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September 18, 2020

VIA ELECTRONIC FILING
Chief Justice Tani Gorre Cantil-Sakauye
and Honorable Associate Justices
Supreme Court of California
350 McAllister Street
San Francisco, CA 94102-4797

Re: *Johnson v. Monsanto Co.*, Sup. Ct. Case No. S264158,
Court of Appeal, 1st App. Dist., Div. One,
Case Nos. A155940 & A156706

Dear Chief Justice Cantil-Sakauye and Honorable Associate Justices:

Amicus curiae CropLife America supports the Petition for Review filed by defendant Monsanto Company in *Johnson v. Monsanto Co.*, Supreme Court Case No. S264158. Review is especially appropriate in light of the important issue of federal preemption law presented by the Petition—in particular, whether plaintiff's common law failure-to-warn claims are preempted under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 *et seq*.

The Court of Appeals here erroneously refused to recognize the preemptive effect of the U.S. Environmental Protection Agency's ("USEPA") longstanding expert determination—reached and repeatedly reaffirmed in the exercise of its FIFRA pesticide registration

authority—that glyphosate is not likely to cause cancer in humans. Under FIFRA, glyphosate manufacturers are prohibited from including cancer warnings on their federally regulated labels, and state common law cancer warning requirements are preempted. The Court of Appeals' decision to the contrary was based on a fundamental misunderstanding of both Supreme Court precedent and the USEPA's regulatory role under FIFRA. Its holding threatens to subject manufacturers to inconsistent pesticide labeling requirements in the 50 states—in conflict with the U.S. Supreme Court's strong caution against such patchwork state requirements. *See Bates v. Dow Agrosciences LLC,* 544 U.S. 431, 452 (2005). Especially in light of the large number of similar claims pending in the courts of California and elsewhere, this Court should grant the petition to review this important question of federal preemption.

I. INTEREST OF THE AMICUS

CropLife America, established in 1933, is the national trade association for the plant science industry, representing developers, manufacturers, formulators, and distributors of crop protection products and plant science solutions for agriculture and pest management in the United States. CropLife America's member companies produce, sell, and distribute virtually all crop protection products, including herbicides, insecticides, and fungicides, which American farmers use to provide consumers with abundant food and

fiber. CropLife America is committed to the safe and responsible use of the industry's products.

CropLife America's members are deeply invested in the discovery and development of new crop protection products and product uses and are intimately familiar with FIFRA's "comprehensive" federal regulation of pesticides. *See Ruckelshaus v. Monsanto Co.*, 467 U.S. 987, 991 (1984). CropLife America is particularly concerned about preserving the uniform federal labeling regime established by FIFRA and ensuring that judicial decisions are based on proper understandings of that statute's regulatory scheme.

The USEPA makes pesticide registration decisions on the basis of substantial scientific and technical information provided at significant cost to the manufacturers. CropLife America member companies spend, on average, $286 million and 11.3 years on research, development, and registration on crop protection products that reach the marketplace.[1] The costs of registering a new pesticide has increased in recent years, due in large part to a rise in the volume and

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[1] *See generally* Phillips McDougal, The Cost of New Agrochemical Product Discovery, Development and Registration in 1995, 2000, 2005-8 and 2010 to 14, A Consultancy Study for CropLife International, CropLife America and the European Crop Protection Association, at 3-4 (Mar. 2016), *available at* https://croplife.org/wp-content/uploads/2016/04/Cost-of-CP-report-FINAL.pdf; *see also* Press Release Accompanying Study (Apr. 13, 2016), *available at* http://www.croplifeamerica.org/news/2017/10/26/cost-of-crop-protection-innovation-increases-to-286-million-per-product ("Study Press Release").

complexity of environmental safety and toxicology data required by USEPA and other regulatory bodies as part of registration and registration review.[2] FIFRA mandates the periodic review of pesticide registrations and USEPA has promulgated regulations to review each registration to determine if based on current scientific and other knowledge, including effects on human health, each registration continues to meet the FIFRA standard.[3] The registration costs and the costs to maintain the registration reflect the thoroughness of USEPA's environmental and human safety review process under FIFRA.

CropLife America's member companies have a particular interest in the regulation of glyphosate-based products, including Monsanto's Roundup products. CropLife America's member companies manufacture and distribute products containing glyphosate, which is the most widely used herbicide in the world—and one of the most widely studied.

Pesticide manufacturers face tens of thousands of lawsuits like this one throughout the country. These lawsuits ask lay juries to make decisions regarding the content of pesticide labels, including appropriate product warnings. But FIFRA delegates *to the USEPA* the authority to determine and approve appropriate pesticide labeling. *See* Statutory Background, Section II, *infra*. Permitting a jury to dictate the content of pesticide warnings would frustrate FIFRA's exclusive

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[2] *See* Study Press Release, *supra* n.1.

[3] 7 U.S.C. § 136a(g) and 40 C.F.R. §§ 155.40 et. seq.

federal labeling framework and will subject manufacturers to a discordant and unworkable patchwork of state regulatory schemes that conflict with their obligations under federal law.

The Supreme Court warned against the "significant inefficiencies for manufacturers" that such an approach would entail: "[I]magine 50 different labeling regimes prescribing the color, font size, and wording of warnings." *Bates*, 544 U.S. at 452. Yet that is precisely what the ruling below permits and even requires—in contravention of Congress's determination to commit the content of pesticide labels to the USEPA's exclusive judgment. Amicus have a strong interest in asking this Court to grant review here to ensure the uniformity contemplated by Congress in enacting FIFRA. *See, e.g.*, 7 U.S.C. § 136v(b) ("Uniformity").

II. STATUTORY BACKGROUND

FIFRA governs the sale, use and labeling of "pesticides," which includes not only substances intended to prevent and control pests, but also, as relevant here, "any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant." 7 U.S.C. § 136(u). FIFRA makes it unlawful for any person to "distribute or sell to any person any pesticide that is not registered" under the statute. 7 U.S.C. § 136a(a). FIFRA's registration process requires the USEPA to comprehensively evaluate product safety and risks to human health

and the environment in registering any pesticide.[4] The statute requires registrants to provide substantial scientific data to support the safety and health effects of a pesticide. *See* 7 U.S.C. § 136a(c)(1)(F) (requiring submission of test results and supporting data); *id.* § 136a(c)(2)(A) (requiring USEPA to publish guidelines specifying the information required to support registration); *see also generally* 40 C.F.R. pt. 158.

The USEPA will register a pesticide only after it determines in the exercise of its expert scientific judgment that: 1) the pesticide's composition warrants the proposed claims for it; 2) its labeling and other material required to be submitted comply with the requirements of FIFRA; 3) it will perform its intended function without unreasonable adverse effects on the environment; and 4) when used in accordance with widespread and commonly recognized practice, the pesticide will not generally cause unreasonable adverse effects on the environment. 7 U.S.C. § 136a(c)(5). Once registered, the USEPA conducts a comprehensive review of the registration at least every 15 years. *See* 7 U.S.C. § 136a(g); 40 C.F.R. § 155.40 *et seq*.

Critical to the registration process is the content of the product's label, which USEPA approves as part of registering the pesticide. The

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[4] *See* USEPA Pesticide Registration Manual: Introduction ("Before any pesticide product that EPA has not exempted from registration requirements can be lawfully sold or distributed, EPA performs a rigorous, comprehensive scientific assessment of the product, resulting in a registration decision."), *available at* https://www.epa.gov/pesticide-registration/pesticide-registration-manual-introduction.

USEPA will not register a pesticide unless it "has determined that the product is not misbranded . . . and its labeling and packaging comply with the applicable requirements" of FIFRA and its regulations. 40 C.F.R. § 152.112(f). FIFRA's regulations provide that a product label "is required to bear hazard and precautionary statements for humans and domestic animals" as prescribed in some detail in those regulations. 40 C.F.R. § 156.60. Any "[s]pecific statements pertaining to the hazards of the product and its uses must be approved by the [USEPA]." 40 C.F.R. § 156.70(c).

A pesticide is misbranded if its labeling "bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular." 7 U.S.C. § 136(q)(1)(A); *see also* 40 C.F.R. § 156.10(a)(5). It is unlawful to distribute or sell any misbranded pesticide. 7 U.S.C. § 136j(a)(1)(E).

The States' role in regulation of pesticides is carefully circumscribed by FIFRA amendments added in 1972. *See Bates*, 544 U.S. at 439. FIFRA preserves the primacy of the USEPA and federal law, recognizing the States' authority to "regulate the sale or use of any federally registered pesticide or device in the State, but *only if and to the extent* the [state] regulation does not permit any sale or use prohibited by this subchapter." 7 U.S.C. § 136v(a) (emphasis added). The States' role is even more circumscribed with respect to product labeling. States may enforce only requirements that are *fully consistent* with USEPA's labeling requirements: "Such state shall not impose or continue in effect any requirements for labeling or packaging

in addition to or different from those required under this subchapter." *Id.* § 136v(b); *see Bates*, 544 U.S. at 443.

III. REASON FOR GRANTING THE PETITION: THE PETITION RAISES IMPORTANT FIFRA PREEMPTION ISSUES MERITING THIS COURT'S REVIEW

The Court of Appeals' decision merits review here because it raises important questions of law regarding the proper application of both express and implied federal preemption principles to FIFRA's federal pesticide labeling regime. *See* Cal. Rules of Court 8.500(b)(1).

The Court of Appeals' opinion is grounded in a misunderstanding of both the USEPA's role in registering pesticides and the U.S. Supreme Court's FIFRA preemption jurisprudence. It creates an insoluble problem for pesticide manufacturers. Those manufacturers have been expressly instructed by USEPA that they *may not* include a cancer warning on their glyphosate product labels because such a warning would be misleading, yet now face millions of dollars of liability under state law for not including the very warning that the USEPA has declared unlawful. Review is necessary here to prevent confusion in California's lower courts and to ensure that state juries do not become an instrument for upsetting Congress's carefully articulated FIFRA regulatory scheme.

"The Supremacy Clause provides a clear rule that federal law 'shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.'" *Arizona v. United States*, 567

U.S. 387, 399 (2012) (quoting U.S. Const. Art. VI, cl. 2). Federal law thus preempts state law in either of two circumstances at issue here. First, Congress can expressly preempt state law. *See, e.g.*, *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). Second, federal law impliedly preempts state law where, among other things, it is impossible for a regulated entity to comply with both. *See, e.g.*, *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 570 U.S. 472, 480 (2013). The Court of Appeals' opinion misapplied controlling legal principles in analyzing each branch of preemption.

A. The Court of Appeals' Misconstrued Controlling Law Regarding FIFRA's Express Preemption Provision

FIFRA explicitly forbids States from imposing "any requirements" for pesticide labeling "in addition to or different from" those required by federal law. 7 U.S.C. § 136v(b). The Supreme Court has construed "any requirements" in FIFRA to include not only state statutes and regulations, but also "common law duties." *See Bates,* 544 U.S. at 443-44; *see also Riegel*, 552 U.S at 324. FIFRA's uniform labeling provision thus "pre-empts any statutory or common-law rule that would impose a labeling requirement that diverges from those set out in FIFRA and its implementing regulations." *Bates*, 544 U.S. at 452. While the Court of Appeals stated the correct standard (Slip. op. at 41), its application of that standard to USEPA's regulation of glyphosate-based product labels was fundamentally flawed.

Key to the application of FIFRA's express preemption provision here is FIFRA's misbranding provision. A pesticide label must not

contain any statement or representation that is "false or misleading in any particular." *See* 7 U.S.C. § 136j(a)(1)(E); *id.* § 136(q); *see also* 40 C.F.R. § 156.10(a)(5). USEPA will not register a pesticide unless it concludes that the product is not mislabeled. 40 C.F.R. § 152.112(f). A state requirement that permits the sale of a mislabeled product (or indeed, compels it, as the jury verdict here does) runs afoul of § 136v(b) by imposing state labeling requirements that conflict with the federal prohibition on such mislabeled sales.

California's common law duty-to-warn claims plainly diverge from the labeling requirements imposed by the USEPA for glyphosate-based products. The verdict here was based on the jury's conclusion that Monsanto has an obligation to warn consumers that glyphosate may cause cancer. But for almost three decades, the USEPA has repeatedly and explicitly concluded in both registering and reviewing the registration for glyphosate that it does not pose a cancer risk. Consistent with this longstanding conclusion, the USEPA's Office of Pesticide Programs warned in an August 2019 letter to all registrants that a state-law cancer warning requirement for glyphosate "constitute[s] a false and misleading statement" in violation of FIFRA's misbranding provision.[5]

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[5] USEPA Office of Pesticide Programs August 7, 2019 Letter ("USEPA Aug. 7, 2019 Letter"), *available at* https://www.epa.gov/sites/production/files/2019-08/documents/glyphosate_registrant_letter_-_8-7-19_-_signed.pdf.

The Court of Appeals nevertheless rejected Monsanto's argument that the USEPA's repeated assessments of no cancer risk mandated a preemption holding. The court below concluded that *Bates v. Dow Agrosciences LLC* "informs us that the existence of these [registration] requirements and actions are not enough, standing alone, to preempt state failure-to-warn claims." Slip. op. at 45 (citing *Bates*, 544 U.S. at 450-51). But *Bates'* proposition that certain state law failure-to-warn claims might survive FIFRA preemption cannot be divorced from the factual context of that case. In *Bates*, the USEPA had not reviewed the label representations that were challenged by plaintiff's state law claims; indeed, the USEPA explicitly had waived its review of the product claims at issue there. *See* 544 U.S. at 440.

Bates was therefore not a case, like this one, where jurors were asked to second-guess the USEPA's scientific judgments. The *Bates* plaintiffs, who claimed their peanut crops had been harmed by their use of the pesticide "Strongarm" in areas where soil pH levels exceeded 7.0, asserted state law claims challenging the label's express assertion that the pesticide was suitable for "all areas where peanuts are grown." *Id.* In registering Strongarm and approving its label, the USEPA had not, in fact, reviewed or approved any of the label's efficacy claims. Acting under authority delegated by Congress (an authority that does not exist for product safety), the USEPA had waived review of product efficacy, leaving the responsibility to comply with FIFRA solely to the registrant. *Id.* The USEPA's general waiver confirmed that its "approval of a pesticide label does not reflect any determination on the

part of EPA that the pesticide will be efficacious or will not damage crops or cause any other property damage." *Id.* *Bates* thus grounded its preemption analysis on the fact that "Congress amended FIFRA to allow EPA to waive efficacy review of newly registered pesticides." *Id.* at 450.

When *Bates* suggested that juries may, in certain circumstances, appropriately consider FIFRA mislabeling issues, *id.* at 451-52, the Court was not suggesting that lay juries could set aside the USEPA's expert scientific judgments. Instead, the Court merely left open the possibility that a lay jury might occupy the space *left vacant* by the USEPA's explicit waiver of efficacy review. Where the USEPA had not exercised its expertise to review a registrant's efficacy claims, state law might have some role to decide what warnings were required.

Bates offers no refuge to plaintiffs here, where the USEPA has consistently and repeatedly, as required by FIFRA, exercised its expert authority to conclude that glyphosate does not cause cancer. That expert determination reaches back as far as the early 1990s, when, acting on the recommendation of a scientific peer review committee, the USEPA classified glyphosate as "Group E" for carcinogenicity, formally concluding that there was "evidence of non-carcinogenicity for humans."[6] It reiterated that finding in a formal rule establishing

[6] *See* EPA, R.E.D. Facts, Glyphosate, at 2 (Sept. 1993), *available at* https://archive.epa.gov/pesticides/reregistration/web/pdf/0178fact.pdf.

pesticide tolerances for glyphosate in 1997,[7] and again in subsequent tolerance rulemakings in response to public comments.[8]

In 2009, the USEPA opened a new periodic registration review of glyphosate. This process has been conducted over more than a decade and involves extensive review of glyphosate's environmental safety and toxicology. After review by both the USEPA's Cancer Assessment Review Committee and a Scientific Advisory Panel, the USEPA published a Revised Glyphosate Issue Paper evaluating the carcinogenic potential of the herbicide in December 2017.[9] The agency concluded that "available data and weight-of-evidence clearly do not support the descriptors 'carcinogenic to humans,'" or even "'likely to be carcinogenic to humans.'"[10] Instead, the USEPA concluded that the

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[7] Final Rule: Glyphosate; Pesticide Tolerances, 62 Fed. Reg. 17,723, 17,724 (Apr. 11, 1997).

[8] Final Rule: Glyphosate; Pesticide Tolerances, 67 Fed. Reg. 60,934, 60,936 (Sept. 27, 2002); *see also* Final Rule: Glyphosate, Pesticide Tolerances, 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008) ("There is extensive database available on glyphosate, which indicate that glyphosate is not mutagenic, not a carcinogen, and not a developmental or reproductive toxicant.").

[9] USEPA, Office of Pesticide Programs, *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential*, at 12 (Dec. 12, 2017), *available at* https://usrtk.org/wp-content/uploads/2019/04/REVISED_GLYPHOSATE_ISSUE_PAPER_EVALUATION_OF_CARCINOGENIC_POTENTIAL-1.pdf.

[10] *Id.* at 144.

scientific evidence most strongly supported a description of glyphosate as "not likely to be carcinogenic to humans."[11]

In January 2020, after notice and extensive public comment, the USEPA published the Glyphosate Interim Registration Review decision based on this scientific conclusion: "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*."[12]

The Court of Appeals nevertheless declined to give credence to the USEPA's expert determinations. It held that the USEPA's determinations lack the "force of law." Slip op. at 45. But the court misunderstood the point of this inquiry. In *Merck Sharp & Dohme Corp. v. Albrecht*, the Supreme Court explained that, to be have preemptive effect, an agency pronouncement must result from "agency actions taken pursuant to the FDA's congressionally delegated authority." 139 S. Ct. 1668, 1679 (2019).

That USEPA's determination—that glyphosate does not cause cancer—resulted from agency action within the scope of its congressionally delegated authority here is undeniable. FIFRA

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[11] *Id.*

[12] USEPA: Glyphosate, Interim Registration Review Decision Case No. 0178 (Jan. 22, 2020), at 10 (emphasis added), *available at* https://www.epa.gov/sites/production/files/2020-01/documents/glyphosate-interim-reg-review-decision-case-num-0178.pdf.

requires that the USEPA determine in registering a pesticide that it will not have "unreasonable adverse effects on the environment," including human health. 7 U.S.C. § 136a(c)(5)(D). Many of the USEPA's repeated determinations, such as those made in multiple tolerance rulemakings, resulted from APA notice-and-comment procedures. *See Albrecht*, 139 S. Ct. at 1679 (noting "notice and comment" rulemaking procedures sufficient to confer "force of law" to agency action). The USEPA's recent Interim Registration Review Decision, which reaffirmed its longstanding "no cancer risk" conclusion, was similarly promulgated after notice and extensive public comment and is plainly agency action taken pursuant to congressionally delegated authority—specifically, the USEPA's registration review process of 7 U.S.C. § 136a(g).

In these circumstances, the USEPA's repeated registration and registration review of glyphosate, and its consistent determination that glyphosate does not cause cancer, is preemptive of state legal requirements. *See Riegel*, 552 U.S. at 322-23 (finding expressly preempted state common law negligence and mislabeling claims concerning medical device where they contradicted federal requirements established by agency's device approval). The jury verdict here violates § 136v(b)'s prohibition on state law requirements that are "different from those required under [FIFRA]." 7 U.S.C. § 136v(b). And because a state cancer warning would constitute misbranding under FIFRA, the verdict also violates § 136v(a)'s prohibitions on state regulations permitting sales prohibited by FIFRA.

Id. § 136v(a). The Court of Appeals decision should be reviewed, and the jury verdict below reversed.

B. The Court of Appeals' Erroneous Implied Preemption Ruling is Based on a Fundamental Misunderstanding of USEPA's Registration Review Processes

The Court of Appeals' decision also misapplied the doctrine of implied "impossibility" preemption. *See Albrecht*, 139 S. Ct. at 1678-79; *Wyeth v. Levine,* 555 U.S. 555, 571 (2009). The Court of Appeals' affirmance of a jury verdict for failure-to-warn places manufacturers in an impossible dilemma. The USEPA has made clear that those manufacturers cannot include a cancer warning on their glyphosate label because such a warning would be misleading. Yet, as a result of the ruling below, manufacturers are faced with potentially substantial damages claims under state law for failing to provide the very warning that federal law prohibits. This is precisely the impossibility against which federal preemption law protects. *See, e.g., PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618-19 (2011). Especially given the number of cases likely to raise this issue, this Court's review is necessary to correct the lower court's erroneous answer to this important question.

As the Supreme Court has repeatedly held, a state duty-to-warn claim is impliedly preempted by federal law where there is "clear evidence" that the relevant federal regulatory agency would not have approved the warning that state law purports to require. *Albrecht*, 139 S. Ct. at 1676; *Wyeth*, 555 U.S. at 571. The Court of Appeals agreed that this standard applied to FIFRA labeling decisions, concluding that

a "defendant may establish a preemption defense to a state failure-to-warn claim by providing clear evidence that the EPA would not have approved a label change." Slip op. at 48. Yet it seriously misapplied the rule in light of its misunderstanding of the USEPA's authority and actions.

There is no doubt that the USEPA *would not* have approved a label change that comports with the jury's findings here. The USEPA's August 2019 letter states that a glyphosate label containing the cancer warning found lacking by the California jury would be "false and misleading," and thus mislabeled.[13] And long before the trial here, the agency had consistently concluded that glyphosate does not cause cancer and continues to do so after each review required under FIFRA. *See* discussion, *supra*, Section III.A.

The Court of Appeals recognized that Monsanto "has pointed to evidence that arguably would support an impossibility defense." (Slip. op. 49). "It is no doubt true," it concluded, that "the EPA currently takes the position that glyphosate is not harmful to humans and that a cancer warning on glyphosate is unnecessary." *Id.* at 51. The court nevertheless declined to find impossibility preemption based on its idiosyncratic review of the USEPA's actions. "On the record before us, we cannot conclude that Monsanto has established a preemption defense based on the notion that the EPA would not have approved a label change that warned of the Roundup products' potential link to

[13] USEPA August 7, 2019 Letter at 1.

cancer." *Id.* It found its review of the USEPA's emphatic rejection of a cancer warning was lacking in evidence of "whether all material information was submitted to the agency (here, the EPA) and the nature and scope of the agency's determination." *Id.*

That reasoning is based on a flawed understanding of USEPA's processes. Contrary to the Court of Appeals' unfounded concern, the USEPA had available to it all of the scientific evidence and expert commentary necessary to determine that glyphosate is unlikely to cause cancer. The registration review process that resulted in USEPA's finding of non-carcinogenicity was not based simply on information submitted by Monsanto, but on extensive data submitted by all parties with an interest in the registration review proceedings. *See* 40 C.F.R. § 155.50. As part of its review, the USEPA "may identify, either in the [public notice], or at any other time, data or information that it does not have but which may be useful, if available, for consideration in the registration review." *Id.* § 155.50(c). "*Any person* may submit data or information in response to such identification." *Id.* (emphasis added) The review process also includes extensive stakeholder engagement. 40 C.F.R. § 155.52.

In this case, the USEPA conducted a systematic review of the open literature to identify studies that could inform the human carcinogenic potential of glyphosate [14] and considered thousands of

[14] *See* USEPA, *Glyphosate Draft Human Health Risk Assessment in Support of Registration Review*, Dec. 12, 2017, *available at*

comments from interested persons regarding glyphosate registration review.[15] Numerous commenters from public health organizations and consumer groups—such as the Natural Resources Defense Council, the Center for Biological Diversity and the Pesticide Action Network—submitted extensive comments.[16] Many based their comments on the 2015 report of the World Health Organizations International Agency for Research on Cancer ("IARC"), the sole international body that has suggested a cancer link for glyphosate.[17]

The USEPA's registration review decision resulted from an independent review of the IARC's conclusion, which the USEPA rejected as unsupported by the available evidence. In an April 2019 proposed "Proposed Interim Registration Review Decision" (later accepted in its interim registration review decision), the USEPA concluded that its "independent evaluation of the carcinogenic potential of glyphosate . . . has determined that glyphosate is 'not likely to be carcinogenic to humans.'"[18] The agency explained that its "cancer

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https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0068.

[15] *See* USEPA Office of Pesticide Programs, *Glyphosate, Response to Comments on the Human Health Draft Risk Assessment*, Apr. 23, 2018, *available at* https://www.epa.gov/sites/production/files/2019-04/documents/hed-rtc-signed.pdf.

[16] *Id.* at 1.

[17] *Id.* at 2.

[18] USEPA, Glyphosate: Proposed Interim Registration Review Decision, Case No. 0178 (Apr. 2019) at 7, *available at*

evaluation is more robust than IARC's evaluation," which "only considered a subset of the studies included in the EPA's evaluation" and included "some studies [excluded by USEPA] that were not appropriate for determining the human carcinogenic potential of glyphosate."[19] The USEPA further noted that its cancer classification is "consistent with other international expert panels and regulatory authorities," including government regulators in Canada, Australia, Germany, New Zealand and the European Food Safety Authority and European Chemical Agency.[20] Based on its own independent evaluation of the scientific evidence, the USEPA thus determined that any pesticide products containing a cancer warning for glyphosate would be "misbranded pursuant to" FIFRA.[21]

Contrary to the Court of Appeals' reasoning, the USEPA has, in fact and in law, been fully informed of the possible justification for a cancer warning and emphatically rejected such a warning as inconsistent with prevailing science and with FIFRA. The Court of Appeals thus improperly rejected impossibility preemption. Review

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https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-2344.

[19] *Id.*

[20] *See* USEPA Aug. 7, 2019 Letter at 1; *see also National Ass'n of Wheat Growers v. Becerra*, No. 2:17-cv-2401, 2020 WL 3412732, at *9 (E.D. Cal. June 22, 2020) ("[T]he fact remains that every government regulator of which the court is aware, with the exception of the IARC, has found that there was no or insufficient evidence that glyphosate causes cancer.").

[21] USEPA Aug. 7, 2019 Letter at 1.

should be granted to give proper effect to the USEPA's expert scientific judgments made in the exercise of its exclusive authority over the content of product warning labels and to alleviate the conundrum in which manufacturers find themselves as a result of the Court of Appeals' misapplication of impossibility preemption standards.

CONCLUSION

For the reasons stated herein and in the Petition, the Court should grant review of the Court of Appeals' erroneous FIFRA preemption ruling upholding the jury verdict on plaintiff's failure-to-warn claim.

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Respectfully submitted,

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PROOF OF SERVICE

Johnson v. Monsanto Company
Case No. S264158

STATE OF CALIFORNIA, COUNTY OF LOS ANGELES

At the time of service, I was over 18 years of age and not a party to this action. I am employed in the County of Los Angeles, State of California. My business address is 633 West Fifth Street, Suite 1900, Los Angeles, CA 90071.

On September 18, 2020, I served true copies of the following document(s) described as **AMICUS LETTER** on the interested parties in this action as follows:

BY E-MAIL OR ELECTRONIC TRANSMISSION: Based on a court order or an agreement of the parties to accept service by e-mail or electronic transmission via Court's Electronic Filing System (EFS) operated by ImageSoft TrueFiling (TrueFiling) as indicated on the attached service list:

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San Francisco Superior Court Honorable Garrett L. Wong Department 206 400 McAllister St. San Francisco, CA 94102-4514	**Case No. CGC16550128** *Via U.S. Mail*

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

Executed on September 18, 2020, at Los Angeles, California.

/s/ Melissa Hernandez
MELISSA HERNANDEZ