No. 24-1068

In the Supreme Court of the United States

MONSANTO COMPANY,
Petitioner,

v.

JOHN L. DURNELL,
Respondent.

On Writ of Certiorari to the
Missouri Court of Appeals

BRIEF FOR THE AMERICAN ASSOCIATION FOR JUSTICE AND PUBLIC JUSTICE AS AMICI CURIAE SUPPORTING RESPONDENT

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INTEREST OF AMICI CURIAE

The American Association for Justice (AAJ) is a national, voluntary bar association established in 1946 to strengthen the civil justice system, preserve the right to trial by jury, and protect access to the courts for those who have been wrongfully injured. With members in the United States, Canada, and abroad, AAJ is the world's largest plaintiffs' trial bar. AAJ's members primarily represent plaintiffs in personal injury actions, employment rights cases, consumer cases, and other civil actions—including product liability claims for injuries caused by pesticides such as Roundup.

Throughout its nearly 80-year history, AAJ has served as a leading advocate for the right of all Americans to seek legal recourse for wrongful conduct. AAJ has a strong interest in preserving the rights of all persons who have been injured by Roundup—and other dangerous products—to obtain justice via the tort system. Based on its members' experience with pesticide-related tort litigation—and its organizational concern for the development of the law in this area—AAJ is well-positioned to explain why the expansion of federal preemption Monsanto urges in this case is both ill-conceived and contrary to precedent.

Public Justice is a national public interest legal advocacy organization that specializes in precedent-setting and socially significant civil litigation. Public Justice maintains an Access to Justice Project dedicated to ensuring that consumers, workers, and others can obtain redress through the civil justice system. Consistent with that goal, Public Justice has long fought excessive federal preemption of state-law claims in cases involving dangerous products. As part of that work, Public Justice has represented plaintiffs or participated

as amici in numerous cases urging courts to hold that state failure-to-warn claims involving Roundup are not preempted, and it does so again here.

INTRODUCTION AND SUMMARY OF ARGUMENT

The history of pesticide regulation in the United States is primarily a history of state law, and nothing in FIFRA's text or structure suggests that Congress intended to change that. "The purpose of Congress," of course, "is the ultimate touchstone" in any preemption analysis. *Wyeth v. Levine*, 555 U.S. 555, 565 (2009). And this Court will not assume a congressional purpose to strip states of their traditional authority to protect the health and safety of their citizens unless that purpose is "clear and manifest." *Id.*

Here, Congress did nothing to suggest that it intended to limit the states' historic authority to regulate dangerous chemicals within their borders—much less did it make that purpose "clear and manifest." "To the contrary, the statute leaves ample room for States and localities to supplement federal efforts." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 442 (2005). FIFRA's statutory language reflects a deliberate choice: a limited federal system of labeling regulation supplemented by traditional forms of state regulation and common-law enforcement. Protecting the balance that Congress struck honors congressional intent while preserving the states' sovereign authority to regulate "in a field which [they] have traditionally occupied." *Wyeth*, 555 U.S. at 565.

Congress's decision to preserve historic state regulation and common-law enforcement is subject only to a narrow exception preempting state labeling requirements that are "in addition to or different from"

FIFRA's own. *Bates*, 544 U.S. at 431 (quoting 7 U.S.C. § 136v(b)). State common-law claims that *parallel* FIFRA's requirements are therefore not preempted. And that is the case with Missouri's common-law cause of action for failure to warn. Monsanto's duty under Missouri law is substantially the same as its duty under FIFRA: Both require it to adequately warn users of the potential dangers of its product with warnings that are adequate and necessary to avoid injuring consumers. Because state failure-to-warn laws impose requirements similar to FIFRA's—not new or different ones—the statute does not preempt them.

To read FIFRA as barring such state-law claims would effectively immunize manufacturers of dangerous products from accountability under state law—seriously undermining the states' longstanding authority to protect their citizens against deadly chemicals within their borders. Congress, however, enacted FIFRA against a backdrop of entrenched state authority over pesticide regulation—a backdrop that triggers the well-settled presumption that Congress does not lightly displace the states' historic police powers. Thus, "in all pre-emption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied," this Court starts with the "assumption that the historic police powers of the States were not to be superseded" absent "the clear and manifest purpose of Congress." *Wyeth*, 555 U.S. at 565.

The broad interpretation of FIFRA's express-preemption provision adopted by the Solicitor General and Monsanto also runs afoul of the "major questions doctrine," which this Court has articulated in recent decisions like *Learning Resources, Inc. v. Trump*, 146 S. Ct. 628, 641 (2026). The doctrine applies when an agency

asserts "unprecedented" authority to "intrude[] into an area that is the particular domain of state law." *Alabama Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 594 U.S. 758, 764–65 (2021). By holding that the EPA's authority to approve labels silently preempts the states' historic authority to protect the health and safety of their citizens, Monsanto's position would do exactly that. FIFRA's narrow preemption of state requirements that are "in addition to or different from" its own cannot plausibly bear the weight of wiping out common-law tort claims nationwide. Congress does not hide elephants in mouseholes, and if it really intended to deprive injured parties of traditional common-law remedies provided by the states, it would have said so much more explicitly.

Nor is there any basis for applying the "demanding defense" of implied preemption under FIFRA. *Wyeth*, 555 U.S. at 573. Impossibility preemption requires more than just a "hypothetical or potential conflict" between state and federal law. *Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982). Given the historic role that state law plays in regulating health and safety, establishing impossibility requires a manufacturer to show through "clear evidence" that it "fully informed" the agency "of the justifications for the warning required by state law," but that the agency "would not approve a change." *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 303 (2019). But as Missouri's court of appeals recognized in rejecting Monsanto's preemption defense, the company did neither here: "The record contains no evidence that [it] either informed the EPA of the justifications for a change to its warning label or that the EPA … would not approve such a warning." Pet. App. 9.

This Court should affirm the court of appeals' decision. If the Court were to adopt Monsanto's position

instead, it would close the courthouse doors to many Americans who have been harmed by unreasonably dangerous products. It would also shield manufacturers from any accountability for marketing unsafe products, incentivizing them to use their resources to pressure regulatory agencies for some basis to argue impossibility preemption instead of compensating injured consumers or improving the safety of their products. At bottom, Monsanto's bid for immunity is based not on federal law but on informal agency actions (or even inaction). The Supremacy Clause, as this Court has repeatedly made clear, demands more.

ARGUMENT

I. The EPA's decisions to register glyphosate and approve Monsanto's label do not preempt state failure-to-warn claims.

A. When Congress enacted FIFRA, it did so against a backdrop of robust and longstanding state-law enforcement.

1. Before FIFRA, the regulation of pesticides had long been the province of the states, which "provided the primary and possibly the exclusive source of regulatory control over the distribution of poisonous substances." *Bates*, 544 U.S. at 437.[1] And the states have long relied on their common-law tort systems as the primary means of protecting citizens from dangerous chemicals. "Courts entertained tort litigation against pesticide manufacturers since well before the passage of FIFRA in 1947, and such litigation [remained] a common feature of the legal landscape" after its passage. *Id.* at 440–41. That history reflects what this Court described in *Bates* as "a long

[1] Unless otherwise specified, all internal quotation marks, citations, and alterations are omitted from quotations throughout.

available form of compensation" rooted in the "history of tort litigation against manufacturers of poisonous substances." *Id.* at 449.

Missouri's tort system exemplifies this tradition. The "core concern in strict tort liability law is safety," *Nesselrode v. Exec. Beechcraft, Inc.*, 707 S.W.2d 371, 375 (Mo. 1986), and Missouri's common law addresses that concern by serving to "deter harmful conduct and to ensure that innocent victims of that conduct will have redress." *Elam v. Alcolac, Inc.*, 765 S.W.2d 42, 176 (Mo. Ct. App. 1988). The state's tort law also serves to notify consumers of risks to their "well-being, health and very lives"—risks about which they would otherwise "know little or nothing." *Morrow v. Caloric Appliance Corp.*, 372 S.W.2d 41, 55 (Mo. 1963). And it ensures "that the costs of the pervasive injury which result from mass exposure to toxic chemicals [are] borne by those who can control the danger and make equitable distribution of the losses, rather than by those who are powerless to protect themselves." *Elam*, 765 S.W.2d at 176; *see also Elmore v. Owens-Illinois, Inc.*, 673 S.W.2d 434, 438 (Mo. 1984); *Morrow*, 372 S.W.2d at 54. Tort liability rules "promote care and punish neglect by placing the burden of their breach on the person who can best avoid the harm." *Zueck v. Oppenheimer Gateway Props., Inc.*, 809 S.W.2d 384, 388 (Mo. 1991).

The tort system's role in regulating dangerous products is a traditional exercise of the state's historic police power. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996) (recognizing regulation of health and safety as an area of state police power); *cf. Ex parte Taft*, 225 S.W. 457, 461 (Mo. 1920) (noting the state's traditional authority to protect "the life and health of the citizen"). Tort liability functions not merely as a vehicle

for compensation, but as an enforcement mechanism operating alongside—and filling the gaps left by—state-law statutory and regulatory regimes protecting the public's health and safety. Common-law suits address risks that state agencies cannot fully anticipate or police, deter misconduct that might evade administrative oversight, and surface hazards not yet identified by regulators. *See Wyeth*, 555 U.S. at 578–79; Thomas O. McGarity, *The Preemption War* 237 (2008). History bears this out: Tort litigation has repeatedly exposed dangerous products and prompted regulatory reassessment, label changes, and product withdrawal. *See, e.g.*, *In re Takata Airbag Prods. Liab. Litig.*, 193 F. Supp. 3d 1324 (S.D. Fla. 2016); *In re Silicone Gel Breast Implants Prods. Liab. Litig.*, 887 F. Supp. 1455 (N.D. Ala. 1995); *Grimshaw v. Ford Motor Co.*, 119 Cal. App. 3d 757 (1981).

2. When Congress turned its attention to pesticide regulation in 1947, it did so with full awareness of that historical state role. By then, tort litigation against pesticide manufacturers was already "a common feature of the legal landscape." *Bates*, 544 U.S. at 440–41. And Congress made a deliberate choice to preserve "the States' continuing role in pesticide regulation." *Id.* at 439. Far from displacing traditional state tort-law remedies, Congress established in FIFRA what this Court has described as a "relatively decentralized scheme that preserves a broad role for state regulation." *Id.* at 450.

"Most significantly," states under FIFRA "may ban or restrict the uses of pesticides that EPA has approved." *Id.* Section 136v(a) does so by expressly "confirm[ing] the State's broad authority to regulate the sale and use of pesticides," providing that a state "may regulate the sale or use of any federally registered pesticide or device in the State." *Id.* at 439 (quoting 7 U.S.C. § 136v(a)). "Under

§ 136v(a), a state agency may ban the sale of a pesticide if it finds, for instance, that one of the pesticide's label-approved uses is unsafe." *Id.* at 446. That is true even if the state's conclusion contradicts the EPA's own findings, and even if the ban "induce[s] the manufacturer to change its label to warn against this questioned use." *Id.*

FIFRA's only limitation on state authority is set forth in the Act's preemption clause. 7 U.S.C. § 136v(b). As this Court explained in *Bates*, that "narrow" provision is "fully consistent with the concurrent authority of the Federal and State Governments in this sphere." 544 U.S. at 450–52. Although section 136v(b) "reaches beyond positive enactments … to embrace common-law duties," *id.* at 443, it "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 7 U.S.C. § 136v(b)). As this Court recognized in *Bates*, a common-law labeling requirement under state law is therefore "not pre-empted by § 136v(b) if it is equivalent to, and fully consistent with, FIFRA's misbranding provisions." 544 U.S. at 447. For example, a state-law tort claim challenging specific labeling language mandated by a duly promulgated EPA regulation would be preempted. *Id.* at 453. But a claim challenging an EPA-approved label based on a state-law standard that mirrors FIFRA's own requirements would not be. *See id.* at 447.

That conclusion is reinforced by *Bates*'s recognition that, "[a]s a part of their supplementary role," states retain "ample authority to review pesticide labels to ensure that they comply with both federal and state labeling requirements." *Id.* at 442. Indeed, "[n]othing in the text of FIFRA would prevent a State from making the violation of a federal labeling or packaging requirement a

state offense, thereby imposing its own sanctions on pesticide manufacturers who violate federal law." *Id.*

3. Missouri's failure-to-warn claim satisfies that standard. Under Missouri law, a claim for failure to warn "requires a plaintiff to prove … that a defendant did not give adequate warning of the danger of a product, and contains no element requiring proof of the defendant's knowledge or intent." *Durnell v. Monsanto Co.*, 707 S.W.3d 828, 832 (Mo. Ct. App. 2025). And FIFRA similarly prohibits labels that lack warnings "'necessary' and 'adequate' to protect human health." *Hardeman v. Monsanto Co.*, 216 F. Supp. 3d 1037, 1038 (N.D. Cal. 2016); *see* 7 U.S.C. §§ 136(q)(1)(A), (F), (G). Specifically, the statute authorizes the EPA to seek civil and criminal penalties against the manufacturer of a registered pesticide that the agency determines is "misbranded." *Bates*, 544 U.S. at 439 n.11. A duly registered pesticide is misbranded under FIFRA if the label "does not contain adequate instructions for use, or if its label omits necessary warnings or cautionary statements." *Id.* at 438 (explaining that "it is unlawful under the statute to sell a pesticide that is registered but nevertheless misbranded"). This "prohibition on misbranding effectively imposes a strict-liability standard," imposing a continuing obligation that holds a manufacturer liable for omitting a warning regardless of "knowledge or intent." *Carson v. Monsanto Co.*, 92 F.4th 980, 991 (11th Cir. 2024).

Missouri's strict-liability cause of action for failure to warn imposes the same substantive obligation. As the court of appeals held in this case, the "practical effect of both FIFRA's prohibition on misbranding under section 136(q)(1)(G)" and Missouri's state-law tort "are the same: both require a pesticide manufacturer to adequately warn

users of the potential dangers of using its product, regardless of the manufacturer's knowledge or intent." *Durnell*, 707 S.W.3d at 833. And because the state-law claim enforces FIFRA's substantive obligation through a traditional state remedy rather than imposing anything "in addition to or different from" federal requirements, it is not preempted. *Id.*

Courts across the country have reached the same conclusion, holding that FIFRA does not restrain the states' traditional powers to regulate labeling using common-law duty-to-warn claims. *See, e.g.*, *Dennis v. Monsanto Co.*, 116 Cal. App. 5th 322, 333 (Cal. Ct. App. 2025) (recognizing that FIFRA "expressly allows states to continue their own regulatory efforts"); *see also Caranci v. Monsanto Co.*, 338 A.3d 151 (Pa. Super. Ct. 2025); *Johnson v. Monsanto Co.*, 554 P.3d 290 (Or. Ct. App. 2024). Just as a failure-to-warn claim requires "manufacturers of pesticides to provide a label that warns of health risks," these courts have recognized, "FIFRA requires [them] to include on their labels a warning or caution statement that is adequate to protect health and the environment." *Caranci*, 338 A.3d at 168 (holding that FIFRA's requirements are similar enough to those of state-law failure-to-warn claims that state law is not preempted).

4. State tort law does not merely coexist with FIFRA's requirements—it actively supports and supplements them. As this Court recognized in *Bates*, "[p]rivate remedies that enforce federal misbranding requirements … aid, rather than hinder, the functioning of FIFRA." 544 U.S. at 451. That's because "the threat of a damages remedy will give manufacturers an additional cause to comply" with their obligations under federal law. *Id.* at 448. And "history emphasizes the importance of providing

an incentive to manufacturers to use the utmost care in the business of distributing inherently dangerous items." *Id.* at 450. The "under-enforcement" of their obligations "creates not only financial risks for consumers, but risks that affect their safety and the environment as well." *Id.*

Moreover, "FIFRA contemplates that pesticide labels will evolve over time, as manufacturers gain more information about their products' performance in diverse settings." *Id.* at 451. State-law "tort suits can serve as a catalyst in this process: By encouraging plaintiffs to bring suit for injuries not previously recognized as traceable to pesticides," state litigation can expose new dangers, prompt manufacturers to petition the EPA for more detailed labeling, and supply the agency with information it would not otherwise have. *Id.* at 451. The "specter of damage actions," moreover, "may provide manufacturers with added dynamic incentives to continue to keep abreast of all possible injuries stemming from use of their product" and make improvements to avoid suit. *Id.*

This gap-filling function is critical because the EPA cannot do it alone. The agency operates with finite resources and depends substantially on information supplied by the regulated entities themselves. *See Wyeth*, 555 U.S. at 578. There are more than 57,000 pesticides registered under FIFRA, and the EPA cannot continuously monitor every one or anticipate every risk associated with every possible use. *See* EPA, Active Pesticide Product Registration Informational Listing, *at* https://perma.cc/59TT-QU9Y. When that process fails—when registrants supply incomplete data, or when risks emerge only after years of exposure—state tort law is among the few mechanisms available to surface those risks and protect the public.

The alternative reading would be both anomalous and harmful. Interpreting section 136v(b) to bar state failure-to-warn claims would confer virtual immunity on pesticide manufacturers—eliminating a critical safeguard against dangerous products and stripping states of their sovereign authority to protect their citizens. *See Medtronic*, 518 U.S. at 487. That reading would also produce a structural contradiction: Congress's express preservation of the states' authority to ban a pesticide outright—a far more drastic intervention—cannot be reconciled with a construction of FIFRA that forbids the far less restrictive remedy of awarding damages for failure to warn. *See Bates*, 544 U.S. at 446; 7 U.S.C. § 136v(a). Congress does not hide elephants in mouseholes, and it does not silently eliminate centuries-old remedies while expressly preserving even broader state powers.

B. If Congress intended to deprive injured parties of a long-established remedy, it would have said so much more explicitly.

The view of preemption pushed by the Solicitor General and Monsanto asks this Court to read FIFRA as expressing Congress's intent to extinguish decades of state tort law and strip injured plaintiffs of their only meaningful remedy. That is not a reading that this Court should reach easily. The words of a statute must be read "in their context and with a view to their place in the overall statutory scheme." *W. Va. v. EPA*, 597 U.S. 697, 721 (2022). When a reading would displace the states' historic police powers, or confer vast and previously unacknowledged authority on a federal agency, courts demand that Congress say so clearly. Here, it did not.

1. Because "Congress legislated here in [a] field which the States have traditionally occupied," any preemption

analysis must "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). That "presumption against pre-emption" affords "respect for the States as independent sovereigns in our federal system," *Wyeth*, 555 U.S. at 565 n.3, and reflects a recognition that Congress's decision to "legislate in areas traditionally regulated by the States" is "an extraordinary power" that Congress "does not exercise lightly." *Gregory v. Ashcroft*, 501 U.S. 452, 460 (1991). Refusing to exercise caution on questions of preemption jeopardizes the "validity and effectiveness" of state laws that Congress did not intend to displace and a state's own determination of what is "important to its scheme of governance." S*ee Ariz. v. Inter Tribal Council of Ariz., Inc.*, 570 U.S. 1, 21 (2013) (Kennedy J., concurring).

This principle is at its strongest here because the regulation of dangerous substances implicates the states' paramount interest in protecting the health and safety of their citizens. Because matters of health and safety are "primarily, and historically, matters of local concern," states traditionally enjoy "great latitude" under their police powers to regulate in those areas. *Medtronic*, 518 U.S. at 475. And the "long history of tort litigation against manufacturers of poisonous substances adds" further "force to the basic presumption." *Bates*, 544 U.S. at 449. "[B]ecause the States are independent sovereigns in our federal system," this Court has "long presumed that Congress does not cavalierly pre-empt state-law causes of action." *Medtronic*, 518 U.S. at 485 (applying the presumption to claimed preemption of state common-law claims). That is true notwithstanding the fact that the federal government "has regulated drug labeling for

more than a century." *Wyeth*, 555 U.S. at 565 n.3. "The presumption … accounts for the historic presence of state law but does not rely on the absence of federal regulation." *Id.*

The "effect" of this principle is to "support, where plausible, 'a narrow interpretation' of an express pre-emption provision." *CTS Corp. v. Waldburger*, 573 U.S. 1, 19 (2014). Thus, "without clear manifestation of congressional purpose," there can be no preemption of state warning-label requirements. *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 387 (2002). "In areas of traditional state regulation," this Court "assume[s] that a federal statute has not supplanted state law unless Congress has made such an intention 'clear and manifest.'" *Bates*, 544 U.S. at 449.

Congress has not done so here. Given FIFRA's narrow preemption language and express preservation of the states' continuing role in regulating dangerous chemicals, it cannot be said that Congress "clear[ly] and manifest[ly]" preempted state failure-to-warn claims. Even if there were "a plausible alternative reading of § 136v(b)" that preempted such claims, this Court "would nevertheless have a duty to accept the reading that disfavors pre-emption." *Id.* at 449.

2. Reading the scope of FIFRA preemption narrowly also respects this Court's presumption against an agency's unprecedented and expansive assertion of broad authority over matters outside its normal ken—what this Court in recent cases has denominated the "major-questions doctrine." Like the "presumption against preemption in matters of traditional state control," *Massachusetts v. U.S. Dep't of Transp.*, 93 F.3d 890, 895 (D.C. Cir. 1996), "the major questions doctrine is a tool of statutory interpretation," *Save Jobs USA v. U.S. Dep't of*

Homeland Sec., Off. of Gen. Couns., 111 F.4th 76, 80 (D.C. Cir. 2024). Its "function … is simple—to help courts figure out what a statute means." *Id.*

The doctrine comes into play when "the history and the breadth of the authority that [the agency] has asserted … provide[s] a reason to hesitate before concluding that Congress meant to confer such authority." *West Virginia*, 597 U.S. at 721. In *Alabama Association of Realtors v. Department of Health & Human Services*, for example, the Court reinstated a district court's decision invalidating a moratorium on evictions imposed by the Centers for Disease Control to slow the spread of COVID-19. 594 U.S. 758, 764–65 (2021). The CDC, the Court explained, was claiming a "vast" power, of a type never before asserted, in "an area that is the particular domain of state law: the landlord-tenant relationship." *Id.* at 764.

Likewise, the Solicitor General and Monsanto claim that the EPA has the authority—simply by approving a label—to preempt the traditional role of states in protecting their residents. That would significantly alter the balance of federal and state power, working an "unprecedented" expansion of authority to "intrude[] into an area" that has historically been "the particular domain of state law." *Id.* The "lack of historical precedent" for the EPA's claimed authority "is a telling indication" that the authority is beyond the agency's "legitimate reach." *Learning Res., Inc. v. Trump*, 146 S. Ct. 628, 641 (2026).

If the EPA's determinations could so easily preempt state law, FIFRA would wipe out state-law warning claims involving federally registered products. That would "create[] not only financial risks for consumers, but risks that affect their safety and the environment as well." *Bates*, 544 U.S. at 450. "It is difficult to believe that

Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984). The implications for federalism (not to mention public safety) would be unacceptable in any case, but it is especially intolerable in the context of a statute like FIFRA, which was designed to ensure that states have concurrent authority to protect the public from hazardous products. *See Bates*, 544 U.S. at 450–51. For similar reasons, this Court in *Wyeth* declined to hold that FDA approval implicitly preempted state failure-to-warn claims, in part because accepting that reading would mean the agency had been silently exercising a vast preemptive power for decades without anyone noticing. 555 U.S. 555.

If Congress really "wishes to significantly alter the balance between federal and state power," as Monsanto claims it has done here, this Court requires it to do so in "exceedingly clear language." *Alabama Ass'n of Realtors*, 594 U.S. at 764. Even if the statutory text could be read to delegate the asserted power, the "context" counsels "skepticism" that Congress would have delegated "highly consequential power" through ambiguous language. *Learning Res.*, 146 S. Ct. at 639. "Congress … does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001). Instead, "something more than a merely plausible textual [statutory] basis for the agency action is necessary." *West Virginia*, 597 U.S. at 723.

Accordingly, the EPA must "point to clear congressional authorization" to justify its extraordinary assertion of power to foreclose the authority of states to protect their own citizens from dangerous chemicals. *Id.*

at 774. And again, it cannot do so. Nothing in FIFRA purports to preempt the authority of states to protect the health and safety of their own citizens. On the contrary, the statutory language reflects Congress's intent to ensure that this authority is preserved. To instead preempt state causes of action "would be inconsistent with—in fact, would overthrow—the Act's structure and design." *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 321 (2014).

The closest that Congress came in FIFRA is in the provision preempting state-law requirements that are "in addition to or different from" FIFRA's own requirements. 7 U.S.C. § 136v(b). But that language, on its face, just imposes a narrow restriction on *conflicting* state labeling rules. That innocuous phrase cannot bear the weight of wiping out common-law tort claims nationwide. As this Court noted in *Bates*, "it seems unlikely that Congress considered a relatively obscure provision like § 136v(b) to give pesticide manufacturers virtual immunity from certain forms of tort liability." 544 U.S. at 450. "If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly." *Id.* at 449–50.

II. There is no implied preemption here, either.

A. Under this Court's settled approach to impossibility preemption, failure-to-warn claims must be allowed to proceed unless a manufacturer can clearly show actual impossibility.

Implied preemption is, as this Court has held time and again, "a demanding defense." *Wyeth*, 555 U.S. at 573. In conducting the analysis, the Court does not countenance "freewheeling judicial inquiry into whether a state statute

is in tension with federal objectives," but only "whether the ordinary meanings of state and federal law conflict.'" *Id.* at 588 (Thomas, J., concurring in judgment). In the case of implied impossibility preemption, that conflict must make it "*impossible* for a private party to comply with both state and federal requirements." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011) (emphasis added). As this Court made clear in *Merck*, impossibility preemption does not deal in hypotheticals. *See* 587 U.S. at 315. To answer it, a "judge must simply ask himself or herself whether the relevant federal and state laws 'irreconcilably conflict.'" *Id.*

This understanding follows from settled preemption principles. It is "not enough," the Court has held, for there to be a "possibility of impossibility." *Id.* at 314 (emphasizing that, "where the laws of one sovereign permit an activity that the laws of the other sovereign restrict or even prohibit," there is no impossibility preemption). Instead, impossibility exists only where federal law *actually* "prohibit[s] the … manufacturer from adding any and all warnings to the … label that would satisfy state law." *Id.* at 313-14. And that remains true, the Court held, even where an agency still has the "authority to reject labeling changes" to a product. *Id.* at 312. Regardless of an agency's authority, the manufacturer bears the "ultimate responsibility for its label"; it therefore cannot avoid "state laws that would penalize [it] for failing to warn consumers of the risks" associated with its product without clearly showing that compliance would in fact force it to violate federal law. *Id.*

This Court in *Wyeth* announced a series of "cornerstone[]" principles to govern the analysis when a manufacturer argues that it is impossible for it to comply with both state-law labeling obligations and its federal

labeling duties. 555 U.S. at 565. There, the plaintiff sued a drug manufacturer for failing to add a warning about the risk of gangrene from a drug's intravenous administration. *See id.* at 571. The manufacturer argued that it could not have adopted the warning because federal regulations prevented it from changing its drug's label. *See id.* at 570–71.

This Court, however, rejected that "cramped reading" of the regulation, holding that the failure-to-warn claim was not preempted. *Id.* at 570. The Court noted that the federal agency's regulatory process permitted manufacturers to add new warnings to their labels, which meant that Wyeth "could have … added a stronger warning" about the drug in question. *Id.* at 555. And the Court reinforced that conclusion by recognizing that it is the *manufacturer's* primary responsibility—not the agency's—to ensure that its label is accurate and its product is safe. *Id.* at 568–73; *see also Bates*, 544 U.S. at 438 (noting that "manufacturers have a continuing obligation to adhere to FIFRA's labeling requirements"). The mere possibility that an agency *might* act to reject changes to a label was not enough to trigger impossibility preemption in a failure-to-warn case. *Wyeth*, 555 U.S. at 571. Rather, there must be "clear evidence" that the agency "would not have approved [the] change" in question. *Id.*

This Court in *Merck* further elaborated on the impossibility-preemption standard. Although the Court chose not to "further define *Wyeth*'s use of the words 'clear evidence' in terms of evidentiary standards," it identified the only type of evidence that could count: those "agency actions" taken pursuant to congressionally delegated authority and that "carry[] the force of law"—such as "notice-and-comment rulemaking setting forth

labeling standards" or "formally rejecting a warning label that would have been adequate under state law." 587 U.S. at 315–16 (noting that preemption "takes place only when and if the agency is acting within the scope of its congressionally delegated authority").

The Court's analysis in *Merck* established a two-step framework for determining whether a product manufacturer has met the "demanding defense" of impossibility preemption. *Id.* at 313. *First*, a court must determine whether the manufacturer "fully informed" the agency of a product's risks; if it failed to do so, the inquiry stops there, and no impossibility preemption can exist. *Id.* at 314. *Second*, if (and only if) the agency *was* fully informed of a product's risks, the manufacturer must then show that the agency, acting within the scope of its lawful authority, "would not approve" a change to a product's label. *Id.* In those circumstances—and only those circumstances—a court is justified in reaching a conclusion that state-law failure-to-warn claims are preempted.

The Third Circuit's decision in *In re Avandia Marketing, Sales and Products Liability Litigation*, 945 F.3d 749 (3d Cir. 2019), illustrates how this approach works in practice. A manufacturer sought to bar state-law failure-to-warn claims under an impossibility-preemption defense by arguing first that it "fully informed" the agency about the product's safety risks because it "provided all 'material' information" to the agency and second that the agency had actually "rejected the proposed warning." *Id.* at 758.

The Third Circuit rejected both claims, holding that the manufacturer had "failed to satisfy either prong of *Merck*'s two-prong test." *Id.* For starters, the court explained that the manufacturer had "not shown" that it

fully informed the agency "of the justification[] for the warning required by state law" because the agency itself had found the information provided to be "inadequate" and informed the manufacturer that it "needed to submit various data and information in order to address the deficiency." *Id.* The manufacturer had argued that none of the additional requested information was "'material' to its proposed warning," but the Third Circuit flatly dismissed this argument. *Id.* at 759. A manufacturer "is not the arbiter of which data and information is or is not 'material'" to an agency's decision "to approve or reject a change to a [product's] label." *Id.* Instead, it is the agency that can "determine what information is 'material' to *its own* decision to approve or reject a labelling change." *Id.* And, the Third Circuit went on to explain, the question of whether an agency was fully informed must be "tethered in time to the question of whether the [agency] indeed rejected the proposed warning." *Id.* Were it otherwise, "the 'fully informed' prong of the test espoused in *Merck* would be rendered superfluous." *Id.*

The court also rejected the manufacturer's effort to show that the agency actually "rejected the proposed warning." *Id.* at 759–60. The manufacturer attempted to point the court to an agency letter stating that the manufacturer's request for a label change was "not approvable." *Id.* at 759. But the court explained that the agency refused to approve the label "because the information presented" was "inadequate"—not because the agency "was unconvinced of the need for a strong warning." *Id.* at 759–60. "At most," the court explained, the letter indicated that it was "*possible*" that the agency "could have rejected the label change *after* receiving the various data and information it requested." *Id.* at 760. But, the court reiterated, "the possibility of impossibility is not enough." *Id.*

B. Monsanto has failed to meet its demanding burden here.

Given that settled framework, Monsanto's arguments in support of impossibility preemption cannot succeed. Just as in *Avandia*, because Monsanto failed to fully inform the EPA of Roundup's risks and failed to present evidence that the agency specifically rejected a proposed warning label, it "has failed to satisfy either prong of *Merck*'s two-prong test." 945 F.3d at 758.

1. Consider first Monsanto's argument that the EPA is "fully informed" of Roundup's risks. It first relies (at 48) on outdated EPA reviews of the science on glyphosate. And then, falling back, it suggests that, even if these older reviews are insufficient, an informal EPA letter from 2019 stating that glyphosate alone is "not likely to be carcinogenic to humans" demonstrates that the agency has been fully informed within the meaning of *Merck*.

But, as explained, it is *Monsanto*'s job, not the EPA's, to evaluate the safety of its own product and inform the agency about what it knows. *See* 40 C.F.R. § 159.184(a)–(b); *Bates*, 544 U.S. at 438 (noting that manufacturers "must submit … supporting data" and "have a continuing obligation to adhere to FIFRA's labeling requirements"). And the record does not show that the EPA has *any* data from Monsanto about whether Roundup causes cancer as it is formulated and sold. *See* Resp. Br. at 47 n.47. In its most recent Interim Registration Review Decision, the agency only confirmed its conclusion that glyphosate *alone* is "not likely to be carcinogenic to humans." Pet. App. 31. Mr. Durnell, however, "introduced evidence suggesting that *formulated* Roundup"—which includes additional ingredients like surfactants—"is more toxic or genotoxic than glyphosate alone." JA 111 (emphasis

added). And Monsanto "never tested the formulated Roundup product," "suggesting that it either knew the results would show that formulated Roundup is carcinogenic or was afraid of the results." *Id.* at 109. Nor has Monsanto "fully informed" the EPA even of the risks of glyphosate alone. As even the government notes (at 10), the EPA's "current reregistration process for glyphosate" in fact "remains ongoing." U.S. Br. at 10.

All this demonstrates why Monsanto cannot satisfy the first step under *Merck*'s framework. Monsanto has never done the tests necessary to fully inform the EPA of Roundup's risks. *See In re Avandia*, 945 F.3d at 759. That alone is enough to preclude impossibility preemption.

2. For the same reasons that it cannot be said to have "fully informed" the EPA of Roundup's danger—including the agency's own admission that its glyphosate "review process" remains ongoing—Monsanto also cannot meet *Merck*'s second requirement: to show that the EPA would have rejected any proposed warnings on Roundup's label. 587 U.S. at 314.

Monsanto's reliance (at 33) on an informal letter that the EPA sent in August 2019 cannot help it here. The letter, once again, was about *glyphosate*—not formulated Roundup. *See* Pet. App. 40 (disapproving of a warning for which "the only basis … is glyphosate"). And, regardless of its contents, this letter is not an exercise of the EPA's congressionally delegated authority and so is incapable of exerting preemptive force. As *Merck* makes clear, when it comes to impossibility preemption, only agency actions taken "within the scope of [an agency's] congressionally delegated authority" can create preemption, "for an agency literally has no power to act, let alone pre-empt the validly enacted legislation of a sovereign State, unless and until Congress confers power upon it" to do so.

587 U.S. at 315; *see also id.* at 328 n.* (Thomas, J., concurring) (noting that "the only proper agency actions are those that are set forth in, or necessarily follow from, the statutory text, and they must have the force of law to be pre-emptive").

FIFRA does not authorize the EPA to use a letter like this one to approve or disapprove a warning label. If the agency determines that a pesticide "does not comply with" FIFRA, it may "issue a notice" either "cancel[ing] its registration or … chang[ing] its classification, or … hold a hearing to determine whether or not its registration should be canceled or its classification changed." 7 U.S.C. § 136d(b). It may also seize or condemn the products, *id.* at § 136k(b); issue orders to stop a pesticide's sale or use, *id.* at § 136k(a); or impose certain penalties for unlawful acts, *id.* at § 136j. The August 2019 EPA letter takes none of these congressionally delegated agency actions—it merely makes a request. And that is not enough.

Indeed, courts have long held that similarly informal agency communications cannot satisfy the impossibility preemption standard. In *Fellner v. Tri-Union Seafoods, LLC*, for instance, an informal letter written by the agency's commissioner offered the opinion that a warning on a tuna can would constitute mislabeling—but, like the EPA's letter, did not take any action in exercise of the agency's authority. 539 F.3d 237, 254–55 (3d Cir. 2008). The Third Circuit held that the letter lacked preemptive effect. *Id.* at 255–56. To preempt state law, the court held, an agency "must actually exercise its authority in a manner in fact establishing the state warning as false or misleading under federal law." *Id.* at 255. "[I]nformal views expressed in [a] Commissioner's letter will not preempt [a] lawsuit." *Id.*; *see also In re Avandia*, 945 F.3d

at 760 (noting that "informal phone conversations" or stock warnings about potential misbranding are not the kind of agency action *Merck* contemplates); *Gustavsen v. Alcon Labs., Inc.*, 903 F.3d 1, 14 (1st Cir. 2018) (rejecting reliance on "sporadic" agency actions "made by mid-level [agency] scientists, or even a single 'reviewer'" because it is "far from clear" that they "reflect the 'fair and considered' judgment of the agency").

So, too, here. Because the August 2019 EPA letter was written by an individual at the Office of Pesticide Programs and took no formal action, it is insufficient to trigger impossibility preemption.

3. At bottom, Monsanto's impossibility-preemption arguments track the hypothetical impossibility approach to preemption that the Court in *Merck* rejected. Monsanto suggests that if it *were* to supplement its label with a warning about the specific risks of Roundup, *then* the EPA would consider the product misbranded. But the EPA has never had occasion to consider the evidence of Roundup's danger to consumers; it has never seen the research about formulated Roundup, which Monsanto has refused to conduct; and the agency's research on glyphosate alone is ongoing and incomplete. *Merck* squarely rejects such a speculative approach to preemption. Adopting Monsanto's position would not only contravene *Merck*, but would also reward manufacturers for sticking their heads in the sand—including those that refuse to conduct studies on their own products' safety.

Monsanto's position on impossibility preemption, if adopted by this Court, would close the courthouse doors to many Americans who have been harmed by unreasonably dangerous products. The immunity Monsanto seeks is not based on federal law, as the Supremacy Clause demands, but on informal agency

actions or even agency inaction. Allowing manufacturers to shield themselves from any accountability for marketing unsafe products based on such informal grounds would incentivize manufacturers to re-direct their resources away from ensuring the safety of their products and toward campaigns designed to pressure regulatory agencies—and even individual regulators—to supply them a basis for arguing impossibility preemption. Neither this Court's preemption decisions nor FIFRA permits such a result.

CONCLUSION

This Court should affirm the Missouri court of appeals' denial of Monsanto's preemption defense.

Respectfully submitted,

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