Nos. 19-16636, -16708

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

EDWIN HARDEMAN,
Plaintiff-Appellee/Cross-Appellant,

v.

MONSANTO COMPANY,
Defendant-Appellant/Cross-Appellee.

On Appeal from the U.S. District Court for the Northern District of California,
No. 16-cv-00525 & 16-md-02741 (Chhabria, J.)

BRIEF AMICUS CURIAE OF CROPLIFE AMERICA IN SUPPORT OF DEFENDANT-APPELLANT MONSANTO COMPANY

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Amicus Curiae CropLife America certifies that it has no parent, subsidiaries, or affiliate entities (corporate or otherwise) that have issued stock or debt securities to the public, and no publicly held entity (corporate or otherwise) owns 10% or more of its stock.

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INTEREST OF THE AMICUS CURIAE

CropLife America, established in 1933, is the national trade association for the plant science industry, representing developers, manufacturers, formulators, and distributors of crop protection chemicals 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.[1]

CropLife America's members are deeply invested in the discovery and development of new crop protection products and product uses and are thus intimately familiar with the comprehensive federal regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 *et seq.* When the U.S. Environmental Protection Agency ("EPA") makes a registration decision, it does so on the basis of substantial scientific and technical information provided at significant cost to the manufacturers. CropLife America

[1] All parties consent to the filing of this brief. Pursuant to Fed. R. App. P. 29(a)(4)(E), CropLife America states that no party's counsel authored this brief in whole or in part. Bayer Corp., defendant Monsanto's parent company, is a member company of CropLife America and pays dues as a member, but, apart from those dues, did not contribute money intended to fund preparation or submission of this brief. No person other than CropLife America and its members contributed money intended to fund preparation or submission of this brief.

member companies spend, on average, $286 million and 11.3 years on research, development and registration—roughly the time it took from the creation of NASA to its putting a man on the moon—on crop protection products that reach the marketplace.[2] The costs of registering a new pesticide has increased in recent years, due in large part to a rise in the volume and complexity of environmental safety and toxicology data required by EPA and other relevant regulatory bodies.[3] These costs reflects the thoroughness of FIFRA's environmental and human safety review process.

CropLife America's member companies have a keen interest in the legal framework of FIFRA, including especially the interrelationship between federal and state regulation of pesticides. CropLife America's member companies also have a substantial interest in the regulation of glyphosate-based products, like Monsanto's Roundup products at issue in this case. CropLife America's member companies manufacture and distribute products containing glyphosate, which is the

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[2] *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 3-4 (March 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-1 ("Study Press Release").

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

most widely used herbicide in the world—and is also one of the most widely studied.

The preemption issues in the case reach well beyond Roundup and glyphosate, however. The district court's decisions under review raise the fundamental question of whether specific pesticide labeling requirements imposed by EPA in the exercise of expert scientific judgments under FIFRA can be overridden by the verdicts of lay juries under state law across a wide array of regulated pesticides. CropLife America respectfully submits this brief in support of Monsanto to help the Court understand the regulatory framework of FIFRA, including the EPA's role in registering products and approving labeling, FIFRA's preemptive effect on state labeling requirements, and in particular here, the preemptive effect of EPA's repeated determinations that glyphosate does not cause cancer. CropLife America's comprehensive understanding of FIFRA can assist the Court here. CropLife America respectfully submits that a proper understanding of FIFRA should lead the Court to reverse the judgment below.

INTRODUCTION AND SUMMARY OF ARGUMENT

In light of FIFRA's comprehensive federal regulation of glyphosate product labeling, the district court's decisions permitting California's failure to warn claims to be decided by a jury run afoul of the Supremacy Clause. *See* U.S. Const., art. VI, cl. 2. Plaintiff's claims are both expressly and impliedly preempted.

First, Congress may exercise the power to preempt state law "by enacting a statute containing an express preemption provision." *Arizona v. United States*, 567 U.S. 387, 399 (2012) (citation omitted); *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321-22 (2008). Here, Congress *has* explicitly preempted any state labeling requirements that are "in addition to or different from those required under [FIFRA]." *See* 7 U.S.C. § 136v(b). But that is precisely what the district court's ruling permits, allowing a jury deciding state common law duty-to-warn claims to require defendant Monsanto to place on its labels a cancer warning that the EPA has itself rejected as false and misleading.

The district court's reliance on *Bates v. Dow Agrosciences LLC*, 554 U.S. 431 (2005), to support its preemption analysis was misplaced. *Bates* differed from this case in one critical respect not considered by the district court. In *Bates*, the EPA had waived review of the label's efficacy claims, leaving it to the manufacturer to assure compliance with FIFRA's relevant labeling requirements. Here, by contrast, the EPA has carefully and repeatedly reviewed the relevant

scientific data underlying the label and each time formally concluded that glyphosate *does not* cause cancer—and thus that a cancer warning is not appropriate. The jury verdict here directly contradicts the EPA's expert scientific judgment and establishes divergent state law requirements in contravention of FIFRA's express preemption provision.

Second, FIFRA also *impliedly* preempts the plaintiff's duty-to-warn claims. Implied preemption "can exist even when Congress has chosen to include an express preemption clause in a statute." *Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199, 1204 (9th Cir. 2002); *see also, e.g.*, *Arizona*, 567 U.S. at 406. As relevant here, implied preemption occurs when it is "'impossible for a private party to comply with both state and federal requirements.'" *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1672 (2019) (citation omitted).

Consistent with more than 20 years of its own, independent scientific findings that glyphosate does not pose a threat of cancer, the EPA has concluded that a state labeling requirement warning that glyphosate poses a cancer risk would be false and misleading and would therefore constitute misbranding under FIFRA.[4] The EPA's consistent scientific findings, which culminated in its August 2019

[4] August 7, 2019 EPA Letter to Glyphosate Registrants ("Aug. 7, 2019 EPA Letter"), *available at* https://www.epa.gov/sites/production/files/2019-08/documents/ glyphosate_registrant_letter_-_8-7-19_-_signed.pdf.

letter to registrants directing that glyphosate labels *not* include California's Prop 65 cancer warning, preempt the jury's verdict here.

Finally, affirming the jury verdict in this case would upset the careful balance struck by the EPA in approving glyphosate pesticide labels and would have real world costs. Requiring unnecessary cancer warnings could discourage socially and economically useful applications of glyphosate, as well as pose real health risks to consumers when considering alternatives. A jury should not be allowed to set aside the EPA's expert, science-based judgment on the appropriate labeling for glyphosate. The verdict should be reversed.

BACKGROUND

I. FIFRA'S "COMPREHENSIVE" REGULATION OF PESTICIDE LABELS

The proper application of preemption rules to this case requires an understanding of FIFRA, which the Supreme Court has repeatedly described as a "comprehensive regulatory statute." *Ruckelshaus v. Monsanto Co.*, 467 U.S. 987, 991 (1984). 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).

A. FIFRA Registration

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). The FIFRA registration process requires the EPA to comprehensively evaluate product safety and risks to human health and the environment in registering any pesticide.[5] The statute thus 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); (c)(2)(A) (requiring EPA to publish guidelines specifying the information required to support registration).

The EPA's FIFRA registration data regulations require extensive scientific health and safety data for each registered pesticide. *See generally* 40 C.F.R. pt. 158. A registrant must submit substantial data relating to the toxicology of the pesticide, including, in particular, studies relating to the likelihood that a particular pesticide could cause cancer in laboratory rodents. 40 C.F.R. § 158.500(d) (required toxicology data, including "Carcinogenicity—two rodent species" for pesticides used on food or likely to result in significant human exposure over a considerable portion of the human life span).

[5] *See* EPA 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.

The EPA "shall register a pesticide" only if it determines "when considered with any restrictions imposed," the pesticide meets four general requirements: 1) its composition is such as to warrant 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) that when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment. 7 U.S.C. § 136a(c)(5).

The statute defines "unreasonable adverse effects on the environment" to mean "any unreasonable risk to man or the environment," a calculus that requires the EPA to balance the "economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. § 136(bb). It also includes "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under" the Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 346a. *See* 7 U.S.C. § 136(bb). The statute allows the EPA to waive data requirements pertaining to efficacy of the product and register a pesticide without reviewing efficacy. 7 U.S.C. § 136a(c)(5)(D); *see Bates*, 544 U.S. at 440. But there is no similar waiver authority for the EPA's responsibility to review a pesticide for "unreasonable adverse effects on the environment"—the EPA must

conduct this searching review, including review of toxicology data, in every pesticide registration.

Congress requires the EPA to reevaluate at least once every fifteen years whether a pesticide continues to satisfy FIFRA's registration standards. *See* 7 U.S.C. § 136a(g); 40 C.F.R. § 155.40 *et seq.* (registration review regulations). This process involves a review of the applicable science under public notice and comment procedures. *See* 40 C.F.R. § 155.50.

B. FIFRA Labeling Requirements

A central focus of the EPA's registration (and re-registration) review process is review and approval of the product's label. "Pesticide product labels provide critical information about how to safely and legally handle and apply pesticides."[6] A "critical function of the label is to translate the results of the science evaluations into a set of conditions, directions, precautions, and restrictions that define who may use a pesticide, as well as where, how, how much, and how often it may be used."[7]

The EPA's Label Review Manual, which provides guidance on the review process, notes that the accuracy of the label is "vital" to the EPA's (and other

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[6] EPA, Office of Pesticide Programs, Label Review Manual at 1-2, *available at* https://www.epa.gov/sites/production/files/2018-04/documents/lrm-complete-mar-2018.pdf.

[7] *Id*.

agencies') management and mitigation of pesticide risks; to these agencies' enforcement of pesticide production, distribution and use requirements; to registrants, including manufacturers and their supplemental distributors; to pesticide applicators, who rely on the label for use instructions and hazard and safety information; and to the general public.[8]

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. These regulations require a registrant to provide, on the front panel of the label, the appropriate "signal word" for the pesticide,[9] a child hazard warning ("Keep Out of Reach of Children"),[10] and, for certain products, a first aid statement. 40 C.F.R. § 156.60(a)(1). "When data or other information show that an acute hazard may exist to humans or domestic animals, the label must bear precautionary statements describing the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or toxic effect or to mitigate the effect." 40 C.F.R. § 156.70(b).

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[8] *Id*.

[9] EPA regulations establish four different toxicity categories for acute hazards of pesticide products. 40 C.F.R. § 156.62. The categories relate to the various routes of exposure of a pesticide (*e.g.*, oral, dermal, inhalation, eye irritation and skin irritation). A "signal word" reflecting the highest toxicity category of the product must appear on the front label. These words express the risks associated with the product, and include "Danger," "Warning" and "Caution." *Id.* § 156.64.

[10] 40 C.F.R. § 156.66(a).

Notably, any "[s]pecific statements pertaining to the hazards of the product and its uses must be approved by the [EPA]." 40 C.F.R. § 156.70(c).

The EPA 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). A pesticide is misbranded, for present purposes, 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). A pesticide is also misbranded if its label "does not contain a warning or caution statement which may be necessary and . . . is adequate to protect health and the environment." 7 U.S.C. § 136(q)(1)(G). EPA may only approve a pesticide registration if it has concluded that the product is not misbranded. 40 C.F.R. § 152.112(f). Thus, EPA affirmatively determines that the label does not include "false or misleading" statements and contains warnings necessary to protect health.[11] It is unlawful to distribute or sell any misbranded pesticide. 7 U.S.C. § 136j(a)(1)(E).

[11] *See* David M. Whitacre & Kristin R. Eads, Defending Pesticides in Litigation § 6:2, at 122 (Thomson Reuters 2012 ed.) ("As a general matter, EPA approval of a pesticide label reflects EPA's affirmative determination that the pesticide is not mislabeled," *i.e.*, that it is not false and misleading "in any particular.")

Once approved, a label must accompany the sale of the pesticide, 7 U.S.C. § 136j(a)(2)(A), and may generally be amended only with the approval of the EPA. 40 C.F.R. § 152.44(a) ("any modification in the composition, labeling, or packaging of a registered product must be submitted with an application for amended registration"). The registrant cannot add a new health hazard to the "precautionary statement" of the label without EPA approval.[12]

C. The Role of the States in FIFRA's Scheme

Congress addressed the States' role in pesticide regulation in the 1972 FIFRA amendments. *Bates*, 544 U.S. at 439. While providing the States certain leeway to regulate the sale and use of pesticides within their borders, FIFRA preserves the primacy of the EPA and federal law. Thus, FIFRA grants the States authority to "regulate the sale or use of any federally registered pesticide or device in the State," but does so "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).

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[12] The EPA permits "minor modifications to registration having no potential to cause unreasonable adverse effects to the environment" to be effectuated without notification or approval by the agency. 40 C.F.R. § 152.46(b). Those "minor modifications" cannot involve "change in the ingredients statement, signal word, use classification, precautionary statements, statements of practical treatment (First Aid), physical/chemical/biological properties, storage and disposal, or directions for use." EPA, Office of Pesticide Programs, Pesticide Registration Notice (PRN) 98-10: Notifications, Non-Notifications and Minor Formulation Amendments at 8 (Oct. 22, 1998), *available at* https://www.epa.gov/sites/production/files/2014-04/documents/pr98-10.pdf.

The States' role is even more circumscribed with respect to product labeling. States may enforce only requirements that are *fully consistent* with EPA'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 452. FIFRA supervision of pesticide labeling is thus "exclusive." *See Indian Brand Farms, Inc. v. Novartis Crop Protection Inc.*, 617 F.3d 207, 214 (3d Cir. 2010).

Finally, a State may register within its borders certain additional uses of pesticides already registered by the EPA, but only "if registration for such use has not previously been denied, disapproved, or canceled by the Administrator." 7 U.S.C. § 136v(c)(1). FIFRA reserves to the EPA authority to disapprove a state-issued registration within 90 days of a State's additional-use registration. *Id*. § 136v(c)(2). Where a State lacks adequate controls, the EPA may suspend the State's authority to register pesticides until those controls are put in place. *Id.* § 136v(c)(4)

ARGUMENT

"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*, 567 U.S. at 399 (quoting U.S. Const. Art. VI, cl. 2). Federal law thus preempts state law in either of two circumstances relevant here. First, Congress can explicitly 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. v. Bartlett*, 570 U.S. 472, 480 (2013). FIFRA implicates both branches of preemption doctrine.

I. FIFRA EXPRESSLY PREEMPTS CALIFORNIA'S COMMON LAW REGULATION OF GLYPHOSATE LABELING

A. The California Judgment Imposes a Duty-to-Warn Requirement that Diverges from FIFRA

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). In *Bates*, the Supreme Court held that "any requirements" includes not only state statutes and regulations, but also "common law duties." 554 U.S. at 443-44; *see also Riegel*, 552 U.S at 324. Thus, FIFRA's uniform labeling provision "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.

California's common law duty-to-warn claims, as applied to Monsanto's glyphosate-based Roundup products, plainly diverge from the labeling requirements imposed by the EPA under FIFRA's mandate that a pesticide label not be mislabeled—*i.e.*, that the 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).

The verdict below was based on the jury's conclusion that Monsanto has an obligation to warn consumers that glyphosate may cause cancer. But the EPA has repeatedly and explicitly concluded that glyphosate does not pose a cancer risk and, for that reason, has determined that a cancer warning is not required or even appropriate. Acting on the recommendation of a scientific peer review committee in the early 1990s, the EPA classified glyphosate as "Group E" for carcinogenicity, formally concluding that there was "evidence of noncarcinogenicity for humans."[13] It reiterated that finding in a formal rule establishing pesticide tolerances for

[13] *See* EPA, R.E.D. Facts, Glyphosate at 2 (Sept. 1993), *available at* https://archive.epa.gov/pesticides/reregistration/web/pdf/0178fact.pdf ("In June 1991, EPA classified glyphosate as a Group E oncogen—one that shows evidence of non-carcinogenicity for humans—based on the lack of convincing evidence of carcinogenicity in adequate studies.").

glyphosate in 1997,[14] and repeatedly in subsequent tolerance rulemakings in response to comments alleging that glyphosate causes cancer.[15]

The EPA opened a new periodic registration review of glyphosate in 2009. This process has been conducted over a decade and involves extensive review of glyphosate's environmental safety and toxicology. After further review by both the EPA's Cancer Assessment Review Committee and a Scientific Advisory Panel, the EPA published a Revised Glyphosate Issue Paper evaluating the carcinogenic potential of the herbicide in December 2017. "As part of this process, the hazard and exposure of glyphosate are reevaluated to determine its potential risk to human and environmental health," incorporating "new science."[16] The review included assessment of "63 epidemiological studies, 14 animal carcinogenicity studies, and nearly 90 genotoxicity studies for the active ingredient glyphosate."[17] The agency concluded that "available data and weight-of-evidence clearly do not support the

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

[15] 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.").

[16] EPA, 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.

[17] *Id.* at 144.

descriptors 'carcinogenic to humans,'" or even "'likely to be carcinogenic to humans.'"[18] Instead, the EPA concluded that the scientific evidence most strongly supported a description of glyphosate as "not likely to be carcinogenic to humans."[19]

This assessment was concluded after the International Agency for Research on Cancer ("IARC") determined that glyphosate was a probable carcinogen. Based on its contrary assessment, the EPA issued a "Proposed Interim Registration Review Decision" for glyphosate in April 2019, concluding that its "independent evaluation of the carcinogenic potential of glyphosate . . . has determined that glyphosate is 'not likely to be carcinogenic to humans.'"[20] The EPA considered and expressly rejected the IARC's cancer conclusion, explaining that EPA's "cancer 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 EPA] that were not appropriate for determining the human carcinogenic potential of glyphosate."[21]

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[18] *Id.*

[19] *Id.*

[20] EPA, Glyphosate: Proposed Interim Registration Review Decision, Case No. 0178 at 7 (Apr. 2019), *available at* https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-2344.

[21] *Id.* The EPA also criticized the IARC study for its relative lack of transparency: "IARC meetings are not accessible to the public. Its deliberations are closed, its process does not allow for public comments to be submitted for consideration,

As a result of this decade-long process, assisted by expert scientific peer review, the EPA has explicitly determined not only that no cancer warning is warranted, but further that a cancer warning would be unlawful. In its August 2019 letter to all glyphosate registrants, EPA's Office of Pesticide Programs reiterated that it "disagrees with IARC's assessment of glyphosate."[22] The EPA 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.[23] In light of its explicit rejection of the IARC's cancer finding, the EPA determined that it would consider California's Proposition 65 warning language—that glyphosate may cause cancer in humans—"to constitute a false and misleading statement."[24] The EPA concluded, based on its own independent evaluation of the scientific evidence, that any pesticide products containing a cancer warning for glyphosate would be "misbranded pursuant to" FIFRA.[25]

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there are no materials provided in advance of the meeting, and IARC's reports are final without an external peer review." *Id.* at 8.

[22] Aug. 7, 2019 EPA Letter at 1.

[23] *Id.*

[24] *Id.*

[25] *Id.*

The jury's verdict finding Monsanto liable for failing to warn of the cancer-causing potential of glyphosate thus established a state law labeling requirement directly contrary to the labeling requirement imposed by the EPA under FIFRA. In similar circumstances in *Riegel*, the Supreme Court held state common law negligence and mislabeling claims concerning a medical device to be preempted under an express preemption provision identical in relevant respect to FIFRA (*see* 21 U.S.C. § 360k(a)). The Court found the state law claims preempted because they contradicted federal requirements specific to the particular device, established when the FDA approved the device based on the agency's determination that it was safe and thereby barred modifications to its configuration or labeling without permission. *See* 552 U.S. at 322-23.

Similarly, finding Monsanto liable under state law for not having a cancer warning contradicts the EPA's explicit findings that glyphosate does not cause cancer and its prescription of a label that does not contain that warning. Because the state common law claims, like those in *Riegel*, would impose state law requirements that are "different from or in addition to" federal glyphosate labeling requirement established by the EPA under FIFRA, they are preempted. And in light of the EPA's consistent findings that glyphosate does not pose a cancer risk to humans, enforcement of this state law cancer warning requirement would also contradict and be preempted by FIFRA's misbranding provisions. *See* 7 U.S.C. §

136j(a)(1)(E); *id.* § 136(q); *see also* 40 C.F.R. § 156.10(a)(5) (pesticide is misbranded "if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims").

B. The District Court's Preemption Rulings Fundamentally Misapply *Bates*

The district court's conclusion to the contrary is based on a fundamental misreading of *Bates.* From *Bates*, the district court mined the proposition that "the mere fact that the EPA has approved a product label does not prevent a jury from finding that the same label violates FIFRA." *Hardeman v. Monsanto Co.*, 216 F. Supp. 3d 1037, 1038 (N.D. Cal. 2016). But that proposition cannot be divorced from the factual context of *Bates*, where, unlike here, the EPA had not reviewed the label representations that were challenged by plaintiff's state law claims.

Bates makes plain that failure-to-warn claims, like those at issue here, have the potential to displace Congress's comprehensive scheme by interfering with the EPA's exclusive authority to determine the content of pesticide labels. "[I]magine 50 different labeling regimes prescribing the color, font size, and *wording of warnings*." *Bates*, 544 U.S. at 452 (emphasis added). A multi-jurisdictional labeling regime is foreclosed by FIFRA's preemption provision precisely because it "would create significant inefficiencies for manufacturers." *Id.* The labeling

preemption provision addresses "the industry's need for uniformity,"[26] a fact confirmed by the very title of the preemption provision—"Uniformity." *See* 7 U.S.C. § 136v(b).

The district court concluded that *Bates* was untroubled by the prospect that state law misbranding claims might "giv[e] juries in 50 states the authority to give content to FIFRA's misbranding prohibition." *Hardeman v. Monsanto*, 216 F. Supp. 3d 1037, 1038 (N.D. Cal. 2016) (quoting *Bates*, 544 U.S. at 448). That is incorrect. While *Bates* left open the possibility that the state law claims at issue might survive preemption, it did not hold that the plaintiff's failure-to-warn claims in that case were legally permissible. Instead, the Court remanded for a factual determination as to whether those claims imposed requirements that "diverged" from FIFRA. *Bates*, 544 U.S. at 452. *Bates* "emphasiz[ed] that a state labeling requirement *must in fact* be equivalent to a requirement under FIFRA in order to survive preemption." *Id*. at 453 (emphasis added).

In considering this case, it is therefore critical to understand what the jurors in *Bates* were asked to decide. *Bates* was not a case, like this one, where jurors were asked to second-guess the scientific judgment of the EPA, the federal agency charged with administration and enforcement of FIFRA. The plaintiffs there, who

[26] *See Bates*, 544 U.S. at 452 n.26 (quoting Hearings on Federal Pesticide Control Act of 1971, House Committee on Agriculture, 92d Cong., 1st Sess., 281-283 (1971)).

believed 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 claim that the pesticide was suitable for "all areas where peanuts are grown." *Id*. at 440. In registering Strongarm and approving its label, the EPA had not, in fact, reviewed or approved any of the label's claims of efficacy of the herbicide in support of peanut crops.

Instead, acting under authority delegated by Congress, the EPA had waived review of the efficacy of products, leaving the responsibility to comply with FIFRA's requirements solely to the registrant. *Id.* at 440. Congress granted the EPA authority to waive review of efficacy claims in FIFRA amendments, in response to "EPA's concern that its evaluation of pesticide efficacy during the registration process diverted too many resources from its task of assessing the environmental and health dangers posed by pesticides." *Id.* The EPA thus issued a general waiver, in which it confirmed that "EPA's 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.* The Court thus grounded its preemption analysis, in part, on the fact that "Congress amended FIFRA to allow EPA to waive efficacy review of newly registered pesticides." *Id.* at 450.

Accordingly, while *Bates* suggested that juries might, in certain circumstances, appropriately consider FIFRA mislabeling issues, *id.* at 451-52, the Court was not suggesting that lay juries could set aside expert scientific judgments made by the EPA. Instead, the Court merely left open the possibility that a lay jury might occupy the space *left vacant* by the EPA's waiver of efficacy review.[27] A State with a misbranding prohibition paralleling the prohibition imposed by FIFRA may, of course, enforce its requirement. And absent any EPA determination that the federal requirements have been satisfied, a judgment under state law might not impose requirements that diverge from those imposed by FIFRA. Put differently, state law in that case could lawfully supply an *additional* remedy for mislabeling already prohibited by FIFRA without imposing substantive labeling requirements *different from* those prescribed by the EPA under FIFRA. *Id.*

This case presents a much different sort of claim. Plaintiff's failure-to-warn claim required a lay jury to reweigh expert scientific questions determined and redetermined by the EPA. *See* discussion, *supra*, at 15-19. Unlike the efficacy claims at issue in *Bates*, Congress has required the EPA to play the critical role in determining whether a pesticide, "when used in accordance with widespread and

[27] While the Court was not troubled that "properly instructed jurors might on occasion reach contrary conclusions on a similar issue of misbranding." *Id*. at 452, there it was highlighting the possibility of "contrary conclusions" among different juries—not jury determinations that directly conflict with expert factual judgments made by the EPA itself.

commonly recognized practice, . . . will not generally cause unreasonable adverse effects on the environment," including human health. 7 U.S.C. § 136a(c)(5)(D). The EPA cannot waive that review; indeed, it is so central to FIFRA's purpose that Congress permitted the EPA to waive efficacy review in order to devote more resources to protecting human health and the environment as part of the registration process. *Bates*, 544 U.S. at 440. Yet the district court's ruling would ask a lay jury to second-guess that determination here.

Bates simply cannot be read to support such a practice. Indeed, it suggests just the opposite. In discussing examples of state law requirements that would be preempted by FIFRA, the Court cited an example of state law requirements that would require more strident warnings than those mandated by the EPA's own scientific findings of pesticide toxicity: "For example, a failure-to-warn claim alleging that a given pesticide's label should have stated 'DANGER' instead of the more subdued 'CAUTION' would be pre-empted because it is inconsistent with 40 CFR § 156.65 (2004), which specifically assigns these warnings to particular classes of pesticides based on their toxicity." *Bates*, 544 U.S. at 453.

The effect of the jury verdict here is the same. The EPA's consistent finding—that glyphosate is not a carcinogen—dictates that, in order to be properly labeled, the label cannot contain a cancer warning. California's contrary warning that glyphosate may cause cancer directly contradicts that federal requirement.

Like a state requirement of a higher signal word than that required by the EPA's toxicity findings, a state common law cancer labeling requirement is preempted because it is "in addition to or different from" FIFRA's requirements, as established by the EPA. *See* 7 U.S.C. § 136v(b).

II. FIFRA ALSO IMPLIEDLY PREEMPTS CALIFORNIA'S COMMON LAW REGULATION OF GLYPHOSATE LABELING

Plaintiff's state law claims are also foreclosed under "impossibility" preemption. *See Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019); *Wyeth v. Levine,* 555 U.S. 555, 571 (2009). 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. *Merck*, 139 S. Ct. at 1676; *Wyeth*, 555 U.S. at 571.

In its most recent foray into impossibility preemption, the Supreme Court explained what it meant for a state duty-to-warn claim to conflict with federal law. The FDCA, at issue in *Merck,* permitted a drug manufacturer to change a label without advance FDA approval if the changes were necessary to reflect newly acquired information. 139 S. Ct. at 1679. (The FDA could, however, reject any label changes after the manufacturer unilaterally made them. *Id.*). On the basis of that self-amendment process, the Court reasoned that a drug manufacturer "ordinarily" would not be able to show an actual conflict between state and federal

law because it could always take matters into its own hands to comply with state law.[28]

Notwithstanding this ordinary rule, *Merck* nevertheless held the state duty-to-warn claims there preempted. It did so because there was "clear evidence" that the FDA, when fully informed of the risks at issue, would decline to approve the labeling change required by state law. *Merck*, 139 S. Ct. at 1678; *see also Wyeth*, 555 U.S. at 571.

That standard is plainly satisfied here. The EPA'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.[29] That letter, of course, came months after the jury verdict in this case. But the letter merely confirmed what has been true for decades: since the EPA has consistently concluded, in agency notice and comment proceedings, that glyphosate did not cause cancer, no cancer warning is appropriate or permitted under FIFRA. The

[28] Unlike the drug manufacturer in *Merck*, pesticide manufacturers have little discretion to unilaterally amend their labels without EPA approval. *See discussion, supra*, at 12 & n.12. Therefore, the "ordinary" presumption against preemption applicable in the circumstances of *Merck* would not apply in the FIFRA labeling context. *Compare Merck*, 139 S. Ct. at 1679 *with PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618-19 (2011) (finding impossibility preemption where generic drug manufacturer unable to change label unilaterally).

[29] EPA August 7, 2019 Letter, *supra* n. 4.

EPA reaffirmed these findings even after considering the 2015 IARC report on which plaintiffs based their failure to warn claim. *See* discussion, *supra*, at 17-19.

While the August 2019 EPA letter provides an emphatic response to the question posed by *Merck*—whether a fully informed EPA would have approved the warning required by California law—the EPA had *already* answered that question on numerous occasions. EPA's scientific judgments that glyphosate does not cause cancer—and its consequent rejection of the IARC's contrary conclusion—are entitled to deference in the preemption analysis and doom plaintiff's claims.

The district court's rejection of impossibility preemption as a matter of law cannot stand. The district court reasoned that FIFRA impossibility preemption was no longer available after *Bates*. *In re Roundup Prods. Liability Litig.*, 364 F. Supp. 3d 1085, 1088 (N.D. Cal. 2019). But *Bates* did not implicitly reject the application of impossibility preemption; indeed, the court of appeals' decision under review had not even relied on that principle. *See Dow Agrosciences LLC v. Bates,* 332 F.3d 323, 329 (5th Cir. 2003) (deciding whether claims were "within [the] scope of FIFRA's express preemption clause"). *Bates* thus leaves in place this Court express holding in *Nathan Kimmel* that FIFRA's express preemption clause does not foreclose implied preemption. *Nathan Kimmel*, 275 F.3d at 1204 ("Implied conflict preemption can exist even when Congress has chosen to include an express preemption clause in a statute."); *see also, e.g.*, *Arizona*, 568 U.S. at 406

(express preemption "does not bar the ordinary working of conflict preemption provisions" or "impose a special burden" on implied preemption analysis) (internal quotations and citation omitted).

The district court's conclusion that impossibility preemption "fails on the merits," 364 F. Supp. 3d at 1088, is also erroneous. The court reasoned that California's statutory authority to ban the sale of glyphosate necessarily implies a lesser-included power to "impose state-law duties that might require Monsanto to seek EPA approval before selling an altered version of Roundup in California." *Id.* But this completely misreads FIFRA Section 136v, which explicitly grants States a role in regulating the "sale or use" of federally registered pesticides subject only to the limitation that the States not permit any sale or use prohibited by FIFRA (such as, here, permitting sale of misbranded pesticides). *See* 7 U.S.C. § 136v(a). FIFRA's labeling "Uniformity" provision, by contrast, explicitly denies the States *any role* in determining the content of pesticide labels. *Id.* § 136v(b); *see Bates*, 544 U.S. at 452.

III. THE JURY VERDICT HERE IMPOSES SUBSTANTIAL HEALTH, SAFETY AND ECONOMIC COSTS ON THE AMERICAN PUBLIC.

Finally, imposing liability under state law for mislabeling a pesticide that EPA has determined safe for human use on the basis of a lay jury's determination that the EPA misconstrued the relevant science imposes real world costs that should not escape this Court's consideration. In enacting and amending FIFRA,

Congress delegated to the EPA the task of weighing the "economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. § 136(bb).[30] The EPA has approved (and re-approved) the use of glyphosate on the grounds that it is a highly effective herbicide with a broad spectrum of "use in agriculture, including horticulture, viticulture, and silviculture, as well as non-agricultural sites including commercial, industrial and residential areas."[31] Glyphosate is the leading active ingredient used to control noxious and invasive weeds in aquatic systems, pastures and range lands, forestry and rights-of-way—thus helping to contain mosquito-borne diseases, keeping roadways and railroad tracks safe, and allowing for distribution of goods, services and utilities.[32]

At the same time, the EPA has not "identif[ied] any human health risks from exposure to any use of glyphosate."[33] Given this combination of low risk and high reward, "[g]lyphosate is the most commonly used agricultural herbicide in the United States, in terms of area treated."[34] Its usage has increased from 1.4 million

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[30] Cornell University's Pesticide Safety Education Program has prepared a useful guide to the factors considered by EPA in its FIFRA risk/benefit analysis, *available at* http://psep.cce.cornell.edu/issues/risk-benefit-fifra.aspx.

[31] *See* EPA, Glyphosate: Proposed Interim Registration Review Decision, *supra* n. 20, at 34 ("Benefits Assessment").

[32] *Id.* at 34.

[33] *Id.* at 35.

[34] *Id*. at 34.

pounds at the time of its initial registration in 1974 to approximately 280-290 million pounds in 2014.[35]

A state law requirement that glyphosate manufacturers warn of carcinogenicity when there is none—*i.e.*, an "excessive" warning—would have deleterious real world economic and health effects on the public. A cancer risk warning would discourage the widespread use of glyphosate with a resulting loss of crop yields and other benefits from use. Unsupported warnings may lead consumers to avoid buying economically and social useful products that do not pose a risk of harm.[36]

And, despite the tendency to think "better safe than sorry," unnecessary and unsupported warnings "are not innocuous. If warnings indicate a high relative risk when there is none, they will distort relative product comparisons, thus compromising credibility."[37] A farmer choosing between glyphosate and an alternative pesticide that the EPA *has* determined poses a cancer risk might be indifferent between the two, thus exposing the farmer to a real cancer risk when the use of glyphosate would have posed none. *See e.g.*, *Dowhal v. Smithkline*

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[35] Revised Glyphosate Issue Paper, *supra* n. 16, at 16.

[36] *See, e.g.*, *Post Foods, LLC v. Superior Court of Los Angeles Cty.*, 235 Cal. Rptr. 3d 641, 649 n.5 (Ct. App. 2018), *as modified on denial of rehearing* (Aug. 15, 2018) ("[W]hether a Proposition 65 warning on whole grain cereals would lead to labels on otherwise healthful foods . . . presents a concern.").

[37] W. Kip Viscusi, *Individual Rationality, Hazard Warnings, and the Foundations of Tort Law*, 48 Rutgers L. Rev. 625, 665 (1996).

Beecham Consumer, 12 Cal. Rptr. 3d 262, 274 (2004) (finding no basis to question FDA's determination that placing Proposition 65 warnings on nicotine patch packaging "might lead pregnant women to believe that NRT products were as dangerous as smoking, or nearly so, and thus discourage the women from stopping smoking").

In short, there is a real world cost, both economic and in terms of human health, to "crying wolf." This cost reinforces the need to exercise caution in permitting a jury to second-guess the EPA's expert determinations on the carcinogenic potential of glyphosate. Consistent with decades of scientific study, the EPA has determined that there is no cancer risk. The jury verdict below, which overrides that expert determination, is preempted.

CONCLUSION

For the reasons stated herein, the district court's judgment should be reversed.

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Respectfully submitted,

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Pursuant to Fed. R. App. P. 32(a)(7)(C), the undersigned hereby certifies that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B)(i) and Rule 29(a)(5).

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/s/ Shannen W. Coffin

December 19, 2019

CERTIFICATE OF SERVICE

I hereby certify that on this 19th day of December 2019, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit using the appellate CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

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