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June 28, 2018

Honorable Chief Justice
Tani Cantil-Sakauye
and Associate Justices
Supreme Court of California
350 McAllister Street
San Francisco, CA 94102-4783

Re: *Monsanto Co. v. Office of Environmental Health Hazard Assessment et al.*,
(Petitions for Review filed May 29, 2018)
Supreme Court, Case No. S249056
Fifth Appellate District, Case No. F075362
Superior Court, Fresno County, Case No. 16CECG00183

Dear Chief Justice Cantil-Sakauye and Associate Justices:

Amici curiae the National Association of Manufacturers (NAM), American Tort Reform Association (ATRA), and Chamber of Commerce of the United States of America (U.S. Chamber) support the Petition for Review filed by Monsanto Company in the above-referenced matter.

INTERESTS OF *AMICI CURIAE*

The NAM, ATRA, and the U.S. Chamber respectfully urge this Court to grant review of this case to address the serious constitutional questions presented in Monsanto's Petition relating to the listing of chemicals under Proposition 65. Due to the costs borne by manufacturers and the public by the listing of a chemical under Proposition 65, the delegation of authority and procedures related to determining what chemicals should be listed is an issue of statewide importance, and of particular importance to *amici*.

The NAM is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 states. Manufacturing employs more than 12 million men and women, contributes $2.25 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for more than three-quarters of all domestic private-sector research and development. The NAM is the voice of the

manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States.

ATRA, founded in 1986, is a broad-based coalition of businesses, corporations, municipalities, associations, and professional firms that have pooled their resources to promote reform of the civil justice system with the goal of ensuring fairness, balance, and predictability in civil litigation. For over two decades, ATRA has filed *amicus curiae* briefs in cases that address important civil justice issues.

The U.S. Chamber is the world's largest business federation. It represents 300,000 direct members and indirectly represents the interests of more than 3 million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files amicus curiae briefs in cases that raise issues of concern to the nation's business community.

WHY REVIEW SHOULD BE GRANTED

I. Proposition 65 Was Intended To Provide The Public With Warnings About Chemicals "Known To The State" To Cause Cancer Or Reproductive Toxicity But Instead Has Imposed On Manufacturers And Other Businesses Regulations That Have No Meaningful Impact On Public Health.

Good intentions do not always result in good law. Proposition 65 was passed as a "right-to-know" law, intended to address the public's growing concerns about exposure to toxic chemicals. *See* Proposition 65 1986 Ballot Initiative, https://oehha.ca.gov/media/downloads/proposition-65/general-info/prop65ballot1986.pdf. Under Proposition 65, product sellers must provide warnings to Californians about exposure to chemicals that can cause cancer, birth defects, and other reproductive harm. *See* Health & Safety Code §§ 25249.5 -25249.13. The State of California maintains a list of these chemicals. *See* The Proposition 65 List, https://oehha.ca.gov/ proposition-65/proposition-65-list. The list has grown to include over 900 chemicals, substances, and exposure scenarios.

While an informed public is a laudable goal, Proposition 65 falls far short of this goal. The criticisms of Proposition 65 are legion. Chief among them is warning fatigue from the plethora of Proposition 65 warnings that must be issued. The California public now sees Proposition 65 warnings on everything and in virtually every location—in parking lots, gas stations, amusement parks, office buildings, hotels, coffee houses, on food and beverages, in stores, and on virtually every type of product imaginable. To illustrate, a typical California hotel's required warnings would include the following:

> mercury in seafood; secondhand tobacco smoke; cleaning supplies and related activities; on-site construction; furnishings, hardware, and electrical components, including furniture, window treatment, locks, keys, electrical equipment, and carpeting; personal hygiene and medical supplies, including soaps, shampoos, and first aid supplies; hotel water supply systems, including faucets and other plumbing components; combustion sources, including automobile engines, gas stoves, fireplaces, and candles; office and art supplies and equipment, including carbonless paper, marking pens, copier machine chemicals, glues, crayons, and paints; landscaping supplies and pesticides; food and beverage service, including broiled and barbequed foods; transportation-related exposures, including motor fuels and engine exhaust; equipment and facility maintenance, including motor oil changes, carburetor cleaning, battery replacement, and facility repairs; retail sales; and recreation facilities, swimming pools, hot tubs and beaches, including beach sand (which can contain quartz sand, a form of carcinogenic crystalline silica).

Michael L. Marlow, *Too Much (Questionable) Information? Do the Benefits of California's Proposition 65 Carcinogen Right to Know Law Outweigh Its Costs*, 36 Regulation 20, 22 (2013) (citing a 2004 hospitality law conference paper by attorney Suzanne Henderson). Inundated with such warnings, consumers stop paying attention, and the warnings become background noise. Michael Barsa, *California's Proposition 65 and the Limits of Information Economics*, 49 Stan. L. Rev. 1223, 1228-31 (1997). At least one study has concluded that Proposition 65's ubiquitous warnings have not improved public health outcomes. *See* Marlow, *supra*.

California courts recognize the dangers of over-warning. In upholding an exemption to Proposition 65 for chemicals that are naturally occurring in food, a California appellate court observed, "[s]ince one of the principal purposes of [Proposition 65] is to provide 'clear and reasonable warning' of exposure to carcinogens and reproductive toxins, such warnings would be diluted to the point of meaninglessness if they were to be found on most or all food products." *Nicolle-Wagner v. Deukmejian*, 230 Cal. App. 3d 652, 661 (1991). Similarly, in another context, this Court acknowledged that requiring warnings "in all instances would place an onerous burden" on manufacturers and "invite mass consumer disregard for the warning process." *Johnson v. Am. Standard, Inc.,* 43 Cal. 4th 56, 70 (2008) (quoting *Finn v. G.D. Searle & Co.,* 35 Cal. 3d 691, 701 (1984) (quoting Twerski et al., *The Use and Abuse of Warnings in Products Liability–Design Defect Litigation Comes of Age*, 61 Cornell L. Rev. 495, 521 (1976)).

Fueling the propagation of warnings is the purported enforcement of Proposition 65 by "bounty hunters," who are financially incentivized to make claims against manufacturers, whether merited or not. *See* Anthony T. Caso, *Bounty Hunters and the Public Interest - A Study of California Proposition 65*, 13 Engage: The J. of the Fed. Soc. Prac. Groups 30, 33 (2012) (detailing criticisms of the bounty hunter system). Proposition 65 can be enforced by public prosecutors or by "any person in the public interest." Health & Safety Code §§ 25249.7(c) & (d). Penalties for violations are steep and include civil penalties up to $2,500 per day for each violation. *Id.* § 25249.7(b). When brought by a private party or bounty hunter, the bounty hunter can receive not only 25% of these penalties but also attorneys' fees. *Id.* § 25249.12(d); Civ. Proc. Code § 1021.5.

Manufacturers and other businesses facing the prospect of stiff penalties and fee awards in bounty hunter litigation often make the reasonable business decision to settle then agree to issue even *more* warnings. Settlement payouts totaled over $25 million in 2017 and over $30 million in 2016. Cal. Atty. Gen., *Annual Reports of Settlement*, https://oag.ca.gov/prop65/annual-settlement-reports (last visited June 28, 2018). As one court noted, the burden-shifting provisions of Proposition 65 "make the instigation of Proposition 65 litigation easy—and almost absurdly easy at the pleading stage and pretrial stages." *Consumer Def. Group v. Rental Housing Indus. Members*, 137 Cal. App. 4th 1185, 1215 (2006). Indeed, defendants can prevail at the pretrial stage only if they can show, for example, that "the exposure [of the listed chemical from their product] will have no observable effect assuming exposure at one thousand (1000) times the level in question . . . ." Health & Safety Code § 25249.10(c) (explaining the maximum allowable daily limit, or MADL, for a reproductive toxin). Demonstrating a lengthy history of safe use is not sufficient. *See Consumer Cause, Inc. v. Smilecare*, 91 Cal. App. 4th 454, 470-71 (2001) (rejecting declaration as having no weight because it did not address the relevant factors under the exposure exemption, even though it stated that the product at issue had been safely used throughout the country for 150 years). "[T]he burden shifting provisions make it virtually impossible for a private defendant to defend a warning action . . . short of actual trial." *Consumer Def. Group*, 137 Cal. App. 4th at 1214.

As Proposition 65 warnings continue to proliferate, it is unsurprising that some labels now defy common sense and are of questionable value. For example, courts have ordered that Proposition 65 requires the listing of warnings for barbecues because of exposure to carbon monoxide from burning propane, charcoal, or wood. Consent judgment, *Ecological Rights Found. v. Lodge Mfg. Co.,* No. CGC-16-555067 (Cal. Sup. July 19, 2017). And that it requires warnings for French fries because acrylamide is naturally created when potatoes are browned. Consent Judgment as to Defendant KFC Corporation, *State of California v. Frito-Lay, Inc. et al.*, No. BC 338956 (Cal. Sup. April 20, 2017) (agreeing to warnings for acrylamide, which also state the "FDA has not advised people to stop eating baked or fried potatoes"). Coffee too now comes with warnings, again because acrylamide is naturally created when beans are roasted. Statement of Decision After Trial, *Council for Educ. & Research on Toxics v. Starbucks*, No. BC435759

(May 7, 2018) (finding that defendants failed to meet their burden of proving "no significant risk level" to avoid a Proposition 65 warning). Assaulted by this constant barrage of warnings, Californians may understandably believe that if everything is a problem, nothing really is.

II. Compounding The Issues With Proposition 65 Is That IARC Has Been Improperly Delegated Power To Decide What Should Require A Warning.

A. The General Consensus, Other Than Within IARC, Remains That Glyphosate Is Not Likely To Be Carcinogenic.

The chemical at issue in this case is glyphosate, a compound that has been determined by various agencies, including the U.S. Environmental Protection Agency, to be safe. U.S. EPA, *EPA Releases Draft Risk Assessments for Glyphosate* (Dec. 18, 2017), *available at* https://www.epa.gov/pesticides/epa-releases-draft-risk-assessments-glyphosate. Nonetheless, a single entity, the International Agency for Research on Cancer (IARC), an affiliate agency of the World Health Organization (WHO), reached a different conclusion and classified glyphosate as "probably carcinogenic to humans." IARC, *IARC Monographs Volume 112: evaluation of five organophosphate insecticides and herbicides* (Mar. 20, 2015), http://www.iarc.fr/en/media-centre/iarcnews/pdf/MonographVolume112.pdf.

After IARC's announcement, some agencies, including others within the WHO, reevaluated their previous conclusions and nonetheless came to the same conclusion as before: glyphosate is unlikely to be carcinogenic to humans. The Joint FAO/WHO Meeting on Pesticide Residues (JMPR), an international expert scientific group administered by the Food and Agriculture Organization of the United States and the WHO, concluded that glyphosate is "unlikely to pose a carcinogenic risk to humans exposed via the diet." JMPR, *Results of joint FAO/WHO Meeting on Pesticide Residues* (May 24, 2016), http://www.euro.who.int/en/health-topics/disease-prevention/food-safety/news/news/2016/05/results-of-joint-faowho-meeting-on-pesticide-residues-jmpr. The European Food Safety Authority (EFSA) similarly evaluated the risks, taking into consideration IARC's review, and concluded:

> The substance is unlikely to be genotoxic (*i.e.*, damaging to DNA) or to pose a carcinogenic threat to humans. Glyphosate is not proposed to be classified as carcinogenic under the EU regulation for classification, labelling, and packing of chemical substances. In particular, all the Member State experts but one agreed that neither the epidemiological data (*i.e.*, on humans) nor the evidence from animal studies demonstrated causality between exposure to glyphosate and the development of cancer in humans.

EFSA, *Glyphosate*, https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/efsaexplainsglyphosate151112en.pdf (last visited June 28, 2018).

In November 2017, the European Union voted to approve its authorization to permit glyphosate's sale for another five years. Danny Hakim, *Glyphosate, Top Selling Weed Killer, Wins E.U. Approval for 5 Years*, The New York Times (Nov. 27, 2017), *available at* https://www.nytimes.com/2017/11/27/business/eu-glyphosate-pesticide.html.

B. Notwithstanding IARC's Unilateral And Controversial Determination, The Proposition 65 Requirements (And The Attendant Burdens) Are Automatic Under California Law.

Once IARC came to its conclusion, the Proposition 65 listing was automatic. Health & Safety Code § 25249.8(a). Under Proposition 65, a chemical *must* be listed if it meets any one of a number of criteria. One of these mandatory listing criteria is that the chemical is a substance identified by reference in Labor Code sections 6382(b)(1) or 6382(d), which includes substances classified by IARC as human or animal carcinogens. Labor Code § 6382(b)(1).

Delisting a chemical once it has been listed under Proposition 65 is an uphill battle. Office of Environmental Health Hazard Assessment's listing of a substance is purely ministerial after IARC makes the decision to categorize a substance as "probably" carcinogenic. A search for recent successful challenges to a Proposition 65 listing turned up only one: *Styrene Info. & Research Ctr. v. Office of Envtl. Health Hazard Assessment*, 210 Cal. App. 4th 1082 (2012). There, a court prevented the listing of two substances, but only because they were classified by IARC as "Group 2B"–a group that includes substances for which "there was sufficient evidence of carcinogenicity in animals but *inadequate evidence for humans*." *Id.* at 1095 (emphasis added). No judicial mechanism exists, however, to delist a Group 2A chemical such as glyphosate, identified as "probably" carcinogenic, even where there is a basis to contest IARC's classification.

Notably, the scientific underpinnings of IARC's glyphosate decision are so uncertain that a federal court has already found that requiring a warning for glyphosate may violate the First Amendment because it could compel speech that would be misleading to the average consumer. *See* Memorandum and Order re: Motion for Preliminary Injunction, *Nat'l Ass'n of Wheat Growers, et al. v. Zeise et al.*, 2:17-cv-02401, 2018 WL 1071168 (E.D. Cal. Feb. 26, 2018). The district court granted a preliminary injunction enjoining Proposition 65's warning requirement for glyphosate, explaining that "a reasonable consumer would not understand that a substance is 'known to cause cancer' where only one health organization had found that the substance in question causes cancer and virtually all other government agencies and health organizations that have reviewed studies on the chemical had found there was no evidence that it caused cancer. Under these facts, the message that glyphosate is known to cause cancer is misleading at best." *Id.* at *14. Yet glyphosate will remain listed under Proposition 65 because of IARC's finding, notwithstanding the district court's conclusion that the listing is profoundly misleading.

The absence of a *governmental* authority to oversee the decision to list a chemical on the Proposition 65 list creates problems that are glaringly apparent here. The Proposition 65 listing occurs even if another agency designated by the Labor Code, such as the U.S. Environmental Protection Agency, fundamentally disagrees with IARC about the carcinogenicity of the chemical.

III. Given The Significant Impact That A Proposition 65 Listing Can Have On Businesses And Consumers, The Listing Process Is Itself A Question Of Great Importance.

The listing of chemicals under Proposition 65 that are not likely to actually cause cancer substantially and adversely affects manufacturers and other businesses. A Proposition 65 listing alone, for any one of a manufacturer's product, causes immediate reputational harm. Proposition 65 also incentivizes a high rate of bounty hunter lawsuits, which do not vindicate the intended purpose of Proposition 65. Where the chemical is actually safe, there can be no benefit; only the absurdity remains.

First, any Proposition 65 litigation and warnings will negatively affect a business's reputation. No manufacturer or business wants to be accused of exposing its customers to a substance that causes cancer. No manufacturer or business wants to label its products as being "known" to the State of California to cause cancer where it believes this to be untrue. Where a listing is erroneous, the harms are disproportionately harsh: a manufacturer or other business that is sued for the failure to warn faces a choice to either settle (which does nothing to lessen the reputational harm) or a long and expensive fight, necessitating a battle of the experts (which it may not win because the defendant has the burden of proof that it is not violating Proposition 65). And the financial penalties can be crippling if the business loses.

Second, in somewhat circular logic, once a chemical is listed under Proposition 65, that fact is then cited in lawsuits as "proof" that the chemical causes cancer. For example, in the case of glyphosate, numerous lawsuits across the country have been filed alleging design defects, failure to warn, and negligence. *See e.g.*, *Giglio v. Monsanto Co.*, No. 3:15-cv-2279, Doc. No. 17, at 9 n.5 (S.D. Cal. Nov. 27, 2015); *Rubio v. Monsanto Co.*, No. 2:15-cv-7426, Doc. No. 53, at 13 n.7 (C.D. Cal. Dec. 18, 2015). Even in cases filed outside of California, the listing of glyphosate under Proposition 65 is part of the factual narrative in the Complaint. *See e.g.*, Complaint, *Butsch v. Monsanto Co.*, No. 2:16-cv-01112-EAS-KAJ (S.D. Ohio Nov. 18, 2016).

Third, doing nothing in response to an erroneous listing is a perilous proposition in light of the litigation risk. Proposition 65 requires any company with ten or more employees to comply. Health & Safety Code §§ 25249.6, 25249.11(b). That includes many small companies that cannot afford to fight. Yet, a warning that a product can expose the consumer to a chemical

"known to the State to cause cancer" may be spreading false information. Manufacturers and other businesses are thus put in an untenable position.

Finally, the effects of a Proposition 65 listing extend beyond the borders of California. Given the complexities of modern supply chains, manufacturers and other businesses must either incur the prohibitive costs of creating different labels for different jurisdictions or put Proposition 65 warning labels on their products sold in other markets. Moreover, some may even choose to stop distributing products to California, which negatively impacts consumer choice and competition in California. The problem is Proposition 65 is often misunderstood, even in California, where such warnings can be alarmist and drive down demand. Businesses that have the option may look to costly reformulations of their products to avoid including a Proposition 65 chemical, even if it means the product is less beneficial or useful. Moreover, reformulating a product to avoid a chemical that is listed under Proposition 65 (but is unlikely to actually cause cancer) and replacing that chemical with something else that may have other negative impacts (but does not implicate Proposition 65) fails to advance *any* real public health interest, particularly when the replacement chemicals may be backed by less research than existing, widely-used chemicals.

Manufacturers and other businesses are not the only ones negatively affected by unwarranted listings for chemicals that are unlikely to be carcinogenic. Unnecessary listings lead to more warning fatigue. Consumers will either overestimate the risk of these products or ignore the labels altogether, thus reducing the effectiveness of warning labels for those products that truly do pose hazards. *See* Lars Noah, *The Imperative to Warn: Disentangling the Right to Know from the Need to Know about Consumer Product Hazards*, 11 Yale J. on Reg. 293, 381 (1994). Where the public cannot even be sure whether the chemicals actually cause cancer, warning signs become useless and dangerous. Such listings obscure real risks because the public cannot discern whether something poses any risk at all.

All of this underscores the importance of ensuring that only appropriate substances are listed under Proposition 65 based on sound and generally-accepted science and that those listings are not delegated to a foreign entity such as IARC. As has become apparent in the 30 years since Proposition 65's passage, this well-intentioned "right-to-know" law has spawned litigation of dubious public value. Given all of the consequences that arise from listing a chemical, the listing process itself is of critical importance to this State's manufacturing and businesses. The question of what safeguards must be in place and what standards must be met before a chemical is listed under Proposition 65 is worthy of this Court's review. This is especially so where, as here, every agency that has considered the question, other than IARC, has concluded that glyphosate is *not* likely to be carcinogenic to humans, and where IARC nonetheless has dictated the resulting Proposition 65 listing. This Court should grant review to address the many issues of importance that flow from this improper delegation of listing authority to the non-governmental IARC.

CONCLUSION

For the foregoing reasons, *amici* respectfully ask this Court to grant review in this case.

Respectfully submitted,
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By: s/ *Emily T. Kuwahara*
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CERTIFICATE OF SERVICE

I, Denise A West, state:

My business address is 515 South Flower St., 40th Floor, Los Angeles, CA 90071. I am over the age of eighteen years and not a party to this action.

On the date set forth below, I served the foregoing document(s) described as:

Amicus Curiae Letter of National Association of Manufacturers, American Tort Reform Association and Chamber of Commerce of the United States of America in Support of Petition for Review filed by Monsanto Company

on the following person(s) in this action:

PLEASE SEE ATTACHED SERVICE LIST

☒ BY FIRST CLASS MAIL: I am employed in the City and County of Los Angeles where the mailing occurred. I enclosed the document(s) identified above in a sealed envelope or package addressed to the person(s) listed above, with postage fully paid. I placed the envelope or package for collection and mailing, following our ordinary business practice. I am readily familiar with this firm's practice for collecting and processing correspondence for mailing. On the same day that correspondence is placed for collection and mailing, it is deposited in the ordinary course of business with the United States Postal Service.

I declare under penalty of perjury under the laws of the United States and the State of California that the foregoing is true and correct.

Executed on June 28, 2018, at Los Angeles, California.

s/ *Denise A. West*
Denise A. West

Monsanto Co. v. Office of Environmental Hazard Assessment et al.,
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