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 OF WASHINGTON LEGAL FOUNDATION AND ALLIED EDUCATIONAL FOUNDATION AS *AMICI CURIAE* SUPPORTING PETITIONER

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QUESTIONS PRESENTED

1. Whether the Federal Insecticide, Fungicide, and Rodenticide Act preempts state-law failure-to-warn claims where the warning cannot be added to a product without Environmental Protection Agency approval and EPA has repeatedly rejected the warning.

2. Whether a punitive-damages award that is four times a substantial compensatory-damages award violates the Fourteenth Amendment's Due Process Clause when the defendant acted reasonably.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

TABLE OF AUTHORITIES
(*continued*)

Page(s)

Constitutional Provision

Statutes

TABLE OF AUTHORITIES
(*continued*)

Page(s)

Regulations

Other Authorities

TABLE OF AUTHORITIES
(*continued*)

Page(s)

INTERESTS OF *AMICI CURIAE*[*]

Washington Legal Foundation is a nonprofit, public-interest law firm and policy center with supporters nationwide. WLF promotes free enterprise, individual rights, limited government, and the rule of law. It often appears as *amicus curiae* in cases about California's Proposition 65. *See, e.g.*, *Nat'l Assoc. of Wheat Growers v. Bonta*, No. 20-16758 (9th Cir. brief filed May 19, 2021); *Monsanto Co. v. Off. of Env't Health Hazard Assessment*, 22 Cal. App. 5th 534 (2018).

WLF's Legal Studies Division also regularly publishes pieces by outside experts on glyphosate. *See, e.g.*, Claire C. Weglarz, *Unsound Expansion of Strict Liability Failure to Warn in California:* Johnson v. Monsanto Co., WLF LEGAL OPINION LETTER (July 9, 2021); Victor E. Schwartz & Christopher E. Appel, *Roundup Cases May Be a New Example of an Old Problem: The* Post Hoc *Fallacy*, WLF LEGAL BACKGROUNDER (Aug. 9, 2019).

Allied Educational Foundation is a nonprofit charitable and educational foundation based in Tenafly, New Jersey. Founded in 1964, AEF promotes education in diverse areas of study, including law and public policy. It has appeared as *amicus* often in this Court.

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[*] No party's counsel authored any part of this brief. No person or entity, other than *amici* and their counsel, paid for the brief's preparation or submission. After timely notice, all parties consented to *amici*'s filing this brief.

INTRODUCTION

Recently, the United Kingdom of Great Britain and Northern Ireland withdrew from the European Union. Brexit was controversial both in England and abroad. But after a nationwide referendum and multiple general elections, the British people spoke loudly in support of leaving the EU.

The rallying cry behind Brexit was a feeling that Britain was no longer making key policy decisions for its citizens. Rather than resulting from the British Parliament's own deliberations, decisions affecting Brits were being made by Brussels. And the European Parliament made decisions binding Britain using European analysis based on European interests.

This case presents a similar issue. Americans' elected representatives gave the Environmental Protection Agency authority over pesticides. EPA makes decisions based on its well-funded research that focuses on what is best for Americans. This, of course, is a regulation of commerce between the several States and foreign nations.

Under the Supremacy Clause, the States cannot overrule this federal policy decision. But that has never stopped California from passing laws that are both expressly and conflict preempted by federal law. California enacted Proposition 65 and allowed others around the world to decide what poses a risk to Americans. Activists exploited this legislation to achieve their policy goals using civil litigation.

Realizing that any researcher following the scientific method would find glyphosate poses no risk to humans, activists built in multiple backup plans. A substance is covered by Prop 65 if only one of a smorgasbord of alphabet-soup agencies finds it potentially harmful to humans.

This has caused dire consequences in California. Companies are placed in the impossible position of either ignoring federal law or facing massive liability for not following California law. After massive judgments in these cases, California piles on more by allowing juries to impose outsized punitive damages awards that violate the Fourteenth Amendment's Due Process Clause. Enough is enough. This Court's intervention is necessary, yet again, to remind California that it too is bound by federal law.

STATEMENT

Adopted by California voters in 1986, Prop 65 provides that "[n]o person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer * * * without first giving clear and reasonable warning to such individual." Cal. Health & Saf. Code § 25249.6. The State publishes a list of chemicals "known to the state" to cause cancer. *Id.* § 25249.8(a). That list must include any substance identified as a potential carcinogen in experimental animals by the International Agency for Research on Cancer. *See* Cal. Labor Code § 6382(b)(1); Cal. Health & Saf. Code § 25249.8(a). All products including a detectable amount of one of the listed chemicals must include the warning. *See* Cal. Health & Saf. Code § 25249.6.

But state law is not the final word on labeling pesticides. Under the Federal Insecticide, Fungicide, and Rodenticide Act, companies must register a pesticide before selling it in the United States. 7 U.S.C. § 136a(a). The registration must include proposed labeling with any health warnings. *E.g.*, *id.* § 136a(c); 40 C.F.R. §§ 156.10(a)(1)(vii), 156.60, 158.500. After EPA approves a label, it may not be altered without EPA approval. *See Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 438 (2005); 7 U.S.C. §§ 136a(c)(1), 136j(a)(1)(B). This means that a company cannot include a Prop 65 warning on a pesticide without EPA approval.

From the early 1980s until the early 2010s, Respondents used Roundup on their property. After being diagnosed with non-Hodgkin's lymphoma, they sued Monsanto claiming that Roundup caused their non-Hodgkin's lymphoma because it contains glyphosate.

After the Superior Court refused to recognize that federal law preempted Respondents' claims, the case went to trial. A jury awarded them over $54 million in compensatory damages and $2 billion in punitive damages. The trial court reduced that amount to about $18 million in compensatory damages and $69 million in punitive damages.

Monsanto appealed to the California Court of Appeal. As it has repeatedly done, that court held that federal law cannot preempt California's labeling requirements. Pet. App. 30a. In its view, FIFRA cannot impliedly preempt a state law. *See id.* Then, ignoring the decisions of several federal courts of appeals, the court held that a punitive to

compensatory damages ratio of 4:1 is permissible—even when compensatory damages are significant. Pet. App. 80a, 82a. Because the Supreme Court of California abdicated its responsibility to ensure that federal law is properly applied in the State, Pet. App. 1a, Monsanto seeks certiorari.

SUMMARY OF ARGUMENT

I.A. Congress gave EPA the power to regulate pesticide labels and to decide what warnings are scientifically appropriate. EPA's analysis of glyphosate shows that it poses no risk to humans. Unsurprisingly, every other reputable agency in the world to investigate the question has reached the same conclusion.

The plaintiffs' bar, however, found a loophole in Prop 65. Rather than allow the scientific agencies to review data unbiasedly, it got two moles onto one overseas agency. Relying on the same data that other groups—including California regulators—used to find no risk, the agency found that glyphosate may cause cancer in humans. So the warning that California requires is based on rent seeking—not science.

B. Companies will face an impossible decision if the Court of Appeal's decision stands. They must either follow federal law and subject themselves to billions of dollars in damages or add a warning and break federal law. Companies will act rationally and stop making pesticides and stop innovating. This will decrease food security both in the United States and abroad. In other words, people could starve if the decision remains.

II. State courts have recently abandoned this Court's preemption jurisprudence. Rather than looking at whether the federal statutory and regulatory scheme impliedly preempt state laws, these state courts have held that States can impose any labeling requirements they want. This case gives the Court the chance to correct those errors and send a strong message about proper application of its preemption jurisprudence.

III. This Court should also grant review to resolve a split among lower courts on how to apply its due-process precedents. The Court has said that when there is a substantial award of compensatory damages, the Due Process Clause may limit a punitive damages award to the amount of the compensatory award. Many courts have properly heeded this guidance. But the California Court of Appeal did not do so here.

Capping the ratio of punitive damages to substantial compensatory damages at 1:1 ensures that parties know their risk of exposure. Rather than having to guess at potential punitive damages, companies would know that, when a damages award is substantial, they may be forced to pay only the same amount in punitive damages. This ensures compliance with the Due Process Clause.

ARGUMENT

I. WHETHER STATE-LAW FAILURE-TO-WARN CLAIMS OVER GLYPHOSATE ARE PREEMPTED BY FIFRA IS AN ISSUE OF NATIONAL IMPORTANCE.

The Constitution provides that when state law conflicts with federal law, federal law prevails. *See* U.S. Const. art. VI, § 2. But the California courts treat this command as a mere suggestion. This Court often must reverse decisions from California because its courts allow state law to trump federal law. *E.g.*, *Bristol-Myers Squibb Co. v. Superior Ct. of Cal., S.F. Cnty.*, 137 S. Ct. 1773 (2017); *DIRECTV, Inc. v. Imburgia*, 577 U.S. 47 (2015). The Court should once again step in and remind California that it too must play by the rules.

A. The Process For Listing Glyphosate As Dangerous To Humans Was Unscientific Rent Seeking.

One reason that Congress gave EPA the power to regulate pesticide labels is because of the agency's scientific expertise. Rather than leave it up to state agencies, Congress found it necessary to nationalize the label-approval process. Yet under the Court of Appeal's decision, each State can make its own decisions about pesticides. Even if that decision is based on zero scientific evidence, companies like Monsanto must comply with the labeling requirements. Allowing such state-level decisions eviscerates Congress's policy goal of national uniformity for pesticide labeling.

1. IARC's working group's decision that glyphosate is a carcinogen is an outlier. No other scientific agency has reached the same conclusion. In fact, they all have reached the opposite conclusion; glyphosate poses no risk to humans. In 1997 and 2007, the California Office of Environmental Health and Hazard Assessment determined that glyphosate is unlikely to pose a cancer hazard to humans. *See* Am. Pet., ¶ 35, *Monsanto Co. v. Cal. Citrus Mut.*, 2017 WL 3784249 (Cal. Super. Mar. 20, 2017) (No. 16-CE-CG-00183). These determinations were made after reviewing the same dataset that led the IARC to reach the opposite conclusion. *Id.* ¶ 36.

So a California regulatory body found that glyphosate poses no risk to humans. But under Prop 65, this determination means nothing if activists can persuade another agency to reach the opposite conclusion. Here, activists asked many agencies to find that glyphosate causes cancer. Most reached the same result that the California did. The German Federal Institute for Risk Assessment, European Food Safety Authority, Canadian Pest Management Regulatory Authority, and World Health Organization all have found no evidence that glyphosate harms humans. *See* Am. Pet., *supra* ¶¶ 37-48.

Most importantly, however, is EPA's conclusions about glyphosate. EPA found that there are "[n]o risks of concern to human health from current uses of glyphosate." EPA, *Glyphosate*, https://bit.ly/38xdm3Q (last visited Apr. 18, 2022). If products like Roundup are "used according to label directions," they "do not result in risks to children or adults." *Id.*

There is similarly "[no] indication that children are more sensitive to glyphosate." EPA, *supra*. EPA reviewed "numerous studies from [many] sources" and "found no indication that children are more sensitive to glyphosate from *in utero* or post-natal exposure." *Id.*

After "undergo[ing] Tier I screening under EPA's Endocrine Disruptor Screening Program," EPA found "[n]o indication that glyphosate is an endocrine disruptor." EPA, *supra*. In other words, "data do not indicate that glyphosate has the potential to interact with the estrogen, androgen or thyroid signaling path." *Id.*

More to the point, EPA found "[n]o evidence that glyphosate causes cancer in humans." EPA, *supra*. When reaching this decision, it "considered a significantly more extensive and relevant dataset than" IARC. *Id.* EPA examined "studies submitted to support registration of glyphosate and studies EPA identified in the open literature." *Id.*

This finding "is consistent with other international expert panels and regulatory authorities." EPA, *supra*. Along with those agencies listed above, others that have found glyphosate poses no risk to humans include the "New Zealand Environmental Protection Authority[] and the Food Safety Commission of Japan." *Id.*

2. Despite this overwhelming scientific evidence that glyphosate poses no risk to humans, IARC found that it is a carcinogen. How could such a supposedly expert agency veer so far off course? The answer is simple, unethical rent seeking.

Christopher Portier played a leading role in IARC's evaluation of glyphosate despite a severe financial conflict of interest. Before joining IARC, Portier was affiliated with the Environmental Defense Fund, which litigates against all use of pesticides. Although lacking any glyphosate expertise or experience, Portier chaired the IARC committee that proposed glyphosate as a substance to be studied by an IARC working group. He then served as a specialist and advisor to that working group.

Portier did not disclose his financial ties to law firms that sued Monsanto for glyphosate's alleged carcinogenicity. The same week that IARC listed glyphosate as a probable human carcinogen, Portier signed a lucrative consulting contract with two law firms, under which he assisted the firms with their glyphosate litigation. Portier soon made over $160,000. *See* Ben Webster, *Weedkiller Scientist Was Paid £120,000 by Cancer Lawyers*, Times of London (Oct. 18, 2017), https://bit.ly/3DJRXQv. Portier admitted that he had been hired by one of the law firms at least two months before the IARC issued its glyphosate determination. *Id.*

Portier's unethical rent seeking did not stop there. Later, he lobbied extensively for acceptance of the IARC's determination by governmental bodies and for rejecting contrary findings by other scientific groups. When Portier engaged in such activities, however, he neglected to mention that he was on the plaintiffs' bar's payroll.

Similarly troubling is the conduct of retired epidemiologist Aaron Blair, who led IARC's review of glyphosate. Blair was aware of significant scientific

evidence showing that glyphosate is not a human carcinogen, yet he did not bring that evidence to the IARC working group's attention. Kate Kelland, *Cancer Agency Left in the Dark over Glyphosate Evidence*, Reuters (June 14, 2017), https://reut.rs/370z8wf.

One of the largest and best surveys of the effects of pesticide use on humans is the Agricultural Health Study, a study of about 89,000 American agricultural workers that has been gathering detailed health information for 25 years. Blair played a key role in a research study based on AHS data. In 2013, the researchers issued a draft report that concluded that glyphosate was not a human carcinogen. Yet when the final study was published, it omitted any discussion of glyphosate.

Blair said that the glyphosate material was deleted from the published study "because there was too much to fit into one scientific paper." Kelland, *supra*. But independent scientists who reviewed the draft study found no legitimate reason to exclude the glyphosate findings. *Id.* Blair conceded that the material exonerated glyphosate and would have affected IARC's final determination had it been presented. *Id.* The material was never considered by the IARC working group, however, because Blair hid it. This suggests that Blair deliberately concealed his research findings—not the type of conduct one would expect from a scientist supervising a purportedly unbiased study of glyphosate.

So the scientific evidence shows that glyphosate is not a carcinogen. Every reputable scientific body to examine the issue, including

California's regulator and EPA, reached this result. The only contrary finding comes from a group that was infiltrated by the plaintiffs' bar's moles. Requiring a glyphosate warning thus undermines Congress's goal of ensuring that pesticide labels present only information that is scientifically accurate. This causes consumers to pay less attention to the warnings on pesticide labels backed by rigorous scientific inquiry.

B. Companies Will Not Invest In Pesticides If They Will Face Liability For Complying With Federal Law.

If this Court declines to hear this appeal, immense consequences will follow. One of the main reasons that companies are willing to devote limited resources to developing and distributing pesticides is that they are protected from frivolous state-law claims. They understand that, under FIFRA and this Court's precedent, state-law claims for adhering to EPA regulations are preempted by federal law. But if the Court of Appeal's decision stands, this assurance will vanish. Companies will have to face the impossible choice of either complying with federal law or risking billions of dollars in state-law damages.

When faced with potential liability that dwarfs possible profits, the companies may decide that the risks outweigh the rewards. This means companies will produce fewer effective pesticides. And fewer effective pesticides means less, and more expensive, food.

"Pesticides play an important role in making sure there is enough food for everyone, by protecting crops from pests like insects, weeds, and fungal diseases." *Pesticides and food safety*, Government of Canada (Jan. 18, 2021), https://bit.ly/3uhVOkq; *see Improved Management of Herbicides in Conservation Agriculture Systems Using Nuclear Techniques*, Int'l Atomic Energy Agency, https://bit.ly/3JfL3n3 (last visited Apr. 18, 2022) ("The use of herbicides is one of the potential factors that make agricultural intensification economically viable, hence improve food security."). Glyphosate is one of the three most popular pesticides. *See id.*

If companies must stop innovating and cannot use glyphosate for fear of failure-to-warn liability, farmers will have to use less-effective pesticides. That will lead to lower food yields. Then the laws of supply and demand will take over and food prices will rise. The poorest among us will be unable to put food on the table or will have to choose between medicine and food.

Although this may appear to be a one-off decision, the lynchpin to our nation's pesticide industry is the predictability of federal law. If a single state court can go off the rails and impose billions of dollars in costs, then companies must factor that into their cost-benefit analysis. Many may decide that the intolerable risk is not worth taking.

So the legal problems with the Court of Appeal's decision is not the only reason to grant review here. This case affects the wider pesticide industry. Blessing—through silence—the Court of Appeal's opinion will discourage innovation. This

Court should not take that risk. Rather, it should hear this case and reaffirm the supremacy of federal law.

II. THIS CASE COULD RESOLVE UNCERTAINTY ABOUT IMPLIED PREEMPTION IN OTHER AREAS.

This case would clarify the scope of implied preemption under FIFRA. But it would also help clarify implied preemption in other areas too. State courts continue to incorrectly hold that federal laws do not impliedly preempt state laws about labeling—even when it is impossible to comply with both regulatory schemes. This case presents the Court with the opportunity to fix the problem.

The Court of Appeal tried to distinguish this case from those under the Food, Drug, and Cosmetic Act. *See* Pet. App. 29a-30a. But as described in the Petition (at 16-17), the preemption analysis under FIFRA is virtually the same as that under the FDCA. So it comes as no surprise that a split is also present among lower courts about the breadth of preemption for drug labels. A failure-to-warn claim is preempted by the FDCA if (1) the warning could not have been added without prior FDA approval, *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617-19 (2011), or (2) there is "clear evidence" that the FDA would not approve a warning required under state law. *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1672 (2019) (quoting *Wyeth v. Levine*, 555 U.S. 555, 571 (2009)).

Some courts have properly applied the FDCA's preemption claim by holding that, under the FDCA, drug companies cannot unilaterally change a drug's label to warn of off-label uses. *Byrd v. Janssen*

Pharm., Inc., 333 F. Supp. 3d 111, 117, 120 (N.D.N.Y. 2018); *see* 21 C.F.R. §§ 201.57(a)(6), (a)(7), (a)(10), (a)(11), (c)(2)(ii). But other courts have reached the opposite conclusion. In these courts' views, state failure-to-warn claims for off-label use are not preempted by this statutory and regulatory structure. *See, e.g.*, *A.Y. v. Janssen Pharms. Inc.*, 224 A.3d 1, 17 (Pa. Super. 2019).

So this Court can clarify implied preemption under both FIFRA and the FDCA by granting the Petition. It should seize the day and give lower courts direction on how to apply the Court's preemption precedent. The Court should not allow state courts to continue to ignore that precedent and permit failure-to-warn claims for labels regulated by federal agencies.

III. REVIEW IS NEEDED TO CLARIFY THE LIMITS ON PUNITIVE-DAMAGES AWARDS.

Many courts continue to ignore due-process limits on punitive damage awards, which were already "well established" two decades ago. *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 416 (2003). Ignoring due-process principles deprives defendants of their right to "fair notice * * * of the severity of the penalty that a State may impose." *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 574 (1996) (citations omitted). This leads to an "arbitrary deprivation of property" by punitive damages bearing no relation to the plaintiffs' injury. *Honda Motor Co. v. Oberg*, 512 U.S. 415, 432 (1994). The decision here is particularly egregious because it is based on junk science that EPA and almost every other scientific body in the world has rejected.

In *State Farm*, the Court said that "[w]hen compensatory damages are substantial," a 1:1 ratio between compensatory damages and punitive damages may "reach the outermost limit of the due process guarantee." 538 U.S. at 425. Some courts have disregarded this guidance as nonbinding "dicta." *E.g.*, *Cote v. Philip Morris USA, Inc.*, 985 F.3d 840, 849 (11th Cir. 2021) (citation omitted). Other courts have taken this Court at its word and imposed a 1:1 limit on punitive damages when there is a substantial compensatory award. *E.g.*, *Saccameno v. U.S. Bank Nat'l Ass'n*, 943 F.3d 1071, 1090 (7th Cir. 2019).

Although the exact line of what is substantial is blurry, the judgment here meets any standard for a substantial award. For example, the Tenth Circuit has held that a $630,000 award is substantial. *Jones v. United Parcel Serv., Inc.*, 674 F.3d 1187, 1208 (10th Cir. 2012). In the Sixth Circuit, $400,000 suffices. *Bach v. First Union Nat. Bank*, 486 F.3d 150, 156 (6th Cir. 2007). The judgment here is 27 times the size of a substantial award in the Tenth Circuit and 42 times the size of a substantial award in the Sixth Circuit. So it qualifies as substantial under any test.

B. Despite the Court's prior reluctance to specify "a bright-line ratio," *State Farm*, 538 U.S. at 425, the Court should impose a firm 1:1 cap on the ratio of punitive to compensatory damages when compensatory damages are substantial. Such a cap would ensure that punitive damages bear some reasonable relationship to the harm and stay within constitutional bounds.

Developments after *State Farm* show why the Court should draw a bright-line ratio for punitive

damages to substantial compensatory damages. Despite hopes that *State Farm* would ensure defendants knew of their punitive-damage exposure, it did not "reduce the inconsistency or unpredictability of punitive damages awards." Laura J. Hines & N. William Hines, *Constitutional Constraints on Punitive Damages: Clarity, Consistency, and the Outlier Dilemma*, 66 Hastings L.J. 1257, 1257 (2015).

To solve the problem in maritime suits, the Court held that a 1:1 ratio was the maximum permissible punitive damages award after a $500 million compensatory-damages award. *Exxon Shipping Co. v. Baker*, 554 U.S. 471, 514-15 (2008) (citing *State Farm*, 538 U.S. at 425). The Court should also place a 1:1 cap on non-maritime punitive-damage awards. This is the only way that defendants will have notice of potential liability—notice that is required by the Due Process Clause.

Exxon's concerns about predictability and fairness apply equally in non-maritime cases. *See* Jill Wieber Lens, *Procedural Due Process and Predictable Punitive Damage Awards*, 2012 B.Y.U. L. Rev. 1, 25 (2012). "The real problem" is "the stark unpredictability of punitive damage awards," which "leads to inconsistency because two cases involving very similar facts can produce dramatically different punitive awards." *Id.* at 4, 7 (cleaned up). The Court of Appeal's decision highlights those concerns. In most States and regional circuits, a failure-to-warn suit over a nonexistent threat from glyphosate would result in plaintiffs' counsel paying substantial sanctions. It may even result in disciplinary proceedings for filing frivolous claims. But in

California and the Ninth Circuit, plaintiffs' counsel can laugh all the way to the bank with their substantial contingency fees.

The solution is a 1:1 ratio between punitive damages and substantial compensatory damages. *Exxon*, 554 U.S. at 514-15. The 1:1 ratio used in *Exxon* was not based on unique aspects of maritime law. Rather, it was based on the median ratio of state-court awards. *See id.* at 512-13. This shows that the 1:1 ratio that the Court adopted for maritime cases in *Exxon* is also appropriate in other civil cases.

This case presents a good vehicle for the Court to address the issue. It is undisputed that the judgment here is substantial. So the Court wouldn't have to decide that issue. And Monsanto's conduct was completely legal. It operated under federal law, which preempts conflicting state laws. Thus, the Court need not examine egregious factual findings. The Court should therefore grant the Petition to also clarify the constitutional limits on punitive damages.

CONCLUSION

The Court should grant the Petition.

Respectfully submitted,

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