No. 21-

IN THE

Supreme Court of the United States

MONSANTO COMPANY,

Petitioner,

v.

ALBERTA PILLIOD AND ALVA PILLIOD,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE COURT OF APPEAL OF CALIFORNIA

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

Petitioner manufactures the herbicide Roundup. For decades, the Environmental Protection Agency (EPA) has exercised its delegated authority under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to find that neither Roundup nor its active ingredient, glyphosate, causes cancer in humans. EPA has authorized Roundup for sale, repeatedly approved Roundup's labeling without a cancer warning, and informed pesticide registrants that including a cancer warning on the labeling of a glyphosate-based pesticide would render it "misbranded" in violation of federal law. FIFRA itself, moreover, bars States from "impos[ing] … any requirements for labeling … in addition to or different from those required under [FIFRA]." 7 U.S.C. §136v(b). Respondents were nonetheless awarded over $17 million in compensatory damages and nearly $70 million in punitive damages after a California jury found that the omission of a cancer warning from Roundup's label violated state law. The questions presented are:

1. Whether FIFRA preempts a state-law failure-to-warn claim where the warning cannot be added to a product without EPA approval and EPA has repeatedly concluded that the warning is not appropriate.

2. Whether a punitive-damages award that is a fourfold multiple of a substantial compensatory-damages award violates the Fourteenth Amendment's Due Process Clause where the defendant acted in accordance with the scientific and regulatory consensus regarding the safety of its product.

CORPORATE DISCLOSURE STATEMENT

Monsanto Company is an indirect, wholly owned subsidiary of Bayer AG, a publicly held corporation. No other publicly held corporation owns 10% or more of Monsanto's stock.

RELATED PROCEEDINGS

Pilliod v. *Monsanto Company*, No. S270957 (Supreme Court of California) (petition for review denied November 17, 2021).

Pilliod v. *Monsanto Company*, No. A158228 (First Appellate District, Division 2) (opinion and judgment issued August 9, 2021; petition for rehearing denied August 25, 2021).

Pilliod v. *Monsanto Company*, No. RG17862702 (Alameda County Superior Court) (judgment issued July 26, 2019).

TABLE OF CONTENTS

TABLE OF CONTENTS—Continued

TABLE OF CONTENTS—Continued

TABLE OF AUTHORITIES

CASES

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

DOCKETED CASES

CONSTITUTIONAL AND STATUTORY PROVISIONS

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

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Monsanto Company respectfully petitions for a writ of certiorari to review the judgment in this case of the Court of Appeal of California.

INTRODUCTION

Monsanto manufactures Roundup, the world's most widely used herbicide. Roundup's active ingredient is glyphosate. Like any herbicide, glyphosate is subject to extensive regulatory scrutiny by the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA's scrutiny includes reviewing whether glyphosate poses risks to humans and ensuring any risks are communicated to the public.

For decades, EPA has studied the enormous body of science on glyphosate and repeatedly concluded that glyphosate does not cause cancer in humans. Indeed, as EPA explained in a case raising claims similar to this one, it has approved 44 versions of Roundup labeling since 1991—each without a cancer warning. And in 2019, it instructed glyphosate manufacturers that no request to add a cancer warning would be approved because such a warning would be false and misleading.

Despite EPA's repeated findings—confirmed by national regulators around the world, including in Australia, the European Union, Canada, and New Zealand—a working group at the International Agency for Research on Cancer (IARC) classified glyphosate in 2015 as "probably carcinogenic to humans." EPA and other regulators reviewed and rejected IARC's conclusion, which did not identify either the circumstances under which glyphosate might cause cancer or the amount of exposure required. Nonetheless, based on the slender IARC reed, thousands of litigants (including respondents Alberta and Alva Pilliod) have sued Monsanto, asserting that it failed to warn them about alleged cancer risks associated with Roundup.

The Court of Appeal's decision here—affirming combined awards that total nearly $87 million, including approximately $70 million in punitive damages—merits review because it conflicts with this Court's and other appellate courts' decisions on two important federal questions.

First, the Court of Appeal held that FIFRA did not preempt respondents' state-law claims regarding Monsanto's omission of a cancer warning from Roundup's label, even though EPA had repeatedly concluded that such a warning would be false and thus prohibited by

FIFRA, and even though FIFRA bars States from "impos[ing] … any requirements for labeling … in addition to or different from those required under [FIFRA]," 7 U.S.C. §136v(b). That contravenes this Court's holding that any state labeling requirement not "*genuinely* equivalent" to a FIFRA labeling requirement is preempted. *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431, 454 (2005). The decision below also departs from how this Court and others have understood a nearly identical preemption provision in another federal statute. This Court recently called for the views of the Solicitor General on this precise question in *Monsanto* v. *Hardeman*, No. 21-241.

Second, the Court of Appeal upheld a massive punitive-damages award—roughly four times the substantial compensatory damages respondents received—even though Monsanto's labeling followed the near-unanimous scientific and regulatory consensus that glyphosate does not cause cancer. That holding cannot be squared with *State Farm Mutual Automobile Insurance Co.* v. *Campbell*, 538 U.S. 408 (2003), which states both (1) that the "absence" of evidence of reprehensibility "renders any [punitive-damages] award suspect," and (2) that a 1:1 punitive-compensatory ratio "reach[es] the outermost limit of the due process guarantee" when the defendant's conduct is not particularly reprehensible and a plaintiff has already been awarded significant compensatory damages, *id.* at 419, 425. The decision below also deepens an existing divide between courts that adhere to *State Farm*'s 1:1 ratio and those that allow larger punitive damages in similar circumstances.

Because these two recurring and important questions merit the Court's review, the petition should be

granted or else held pending the Court's disposition of the petition in *Hardeman*.

OPINIONS BELOW

The California Supreme Court's order denying Monsanto's petition for review, App.1a, is unreported, as is the order of the California Court of Appeal denying Monsanto's petition for rehearing, App.143a-144a. The California Court of Appeal's opinion, App.3a-91a, is reported at 282 Cal. Rptr. 3d 679. The trial court's amended decision denying Monsanto's motion for judgment notwithstanding the verdict and conditionally granting Monsanto's motion for a new trial, App.115a-142a, is unreported but available at 2019 WL 3540107. The trial court's decision denying Monsanto's motion for summary judgment, App.93a-114a, is unreported but available at 2019 WL 2158266.[1]

JURISDICTION

The California Supreme Court denied Monsanto's petition for review on November 17, 2021. On January 27, 2022, Justice Kagan extended the time for filing this petition through March 17, 2022. This Court has jurisdiction under 28 U.S.C. §1257(a).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Article VI, clause 2 of the United States Constitution provides:

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[1] The trial court's amended decision on Monsanto's post-trial motions "expand[ed] on and clarifie[d] some of the court's thinking." App.115a n.1. Because all relevant parts of the court's original decision appear in the amended decision, this petition cites to the latter.

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof … 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.

Section 136v(b) of Title 7 of the United States Code provides:

> 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.

Section 1 of the Fourteenth Amendment to the United States Constitution provides in relevant part:

> No state shall … deprive any person of life, liberty, or property, without due process of law[.]

STATEMENT[2]

A. FIFRA's Regulatory Scheme

FIFRA is a "comprehensive regulatory statute" governing "the use, as well as the sale and labeling, of pesticides." *Bates*, 544 U.S. at 437. No pesticide may be sold or distributed domestically without EPA registration. 7 U.S.C. §136a(a). The registration process requires manufacturers to submit voluminous scientific and safety data (including carcinogenicity studies), as well as proposed labeling that includes any precautionary statements regarding potential effects on human

[2] Citations to "AA" refer to the Appellant's Appendix, and citations to "RT" refer to the Reporter's Transcript. These two sets of documents comprise the appellate record filed with the Court of Appeal.

health. *E.g.*, *id.* §136a(c); 40 C.F.R. §§156.10(a)(1)(vii), 156.60, 158.500.

To register a pesticide, EPA must determine both that the pesticide poses no unreasonable risk of adverse effects on human health, *see* 7 U.S.C. §§136a(c)(5)(C), 136(bb); 40 C.F.R. §152.112(e), and that its labeling complies with FIFRA's misbranding prohibition, *see* 7 U.S.C. §136a(c)(5)(B). "A pesticide is 'misbranded' if its label contains a statement that is 'false or misleading in any particular,'" *Bates*, 544 U.S. at 438, or "does not contain a warning or caution statement which may be necessary and if complied with … is adequate to protect health and the environment," 7 U.S.C. §136(q)(1)(G).

To "ensure that each pesticide's registration is based on current scientific and other knowledge," 40 C.F.R. §155.40(a)(1), EPA must review a registration every 15 years, 7 U.S.C. §136a(g)(1)(A)(iv). This process requires EPA to consider both whether any "labeling changes" are necessary given new information and whether the product still meets FIFRA's requirements, including not being misbranded. 40 C.F.R. §155.58(b).

Pesticide registrants have a continuing obligation to comply with FIFRA's labeling requirements. It is illegal to distribute a pesticide with labeling substantially different than the EPA-approved labeling. 7 U.S.C. §§136a(c)(1), 136j(a)(1)(B). As the United States explained in *Hardeman*, "[t]he label is the law." U.S. Br. 1, *Hardeman* v. *Monsanto Co.*, Nos. 19-16636, 19-16708 (9th Cir. Dec. 20, 2019) (U.S. *Hardeman* Br.).[3]

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[3] The Court of Appeal took judicial notice of "the legal arguments asserted by the United States" in the *Hardeman* amicus brief. App.23a n.11.

Once EPA approves a pesticide's labeling, the manufacturer must seek approval for virtually any substantive change to the labeling or composition of the pesticide. 40 C.F.R. §§152.44, 152.46; 7 U.S.C. §136a(c)(9)(C). Certain minor changes may be made through a streamlined "notification" process, 40 C.F.R. §152.46, but any changes to "precautionary statements" require prior EPA approval, *see* EPA, Office of Pesticide Programs, *Pesticide Registration Notice 98-10* at 8 (Oct. 22, 1998), https://tinyurl.com/yejwzhkt.

Recognizing that divergent state laws could impair interstate commerce in pesticides, FIFRA limits the "[a]uthority of States" to regulate pesticides. 7 U.S.C. §136v. Specifically, FIFRA provides—in a subsection entitled "Uniformity"—that States may not impose "any requirements for *labeling or packaging* in addition to or different from those required under [FIFRA]." *Id.* §136v(a)-(b) (emphasis added). Congress thus sought to ensure manufacturers would not have to comply with "50 different labeling regimes." *Bates*, 544 U.S. at 452.

B. Glyphosate's Regulatory History

Glyphosate, Roundup's active ingredient, is one of the "most commonly used herbicide[s] around the world," having been approved for use by over 100 countries due to its "low toxicity" on humans and the environment. 6 AA7257. EPA has registered pesticides containing glyphosate since 1974. App.4a. In doing so, the agency has repeatedly evaluated whether glyphosate is carcinogenic. *See* EPA, *Revised Glyphosate Issue Paper* 12 (Dec. 12, 2017), http://tinyurl.com/eparevdglyphosate. For example, in response to a 1983 study raising concerns about potential carcinogenicity, EPA re-evaluated glyphosate's effects on human

health. App.5a. EPA considered numerous studies in rodents, none of which showed "convincing evidence" that glyphosate was carcinogenic. 9 AA10136. EPA therefore "classified glyphosate as a Group E carcinogen"—signifying "evidence of non-carcinogenicity in humans." 9 AA10121; *see also* App.5a. EPA has repeatedly reaffirmed that classification, concluding in a 2004 Final Rule, for instance, that "[g]lyphosate has no carcinogenic potential." 69 Fed. Reg. 65,081, 65,086 (Nov. 10, 2004); *accord* 62 Fed. Reg. 17,723, 17,728 (Apr. 11, 1997) ("Data indicate … evidence of noncarcinogenicity for studies in humans."). Regulators worldwide have similarly found that glyphosate does not cause cancer in humans. App.7a; 9 AA9924-9925, 10092-10102, 10213-10214; 13 RT1927:1-1928:3.

Against this global consensus, a working group at IARC classified glyphosate in 2015 as "probably carcinogenic to humans." App.6a. IARC's classification is merely a "hazard assessment," 14 RT2214:6, the "first step" in a public-health assessment designed to "identify cancer hazards even when risks are very low at current exposure levels," 9 AA10234-10235. IARC did not determine that glyphosate poses a risk of cancer to humans at real-world exposure levels. 9 AA10231.

Following IARC's classification, EPA conducted another "systematic review" of the scientific literature on glyphosate, including all studies IARC considered. *See Revised Glyphosate Issue Paper* 13, 144. At the end of that review, EPA concluded again that glyphosate is "not likely to be carcinogenic to humans." *Id.* at 144. EPA reaffirmed that determination yet again in 2020 when, in connection with its formal glyphosate-registration review, it "thoroughly assessed risks to humans from exposure to glyphosate from all registered uses and all routes of exposure and did not

identify any risks of concern," including risks of "cancer effects." EPA, *Glyphosate: Interim Registration Review Decision* 9 (Jan. 2020), https://tinyurl.com/5b7c8awa. EPA again authorized labeling for glyphosate without any cancer warning. *See id.* at 23-27.

EPA also confirmed its rejection of IARC's findings in a 2019 letter informing glyphosate registrants that it would not approve modifying the labels of glyphosate-based products to include a cancer warning. *See* App.161a-163a. "Given EPA's determination that glyphosate is 'not likely to be carcinogenic to humans,'" the agency stated, EPA considers a warning that glyphosate is carcinogenic "to constitute a false and misleading statement" that violates FIFRA's prohibition against misbranding. App.162a (quotation marks omitted). The letter was consistent with the fact that EPA has approved 44 versions of Roundup's label without a cancer warning. U.S. *Hardeman* Br. 26.

EPA has maintained its conclusion that glyphosate is not carcinogenic to this day. Last spring, the agency explained to the Ninth Circuit that "glyphosate is not likely to be a human carcinogen and poses no human-health risks of concern," stressing that "the record underlying these conclusions is robust, reflecting more than a decade of analysis and thorough review of the scientific literature." EPA Br. 1, *NRDC* v. *EPA*, Nos. 20-70787, 20-70801 (9th Cir. May 18, 2021).[4]

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[4] Because glyphosate is Roundup's principal ingredient, this petition treats "Roundup" and "glyphosate" as synonymous. Although the Court of Appeal noted that "[g]lyphosate is not the only ingredient in Roundup," App.8a, neither the court's preemption analysis nor its punitive-damages analysis turned on the presence of non-glyphosate ingredients in Roundup. Moreover, because EPA has registered over 500 glyphosate products, "the agency has

C. Proceedings Below

1. Respondents used Roundup on their residential properties for roughly three decades, starting in 1982. App.10a. In 2011, Mr. Pilliod was diagnosed with non-Hodgkin's lymphoma, a form of cancer. App.9a. Mrs. Pilliod was diagnosed with non-Hodgkin's lymphoma in 2015. App.9a-10a.

Respondents sued Monsanto in June 2017, alleging that their exposure to Roundup caused them each to develop non-Hodgkin's lymphoma. App. 13a-14a. Their complaint raised claims of design defect and failure to warn. App.14a. Respondents pleaded (and ultimately tried) their design-defect claim solely on the basis of a "consumer expectations" theory. *See id.* Under this California-law doctrine, respondents' "claims were based on Monsanto's labeling, marketing, and promotion of Roundup." *Id.*

Monsanto moved for summary judgment on the ground that respondents' claims were both expressly and implicitly preempted by FIFRA. App.111a. The trial court denied the motion, summarily rejecting the express-preemption defense by "adopt[ing]" the reasoning of two trial courts in similar Roundup cases. *Id.* And it rejected implied preemption both "as a matter of law," because "FIFRA allows states to regulate or ban

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assessed new inert ingredients at multiple points over the years for different formulations of glyphosate" and "incorporate[s] into [its] risk assessment[s]" "[a]ll studies of adequate scientific caliber" on different formulations containing glyphosate. 6 AA6501. In other words, EPA's evaluation of glyphosate-based products has encompassed both glyphosate and "any inert ingredients." EPA, *Response from the Pesticide Re-evaluation Division to Comments on the Glyphosate Proposed Interim Decision* 6 (Jan. 16, 2020), https://tinyurl.com/426uuejz.

pesticides that have been federally approved," and due to the existence of "triable issues of material fact" as to whether EPA would bar Monsanto from adding a cancer warning to Roundup's label. App.112a.

After trial, a jury returned a verdict in respondents' favor. App.22a. Mrs. Pilliod was awarded approximately $37 million in compensatory damages (approximately $34 million of which was for non-economic loss) and $1 billion in punitive damages. *Id.* Mr. Pilliod was awarded over $17 million in compensatory damages (all but $47,000 of which was for non-economic loss) and $1 billion in punitive damages. *Id.*[5]

After trial, Monsanto moved for judgment notwithstanding the verdict or a new trial. App.22a. Among other arguments, Monsanto renewed its preemption defense, which the trial court denied again. App.119a-120a. Monsanto also argued that the damages awards were excessive. App.22a. The trial court agreed and granted Monsanto a new trial unless each respondent accepted a reduced award—roughly $56 million for Mrs. Pilliod, including roughly $45 million in punitive damages, and roughly $31 million for Mr. Pilliod, including roughly $24 million in punitive damages. App.141a-142a. On punitive damages, the court concluded that Monsanto's conduct was "reprehensible" but that "the constitutionally permissible punitive damages" awards for each respondent was an amount equal to "four times [their] … combined … compensatory damages." App.141a. Respondents accepted the reduced awards. App.4a.

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[5] The non-economic damages compensated for emotional distress, pain, and suffering as well as considerations like "impaired enjoyment of life." App.127a-130a.

2. The Court of Appeal affirmed. App.4a.

a. The court first held that FIFRA neither expressly nor implicitly preempts respondents' claims. App.27a-31a.

As to express preemption, the panel "assum[ed] that [respondents'] claims … are entirely based on labeling and packaging requirements." It nevertheless "conclude[d] that there is no express preemption here … because Monsanto identifies no state-law requirements that are in addition to or different from the misbranding requirements imposed by FIFRA." App.27a. The court reached this conclusion after "[c]onsider[ing] the elements of [respondents'] state law claims" and comparing them to FIFRA's definition of a "misbranded" pesticide. App.27a-28a (citing *Hardeman* v. *Monsanto*, 997 F.3d 941, 955 (9th Cir. 2021), *pet. for cert. filed*, No. 21-241 (Aug. 16, 2021)). The court acknowledged that EPA had repeatedly approved Roundup's labeling but held that EPA's actions were "not a defense to a claim of misbranding." App.28a (citing 7 U.S.C. §136a(f)(2)).

The Court of Appeal also rejected Monsanto's implied-preemption arguments. The court was "not persuaded that the doctrine [of implied preemption] can be reconciled with FIFRA, which confirms that states are authorized to regulate the sale and use of pesticides and authorizes states to ban the sale of a pesticide that it finds unsafe." App.30a. The panel distinguished the authorities Monsanto cited on the ground that they involved the Medical Device Amendments to the Food, Drug, and Cosmetics Act, a statute that the court said "differ[ed] from [FIFRA] in important respects where preemption provisions are concerned." *Id.* (citing *Hardeman*, 997 F.3d at 958-959).

b. Over a dissent, the Court of Appeal affirmed the trial court's reduced punitive-damages award, App.82a.

The Court of Appeal acknowledged that respondents' compensatory-damages awards were "undoubtedly substantial," but it held that punitive damages quadruple those awards were nevertheless constitutional. App.79a. That was so, the court reasoned, because the "reduced compensatory damages … did *not* include a punitive component" and because "reprehensible conduct remains to be punished and deterred." App.80a, 82a.

Justice Richman dissented. He viewed "Monsanto's reprehensibility [a]s at the lower end," App.89a. Given that, and the fact that "Monsanto has already been met with enormous punitive damages awards" in other cases (including *Hardeman*), he would have held that a 1:1 ratio of punitive damages to compensatory damages represented the "outermost limit" of constitutionality. App.89a-90a.

The Court of Appeal unanimously rejected respondents' argument that the trial court erred in reducing their punitive damages award. App.79a.

3. Over Justice Richman's dissent, the Court of Appeal denied Monsanto's rehearing petition. App.143a. The California Supreme Court denied Monsanto's subsequent petition for review in a summary order. App.1a.

REASONS FOR GRANTING THE PETITION

I. THE COURT OF APPEAL'S PREEMPTION HOLDING WARRANTS REVIEW

A. Express Preemption

All of respondents' claims rest on the theory that Monsanto violated a California duty to warn consumers that glyphosate is a potential carcinogen. *See* App.27a. But EPA—exercising authority delegated under FIFRA—has repeatedly concluded that glyphosate poses no cancer risk in humans and therefore warrants no cancer warning. The California duty thus imposes a requirement "'in addition to or different from'" what EPA requires in administering FIFRA. *Bates*, 544 U.S. at 439 (quoting 7 U.S.C. §136v(b)). It is accordingly preempted. *Id.* at 453. The Court of Appeal's contrary decision merits review not only because it conflicts with *Bates* and other decisions of this Court, but also because it creates uncertainty regarding how to apply this Court's preemption precedent more broadly. *See Merck Sharp & Dohme Corp.* v. *Albrecht*, 139 S.Ct. 1668, 1676 (2019) (certiorari granted to resolve "uncertainties" regarding "the application of [implied preemption under] *Wyeth*" v. *Levine*, 555 U.S. 555, 571 (2009)).

1. The decision below conflicts with *Bates*

a. *Bates* held that a state-law claim is expressly preempted by 7 U.S.C. §136v(b) if the state law on which the claim rests (1) imposes a "requirement for labeling or packaging" that is (2) "in addition to or different from" a requirement under FIFRA. 544 U.S. at 444. The Court of Appeal's analysis of preemption here expressly "assum[ed]" that respondent's claims fall

under the first of these prongs. App.27a. Those claims also fall under the second.

Pursuant to its authority under FIFRA, *see* 7 U.S.C. §136a(c), and based on its repeated conclusion that glyphosate is not carcinogenic, *see supra* pp.7-9, EPA has for decades registered Roundup for sale without a cancer warning. And in 2020, EPA reiterated—after a notice-and-comment process that "thoroughly assess[ed] risks to humans from exposure to glyphosate"—that glyphosate presents no "risks of concern" and requires no cancer warning. *Interim Registration Review Decision* 9. Indeed, EPA has concluded that a cancer warning like the one respondents sought would be "false and misleading," making the product "misbranded pursuant to" 7 U.S.C. §136j(a)(1)(E). App.162a.

Bates compels the conclusion that any divergent state-law labeling requirement—including the one imposed here, mandating a cancer warning EPA has rejected—is expressly preempted. In explaining the contours of express FIFRA preemption, *Bates* "emphasize[d] that a state-law labeling requirement must *in fact* be equivalent to a requirement under FIFRA in order to survive pre-emption." 544 U.S. at 453 (emphasis added). In other words, "nominal[] equivalen[ce]" is not enough. *Id.* at 454. Only state-law claims that truly parallel a federal requirement survive—a category *Bates* concluded might encompass challenges to warnings about the *effectiveness* of a product, because EPA had not taken a position on efficacy. *Id.* at 440, 453-454. *Bates* was clear, however, that where EPA determines that a pesticide should be accompanied by one health warning (such as "CAUTION"), and a jury concludes under state law that the label should include a more aggressive one (such as "DANGER"), state law is

preempted. *Id.* at 453. That is the situation here: California would require a cancer warning on Roundup's labeling that EPA has determined is not appropriate.

The decision below likewise departs from *Riegel* v. *Medtronic*, 552 U.S. 312 (2008). *Riegel* addressed whether state-law claims regarding a medical device's design and labeling were preempted under the Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act (FDCA). *Id.* at 320-322. Using language similar to FIFRA, the MDA preempts "any requirement which is different from, or in addition to, any requirement applicable under this chapter to the device." 21 U.S.C. §360k(a)(1). Although the MDA, like FIFRA, generally requires warnings necessary to protect health, *see id.* §352(f), *Riegel* held the state-law claims there preempted to the extent they imposed specific requirements "different from or in addition to" those imposed through the Food and Drug Administration's (FDA) pre-market approval process. 552 U.S. at 323, 330. As the Court explained, "FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." *Id.* at 323.

Riegel's holding and reasoning are fully applicable here. For starters, *Bates* recognized the relevance of FDCA precedent in interpreting FIFRA, finding "strong support" for its reading of §136v(b) in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), a decision that interpreted the same provision at issue in *Riegel*. *See Bates*, 544 U.S. at 447; *see also Gomez-Perez* v. *Potter*, 553 U.S. 474, 479 (2008) (when analyzing the text of a statute, this Court is "guided by [its] prior decisions interpreting similar language in" other statutes). Moreover, this case presents the same basic situation as *Riegel*, i.e., a federal agency determining the appropriate point along a possible spectrum. When EPA

registers a product and approves the labeling, it determines that *that* labeling, not labeling more (or less) aggressive, provides appropriate warning. That is why manufacturers cannot substantively change a registered pesticide's labeling unilaterally. *See supra* p.7.

b. The Court of Appeal's error flowed primarily from it assessing FIFRA's requirements at too high a level of generality. Specifically, the court deemed FIFRA and California law "parallel" because "the elements of [respondents'] state law claims" did not include any elements "that are different from or in addition to the requirements of FIFRA." App.27a-28a (citing *Hardeman*, 997 F.3d at 955). This conclusion, the court stated, followed from the fact that California law requires warning of a "known or knowable" risk, while FIFRA requires a warning when "necessary" and "adequate" to protect public health. *Id.*

Bates forecloses this reasoning—which would both render FIFRA's preemption provision nearly meaningless and undermine the uniformity in pesticide labeling Congress sought to ensure. As this Court explained, the fact that both FIFRA and state law require a generic warning about risks is not enough to avoid preemption; rather, preemption turns on whether state law requires *specific* warnings that EPA, in administering FIFRA, does not. *See* 544 U.S. at 453. The crucial question is whether the labeling requirements that a State applies to a particular pesticide—including those "prescribing the … wording of warnings" (like "DANGER")—are different from what EPA requires for that same pesticide (like "CAUTION"). *Id.* at 452.

Even though *Bates*'s CAUTION/DANGER example featured prominently in Monsanto's briefing below, the Court of Appeal ignored it. Instead, the court held

that EPA's authoritative determination about the carcinogenicity of glyphosate was irrelevant to preemption in light of 7 U.S.C. §136a(f)(2). App.28a. But that provision merely states that while "registration" of a pesticide under FIFRA is "prima facie evidence" that a pesticide's labeling "compl[ies] with the registration provisions of the subchapter," registration is not "a defense for the commission of any offense *under [FIFRA]*." 7 U.S.C. §136a(f)(2) (emphasis added). In other words, it "stands for the unremarkable proposition that a registration is not a defense against an allegation that a product violates the terms of that registration." *Reckitt Benckiser, Inc.* v. *Jackson*, 762 F.Supp.2d 34, 45 (D.D.C. 2011). Respondents' claims do not arise "under" FIFRA; they arise under California tort law. Section 136a(f)(2) thus has "no bearing on" whether FIFRA preempts those claims. *MacDonald* v. *Monsanto Co.*, 27 F.3d 1021, 1025 n.4 (5th Cir. 1994).

As this last quotation demonstrates, the Court of Appeal's interpretation of §136a(f)(2) is not just wrong, it also splits from *MacDonald*, deepening an existing division of authorities, *see Hardeman*, 997 F.3d at 956-957 & n.6 (relying on §136a(f)(2) to reject a preemption defense). The court's ruling, moreover, means that an EPA determination that a warning label is unnecessary (or, as here, false and misleading) would never be preemptive. The result would be the very proliferation of divergent state and federal labeling requirements Congress sought to avoid in delegating pesticide regulation to an expert federal agency. *See supra* p.7.

Finally, the Court of Appeal invoked *Bates*'s observation that "FIFRA contemplates that pesticide labels will evolve over time," with "tort suits [potentially] serv[ing] as a catalyst in this process," 544 U.S. at 451, *quoted in* App.28a. This notion of evolving pesticide

labeling might make sense in the *efficacy* context, where EPA has waived its own evaluation of efficacy claims, *see supra* p.15. But that notion makes no sense here, where EPA has repeatedly considered—and rejected—the very warning respondents seek, *see supra* pp.7-9. Indeed, under the Court of Appeal's reasoning, a jury could hold a manufacturer liable for failing to include a "DANGER" warning on its label even when EPA requires a "CAUTION" warning. As *Bates* makes clear, however, FIFRA would preempt such a claim. *Supra* pp.15-16.

2. The decision below deepens uncertainty over how to apply similarly worded express-preemption provisions

The Court of Appeal's construction of FIFRA's key preemptive language—"in addition to or different from," 7 U.S.C. §136v(b)—conflicts with this Court's and multiple circuits' interpretation of virtually identical preemption provisions in other federal laws.

Similar language appears in a wide range of statutes, including those regulating medical devices, meat, poultry, and motor vehicles. *See* 21 U.S.C. §360k(a) (MDA); *id.* §467e (Poultry Products Inspection Act); *id.* §678 (Federal Meat Inspection Act); 49 U.S.C. §30103(b) (National Traffic and Motor Vehicle Safety Act). And this Court has noted that such preemptive language "sweeps widely." *National Meat Association* v. *Harris*, 565 U.S. 452, 459 (2012). But under the Court of Appeal's restrictive reading, state requirements are preempted only if inconsistent with federal requirements at a high level of generality. This reading creates divergence among appellate courts, threatening considerable confusion because courts routinely look to decisions interpreting similar statutory language when

determining the scope of express preemption provisions. *See supra* p.16; *McMullen* v. *Medtronic, Inc.*, 421 F.3d 482, 488-489 (7th Cir. 2005) (relying on *Bates* in applying the MDA's preemption provision).

In particular, lower courts have diverged regarding whether, to survive preemption, a state-law claim must merely be consistent with federal law at the highest level of generality, or instead must be consistent with how federal law is *actually applied* by the responsible agency. The Court of Appeal here—and the Ninth Circuit in *Hardeman*—embraced the first approach, deeming it sufficient to avoid preemption that both state and federal law generally require warnings about pesticides' health risks. App.27a-28a; *see also Hardeman*, 997 F.3d at 955. But other courts applying the MDA's virtually identical preemption provision have rejected that approach, holding that a state-law claim must establish a violation of an existing, specific *federal* requirement to be a parallel claim that survives preemption. *See Brooks* v. *Mentor Worldwide LLC*, 985 F.3d 1272, 1279-1280 & n.2 (10th Cir. 2021); *Shuker* v. *Smith & Nephew PLC*, 885 F.3d 760, 776 (3d Cir. 2018); *Bass* v. *Stryker Corp.*, 669 F.3d 501, 509-510 (5th Cir. 2012); *Wolicki-Gables* v. *Arros International, Inc.*, 634 F.3d 1296, 1301-1302 (11th Cir. 2011). This inconsistency reflects a "struggle[]" among appellate courts "when it comes to trying to decide whether particular state claims do or don't 'parallel' putative federal counterparts.'" *Caplinger* v. *Medtronic, Inc.*, 784 F.3d 1335, 1338 (10th Cir. 2015) (Gorsuch, J.); *see also In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, 623 F.3d 1200, 1204 (8th Cir. 2010) ("The contours of the parallel claim exception … are as-yet ill-defined."). This Court's review is needed to ensure consistent interpretation of language that Congress has

adopted to effectuate preemption in numerous federal statutes. *See Rowe* v. *New Hampshire Motor Transport Association*, 552 U.S. 364, 369-370 (2008) ("similar [preemption] language" should be applied consistently across federal statutes).

B. Conflict Preemption

The decision below is inconsistent with this Court's holding that state law is implicitly preempted to the extent it "conflict[s] with federal law." *Mutual Pharmaceutical Co.* v. *Bartlett*, 570 U.S. 472, 479-480 (2013). Such a conflict exists where it is "impossible for a private party to comply with both state and federal requirements." *Id.* at 480. In the context of labeling requirements, that impossibility arises (1) where the warning could not have been added without prior federal approval, *PLIVA, Inc.* v. *Mensing*, 564 U.S. 604, 617-619 (2011), or (2) where there is "clear evidence" that the relevant federal agency would not approve a warning required under state law, *Wyeth*, 555 U.S. at 571; *see also Merck*, 139 S.Ct. at 1678-1679. Both situations are present here.

First, Monsanto could not have added a cancer warning to Roundup's label without prior EPA approval. *See supra* p.7. In *PLIVA*, this Court held that a state-law failure-to-warn claim was preempted where federal law barred a manufacturer from adopting, without prior federal approval, a labeling change that state law requires. 564 U.S. at 617-618. It is irrelevant, *PLIVA* explained, that the manufacturer might have persuaded the relevant agency to approve that change after the fact. *Id.* at 619. Because "[t]he question for 'impossibility' [preemption] is whether the private party could *independently* do … what state law requires," state law is preempted wherever the manufacturer's

ability to comply with state law depends upon prior agency approval. *Id.* at 620-621 (emphasis added).

Under *PLIVA*, respondents' claims here are preempted. Selling a pesticide with labeling that makes "any claims" "substantially differ[ent]" from the EPA-approved labeling is unlawful. 7 U.S.C. §136j(a)(1)(B), (2)(G); *see also id.* §136a(c). And pesticide manufacturers may not change substantive aspects of their products' labeling without EPA's prior approval. *See* 40 C.F.R. §§152.44, 152.46; *see also supra* p.7. To change labeling, a manufacturer must submit an amended registration application that includes all data relevant to the requested change. *See* 40 C.F.R. §§152.44(a), 152.50. "[T]he application must be approved by [EPA] before the product, as modified, may legally be distributed or sold." *Id.* §152.44(a). Like the manufacturer in *PLIVA*, therefore, Monsanto could not have "independently do[ne] … what state law require[d]," 564 U.S. at 620.

Second, respondents' claims are implicitly preempted for the independent reason that EPA would reject a cancer warning for Roundup's labeling. *See Wyeth*, 555 U.S. at 571; *Merck*, 139 S.Ct. at 1678-1679.

For decades, EPA has (based on repeated reviews of the scientific literature) consistently approved glyphosate, and Roundup's labeling, *without* a cancer warning. *See supra* pp.7-9. Even after the IARC working group's "hazard identification," EPA—following a "systematic review," including all the studies IARC considered—confirmed the conclusion it has reached for years: Glyphosate is "not likely to be carcinogenic to humans." *Revised Glyphosate Issue Paper* 144; *see also supra* pp.8-9. Any remaining doubt about whether EPA would approve a cancer warning for

glyphosate dissipated in 2019, when EPA informed glyphosate registrants that, "[g]iven EPA's determination that glyphosate is 'not likely to be carcinogenic to humans,'" EPA considers any warning that glyphosate *is* carcinogenic "to constitute a false and misleading statement" that violates FIFRA's prohibition against "misbranded" substances. App.162a.

The Court of Appeal disregarded all this because it was "not persuaded" that the impossibility doctrine applies to FIFRA at all. App.30a. In particular, the court noted that *PLIVA*, *Wyeth*, and *Merck* all involved the FDCA rather than FIFRA. App.29a-30a. And FIFRA differs from FDCA, the court reasoned, in that FIFRA contains an express preemption clause, authorizes "states … to regulate the sale and use of pesticides[,] and authorizes the states to ban the sale of a pesticide that it finds unsafe." App.30a.

None of these distinctions holds water. As an initial matter, this Court has held that an express preemption clause, "by itself, does not foreclose (through negative implication) 'any possibility of implied … preemption.'" *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 869 (2000). The ability of states to regulate pesticides, moreover, is necessarily cabined by both the express preemption provision in §136v(b) *and* the Supremacy Clause's limitations, including the doctrine of implied preemption. As this Court has explained, "the existence of a conflict cognizable under the Supremacy Clause does not depend on express congressional recognition that federal and state law may conflict." *Crosby* v. *National Foreign Trade Council*, 530 U.S. 363, 388 (2000). Finally, states' authority to "regulate the sale or use of" a pesticide, 7 U.S.C. §136v(a), is irrelevant to states' authority to "impose … any requirements *for labeling or packaging*," *id.*

§136v(b) (emphasis added). It is the latter authority, which FIFRA preempts, that is at issue here.

C. The Scope Of FIFRA Preemption Is An Issue Of National Importance

FIFRA is a "comprehensive regulatory statute" that grants EPA significant power to ensure uniformity in pesticide labeling requirements. *Ruckelshaus* v. *Monsanto Co.*, 467 U.S. 986, 991-992 (1984). The Court of Appeal's decision undermines that uniformity.

Indeed, the decision below is antithetical to both FIFRA's uniformity goal and Congress's choice to empower EPA to enforce it. The decision permits precisely what *Bates* feared: "50 different labeling regimes prescribing the … wording of warnings," creating "significant inefficiencies for manufacturers," 544 U.S. at 452. Other courts have similarly observed that failure to apply preemption principles properly can lead to "an anarchic patchwork of federal and state regulatory programs." *Engine Manufacturers Association* v. *EPA*, 88 F.3d 1075, 1079 (D.C. Cir. 1996). As one court put it, "applying the conflicting tort principles of 50 different states to … interstate and international" agreements "would make a mess of things." *United Airlines, Inc.* v. *Mesa Airlines, Inc.*, 219 F.3d 605, 611 (7th Cir. 2000); *accord Moss* v. *Parks Corp.*, 985 F.2d 736, 739 (4th Cir. 1993) (preemption alleviates "the impracticality of having the states [require] potentially fifty different labels").

Under the regime the Court of Appeal endorsed, each State could—based on the tiniest sliver of scientific support—mandate warnings carefully considered and rejected by EPA simply because they were generally consistent with a duty to warn of possible health

risks. A single study, even one found unreliable by EPA, could thus spur countless divergent labeling requirements. And even if there was agreement that some warning was necessary, there might not be a single warning a company could adopt to fulfill its state-law obligations. For example, a California district court has held that several potential warnings the State proposed for glyphosate are inaccurate. *See National Association of Wheat Growers* v. *Becerra*, 468 F.Supp.3d 1247, 1259 (E.D. Cal. 2020). Under the decision below, these difficulties could be multiplied by litigation brought in different States, each potentially requiring a different warning.[6]

Differences in labeling also risk consumer confusion. For example, following the Court of Appeal's decision, a Nevadan who visits California may be misled to believe that a pesticide sold in California is more dangerous than the formulation sold in Nevada (or vice versa). And if Nevada itself requires manufacturers to add a glyphosate warning, even a slight difference in wording (for example "CAUTION: this product contains glyphosate" as opposed to "WARNING: Cancer") could cause consumer confusion about the product's safety. Put simply, if the decision below is correct, "[m]anufacturers might have to print 50 different labels, driving consumers who buy [pesticides] in more than one state crazy." *Turek* v. *General Mills, Inc.*, 662 F.3d 423, 426 (7th Cir. 2011). Few things are more likely to cause doubt on the reliability of warnings than

[6] Nor is there any guarantee that such diverging verdicts would only appear across state lines. In fact, since the decision below, California state-court juries ruled in *Monsanto's* favor in two cases raising materially identical claims to those here. Feeley, *Bayer Scores Another Roundup Trial Victory in California*, Bloomberg (Dec. 9, 2021), https://tinyurl.com/3r2sjyz8.

state-by-state variances reflecting the vagaries of juries' divergent resolution of duty-to-warn claims. Avoiding all this confusion and disruption warrants the Court's review.

D. Alternatively, This Petition Should Be Held Pending Resolution of *Hardeman*

If review is not granted on question 1, then the petition should be held pending disposition of the *Hardeman* petition. That case—in which the Court has invited the Solicitor General to file a brief expressing the views of the United States—presents the same first question as the petition here. Both cases also involve claims against Monsanto under California law for failing to include a cancer warning on Roundup's label. *Hardeman*, 997 F.3d at 952; *supra* p.10. As noted, moreover, the Court of Appeal's decision here relied heavily on the Ninth Circuit's decision in *Hardeman*. *See supra* p.12; App.28a, 30a.

II. THE COURT OF APPEAL'S PUNITIVE-DAMAGES HOLDING WARRANTS REVIEW

Due process forbids levying "grossly excessive" or "arbitrary punishment[] on a tortfeasor." *State Farm*, 538 U.S. at 416. And because "[p]unitive damages pose an acute danger of arbitrary deprivation of property," this Court has limited them to cases where the defendant's conduct is "reprehensible" and "the measure of punishment is both reasonable and proportionate to the amount of harm to the plaintiff and to the general damages recovered." *Id.* at 417, 419, 426 (brackets in original). In the ordinary course, the Court has explained, when "compensatory damages are substantial," a punitive-damages award "equal to compensatory damages"

represents "the outermost limit" of what due process allows. *Id.* at 425.

Here, the Court of Appeal acknowledged that respondents' compensatory damages were "undoubtedly substantial," App.79a, and it did not dispute the dissent's conclusion that "reprehensibility is at the lower end," App.89a. The court nevertheless upheld punitive-damages awards of $24.5 million and $45 million, each of which was roughly quadruple the respective compensatory award. In affirming these 4:1 ratios, the decision below deviated from *State Farm*'s guidance and deepened an entrenched disagreement among appellate courts over the maximum permissible ratio of punitive damages to compensatory damages.

A. The Court of Appeal Deepened A Conflict Among Appellate Courts By Affirming A 4:1 Ratio Where Compensatory Damages Were High And Reprehensibility Was Not

Since *State Farm*, federal and state appellate courts have divided over whether a punitive-damages award may exceed a compensatory-damages award when the latter is substantial and the defendant's conduct is not especially blameworthy.

The majority of courts facing those circumstances have followed *State Farm*'s guidance that punitive damages should be limited to a 1:1 ratio. For example, the Seventh Circuit has instructed that a "substantial" compensatory "award merits a ratio closer to 1:1." *Saccameno* v. *United States Bank National Association*, 943 F.3d 1071, 1090 (7th Cir. 2019). The Tenth Circuit has similarly vacated a punitive-damages award as excessive on the ground that "a ratio of 1:1 may be the most the Constitution will permit" when the defendant

did not (1) "intend[]" to cause damage or (2) "engage[] in particularly egregious behavior." *Lompe* v. *Sunridge Partners, LLC*, 818 F.3d 1041, 1069, 1073 (10th Cir. 2016). The Second, Sixth, and Eighth Circuits, as well as the South Dakota Supreme Court, have taken similar approaches. *See Boerner* v. *Brown & Williamson Tobacco Co.*, 394 F.3d 594, 603 (8th Cir. 2005); *Thomas* v. *iStar Financial, Inc.*, 652 F.3d 141, 149 (2d Cir. 2011); *Morgan* v. *New York Life Insurance Co.*, 559 F.3d 425, 443 (6th Cir. 2009); *Roth* v. *Farner-Bocken Co.*, 667 N.W.2d 651, 671 (S.D. 2003).

Here, in contrast, the Court of Appeal held that a 1:1 ratio could be exceeded in a case with substantial compensatory damages, without finding particularly reprehensible conduct. That conclusion aligns with the Ninth Circuit's approach, which treats quadruple punitive damages "as a good proxy for the limits of constitutionality" if the defendant's "behavior is not particularly egregious." *Planned Parenthood of Columbia/Willamette Inc.* v. *American Coalition of Life Activists*, 422 F.3d 949, 962 (9th Cir. 2005). The decision below also aligns with decisions from the Eleventh Circuit and the Montana Supreme Court. *See, e.g.*, *Cote* v. *Philip Morris USA, Inc.*, 985 F.3d 840, 849 (11th Cir. 2021) (describing *State Farm*'s 1:1 ratio language as "dicta"); *Seltzer* v. *Morton*, 154 P.3d 561, 614-615 (Mont. 2007) (approving a 9:1 ratio).

This division over the constitutional limits on punitive-damages awards is entrenched and unlikely to resolve itself. And although this Court has denied other petitions raising questions about the appropriate punitive-damages multiplier under *State Farm*, those cases involved procedural complications not present here. For example, in *Johnson & Johnson* v. *Ingham*, 141 S.Ct. 2716 (2021), the defendants were jointly and

severally liable for punitive damages. And *TransUnion LLC* v. *Ramirez*, 141 S.Ct. 972 (2020), involved statutory rather than compensatory damages.

B. The Decision Below Is Wrong

1. The Court of Appeal's punitive-damages holding contravenes *State Farm*'s guidance that, in cases like this, a 1:1 ratio is likely the maximum the Constitution allows. 538 U.S. at 425. The 1:1 ratio is an important limitation because punitive-damages awards must be "both reasonable and proportionate" to the harm suffered by the plaintiff and to the "general damages recovered." *Id.* at 426. Where a plaintiff has received a significant sum in compensatory damages, an inflated punitive award looks less like "deterrence and retribution" and more like the "irrational and arbitrary deprivation" of property. *Id.* at 416, 429. Moreover, where compensatory damages account largely for emotional distress—as here, *see supra* n.5—punitive awards become "duplicat[ive]." *State Farm*, 538 U.S. at 426.

The Court of Appeal's dismissal of *State Farm* as irrelevant, App.80a, was unwarranted. To begin with, the majority, the dissent, and the trial court all recognized that the compensatory awards were substantial. App.80a; App. 84a; App.138a. Moreover, the Court of Appeal majority did not dispute that (1) "there was consensus among regulatory agencies that Roundup did not cause a risk to humans at real world exposure levels"; (2) "[t]here was no evidence that Monsanto believed, let alone knew, that Roundup or glyphosate were carcinogenic"; and (3) there was "no evidence that Monsanto hid any scientific study from regulators or the scientific community," App.88a; *see also supra* pp.7-9. "Superimposed on all the above," the dissent noted,

"is the fact that Monsanto has already been met with enormous punitive damage awards … based fundamentally on the same general set of facts" and faces 'thousands of cases that loom in the future.'" App.89a. Under the circumstances, a 1:1 ratio was "the right result." App.90a.

More fundamentally, the Court of Appeal erred in upholding *any* punitive damages award. Because the purpose of punitive damages is to punish wrongdoers and deter similar misconduct in the future, "the most important indicium of the reasonableness of a punitive damages award is the degree of reprehensibility of the defendant's conduct." *BMW* v. *Gore*, 517 U.S. 559, 574-575 (1996). Accordingly, "the absence" of evidence of reprehensibility "renders any [punitive damages] award suspect." *State Farm*, 538 U.S. at 419.

Although it recited the factors *State Farm* enumerated as relevant to assessing reprehensibility, the Court of Appeal's application of those factors was flawed, because Monsanto's conduct was not reprehensible in any reasonable sense of the word. In particular, Monsanto's labeling of Roundup followed a world-wide regulatory evaluation of the scientific evidence and the resulting consensus that glyphosate is non-carcinogenic. *See supra* pp.8, 29. Punishing a company in this circumstance raises the same "fundamental due process concerns" present in other cases where this Court has expressed doubts about punitive damages: "risks of arbitrariness, uncertainty, and lack of notice," *Philip Morris USA* v. *Williams*, 549 U.S. 346, 354 (2007); *see also Landgraf* v. *USI Film Products*, 511 U.S. 244, 266, 281 (1994) ("[R]etroactive imposition of punitive damages would raise a serious constitutional question."). This Court should grant certiorari to

clarify the scope of this important due-process limit on the award of punitive damages.

CONCLUSION

The petition for a writ of certiorari should be granted or else held pending this Court's disposition of the petition in *Hardeman*.

Respectfully submitted.

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