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Legal Sidebar

Preemption in the Federal Insecticide, Fungicide, and Rodenticide Act

May 2, 2025

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) directs the U.S. Environmental Protection Agency (EPA) to regulate the sale and use of pesticides in the United States. FIFRA generally does not preempt state or local regulation of pesticides, and states continue to regulate pesticides, including by providing causes of action in tort for certain injuries alleged to have arisen from pesticide use. FIFRA does, however, preempt some state and local regulation of pesticide labels. Federal circuit courts disagree as to whether FIFRA preempts certain state claims arising from pesticide sale or use that allege a failure to warn or similar torts. Each of the three circuit courts to consider the question has done so in cases involving alleged harm arising from the use of glyphosate-containing pesticides.

This Sidebar begins with a brief summary of the relevant provisions of FIFRA and related regulations. It proceeds with a discussion of the federal circuit court opinions that have considered whether FIFIRA preempts state failure to warn claims arising from pesticide use. It concludes with considerations for Congress.

FIFRA Background

FIFRA imposes a number of requirements on pesticide manufacturers and other parties. Most important to the question of preemption and the current disagreement among some federal circuit courts are the requirement to register pesticides with EPA, labeling requirements, and the prohibition on the sale of misbranded pesticides.

Registration, Labeling, and Misbranding

"Pesticide" as used in FIFRA includes substances used to control any "pest," which includes "any insect, rodent, nematode, fungus, weed" or any organism EPA declares to be a pest. FIFRA generally prohibits the sale or distribution of a pesticide in the United States that has not been registered with EPA. FIFRA directs EPA to register a pesticide upon making certain determinations, including that, when used normally, the pesticide will not cause "unreasonable adverse effects on the environment" and that the pesticide's label complies with all requirements of FIFRA. The statute defines "unreasonable adverse effects on the environment" as unreasonable risk to man or the environment or human dietary risk. To

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LSB11304

allow EPA to make the required determinations, the statute establishes a registration procedure requiring the submission of certain data and materials, including a copy of the pesticide's label and directions for use. EPA has promulgated regulations further detailing registration procedures and requirements. EPA will register a pesticide only if it determines that, among other things, the application includes data sufficient to allow it to make the findings required by statute for registration and that the pesticide is not misbranded.

FIFRA requires EPA to re-review registrations periodically. EPA has authority to cancel a registration if it determines that the pesticide or its labelling is inconsistent with FIFRA or causes unreasonable harm. FIFRA also imposes an ongoing post-registration reporting requirement on pesticide registrants, requiring that they report to EPA "additional factual information regarding unreasonable adverse effects on the environment" and, pursuant to regulations promulgated under FIFRA, information about toxic or adverse effects, including "delayed or chronic" adverse effects.

EPA has established regulations detailing the content required on pesticide labels. All labels must include directions for use "adequate to protect the public . . . and to prevent unreasonable adverse effects on the environment." All labels must also bear hazard and precautionary statements for both human and environmental hazards. EPA regulations further provide that, except for minor modifications and subject to EPA discretion, registrants must submit an application for amended registration before modifying the labeling or packaging of a registered pesticide.

FIFRA also prohibits the sale or distribution of a pesticide if "claims made for it as a part of its distribution or sale substantially differ" from claims submitted as part of the registration application, or if the pesticide is misbranded. The statute defines "misbranded" to include, among other things, a pesticide with a label lacking a "warning or caution statement . . . adequate to protect health and the environment."

Under Section 3 of FIFRA, registration of a label with EPA is not a defense to allegations that an entity has violated the statute. Instead, registration constitutes only prima facie evidence of compliance with FIFRA's requirements, including the prohibition on marketing misbranded products.

Preemption under FIFRA

The Constitution's Supremacy Clause provides that where a federal law and state law conflict, federal law preempts state law. Congress has the authority to craft laws that define the scope of their preemption of state laws; a federal statute can expressly preempt state law where the statute includes an express preemption provision. Where Congress is silent on preemption, a federal law can impliedly preempt state law in certain circumstances, including where compliance with both federal and state law is impossible (known as conflict preemption) and where Congress has established a comprehensive framework indicating an intent to exclude state regulation (known as field preemption).

FIFRA both expressly preempts certain aspects of state regulation of pesticides and explicitly allows for continued state regulation of other aspects—namely their sale and use. Section 24(a) of FIFRA (7 U.S.C. § 136v(a)) explicitly allows states to regulate the sale and use of pesticides as long as the state does not permit any sale or use otherwise prohibited under FIFRA. Although FIFRA impliedly preempts any state law that directly conflicts with a federal requirement or prohibition, in *Wisconsin Public Intervenor v. Mortier* the Supreme Court held that FIFRA's regulatory scheme is not "so pervasive" as to support an inference that Congress intended to "occupy the field" of pesticide regulation. In that case, the Court held that FIFRA did not preempt a local ordinance requiring a permit for the aerial application of pesticides.

Although FIFRA expressly allows states to continue regulating certain aspects of pesticides, Section 24 of FIFRA also includes an express preemption provision *limiting* state pesticide regulation by prohibiting states from imposing "any requirements for labeling or packaging in addition to or different from those required under" the statute. The statute defines "labeling" broadly to include "all labels and all other

written, printed, or graphic matter accompanying the pesticide or device at any time," as well as material to which the label or literature accompanying the pesticide refers.

In 2005, the Supreme Court addressed the application of FIFRA's preemption provisions to state tort claims that turn on information provided to the user by the manufacturer. In *Bates v. Dow*, farmers had brought state law claims against a pesticide manufacturer, including fraud, negligent failure-to-warn, and breach of warranty, all arising from their use of a registered pesticide on their peanut crops. The U.S. Court of Appeals for the Fifth Circuit (Fifth Circuit) affirmed dismissal of those claims, reasoning that, because success on those claims would "induce" the manufacturer to alter the pesticide's label, they were preempted under FIFRA.

The Supreme Court vacated the Fifth Circuit's decision. The Court observed that FIFRA's express preemption provision applies only to "requirements," and determined that those "requirements" include not only statutes and regulations, but also common law duties like those at issue in this case. To determine the scope of preemption under FIFRA, the Court applied a two-part test based in the language of the statute: FIFRA preempts a state law requirement if (1) the state requirement is "a requirement *for labeling or packaging*" and (2) the packaging or labeling requirement is "*in addition to or different from* those required" under FIFRA, including its implementing regulations. The Court rejected the lower court's "inducement" test, holding that an "event" like a successful jury verdict that could "motivate" a manufacturer to change a label is not a "rule of law that must be obeyed," and thus not a "requirement." The court held that most of the peanut farmers' claims, including breach of warranty, were not preempted because they did not establish rules requiring any particular labeling or packaging and thus were not labeling or packaging requirements.

The Court held that, unlike their other claims, plaintiffs' claims for fraud and negligent failure-to-warn rested on common law duties that did constitute requirements for labeling or packaging. Proceeding to the second step of the test, the Court held that those claims would not be preempted if the state requirements were "parallel requirements" "equivalent to, and fully consistent with" the misbranding provision of FIFRA, regardless of whether the state requirements explicitly incorporated FIFRA's standards. The Court observed that this reading, under which a state is free to make violation of FIFRA a state offense punishable by state sanctions, aided the "functioning" of FIFRA.

The Court did not, however, decide whether FIFRA in fact preempted those claims. Instead, the Court remanded the case for the lower court to make that determination.

FIFRA and Glyphosate in the Courts

Glyphosate is a chemical widely used to control weeds. The existence and magnitude of risks associated with the widespread use of glyphosate, including how regulators should account for those possible risks, has been the subject of significant debate for the last decade.

EPA first registered pesticides containing the active ingredient glyphosate in 1974. In 1994, EPA determined that glyphosate met eligibility requirements for reregistration under FIFRA based on "its conclusions regarding human and environmental risks associated" with normal use. Researchers and regulatory agencies, however, have reached varied conclusions on whether glyphosate poses a risk of cancer in humans. In 2015, an agency of the World Health Organization released a report concluding that glyphosate was "probably carcinogenic to humans." In 2017, California categorized glyphosate as a chemical known to the state to cause cancer, triggering a requirement for a warning label under California's Proposition 65. In 2019, as part of its regular re-review of glyphosate, EPA issued a proposed conclusion that glyphosate was not likely to cause cancer in humans. EPA later issued a Glyphosate Interim Registration Review Decision, which was partially vacated by the U.S. Court of Appeals for the Ninth Circuit (Ninth Circuit) and subsequently withdrawn by the agency. Also in 2019, EPA sent an

informal letter to registrants of pesticides that include glyphosate stating that the agency had determined that glyphosate is not likely to be carcinogenic to humans, and that because of that finding, a label carrying the required Proposition 65 warning would be considered misbranded under FIFRA.

Plaintiffs have brought a number of lawsuits based on damages allegedly caused by glyphosate-containing pesticides. To date, these cases have resulted in three federal appellate court opinions on whether FIFRA preempts state failure to warn claims in the context of glyphosate-containing pesticides.

No Preemption: *Hardeman* and *Carson*

Two federal circuit courts have held that FIFRA does not preempt state law failure to warn claims.

In 2021, the Ninth Circuit decided *Hardeman v. Monsanto*, a case in which a plaintiff alleged that Roundup, a registered glyphosate-containing pesticide, caused his non-Hodgkin's lymphoma and that Monsanto Company, the manufacturer of the pesticide, violated California's common law duty to warn. The plaintiff had prevailed in the trial court and a jury had awarded him more than $5,000,000 in compensatory damages and $75,000,000 in punitive damages, which the district court reduced to $20 million. After the trial court denied its post-trial motion for judgment as a matter of law, Monsanto appealed to the Ninth Circuit. On appeal, Monsanto argued, among other things, that FIFRA both expressly and impliedly preempted the plaintiff's claim. The Ninth Circuit rejected those arguments, allowing the reduced damages award to stand.

In February 2024, the U.S. Court of Appeals for the Eleventh Circuit (Eleventh Circuit) decided a similar appeal. In *Carson v. Monsanto*, a plaintiff alleged that use of Roundup caused his malignant fibrous histiocytoma, a form of cancer, and brought a number of claims against Monsanto based in Georgia law, including a failure to warn claim. Monsanto argued that this claim was expressly and impliedly preempted by FIFRA, and the district court agreed. On appeal however, the Eleventh Circuit rejected Monsanto's preemption arguments on grounds similar to those in *Hardeman*.

No Express Preemption

To determine whether FIFRA expressly preempts a state law failure to warn claim, both the Ninth Circuit and the Eleventh Circuit applied the two-part *Bates* test. At the first step, the Ninth Circuit held, with little discussion, that the state law duty constituted a "requirement for labeling and packaging" because it was "based on" the absence of an "adequate warning on a label." The Eleventh Circuit similarly found the first step satisfied, observing that both parties agreed that Georgia's duty to warn constituted a requirement for labeling and packaging.

At the second step of the *Bates* test, the Ninth Circuit held that FIFRA does not preempt a state law labeling requirement if the state law requirement is "equivalent to" and "fully consistent" with FIFRA, meaning that both laws impose "parallel requirements." The Ninth Circuit further held that a state law labeling requirement is parallel to FIFRA if a violation of the state law duty would also constitute a violation of FIFRA's misbranding provision. The Ninth Circuit observed that under FIFRA's misbranding provision, a pesticide label must "contain a warning or caution statement which may be necessary and if complied with . . . is adequate to protect health and the environment." The Ninth Circuit held that this language, as defined in the statute, "contemplates" cancer risk. The Ninth Circuit then looked to the content of the duty to warn under California law, describing two standards under state law: strict liability, requiring a manufacturer to warn of a health risk if it is "known or knowable;" and negligence, requiring a manufacturer to warn of any risk "a reasonably prudent manufacturer would have known and warned about." Comparing these two state law duties with FIFRA's misbranding provision, the Ninth Circuit held that FIFRA's branding provision is broader than the duty imposed by California's negligence standard and "at a minimum" consistent with the duty imposed by California's negligence standard. Because these state

law duties are "parallel" to FIFRA's misbranding provision, the Ninth Circuit held, the plaintiff's state claim under state law "effectively" enforced FIFRA and was therefore not preempted.

The Eleventh Circuit proceeded similarly at the second step of the *Bates* test. The court focused on FIFRA's misbranding prohibition, which it characterized as imposing strict liability. The court held Georgia's common law duty to provide "an adequate warning" of "nonobvious foreseeable dangers" that a manufacturer "knows or reasonably should know" arise from use of the product was narrower than the FIFRA misbranding requirement. The court observed that Georgia common law does not "exactly track" the language of FIFRA, but was nevertheless fully consistent with and parallel to FIFRA's misbranding provision, and therefore not expressly preempted.

Both courts also rejected Monsanto's arguments that EPA's registration of Roundup without a cancer warning on the label and other EPA actions also expressly preempted state failure to warn claims. The Ninth Circuit held that, because registration is merely prima facie evidence of compliance, not a defense against "the commission of any offense" under FIFRA, a registration decision is not "dispositive of FIFRA compliance" and therefore could not be "conclusive" on the question of whether a state law requirement was "in addition to or different from" FIFRA's requirements. The Ninth Circuit separately held that neither EPA registration nor EPA's 2019 letter carried the force of law, as would be required for preemption. Regarding the 2019 letter, the court concluded that it was analogous to an informal policy opinion letter and not the product of any formal administrative procedure sufficient to give it the force of law.

The Eleventh Circuit employed similar reasoning, but specified that the reference to "requirements" in FIFRA's preemption provision "compels" the force-of-law analysis. The Eleventh Circuit also pointed to the fact that EPA can revoke registration, in addition to the prima facie evidence provision, in determining that registration decisions do not carry the force of law. The Eleventh Circuit also compared registration under FIFRA with the pre-market approval process for medical devices under the Food, Drug, and Cosmetics Act (FDCA), which the Supreme Court held in *Riegel v. Medtronic, Inc.* expressly preempts state law strict liability and negligence claims over a device's label. The court determined that FIFRA and the FDCA included similar preemption provisions, but held that, when "read . . . in context," key differences between the two statutory schemes and approval processes showed that FIFRA's preemption provision did not have the same effect as the FDCA's preemption provision. Among these differences, the court contrasted the "relatively decentralized scheme" of FIFRA with the "decidedly centralized" scheme of the FDCA. The court also observed, citing *Riegel*, that premarket approval under the FDCA "presents a 'rigorous' conclusion" of device safety and effectiveness, while FIFRA registration is only prima facie evidence of FIFRA compliance.

No Implied Preemption

Both courts also rejected arguments that FIFRA *impliedly* preempts state duty to warn claims. Both the Ninth Circuit and the Eleventh Circuit held that to prevail, Monsanto would have to show that compliance with both the state and federal requirement was impossible. To do so, both courts explained that Monsanto would have to show "clear evidence" that (1) EPA was "fully informed" of the "justifications" for the cancer warning, (2) EPA informed Monsanto that it would not approve an amended label carrying the cancer warning, and (3) EPA's denial carried the force of law. Observing that Monsanto's implied preemption argument rested on the same agency actions it had already determined did not carry the force of law—EPA's registration and EPA's 2019 letter—the Ninth Circuit held Monsanto could not make the necessary showing.

The Eleventh Circuit agreed. The Eleventh Circuit also discussed Monsanto's obligation to show that EPA informed Monsanto that it would not approve an amended label carrying the cancer warning required under Georgia common law. The court characterized Monsanto's argument as chiefly relying on EPA's re-

registration determinations for glyphosate and EPA's 2019 letter. Regarding EPA's re-registration decision, the court observed that Monsanto did not request, and EPA did not consider, a cancer warning. Therefore, the court held, the re-registration decision was not evidence that EPA informed Monsanto that it would not approve an amended label. Similarly, the court observed that EPA's 2019 letter related only to the warning required under California's Proposition 65, and therefore was not evidence that EPA had informed Monsanto that it would not approve *any* cancer warning. The court therefore held that FIFRA did not impliedly preempt the state-law cause of action.

The Ninth Circuit separately rejected Monsanto's argument that FIFRA impliedly preempted the state duty to warn because EPA regulations did not permit Monsanto to "unilaterally" add a warning to the Roundup label, making compliance with both federal and state law impossible. Monsanto relied primarily on a Supreme Court opinion, *PLIVA, Inc. v. Mensing*, concerning the regulatory scheme for generic drugs. In distinguishing that scheme from FIFRA, the Ninth Circuit pointed to an EPA regulation under which manufacturers can apply for an amended registration with proposed labelling changes and to a separate regulation that allows manufacturers to make "minor modifications" without prior EPA approval. The court held that because these regulatory provisions could have allowed Monsanto to amend the Roundup label to add a cancer warning, compliance with both federal and state law was not impossible, and therefore the state law was not impliedly preempted. The Eleventh Circuit applied a similar analysis to Monsanto's *Mensing* argument.

Preemption: *Schaffner*

In August 2024, the U.S. Court of Appeals for the Third Circuit (Third Circuit), breaking with the Ninth and Eleventh Circuits, issued an opinion in *Schaffner v. Monsanto* holding that FIFRA expressly preempted a state law failure to warn claim. The court did not address implied preemption.

As with *Hardeman* and *Carson*, this case involved a plaintiff's claim that exposure to Roundup caused his cancer. Like the courts in those cases, the Third Circuit looked to the Supreme Court's analysis in *Bates* to determine whether FIFRA expressly preempted the state-law claim, here based in Pennsylvania law. Because both parties conceded that the Pennsylvania law was a "requirement for labeling or packaging," the Third Circuit's analysis focused on whether the state law constituted a "parallel requirement" under the second step of the *Bates* test. Before applying the parallel requirements test, the court determined "the federal requirement that must be compared" with the Pennsylvania requirement, which the court called the "Federal Comparator." To identify the Federal Comparator, the court first examined registration regulations promulgated under FIFRA as regulations "that give content to" FIFRA's misbranding provision. The court held that these regulations prohibited Monsanto from adding a cancer warning to the Roundup label. The court then ruled, relying in part on *Riegel*, that those registration regulations constituted a "requirement" because the approval of a registration imposes a substantive restriction on the content of a pesticide's label.

The Third Circuit characterized the decisions of the *Hardeman* and *Carson* courts as using FIFRA's misbranding provision, standing alone, as the Federal Comparator. The Third Circuit rejected that position. Rather, the court held, the Federal Comparator must incorporate regulations that "specifically identify the contents" of a pesticide label, including the regulation requiring approval of an amended registration application before modifying a pesticide label. The court held that this regulation "gives content" to FIFRA's misbranding prohibition. Having determined that the Federal Comparator includes EPA's preapproval regulation, the court held that the absence of a cancer warning did not violate the preapproval regulation because EPA had approved the Roundup label without a cancer warning. The court then ruled that state law duty to warn was therefore not equivalent to FIFRA, and was preempted.

The court went on to hold that the fact that registration is merely prima facie evidence of compliance with FIFRA was not relevant to its inquiry, because the "only role" the court assigned registration in the

opinion was that of "determining the content of a requirement imposed under FIFRA." The Court also held, in contrast to the Ninth and Eleventh Circuits, that a force of law analysis was required only in cases of implied preemption, and not where, as here, a statute includes an express preemption provision.

Issues for Congress

Currently, there is a split among federal courts of appeals on the question of whether FIFRA preempts state-law failure to warn claims for harms allegedly arising from use of registered pesticides. This circuit split creates uncertainty for both pesticide manufacturers and consumers. The Supreme Court has not yet opined on the preemption question. Monsanto filed a petition for certiorari seeking review of the Ninth Circuit's ruling in *Hardeman*; the Supreme Court denied the petition in June 2022. More recently, on April 4, 2025, Monsanto filed a petition for certiorari seeking review of a state court opinion presenting the same question of whether FIFRA preempts state-law failure-to-warn claims. Monsanto subsequently filed two additional petitions for certiorari in other cases presenting the same question. Should the Court choose to take any of these cases, it could resolve the question on which the federal courts of appeals are currently split.

Congress, however, could also amend FIFRA to either expressly preempt state law failure-to-warn claims or to explicitly state that it does not preempt such claims. Several bills were introduced in the 118th Congress that would have amended the FIFRA provision that limits state and local regulation of pesticide labels. Some of those proposals would have directed that the provision "be applied to require uniformity in national pesticide labeling," while others would have entirely removed the provision.

Amending the law to expressly preempt state law failure-to-warn claims would eliminate an avenue of recovery states have chosen to provide, while also bringing certainty to pesticide manufacturers, who would no longer be subject to such claims as defined in the law of each state. Alternatively, amending FIFRA to explicitly not preempt such claims would lead pesticide manufacturers to continue to face those disparate claims, while also preserving states' ability to provide those claims as avenues for recovery.

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