a scientific disagreement does not create a "controversy" within the meaning of the First Amendment that could invalidate a warning requirement. *Id*. at 848. Indeed, that case makes clear that the First Amendment does not bar the State from requiring a warning even if a scientific consensus has not yet emerged. *Id*. In any event, to ensure that consumers are in no way misled by the overall import of the warning, the Attorney General's proposed warning provides relevant context explaining what it means for a chemical to be a known carcinogen under Proposition 65, as well as information about EPA's divergent finding.

The warning clearly furthers California's substantial interest in protecting the health and welfare of its people by requiring companies to provide them with information they can use to make a choice to avoid or minimize their exposure by taking certain basic precautions. The First Amendment simply does not entitle businesses that expose individuals to significant amounts of a chemical identified as a carcinogen by an international expert cancer research agency to refuse to inform them of this carcinogenicity determination.

STANDARD OF REVIEW

This Court reviews a grant of summary judgment de novo. *L. F. v. Lake Wash. Sch. Dist.* #414, 947 F.3d 621, 625 (9th Cir. 2020); *see also Def. of Wildlife v. Zinke*, 856 F.3d 1248, 1256 (9th Cir. 2017) (court reviews de novo a district court's rulings granting or denying cross-motions for summary judgment). Viewing the evidence in the light most favorable to the non-moving party, the Court must determine "whether there are any genuine issues of material fact and whether the district court correctly applied the relevant substantive law." *L. F. v. Lake Wash. Sch. Dist.* #414, 947 F.3d at 625 (citation omitted).

When the constitutionality of a statute is challenged, this Court first determines whether the statute can be reasonably construed to avoid the

constitutional difficulty. *Ellis v. Bhd. of Ry., Airline & S.S. Clerks, Freight Handlers, Exp. & Station Employees*, 466 U.S. 435, 444 (1984); *see also Arizonans for Official English v. Arizona*, 520 U.S. 43, 78 (1997) (citations, ellipses, and internal quotation marks omitted) (A "cardinal principle" is that courts must "ascertain whether a construction is fairly possible that will contain the statute within constitutional bounds").

ARGUMENT

The district court misapplied controlling Supreme Court and Ninth Circuit case law to conclude that any Proposition 65 warning for glyphosate would necessarily be misleading, and that therefore the Proposition 65 warning requirement for glyphosate is unconstitutional. In this section, the Attorney General demonstrates that district court's conclusion was erroneous, arguing that relaxed scrutiny applies to compelled commercial speech; that the Attorney General's proposed warning, analyzed under *Zauderer*, falls within the bounds of the First Amendment; and that the Attorney General's warning passes muster even if the Court applies the less deferential standard of review set forth in *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980).

I. DISCLOSURE REQUIREMENTS FOR COMMERCIAL SPEAKERS ARE SUBJECT TO REDUCED SCRUTINY UNDER THE FIRST AMENDMENT.

Supreme Court "jurisprudence has emphasized that 'commercial speech [enjoys] a limited measure of protection, commensurate with its subordinate position in the scale of First Amendment values,' and is subject to 'modes of regulation that might be impermissible in the realm of noncommercial expression.'" *Bd. of Trs. of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 477 (1989) (quoting *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 456 (1978)) (alteration in original). This already-limited level of protection is further circumscribed when the speech in question is compelled rather than restricted: "First Amendment interests implicated by disclosure requirements are substantially weaker than those at stake when speech is ctually suppressed." *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 n.14 (1985); *National Institute of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361, 2372 (2018) (*NIFLA*) ("This Court's precedents have applied a lower level of scrutiny to laws that compel disclosures in certain contexts"). First Amendment protection for commercial speech is "justified principally by the value to consumers of the information such speech provides," such that "[a party's] constitutionally protected interest in

not providing any particular factual information in his advertising is minimal." *Zauderer*, 471 U.S. at 651 (emphasis in original).

Recent cases in this Court have confirmed the applicability of the *Zauderer* standard to compelled commercial speech. In *American Beverage Ass'n v. City & County of San Francisco*, 916 F.3d 749 (9th Cir. 2019) (en banc), this Court held that *Zauderer's* reduced scrutiny standard applies to all laws that compel "disclosure of factual, noncontroversial information . . . in commercial speech." *American Beverage*, 916 F.3d at 755 (quoting *NIFLA*, 138 S. Ct. at 2372) (internal quotation marks omitted). The Court reaffirmed this holding in *CTIA II*, 928 F.3d 832. There, the Court specifically rejected the argument that the compelled disclosure at issue should be analyzed under *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980), holding instead that *Zauderer* applied. *CTIA II*, 928 F.3d at 841-44.

II. A GLYPHOSATE WARNING REQUIRED BY PROPOSITION 65 CAN COMPLY WITH THE FIRST AMENDMENT.

Contrary to the district court's conclusion, a warning for glyphosate that complies with Proposition 65 can be purely factual, uncontroversial, and

not unduly burdensome, and thus comply with the First Amendment.[77] Moreover, any such warning will be reasonably related to the State's substantial interest in protecting Californians' health and safety, because it will provide them with information they can use to decide whether to minimize their exposure to a chemical IARC has identified as a carcinogen.

Because the district court erroneously concluded that there could be no Proposition-65-compliant warning for glyphosate that also passed muster under the First Amendment, to prevail here, the Attorney General need only demonstrate that there exists *one* such warning. Therefore, although the Attorney General contends that the optional safe-harbor warning applied to glyphosate[78] complies with the First Amendment for purposes of this appeal, the Attorney General offers the same warning he offered to the district court

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[77] In this brief, the Attorney General analyzes a glyphosate warning that *can* be given, because to date, there have been no compelled Proposition 65 warnings for glyphosate. Plaintiffs filed their lawsuit shortly after the chemical was placed on the Proposition 65 list, before enforcement actions could be filed, and enforcement has been enjoined since February 2018. 1-ER-39 at 57-58.

[78] The safe harbor warning for glyphosate in a consumer product would read: "**WARNING**: This product can expose you glyphosate, a chemical known to the State of California to cause cancer." Cal. Code Regs. tit. 27, § 25603(a)(2)(A).

in connection with his cross-motion for summary judgment.[79] This proposed warning takes advantage of Proposition 65's flexibility by providing additional factual context that specifically explains how, pursuant to the statute, the State can be said to "know" that glyphosate causes cancer:

> **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.[80]

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[79] There are other warning variations, including the additional warnings proposed by the Attorney General to the district court, 1-ER-5 at 30-31, that would comply with the First Amendment and with Proposition 65. For example, a valid warning could replace "known to cause cancer under Proposition 65" with "has been identified as causing cancer under California's Proposition 65" or something similar. *See, e.g., supra* at 15. A valid warning could also provide information on how to reduce exposures. *Cf.* Cal. Code Regs. tit. 27, § 25601(e) (safe harbor warning content may include supplemental information that provides information on how to reduce or avoid exposure to the identified chemical(s)). However, it is unnecessary for this Court to consider other warning language, because the warning presented here satisfies the First Amendment and complies with Proposition 65.

[80] Pesticide labels regulated by EPA and the California Department of Pesticide Regulation may substitute the word "**NOTICE**" or "**ATTENTION**" for the word "**WARNING**." Cal. Code Regs. tit. 27, § 25603(d).

A. The Attorney General's Proposed Warning for Glyphosate Complies with *Zauderer* and *CTIA II*.

This case presents an unusual set of circumstances. This is the first First Amendment challenge to the Proposition 65 warning requirement for a chemical over which two authoritative bodies (IARC and EPA), each recognized as a source for identifying and listing carcinogens under Proposition 65, have contemporaneously reached differing conclusions. By accounting for these circumstances, the Attorney General's proposed warning survives First Amendment scrutiny under *Zauderer* and its progeny because, as detailed below, it is (1) purely factual; (2) uncontroversial; (3) reasonably related to a substantial state interest; and (4) not unduly burdensome. *See CTIA II*, 928 F.3d at 845-849; *American Beverage*, 916 F.3d at 756.

In *CTIA II*, this Court upheld the constitutionality of a city ordinance requiring retailers of cell phones to inform prospective purchasers that carrying cell phones in certain ways could cause them to exceed guidelines for radio-frequency radiation promulgated by the Federal Communications Commission (FCC). 928 F.3d at 837. The Court upheld the warning despite the fact that the safety of exposure to cell phone radiation was the subject of scientific disagreement, and despite the plaintiff industry group's assertion

that the required disclosure was "inflammatory and misleading," and thus "controversial" and not "purely factual." *Id*. at 847-48. The Court examined the language of the warning sentence by sentence, and in addition to concluding that every sentence was literally truthful, held that the warning as a whole was not misleading. *See id*. at 846-49.

In addition, the Court expressly rejected the argument that the warning was "controversial," despite the "controversy concerning whether radio-frequency radiation from cell phones can be dangerous . . . ." *Id*. at 848. Distinguishing the compelled speech held unconstitutional in *National Institute of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361 (2018), it noted that "[w]e do not read the Court as saying broadly that any purely factual statement that can be tied in some way to a controversial issue is, for that reason alone, controversial." *CTIA II,* 928 F.3d at 845. As the Court explained,

> The dispute in *NIFLA* was whether the state could require a clinic whose primary purpose was to oppose abortion to provide information about "state-sponsored services," including abortion. *While factual, the compelled statement took sides in a heated political controversy*, forcing the clinic to convey a message fundamentally at odds with its mission.

Id. at 845 (emphasis added).

In the present case, the Attorney General's nuanced warning – which provides accurate information about IARC's finding that glyphosate is a carcinogen, and EPA's opposing viewpoint – complies with the First Amendment while providing people with access to information they need to make their own decisions about whether or not to use glyphosate-based herbicides, and whether or not to take precautions before using them if they choose (or are required) to use them.

Like the warning upheld in *CTIA II*, each sentence of the Attorney General's proposed warning contains indisputably accurate factual statements, and there is nothing misleading about the warning as a whole. Like the warning in *CTIA II*, the Attorney General's warning provides information similar to that supplied by federal agencies, *see infra* at 62-65, and directs people to a source of additional information for further research. 928 F.3d at 847-48. Indeed, plaintiffs provided no evidence that the average Californian would consider the warning misleading, or understand it to mean something other than what it says: that IARC reached one conclusion about carcinogenicity, EPA another, and that more information about glyphosate and links to these findings can be found on the Proposition 65 warnings website.

1. The Warning is Purely Factual.

The Attorney General's proposed warning explains in plain terms what it means that California has determined that glyphosate is "known to cause cancer under Proposition 65." Under Proposition 65, "known to [the state to] cause cancer" is specifically defined to mean that a chemical was placed on the Proposition 65 list by operation of one of the four statutory listing methods, Cal. Health & Safety Code § 25249.8; *ExxonMobil Corp. v. OEHHA*, 169 Cal. App. 4th 1264, 1269 (Cal. Ct. App. 2009). Glyphosate is "known to the state to cause cancer" within the meaning of the Proposition 65 because IARC's carcinogenicity determination triggered glyphosate's inclusion on the Proposition 65 list pursuant to the Labor Code listing mechanism.

Analyzing the warning sentence by sentence, as the Court did in *CTIA II*, underscores the extent to which the warning is purely factual.

The first sentence of the proposed warning – "**WARNING**: This product can expose you to glyphosate." – is necessarily factual. The warning will only be used on products that could, in fact, expose people to glyphosate.

The second sentence is also entirely factual. "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 that it is probably carcinogenic to humans." Every statement in this sentence is incontestably true. The sentence sets out the State's determination "that glyphosate is known to cause cancer under Proposition 65" – a determination that led to its placement on the Proposition 65 list, an action whose constitutionality was upheld last year by a unanimous California court of appeal, *Monsanto v. OEHHA*, 22 Cal. App. 5th at 540; explains the basis for the State's determination ("because the International Agency for Research on Cancer has classified it as a carcinogen"); and states explicitly what IARC found. Thus, for the average individual who is not likely to understand what it means for a chemical to be "known to cause cancer" under Proposition 65, the sentence explains it.

The third sentence in the warning is also a factual statement. "The EPA has concluded that glyphosate is not likely to be carcinogenic to

humans." This sentence accurately reflects EPA's statements about its conclusion.[81]

The last sentence provides an instruction, not a fact: it tells consumers to consult the official State of California Proposition 65 warnings website, www.P65warnings.ca.gov, for more information. Like the warning at issue in *CTIA II*, which directed consumers to consult their user manuals for additional information, 928 F.3d at 838, the warning here directs consumers to the Proposition 65 warning website, whose fact sheet on glyphosate (https://www.P65warnings.ca.gov/sites/default/files/downloads/factsheets/glyphosate_fact_sheet.pdf) provides detailed information from six different agencies, including EPA, ECHA, and the Joint FAO/WHO Meeting on Pesticide Residues, along with information on how to reduce exposure.[82]

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[81] Glyphosate Interim Registration Review Decision (January 2020), available at https://www.epa.gov/sites/production/files/2020-01/documents/glyphosate-interim-reg-review-decision-case-num-0178.pdf, at 10 ("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.")

[82] *See* 10-ER-2276; *CTIA II*, 928 F.3d at 847 (discussing warning's instruction to consult user manual as part of *Zauderer* inquiry).

In short, the Attorney General's proposed warning presents in summary form the findings of the two authoritative bodies under Proposition 65 to have reached conclusions on the carcinogenicity of glyphosate.

The district court attempted to distinguish the Attorney General's warning from the warning upheld in *CTIA II* on the ground that the disclosure at issue there did not "make any claims that failure to comply with . . . guidelines would cause any particular effect . . . ." 1-ER-5 at 33. But there is no meaningful distinction to be drawn between the two cases. The city ordinance at issue in *CTIA II* required retailers to warn consumers that holding their cell phones in certain ways could cause consumers to exceed the FCC guidelines for radiation. Though the warning at issue did not state that exceeding the FCC guidelines would cause a particular harm to consumers, the Court still found that the city's compelled disclosure about radiation furthered the government's substantial interest in protecting the health and safety of consumers. *CTIA II*, 928 F.3d at 845-46. The city's compelled disclosure thus necessarily warned of a potential health effect. If it were otherwise, the warning could not have advanced the city's interest in protecting consumers' health and safety. That the city's warning does not explicitly name the particular potential adverse health effects of excessive

radiation exposure while the proposed warning in this case specifically warns of cancer is a distinction without difference.

2. The Warning Is Uncontroversial.

Despite Monsanto's efforts to influence EPA's and other agencies' findings, and to create the appearance of more of a scientific controversy about the safety of glyphosate than actually exists,[83] the warning language itself is uncontroversial under *CTIA II* and the Supreme Court's decision in *NIFLA*, for two reasons.

First, as this Court held in *CTIA II*, if the speech to be compelled is factually accurate, the First Amendment does not prohibit compelled disclosures relating to any topic over which there exists some scientific disagreement. *See CTIA II*, 928 F.3d at 848 (despite controversy over the risk from radio-frequency radiation from cell phones, Berkeley's required disclosure was "uncontroversial" for purposes of the First Amendment analysis). A risk need not be a "universally acknowledged health risk" to be the subject of a required warning. If it were otherwise, compelled speech on a broad range of public health and safety topics would be prohibited,

[83] *See* discussion *supra* at 37-38.

hampering the exercise of government regulation long held to be permissible.[84] *Cf. NIFLA*, 138 S. Ct. at 2376 (the Supreme Court does "not question the legality of health and safety warnings long considered permissible"). Indeed, in the case of tobacco smoke, it took decades to build a scientific consensus about its risks, in large part because the tobacco industry lobbied hard to sow doubt.[85] The First Amendment does not require such an extensive incubation period before the State can compel disclosure of information based on the reliable findings of a renowned expert scientific agency. Businesses have no constitutional right to withhold that information. *See Zauderer*, 471 U.S. at 651 ("[a party's] constitutionally

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[84] As the Second Circuit noted in *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104 (2d Cir. 2001) (upholding state statute requiring manufacturers to label products and packaging to inform consumers of mercury content in their products), "Innumerable federal and state regulatory programs require the disclosure of product and other commercial information . . . . To hold that the Vermont statute is insufficiently related to the state's interest in reducing mercury pollution would expose these long-established programs to searching scrutiny by unelected courts. Such a result is neither wise nor constitutionally required." 272 F.3d at 116 (citing among others, disclosure requirements for campaign contributions, securities, tobacco products, prescription drug advertisements, workplace hazards, and pesticide formulas).

[85] U.S. Dep't of Health and Human Services, The Health Consequences of Smoking—50 Years of Progress, A Report of the Surgeon General, https://www.ncbi.nlm.nih.gov/books/NBK179276/pdf/Bookshelf_NBK179276.pdf, at 20-22.

protected interest in *not* providing any particular factual information in his advertising is minimal") (emphasis in original).

Second, the scientific debate over whether glyphosate causes cancer is distinguishable from the kind of moral or ethical controversy at issue in *NIFLA*, where health care providers were required to post a message relating to abortion, one of the most politically divisive issues of our day. *NIFLA*, 138 S. Ct. at 2372. Indeed, this Court highlighted the distinction in *CTIA II*. 928 F.3d at 848. Despite the parties' disagreement about the safety of cell phone radiation exposure, the court held Berkeley's required disclosure "uncontroversial within the meaning of NIFLA [because it] does not force cell phone retailers to take sides in a heated political controversy." *CTIA II*, 928 F.3d at 848 (citing *NIFLA*, 138 S. Ct. at 2376). Thus, although the potential carcinogenicity of glyphosate has been a subject of intense press coverage, and, like the safety of radio-frequency radiation, the subject of scientific debate, the warning is not "controversial" for purposes of *Zauderer*. Unlike abortion, which was at issue in *NIFLA*, and is "anything but an 'uncontroversial' topic," *NIFLA*, 138 S. Ct. at 2372, cancer is not controversial. A factual Proposition 65 warning would not require plaintiffs

"to convey a message fundamentally at odds with their [political] mission."[86] *CTIA II*, 928 F.3d at 845.

3. The Warning Is Not Misleading.

Nor is the Attorney General's proposed warning misleading. To the contrary, it presents clearly and fairly why and how California has concluded that glyphosate is a carcinogen. Taken as a whole, the warning conveys truthful and accurate information to individuals who may be exposed to large amounts of the pesticide, in order to enable them to make their own decisions about whether to minimize or eliminate their exposures to it. It also directs them to the Proposition 65 warnings website (www.P65warnings.ca.gov) for additional information if they wish to learn more about the cancer risk they may face by using glyphosate, or how to take precautions to minimize exposure.

Notwithstanding these facts, the district court held that the warning was misleading, reasoning that the most "obvious" reading of a warning stating that glyphosate is "known to cause cancer" is that any "exposure to glyphosate *in fact* causes cancer." 1-ER-5 at 24 (emphasis added). But the

[86] Given the sui generis approach to the definition of "controversial" in *NIFLA*, until the doctrine is developed further, it is far from clear that disclosures about any subject other than abortion should be considered inherently controversial for purposes of First Amendment analysis.

district court's conclusion disregards the language of the Attorney General's proposed warning, which specifically states that glyphosate is "known to cause cancer *under Proposition 65*," and explains exactly what this means — that California has concluded glyphosate is a carcinogen because IARC has found it causes cancer in animals and is probably carcinogenic to humans. Even if the meaning of the phrase "known to cause cancer under Proposition 65" may not ordinarily be clear to the average consumer, when read in context of the entirety of the warning, there is no basis to conclude that consumers and employees would understand it to mean something other than what it says.

Further, 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 – especially in light of the warning's inclusion of the EPA determination. Indeed, it is just as plausible that a typical Californian would interpret the warning to mean that a state agency had determined that glyphosate met certain defined criteria for identification as a carcinogen.

Perhaps most troubling to the district court was that the proposed warning listed the conclusions of IARC and EPA only, suggesting an "equal

weight for and against the authority that glyphosate causes cancer . . . ." 1-ER-5 at 31. This was particularly problematic, in the court's view, because the court considered IARC's carcinogenicity determination to be outweighed by the findings of all of the other agencies to have addressed the issue. *Id.* at 29-30. The flaw in the district court's analysis is that it relied on a "count-the-noses" approach to conclude that glyphosate did not cause cancer, while disregarding two important facts: (1) as discussed *supra* at 28-31, some of the agencies plaintiffs referenced undertook only an assessment of cancer *risk* attributable to glyphosate, rather than a hazard assessment, meaning their analyses were therefore not relevant; and (2) not every agency's carcinogenicity determination carries equal weight.

IARC is a respected international cancer-evaluation agency, and it undertook a robust evaluation of glyphosate's carcinogenicity. In so doing, IARC convened a panel of experts screened for conflicts of interest, including scientists from EPA, the U.S. National Cancer Institute, the U.S. National Institute of Environmental Health, and the California Environmental Protection Agency; professors from Texas A&M University and Mississippi State University; and experts from Australia, Canada, Chile, France, Finland, Italy, New Zealand, and the Netherlands. These experts

concluded, *by consensus*, that glyphosate causes cancer in laboratory animals and is a probable human carcinogen.[87]

The validity of IARC's hazard assessment is bolstered both by several scientific publications and by OEHHA's careful review and conclusion that glyphosate caused cancer in laboratory animals by mechanisms that can operate in humans. It is also supported by the fact that the juries in *Johnson v. Monsanto Company* and *Pilliod v. Monsanto Co.* found that the cancer risks from glyphosate-based pesticides were "known or knowable." 10-ER-2255 at 2158; 10-ER-2168 at 2173.

Moreover, in meeting the voters' demand that a company that exposes individuals to a listed carcinogen must inform them of the carcinogenicity determination that triggered the listing, the Attorney General's proposed warning is similar to information required, or provided, by five federal agencies charged with protecting public health and safety.[88] For example, as discussed *supra* at 20-21, OSHA requires that businesses provide Safety Data Sheets to workers who may be exposed to hazardous chemicals, and that these Safety Data Sheets state "[whether] the hazardous chemical . . .

[87] 4-ER-727 at 751; 7-ER-1201 at 1202-1203.
[88] *See* the proposed warning, *supra* at 49.

has been found to be a potential carcinogen in the [IARC] Monographs (latest edition), or by OSHA."[89] 29 C.F.R. § 1910.1200, App. D. The U.S. Department of Health and Human Services Agency for Toxic Substances and Disease Registry's (ATSDR) online fact sheet about glyphosate states:

> **Can glyphosate cause cancer?**
>
> There have been several agencies and organizations both in the United States and internationally that have reviewed studies and made an assessment about whether glyphosate could cause cancer.
>
> The U.S. Environmental Protection Agency (EPA) classification for glyphosate is "not likely" to be carcinogenic (causing cancer) to humans, based on evidence from animals and humans.
>
> The International Agency for Research on Cancer (IARC) has classified glyphosate as "probably" carcinogenic to humans, which means there was sufficient evidence to find

[89] Monsanto lists IARC's 2015 carcinogenicity determination (while simultaneously disavowing it) on at least one of its Safety Data Sheets. 6-ER-1237. The October 15, 2015 Safety Data Sheet for Roundup® Ready-to-Use Weed & Grass Killer III, indicates, under "OSHA Status," "This product is hazardous according to the OSHA Hazard Communication Standard, 29 CFR 1910.1200." 6-ER-1237 at 1239. Under "Toxicological Information – Carcinogenicity," the Safety Data Sheet states,

> Not carcinogenic in rats or mice. *Listed as Category 2A by the International Agency for Research on Cancer (IARC) but our expert opinion is that classification as a carcinogen is not warranted.*

6-ER-1237 at 1243 (emphasis added). Because it is unclear whether such a Safety Data Sheet would comply with the OSHA regulations, it might or might not eliminate the need for a separate Proposition 65 warning. *See* Cal. Code Regs. tit. 27, § 25606.

> cancer in animals, but limited evidence finding cancer in humans.[90]

In this sense, the Attorney General's proposed warning, like the warning in *CTIA II*, "provides in summary form information that [a federal agency] has concluded consumers should know in order to ensure their safety." *CTIA II*, 928 F.3d at 847.

In addition, three other federal agencies all considered "authoritative bodies" under Proposition 65 – the FDA, NTP, and EPA itself – have issued fact sheets about glyphosate that include information about the 2015 IARC carcinogenicity determination, followed by information about other international organizations' conclusions. 2-ER-102 at 115-116, ¶¶ 58-60; 11-ER-2283 at 2283-2286; 11-ER-2287 at 2287-2291; 11-ER-2292 at 2292-2295. All four federal agencies consider it important for consumers and workers to have the information about the IARC determination. *See* 11-ER-2280 at 2282; 11-ER-2283 at 2285; 11-ER-2288; 11-ER-2293. There is no reason to conclude that information similar to that provided by these federal

[90] *See* 11-ER-2282; https://www.atsdr.cdc.gov/toxfaqs/tfacts214.pdf. Despite referring to "several agencies and organizations both in the United States and internationally" that have made such assessments, ATSDR's fact sheet, like the Attorney General's proposed warning, only references the IARC and EPA determinations, suggesting that they carry the most weight.

agencies is misleading when contained in a warning provided by a company responsible for the exposures.

In any event, while the proposed warning is necessarily abbreviated because a line must be drawn regarding which agency conclusions to include (here, it is logically drawn to include the two authoritative bodies to have specifically evaluated glyphosate's carcinogenicity),[91] consumers who want additional information – including the findings of other agencies - are directed to the Proposition 65 warnings website at www.P65warnings.ca.gov (just as the Berkeley ordinance at issue in *CTIA II* directed consumers to their phones' user manuals for more information, *see* 928 F.3d at 847).

4. The Warning Is Reasonably Related to the State's Substantial Interest in Protecting Public Health and Safety.

There can be no dispute that cancer is a grave concern, and that the State has a substantial interest in reducing its population's risk of contracting cancer. When an organization of IARC's stature determines that a chemical

[91] By including a reference to the EPA determination, which was not required (although permitted) by Proposition 65, the warning advances important First Amendment speech principles. *See, e.g.*, *Zauderer*, 471 U.S. at 651 (First Amendment protection for commercial speech is justified by the value the speech provides to consumers); *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 757 (1976) (citation omitted) (recognizing "a First Amendment right to receive information and ideas").

is a carcinogen, and assigns it to its second highest cancer classification because of the hazard it presents, California has a vital public health and safety interest in ensuring that businesses provide people with these facts so they can make informed decisions to protect themselves. *See CTIA II*, 928 F.3d at 845 ("There is no question that protecting the health and safety of consumers is a substantial government interest."); *NIFLA*, 138 S. Ct. at 2376 (the Supreme Court does "not question the legality of health and safety warnings long considered permissible[.]") This informational goal is "inextricably intertwined," *Sorrell*, 272 F.3d at 115, with the public health and safety goals enumerated in the preamble to the proposed law in the ballot pamphlet.[92]

When voters enacted Proposition 65, they were concerned that they were not adequately protected from exposures to chemicals with potential adverse health impacts. In determining which chemical exposures required a

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[92] "*The people therefore declare their rights: (a) To protect themselves and the water they drink against chemicals that cause cancer, birth defects, or other reproductive harm. (b) To be informed about exposures to chemicals that cause cancer, birth defects, or other reproductive harm. (c) To secure strict enforcement of the laws controlling hazardous chemicals and deter actions that threaten public health and safety . . . .*" 2-ER-118 at 120.

warning and when, the voters placed great weight on the findings of certain well-regarded governmental and non-governmental organizations. The voters wanted to make sure that businesses would be responsible for warning them of exposures to chemicals *any* of these entities had found were likely to cause cancer or reproductive harm, regardless of what other entities concluded (or did not conclude). *See Monsanto v. OEHHA,* 22 Cal. App. 5th at 556.

The statute's emphasis on providing information that would allow individuals to make informed choices thus anticipated a situation like the one here, where IARC has found that a chemical can cause cancer but another authoritative body under the statute, EPA, has not. Under these circumstances, the voters specifically wanted persons exposed to the IARC-identified chemical to receive the warnings, "regardless of whether other identified listing agencies or processes agree." *Id.* Indeed, as noted above, federal agencies tasked with protecting human health – including ATSDR, NTP, the FDA, and EPA itself – have deemed information about the 2015 IARC carcinogenicity determination important enough to provide to

consumers.[93] There can be little doubt that California has a substantial interest in requiring businesses to disseminate this information.[94]

5. The Warning Is Neither Unjustified Nor Unduly Burdensome.

Finally, the Attorney General's proposed warning is neither unjustified nor unduly burdensome, for four reasons.

First, Proposition 65 does not require a business to provide a warning where it can demonstrate that the exposure does not pose a significant risk of cancer. *See* Cal. Health & Safety Code § 25249.10(c). Unrebutted evidence in the record before the district court demonstrated that exposures to glyphosate in food products would fall below the NSRL, and thus would not require warnings. 6-ER-1368 at 1370-1376; *see* discussion *supra* at 27-28.

Second, for occupational exposures, a warning is adequate if it meets the requirements of the federal Hazard Communication Standard. Cal. Code Regs. tit. 27, § 25606. Pursuant to this provision in the Proposition 65

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[93] 11-ER-2280 at 2282; 11-ER-2283 at 2285; 11-ER-2287; 11-ER-2292 at 2293.

[94] As a practical matter, because of the high safe-harbor NSRL set by OEHHA, and because of the role of the Attorney General's Office in discouraging unmeritorious notices, a warning will only be compelled for businesses exposing Californians to comparatively large amounts of glyphosate. *See* discussion *supra* at 15-17.

regulations, where pesticide manufacturers like Monsanto and companies whose workers are required to use glyphosate fully comply with the warning and labeling requirements of the OSHA regulations, no separate Proposition 65 warning need be provided at all.[95] *Id*.

Third, if circumstances mandate a Proposition 65 warning for a particular exposure, the statute and regulations would not require it to be so large that it would threaten either to chill or to "drown out" plaintiffs' own speech. *Cf. American Beverage*, 916 F.3d at 757.

In *American Beverage*, where the ordinance at issue required a warning to occupy 20% of the total advertising space, this Court explained that the warning would "'drown[] out [p]laintiffs' messages and 'effectively rule[] out the possibility of having [an advertisement] in the first place,'" *id*. (quoting *NIFLA*, 138 S. Ct. at 2378). In contrast, in *CTIA II*, the Ninth Circuit held that Berkeley's ordinance requiring retailers to provide notice to customers regarding radio-frequency radiation exposure was not unduly burdensome because it could be satisfied with a single 8.5 by 11-inch posted notice or a 5 by 8-inch handout to which retailers could add additional information. 928 F.3d at 849. The Court explained that such a requirement

[95] Whether or not Monsanto's current Safety Data Sheets comply with the OSHA regulations is beyond the scope of this appeal.

"[did] not interfere with advertising or threaten to drown out messaging" by the retailers. *Id.*

Similarly, nothing in Proposition 65 or its implementing regulations requires warnings that are so large that they will interfere with or "drown out" other messaging, rendering them unduly burdensome.[96] *See CTIA II*, 928 F.3d at 849. Proposition 65 warnings need only 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." Cal. Code Regs. tit. 27, § 25601(c) (safe harbor warnings).

Moreover, the size of any required warning will not prevent plaintiffs from saying whatever they wish about their product on their websites (as Monsanto's parent company does already, https://www.bayer.com/en/glyphosate/is-glyphosate-safe), or on other parts

[96] The First Amendment inquiry asks how burdensome is the act of providing the warning. See *CTIA II*, 928 F.3d at 849 ("This minimal requirement does not interfere with advertising or threaten to drown out messaging by the cell phone retailers subject to the requirement.")

of their label, in advertisements, in public statements, or to their distributors (although other laws or regulations might). The fact that the warning makes clear that the determination is California's, not their own, enables businesses to further distance themselves from the warning if they so desire. This was an important factor in the Court's analysis in *CTIA II*. 928 F.3d at 848-49.

Fourth, any contention that providing the warning would be unduly burdensome is further undermined by a preliminary settlement by which Monsanto has agreed to request permission from EPA to provide the same type of information in the warning the Attorney General has proposed here.[97]

In sum, the Attorney General's proposed warning survives scrutiny under *Zauderer* because the warning is purely factual and uncontroversial; because requiring businesses to disseminate information about IARC's carcinogenicity determination advances the State's substantial interest in

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[97] On February 3, 2021, Monsanto's parent company announced a tentative settlement of a class action lawsuit against Monsanto in the Northern District of California. *See* https://media.bayer.com/baynews/baynews.nsf/id/Bayer-announces-agreement-with-plaintiffs-counsel-on-class-plan?Open&parent=news-overview-category-search-en&ccm=020. Pursuant to this settlement, which requires court approval, Monsanto has agreed, among other things, to request permission from EPA to include links on its labeling to the views of different agencies, including IARC, regarding the carcinogenicity of glyphosate. *See* https://www.lieffcabraser.com/pdf/Class_Plan_Documents.pdf, Settlement Agreement, Article IX.

protecting public health and safety; and because the warning is neither unjustified nor unduly burdensome.

B. The Proposed Warning in this Case Also Complies with *Central Hudson.*

If this Court were to hold – which it should not – that the Attorney General's proposed warning is not "purely factual" and uncontroversial, and that *Zauderer* thus does not apply here, the proposed warning would still pass muster under the stricter standard of *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557 (1980). Under *Central Hudson*, if a state wishes to regulate commercial speech, the state "must assert a substantial interest to be achieved," "the regulatory technique must be in proportion to that interest[,]" and "[t]he limitation on expression must be designed carefully to achieve" the state's goal. *Central Hudson*, 447 U.S. at 564. Critically, the Supreme Court has made clear that *Central Hudson* did not impose a least-restrictive-means test under which there must be no conceivable alternative to the State's chosen means. *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 5556 (2001). Instead, there must be a "fit" between the legislature's ends and the means chosen to accomplish those ends, one that "is not necessarily perfect, but reasonable[,]" "in proportion to the

interest served[,]" and "narrowly tailored" to achieve the desired objective. *Fox*, 492 U.S. at 478, 480 (citations and internal quotation marks omitted).

In contrast to the unduly burdensome regulations at issue in *Central Hudson,* which completely banned promotional advertising by a utility, 447 U.S. at 572, and *American Beverage*, which mandated a warning that would occupy 20% of the advertisement space, 916 F.3d at 757, the Proposition 65 warning requirement for glyphosate is narrowly tailored to require businesses to provide information the State has a substantial interest in disseminating effectively. *See Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d, 18 at 26 (D.C. Cir. 2014) ("[t]he self-evident tendency of a disclosure mandate to assure that recipients get the mandated information may in part explain why, where that is the goal, many such mandates have persisted for decades without anyone questioning their constitutionality.").

Indeed, while all the First Amendment requires is a "reasonable fit" between the State's means and its objective, it is difficult to conceive of a more targeted means of meeting the State's objective in this case. While the State provides information about glyphosate on its own website, www.oehha.ca.gov, and on the Proposition 65 warnings website, www.P65warnings.ca.gov, occupational, package, and point-of-sale warnings are necessary to ensure that the specific information voters wanted

conveyed about IARC's determination actually reaches persons most in need of the information.

Proposition 65's flexibility with respect to warning language, coupled with the existence of the NSRL, further strengthens the "fit" between the State's objective and its chosen means. The statute's flexibility means that businesses that must provide warnings may tailor them to the unique factual circumstances of this case, in which two authoritative bodies under Proposition 65 have reached different conclusions about glyphosate's carcinogenicity. As discussed *supra* at 14-15, California courts have approved settlements with nuanced warning language that includes additional factual context, and does not include the "known to the State" phrasing that the district court found objectionable.[98] And the 1,100 µg/day NSRL for glyphosate means that many exposures will not require a warning, reflecting the fact that the State's means are narrowly drawn to accomplish the objective of making sure that people who would be most at risk are

[98] *See* 4-ER-662 at 672 (court-approved warning for acrylamide in potato chips and French fries notes that acrylamide is created during cooking, and that the FDA has not advised people to stop eating potato chips or foods that contain acrylamide as a result of cooking).

informed of IARC's carcinogenicity determination.[99] On the other hand, warnings may be required on glyphosate-based herbicides where they could make a material difference to the choices of people like Alva and Alberta Pilliod, Edwin Hardeman, and Dewayne Johnson – who called Monsanto twice in an unsuccessful attempt to learn if there was any link between glyphosate and non-Hodgkin's lymphoma.

CONCLUSION

The First Amendment does not prevent the State from requiring businesses to warn Californians of significant exposures to chemicals designated by certain expert agencies as carcinogens, even in the absence of complete scientific consensus. The Court should reverse the district court's order, vacate the judgment, and instruct the district court to enter judgment for the Attorney General.

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[99] Further, businesses exposing consumers to more than 1,100 µg/day may attempt to demonstrate that a higher NSRL should apply.

Dated: February 12, 2021

Respectfully submitted,

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STATEMENT OF RELATED CASES

Counsel is aware of no related cases within the meaning of Circuit Rule 28-2.6.

Dated: February 12, 2021

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UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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9th Cir. Case Number(s) 20-16758

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STATUTORY ADDENDUM

Proposed Law

Safe Drinking Water and Toxic Enforcement Act of 1986

Section 1. The people of California find that hazardous chemicals pose a serious potential threat to their health and well-being, that state government agencies have failed to provide them with adequate protection, and that these failures have been serious enough to lead to investigations by federal agencies of the administration of California's toxic protection programs. The people therefore declare their rights:

(a) To protect themselves and the water they drink against chemicals that cause cancer, birth defects, or other reproductive harm.

(b) To be informed about exposures to chemicals that cause cancer, birth defects, or other reproductive harm.

(c) To secure strict enforcement of the laws controlling hazardous chemicals and deter actions that threaten public health and safety.

…

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.

…

Cal. Health & Safety Code § 25249.10

§ 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.

Title 27 California Code of Regulations § 25306

§ 25306. Chemicals Formally Identified by Authoritative Bodies

(a) Pursuant to section 25249.8(b) of the Act, a chemical is known to the state to cause cancer or reproductive toxicity if the lead agency determines that an authoritative body has formally identified the chemical as causing cancer or reproductive toxicity, as specified in this section.

…

(e) For purposes of this section, "as causing cancer" means that either of the following criteria has been satisfied:

(1) Sufficient evidence of carcinogenicity exists from studies in humans. For purposes of this paragraph, "sufficient evidence" means studies in humans indicate that there is a causal relationship between the chemical and cancer.

(2) Sufficient evidence of carcinogenicity exists from studies in experimental animals. For purposes of this paragraph, "sufficient evidence" means studies in experimental animals indicate that there is an increased incidence of malignant tumors or combined malignant and benign tumors in multiple species or strains, in multiple experiments (e.g., with different routes of administration or using different dose levels), or, to an unusual degree, in a single experiment with regard to high incidence, site or type of tumor, or age at onset.

…

(m) The following have been identified as authoritative bodies for the identification of chemicals as causing cancer:

(1) International Agency for Research on Cancer
(2) National Institute for Occupational Safety and Health
(3) National Toxicology Program
(4) U. S. Environmental Protection Agency
(5) U. S. Food and Drug Administration

Title 27 California Code of Regulations § 25904

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

(a) Pursuant to Section 25249.8(a) of the Act, a chemical or substance shall be included on the list of chemicals known to the state to cause cancer if it is a chemical or substance identified by reference in Labor Code Section 6382(b)(1) as causing cancer.

(b) A chemical or substance shall be included on the list if it is classified by the International Agency for Research on Cancer (IARC) in its IARC Monographs series on the Evaluation of Carcinogenic Risks to Humans (most recent edition), or in its list of Agents Classified by the IARC Monographs, as:

(1) Carcinogenic to humans (Group 1), or

(2) Probably carcinogenic to humans (Group 2A) with sufficient evidence of carcinogenicity in experimental animals, or

(3) Possibly carcinogenic to humans (Group 2B) with sufficient evidence of carcinogenicity in experimental animals. A chemical or substance for which there is less than sufficient evidence of carcinogenicity in experimental animals and classified by IARC in Group 2B shall not be included on the list.

…