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

REPLY BRIEF FOR PETITIONER

DAVID M. ZIONTS
MICHAEL X. IMBROSCIO
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street NW
Washington, DC 20001
(202) 662-6000

K. LEE MARSHALL
BRYAN CAVE LEIGHTON PAISNER
Three Embarcadero Center
San Francisco, CA 94111

PAUL D. CLEMENT
Counsel of Record
MATTHEW D. ROWEN
JAMES Y. XI
NICCOLO A. BELTRAMO
CLEMENT & MURPHY, PLLC
706 Duke Street
Alexandria, VA 22314
(202) 742-8900
paul.clement@clementmurphy.com

Counsel for Petitioner

April 17, 2026

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REPLY BRIEF

For 50 years, EPA has exhaustively studied glyphosate and repeatedly determined, pursuant to its delegated registration authority under FIFRA, that glyphosate does not cause cancer. Consistent with that (correct) conclusion, EPA has approved hundreds of labels bearing no cancer warning for Monsanto's Roundup products. Durnell nevertheless seeks to hold Monsanto liable for omitting the cancer warnings that EPA has expressly determined are not required. Given that FIFRA expressly preempts state-law labeling requirements that are "in addition to or different from those required under" the statute, 7 U.S.C. §136v(b), the case for preemption here is straightforward. Indeed, Durnell's label-based failure-to-warn claims are doubly preempted because Monsanto could not unilaterally alter the label's precautionary warnings to include a cancer warning.

Remarkably, Durnell does not deny that the decision below allows state-court juries to consider the same evidence as EPA and come to different conclusions as to what belongs on the label. Rather than shy away from such disuniformity, Durnell leans in, insisting that *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024), silently overruled decades of preemption law. Absent an express delegation of authority to bind the judiciary, which neither FIFRA nor any other statute includes, Durnell insists that juries are free to require warnings in addition to or different from those required by EPA in the registration process. There are ample reasons this theory escaped Durnell and everyone else below. It draws no support from *Loper* and is flatly inconsistent

with the text of §136v(b) and Congress' stated intent to ensure "uniformity" in labeling.

Durnell's other arguments are more conventional, but no more persuasive. The reality is that while Congress preserved a role for states, that role did not extend to safety warnings on the label. There, Congress wanted EPA to instill uniformity and expressly preempted state efforts to supplement or disagree. The decision below cannot be reconciled with Congress' judgment and should be reversed.

ARGUMENT

I. FIFRA Expressly Preempts Durnell's Failure-To-Warn Claim.

A.1. Durnell concedes that his failure-to-warn claim imposes state-law labeling requirements for purposes of §136v(b). He has no real choice given this Court's square holding in *Bates* that FIFRA's express preemption clause applies to requirements imposed by state tort law. *See Bates v. Dow Agrosciences*, 544 U.S. 431, 443 (2005). Durnell also acknowledges that EPA evaluates cancer and other safety risks as part of the registration process, that EPA makes a judgment about the required warnings that must be included on the label, and that those label determinations impose binding federal requirements on Monsanto. And Durnell concedes that the labeling requirements imposed by his Missouri jury differ from those imposed by EPA. That should be fatal under the plain text of §136v(b). Undeterred, Durnell contends he can escape preemption on the theory that the only federal "requirements" that matter for §136v(b) are those imposed by FIFRA itself, not those imposed via EPA's registration decisions under FIFRA. Durnell.Br.20.

Because FIFRA does not explicitly delegate to EPA the "authority to render conclusive pronouncements on the meaning of FIFRA's misbranding provisions" that "bind the judiciary," Durnell asserts that FIFRA's express preemption provision does not bar his (or *any*) failure-to-warn claim. Durnell.Br.22, 24. In his view, state-court juries and EPA can look at the same evidence and come to opposite conclusions about the requisite warnings and one determination takes no precedence over the other.

That remarkable submission is flawed on multiple levels, starting with §136v(b)'s text, which squarely forecloses Durnell's theory that the only federal "requirements" that matter are those imposed directly by the statute. FIFRA preempts state-law requirements "in addition to or different from those required *under*"—not *by*—"this subchapter." 7 U.S.C. §136v(b) (emphasis added). As Monsanto's opening brief explained at length, that choice of preposition was intentional and consequential, signaling Congress' intent to protect decisions made by EPA under the statute from being displaced or supplemented and ensuring the primacy and uniformity of the label approved by EPA as part of the registration process under FIFRA. Monsanto.Br.26-28; *accord* U.S.Br.18.

Durnell's only response is a footnote deriding Monsanto (and the United States) for relying on Congress' "choice of preposition." Durnell.Br.24 n.20. But there is no preposition exception to textualism. Nor could there be, as the key to the meaning of a particular statutory phrase often turns on "so simple a word as a preposition." Antonin Scalia & Bryan

Garner, *Reading Law: The Interpretation of Legal Texts* 71 (2012). That includes the word "under." *See, e.g.*, *Pereira v. Sessions*, 585 U.S. 198, 215 (2018); *Nat'l Ass'n of Mfrs. v. Dep't of Def.*, 583 U.S. 109, 124 (2018). Congress' decision to use "*required under* this subchapter" is especially telling here, because it used "*required by* this subchapter" elsewhere in FIFRA. Monsanto.Br.27 (collecting examples). Not only does Congress know how to use different words—prepositions no less than gerunds, nouns, or verbs—to convey different meanings in the same statute, but its own drafting guides underscore that "by" and "under" convey different meanings, and the latter encompasses regulatory actions taken under the authority granted in the statute. Monsanto.Br.26-28 (citing House and Senate drafting manuals).

2. The problems with Durnell's position go beyond statutory text. It equally defies this Court's precedents. Durnell contends that the relevant question is whether the statute "delegates" the agency "powers to bind the judiciary to its interpretations and applications of the statutory misbranding provisions." Durnell.Br.22. That position is contrary to decades of this Court's caselaw. Take *Riegel v. Medtronic*, 552 U.S. 312 (2008), for example, a case Monsanto and the United States addressed at length. There, this Court held that a similarly worded provision in the Medical Device Amendments preempted state-law tort claims seeking to hold a manufacturer liable for the dangers of a medical device marketed in a form that received FDA premarket approval. *Id.* at 321-22. The MDA no more expressly delegates FDA the authority to "bind the judiciary" to its misbranding determinations than FIFRA expressly grants that authority to EPA. Yet

the Court held that FDA's determinations in the premarket-approval process imposed product-specific federal "requirements under" the MDA that in turn displaced additional or different state-law requirements. *Id.* at 322-23; *see Medtronic v. Lohr*, 518 U.S. 470, 501 (1996). One could have just as easily said there (as Durnell says here) that "[FDA]'s determinations that a label complies with [the MDA]'s misbranding provisions are nothing more than [FDA]'s opinion," Durnell.Br.21, and should not "bind juries under a doctrine akin to nonmutual collateral estoppel," Durnell.Br.17. *Riegel* said the opposite and treated FDA's determinations about the label as binding federal requirements with preemptive effect under the plain terms of a materially identical express preemption clause.

Remarkably, Durnell barely engages with *Riegel*, relegating it to three paragraphs at the very back of his brief. Durnell.Br.49-50. Durnell claims *Riegel* is distinguishable because the MDA "banned manufacturers from altering an FDA-approved device or its labeling absent FDA permission," and "no one in *Riegel* even … argue[d] that the FDA-approved medical device violated the [FDCA's] separate statutory misbranding prohibitions." Durnell.Br.49-50. That is wrong twice over. FIFRA, no less than the MDA, prohibits manufacturers from unilaterally adding a precautionary warning. *See infra*, pp.17-19. And the *Riegel* plaintiffs specifically argued that their claims escaped preemption because they sought "to enforce duties parallel to the MDA's general labeling rules," including the federal-law prohibition on "the marketing of a misbranded product." Pet'rs.Br.41, *Riegel v. Medtronic*, No. 06-179 (U.S. Aug. 27, 2007).

Durnell's purported distinctions fail because *Riegel* is indistinguishable.

More fundamentally, Durnell's search for an express delegation of authority to "bind the judiciary" mistakes this federalism/preemption case for a separation-of-powers dispute. The issue both here and in *Riegel* is not whether the executive can bind the judiciary, but whether federal requirements imposed by a federal agency take precedence over the contrary determinations of state juries. The answer in both cases is plainly yes, as underscored by the reality that §136v(b) is in a section about state authority and in a subsection entitled "[u]niformity."

Rather than grapple with *Riegel*, Durnell seeks refuge in *Bates*. But *Bates* actually devastates Durnell's effort to reconceive decades of preemption law. *Bates* involved a complaint about a label's failure to address the product's efficacy in high-pH soils. EPA's registration decision there did not evaluate efficacy at all, as Congress directed EPA to focus its efforts on safety. *See* 544 U.S. at 440. Here, by contrast, Durnell's claim concerns Roundup's safety, i.e., the issue Congress *required* EPA to focus on in the registration process. Monsanto.Br.32-34. Thus, the parts of *Bates* that Durnell invokes are plainly irrelevant, while the balance of *Bates* is fatal to Durnell's only-statutory-requirements-preempt theory. In particular, *Bates* explained that the prototypical example of a preempted state-law requirement is one demanding a "DANGER" label for a pesticide when EPA has determined that the label should read "CAUTION" instead. 544 U.S. at 453. Needless to say, it was not Congress itself that

required CAUTION labels on particular pesticides, but EPA exercising its authority *under* FIFRA. *See* Monsanto.Br.39-40; U.S.Br.18-19.

Yet, under Durnell's view that FIFRA "delegates to the judiciary and not EPA the power to determine whether" a particular pesticide is "misbranded," Durnell.Br.21, a state-court jury *could* require a pesticide manufacturer to include a "DANGER" warning when EPA requires a "CAUTION" warning. Durnell simply ignores this discussion in *Bates,* despite both Monsanto and the United States highlighting it. Monsanto.Br.39-40; U.S.Br.18-19. The reason for that omission is obvious: If Durnell were right, then *Bates*'s DANGER/CAUTION discussion was wrong, and all the other careful distinctions this Court drew in *Bates* were beside the point. In fact, under Durnell's position, it would not matter if EPA promulgated a regulation stating that a cancer warning is unnecessary for glyphosate products—or even a regulation affirmatively *forbidding* cancer warnings on glyphosate products—the jury could still override EPA's considered judgment about federal requirements because only FIFRA itself (not agency actions under FIFRA) can have preemptive effect.[1] Worse still, because Durnell

[1] Of course, "lay juries are in no sense anathema to FIFRA's scheme," since "juries necessarily pass on allegations of misbranding" in "criminal prosecutions." *Bates*, 544 U.S. at 452. But such criminal prosecutions are rare, the jury's role flows from the Sixth Amendment, and federal criminal juries do not impose different or additional state-law requirements. Moreover, the very possibility of a criminal prosecution for deviating from EPA's labeling requirements underscores that they are legally binding requirements under FIFRA.

reads FIFRA as simply setting forth standards like "misbranding," not actual requirements, Durnell would effectively render §136v(b) a nullity.

It is thus no accident that Durnell's position facilitates precisely the sort of disuniformity and conflict Congress sought to eliminate in §136v(b). Under Durnell's position, a state jury could conclude that *failing* to include a particular warning on a label violates state law, while EPA could conclude that *including that same warning* violates FIFRA's misbranding provision. That risk is hardly hypothetical. While Durnell insists that Monsanto must provide a cancer warning on its glyphosate products to comply with Missouri law, EPA determined in 2019 that including a warning that glyphosate is known "to cause cancer" *would render a pesticide affirmatively misbranded*. Monsanto.Br.16-17.[2] Indeed, Durnell's position would create the ultimate patchwork, as a pesticide manufacturer could not only face a federal requirement and 50

[2] Durnell alternatively claims that Monsanto could "easily provide an adequate cancer warning that is irrefutably truthful and not misleading," such as "[IARC] considers glyphosate probably carcinogenic to humans." Durnell.Br.39. But that is not the warning Durnell wants or sought below; he wants a cancer warning, not a controversy warning, and EPA has determined that the former is misguided and would render Roundup misbranded. Moreover, even a controversy warning is "misleading" because it "elevates one side" of a "scientific debate" over the other. *Nat'l Ass'n of Wheat Growers v. Bonta*, 85 F.4th 1263, 1278-79 (9th Cir. 2023). And while EPA briefly suggested in 2022 that it might approve a warning advising consumers of both California's view that Roundup poses cancer risks and EPA's contrary view, Durnell notably does not propose (and has never proposed) that Janus-like warning. *See* Durnell.Br.39.

different state requirements, but the requirements for the label within a state would vary from jury to jury. The attraction of such a regime to the plaintiffs' bar is obvious. The idea that this is what Congress had in mind in a provision entitled "Uniformity" is absurd.

3. Durnell's problem with precedent extends well beyond *Riegel* and *Bates*. His theory contradicts decades of preemption precedents that take as a starting point that agency actions can have preemptive effect via express preemption clauses (and via conflict preemption to boot). *See, e.g.*, *Nat'l Meat Ass'n v. Harris*, 565 U.S. 452, 460-61 (2012); *Geier v. Am. Honda Motor*, 529 U.S. 861, 869 (2000). Indeed, the long struggle to confirm and reaffirm that state tort law imposes "requirements" or constitutes "regulation" for purposes of various preemption clauses would have been beside the point if the only federal requirements were those imposed directly by statutes or via an express delegation to the agency to bind the judiciary. Tellingly, Durnell does not identify a single example of the kind of express, bind-the-judiciary delegations he deems necessary.

Durnell's only answer to decades of precedent is that *Loper* changed preemption law, effectively wiping the slate clean. Indeed, Durnell invokes *Loper* more than any case save *Bates* (and four times as often as *Riegel*). That is all more than a little surprising, as *Loper* never so much as mentions preemption, let alone purports to overturn decades of federal preemption law, which is likely why this argument never occurred to Durnell in the lower courts or in opposing certiorari, and has escaped the notice of

almost all his amici and numerous courts wrestling with preemption in the post-*Loper* world.

That is not the result of a massive collective failure to issue-spot. No one doubts that this Court has the final say over the meaning and scope of §136v(b); nor is EPA championing some second-best construction of §136v(b). Durnell's problem is that the single-best construction of §136v(b) makes plain that labeling requirements imposed by EPA acting under FIFRA cannot be displaced or supplemented by different or additional requirements imposed by juries wielding state-law failure-to-warn theories. Similarly, no one denies that "a federal agency may pre-empt state law only when and if it is acting within the scope of its congressionally delegated authority." *New York v. FERC*, 535 U.S. 1, 18-19 (2002). But not even Durnell claims that EPA exceeded its authority when determining that Monsanto need not include a cancer warning on Roundup product labels, presumably because FIFRA expressly charges EPA with the responsibility of registering pesticides and "determin[ing]" whether the pesticide's "labeling and other material required to be submitted comply with the requirements of this subchapter." 7 U.S.C. §136a(c)(5)(B). That includes the requirement that the label include all "warning[s]" and "caution statement[s]" necessary "to protect health." *Id.* §136(q)(1)(G). Once EPA makes that determination about the requisite warnings, those requirements displace different or additional state-law requirements under the plain terms of §136v(b). *Loper* may change a lot, but it has zero relevance for that straightforward construction of FIFRA's unambiguous statutory text.

4. Returning to arguments actually raised below, Durnell suggests that "EPA's approval of a label during the registration process" cannot support preemption because the agency's "findings during the registration process are based on the limited information submitted at that time." Durnell.Br.23. That argument misdescribes the registration process and ignores registrants' ongoing obligations. In fact, EPA is not limited to evaluating the data in the manufacturer's initial submission. If EPA deems that initial filing deficient, FIFRA empowers it to request additional information. Monsanto.Br.24. FIFRA also requires registrants to continuously apprise EPA of additional information that the pesticide may pose unreasonable risks to human health. *See* 7 U.S.C. §136d(a)(2). And EPA may enlist panels of experts to peer-review new information. Monsanto.Br.24. Here, for example, EPA commissioned multiple reviews in response to IARC's findings about glyphosate, which culminated in an 87-page report from its Cancer Assessment Review Committee and a 216-page report from its Office of Pesticide Programs. Monsanto.Br.14. In preparing those reports, EPA reviewed hundreds of scientific sources and

references—including all relevant evidence considered by IARC.[3] Monsanto.Br.14.[4]

It is hardly "untenable" to think that Congress would insulate that kind of exhaustive consideration from second-guessing by lay juries. Durnell.Br.23. Durnell's contrary view ignores the real costs of overwarning. FIFRA strikes a balance between safety considerations and ensuring that pesticides are

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[3] Durnell claims that "EPA has never considered whether all of the ingredients in Roundup … combined with glyphosate can cause cancer." Durnell.Br.47 n.47. That is wrong. EPA has a statutory obligation to determine whether a "pesticide," not just its active ingredient, causes unreasonable adverse health effects. 7 U.S.C. §136a(a); *see id.* §136(u). EPA recognizes that "[t]he entire formulation, including the inert ingredients, must meet [the registration] standard." EPA, *Pesticide Registration Manual: Chapter 8—Inert Ingredients* (Sept. 22, 2025), https://perma.cc/E4PN-3DYL. And EPA has specifically responded to comments about inert ingredients in glyphosate-based products. *See* EPA, *Glyphosate: Response to Comments on the Human Health Draft Risk Assessment* 7-9 (Apr. 23, 2018), https://perma.cc/QPC4-FHNE.

[4] Durnell's amici assert that "EPA's conclusion was based in large part" on a paper recently retracted over ghost-writing concerns. Oreskes.Amicus.Br.3; see Landrigan.Amicus.Br.19-31. But those concerns were refuted after an investigation by New York Medical College, which found "no evidence" of ghost writing. Warren Cornwall, *Update: After quick review, medical school says no evidence Monsanto ghostwrote professor's paper*, Science (Mar. 23, 2017), https://perma.cc/5N7K-PKDU. Regardless, EPA considered countless other sources (many more than IARC), and EPA's conclusion reflects the shared consensus of regulators worldwide. Monsanto.Br.14-16. Moreover, the proper place to air amici's concerns is with the agency, not by injecting fraud-on-the-agency theories into state tort claims. *See Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347-48 (2001).

available to meet pest-control needs. Monsanto.Br.41-42. To that end, FIFRA requires EPA to "tak[e] into account the economic, social, and environmental costs *and benefits* of the use of [the] pesticide" when assessing whether a warning is "necessary and … adequate to protect health and the environment." 7 U.S.C. §136(bb), (x), (q)(1)(G) (emphasis added); *see also id.* §136d(b) (requiring EPA to account for impact on "food prices" and "the agricultural economy" before initiating cancellation procedures); 40 C.F.R. §152.170(a) (requiring EPA to consider risks and benefits before imposing use restrictions). And if EPA concludes that some warning is appropriate to "mitigate … hazard(s)," 40 C.F.R. §152.170(a)(2), it often imposes use warnings designed to target and mitigate risks, rather than broad health warnings that could deter safe uses, *see id.* §152.170(e)(2).

Lay juries are poorly equipped to evaluate the need for warnings, but they have even less capacity to evaluate the countervailing social and economic benefits of a registered pesticide. As this Court has observed, juries "see[] only the cost of a more dangerous design" through the dramatic prism of a single injured plaintiff present in the courtroom without seeing the countervailing benefits to widely dispersed absent individuals. *Riegel*, 552 U.S. at 325; *accord* U.S.Br.34-35.[5]

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[5] The MDL Leadership observes that the Ninth Circuit vacated EPA's 2020 interim registration review in 2022. MDL.Amicus.Br.20-21. But a 2022 decision cannot alter what was required under FIFRA before 2018, the last time Durnell used Roundup. Regardless, nothing in the Ninth Circuit's 2022

5. Durnell and his amici emphasize that "registration" of a pesticide under FIFRA is not "a defense for the commission of any offense under this subchapter." 7 U.S.C. §136a(f)(2). No one has suggested otherwise. Marketing a registered pesticide without the EPA-required label would be an obvious misbranding offense, and several other violations could occur with a registered pesticide, Monsanto.Br.38, including a failure to apprise EPA of new information bearing on unreasonable risks to human health. *See* 7 U.S.C. §136j(a)(1)(B); *id.* §136d(a)(2). But the fact that registration does not provide immunity in no way negates the notion that EPA's labeling determinations pursuant to the registration process impose binding federal requirements. *Riegel* reinforces this point, as Monsanto emphasized, Monsanto.Br.28-29, and Durnell ignores. Even though premarket approval under the MDA was not a defense to agency misbranding charges, the Court nevertheless held that the approval process imposed device-specific federal "requirements" with preemptive effect under the MDA's similarly-worded preemption provision. *See Riegel*, 552 U.S. at 322-23.

Durnell emphasizes the second sentence of §136a(f)(2) and suggests that by treating registration as "prima facie evidence" of regulatory compliance, the statute makes clear that registration decisions are not conclusive. Durnell.Br.29. But as already explained, no one is arguing that registration alone immunizes a

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decision casts doubt on EPA's earlier registrations or EPA's post-2022 approvals of glyphosate product labels without cancer warnings.

manufacturer from an EPA enforcement action if a registered product is subsequently marketed with, *inter alia*, a non-compliant label or in a non-compliant formulation. Moreover, as the United States explained, this sentence was added to FIFRA to give registration decisions *more* weight than they had under the prior registration-as-of-right regime, not to undermine the simultaneously added §136v(b). U.S.Br.26-27.

Durnell's argument once again has a text problem, as §136v(b) and §136a(f)(2) are focused on fundamentally different things. The former is in a subsection entitled "[u]niformity" and is specifically directed to the question presented—i.e., whether states may impose additional or different labeling requirements relative to those required under federal law. The latter is in a subsection buried deep in FIFRA's registration provision labeled "[m]iscellaneous" and merely underscores that registration alone is no defense to offenses under FIFRA. Those different titles and subject matters confirm the critical point: Registration decisions do not provide a complete defense, but they still impose "rule[s] of law that must be obeyed," i.e., federal requirements that displace contrary state requirements and thus ensure uniformity. *Bates*, 544 U.S. at 445, 452.

B. Even if Durnell were correct that the only relevant federal requirements are FIFRA's general misbranding standards, he would still have a problem because FIFRA requires the consideration of a pesticide's costs *and benefits*, while Missouri common law does not. Monsanto.Br.40-43; U.S.Br.24-25.

Durnell concedes that difference, but insists that FIFRA's prohibition on the sale of pesticides with a false or misleading label does not require consideration of costs and benefits. Durnell.Br.33-34. That gets Durnell nowhere, as his claim below was that Monsanto failed to include an adequate warning on its Roundup labels—not that the labels were false or misleading in any respect. Pet.App.6.[6]

C. Unimpressed by *Loper*-based arguments that have not surfaced in the extensive MDL litigation, the MDL Leadership amici offer their own alternative argument, theorizing that Durnell's claims may proceed because his failure-to-warn claim is "a permissible exercise of the state authority to regulate pesticide *use* that §136v(a) preserves," rather than a regulation of the label, which FIFRA preempts. MDL.Amicus.Br.17. One immediate problem with that alternative argument is that Durnell explicitly disavows it. *See* Durnell.Br.50 ("Durnell concedes that Missouri's failure-to-warn law imposes some 'requirements for labeling' within the meaning of 7

[6] With no viable argument on the merits, Durnell asserts forfeiture, complaining that Monsanto failed to ask for a *Bates* instruction at trial. Durnell.Br.34. But Monsanto repeatedly raised its preemption defenses before the charge conference and the trial court noted the continuing objection. Mo.App.Dkt.3 at 44; Mo.App.Dkt.7 at 8-21; Mo.App.Dkt.100 at 31-33; Mo.App.Dkt.104 at 32-34. That may explain why Durnell never raised this concern below, forfeiting any forfeiture. Regardless, the issue that divided the circuits does not turn on the details of Missouri law, but the more fundamental question whether lay juries can impose labeling requirements that contradict or supplement those required by EPA in the registration process.

U.S.C. §136v(b).”). But even putting that aside, the MDL Leadership’s argument is wrong. A warning to wear personal protective equipment would still be different from and in addition to what EPA required and thus would still be preempted by §136v(b). Indeed, in its 1993 re-registration decision, EPA specifically instructed registrants (under the heading “Labeling Requirements for End-Use Products”) “not [to] add any additional personal protective equipment requirements to the labels of glyphosate end-use products.” EPA, *Reregistration Eligibility Decision (RED) Glyphosate* 72-73 (Sept. 1993), https://perma.cc/528H-F4FN.

II. FIFRA Impliedly Preempts Durnell’s Failure-To-Warn Claim.

Even if Durnell’s failure-to-warn claim were not expressly preempted by FIFRA, it would be impliedly preempted, as claims like Durnell’s put Monsanto in an impossible position. State-law claims are preempted if the defendant cannot “independently do under federal law what state law requires of it.” *PLIVA v. Mensing*, 564 U.S. 604, 620 (2011). And “when a party cannot satisfy its state duties without the Federal Government’s special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes.” *Id.* at 623-24. That is the case here. Once EPA approved the label for Roundup, federal law prohibited Monsanto from “independently” changing the label to add a cancer warning that EPA had not approved. Monsanto.Br.45; U.S.Br.31-32.

1. Durnell claims that EPA regulations actually "*allow* Monsanto to unilaterally add cancer warnings." Durnell.Br.40. That is a bold claim in the face of the United States' contrary position. U.S.Br.32-33. It is also wrong. EPA regulations make clear that when it comes to cancer warnings and other precautionary statements, the registrant cannot unilaterally change the label. *See* Monsanto.Br.45; U.S.Br.31; 40 C.F.R. §§156.70(c), 152.44(a). Durnell ignores all of that. Instead, he claims that EPA may permit certain label modifications to "proceed through notification without the need for EPA approval." Durnell.Br.40 (citing 40 C.F.R. §152.46(a)). EPA pointedly disagrees. U.S.Br.32-33. Indeed, EPA has made clear at all times relevant to this litigation that "[m]inor label changes … may be made by notification" only if they "involve *no change[s] in … precautionary statements*." EPA, *Pesticide Registration Notice 95-2*, at 6 (May 31, 1995), https://perma.cc/C8XM-7NAZ ("PRN 95-2") (emphasis added); *accord* EPA, *Pesticide Registration Notice 88-6*, at 2-3 (Aug. 12, 1988), https://perma.cc/8XYM-BAC7 (same); EPA, *Pesticide Registration Notice 98-10*, at 8 (Oct. 22, 1998), https://perma.cc/WBX8-79RT ("PRN 98-10") (same); EPA, *Pesticide Registration Notice 2000-5* (May 10, 2000), https://perma.cc/ANB4-UGG9 (similar).[7]

Durnell ultimately concedes Monsanto's inability to alter the label's precautionary statements, but

[7] By contrast, and consistent with the safety-efficacy dichotomy recognized in *Bates*, EPA allows manufacturers to make unilateral changes to *efficacy statements*. *See* PRN 95-2 at 8. Thus, Durnell's suggestion (at 48-49) that *Bates* undermines Monsanto's implied-preemption argument is misplaced.

nevertheless insists that Monsanto could have added a cancer warning to other "*sections* of the label." Durnell.Br.41. The idea that a cancer warning would belong somewhere besides the label's "precautionary statements" flunks the test of common sense. It also contradicts EPA regulations, which sensibly provide that "[h]uman hazard and precautionary statements as required must appear together on the label or labeling under the general heading 'Precautionary Statements.'" 40 C.F.R. §156.70(a); *accord id.* §156.10(h)(2) (1995).

Durnell claims that even if subsequent regulations tied Monsanto's hands, PRN 95-2 allowed Monsanto to add a cancer warning in the "advisory statements" section of the label between 1996 and 2000. Durnell.Br.40-41. Wrong again. PRN 95-2 allowed "[a]dvisory statements (such as those related to use precautions, efficacy, crop damage and product incompatibility)" to be "added or revised" via "notification" only if such statements "do not trigger … human health" concerns. PRN 95-2 at 4. So, while PRN 95-2 authorized the addition of "minor, low risk" statements, such as "[t]his product is not recommended for use on natural marble surfaces," it did not authorize adding a cancer warning. *Id.* at 2, 4. During 1996-2000, and before and since, the addition of a cancer warning would be a major change that would belong in the label's precautionary statements and could not be executed unilaterally. Indeed, PRN 95-2 itself confirmed that "[m]inor label changes … may be made by notification" only if they

"involve no changes in … precautionary statements." PRN 95-2 at 6.[8]

2. Perhaps recognizing that EPA's regulations doom his argument, Durnell shifts to attacking those regulations, once again invoking *Loper* and insisting that "EPA lacks statutory authority to impose a preclearance requirement for label modifications." Durnell.Br.40. But FIFRA could not be clearer on this point. The statute expressly charges EPA with the responsibility of registering pesticides and "determin[ing]" whether the pesticide's "labeling and other material required to be submitted comply with the requirements of this subchapter." 7 U.S.C. §136a(c)(5)(B). And it provides in no uncertain terms that "[i]f the labeling or formulation for a pesticide is changed, the registration shall be amended to reflect such change if the Administrator determines that the change will not violate any provision of this subchapter." *Id.* §136a(f)(1). EPA's decision to prohibit the unilateral addition of precautionary statements to labels that EPA has already approved thus implements EPA's statutory obligation to register pesticides and ensure that their labeling complies with FIFRA's requirements. Allowing

[8] Durnell observes that an EPA biologist once permitted Monsanto's parent to unilaterally add a disclaimer that a *different* (i.e., non-glyphosate) product "contain[ed] a chemical known to the state of California to cause cancer." Durnell.Br.41 n.42. But as EPA has acknowledged, its employees sometimes make "implementation mistakes." Monsanto.Br.18 n.5. Regardless, Durnell seeks a warning not about California's view but about Roundup's cancer risks. Those are not the same thing. *See Schaffner v. Monsanto*, 113 F.4th 364, 384 n.12 (3d Cir. 2024); U.S.Br.33.

manufacturers to make major changes to labels without the agency's approval would abdicate EPA's responsibility under FIFRA to ensure any "change[s]" to the "labeling" "will not violate" the statute. *Id.*

Durnell questions why Congress would authorize EPA to prohibit manufacturers from unilaterally adding warnings that the manufacturer thinks are "necessary … to protect health and the environment" or to avoid rendering the label "false or misleading." Durnell.Br.40. There is no mystery. Unlike Durnell, Congress (perhaps because its members include representatives from farm States, *see* Nebraska.Amicus.Br.13-22), is not insensitive to the risks of overwarning and is sensitive to the reliance interests of farmers and others who have used a product safely for years. Thus, in assessing whether a warning is necessary to protect health, EPA is obligated to "tak[e] into account the economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. §136(bb); *see id.* §136(x). That is the exact type of cost-benefit balancing that the agency is best suited to conduct, and that a jury seeing only one side of the equation cannot fairly assess. *Accord* U.S.Br.34-35. Congress also recognized that adding an unwarranted warning, such as a cancer warning based on an IARC view that EPA has exhaustively considered and expressly rejected, can cause users to resort to less safe or less effective alternatives, and can render a label affirmatively "false or misleading." 7 U.S.C. §136(q)(1); *see* Monsanto.Br.17.

3. Durnell claims that even if federal law prohibited Monsanto from unilaterally adding a

cancer warning to Roundup, Monsanto could have complied with both state and federal law by simply refusing to sell Roundup. The Court squarely rejected that no-impossibility-just-stop-selling argument in *Mutual Pharmaceutical v. Bartlett*, 570 U.S. 472 (2013). There, the lower court held that regulated parties were not placed between a rock and a hard place because they could simply withdraw from the market. This Court squarely "rejecte[d] this 'stop-selling' rationale." *Id.* at 488. An "actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability." *Id.* "Indeed, if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be 'all but meaningless.'" *Id.* (quoting *PLIVA*, 564 U.S. at 621).

Durnell tries to distinguish *Bartlett* on the theory that this case involves federal and state laws that "both *require* a party to cease acting"—namely "to *not sell* a misbranded pesticide." Durnell.Br.44. That is no distinction at all. The plaintiffs in *Bartlett* (and *PLIVA*) could have similarly upped the level of generality and argued that the relevant "duty" under both state and federal law was to "not … sell the drug[s] without adequate warnings." *Bartlett*, 570 U.S. at 489 n.5; *see* 21 U.S.C. §355(a); *id.* §355(j)(2)(A)(v). But that abstraction would ignore that federal law allowed the sales of the product as labeled and prevented the defendant from unilaterally changing the label to comply with state tort law. That is the relevant level of generality and what rendered the state-law claims preempted in *Bartlett*, 570 U.S. at 486-87, and *PLIVA*, 564 U.S. at 619-20. That

reasoning applies with equal force here. *See* Monsanto.Br.45-46; U.S.Br.31-33.

4. Finally, even if (contrary to reality) agency regulations allowed Monsanto to unilaterally add a cancer warning without prior EPA approval, Durnell's claim would still be preempted because Monsanto has put forth "clear evidence" that EPA would ultimately reject that warning. Monsanto.Br.47-50. Durnell does not meaningfully dispute that EPA has already made clear that it would reject any warning that glyphosate is carcinogenic. Monsanto.Br.48. Instead, he quibbles that some of Monsanto's evidence involves letters to registrants of glyphosate, rather than Monsanto alone. Durnell.Br.43. But he never even tries to explain why EPA would permit a glyphosate-causes-cancer warning for Roundup when it has rejected such warnings for glyphosate products generally. Nor can he seriously dispute that EPA was "fully informed" of the "justifications for the warning required by state law," and that EPA nevertheless informed manufacturers that it would not approve changing the label to include the warning—and in fact, deemed the warning affirmatively misleading. *Merck Sharp & Dohme v. Albrecht*, 587 U.S. 299, 314 (2019).

Durnell thus pivots to arguing that the Court should not "import the clear-evidence regime" from the FDCA "into FIFRA" because FIFRA freely allows manufacturers to make unilateral changes, so there is no "mechanism for EPA to force a manufacturer to undo a unilateral change." Durnell.Br.42-43. But that just rehashes Durnell's mistaken argument that pesticide manufacturers can make unilateral changes

to precautionary statements, ignores EPA's authority to reject changes made by notification, *see* PRN 98-10 at 19, and defies the reality that EPA has studied glyphosate extensively and made clear that it would not allow a label-change in this context. In the end, there is just no escaping that the broader regulatory regime reinforces what §136v expressly provides: Durnell's state-law claims are preempted.

III. Durnell's Claim Threatens American Agriculture And Innovation.

Durnell has no real response to the threat his approach poses to American agriculture and innovation. *See* Monsanto.Br.50-53. Under his theory, pesticide manufacturers have no way to know whether a pesticide is misbranded until they see what comes out of a particular jury box. Even different juries in the same state could assess the evidence and requisite warnings differently. And EPA would be powerless to provide any advance clarity or uniformity, despite its superior ability (and congressional mandate) to consider scientific data and weigh costs and benefits. That is a recipe for exactly the sort of disuniformity FIFRA seeks to prevent. And it would skew the analysis in plaintiff-friendly (but agriculture-unfriendly) ways, as juries consider only half the equation and do so through the prism of an injured plaintiff with disastrous results for American food production and innovation. *See* CropLife.Br.32-36; Farm.Bureau.Br.5-11.

That is no hypothetical concern. Despite EPA's repeated determinations that glyphosate does not cause cancer, plaintiffs have parlayed IARC's misguided finding into billions in liability in Roundup-

related litigation, driving an important tool from the consumer market and threatening its availability for farmers nationwide.[9] Durnell can dismiss those concerns as mere "policy consequences," Durnell.Br.27-28, but the threat is real and the stakes are high. As the President recently explained, "[l]ack of access to glyphosate-based herbicides would critically jeopardize agricultural productivity," making it "untenable for [farmers] to meet growing food and feed demands" in the United States. Exec. Order No. 14387, §1 (Feb. 18, 2026).

FIFRA seeks balance and uniformity. The plaintiffs' bar seeks something altogether different, without regard to whether it drives products that farmers need from the market. The Court should vindicate Congress' judgment.

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[9] The MDL Leadership claims that after the recently announced proposed class settlement, this appeal affects only "two cases." MDL.Amicus.Br.14. That is wrong. Resolution of this case remains critical for the approximately 250 cases unaffected by the settlement, for opt-out cases, and for the future of innovation. Monsanto.Br.52 n.9.

CONCLUSION

This Court should reverse.

Respectfully submitted,

DAVID M. ZIONTS
MICHAEL X. IMBROSCIO
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street NW
Washington, DC 20001
(202) 662-6000

K. LEE MARSHALL
BRYAN CAVE LEIGHTON PAISNER
Three Embarcadero Center
San Francisco, CA 94111

PAUL D. CLEMENT
Counsel of Record
MATTHEW D. ROWEN
JAMES Y. XI
NICCOLO A. BELTRAMO
CLEMENT & MURPHY, PLLC
706 Duke Street
Alexandria, VA 22314
(202) 742-8900
paul.clement@clementmurphy.com

Counsel for Petitioner

April 17, 2026