No. 21-1272

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

BRIEF IN OPPOSITION FOR RESPONDENTS

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QUESTIONS PRESENTED

In *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005), this Court held that the Federal Insecticide, Fungicide, and Rodenticide Act preempts only state-law labeling requirements that are broader than the statute's misbranding standard. State-law claims "that require manufacturers to design reasonably safe products" are not preempted because they impose no labeling requirements. *Id.* at 444. The same is true of claims that target product marketing, because they do not "require[] that manufacturers label or package their products in any particular way." *Id.*

Respondents developed non-Hodgkin lymphoma after long exposure to petitioner Monsanto Company's weedkiller, Roundup. A jury found that Roundup caused respondents' cancer and held Monsanto liable in strict liability and negligence for designing a defective product and failing to warn of its danger in off-label marketing. Because Monsanto knew, but concealed, that Roundup was carcinogenic, the jury awarded punitive damages. Based on that reprehensible conduct, the California Court of Appeal held that reduced punitive damages of four times compensatory damages were within constitutional limits.

The questions presented are:

1. Whether the California Court of Appeal correctly applied *Bates* in holding respondents' failure-to-warn claims were not preempted when they were equivalent to the statute's misbranding standard.

2. Whether this Court should adopt a new constitutional rule limiting the ratio between compensatory and punitive damages to 1:1 when compensatory damages are substantial, no matter how reprehensible the defendant's conduct.

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INTRODUCTION

Monsanto has known for decades that its popular weedkiller, Roundup, can cause cancer. But the company has refused to make its product safer or to inform consumers in off-label marketing they should exercise caution when using it. Instead, Monsanto has attacked those who questioned Roundup's safety.

Respondents Alva and Alberta Pilliod are among Monsanto's victims. Unaware of the dangers, they used Roundup for decades before being diagnosed with non-Hodgkin lymphoma, a deadly blood cancer. The jury found that Roundup caused that cancer and that Monsanto's reprehensible conduct warranted significant punitive damages. A remarkably thorough appellate decision affirmed that judgment.

In this Court, Monsanto reprises its lead argument from *Monsanto Co. v. Hardeman*, No. 21-241 (pet. docketed Aug. 18, 2021), arguing the Pilliods' failure-to-warn claims impose labeling requirements preempted under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-136y, or FIFRA. This Court called for the views of the Solicitor General in *Hardeman* on December 13, 2021. On May 10, 2022, the Solicitor General recommended that this Court deny certiorari there because the court of appeals correctly rejected Monsanto's preemption arguments and created no split in authority in doing so. Monsanto's petition here is even less worthy of review: alternative bases exist to affirm the Pilliods' verdict whatever the answer to Monsanto's question presented. And the decision below tracks *Hardeman*, so it too is correct and presents no split. The Court should deny certiorari no matter its disposition of *Hardeman*.

This Court's review of Monsanto's preemption argument here would be purely advisory. *First*,

Monsanto's petition addresses only the Pilliods' failure-to-warn claims, but the Pilliods brought, and won, design-defect claims challenging Roundup's safety, not labeling. In *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005), the leading case on FIFRA preemption, this Court held it was "perfectly clear" that FIFRA does not preempt "claims for defective design" because they "require manufacturers to design reasonably safe products," not "label or package their products in any particular way." *Id.* at 444. *Second*, the Pilliods' failure-to-warn claims were not limited to Roundup's labeling. They also challenged off-label conduct like Monsanto's failure to warn of Roundup's dangers in advertisements the Pilliods saw and on which they relied. Nothing in FIFRA prevented those advertisements from warning consumers that Roundup may be carcinogenic or that they should wear protective gear when spraying the weedkiller. This Court's review of the labeling issue would not affect these alternative bases for affirmance, which Monsanto ignores in its petition.

Even if this Court views the labeling issues as central, there is no need for review because the decision below is correct and there is no split in authority. The California Court of Appeal – like every other appellate court to consider the issue – rightly concluded that neither express nor implied preemption bars failure-to-warn claims based on Roundup's labeling. The U.S. Environmental Protection Agency ("EPA") recently confirmed that FIFRA permits Monsanto to warn consumers that the leading international authority has concluded Roundup is carcinogenic, which makes this petition even less worthy of review.

Finally, Monsanto asks the Court to decree, as a matter of substantive due process, an arbitrary mathematical limit on state punitive damages that

would require courts and juries to ignore the company's reprehensible, decades-long wrongdoing. Yet the company cites no case that restricts punitive damages for comparably reprehensible conduct exposing unwitting consumers to deathly harm. Further review is unwarranted.

STATEMENT

A. Statutory and Regulatory Background

1. FIFRA regulates "the use, as well as the sale and labeling, of pesticides." *Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 437 (2005). As relevant here, the statute proscribes marketing "any pesticide which is . . . misbranded." 7 U.S.C. § 136j(a)(1)(E).[1] A pesticide is "misbranded" if its label contains a statement that is "false or misleading in any particular," § 136(q)(1)(A), or if its label omits adequate instructions for use, necessary warnings, or cautionary statements, § 136(q)(1)(F), (G).

If EPA determines a pesticide is misbranded, it may cancel the pesticide's registration, § 136d(b), issue "stop sale, use, or removal" orders, § 136k(a), and seize misbranded products, § 136k(b). Manufacturers that sell misbranded products face civil and criminal penalties. § 136*l*.

2. FIFRA requires pesticide manufacturers to register their products with EPA. § 136a(a). The agency will register a pesticide if it determines that (1) the product will not cause unreasonable harm to humans and the environment, § 136a(c)(5)(C), (D), and (2) the product's label is not misbranded, § 136a(c)(5)(B). EPA re-reviews a pesticide's registration, including its effects on human health, every fifteen years. § 136a(g)(1)(A).

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[1] Except where otherwise noted, citations to provisions of the U.S. Code are to Title 7.

FIFRA confirms that obtaining registration does not relieve the registrant of liability if the pesticide is misbranded. "In no event shall registration of an article be construed as a defense for the commission of any offense under [FIFRA]," including misbranding. § 136a(f)(2). Instead, registration is merely "prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of [FIFRA]." *Id.* Manufacturers with registered pesticides therefore "have a continuing obligation to adhere to FIFRA's labeling requirements." *Bates*, 544 U.S. at 438.

3. FIFRA "authorizes a relatively decentralized scheme that preserves a broad role for state regulation." *Bates*, 544 U.S. at 450. The statute's only limit on state authority is its "narrow" preemption provision, *id.* at 452, which "prohibits only state-law labeling and packaging requirements that are '*in addition to or different from*' the labeling and packaging requirements under FIFRA," *id.* at 447 (quoting § 136v(b)).

B. Factual Background[2]

1. The active ingredient in Roundup is glyphosate, an herbicide that kills plants at their roots. Roundup's label states, "Roundup formulas target an enzyme in plants, but not in people or pets." AA8879.

Monsanto has had EPA's approval to sell glyphosate-based herbicides since 1974. To get that approval, Monsanto submitted studies testing whether glyphosate caused cancer or cell mutations in animals.

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[2] This Court "view[s] the evidence in the light most favorable" to the jury's verdict. *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 213 (1993).

Tr.3516:15-3529:18. The company contracted Industrial Bio-Test Laboratories ("IBT"), a commercial laboratory, to conduct the studies. Tr.3519:4-22.

IBT's studies were invalid. The lab had created "fraudulent data in support of the registration of a bunch of pesticides," including glyphosate. Tr.3520:7-8. Monsanto and regulators learned about the fraud in 1976. Tr.3527:13-3530:22. But the company continued to sell Roundup. Tr.3529:15-18. At the time, EPA lacked authority to remove fraudulently approved pesticides from the market. AA8990; Tr.3532:18-23.

Seven years passed before there was "a valid mouse study assessing the carcinogenicity" of glyphosate. Tr.3530:3-16. That 1983 study showed that mice exposed to glyphosate had higher rates of kidney tumors and malignant lymphomas. Tr.1670:5-24, 2106:9-23. Based on that result, in 1985, an EPA panel classified glyphosate as a possible human carcinogen. AA8762. EPA requested that Monsanto repeat the mouse study with more mice, AA7200-7201, but the company never did, Tr.3560:6-3561:3.

2. In the 1990s, several published studies concluded that glyphosate and Roundup are genotoxic. AA8394-8397. Genotoxic substances damage genetic information in cells, causing mutations that may lead to cancer. Monsanto retained Dr. James Parry, an expert in genotoxicity, to review the studies. AA8499. He concluded that "[g]lyphosate is capable of producing genotoxicity both *in vivo* and *in vitro*," AA8398, and recommended the company conduct eight tests to learn more, AA8399, 8432-8434. Monsanto still has not conducted most of those tests. Tr.3587:14-3591:22.

After reading one of Dr. Parry's reports, Dr. William Heydens, Monsanto's Product Safety Assessment Strategy Lead, wrote to colleagues:

> We want to find/develop someone who is comfortable with the genetox profile of glyphosate/Roundup and who can be influential with regulators and Scientific Outreach operations when genetox issues arise. My read is that Parry is not currently such a person, and it would take quite some time and $$$/studies to get him there. We simply aren't going to do the studies Parry suggests. Mark, do you think Parry can become a strong advocate without doing this work[?] If not, we should ***seriously*** start looking for one or more other individuals to work with.

AA8387.[3]

Monsanto found another individual to work with. AA8499. In 2000, Dr. Gary Williams was listed as the lead author on an article that concluded Roundup was neither genotoxic nor carcinogenic. Tr.4939:13-4940:23. He did not write the article; Monsanto did. Before publication, Dr. Heydens commented that he "ha[d] sprouted several new gray hairs during the writing of this thing." AA8591. He later "[r]ecall[ed]" how the company "handled" the writing process: "[W]e ghost-write the Exposure Tox & Genetox sections" while outside experts like Dr. Williams "would just edit & sign their names." AA8314.

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[3] Monsanto did not provide Dr. Parry's reports to EPA. That failure to disclose itself violated FIFRA, Tr.3592:22-3594:8, which requires manufacturers to report "factual information regarding unreasonable adverse effects on the environment of [a] pesticide" to EPA on an ongoing basis, § 136d(a)(2); *see* 40 C.F.R. § 159.158(a).

3. Glyphosate is not the only ingredient in Roundup; the product also contains a surfactant. Tr.3124:8-3133:17. In the United States, the surfactant is polyoxyethylated tallow amine ("POEA"). Tr.3124:10-14, 3128:2-13.

POEA is meant to help Roundup penetrate the waxy surface of a leaf, but it has the same penetrative effect on human skin. Tr.3143:6-3147:9. Roundup enters the body through sweat glands, hair follicles, and cells. Once under the skin, Roundup reaches lymphatic vessels and then can circulate within the lymphatic system. Tr.3145:8-16.

POEA makes Roundup more genotoxic. One study showed that POEA and other contaminants made formulated Roundup ten times more genotoxic than glyphosate alone. AA8393. As a result, POEA is banned in Europe, Tr.3103:10-20, 3162:15-17, where Monsanto now sells Roundup with a less toxic surfactant, Tr.3250:21-3251:11. This prompted one Monsanto scientist to ask, "there are non-hazardous formulations so why sell a hazardous one?" AA8659.

Internally, Monsanto instructs employees handling Roundup to wear chemical-resistant gloves and clothing and a face shield. A8770. The company gives no similar instruction to residential users. Tr.3608:17-3609:22.

4. Monsanto never has tested whether Roundup causes cancer. In an internal email, Dr. Donna Farmer, a senior toxicologist at Monsanto, told her colleagues, "you cannot say Roundup is not a carcinogen. We have not done the necessary testing on the formulation to make that statement." AA6906.

Nor has EPA made any formal findings about Roundup's carcinogenicity. In 2017, as part of its re-registration review of glyphosate, EPA determined

that it could not reach "a conclusion regarding the association between glyphosate exposure and risk of [non-Hodgkin lymphoma]." EPA, *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* 68 (Dec. 12, 2017), http://tinyurl.com/eparevdglyphosate. The agency also noted that "farmers and other applicators apply formulations, not the active ingredient alone," *id.* at 137, and acknowledged a need for more research "to determine whether formulation components, such as surfactants, influence the toxicity of glyphosate formulations," *id.* at 144. In its 2019 Interim Glyphosate Review, EPA again acknowledged that it had not determined whether glyphosate "formulations," like Roundup, pose any risks to human health. *See* EPA, *Glyphosate: Proposed Interim Registration Review Decision* 11 (Apr. 2019) ("EPA, *Glyphosate*"), http://tinyurl.com/y6h2u8w6.

5. Monsanto learned in 2014 that the International Agency for Research on Cancer ("IARC") would evaluate whether glyphosate and glyphosate-based products like Roundup are carcinogenic. AA8562. IARC is "the worldwide authority on establishing whether an agent is a carcinogen." Tr.2455:13-15. Monsanto expected that IARC would classify its product as probably or possibly carcinogenic, AA8681, so it planned to "Orchestrate Outcry" with IARC's coming decision, AA8669.

After a year-long evaluation, IARC convened a "working group" of seventeen scientists in 2015. Tr.2117:17-23; AA6628-6629. The scientists reviewed studies of real-world exposure to glyphosate-based products in humans and experimental exposure to pure glyphosate in animals. These studies provided "limited" evidence of cancer in humans and "sufficient" evidence of cancer in experimental animals. AA6631; Tr.2153:16-22. The studies linked glypho-

sate exposure to non-Hodgkin lymphoma. Based on that link, the panel unanimously determined that glyphosate is "probably carcinogenic to humans." AA6628.[4]

In response, Monsanto ghostwrote articles attacking IARC's conclusions. AA8693-8694, 8698. This was not the first time the company had attacked independent researchers studying Roundup: Monsanto scientists long had joked about "playing Whack-a-Mole" with researchers who raised safety concerns. AA6689, 8305.

6. Alva and Alberta Pilliod began spraying Roundup in 1982. Tr.3695:16-3697:5, 3782:4-16. Over the next thirty years, the couple sprayed Roundup on approximately 1,500 days at four properties. Tr.3246:4-3249:12. Alva did 75% of the spraying; Alberta 25%. Tr.2765:20-2766:2. Neither wore protective gear. Tr.2766:17-19.

Alberta thought Roundup was "really safe to use." Tr.3726:7-17. In television commercials she saw, people sprayed Roundup in shorts with no gloves or other protective clothing on. Tr.3731:16-19. Based on those commercials, Alberta told Alva that Roundup "was like sugar water." Tr.3726:7-17.

Alberta also read Roundup's label before using the product. Tr.3725:9-10. The label did not warn her of the risk of cancer or that she should wear protective

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[4] *Amicus* Washington Legal Foundation ("WLF") describes IARC's conclusion as "an outlier" and alleges conflicts of interest in two of the seventeen panelists. WLF Br. 8, 9-11. But Monsanto presented evidence challenging IARC's conclusions and the panelists' interests at trial, the Pilliods rebutted that showing, and the jury returned a unanimous verdict for the Pilliods. Because this Court "view[s] the evidence in the light most favorable" to that verdict, *Brooke Grp.*, 509 U.S. at 213, WLF's arguments lack merit.

equipment while spraying. Tr.3725:11-23. Had Monsanto warned of a cancer risk, Alberta would not have used Roundup. Tr.3725:24-3726:2.

Alva testified that when he started using Roundup he also checked the label for precautions. Tr.3782:16-18. He saw no warnings about cancer or wearing protective gear. Tr.3782:19-23.

In 2011, Alva was diagnosed with diffuse large B-cell lymphoma, an aggressive form of non-Hodgkin lymphoma. Tr.3772:6-14. His cancer metastasized in his bones; tumors caused fractures and pain so severe even morphine could not help. Tr.3772:15-3774:2; AA7114-7118. After months of chemotherapy, Alva's cancer has not recurred. Tr.3808:6-3809:9. But he is no longer physically active. Tr.3775:7-3776:25.

In 2015, Alberta also was diagnosed with large B-cell lymphoma, which metastasized in her brain. Tr.3006:9-10, 3887:6-12, 3977:2-3978:16. She began chemotherapy, which required injections directly into her spine. AA7082-7083. Her cancer recurred in 2016. Tr.3978:20-21. Since 2017, Alberta has taken experimental medication to prevent her brain tumor from growing large again. Tr.3979:21-25; AA7321-7323. She still has double vision, hearing loss, and falls often. Tr.3749:24-3750:25.[5]

Alberta kept using Roundup until 2015, when she became sick. Tr.3740:3-14. Alva kept using Roundup until 2016 or 2017, when he read articles about Roundup causing non-Hodgkin lymphoma. Tr.3794:25-3795:25; AA2716.

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[5] Alberta's cancer returned in 2019. *See* Respondents/Cross-Appellants' Combined Response and Opening Brief at 139 n.21, *Pilliod v. Monsanto Co.*, No. A158228 (Cal. Ct. App. Mar. 31, 2020).

C. Procedural History

1. The Pilliods sued Monsanto in 2017, alleging that their use of Roundup products caused their cancer and seeking compensatory and punitive damages. Pet.App.13a-14a. They brought design-defect and failure-to-warn claims in strict liability and negligence. Pet.App.14a.

At summary judgment, the trial court rejected Monsanto's express- and implied-preemption arguments. Pet.App.111a-112a. The court then denied Monsanto's motion on punitive damages because the Pilliods "ha[d] presented evidence that might support punitive damages." Pet.App.113a.

At trial, the Pilliods presented expert testimony proving that Roundup causes non-Hodgkin lymphoma and that their own exposure to Roundup was a substantial factor in causing their cancers. And the jury heard testimony about Monsanto's reprehensible conduct.

The jury awarded approximately $37 million to Alberta and $18 million to Alva in compensatory damages. Pet.App.151a, 159a. The jury also concluded there was clear and convincing evidence that Monsanto acted with malice or oppression, awarding Alva and Alberta $1 billion each in punitive damages. *Id.*

The trial court denied Monsanto's motion for judgment notwithstanding the verdict. Pet.App.141a. The court conditionally granted Monsanto's motion for a new trial unless the Pilliods accepted reduced damages awards: Alberta's compensatory damages would be approximately $11 million and Alva's would be approximately $6 million. Pet.App.141a-142a. The court held that Monsanto's conduct was "reprehensible" and showed "a conscious disregard for public health," but "the constitutionally permissible

punitive damages" award for each Pilliod was an amount "four times [the] . . . compensatory damages." Pet.App.141a. That left Alberta with approximately $45 million in punitive damages and Alva approximately $25 million in punitive damages. AA8277-8278. The Pilliods accepted the remittitur. AA8279.

2. After the jury's verdict, in August 2019, the Director of the Registration Division of EPA's Office of Pesticide Programs issued a letter to all glyphosate-based product registrants. Pet.App.161a-163a. The Director stated that EPA would no longer approve labeling that warned consumers that glyphosate was a chemical known to California to cause cancer and that manufacturers must remove the warning. Pet.App.162a-163a. This letter was not the product of notice-and-comment rulemaking and took no position on whether Roundup causes cancer.

In April 2022, EPA "clarif[ied]" its position in a letter to California regulators. Resp.App.2a. A higher-ranking official,[6] the Assistant Administrator for the Office of Chemical Safety and Pollution Prevention, wrote that "EPA could approve" (Resp.App.1a) California's newly proposed glyphosate-specific warning:

> CALIFORNIA PROPOSITION 65 WARNING: Using this product can expose you to glyphosate. The International Agency for Research on Cancer classified glyphosate as probably carcinogenic to humans. US EPA has determined that glypho-

[6] The Assistant Administrator reports directly to the EPA Administrator. The Director of the Registration Division reports to the Director of the Office of Pesticide Programs, who reports to the Deputy Assistant Administrator for Pesticide Programs in EPA's Office of Chemical Safety and Pollution Prevention, who reports to the Assistant Administrator. EPA Organizational Chart, https://www.epa.gov/aboutepa/epa-organization-chart.

> sate is not likely to be carcinogenic to humans; other authorities have made similar determinations. A wide variety of factors affect your potential risk, including the level and duration of exposure to the chemical. For more information, including ways to reduce your exposure, go to www.P65Warnings.ca.gov/glyphosate.

Resp.App.2a. The Assistant Administrator added that EPA "could" approve the warning "if pesticide registrants" like Monsanto "requested it for inclusion on glyphosate product labels." Resp.App.3a. Because the warning "would not be considered false and misleading," products bearing it "would not be considered misbranded." *Id.*

3. The California Court of Appeal affirmed the trial court, rejecting Monsanto's preemption, punitive damages, and other arguments. Pet.App.3a-83a. The court repeatedly chastised Monsanto for "fail[ing] to adequately discuss the evidence" in its briefing. Pet.App.78a n.35; *see*, *e.g.*, Pet.App.37a ("The trial described in Monsanto's opening brief bears little resemblance to the trial reflected in the record."); Pet.App.41a ("Monsanto does not fairly present the evidence that Roundup is a potential cause of non-Hodgkin's lymphoma"); Pet.App.76a ("Monsanto largely ignores" evidence of its reprehensible conduct).

Preemption. The court found neither express nor implied preemption. Even granting Monsanto the counterfactual assumption "that the Pilliods' claims, including their design defect claim, [we]re entirely based on labeling and packaging requirements," Pet.App.27a, the court concluded that the Pilliods' claims imposed no "requirements that are different from or in addition to the requirements of FIFRA," and so were not expressly preempted. Pet.App.28a.

The court next found no implied preemption, remarking that "we are not aware of any published opinion by any court – state or federal – that adopts Monsanto's positions with respect to impossibility preemption." Pet.App.31a.

Punitive Damages. The court rejected Monsanto's challenge to the Pilliods' punitive-damages awards, Pet.App.68a-82a, concluding that the awards were constitutional under this Court's three guideposts, *see State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 418-19 (2003). *First*, "[t]he harm Monsanto caused was the result of malice," and the company's "conduct was sufficiently reprehensible to warrant the punitive damages as reduced by the trial judge." Pet.App.77a-78a. *Second*, under the circumstances, the "trial court's awards of four times the reduced compensatory damages" did "not exceed constitutional limits." Pet.App.79a. *Third*, earlier punitive-damages awards against Monsanto were not sufficient "to 'punish and deter' Monsanto's conduct" because (1) the company did "not claim to have actually paid these awards," and (2) "Roundup continues to be sold without any cancer warning at hardware stores and elsewhere." Pet.App.82a.

Justice Richman dissented on the amount of punitive damages. Pet.App.84a-91a. He "[a]ssum[ed] . . . that Monsanto's reprehensibility [wa]s at the lower end." Pet.App.89a. Given that assumption, and punitive-damages awards in other Roundup cases, he wrote that "the right result" would have been a 1:1 ratio of punitive damages to compensatory damages. Pet.App.89a-90a.

4. The Court of Appeal denied Monsanto's rehearing petition. Pet.App.143a. The California Supreme Court denied Monsanto's petition for review in a summary order. Pet.App.1a.

REASONS FOR DENYING THE PETITION

I. The Preemption Issue Does Not Warrant Review

Monsanto's petition does not challenge the Pilliods' design-defect and off-label failure-to-warn claims. FIFRA does not reach those claims, and they present an alternative basis to affirm the California Court of Appeal. That court rightly decided the Pilliods' label-based failure-to-warn claims against Monsanto were neither expressly nor impliedly preempted. No appellate decision – or even judge – has adopted Monsanto's position. The petition therefore presents no preemption issue meriting this Court's review.

A. The Pilliods' Claims Are Not Expressly Preempted

"The proper inquiry" when determining whether FIFRA preempts a common-law claim "calls for an examination of the elements of the common-law duty at issue." *Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 445 (2005). For a common-law claim to be preempted, it must set forth (1) "a requirement '*for labeling or packaging*'" (2) "that is '*in addition to or different from*'" one of FIFRA's requirements. *Id.* at 443-44 (quoting § 136v(b)).

1. The Pilliods' design-defect and off-label failure-to-warn claims imposed no labeling or packaging requirements

Monsanto's argument fails at the first step, as the Pilliods' design-defect and off-label failure-to-warn claims imposed no labeling or packaging requirements. Monsanto simply ignores this issue, but it provides an independent basis to reject the company's petition.

Design Defect. The Pilliods' design-defect claims challenged Roundup's design, not its labeling or

packaging. Their strict-liability design-defect claims required Roundup "to perform as safely as an ordinary consumer would have expected when used or misused in an intended or reasonably foreseeable way." Pet.App.147a, 155a. And their negligent design-defect claims required Monsanto not to act "negligent[ly] in designing, manufacturing, or supplying Roundup." Pet.App.149a, 157a. The jury heard evidence that Monsanto designed a deadly product with a toxic surfactant banned abroad, but never once tested whether it was carcinogenic. The jury then concluded that these failures were "a substantial factor in causing harm" to the Pilliods. Pet.App.147a, 149a, 155a, 157a.

FIFRA does not preempt the Pilliods' design-defect claims because those claims did not require Monsanto to "label or package their products in any particular way." *Bates*, 544 U.S. at 444; *see id.* ("petitioners' claims for defective design," among other theories, "are not pre-empted"). Under California law, "the remedy sought" by a design-defect claim "is a change in design of the products." *Arnold v. Dow Chem. Co.*, 110 Cal. Rptr. 2d 722, 737 (Cal. Ct. App. 2001) (holding design-defect claim against pesticide not expressly preempted under FIFRA). No matter how Monsanto labeled Roundup, it could have avoided liability by creating a safer product. As this Court held in *Bates*, "[i]t is perfectly clear" that common-law claims "that require manufacturers to design reasonably safe products" and "use due care in conducting appropriate testing of their products" are not preempted. 544 U.S. at 444. The Pilliods' design-defect claims involved just such requirements, so are not preempted.

Failure To Warn. The Pilliods' failure-to-warn claims were not limited to Roundup's labeling.

Their strict-liability failure-to-warn claims required Monsanto "to adequately warn" of Roundup's "known or knowable" "potential risks." Pet.App.147a-148a, 155a-156a. And their negligent failure-to-warn claims required Monsanto "to adequately warn of the danger or instruct on the safe use of Roundup." Pet.App.150a, 158a. The jury saw advertisements depicting Roundup as a product that ordinary consumers safely could spray without needing any particular precautions or protective gear. And it heard evidence that the Pilliods saw these commercials, relied on them, and sprayed Roundup on their properties for nearly three decades, all the while thinking it "was like sugar water." Tr.3726:7-17. The jury then concluded that "Monsanto's failure to warn" or "lack of sufficient warnings" – whether in its advertising or elsewhere – was "a substantial factor in causing harm" to the Pilliods. Pet.App.148a, 150a, 156a, 158a.

The Pilliods' failure-to-warn claims imposed no requirements for labeling or packaging.[7] These claims did not require Monsanto to "label or package their products in any particular way." *Bates*, 544 U.S. at 444. The company could have avoided liability by adding a warning to its television commercials. *Cf.* Brief for the United States as Amicus Curiae at 20, *Monsanto Co. v. Hardeman*, No. 21-241 (U.S. May 10, 2020) ("SG *Hardeman* Br.") ("Future cases involving similar state-law claims may contemplate warnings through non-labeling mechanisms that would not require altering EPA-approved labeling.").

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[7] Television advertising is not "labeling," which FIFRA defines as "all labels and all other written, printed, or graphic matter" that accompany a pesticide. § 136(p)(2). Like "a sales agent's *oral* representations," *Bates*, 544 U.S. at 444 n.17, a video advertisement does not meet this definition.

No provision of FIFRA prevented Monsanto from disclosing that EPA had approved Roundup based on fraudulent studies or that residential users should wear protective gear when spraying.

Of course, Monsanto also could have avoided failure-to-warn liability by providing adequate warnings on Roundup's labeling. But that does not transform the Pilliods' claims into labeling or packaging requirements subject to section 136v(b). Under *Bates*, "[a] requirement is a rule of law that *must be obeyed*." 544 U.S. at 445 (emphasis added). Monsanto did not have to obey any labeling or packaging rule – it could have kept Roundup's labeling and packaging the same, yet avoided liability by adding a warning to its advertisements.

2. The Pilliods' label-based failure-to-warn claims track FIFRA

The Pilliods' claims based on Monsanto's failure to warn of Roundup's risks in its labeling also are not expressly preempted. Even when a state law, regulation, or common-law claim addresses pesticide labeling, it is preempted only if it imposes requirements that are "in addition to or different from those required under [FIFRA]." § 136v(b). In *Bates*, this Court held that this would not include common-law duties that were "equivalent to, and fully consistent with, FIFRA's misbranding provisions." 544 U.S. at 447; *see id.* at 454 ("[A] manufacturer should not be held liable under a state labeling requirement subject to § 136v(b) unless the manufacturer is also liable for misbranding as defined by FIFRA.").

The Pilliods' failure-to-warn claims imposed the same or narrower requirements as FIFRA's misbranding provisions. *First*, the Pilliods had to prove that Roundup was dangerous "when used in accordance with widespread and commonly recognized

practice." Pet.App.147a-148a, 149a, 156a, 157a. That tracks section 136a(d)(1) (EPA must consider whether a pesticide will cause unreasonable adverse environmental effects when used "in accordance with widespread and commonly recognized practice"), which section 136(q)(1)(G) incorporates into the definition of misbranding. Indeed, the trial court included this language at Monsanto's request even though California's model jury instructions use a different formulation. Tr.5322:1-25. *Second*, the Pilliods' claims required warnings in narrower circumstances than FIFRA does. FIFRA requires a warning "necessary" and "adequate to protect health," § 136(q)(1)(G), while the Pilliods' claims required Monsanto to warn of "known or knowable" risks (strict liability), Pet.App.147a, 155a; or those "a reasonable manufacturer, distributor, or seller" would have warned about "under the same or similar circumstances" (negligence), Pet.App.150a, 158a. Thus, FIFRA (warning must be "necessary" and "adequate to protect health") is broader than the Pilliods' failure-to-warn claims in strict liability (no warning if risk not known or knowable) and negligence (no warning if unreasonable to warn).

Because the Pilliods' label-based failure-to-warn claims parallel FIFRA's misbranding provisions, those claims effectively enforce the statutory misbranding prohibition. "[A] state cause of action that seeks to enforce" these misbranding provisions "'does not impose a requirement that is "different from, or in addition to," requirements under federal law,'" and so is not preempted. *Bates*, 544 U.S. at 447-48 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 513 (1996) (O'Connor, J., concurring in part and dissenting in part)).

3. Monsanto's express-preemption arguments lack merit

Monsanto raises the same express-preemption arguments from its petition in *Hardeman*. Here, as there, those arguments are "incorrect." SG *Hardeman* Br. 6-7.

a. The company's cornerstone argument (at 14-17) is that EPA's decision to register a pesticide and approve its label imposes a "requirement" under FIFRA, so state-law claims that would require labeling changes are preempted. But EPA's decision to register a pesticide is not the last word on whether the pesticide's labeling is misbranded. The agency determines whether a pesticide's warnings are "necessary" and "adequate to protect public health" based on material the manufacturer submits. § 136(q)(1)(G); *see* § 136j(a)(1)(E). If other information, like an "incident[] involving a pesticide's toxic effects," *Bates*, 544 U.S. at 439, shows the labeling is misbranded, EPA's prior registration decision offers a manufacturer no safe harbor: "EPA may institute cancellation proceedings and take other enforcement action if it determines that a registered pesticide is misbranded." *Id.* (citation omitted).

A manufacturer cannot use EPA's registration of its pesticide "as a defense for the commission of any offense under [FIFRA]," including the misbranding offense. § 136a(f)(2). Rather, registration is only "prima facie evidence" that the pesticide is not misbranded. *Id.* As a result, even if EPA approved a label, a judge or jury could find that the same label violates FIFRA. That is why *Bates* recognized that a pesticide can be "registered but nevertheless misbranded." 544 U.S. at 438.

If a pesticide is "registered but nevertheless misbranded," the manufacturer has a duty to update

its label. *Id.* FIFRA does not authorize, much less require, a manufacturer to retain the label of a misbranded pesticide just because EPA registered the pesticide. Indeed, retaining a registered but misbranded label is not a "requirement" of FIFRA – it is a violation. And registration does not establish any relevant "requirement" that might supersede a duty under state law. For this reason – and because EPA's registration of glyphosate did not assess the health risks of glyphosate-based formulations like Roundup – EPA's registration of glyphosate does not preempt the Pilliods' claims.

b. Monsanto argues that section 136a(f)(2) "has 'no bearing on'" preemption because 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.'" Pet.18 (first quoting *MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1026 n.4 (5th Cir. 1994); then quoting *Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34, 45 (D.D.C. 2011)). But that narrow reading of the section does not track its text, which establishes that registration is not a defense to "any offense" under FIFRA, not just violations of the terms of registration. § 136a(f)(2).

Monsanto next argues (at 18) that the Court of Appeal's interpretation of section 136a(f)(2) means "an EPA determination that a warning label is unnecessary . . . would never be preemptive." That is incorrect: EPA can preempt state-law failure-to-warn claims through notice-and-comment rulemaking. *See Bates*, 544 U.S. at 453 n.28 ("To the extent that EPA promulgates [regulations that refine or elaborate upon FIFRA's broadly phrased misbranding standards] in the future, they will necessarily affect the scope of pre-emption under § 136v(b)."). The

agency just has not done so here. *See* SG *Hardeman* Br. 10 ("Neither FIFRA nor its implementing regulations . . . specifically address warnings for chronic health risks like carcinogenicity.").

c. Section 136a(f)(2) also shows why Monsanto cannot rely on *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). *See* Pet.16-17. In *Riegel*, this Court held that FDA's premarket approval of a medical device imposes "requirements" under the preemption clause of the Medical Device Amendments Act of 1976, 21 U.S.C. § 360k(a), and preempts state-law failure-to-warn claims based on inconsistent duties. *See* 552 U.S. at 322-23, 327-30. This Court said FDA's premarket approval of the riskiest medical devices serves as conclusive evidence that "the approved form [of the devices] provides a reasonable assurance of safety and effectiveness." *Id.* at 323. So a plaintiff cannot argue that an approved device "violated state tort law notwithstanding compliance with the relevant federal requirements." *Id.* at 330. But under FIFRA, registration of a pesticide with EPA is only "prima facie evidence" of compliance, § 136a(f)(2), not proof the labeling is "adequate to protect health," § 136(q)(1)(F). And because a manufacturer with a registered product still could be liable for misbranding, it could be liable for state-law claims "that are fully consistent with federal requirements," like the Pilliods'. *Bates*, 544 U.S. at 452.

More generally, the statutory schemes in *Riegel* and here are meaningfully different. The Medical Device Amendments "swept back some state obligations and imposed a regime of detailed federal oversight," *Riegel*, 552 U.S. at 316, while FIFRA "authorizes a relatively decentralized scheme" that leaves States with broad power to regulate pesticide products – including the power to ban the sale of unsafe, but

registered, pesticides, *Bates*, 544 U.S. at 450 (citing § 136v(a)). For medical devices, "premarket approval is specific to individual devices," requiring FDA to determine that the device "offers a reasonable assurance of safety and effectiveness." *Riegel*, 552 U.S. at 322-23. By contrast, FIFRA's misbranding provisions impose only "general standards," *Bates*, 544 U.S. at 453 n.27; *see Medtronic*, 518 U.S. at 501 (no preemption when federal requirements "reflect[ed] important but entirely generic concerns about device regulation generally"), and EPA has acknowledged that it has not determined whether glyphosate "formulations," like Roundup, pose any risks to human health, *see* EPA, *Glyphosate* at 11.

Practically speaking, another difference is that there is no "overwarning" risk under FIFRA. With potentially life-saving drugs or medical devices, overwarning "could discourage appropriate use of a beneficial drug." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1673 (2019). But providing proper warnings on herbicides poses no comparable risk: weeds are not life-threatening, and a person can wear protective gear or use another herbicide. (The Pilliods now use a mixture of vinegar and salt. Tr.3779:19-22.) All these differences justify "different pre-emption results." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 626 (2011).

d. Monsanto's position would have substantial negative effects. It would appear to bar all failure-to-warn claims based on a pesticide's "labeling" other than claims about the pesticide's efficacy. *See* Pet.15. But as *Bates* observed, "it seems unlikely that Congress considered a relatively obscure provision like [FIFRA's preemption provision] to give pesticide manufacturers virtual immunity from certain forms of tort liability." 544 U.S. at 450.

This proposed immunity also would hinder the functioning of FIFRA: State tort actions "'may aid in the exposure of new dangers associated with pesticides,'" giving manufacturers "'added dynamic incentives to continue to keep abreast of all possible injuries stemming from use of their product so as to forestall such actions through product improvement.'" *Id.* at 451 (quoting *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1541-42 (D.C. Cir. 1984)). Just so with the Pilliods, who used Roundup products for nearly thirty years. Their extended exposure, and that of thousands of others, can help inform EPA about the long-term effects of glyphosate-based products like Roundup and aid the agency in carrying out "its task of assessing the environmental and health dangers posed by pesticides." *Id.* at 440.

B. The Pilliods' Claims Are Not Impliedly Preempted

The doctrine of implied preemption does not apply to labeling requirements under FIFRA. But even if the doctrine applied, it would not bar the Pilliods' claims.

1. The doctrine of implied preemption cannot "be reconciled with FIFRA," Pet.App.30a, at least for pesticide-labeling claims. Congress decided that FIFRA preempts state requirements only when they impose labeling or packaging requirements "in addition to or different from those required under [FIFRA]." § 136v(b). Congress also preserved a State's authority "to regulate the sale and use of pesticides" and "to ban the sale of a pesticide that it finds unsafe." Pet.App.30a. Those decisions left no room for claims of implied conflict.

Unsurprisingly, then, this Court did not conduct an implied-preemption analysis in *Bates*. The defendant

had made the argument, *see* Resp. Br. at 36-37, *Bates v. Dow AgroSciences LLC*, No. 03-388 (U.S. Nov. 24, 2004), and if the Court had found implied preemption it would have affirmed rather than remanded. But as Justice Thomas observed in his concurrence, that refusal to apply implied preemption "comports with this Court's increasing reluctance to expand federal statutes beyond their terms through doctrines of implied pre-emption." 544 U.S. at 459 (Thomas, J., concurring in the judgment in part and dissenting in part).

2. Monsanto draws its implied-preemption arguments from prescription drug cases under the Federal Food, Drug, and Cosmetic Act ("FDCA"). This Court conducts an implied-preemption analysis in such cases because Congress has "declined to enact [an express-preemption] provision for prescription drugs." *Wyeth v. Levine*, 555 U.S. 555, 567 (2009). Those cases have little relevance here because FIFRA has an express-preemption provision, and implied preemption does not apply. But even setting that threshold issue aside, Monsanto's implied-preemption arguments lack merit.

a. Monsanto's first implied-preemption theory is that it could not add a warning to Roundup's labels without EPA's approval. Pet.21. But the company misunderstands the case from which it derives this supposed rule: In *PLIVA*, this Court addressed implied preemption in the generic-drug context. Under the FDCA, FDA imposes a "duty of sameness" on generic-drug labels, which must always match the label of the brand-name equivalent drug. 564 U.S. at 616. If a generic-drug manufacturer wants to update a label, it must "ask the agency to work toward strengthening the label that applies to both the generic and brand-name equivalent drug." *Id.* The

manufacturer has no right to update the label on its own, so when a state-law claim imposes a duty to change the label, it is impliedly preempted.

Unlike generic-drug manufacturers, which have a "federal-law duty to keep the label the same," *id.* at 618, pesticide manufacturers "have a continuing obligation to adhere to FIFRA's labeling requirements," *Bates*, 544 U.S. at 438. The statute "contemplates that pesticide labels will evolve over time, as manufacturers gain more information about their products' performance in diverse settings." *Id.* at 451. When an updated label is necessary, a manufacturer generally must submit the revisions to EPA. *See* § 136a(f)(1); 40 C.F.R. § 152.50(e). And when a manufacturer's proposed label is not misbranded, FIFRA provides that EPA "shall" approve it. § 136a(f)(1).

EPA has made clear it would approve a label warning of Roundup's cancer risks. In its April 2022 letter, the agency said that if a company like Monsanto asked to include a warning that IARC "classified glyphosate as probably carcinogenic to humans," "this revised language could be approved by EPA" because it would not be misbranded. Resp.App.2a-3a; *see* SG *Hardeman* Br. 14. As a result, federal law imposes no competing "duty to keep the label the same," and Monsanto's argument lacks merit.

b. Monsanto's second theory is that it cannot add a cancer warning to Roundup labels because EPA would not accept it. Pet.21. Again under the FDCA, state-law failure-to-warn claims are preempted when there is "clear evidence" that FDA would not have approved the warning that state law requires. *Wyeth*, 555 U.S. at 571. The only sources of "clear evidence" of what an agency would do in that kind of hypothetical situation "are agency actions taken pursuant to the FDA's congressionally delegated

authority": "notice-and-comment rulemaking," an order "formally rejecting a warning label," or "other agency action carrying the force of law." *Merck*, 139 S. Ct. at 1679.

There is no "clear evidence" showing the Pilliods' claims are preempted. EPA has promulgated no regulation requiring certain warnings on glyphosate-based product labels and barring others. Nor has the agency taken other formal action rejecting a warning about the cancer risks of Roundup. Instead, the agency has said that if a company like Monsanto asked to include a warning that IARC "classified glyphosate as probably carcinogenic to humans," "this revised language could be approved by EPA." Resp.App.2a-3a. That is the opposite of "clear evidence" showing the Pilliods' claims are preempted.

C. The Petition Does Not Meet The Traditional Criteria For Certiorari

1. No split exists. No appellate judge – let alone panel – has adopted Monsanto's preemption position. Only one other appellate court has considered whether the registration of a label under FIFRA preempts failure-to-warn claims alleging that the manufacturer of a pesticide should have included an additional warning, and it rejected Monsanto's position. *See Hardeman v. Monsanto Co.*, 997 F.3d 941, 954 (9th Cir. 2021), *petition for cert. pending*, No. 21-241 (U.S. Aug. 18, 2021). There is no reason to depart from this Court's general practice of "permitting several courts of appeals to explore" an issue and "waiting for a conflict to develop" before granting review. *United States v. Mendoza*, 464 U.S. 154, 160 (1984).

Monsanto claims that the decision below "deepens uncertainty over how to apply similarly worded express-preemption provisions," citing cases constru-

ing other federal statutes. Pet.19-21. But there is no uncertainty, only different statutory schemes. For example, Monsanto refers to the Federal Meat Inspection Act. Pet.19. That Act "establishes an elaborate system of inspecting live animals and carcasses," and "[o]ver the years, the [Department of Agriculture's Food Safety and Inspection Service] has issued extensive regulations" fleshing out that system. *National Meat Ass'n v. Harris*, 565 U.S. 452, 455-56 (2012) (internal quotation marks and brackets omitted). Because the Act and its accompanying regulations impose many requirements, its preemption provision necessarily "sweeps widely" when blocking applications of additional or different state requirements. *Id.* at 459-60. Here, by contrast, EPA has promulgated "relatively few regulations," so FIFRA's preemption provision is "narrow." *Bates*, 544 U.S. at 452, 453 n.28.

Further, none of Monsanto's statutes has a provision like section 136a(f)(2). Given the Court of Appeal's reliance on that unique feature of FIFRA, there is no serious risk that the decision below will "threaten[] considerable confusion" among courts deciding cases involving different statutory schemes. Pet.19. This Court can address any confusion when it arises.

2. With no circuit conflict, Monsanto's argument for review is that the Court of Appeal's express-preemption holding conflicts with *Bates*. Pet.14-19. But *Bates* leads directly to the Court of Appeal's preemption holding. *See supra* pp. 18-19. And "ordinarily" an appellate-court decision applying one of this Court's precedents to specific facts – "even one deemed to be arguably inconsistent with it – will not be reviewed [on certiorari]." *Hubbard v. United States*, 514 U.S. 695, 720 (1995) (Rehnquist, C.J., dissenting).

Monsanto focuses on an example from *Bates* about a failure-to-warn claim requiring the word "DANGER" rather than "CAUTION." Pet.15-16. The example undermines Monsanto's arguments. EPA, by regulation, "establishe[d] four Toxicity Categories for acute hazards of pesticide products," 40 C.F.R. § 156.62, and then mandated toxicity warnings for qualifying pesticides, *id.* § 156.64. So when a state-law failure-to-warn claim requires "DANGER" when EPA's regulation requires "CAUTION," of course there is preemption: That is a "requirement[] for labeling" that is "different from" what EPA's regulation would "require[]." § 136v(b). There is no such regulation governing warning language for Roundup labels.

If EPA believes as a policy matter that failure-to-warn claims involving glyphosate-based products should be barred, it can promulgate a regulation (subject to judicial review). As with certiorari petitions that challenge a court's interpretation of the advisory Sentencing Guidelines, there is no need for this Court's review when the agency has the power to "fix" any problems created by the decision below.

Monsanto's only countervailing point is that FIFRA's preemption provision seeks to promote uniformity, and the Court of Appeal's decision could permit States to reach different conclusions about particular warnings. Pet.24-25. But the company again overlooks *Bates*, which cautioned against "overstat[ing] the degree of uniformity and centralization that characterizes FIFRA," observing that "the statute authorizes a relatively decentralized scheme that preserves a broad role for state regulation." 544 U.S. at 450.

3. Even if the decision below were wrong and the lower courts were split, certiorari should be denied

because this case is a poor vehicle. Monsanto's question presented is about labeling. But none of the Pilliods' claims was limited to Roundup's labeling. So no matter the answer to the question presented, the result is an affirmance of the Court of Appeal because the jury's verdict rested on non-preempted grounds that Monsanto now has waived. *See supra* pp. 15-18.

Finally, this case comes to the Court "on review of a decision by a state intermediate appellate court." *Huber v. New Jersey Dep't of Env't Prot.*, 562 U.S. 1302, 1302 (2011) (Alito, J., concurring in denial of certiorari). "[D]enial of certiorari is appropriate" in that posture. *Id.*; *see* Sup. Ct. R. 10.

II. The Punitive-Damages Awards Do Not Warrant Review

Monsanto also asks this Court to review the Pilliods' punitive-damages awards. But the company makes no effort to apply the guideposts this Court set out in *BMW of North America, Inc. v. Gore*, 517 U.S. 559, 575 (1996). Instead, as below, Monsanto refuses to acknowledge the facts supporting the jury's and the appellate court's findings on reprehensibility, the most important consideration under existing law. *See* Pet.App.78a n.35; Pet.App.76a ("Monsanto largely ignores" evidence of its reprehensible conduct). This Court's precedent permits significant punitive damages in cases of highly reprehensible conduct. Because the Court of Appeal correctly applied that settled law, further review is unwarranted.

A. The Court Of Appeal's Decision Was Correct

The Court of Appeal diligently scrutinized the Pilliods' punitive-damages awards under *Gore*'s three guideposts: (1) the degree of reprehensibility of the

defendant's misconduct; (2) the disparity between the actual or potential harm suffered by the plaintiff and the punitive damages award; and (3) the difference between the punitive damages awarded by the jury and the civil penalties authorized or imposed in comparable cases. *See* 517 U.S. at 574-75.

1. The court began with reprehensibility, "'[t]he most important indicium of the reasonableness of a punitive damages award.'" *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 419 (2003) (quoting *Gore*, 517 U.S. at 575). Monsanto's conduct caused physical injuries, not just economic ones. "The jury found that Monsanto's conduct caused Alva and Alberta grave physical harm": each developed non-Hodgkin lymphoma, "Alva experienced pain to the point he could barely move" and "endured six rounds of chemotherapy," and "Alberta's chemotherapy regime required multi-day hospital stays and . . . brought on more life changing ailments." Pet.App.77a-78a.

These horrific injuries did not result from an accident or mere negligence. The Pilliods proved "[t]he harm Monsanto caused was the result of malice" and the company's "conduct was sufficiently reprehensible to warrant the punitive damages as reduced by the trial judge." *Id.* The company had shown "intransigent unwillingness to inform the public about the carcinogenic dangers of a product it made abundantly available at hardware stores and garden shops across the country." Pet.App.78a. It "knew that studies supporting the safety of Roundup were invalid when the Pilliods began spraying Roundup in their yards, wearing no gloves or protective gear, spurred on by television commercials showing people spraying Roundup wearing shorts." *Id.*

This was no one-time lapse in judgment or isolated incident. *See State Farm*, 538 U.S. at 419. "Monsanto's conduct involved repeated actions over a period of many years motivated by the desire for sales and profit." Pet.App.78a. For example, the company doubled down on its deception each time new evidence emerged linking Roundup to cancer. *See id.* (Monsanto sought "to 'impede, discourage or distort scientific inquiry and the resulting science about glyphosate' in conscious disregard of public health").

2. Given the extraordinary reprehensibility of Monsanto's conduct, the "trial court's awards of four times the reduced compensatory damages" did "not exceed constitutional limits." Pet.App.79a. The awards, while significant, fall well within the range of awards this Court has upheld. *See*, *e.g.*, *Pacific Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1, 23-24 (1991) (4.2:1 ratio in financial fraud case did not "cross the line"). California reasonably could conclude that a lesser ratio would fail to deter such profitable misconduct by a multi-billion-dollar company. *See* Pet.App.77a n.34; *Gore*, 517 U.S. at 582; *TXO Prod. Corp. v. Alliance Res. Corp.*, 509 U.S. 443, 462 & n.28 (1993) (plurality) (considering defendant's wealth in upholding punitive damages).

3. Under the third guidepost, the Court of Appeal considered that Monsanto had been ordered to pay approximately $30 million in punitive damages in two other Roundup cases. Pet.App.81a. The court concluded that these earlier awards were not sufficient "to 'punish and deter' Monsanto's conduct" because (1) the company did "not claim to have actually paid these awards," and (2) "Roundup continues to be sold without any cancer warning at hardware stores and elsewhere." Pet.App.82a. Because Monsanto's "reprehensible conduct remain[ed] to be punished and

deterred," the Pilliods' punitive-damages awards did not violate due process. *Id.*; *see Gore*, 517 U.S. at 568 ("Punitive damages may properly be imposed to further a State's legitimate interests in punishing unlawful conduct and deterring its repetition.").

B. Monsanto's Proposed Rule Lacks Merit, And Its Purported Circuit Split Is Illusory

1. Monsanto seeks to displace this Court's contextual rule, under which a punitive-damages award "must be based upon the facts and circumstances of the defendant's conduct and the harm to the plaintiff," *State Farm*, 538 U.S. at 425, with a mathematical formula limiting punitive damages to the amount of compensatory damages whenever the latter are "substantial." Pet.i, 27. The Court should decline that invitation.[8]

This Court has "'consistently rejected the notion that the constitutional line is marked by a simple mathematical formula.'" *State Farm*, 538 U.S. at 424 (quoting *Gore*, 517 U.S. at 582); *see also TXO Prod.*, 509 U.S. at 460 (plurality); *Haslip*, 499 U.S. at 18. In *State Farm*, this Court "decline[d] *again* to impose a bright-line ratio which a punitive damages award cannot exceed." 538 U.S. at 425 (emphasis added). And the sentence from *State Farm* that Monsanto holds up as establishing a bright-line rule was non-categorical. *See id.* ("When compensatory damages are substantial, then a lesser ratio, perhaps

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[8] This Court refused an invitation to create such a rule in 2020, *see TransUnion LLC v. Ramirez*, 141 S. Ct. 972 (2020) (rejecting question presented), and last year, *see Johnson & Johnson v. Ingham*, 141 S. Ct. 2716 (2021) (denying certiorari). Monsanto seeks to distinguish these cases by highlighting their "procedural complications." Pet.28. The distinction makes no difference, as Monsanto's petition suffers the far worse "complication" of not actually presenting either question presented.

only equal to compensatory damages, can reach the outermost limit of the due process guarantee.").

A 1:1 cap is a blunt instrument. It would apply no matter how egregious the defendant's misconduct, how many innocent people the defendant endangered, or how much profit the defendant extracted. Defendants that have engaged in reprehensible conduct have more precise tools to try to reduce punitive-damages awards: They can point to past awards to argue they have been punished enough. They can assert that a large award risks leaving nothing for other victims. And in California, they have a statutory right to bifurcate the trial for a separate finding on the amount of punitive damages. *See* Cal. Civ. Proc. Code § 3295(d). Monsanto took none of these options.

2. Monsanto incorrectly claims that courts have divided over whether "punitive damages should be limited to a 1:1 ratio" in cases involving a "substantial" compensatory award. Pet.27. Each decision the company cites limited punitive damages only after applying all the *Gore* factors, starting with reprehensibility.[9] Most expressly disavowed applying any mathematical formula.[10]

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[9] *See*, *e.g.*, *Saccameno v. U.S. Bank Nat'l Ass'n*, 943 F.3d 1071, 1086 (7th Cir. 2019); *Lompe v. Sunridge Partners, LLC*, 818 F.3d 1041, 1073 (10th Cir. 2016); *Thomas v. iStar Fin., Inc.*, 652 F.3d 141, 148 (2d Cir. 2011) (per curiam); *Morgan v. New York Life Ins. Co.*, 559 F.3d 425, 443 (6th Cir. 2009); *Boerner v. Brown & Williamson Tobacco Co.*, 394 F.3d 594, 603 (8th Cir. 2005); *Williams v. ConAgra Poultry Co.*, 378 F.3d 790, 796-97 (8th Cir. 2004); *Roth v. Farner-Bocken Co.*, 667 N.W.2d 651, 665-71 (S.D. 2003).

[10] *See*, *e.g.*, *Saccameno*, 943 F.3d at 1088; *Lompe*, 818 F.3d at 1068; *Thomas*, 652 F.3d at 149; *Boerner*, 394 F.3d at 603; *Williams*, 378 F.3d at 798; *Roth*, 667 N.W.2d at 667-68.

The company suggests that other jurisdictions would have reduced the Pilliods' awards. Pet.27. Even if that claim were true, it would present only a fact-bound disagreement with a court's application of settled law and would not warrant review. Like any multi-factor reasonableness analysis, the *Gore* factors require courts to exercise judgment, and some variation in application is unavoidable.

In fact, the cases Monsanto cites to support its proposed bright-line rule illustrate how courts use the degree of reprehensibility to decide when a higher ratio is permissible. The cases limiting a punitive-damages award to the amount of compensatory damages involved a lack of physical harm to the plaintiff, a low degree of culpability for the defendant, or both.[11] Monsanto's lead cases fit this mold: In *Saccameno*, the defendant's conduct "caused no physical injuries and did not reflect any indifference to [the plaintiff's] health or safety." 943 F.3d at 1088. In *Lompe*, the plaintiff had suffered only minor physical injuries because of her landlord's failure to maintain carbon-monoxide detectors. *See Lompe*, 818 F.3d at 1066. And in *Boerner*, the court disclaimed any "simple formula or bright-line ratio" and acknowledged that "a higher ratio" than 1:1 could be "justif[ied]" in cases with "[f]actors . . . such as the presence of an 'injury that is hard to detect.'" 394 F.3d at 603.

On the other hand, Monsanto's cases upholding higher ratios resemble this one, involving egregious misconduct, serious physical injury, or both. *See Planned Parenthood of Columbia/Willamette Inc. v. American Coal. of Life Activists*, 422 F.3d 949, 958 (9th Cir. 2005) (credible death threats); *Cote v. Philip*

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[11] *See*, *e.g.*, *Morgan*, 559 F.3d at 441-42; *Williams*, 378 F.3d at 797-98; *Roth*, 667 N.W.2d at 667.

Morris USA, Inc., 985 F.3d 840, 847-48 (11th Cir. 2021) (defendant concealed dangers of smoking, contributing to plaintiff's death); *Seltzer v. Morton*, 154 P.3d 561, 606 (Mont. 2007) (defendants "threatened to ruin and devastate" the plaintiff "professionally, personally, and financially").

The variation in ratios between these cases does not reflect a split. It reflects courts' considered application of this Court's precedent, allowing higher ratios only in cases involving more reprehensible conduct, particularly conduct putting profits over safety and exposing consumers to life-threatening risks. This Court's review therefore is unwarranted.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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May 20, 2022

APPENDIX

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[Seal Omitted]

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

April 8, 2022

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AND POLLUTION PREVENTION

Dr. Lauren Zeise
Director
Office of Environmental Health Hazard Assessment
California Environmental Protection Agency
1001 I Street
Sacramento, California 95814

Dear Dr. Zeise:

Thank you for your letter of March 21, 2022, to the U.S. Environmental Protection Agency (EPA) regarding glyphosate and California's Safe Drinking Water and Toxics Enforcement Act of 1986, also known as Proposition 65.

Your letter proposes a revision to previously proposed safe harbor language that businesses could use to satisfy California's notification requirements for certain glyphosate products under Proposition 65. It further requested that EPA provide input on whether the newly proposed language could be approved, if requested by a pesticide registrant, for inclusion on pesticide labels for products containing glyphosate as an active ingredient and sold in California. As explained below, EPA could approve the newly proposed language.

The Agency continues to stand behind its robust scientific evaluation of the carcinogenic potential of glyphosate. Furthermore, EPA's conclusion remains consistent with many international expert panels and regulatory authorities (https://www.regulations.gov/document/EPA-HQ-OPP-2009-0361-0073).

Nonetheless, EPA recognizes that the revised safe harbor language proposed by the Office of Environmental Health Hazard Assessment (OEHHA) acknowledges the EPA position: CALIFORNIA PROPOSITION 65 WARNING: Using this product can expose you to glyphosate. The International Agency for Research on Cancer classified glyphosate as probably carcinogenic to humans. US EPA has determined that glyphosate is not likely to be carcinogenic to humans; other authorities have made similar determinations. A wide variety of factors affect your potential risk, including the level and duration of exposure to the chemical. For more information, including ways to reduce your exposure, go to www.P65Warnings.ca.gov/glyphosate.

The letter from OEHHA further requests that EPA clarify its position as previously stated in its August 7, 2019, letter to registrants regarding products that contain glyphosate. That 2019 letter focused on the application of the default Proposition 65 safe harbor warning language to products containing glyphosate and advised that EPA would no longer approve glyphosate labeling containing that statement because it was in conflict with the Agency's scientific conclusions regarding glyphosate. The Agency concluded that the standard warning language for products containing glyphosate was false or misleading and

therefore, any glyphosate products bearing the statement would be considered misbranded.

While EPA's scientific conclusions regarding the glyphosate cancer classification have not changed since the August 7, 2019, letter to glyphosate registrants, it has determined that the new glyphosate-specific safe harbor language proposed in OEHHA's recent letter is sufficiently clear regarding EPA's position and thus would not be considered false and misleading. Therefore, this revised language could be approved by EPA if pesticide registrants requested it for inclusion on glyphosate product labels, and the products would not be considered misbranded. As stated in OEHHA's letter, EPA notes that inclusion on the product label is one of several methods that companies can use to satisfy California's notification requirements under Proposition 65.

EPA appreciates the constructive approach that California is pursuing to address this matter and looks forward to further strengthening our relationships with our stakeholders as we forge ahead together in our work. We thank you for taking the time to write on this important matter.

Sincerely,

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Michal Freedhoff, Ph.D.
Assistant Administrator