

Monsanto Co. V. Durnell
Supreme Court of the United States
Summary by TFBF Public Policy

Syllabus Summary (KAVANAUGH, J., delivered the opinion of the Court, in which ROBERTS, and THOMAS, ALITO, SOTOMAYOR, KAGAN, and BARRETT joined)

Held: FIFRA expressly preempts Durnell’s state-law failure-to-warn claim because the claim would require Monsanto to add a cancer warning to Roundup’s label.

- FIFRA preempts a state-law labeling requirement that differs from the federal labeling requirements imposed under FIFRA.
- The Court’s precedents make clear and as the parties agree, state tort duties constitute state labeling requirements. (Bates v. Dow Agrosiences LLC, 544 U. S. 431, 443–444.)
- Durnell’s state tort claim would require Monsanto to add a cancer warning to its labels, which is “in addition to” and “different from” Monsanto’s federal-law labeling obligations.
- The Court’s decision in *Riegel v. Medtronic, Inc.*, 552 U. S. 312, further confirms that Durnell’s failure-to-warn claim is expressly preempted.
 - In *Riegel*, the Court addressed the preemption clause in the Medical Device Amendments of 1976, which is nearly identical to FIFRA’s preemption clause.
 - In *Riegel* FDA’s premarket approval of a medical device preempted state-law claims premised on additional or contrary safety requirements.
 - *Riegel* indisputably did resolve the question of whether premarket approval constituted a “requirement” for preemption purposes. (From Kavanaugh Opinion)
- EPA critically evaluates the pesticide’s label to ensure that the label contains all warnings necessary to protect human health, and after EPA decides the appropriate warnings for a pesticide’s label, a manufacturer is legally required to use that label unless and until EPA subsequently approves or requires a new label.
- Additionally, Monsanto is not invoking the mere fact of “registration” as a complete defense to state tort suits but rather is relying on EPA’s specific determination that cancer warnings are not required for glyphosate-based pesticide labels.

Opinion of the Court Summary (Opinion written by Justice Kavanaugh)

- **EPA has repeatedly concluded that glyphosate is not likely to cause cancer**, the agency has not required a cancer warning on Roundup’s label. Importantly, EPA’s regulations require a pesticide manufacturer such as Monsanto to use the EPA-approved pesticide label—here, the Roundup label without a cancer warning—unless and until EPA approves or requires a different label. Moreover, to ensure “[u]niformity” in labeling, FIFRA’s preemption clause prohibits States from imposing any pesticide labeling requirements that are “in addition to or different from” the federal labeling requirements “under” FIFRA.

- But Durnell’s state tort claim would require Monsanto to add a cancer warning to Roundup’s label, contradicting federal law. **Because Durnell’s state tort claim would impose a pesticide labeling requirement “in addition to or different from” the label required by EPA, FIFRA expressly preempts Durnell’s claim.**
- In 1947, Congress passed and President Truman signed the Federal Insecticide, Fungicide, and Rodenticide Act which required that pesticides be registered with the Secretary of Agriculture.
- In 1972, Congress passed and President Nixon signed the Federal Environmental Pesticide Control Act. 86 Stat. 973. That Act “transformed” FIFRA “into a comprehensive regulatory statute” and placed the newly created Environmental Protection Agency in charge of pesticide registration and labeling.
- A pesticide is misbranded if its label contains “any statement” that is “false or misleading” or if the label does not contain “a warning or caution statement which may be necessary and . . . adequate to protect health and the environment.”
- EPA has promulgated extensive regulations fleshing out what it means for a pesticide to be misbranded and dictating what must appear on a pesticide’s label. As relevant here, those regulations specify the required content and placement of precautionary statements such as cancer warnings.
- Importantly, after EPA has registered the pesticide and approved the label, the manufacturer is required to use that label. If a manufacturer does not use the EPA-approved label, it may be subject to civil and criminal penalties.
- After the initial registration and approval of a label, manufacturers must continue to inform EPA of “additional factual information regarding unreasonable adverse effects” of their pesticides. That obligation is enforced through civil and criminal penalties.
- In light of new information or analysis by EPA, the agency at any time may require “additional labeling language” to “mitigate” “identified hazard(s).”
- EPA also must formally review a pesticide’s registration every 15 years.
- In 1974, EPA first registered glyphosate-based pesticides and approved Roundup’s label without a cancer warning. In 1991 and for the more than three decades since, **EPA has repeatedly re-evaluated glyphosate and has repeatedly concluded that glyphosate is not likely to cause cancer.**
- In 2017 and 2019, after the International Agency for Research on Cancer classified glyphosate as a probable carcinogen, EPA re-examined the issue but still adhered to its longstanding position on glyphosate.
- In 2020, in an interim registration review decision, EPA reiterated that same position.
- **EPA’s assessment of glyphosate is shared by many other regulatory bodies around the world that have likewise concluded that glyphosate is not carcinogenic, including regulators in Canada, Australia, Japan, and the European Union.**
- In accordance with **EPA’s view that glyphosate is not likely to cause cancer in humans**, EPA has not required glyphosate-based pesticides like Roundup to include a cancer warning on their labels. **Therefore, as a matter of federal law, Monsanto legally must use a label without a cancer warning unless and until EPA approves or requires a change.**

- FIFRA preempts a state-law labeling requirement that differs from the federal labeling requirements imposed under FIFRA. “Uniformity” in labeling—the textually stated objective of FIFRA’s preemption clause—would otherwise be impossible to achieve.
- This Court’s precedents make clear and as the parties agree, **state tort duties constitute state labeling requirements.**
- **Federal law requires Monsanto to sell Roundup with the label that EPA approved** at the initial registration and that EPA has subsequently re-approved on multiple occasions—that is, the label without a cancer warning. **Durnell’s state tort claim, by contrast, would require Monsanto to add a cancer warning to its labels. That Missouri-law requirement is “in addition to” and “different from” Monsanto’s federal-law labeling obligations.**
- EPA requires robust evidence of a pesticide’s potential carcinogenicity as a part of registration. That is why, with respect to Roundup specifically, EPA has repeatedly evaluated glyphosate’s potential carcinogenicity to ensure that the pesticide “will not generally cause unreasonable adverse effects” on human health and the environment. Moreover, even if Monsanto could unilaterally add a cancer warning to its Roundup label as a “minor modification,” EPA has not required such a warning. Therefore, a state-law requirement purporting to mandate a cancer warning is necessarily “in addition to” or “different from” the relevant federal requirements.
- Durnell’s failure-to-warn claim, meanwhile, would require Monsanto to place a cancer warning on Roundup’s label. That state labeling requirement is “in addition to or different from” EPA’s labeling determinations that do not mandate a cancer warning. **Durnell’s failure-to-warn claim is expressly preempted.**

The Majority Opinion’s Thoughts on Durnell’s Arguments

- First, Durnell (echoed by the dissent) contends that a Missouri failure-to-warn claim, like FIFRA itself, simply requires manufacturers to include adequate warnings to protect human health, and not to include false or misleading statements. **Looking at only FIFRA’s general standard for misbranding rather than the specific requirements imposed under federal law would nullify FIFRA’s preemption clause and the uniformity that Congress sought for safety warnings on pesticide labels.**
- Second, Durnell claims that EPA’s regulations—and its procedures for registering pesticides and approving pesticide labels—exceed or contravene EPA’s statutory authority under FIFRA. Durnell is incorrect. Again, FIFRA empowers EPA to “prescribe regulations to carry out the provisions of [FIFRA].” **And FIFRA expressly directs EPA to register pesticides and “determin[e]” that the pesticide’s “labeling” complies with FIFRA’s many specific requirements.**
- Third, Durnell (also echoed by the dissent) seizes on one of FIFRA’s self-described “[m]iscellaneous” provisions, 7 U. S. C. §136a(f)(2), which provides that “[i]n no event shall registration . . . be construed as a defense for the commission of any offense under this subchapter,” but that registration is “prima facie” evidence of compliance with the registration provisions. Durnell argues that the fact of “registration” of a pesticide like Roundup could not serve as a defense to an EPA enforcement action for misbranding and therefore cannot serve as a defense in a state tort suit that parallels a federal misbranding action.

- That argument would effectively erase FIFRA's express preemption clause. And the argument fails for multiple independent reasons.
- To begin, §136a(f)(2), by its text, does not apply to state tort suits. That provision simply clarifies that registration does not bar EPA enforcement actions against manufacturers for violating FIFRA.
- The premise of Durnell's §136a(f)(2) argument is flawed. It is highly doubtful that EPA would bring an enforcement action for misbranding against a manufacturer for using the EPA-approved and EPA-required label.
- Durnell's failure-to-warn claim does not fault Monsanto for *using* a label different from the EPA-approved labeling. **Durnell instead faults Monsanto for *not using* a label different from the EPA-approved label, but FIFRA's preemption clause expressly preempts any state tort claim that would require a pesticide manufacturer to use a label "in addition to" or "different from" federal requirements imposed under FIFRA.**
- If the manufacturer unilaterally changed the label, as Durnell says Monsanto should have done, the manufacturer would be flouting EPA's regulations and exposing itself to potentially severe federal penalties.
- ***The law is not ordinarily read to retroactively penalize persons for doing what the Government had required them to do.***
- In addition, Durnell's §136a(f)(2) argument does not work for yet another reason. Monsanto is not invoking the mere fact of "registration" as a complete defense to state tort suits. Rather, Monsanto is relying on EPA's specific determination that cancer warnings are not required for glyphosate-based pesticide labels.
- Durnell's policy concern about regulatory lag is amply addressed by the extensive processes that FIFRA and EPA's implementing regulations have established to respond to new or evolving safety information. For example, manufacturers must apprise EPA of new information "regarding unreasonable adverse effects" of their pesticides. That obligation is backed by civil and criminal penalties.

EPA Ensures Public Safety and Federal Law Compliance

- EPA does not sit in an information-free silo. It keeps abreast of new safety developments. EPA may request additional information from manufacturers whenever the Agency "determines that additional data are required to maintain" a pesticide's registration.
- And EPA possesses ample resources to evaluate that information. EPA may solicit "comments, evaluations, and recommendations" to "improve the effectiveness and quality" of EPA's "scientific analyses" from scientific advisory panels.
- In the aftermath of the International Agency for Research on Cancer's classification of glyphosate as probably carcinogenic, EPA commissioned multiple reports about glyphosate's potential carcinogenicity from its Cancer Assessment Review Committee and Office of Pesticide Programs.
- If third parties (like Durnell) want to bring new information to EPA's attention or if they believe that EPA has failed to consider relevant information, those third parties are free to petition EPA to modify, suspend, or cancel a pesticide's registration. **And EPA's decision in response to such a petition is subject to judicial review.**

- And as a matter of law, state tort law may not impose labeling requirements “in addition to” or “different from” federal requirements imposed under FIFRA.

Opinion Closing-

With respect to pesticide labels, FIFRA demands “[u]niformity” and expressly preempts state labeling requirements that are “in addition to” or “different from” federal labeling requirements. §136v(b). Durnell’s state-law failure-to-warn claim would require a cancer warning on Roundup’s label—a requirement “in addition to” and “different from” the label required by EPA under FIFRA. FIFRA therefore expressly preempts Durnell’s claim. We reverse the judgment of the Missouri Court of Appeals and remand the case for further proceedings not inconsistent with this opinion.

It is so ordered.

Summary of Justice Thomas’s Concurring Opinion

“I agree with the Court’s interpretation of the Federal Insecticide, Fungicide, and Rodenticide Act and its application of our preemption precedents. I therefore join its opinion in full.”

In sum, Justice Thomas agrees with the court’s decision, however, he spends the rest of his concurrence addressing what he calls – “underlying constitutional infirmities in the Act.” The Act he refers to is FIFRA. He believes Congress should NOT grant “legislative powers” to federal agencies. He questions whether this “legislative power” of granting the executive branch broad rulemaking authority contradicts the separation of powers clause of the constitution. This is a broad statement, not on just the merits of FIFRA, but the broad “through schemes that exceed even Congress’s powers, there would be far less occasion to address conflicts between agency actions and state law that the Constitution’s Framers would not have envisioned.”

Dissent Summary (JUSTICE JACKSON, with whom JUSTICE GORSUCH joins, dissenting.)

- The Court departs from the near-unanimous view of the many state and federal courts that have rejected this preemption argument. Durnell’s failure to-warn claim is not “in addition to or different from” FIFRA’s mandates; it is *equivalent* to FIFRA’s key labeling requirement—the misbranding prohibition.
- Federal law does not necessarily box out *all* state regulation on a particular issue. Congress can and does enact statutory provisions that specifically define the preemptive scope of the federal law.
- FIFRA expressly limits States’ authority to regulate pesticide labels, but it does not eliminate that authority. Instead, FIFRA preempts only those state “requirements for labeling or packaging in addition to or different from” the requirements under FIFRA. §136v(b). This means that state labeling requirements “equivalent to” FIFRA’s requirements are not preempted. In other words, FIFRA’s preemption clause does not block state-law claims where the violation of state law is also a violation of FIFRA.
- The majority reads into FIFRA a labeling requirement that does not exist, and it reads out of FIFRA the statute’s ongoing prohibition on misbranding. This interpretation cannot be squared with the text of FIFRA or our precedents. Ultimately, the effect of the majority’s interpretation is both remarkable and regrettable, for it unjustifiably closes the courthouse doors to state tort plaintiffs like Durnell.