#### IN THE UNITED STATES COURT OF APPEALS

#### FOR THE NINTH CIRCUIT

## NATIONAL ASSOCIATION OF WHEAT GROWERS, ET AL.,

Plaintiffs-Appellees,

v.

#### ROB BONTA, IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL OF THE STATE OF CALIFORNIA,

Defendant-Appellant.

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

> Case No. 2:17-CV-02401 (Hon. William B. Shubb)

#### SUPPLEMENTAL BRIEF

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Case No. 20-16758

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#### **INTRODUCTION**

Plaintiffs raise a First Amendment challenge to Proposition 65's requirement that businesses provide a cancer warning before exposing consumers to significant amounts of glyphosate, an active ingredient in Monsanto's pesticide Roundup. In the proceedings below, the district court's final judgment enjoined all enforcement of the Proposition 65 warning requirement for glyphosate, and the Attorney General filed a notice of appeal. In light of changes in critical circumstances underlying the district court's ruling, this Court should reverse the judgment, or, in the alternative, vacate and remand to the district court to consider these circumstances in the first instance.

The district court's analysis focused primarily on the language of the general consumer product "safe harbor" warning, which as applied to glyphosate states that the pesticide is "known to the state of California to cause cancer." Cal. Code Regs. tit. 27, § 25603(a); 1-ER-30-32. The court reasoned that this warning was false and misleading because it conveyed that glyphosate "is known to and actually causes cancer," when, according to the court, "every regulator of which the court is aware, with the sole exception of IARC, has found that glyphosate does not cause cancer or that there is insufficient evidence to show that it does." 1-ER-19; 1-ER-23. The district court also rejected three alternative warnings, expressing concern that the Attorney General would not ordinarily accept such language as a suitable

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alternative to the safe harbor warning, and concluding that the alternatives were misleading because they conveyed that glyphosate actually causes cancer, or that there was an equal weight of authority for that view. 1-ER-28-32.

Since the filing of the notice of appeal, intervening developments have altered the basis for the district court's judgment. First, California's lead agency for implementing Proposition 65, the Office of Environmental Health Hazard Assessment (OEHHA), initiated a rulemaking to adopt a new safe harbor warning for exposures to glyphosate. OEHHA completed that rulemaking in September 2022, and adopted a new safe harbor warning regulation that omits the language that troubled the district court. Second, this Court vacated the human health portion of U.S. EPA's (EPA) Interim Registration Review Decision (Decision), which concluded that glyphosate poses "no risks to human health," reasoning that it could not survive substantial-evidence review. *Nat. Res. Def. Council v. U.S. Env't Prot. Agency*, 38 F.4th 34, 45, 62 (9th Cir. 2022) (*NRDC*).

These changed circumstances demonstrate that the district court erred in enjoining all enforcement of Proposition 65's warning requirement for glyphosate. *See* 1-ER-38. As the new safe harbor warning demonstrates, a Proposition 65 warning for glyphosate can provide purely factual and uncontroversial information, information reasonably related to the government's substantial interest in safeguarding the health of its residents, in a manner that is not unduly burdensome.

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Such a warning will therefore comply with *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985) (*Zauderer*), and comport with the First Amendment.

If the Court does not reverse the judgment outright, it should vacate the judgment and remand for the district court to consider whether relief would be warranted in light of these fundamentally-altered circumstances in the first instance.

#### **INTERVENING DEVELOPMENTS**

#### I. OEHHA ADOPTS A NEW SAFE HARBOR WARNING

In September 2022, the Office of Administrative Law approved OEHHA's

new safe harbor warning for glyphosate, which was developed to "tak[e] into

account the concerns expressed [by] the District Court" in the proceedings below.<sup>1</sup>

The new warning provides:

CALIFORNIA PROPOSITION 65 WARNING: Using this product can expose you to glyphosate. The International Agency for Research on Cancer classified glyphosate as probably carcinogenic to humans. US EPA has determined that glyphosate is not likely to be carcinogenic to humans; other authorities have made similar determinations. A wide variety of factors affect your potential risk, including the level and duration of exposure to the chemical. For more information, including ways to reduce your exposure, go to <u>www.P65Warnings.ca.gov/glyphosate</u>.

The new safe harbor warning for glyphosate becomes effective on January 1,

<sup>&</sup>lt;sup>1</sup> Office of Environ. Health Hazard Assessment, Initial Statement of Reasons 12 (July 23, 2021), available at <u>https://tinyurl.com/3jhnd293</u>. If businesses provide this safe harbor warning, they cannot be sued by public or private enforcers of Proposition 65. *See* Cal. Code Regs. tit. 27, § 25607.49(a).

 $2023.^{2}$ 

In 2019, EPA had concluded that the general Proposition 65 consumer product safe harbor warning was "false and misleading" if used in connection with glyphosate, in light of EPA's determination that glyphosate is "not likely to be carcinogenic to humans."<sup>3</sup> During the rulemaking, OEHHA consulted EPA for its views on an initial version of the new proposed safe harbor language. EPA agreed that a slightly revised version would be "sufficiently clear regarding EPA's position and thus would not be considered false and misleading."<sup>4</sup> It stated that the "revised language could be approved by EPA if pesticide registrants requested it for inclusion on glyphosate product labels, and the products would not be considered misbranded." *Id.* This revised language was adopted in the final September 2022 regulation.

#### II. NINTH CIRCUIT VACATES EPA'S DETERMINATION THAT GLYPHOSATE POSES "NO RISKS TO HUMAN HEALTH"

In another recent development, in *NRDC*, 38 F.4th at 45-52, 62, this Court vacated the human health portion of EPA's Decision, in which EPA found that

<sup>&</sup>lt;sup>2</sup> Office of Environ. Health Hazard Assessment, Notice of Adoption: Warnings for Exposures to Glyphosate from Consumer Products (Sept. 8, 2022), available at <u>https://tinyurl.com/yrn7xznb</u>.

<sup>&</sup>lt;sup>3</sup> U.S. EPA, Letter to Registrant (Aug. 7, 2019), available at <u>https://tinyurl.com/2p8u3vcu</u>.

<sup>&</sup>lt;sup>4</sup> U.S. EPA, Letter to Lauren Zeise, Ph.D., Director of Office of Environ. Health Hazard Assessment (April 8, 2022), available at <u>https://tinyurl.com/2p8bbvu7</u>.

glyphosate poses "no risks to human health." The Court held that EPA's classification of glyphosate as "not likely to be carcinogenic to humans" contravened the agency's own Cancer Guidelines, improperly discounted studies reflecting an exposure-response relationship between glyphosate and non-Hodgkin's lymphoma, disregarded tumor results occurring at high doses of glyphosate, and failed substantial-evidence review. In September 2022, EPA withdrew the Decision, explaining that it would "revisit and better explain its evaluation of the carcinogenic potential of glyphosate."<sup>5</sup>

In addition, courts of appeals have issued final judgments upholding jury verdicts against Monsanto. This Court's judgment upholding a jury verdict finding that glyphosate caused the plaintiff's cancer became final earlier this year. *Hardeman v. Monsanto Co.* 997 F.3d 941 (9th Cir. 2021), *cert. denied*, 142 S. Ct. 2834 (2022) (*Hardeman*).<sup>6</sup> This Court noted that, based on the expert testimony, "the jury would likely have reached the same causation verdict even without

<sup>&</sup>lt;sup>5</sup> <u>https://www.regulations.gov/document/EPA-HQ-OPP-2009-0361-14447</u> at 4-6. Notwithstanding the withdrawal, EPA has stated that "[its] underlying scientific findings regarding glyphosate, including its finding that glyphosate is not likely to be carcinogenic to humans, remain the same." <u>https://tinyurl.com/m8n6yr3y</u> (EPA press release). This position continues to be reflected in OEHHA's new Proposition 65 safe harbor warning for glyphosate.

<sup>&</sup>lt;sup>6</sup> In its amicus brief opposing Monsanto's petition for certiorari, the United States noted, among other things, that the new warning language "would not be considered false or misleading." Br. for the U.S. as Amicus Curiae, *Monsanto Co. v. Hardeman,* 2022 WL 1489462 (U.S.), at \*14.

evidence of IARC's classification or with more evidence of regulatory agency rejections of that classification." *Hardeman*, 997 F.3d at 968. A California court of appeal recently upheld compensatory and punitive damages against Monsanto, noting that, "the evidence shows Monsanto's intransigent unwillingness to inform the public about the carcinogenic dangers of" its glyphosate-based products. *Pilliod v. Monsanto Co.*, 67 Cal. App. 5th 591, 643, 647 (2021); *see also Johnson v. Monsanto Co.*, 52 Cal. App. 5th 434, 457-59 (2020) (similar); RB at 23.

#### ARGUMENT

#### I. THE COURT SHOULD REVERSE THE DISTRICT COURT'S JUDGMENT

These recent developments confirm that the district court erred by enjoining enforcement of Proposition 65's warning requirement for glyphosate exposures. The new glyphosate safe harbor warning complies with the standard for compelled commercial speech set forth in *Zauderer*, 471 U.S. 626. Each sentence is factual and accurate, and the warning is not misleading. *See CTIA-The Wireless Ass'n v. City of Berkeley*, 928 F.3d 832, 845-49 (9th Cir. 2019); *Zauderer*, 471 U.S. at 651. Indeed, EPA and the United States, which previously objected to use of the general consumer product safe harbor warning for glyphosate, have acknowledged that the revised warning could be approved for glyphosate-containing products, and would not be considered false or misleading. *Supra* at 4 & nn.4, 6.

The new safe harbor warning also eliminates the grounds on which the district

court enjoined enforcement of Proposition 65. The district court concluded that the requirement that businesses disclose that glyphosate is "known to the state of California to cause cancer" was misleading because the warning, in the court's view, conveyed without qualification that "glyphosate is known to cause and actually causes cancer." 1-ER-23. The new safe harbor warning does not include this language.

The district court also criticized the general safe harbor warning (and three proposed alternatives) for "convey[ing] the message that there is equal weight for and against the authority that glyphosate causes cancer, when the weight of the evidence is that glyphosate does not cause cancer."<sup>7</sup> 1-ER-31. The new warning avoids the suggestion that there is a consensus view about glyphosate's toxicity, or that there is an equal split of opinion. And the recent developments highlighted above have undermined the district court's perception that the warning rests on an outlier view of the science.

Finally, the fact that OEHHA has adopted the new safe harbor warning by regulation eliminates the concerns expressed by the district court, when considering alternatives to the general safe harbor warning, that "any glyphosate warning which does not compel a business to make misleading statements about

<sup>&</sup>lt;sup>7</sup> The district court conceded, however, that "there need not be complete consensus among the scientific community before a warning may be required." 1-ER-33.

glyphosate's carcinogenicity would likely violate the Attorney General's own guidelines . . . . "1-ER-28. The adoption of the new safe harbor warning removes these concerns. The new glyphosate-specific safe harbor warning will protect businesses from suit, Cal. Code Regs. tit. 27, § 25607.49(a), and it will provide consumers who may be exposed to significant amounts of glyphosate with balanced, factual information about glyphosate's cancer hazard classification. The First Amendment does not preclude California from requiring such warnings.<sup>8</sup>

# II. IF THE COURT DOES NOT REVERSE, IT SHOULD VACATE THE JUDGMENT AND REMAND

Alternatively, the Court should vacate the judgment and remand, so the district court may consider the impact of the changed circumstances on plaintiffs' claims.<sup>9</sup> Intervening developments have altered the basis for the district court's judgment: a new safe harbor warning has been adopted; that warning avoids the specific language that troubled the district court; and other developments have undermined the district court's perception that IARC is an outlier in its view of glyphosate's carcinogenicity.

The Court has "broad power" to vacate "any judgment, decree, or order" of

<sup>&</sup>lt;sup>8</sup> OEHHA has set a safe-harbor exposure level that exempts small exposures (*e.g.*, from glyphosate residue in foods), but will not exempt significant exposures (*e.g.*, from spraying large amounts of the pesticide). OB at 27-28; RB at 15, n.12.

<sup>&</sup>lt;sup>9</sup> The Attorney General believes the Court should vacate and remand on or after January 1, 2023, to ensure that the new glyphosate warning will be in effect at that time.

a lower court and to remand for proceedings "as may be just under the circumstances." Lawrence v. Chater, 516 U.S. 163, 166 (1996) (per curiam) (quoting 28 U.S.C. § 2106); see also Nat. Res. Def. Council, Inc. v. Winter, 513 F.3d 920, 922 (9th Cir. 2008) (remand for reconsideration of preliminary injunction following Executive Order and regulatory changes); Hays v. Concannon, 921 F.2d 240, 241 (9th Cir. 1990) (following new legislation). Reviewing courts vacate judgments and remand "in light of a wide range of developments," including new Supreme Court "decisions, State Supreme Court decisions, new federal statutes, administrative reinterpretations of federal statutes, new state statutes, changed factual circumstances, and confessions of error or other positions newly taken by the Solicitor General." Lawrence, 516 U.S. at 166-167 (citations omitted). In such circumstances, the judgment is vacated and remanded so the district court may address substantially-changed circumstances in the first instance. Cf. United States v. Schooner Peggy, 5 U.S. 103, 110 (1801) (appellate courts must apply intervening law that arises "subsequent to the judgment and before the decision of the appellate court").

Whether vacatur is "ultimately appropriate depends further on the equities of the case," including the public interest. *Lawrence*, 516 U.S. at 167-168. The district court's injunction did not consider the new safe harbor warning for glyphosate, and it is based on a view of the science that has been altered by

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intervening developments. Because changed circumstances—which the district court has not yet had an opportunity to address—have significantly altered the basis for its judgment, if the Court elects not to reverse outright in the first instance, it should vacate the judgment and remand on or after the safe harbor warning takes effect on January 1, 2023.<sup>10</sup>

#### CONCLUSION

The Court should reverse the judgment below, or, in the alternative, vacate and remand.

Dated: November 1, 2022

Respectfully submitted,

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<sup>&</sup>lt;sup>10</sup> The Court also has the power under Federal Rule of Appellate Procedure 12.1 to retain jurisdiction and remand for the limited purpose of allowing the district court to consider a motion for an indicative ruling concerning the changed circumstances. *Mendia v. Garcia*, 874 F.3d 1118, 1120 (9th Cir. 2017).

#### UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

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