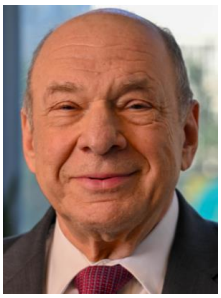
3rd. Circ. Got It Right On Cancer Warning Claims Preemption

By **Lawrence Ebner** (September 10, 2024)



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At last, a federal court of appeals has correctly interpreted and applied the U.S. Supreme Court's 2005 Bates v. Dow AgroSciences LLC opinion in pesticide failure-to-warn litigation.[1]

On Aug. 15, a panel of the U.S. Court of Appeals for the Third Circuit held in Schaffner v. Monsanto Corp.[2] that Section 136v(b) of the Federal Insecticide, Fungicide and Rodenticide Act[3] expressly preempts state law claims alleging that Monsanto — the manufacturer of Roundup, a widely used herbicide — failed to include a cancer warning on its federally regulated and approved product labeling.

Section 136v(b), titled "Uniformity," is an express preemption provision. It declares that a "[s]tate shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under" FIFRA.[4]

The Schaffner opinion, authored by Chief U.S. Circuit Judge Michael A. Chagares, is significant for several reasons. The decision, joined by U.S. Circuit Judges Peter J. Phipps and Cindy K. Chung:

- Directly conflicts with the opinions of two other circuits, each of which holds that FIFRA does not preempt Roundup failure-to-warn claims,[5] thousands of which have been filed around the U.S.;
- Clarifies and establishes a test for applying Bates' notoriously vague "parallel requirements" exception to FIFRA preemption;
- Curtails plaintiffs' ability to pursue personal injury failure-to-warn litigation against producers of numerous other FIFRA-regulated pesticides; and
- Potentially affects product liability claims involving medical devices, which are regulated under a federal statute, the Medical Device Amendments of 1976, containing a preemption provision "closely echoing the language employed by FIFRA's preemption provision."[6]

The purpose of Section 136v(b) is to maintain nationally uniform, federally regulated labeling for each pesticide product granted registration by the U.S. Environmental Protection Agency under FIFRA. As the Third Circuit explained in Schaffner, FIFRA "mandates nationwide uniformity in pesticide labeling by prohibiting states from imposing labeling requirements that are in addition to or different from the requirements imposed under FIFRA itself."[7]

By so doing, FIFRA vests the EPA with exclusive authority to regulate the content of a pesticide product's labeling, including by determining, based on the agency's continual review of scientific data, what health and safety-related label warnings and precautionary statements are necessary, and which are scientifically unwarranted.

In the case of Roundup, the EPA's scientists, over the course of many years, repeatedly

have concluded that the product's active ingredient, glyphosate, does not cause cancer in humans, and thus, that a cancer warning on Roundup labeling is unwarranted.[8]

In fact, in August 2019, the EPA Office of Pesticide Programs' Registration Division director took the extraordinary step of notifying all registrants of glyphosate products that including a California Proposition 65 cancer warning statement on their product labeling would be false and misleading, and thus would render their products misbranded in violation of FIFRA.[9]

Tracking the text of Section 136v(b), the U.S. Supreme Court held in Bates that pesticide-related failure-to-warn claims impose requirements for labeling because they are "premised on common-law rules [that] set a standard for a product's labeling that the [product's] label is alleged to have violated by containing ... inadequate warnings."[10]

Again quoting the statutory text, the court further explained that for a failure-to-warn claim to be preempted by S136v(b), "it must impose a labeling ... requirement that is 'in addition to or different from' those required under [FIFRA]."[11]

Conversely, Bates notes that "a state-law labeling requirement is not pre-empted by §136v(b) if it is equivalent to, and fully consistent with, FIFRA's misbranding provisions."[12] FIFRA defines a product as misbranded if, inter alia, its "label does not contain a warning ... adequate to protect health."[13]

During the past two decades, product liability plaintiffs and their attorneys have seized upon Bates' "'parallel requirements' reading of § 136v(b)"[14] as a facile way for circumventing preemption of pesticide-related failure-to-warn claims. For example, soon after Bates was decided, Leslie A. Brueckner, who was at the time an attorney with Public Justice PC, commented that "most failure-to-warn ... claims will easily pass this test."[15]

Failure-to-warn claims are easier to prove to juries than design defect or manufacturing defect claims, especially in connection with closely regulated products such as pesticides. It is relatively simple to argue, with the benefit of hindsight, that a manufacturer should be held liable because it failed to warn that the product could cause the plaintiff's illness or injury.

The plaintiff in Schaffner, a professional landscaper who used Roundup and developed cancer, argued, based on the parallel-requirements exception that Bates reads into Section 136v(b), "that FIFRA does not preempt the Pa. Duty To Warn because Pennsylvania's standard for defective products is equivalent to FIFRA's statutory misbranding standard."[16]

The Schaffner panel squarely rejected this comparison. The panel acknowledged that "[a]pplying the parallel-requirements test in this fashion, the Courts of Appeals for the Ninth and Eleventh Circuits each held that section 136v(b) does not preempt the similar duties to warn imposed by California and Georgia law."[17]

According to the U.S. Court of Appeals for the Ninth Circuit in Hardeman v. Monsanto Co., "[b]ecause FIFRA's misbranding requirements parallel those of California's common law duty, Hardeman's [Roundup] failure-to-warn claims effectively enforce FIFRA's requirement against misbranding and are thus not expressly preempted."[18]

And in Carson v. Monsanto Co., another Roundup case, the U.S. Court of Appeals for the Eleventh Circuit found that although "Georgia common law does not exactly track FIFRA's

requirements ... the practical effect is the same: both FIFRA and Georgia common law require pesticide manufacturers to warn users of potential risks to health and safety."[19]

Unlike the Ninth and Eleventh Circuits, however, the Third Circuit's Schaffner opinion repudiates this approach to applying the parallel-requirements exception. Rather than adopting an interpretation that renders Section 136v(b) meaningless by enabling an implied exception to swallow the statute's express preemption rule in virtually every failure-to-warn case, the Third Circuit's opinion explains as follows:

> [T]o apply the parallel-requirements test, a court must identify the labeling requirements imposed under state law and under FIFRA, then compare the two to determine whether a pesticide label that violates the state requirement would also violate the federal one. If so, the state-law requirement is equivalent to the federal one and is not preempted. If not, the requirements are not equivalent, and the federal requirement preempts the state one.[20]

More specifically, the court of appeals addressed the question of "whether the Pa. Duty To Warn is in addition to or different from the requirements imposed under FIFRA itself."[21] To make this determination, the court "follow[ed] the approach outlined in Bates,"[22] and also relied on the analytical framework in the Supreme Court's 2008 opinion in Riegel v. Medtronic Inc.,[23] a case applying the Medical Device Amendments' similar preemption provision.

The Schaffner opinion's analysis and application of the parallel-requirements exception consists of a three-step test.

First, quoting Bates, the court of appeals "examine[d] 'EPA regulations that give content to FIFRA's misbranding standards.'"[24] The court specifically pointed to the EPA's preapproval regulation,[25] which "prohibited Monsanto from modifying Roundup's Preapproved Label in order to add the Cancer Warning."[26] The preapproval regulation requires a pesticide registrant to submit to the EPA for review and approval any proposed warning, such as a cancer warning, before it can be added to a pesticide's label.

Second, the court "consider[ed] whether the Preapproval Regulation establishes a 'requirement' for purposes of preemption [and] conclude[d] that it does."[27]

Third, and most important, the court "appl[ied] the parallel-requirements test by comparing the Pa. Duty To Warn with a Federal Comparator that incorporates [the Preapproval Regulation's] regulatory requirement," i.e., the requirement that only warnings approved by EPA can be added to a pesticide's label, rather than "compar[ing] the Pa. Duty to Warn with a Federal Comparator that incorporates the requirement that pesticides not be misbranded solely under the statutory definition of that term."[28]

In other words, the court held that "under both Bates and section 136v(b) itself federal requirements must be articulated at the more specific level when identifying the Federal Comparator in applying the parallel-requirements test."[29]

This third prong of the court's parallel-requirements test recognizes that for the exception to apply, Bates requires considerably more than a cursory comparison between state tort duties and FIFRA's broad definition of misbranding.

Instead, the Supreme Court not "only emphasize[d] that a state-law labeling requirement must in fact be equivalent to a requirement under FIFRA in order to survive preemption,"

but also that "[s]tate-law requirements must … be measured against any relevant EPA regulations that give content to FIFRA's misbranding standards."[30]

The court of appeals therefore explained:

> [T]he parallel-requirements test must involve a comparison to the Preapproval Regulation, and having so held we apply the test. While the Cancer Warning was allegedly required by the Pa. Duty to Warn, it was omitted from Roundup's Preapproved Label and could not have been added to the Roundup label without violating the Preapproval Regulation. Accordingly, the Pa. Duty to Warn is not equivalent to the Federal Comparator, and it is thus preempted under section 136v(b).[31]

The Third Circuit's interpretation and application of the parallel-requirements exception not only is faithful to Bates and the congressional intent underlying Section 136v(b), but also is eminently sensible. The Ninth and Eleventh Circuits' shallow and expansive construction of parallel requirements, and a similar district court interpretation in the Roundup multidistrict litigation,[32] creates a gaping loophole that eviscerates the preemptive effect of Section 136v(b).

In contrast, the Third Circuit's analysis takes into account the manner in which the EPA actually regulates pesticides and their labeling — on a product-by-product basis, following extensive review of active ingredient-specific toxicology and other scientific data.

Imposing liability on a pesticide manufacturer for failing to include on its product label a cancer warning that, as with Roundup, the EPA has concluded is scientifically unwarranted, and would be false and misleading, is exactly the type of state regulation that Section 136v(b) is intended to preempt.

Whether the Supreme Court revisits and clarifies Bates by addressing the Roundup cancer warning FIFRA preemption issue remains to be seen. Meanwhile, the Third Circuit's opinion in Schaffner provides a preemption road map that additional circuits, and federal and state trial courts, should immediately adopt and follow.

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Disclosure: The author, on behalf of the Atlantic Legal Foundation, filed amicus briefs in the Carson and Hardeman cases mentioned in his article. In 2004 he filed an amicus brief in the Bates case on behalf of pesticide industry trade associations.

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[1] Bates v. Dow AgroSciences LLC, 544 U.S. 431 (2005).

[2] Schaffner v. Monsanto Corp., No. 22-3075 (3d Cir. Aug. 15, 2024). A copy of the Opinion ("op.") is available at https://tinyurl.com/5da3mdth.

[3] 7 U.S.C. § 136v(b).

[4] Id.

[5] Carson v. Monsanto Co., 92 F.4th 980 (11th Cir. 2024); Hardeman v. Monsanto Co., 997 F.3d 941 (9th Cir. 2021), cert. denied, 142 S. Ct. 2834 (2022).

[6] Schaffner, op. at 41 (citing 21 U.S.C. § 360k(a)(1)).

[7] Id. at 6.

[8] See Schaffner, op. at 6, 10-11, 26.

[9] FIFRA's multipart definition of "misbranded" also includes product labeling that "bears ... any statement which is false or misleading in any particular." 7 U.S.C. § 136(q)(1)(A). FIFRA makes it unlawful to distribute or sell a pesticide that is misbranded. Id. § 136j(a)(1)(F).

[10] Bates, 544 U.S. at 446; see also Schaffner, op. at 23.

[11] Bates, 544 U.S. at 444; see also Schaffner, op. at 23.

[12] Bates, 544 U.S. at 447.

[13] 7 U.S.C. § 136(q)(1)(G).

[14] Schaffner, op. at 25.

[15] Leslie A. Brueckner, Why Bates Matters: A Response to the Critique of the U.S. Supreme Court's Holding In Bates v. Dow AgroSciences, 20 BNA Toxics L. Rptr. 784 (Aug. 25, 2005). For additional background on the aftermath of Bates, see Lawrence S. Ebner, Can FIFRA Preemption Be Revived?, DRI, For The Defense, (Apr. 2010); Lawrence S. Ebner, FIFRA Preemption After Bates v. Dow AgroSciences, BNA Prod. Safety & Liab. Rptr. (June 13, 2005).

[16] See Bates, 544 U.S. at 447.

[17] Schaffner, op. at 25-26 (citing Carson, 92 F.4th at 991-92; Hardeman, 997 F.3d at 955-56).

[18] Hardeman v. Monsanto Co., 997 F.3d at 955.

[19] Carson, 92 F.4th at 992.

[20] Schaffner, op. at 24.

[21] Id.

[22] Id.

[23] Riegel v. Medtronic Inc., 552 U.S. 312 (2008); see Schaffner, op. at 43 ("The analysis of 'requirements' adopted in Riegel carries over to FIFRA.").

[24] Schaffner, op. at 17 (quoting Bates, 544 U.S. at 453); see also Bates, 544 U.S. at 454 (Breyer, J., concurring) ("stress[ing] the practical importance" of the Court's statement about examining EPA regulations that give content to FIFRA's general misbranding standards).

[25] 40 C.F.R. § 152.44 (Application for amended registration).

[26] Schaffner, op. at 28.

[27] Id.

[28] Id.

[29] Id. at 46.

[30] Bates, 544 U.S. at 453; see also id. at 452 (explaining that §136v(b) "pre-empts any ... common-law rule that would impose a labeling requirement that diverges from those set out in FIFRA and its implementing regulations").

[31] Schaffner, op. at 28.

[32] In re Roundup Prod. Liab. Litig. (MDL No. 2741), 364 F. Supp. 3d 1085, 1087 (N.D. Cal. 2019).