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Next Stop, SCOTUS?: Preemption Holding Creates Circuit Split Over Pesticide Labeling

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The recent decision of the U.S. Court of Appeals for the Third Circuit in *Schaffner v. Monsanto Corp.*, No. 22-3075, 2024 WL 3820973 (3d Cir. Aug. 16, 2024), creates a clear circuit split on an important question of express preemption under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA). An ideologically diverse Third Circuit panel unanimously held that federal law preempts claims that Monsanto is liable under Pennsylvania law for failing to give a cancer warning on its glyphosate-based weed killer, Roundup, because the EPA had registered and approved the product's label under FIFRA *without* requiring such a warning. Such claims, the Third Circuit held, were expressly preempted by FIFRA's "Uniformity" provision, 7 U.S.C. § 136v(b).

The Third Circuit's decision breaks with recent decisions by the Ninth and Eleventh Circuits holding that FIFRA does not preempt state-law failure-to-warn claims regarding glyphosate and cancer. *See Hardeman v. Monsanto Co.*, 997 F.3d 941, 950 (9th Cir. 2021); *Carson v. Monsanto Co. (Carson IV)*, 92 F.4th 980, 992-93 (11th Cir. 2024). The split of authority raises the stakes for potential Supreme Court review of this critical preemption question.

Schaffner involves claims by a plaintiff who suffered non-Hodgkin's lymphoma that he alleged was caused by regular exposure to glyphosate as a professional landscaper and property owner. Schaffner filed suit under Pennsylvania law after the World Health Organization's International Agency for Research on Cancer ("IARC")—alone among national and international regulators—concluded in 2015 than glyphosate is probably carcinogenic to humans. In light of IARC's conclusion, he alleged that Monsanto violated the state's common law duty to warn by failing to warn that the product was known to cause cancer. His case was eventually consolidated as part of a Multi-District Litigation ("MDL") order (*see In re Roundup Prods. Liab. Litig.*, 214 F. Supp. 3d 1346, 1348-49 (J.P.M.L. 2016)). The MDL Court rejected Monsanto's express preemption argument for all cases under its jurisdiction.

As framed by the Third Circuit, Monsanto's appeal presented the question of "whether, once the Environmental Protection Agency ('EPA') registers and approves a pesticide label that omits a particular health warning, a state-law duty to include that warning is preempted by a federal statute expressly preempting any state-law pesticide labeling requirement that differs from or adds to the requirements imposed under federal law." Relying on FIFRA's "Uniformity" provision, which prohibits states from "impos[ing] or continu[ing] in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter," 7 U.S.C. § 136v(b), the Third Circuit held that such a state-law claim was expressly preempted.

By contrast, the Ninth and Eleventh Circuits have held that, while a common law duty-to-warn claim imposes a "requirement" under state law, that requirement is not "in addition to or

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different from" the requirements of FIFRA. To reach that conclusion, the courts examined FIFRA's so-called "misbranding" provision and concluded that state common law claims are co-extensive with the misbranding requirement of FIFRA. FIFRA prohibits the distribution or sale of a pesticide that is "misbranded," 7 U.S.C. § 136j(a)(1)(E), and considers a product misbranded if its label "does not *contain* a warning or caution statement which may be necessary and if complied with . . . is adequate to protect health and the environment." 7 U.S.C. § 136(q)(1)(G).

Reading that requirement at a high level of generality, both the Ninth Circuit in *Hardeman* and the Eleventh Circuit in *Carson* concluded that FIFRA's misbranding requirements "parallel those of [the state's] common law duty" and thus the common law failure-to-warn claims "effectively enforce FIFRA's requirement against misbranding and are thus not expressly preempted." *See Hardeman*, 997 F.3d at 955. Those courts held that EPA's determination not to require a cancer warning on the product's label—a determination repeatedly reached after years of careful scientific study—"are not conclusive as to which common law requirements are 'in addition to or different from' the requirements imposed by FIFRA." *Id.* at 956. Both courts held that this result was compelled by the U.S. Supreme Court's reading of FIFRA's express preemption provision in *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005).

The Third Circuit disagreed, diverging from its sister circuits on the level of generality with which to characterize the federal requirement. At the "core" of the parties' dispute was the question of how to define the relevant federal misbranding requirement. Plaintiff contend that FIFRA required only "that pesticides not be misbranded under the statutory definition of that term," while Monsanto argued that the federal requirement also "incorporate[ed] the omission of the Cancer Warning from Roundup's Preapproved Label." Slip op. at 26.

To answer the question of what FIFRA's misbranding "requirement" was, the Third Circuit drilled down to FIFRA's regulations—in particular, the regulatory "Preapproval" requirement, 40 CFR 152.44(a), which provides that, once approved, a label cannot be modified without the express approval of EPA. Because EPA approved a label without a cancer warning, a determination that EPA made only after careful study of the science (including many rounds of public notice and comment), a state law that requires such a warning is "in addition to" or "different from" FIFRA's labeling requirement. Thus, unlike its sister circuits, the Third Circuit determined that the federal "requirement"—which *Bates* defines as a rule of law that must be obeyed—is that "pesticide's label must conform to its Preapproved Label." The Third Circuit's ruling is consistent with the EPA's own description of its labeling regime: "the label is the law." *See* EPA Office of Pesticide Programs Label Review Manual at 1-2.

Bates raised doubts (without ultimately deciding) that state-law mislabeling claims based on the *efficacy* of a pesticide would be preempted by an EPA registration decision, with respect to a pesticide for which EPA *had waived* efficacy review and not passed on the label's claims of efficacy at all. But the EPA review as to whether glyphosate causes cancer was extensive. Unlike in *Bates,* EPA does not approve the glyphosate labels automatically—instead, it extensively reviews them to determine if they "comply with the requirements of" FIFRA, including the misbranding requirement. 7 USC § 136a(c)(5)(B). Thus, "because regulations promulgated to implement FIFRA require the health warnings on a pesticide's label to conform to the proposed label approved by the EPA during the registration process (the 'Preapproved Label'), and because during Roundup's registration process the EPA approved proposed labels omitting a cancer warning *following an extensive review of scientific evidence concerning Roundup's possible carcinogenicity*," the Third Circuit concluded that the alleged state-law duty to include the Cancer Warning on Roundup's label imposes requirements that are different from those imposed under FIFRA, and that it is therefore

preempted by FIFRA. Slip op. 6 (emphasis added).

Several key differences stand out between the Third Circuit's *Schaffner* decision and the decisions of the Ninth Circuit (*Hardeman*) and Eleventh Circuit (*Carson*).

- First, the Third Circuit showed a willingness to consider not just FIFRA's broad statutory prohibition against mislabeling but also the regulations which, in the language of *Bates*, "give content" to that misbranding standard.
- Second, breaking with its sister circuits, the Third Circuit found support for its holding in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), in which the Supreme Court held that similar pre-market approval provisions of the Medical Device Amendments of 1976 preempted state tort law. The Third Circuit drew parallels between FIFRA's mislabeling requirement and the MDA's preapproval scheme—which, like FIFRA, required agency pre-approval for device safety and effectiveness and preempted laws "in addition to" or "different from" federal requirements.
- Third, unlike the Ninth and Eleventh Circuits, the Third Circuit was not affected by the provision of FIFRA—Section 136a(F)(2)—providing that registration shall not be a defense to commission of an offense, but only prima facie evidence of compliance. The court agreed that EPA registration cannot be dispositive of compliance with FIFRA, but that only means that a registrant cannot overcome liability under FIFRA by virtue of the mere fact of product registration. But, the Third Circuit concluded, "registration affects the content of the requirement under FIFRA, as registration determines what label the pesticide must bear." So unlike its sister circuits, the Third Circuit concluded that it is not the mere fact of registration, but the content that registration requires, that controls under the misbranding requirement.

The *Schaffner* decision is significant. Monsanto has faced thousands of glyphosate-product liability claims. It has settled many, but a large number remain. And while it has had success in many of the cases that have gone to trial on state-law theories like the duty-to-warn claim in *Schaffner*, those verdicts that have gone against it have resulted in hundreds of millions of dollars in liability, which Monsanto continues to fight in many cases on appeal. The disagreement among the circuits on this critical preemption question—which would, if successful, eliminate existing claims for failure to warn of a potential cancer risk—increases the chance of Supreme Court review in the appropriate case and a final resolution of this FIFRA critical preemption issue.

