No. 19-16636

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Monsanto Company,
Defendant/Appellant,

v.

Edwin Hardeman,
Plaintiff/Appellee.

Appeal from the United States District Court
for the Northern District of California
Nos. 3:16-cv-00525 (Hon. Vince Chhabria)

BRIEF OF THE UNITED STATES AS AMICUS CURIAE IN SUPPORT OF MONSANTO

JEFFREY BOSSERT CLARK
Assistant Attorney General
JONATHAN D. BRIGHTBILL
ERIC GRANT
Deputy Assistant Attorneys General
JENNIFER SCHELLER NEUMANN
VARUDHINI CHILAKAMARRI
MATTHEW R. OAKES
Attorneys
Environment and Natural Resources Division
U.S. Department of Justice
Post Office Box 7415
Washington, D.C. 20044
(202) 514-0000
matthew.oakes@usdoj.gov

Of Counsel:

ERIN S. KOCH
AMBER L. ARANDA
Attorneys
EPA Office of General Counsel

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INTRODUCTION

The district court in this case erred. When regulating pesticides under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), EPA has long declared, "The label is the law."[1] For "[i]t is a violation of Federal law to use [a pesticide] in a manner inconsistent with its labeling." 7 U.S.C. § 136j(a)(2)(G). *See also* 40 C.F.R. § 156.10(i)(2)(ii). Every time EPA reviews and approves the label for a registered pesticide, it is making federal law. EPA's decisions must also run a gauntlet of judicial review. And the outcome of that administrative law and judicial-review process then applies to a pesticide's users. It also applies to a pesticide's manufacturer and sellers. It is unlawful for manufacturers and sellers to make claims on their labels that differ from what EPA approves. 7 U.S.C. § 136j(a)(1)(B).

States can generally restrict the sale or use of pesticides. But they cannot "impose or continue in effect any requirements ***for labeling*** or packaging ***in addition to or different from*** those required under this subchapter." 7 U.S.C. § 136v(a), (b) (emphasis added). Through its application of state common law, Plaintiff did exactly that. He claimed that Monsanto failed a legal duty to make additional statements on the label about alleged cancer risks associated with Monsanto's glyphosate

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[1] *See, e.g.*, *EPA, Pesticide Registration Manual* (last updated April 2017), *available at* https://www.epa.gov/pesticide-registration/pesticide-registration-manual.

pesticide—cancer risks that EPA has for decades concluded science does not support.

EPA reviewed and approved Monsanto's glyphosate pesticide label. That approved label was the law tailored to Monsanto's product. Yet Plaintiff asserted safety labeling requirements exist under California law in addition to and different from that required, reviewed, and approved by EPA. Plaintiff is wrong and his lawyers sailed directly into preempted territory in how they opted to try this case.

INTEREST OF THE UNITED STATES

The United States, through the Environmental Protection Agency (EPA), has responsibility for implementing and enforcing the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136-136y. FIFRA generally requires that EPA must register a pesticide and approve its label before that pesticide may be distributed, sold, or used in any State. 7 U.S.C. § 136a. That label, once reviewed and approved by EPA, is controlling. States retain the power to restrict the sale, or use of pesticides within their borders, but they cannot "impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." 7 U.S.C. § 136v(a), (b).

Plaintiff here sued the manufacturer of the pesticide Roundup®. This pesticide contains an active ingredient called glyphosate, which Plaintiff alleges

causes cancer. Plaintiff alleged state law causes of action relating to the manufacturer's failure of the common law legal duty to warn of the alleged risk.

Roundup is registered under FIFRA and its EPA-approved label does not contain a cancer warning. The United States has a strong interest in preserving Congress's express delineation of federal versus state authority, which ensures that the federal government can establish and maintain nationally uniform requirements for the labeling and packaging of pesticides.

The United States files this brief as of right pursuant to Federal Rule of Appellate Procedure 29(a)(2).

STATEMENT OF THE CASE

A. FIFRA

Congress created FIFRA through a series of enactments to regulate the labeling, sale, and use of pesticides, including herbicides. *See Wisconsin Pub. Intervenor v. Mortier*, 501 U.S. 597, 601 (1991). As originally enacted in 1947, *see* ch. 125, 61 Stat. 163, FIFRA "was primarily a licensing and labeling statute." *Mortier*, 501 U.S. at 601 (quoting *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991 (1984)). In 1972, Congress "significantly strengthened FIFRA's registration and labeling standards" in response to "environmental and safety concerns." *Id.*; *see also* Federal Environmental Pesticide Control Act of 1972 (1972 Amendments), Pub. L. No. 92-516, 86 Stat. 973. The 1972 Amendments effectively "transformed FIFRA

from a labeling law into a comprehensive regulatory statute." *Mortier*, 501 U.S. at 601 (quoting *Ruckelshaus*, 467 U.S. at 991). Congress has continued to amend FIFRA in response to experience gained in regulating pesticides. *See, e.g.*, Federal Pesticide Act of 1978 (1978 Amendments), Pub. L. No. 95-396, 92 Stat. 819; Food Quality Protection Act of 1996 (1996 Amendments), Pub. L. No. 104-170, Tit. II, 110 Stat. 1489.

Section 136a(c)(5) of FIFRA provides that EPA "shall register a pesticide" if the agency determines, in light of any restrictions placed on the pesticide's use, that:

> (A) its composition is such as to warrant the proposed claims for it;
>
> (B) its labeling and other material required to be submitted comply with the requirements of this subchapter;
>
> (C) it will perform its intended function without unreasonable adverse effects on the environment; and
>
> (D) 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). EPA has promulgated FIFRA regulations establishing the registration process. *See* 40 C.F.R. § 152 et seq. As part of that process, EPA must and does review and approve of the statements manufacturers propose to make on a label. *See* 40 §§ C.F.R 152.40-152.55. If EPA has reason to believe a pesticide product violates FIFRA's provisions, EPA may issue "stop sale, use, or removal" orders, 7 U.S.C. § 136k(a), the offending products may be seized and condemned, 7 U.S.C. § 136k(b), and the pesticide manufacturer may be subject to civil and

criminal penalties, 7 U.S.C. § 136l. *See* 7 U.S.C. 136j (identifying "[u]nlawful acts").

EPA is required to review each pesticide registration every fifteen years to ensure that each registration continues to satisfy FIFRA's standards. 40 C.F.R. § 155.40(a). EPA also must review and approve any significant change to the labeling or packaging of a FIFRA-registered product. *See* 7 U.S.C. § 136a(c); 40 C.F.R. § 152.44(a).

FIFRA establishes a program for federal-state cooperation in regulating pesticides. *See Mortier*, 501 U.S. at 601-602. Section 136v, captioned "Authority of States," sets forth key principles of that relationship. *See* 7 U.S.C. § 136v. Section 136v(a) recognizes that, as a general matter, States retain their historic authority to regulate pesticide sale or use, provided that a State does not permit a sale or use that FIFRA, or EPA's implementing regulations, prohibit:

> (a) In general
>
> A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.

7 U.S.C. § 136v(a).

Nevertheless, to ensure a uniform nationwide regulation of pesticide labeling, Section 136v(b) forbids a State from imposing any additional or different requirements on pesticide labeling or packaging than those imposed by FIFRA:

> (b) Uniformity
>
> 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.

7 U.S.C. § 136v(b). Sections 136v(c)(1) through (c)(4) set out additional limitations on state-issued registrations. 7 U.S.C. § 136v(c)(2)-(4). In short, Section 136v provides that a State may prohibit the sale or use of any pesticide within its borders. Under specified conditions, a State may also allow a pesticide to be used within its borders for purposes other than those provided in the federal registration.

FIFRA defines the term "label" as "the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers." *Id.* § 136(p)(1). FIFRA defines "labeling" more broadly as:

> [A]ll labels ***and all other written, printed, or graphic matter***: (A) ***accompanying the pesticide or device at any time***; ***or*** (B) to which reference is made on the label or ***in literature accompanying the pesticide*** or device, except to current official publications of the Environmental Protection Agency, the United States Departments of Agriculture and Interior, and the Department of Health and Human Services, State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides.

Id. § 136(p)(2) (emphasis added).

FIFRA prohibits the sale and distribution of misbranded, unregistered, or adulterated pesticides and the use of any registered pesticide in a manner inconsistent

with its labeling. 7 U.S.C. § 136j(a)(1). One way a pesticide may be misbranded is if its label bears a statement that "is false or misleading." 7 U.S.C. § 136(q)(1)(A).

B. California's Proposition 65

Under California's Safe Drinking Water and Toxic Enforcement Act of 1986, Cal. Health & Safety Code §§ 25249.5–25249.14, known as Proposition 65, the Governor of California is required to publish a list of chemicals said to be known to the State to cause cancer. The contents are determined by certain identified entities, including EPA and the International Agency for Research on Cancer. Proposition 65 also prohibits any person in the course of doing business from knowingly and intentionally exposing anyone to the listed chemicals without a prior "clear and reasonable" warning. Cal. Health & Safety Code § 25249.6. This means that the warning must: (1) clearly say that the chemical involved is known to the State of California to cause cancer, or birth defects or other reproductive harm; and (2) be given in such a way that it will effectively reach the person before he or she is exposed to that chemical. 27 Cal. Code Regs. § 25601. California recognizes several ways to provide the mandated warning. Cal. Code Regs. § 25602.

C. History of Glyphosate Review and California's Glyphosate Listing[2]

EPA first reviewed the potential carcinogenic effects of glyphosate in 1985.[3] The reviewing panel concluded that glyphosate, was "possibly carcinogenic to humans," though this conclusion was subsequently amended to a lower risk category after the original data was reassessed. *Id.* at 1. In 1991, EPA reviewed additional glyphosate studies and concluded that the substance should be classified as having "non-carcinogenicity for humans." This designation supported EPA's re-registration of glyphosate in 1993.[4] EPA relied on this 1991 review in a series of glyphosate tolerance rulemakings occurring from 1997 to 2008. *See i.e.*, 62 Fed. Reg. 17,723 (1997); 67 Fed. Reg. 60,936 (2002); 69 Fed. Reg. 65,083 (2004).

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[2] In recounting the history of EPA's glyphosate review the United States cites to government reports and records. This Court may take judicial notice of such reports and records. *See Interstate Natural Gas Co. v. Southern California Gas Co.*, 209 F.2d 380, 385 (9th Cir. 1953) (recognizing that government records and reports are generally appropriate for judicial notice); Fed. R. Evid. 201(b)(2) (The court may judicially notice a fact that "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.").

[3] *See* EPA Office of Pesticides & Toxic Substances, "Second Peer Review of Glyphosate," at 3 (Oct. 30, 1991), available at https://archive.epa.gov/pesticides/chemicalsearch/chemical/foia/web/pdf/103601/417300-1991-10-30a.pdf.

[4] EPA Office of Pesticides and Toxic Substances, "Reregistration Eligibility Decision Glyphosate," (September 1993), available at https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/red_PC-417300_1-Sep-93.pdf.

EPA revised its carcinogen risk assessment guidelines in 2005. The lowest risk category under the 2005 guidelines is "not likely to be carcinogenic to humans."[5] In 2015, during the last Administration, EPA's Cancer Assessment Review Committee reevaluated available glyphosate data, and classified glyphosate as "not likely to be carcinogenic to humans."[6] On December 12, 2017, EPA's Office of Pesticide Programs issued a paper entitled "Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential."[7] EPA undertook this evaluation as part of its 15-year registration review. *Id.* at 12. The 2017 evaluation includes review of existing studies that registrants had not previously submitted to the Agency, as well as a comprehensive literature review. *Id.* at 20-22. In 2017, EPA concluded that "the strongest support" was for a conclusion that glyphosate is "not likely to be carcinogenic in humans." *Id.* at 143. This 2017 paper is part of EPA's glyphosate registration review process—a process that remains ongoing.

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[5] EPA Risk Assessment Forum, "Guidelines for Carcinogen Risk Assessment," at 2-57 (March 2005), available at https://www.epa.gov/risk/guidelines-carcinogen-risk-assessment.

[6] EPA Office of Chemical Safety & Pollution Prevention, "Glyphosate: Report of the Cancer Assessment Review Committee," at 10 (October 1, 2015), available at https://www.biologicaldiversity.org/campaigns/pesticides_reduction/pdfs/EPA-HQ-OPP-2009-0361-0057.pdf.

[7] EPA Office of Pesticide Programs, "Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential," (Dec. 12, 2017), available at https://cfpub.epa.gov/si/si_public_record_Report.cfm?Lab=OPP&dirEntryId=337935.

On July 7, 2017, California listed glyphosate as a substance regulated under Proposition 65, based on the International Agency for Research on Cancer's classification of the pesticide as "probably carcinogenic to humans." Because this listing triggered Proposition 65's warning requirements, many manufacturers that had been registered to use glyphosate reached out to EPA for guidance. Some specifically sought EPA's approval to amend their product labels to satisfy Proposition 65. EPA did approve a limited number of applications allowing the addition of a Proposition 65 glyphosate cancer warning to pesticide labels when requested. EPA did not, however, consider these statements to be "Human Hazard and Precautionary Statements" as administered in 40 C.F.R. § 152.156 Subpart D (156.60 *et seq.*). Because the statement was not a FIFRA required statement, and because it was framed as a statement about California's assessment, it did not receive the same level or review as other parts of the label. These label-change approvals, however, were erroneous because the proposed edits warned of a cancer risk that, according to EPA's assessment, does not exist.[8]

As a result, such a warning instead constituted prohibited misbranding. *See* 7 U.S.C. § 136(q)(1)(A) (defining "misbranded" to include representations that are "false or misleading in any particular"); § 136j(a)(1)(E) (establishing that it is illegal to sell a misbranded pesticide). *See generally* 40 C.F.R. § 152.112(f) (allowing EPA

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[8] *See* n.6, *supra*.

approval of an application under FIFRA Section 3(c)(5), 7 U.S.C. § 136a(c)(5), only where "[t]he Agency has determined that the product is not misbranded").

In an August 7, 2019 letter, EPA informed all glyphosate registrants that EPA had concluded glyphosate is "not likely to be carcinogenic to humans."[9] EPA then stated that products bearing a Proposition 65 warning statement due to the presence of glyphosate are misbranded under FIFRA because such a statement is "false and misleading." *See* EPA August 7 Letter at 1. In support of the representation that glyphosate is "not likely to be carcinogenic," EPA cited to its 2017 glyphosate evaluation. *Id.*

D. Facts and District Court Proceedings

Plaintiff, Edwin Hardeman, who regularly used Roundup for many years beginning in the 1980's, was diagnosed with cancer in 2015. ER2294.[10] In 2016, Mr. Hardeman filed a complaint against Monsanto seeking compensatory, economic, and punitive damages. Mr. Hardeman brought common law claims based on Monsanto's alleged negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing,

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[9] EPA Office of Chemical Safety & Pollution Prevention, Letter from Michael L. Goodis, Director, Registration Division to registrants of glyphosate (Aug. 7, 2019), available at https://www.epa.gov/sites/production/files/2019-08/documents/glyphosate_registrant_letter_-_8-7-19_-_signed.pdf (EPA August 7 Letter).

[10] ER refers to the Excerpts of Record filed with Monsanto's Opening Brief. SER refers to the Supplemental Excerpts of Record filed with this brief.

advertising, distribution, labeling, and sale of Roundup. ER2280; ER2294. Plaintiff filed claims for (1) negligence; (2) design defect; (3) failure to warn; and (4) breach of implied warranty. ER2296-2306.

Monsanto filed a motion to dismiss, arguing that the first three claims were essentially "warnings-based" claims that were expressly preempted by FIFRA. *See Hardeman v. Monsanto Co.*, 216 F. Supp. 3d 1037, 1037-39 (N.D. Cal. 2016), ER117. Monsanto argued that Plaintiff's state-law claims sought to compel a labeling requirement that differed from the label approved by EPA. *Id.* The District Court denied the motion to dismiss, holding that none of the claims were preempted. The district court reasoned that Plaintiff's claims were not preempted because they were consistent with FIFRA. Because FIFRA requires a pesticide label to contain warnings adequate to protect health and the environment, California law similarly requiring warnings of risks is permissible. *Id.*

The district court then conducted a 19-day jury trial. Plaintiff dropped his implied warranty claim prior to trial and tried only his negligence, design defect, and failure to warn claims. During the course of trial, the Court held that Plaintiff's design defect claim relied solely on a consumer expectations test. *See* SER001. This had the effect of converting the design claim to a "warnings-based" claim. *Id.* As a result, all three claims that went to trial were based on a failure to warn theory.

Phase I of the trial concluded with the jury finding that Plaintiff had proved that his exposure to Roundup was a substantial factor in causing his cancer. Phase II concluded with the jury finding that Plaintiff proved "that Roundup's design was defective"; "that Roundup lacked sufficient warnings of the risk of [cancer]," and that "Monsanto was negligent by not using reasonable care to warn about Roundup's [cancer] risk." ER1680-1681. The jury awarded $5,267,634.10 in compensatory damages and $75,000,000 in punitive damages. *Id.* The Court subsequently reduced the punitive damages award to $20,000,000. ER10.

SUMMARY OF ARGUMENT

FIFRA prohibits States from imposing "any requirements" for pesticide labeling that are "in addition to or different from" those required under FIFRA. 7 U.S.C. § 136v(b). Federal law can preempt not only state statutes and regulations, but state common law claims based on duties sounding in tort. The plain terms of FIFRA's prohibition expressly preempt state pesticide labeling requirements, regardless of whether those requirements are expressed through positive enactments or common-law duties.

Under FIFRA, the label is the law. EPA approved the label for the pesticide/herbicide at issue here, Roundup, through a registration process that did not require a cancer warning. In fact, EPA has never required a labeling warning of a cancer risk posed by Roundup, and such a warning would be inconsistent with the

agency's scientific assessments of the carcinogenic potential of the product. Mr. Hardeman nevertheless sought damages under California common law, alleging that Monsanto had failed to adequately warn consumers of cancer risks posed by the active ingredient in Roundup. FIFRA therefore preempts Mr. Hardeman's claims to the extent that they are based on the lack of a warning on Roundup's labeling.

ARGUMENT

FIFRA preempts state tort claims that would subject pesticide manufacturers to inconsistent and additional product labeling requirements.

A. Section 136v(b) preempts State common-law duties that would impose requirements for labeling "in addition to or different from" those required under FIFRA.

Section 136v(b) broadly and expressly prohibits "any requirements for labeling" that are "in addition to or different from" those that FIFRA imposes. 7 U.S.C. 136v(b). Section 136v(b)'s plain text does not distinguish among state labeling requirements based on their origin in a state legislature's enactment of statutes, a state agency's promulgation of rules, or a state court's articulation of common-law standards of care. *See Bates v. Dow Agrosciences LLC*, 544 U.S., 431, 443 (2005). And thus a court's articulation of common-law standards of care can be preempted just like a legislative or regulatory labeling requirement. *Id.*

Mr. Hardeman's failure to warn claims fall within the express preemptive scope of FIFRA. This scope is defined through a two-part test. *See id.* at 444. ***First***,

the state law "must be a requirement '***for labeling or packaging***'; rules governing the design of a product, for example, are not preempted." *Id.* (quoting 7 U.S.C. § 136v(b)). ***Second***, the state law "must impose a labeling or packaging requirement that is '***in addition to or different from*** those required under [FIFRA].'" *Id.* (quoting 7 U.S.C. § 136v(b)). Thus, although FIFRA does not prevent a State from making the violation of federal labeling requirements a state offense and imposing separate sanctions, States cannot impose distinct labeling requirements. *See id.* at 442. Mr. Hardeman's nevertheless based his failure to warn claims on the existence of just such preempted requirements.

First, Monsanto notes that Mr. Hardeman argued to the jury throughout the District Court trial that Monsanto's common law duty included labeling obligations. Monsanto Opening Br. at 25-26. This representation comports with the United States' review of the closing arguments.[11] During his closing statement, counsel declared:

> And one of those requests for admission is that Monsanto says - - they admit, they have never warned that Roundup causes cancer. It's not on the label, Ladies and Gentlemen.

SER28. During his recitation of the scientific evidence counsel followed with:

> Let's go to the animal [studies]. We heard - - remember Dr. Portier testified in Phase One about the mice and rats? The first one, *Knezevich*

[11] The United States has not reviewed all 21 volumes of the trial transcript but our spot review of the record has revealed nothing that would seem to undermine the basic parameters sketched above as to how this case was tried.

> *& Hogan,* 1983 - - this is before Mr. Hardeman ever started spraying Roundup - - when that study came out originally in 1983, if Monsanto had done the right thing and put a warning on the label, we wouldn't be here. We wouldn't be here. Instead, they didn't.

SER30. And finally, when discussing how Monsanto should react to those studies counsel said:

> What is Monsanto's response when they are told that it is - - it is a Category C oncogene[[12]]? A responsible company would first say, should we take this off the market? Or should we test it? Or should we put a warning on it that it is an oncogene? It is going to cause cancer. They don't do anything.

SER35.

Second, FIFRA defines "label" to include "written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers." 7 U.S.C. § 136(p). This definition clearly includes the warnings that counsel referenced at trial. Indeed, in its closing argument, Mr. Hardeman's counsel did not advance any specific examples, ***other than a label warning***, to illustrate how Monsanto could have warned Mr. Hardeman of the cancer risk allegedly posed by Roundup. *See* SER28, 30, 35; https://iaspub.epa.gov/apex/pesticides/f?p=PPLS:1.

Third, even if Mr. Hardeman did raise an argument that Monsanto might have provided a warning someplace other than Roundup's labeling, that does not save Mr.

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[12] An "oncogene" is "a gene found in the chromosomes of tumor cells whose activation is associated with the initial and continuing conversion of normal cells into cancer cells." https://medical-dictionary.thefreedictionary.com/oncogene.

Hardeman's case from preemption. Where a claim relies, even in part, on a prohibited argument, this raises questions of whether the trial record was so infected that the case must be remanded for retrial. *See Coastal Abstract Serv., Inc. v. First Am. Title Ins. Co.*, 173 F.3d 725, 733 (9th Cir. 1999) (remanding jury award of damages for tortious interference where two of the three statements Plaintiff relied upon could not violate the Lanham Act or state defamation standards as a matter of law, and damages based on the third statement could not be isolated in the record), *overruled on other ground by Lexmark, Inc. v. Static Control Components, Inc.*, 572 U.S. 118 (2014). Even if alternate, non-"label" or non-"labeling" warnings could satisfy Monsanto's common-law duties, remand and retrial is still appropriate. Plaintiff's label theory is inextricably intertwined with the evidence relied on by the jury to establish the elements of Plaintiff's claims.

Notably, Mr. Hardeman did not merely seek a label warning that is "different from" EPA's labeling requirements for glyphosate. He added a glyphosate cancer warning to Roundup that EPA rejects. Following California's Proposition 65 listing in 2017, certain companies that were registered to sell and distribute glyphosate sought EPA's approval to amend the labels of their products to include a Proposition 65 cancer warning. Though there were implementation mistakes at an earlier stage, EPA ultimately rejected those warnings. On August 7, 2019, EPA sent a letter to all glyphosate registrants reiterating its disagreement with the International Agency for

Research on Cancer's assessment. A 2017 evaluation of glyphosate by EPA scientists continues to conclude it is "not likely to be carcinogenic to humans." *See* August 7, 2019 letter.

In the 2017 evaluation, EPA specifically considered and rejected the International Agency for Research on Cancer's assessment.[13] Thus, in its August 7 letter, EPA warned that any pesticide products with labels ***bearing*** the Proposition 65 warning due to the presence of glyphosate ***would be deemed misbranded*** pursuant to section 2(q)(1)(A) of FIFRA. The Proposition 65 warning therefore makes a product misbranded because it is misleading.

Mr. Hardeman's alleged legal duty to warn nevertheless required a glyphosate cancer warning on a Roundup label. That not only required a different label (a requirement preempted by FIFRA)—it would almost certainly compel Monsanto to produce a misleading label warning very much at odds with EPA's scientific assessment of the carcinogenic potential of glyphosate, similar to the Proposition 65 warning already rejected by EPA.[14] There is no dispute—nor could there be any

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[13] *See* n.7, *supra*; 2017 study at 13, 23, 32-33, 63-64, and 146.

[14] Distinct from express preemption, implied preemption occurs where "it is impossible for a private party to comply with both state and federal law." *Crosby v. National Foreign Trade Council*, 530 U.S. 363, 372–373 (2000) (internal quotation marks omitted). Implied preemption would also bar Mr. Hardeman's tort theory, to the extent his theory is based on a labeling requirement. *See Wyeth v. Levine*, 555 U.S. 555, 571 (2009) (discussing implied preemption standard). We acknowledge, however, that even in the face of EPA's consistent historic assessment of the cancer

dispute—that FIFRA does not require a warning on Roundup's label that glyphosate causes cancer. To the extent that Mr. Hardeman's theory at trial was tied to Monsanto's failure to include a mandatory state-law-based glyphosate cancer warning on Roundup labels, such a warning is different from the requirements that FIFRA imposed for the labeling and packaging of this product and therefore a legal nullity.

B. The District Court's analysis is erroneous.

In denying Monsanto's motion to dismiss, the District Court held that a state-required glyphosate cancer warning was essentially no different from FIFRA's requirement that label warnings are "adequate to protect health and the environment." *Hardeman v. Monsanto Co.*, 216 F.Supp.3d 1037, 1038 (N.D. Cal.). The District Court compared this general FIFRA standard to California's general strict liability and negligence standards that require a manufacturer to warn of known risks. *Id.* This comparison misses the thrust and full import of FIFRA's preemption provision. It also ignored the fact that EPA had many times addressed the carcinogenic potential of glyphosate ***in particular*** and determined that glyphosate is not likely to be carcinogenic to humans.

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risk posed by glyphosate, EPA mistakenly approved glyphosate cancer warnings on at least two prior occasions. This Court does not need to reach implied preemption, however, because the claims as to labeling and packaging are expressly preempted.

First, in order to avoid federal preemption under FIFRA, it is not enough for a state law merely to be advancing ***similar*** policies or interests. 7 U.S.C. § 136v. Instead, where California general common-law standards impose any inconsistent labeling or packaging requirement, the California common-law claims are be preempted, ***even if the standard supporting those claims is phrased similarly to the standard imposed by Congress through FIFRA***.

Moreover, the potential that glyphosate is carcinogenic to humans is not something that EPA has ignored. EPA has studied and expressly addressed the carcinogenic potential of glyphosate a number of times over the past three decades, *see supra* Statement of the Case § C. And EPA continues to assess it. *See* Glyphosate Proposed Interim Registration Review Decision; Notice of Availability, 84 Fed. Reg. 19782 (May 6, 2019). Through FIFRA, Congress determined that EPA should make these scientific judgments for the nation as a whole. States may, of course, restrict or prohibit the sale or use of pesticides in the State if they disagree with EPA's assessment. But States are prohibited from second-guessing EPA's determination of what risks should be reflected on pesticide labeling. 7 U.S.C. § 136v(a), (b).

Second, the District Court also suggested that EPA's actions under FIFRA were insufficiently formal to trigger preemption. *Hardeman*, 216 F.Supp.3d at 1038-39. That is incorrect. The EPA approved label is a very formal affair that is

the foundation of any FIFRA preemption argument, and that label (and the associated registration process) establishes "requirements" sufficient to support a preemption analysis. The process of registering a pesticide is a scientific, legal, and administrative procedure through which EPA examines the ingredients of the pesticide, where it will be used, the amount, frequency, and timing of its use and storage-related issues. *See* 40 C.F.R. § 152.40-152.55 (Registration Procedures). This process includes evaluation of human health risks, including review of aggregated risks through food, water and residential exposure as well as occupational risks. *See* 40 C.F.R. § 152.112; Pesticide Registration Evaluation Process available at https://www.epa.gov/pesticide-registration/about-pesticide-registration#label; *see also* EPA Pesticide Registration Manual available at https://www.epa.gov/pesticide-registration/pesticide-registration-manual.

Every pesticide product label, including the Roundup label, is reviewed, and must be approved, as part of this process. And EPA seeks to ensure that labels provide clear directions for effective product performance while minimizing risk to human health and the environment. Once a product is registered, EPA posts the approved labels. *See* https://www.epa.gov/pesticide-labels/pesticide-product-label-system-ppls-more-information. Thereafter, "[t]he label is the law." *See, e.g.*, *Introduction to EPA, Pesticide Registration Manual* (last updated April 2017), *available at* https://www.epa.gov/pesticide-registration/pesticide-registration-

manual. And the Supreme Court has recognized that such premarket agency approvals are sufficient to trigger preemption. *See generally Riegel v. Medtronic, Inc.*, 552 U.S. 320, 323 (2008) (holding that premarket approval of individual medical devices were "requirements" sufficient to trigger preemption under the Federal Food, Drug, and Cosmetic Act (FDCA).

Third, the District Court incorrectly stated that Mr. Hardeman's complaint was based on "Monsanto's alleged violation of FIFRA." *Hardeman*, 216 F.Supp.3d at 1038. This is incorrect, too. Mr. Hardeman alleged neither a FIFRA claim nor a claim under the Food, Drug, and Cosmetic Act.

Congress provides for such challenges to the EPA-approved tolerance levels and labels of any Roundup ingredient. For example, individuals may file a petition challenging a pesticide registration action in federal district court. 7 U.S.C. § 136n(a). The label approval is part of such a registration action. EPA must determine that the human dietary risk from pesticide residues in food is consistent with safety standards from the FDCA. *See* 7 U.S.C. 136(bb)(2). And the tolerance is the maximum residue of a pesticide that can legally be present in food or feed. 21 U.S.C. § 346a(a). At the conclusion of these processes, glyphosate labels could have been challenged through FIFRA's judicial review process. Individuals might also petition to request amendment of a tolerance level. *See* 21 U.S.C. § 346a(d); 40

C.F.R. § 180.7. But Mr. Hardeman did not allege either a FIFRA or an FDCA violation regarding glyphosate—neither before EPA nor the district court.

C. FIFRA's preemption of state-law labeling requirements is broad and no exception applies here that would allow Mr. Hardeman's claims to proceed.

With respect to registered product labels, the FIFRA preemption provision is sweeping. It preempts any state law that "would impose a labeling requirement inconsistent with those established by FIFRA." *Worm v. American Cyanimid Co.*, 970 F.2d 1301, 1308 (4th Cir. 1992). A state may impose different or additional ***remedies—or bar or restrict a pesticide use entirely***—but it may not impose different or additional labeling requirements. *Bates*, 544 U.S. at 448.

Despite this broad scope, the Supreme Court has recognized that the FIFRA preemption provision is not unlimited. It did not reach state-law design-defect claims where the particular claim "was not a 'requirement for labeling or packaging' for purposes of FIFRA and thus fell outside the class of claims covered by the express pre-emption provision at issue in that case." *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472, 491 (2013), citing *Bates*, 544 U.S. at 431, 443–444. But that is inapplicable here.

In *Bates*, a group of farmers brought claims under Texas law. They alleged that a pesticide had damaged their crop. On that issue, Congress's 1978 FIFRA amendment had allowed EPA to ***waive*** data requirements pertaining to efficacy and

so approve labels without examining efficacy claims. *Bates*, 544 U.S. at 440. *See also* 7 U.S.C. § 136a(c)(5). EPA invoked this authority, and announced it was waiving efficacy review. *See* 44 Fed. Reg. 27,932 (1979); 40 C.F.R. § 158.640(b) (2004).

When reaching its decision, the Court recognized that FIFRA did not preempt the state-law claims seeking an efficacy-based warning, in part, because EPA did not evaluate the efficacy of the product at issue. *Id.* at 450. So EPA had not—by its non-review of the pesticides' efficacy claims—established a legal standard for state law to conflict with. Here, by contrast, Mr. Hardeman seeks to apply state law to impose a human-health warning. And carcinogenicity is a risk that EPA indisputably ***does (and did)*** evaluate under FIFRA. *See supra* Statement of the Case § C. That is why the farmers' claims were not preempted. *Id.* at 447.

This distinction between efficacy-related label statements and health-related label statements is consistent with other Supreme Court decisions. In *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 497-498 (1996), the Court considered the reach of a similar preemption provision in part of the FDCA. The FDCA, too, provides that no State may establish any requirement relating to the safety or effectiveness of a medical device "which is different from, or in addition to" a requirement mandated by the FDCA. 21 U.S.C. § 360k(a). In *Lohr*, the Court concluded that "general federal regulations governing the labeling and manufacture of all medical devices"

under the FDCA did not necessarily preempt all state tort claims of general applicability. *Id.* at 497-98. But that state tort requirements would be preempted when inconsistent with the FDA's "'specific counterpart regulations or . . . other specific requirements applicable to a particular device'" and its safety. 518 U.S. at 497-498 (quoting 21 C.F.R. § 808.1(d)).

In another case, the Court applied that rule. It held that the FDCA preempted state claims when the "Federal Government ha[d] established requirements applicable to" the particular medical device in question. *Riegel*, 552 U.S. at 321. Thus, under both statutes, the Court has recognized that where the agency had not established specific standards on point, state law claims were not preempted. Nevertheless, in the sphere of regulation where an agency has acted, states cannot impose additional requirements.

As previously noted, EPA has authority over pesticide labels and packaging. *See* 7 U.S.C. §§ 136a, 136q. EPA is required to ensure that labels are not misbranded, and was required by Congress to protect the public from the dissemination of false or misleading information. *See* 7 U.S.C. § 136(q)(1)(A); 40 C.F.R. § 152.112(f). EPA may not approve a pesticide's introduction into commerce unless the Administrator finds that the pesticide "will not generally cause unreasonable adverse effects on the environment" when used in accordance with any EPA-imposed restrictions and "with widespread and commonly recognized

practice." 7 U.S.C. § 136a(c)(5)(D). "Unreasonable adverse effects on the environment" are defined to include "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." *Id.* § 136(bb). And there is no exception to the bedrock requirement that EPA assess health impacts during the pesticide registration process—unlike EPA's ability to opt out of efficacy review.

In fact, forty-four versions of the label for the original formulation of Roundup have been accepted by EPA since 1991. EPA most recently approved the Roundup label in 2009.[15] In EPA's August 7, 2019 letter to glyphosate registrants, EPA clearly expressed its position that a strong glyphosate cancer warning on a pesticide label is misbranding.

Finally, legislative history reveals no Congressional intent to preserve tort actions related to labeling requirements that address the health effects of a product. To the contrary, the Committee Reports supporting Congress's 1972 overhaul of FIFRA contain statements expressing an intent to provide for broad preemption of state requirements respecting pesticide labels. The House Committee Reports states, with reference to Section 136v(b), that "the Committee has adopted language which is intended to completely preempt State authority in regard to labeling and

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[15] A list of approved labels is available by searching the "Product" field of EPA's Pesticide Product and Label System for "Roundup." *See* https://iaspub.epa.gov/apex/pesticides/f?p=PPLS:1.

packaging." H.R. Rep. No. 511, 92d Cong., 1st Sess. 16 (1971). The Senate Committee Report expresses a similar intent, stating "[Section 136v(b)] preempts any State labeling or packaging requirements differing from such requirements under the Act." S. Rep. No. 838, 92d Cong., 2d Sess. Pt. 1, at 30 (1972). Those statements suggest that Congress envisioned that all state labeling or packaging "requirements"—whatever the form—would be preempted.

CONCLUSION

For all of the foregoing reasons, Mr. Hardeman's claims of failure to warn in Monsanto labeling are preempted. The judgment of the district court should be reversed and this case should be either dismissed or, in the alternative, remanded.

Respectfully submitted,

s/ *Matthew R. Oakes*
JEFFREY BOSSERT CLARK
Assistant Attorney General
JONATHAN D. BRIGHTBILL
ERIC GRANT
Deputy Assistant Attorneys General
JENNIFER SCHELLER NEUMANN
VARUDHINI CHILAKAMARRI
MATTHEW R. OAKES
Attorneys
Environment and Natural Resources Division
U.S. Department of Justice
Post Office Box 7415
Washington, D.C. 20044
(202) 514-0000
matthew.oakes@usdoj.gov

Of Counsel:

ERIN S. KOCH
AMBER L. ARANDA
Attorneys
EPA Office of General Counsel

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