Justices Should Give Feds' Roundup Amicus Little Weight

By Lawrence Ebner (May 27, 2022)

The Office of the Solicitor General is widely lauded for its brief-writing skills. Solicitor general briefs, filed in the U.S. Supreme Court on behalf of the United States, set a high standard, both for their crisp writing style and insightful legal analysis.

But the petition-stage amicus brief that the solicitor general filed on May 10 at the court's invitation in Monsanto Co. v. Hardeman is a major disappointment.[1]

From the perspective of product liability defense attorneys, the brief from the solicitor general is a transparently partisan, short-sighted effort to do the plaintiffs bar's bidding on an important federal preemption question that potentially affects thousands of personal injury claims involving use of Monsanto's Roundup herbicide products.

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And in terms of the public interest, the solicitor general's legal arguments seriously undermine the authority of the U.S. Environmental Protection Agency under the Federal Insecticide, Fungicide and Rodenticide Act, or FIFRA, to make carefully considered, science-based determinations as to what specific health-related warnings should — and should not — be included on a particular pesticide's nationally uniform product labeling.

Solicitor General's Shifting Positions on FIFRA Preemption

Pointing to the change in administration, the solicitor general's amicus brief reverses the unequivocal position on FIFRA preemption that U.S. Department of Justice attorneys, with the approval of the solicitor general, vigorously advocated on behalf of the United States before the U.S. Court of Appeals for the Ninth Circuit in the same bellwether product liability suit less than three years ago.[2][3]

The brief, which recommends against Supreme Court review, contends a Ninth Circuit panel correctly held that FIFRA does not preempt plaintiff Edwin Hardeman's state law "failure to warn" claims concerning Roundup's alleged risk of causing non-Hodgkin lymphoma.[4] But the brief makes no attempt to explain why the government's previous position on FIFRA's preemptive scope in the same litigation was incorrect.

Instead, as if it were writing on a clean slate, the solicitor general now contends that FIFRA does not preempt state law product liability claims that are based on a pesticide manufacturer's failure to provide a health-related label warning that the EPA has conclusively determined is scientifically unwarranted.

This is not the first time that the solicitor general, following a change of administration, has reversed its position on FIFRA preemption of pesticide-related failure-to-warn claims.

In the 2005 Bates v. Dow AgroSciences LLC decision,[5] the Supreme Court's only previous decision on FIFRA tort preemption, the solicitor general merits-stage amicus brief,[6] filed during the Bush administration, explained that "the United States reexamined ... its prior position," advocated during the Clinton administration, that FIFRA does not preempt common-law failure-to-warn claims "and concluded that [it] is incorrect."[7]

At the Supreme Court hearing in Bates, where an attorney from the Solicitor General's Office argued on behalf of the U.S. as amicus curiae in favor of preemption, Justice Antonin Scalia observed, "This is a new position for the Government. ... You used to take the opposite position." To which Justice Stephen Breyer added, "So ... you have one administration thinking the one thing and the other thinking the other thing."[8]

Now, the solicitor general, "[i]n light of the ... change in Administration,"[9] i.e., at the behest of the Biden administration and its plaintiffs bar allies and supporters, once again has reversed course on FIFRA preemption.

The Supreme Court should afford little if any weight to the solicitor general's latest reversal of position on FIFRA preemption of pesticide-related failure-to-warn claims, as we see in the high court's 2009 Wyeth v. Levine decision, affording no deference to the U.S. Food and Drug Administration's changed position on preemption of prescription drug failure-to-warn claims, in part because "it reverses the FDA's own longstanding position without providing a reasoned explanation."[10]

The only explanation in the solicitor general's brief for the government's reversal of position midstream in Hardeman — other than self-serving assertions that "[t]he court of appeals correctly held that FIFRA does not preempt [Hardeman's] claims"[11] — is that the administration has changed.

Under analogous circumstances in Wyeth, the court indicated that "[t]he United States' amicus brief is ... undeserving of deference."[12] The same is true for the United States' amicus brief in Hardeman.

Federal preemption is a legal doctrine derived directly from the U.S. Constitution's supremacy clause, which declares that federal law "shall be the supreme law of the land ... anything in the ... laws of any State to the contrary notwithstanding."[13]

In other words, state law is supplanted when it conflicts with federal law. Because federal preemption of conflicting state law is a constitutional rule, it is not a matter of judicial discretion.

A court confronted with a preemption issue must decide whether a state law (in the form of a state statute, state agency regulation or state common law duty) either is or is not preempted — regardless of whether the court thinks, as a matter of policy, that the state law should or should not be preempted.

For the same reason, the preemptive scope of an existing federal statute, such as FIFRA's express preemption provision, Section 24(b), should not depend on which way the political winds are blowing.

Roundup Litigation Background

Hardeman is one of thousands of failure-to-warn suits involving the alleged carcinogenic risks of glyphosate, the active ingredient in Roundup. The active ingredient-specific warnings and precautionary statements on Roundup's nationally uniform product labeling are meticulously regulated by the EPA under FIFRA.

Over the course of more than 35 years, the EPA has reviewed extensive scientific data on glyphosate, and repeatedly and unequivocally concluded that there is "no evidence that

glyphosate causes cancer in humans."[14]

In fact, in 2019 the EPA not only determined that adding a cancer warning to Roundup's labeling — a safe harbor warning that would have been required by California's notorious Proposition 65 "right to know" law — would be scientifically unwarranted, but also false and misleading, and thus, a violation of FIFRA's prohibition against distribution of misbranded pesticides.[15]

Nonetheless, the gravamen of Hardeman's California state law personal injury claims, like those of myriad other Roundup plaintiffs around the United States, is that Monsanto failed to include a cancer warning on Roundup's EPA-regulated and approved product labeling.

Following a jury trial, the U.S. District Court for the Northern District of California awarded Hardeman more than \$25 million in compensatory and punitive damages based on Monsanto's alleged failure to warn.

Unless and until the Hardeman award is overturned on preemption and/or other grounds, the solicitor general's plaintiff-friendly amicus brief will be hailed by the Roundup plaintiffs' bar as "an important legal development with positive ramifications for cancer victims across the country."[16]

FIFRA Section 24(b), a provision titled "Uniformity," expressly preempts a state from regulating the content of pesticide labeling: A "State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those imposed under [FIFRA]."[17]

In Bates the Supreme Court held that state labeling requirements that are "in addition to or different from" the EPA's pesticide labeling requirements include those that are imposed through state common law failure-to-warn claims.[18]

More specifically, the court explained in Bates that Section 24(b) "pre-empts competing state labeling standards ... prescribing the ... wording of warnings."[19] This is because state law failure-to-warn claims — such as those on which Roundup product liability suits are premised — would "set a standard for a product's labeling" that is "in addition to or different from" the specific labeling requirements imposed by the EPA.[20]

Solicitor General's New Myopic View of FIFRA Preemption

The fundamental federal preemption question presented in Hardeman and numerous other pending Roundup cases is whether FIFRA Section 24(b) bars a state law duty to provide a label warning about an alleged human cancer risk that the EPA, in accordance with its authority under FIFRA, has determined does not exist — a label warning that the EPA, which has exclusive authority to regulate the content of pesticide labeling, has conclusively determined, based on extensive review of scientific data, is unwarranted.

The Supreme Court should address this question not only because its resolution may sound the death knell for a multitude of similar Roundup suits, but also because it goes to the heart of FIFRA's allocation of responsibility between the EPA and the states.

In its Bates amicus brief, the solicitor general explained that "[t]he United States ... has a strong interest in preserving Congress's express delineation [in FIFRA] of federal and state authority, which ensures that the federal government can establish and maintain nationally uniform requirements for [pesticide] labeling and packaging."[21]

The Ninth Circuit amicus brief filed on behalf of the United States in Hardeman contains a virtually identical statement.[22] But the politically expedient, tunnel-vision scope of FIFRA preemption advocated in the solicitor general's Hardeman amicus brief not only conflicts with Bates, but also eviscerates the statute's carefully delineated division of authority between the EPA and the states.

Congress, as part of an extensive overhaul of FIFRA in 1972, added Section 24(b) in order "to completely preempt State authority in regard to labeling."[23] This is because Congress, to enhance safety, wanted pesticide products to be used in accordance with nationally uniform labeling whose content is regulated on a product-by-product basis by the EPA, an expert federal regulatory agency.

The solicitor general's newfound view of FIFRA preemption, however, would allow any state, through its tort law, to second-guess the EPA and hold pesticide manufacturers liable for failing to include on product labeling whatever particular warnings a judge or lay jury determines should have been provided.

To circumvent Section 24(b)'s seemingly airtight prohibition against imposition of state labeling requirements that are "in addition to or different from" the EPA's requirements, the solicitor general's amicus brief seizes upon fuzzy language in Bates about "equivalent" state labeling requirements being excluded from preemption.[24]

The solicitor general misreads Bates by contending that preemption does not apply whenever a general state law duty to provide adequate warnings is consistent with FIFRA's general prohibition against distributing pesticides that are "misbranded," such as where a product's label contains inadequate health or safety warnings.[25]

The gaping "equivalency" exception that the solicitor general's Supreme Court brief in Hardeman now reads into Bates would swallow FIFRA's preemption rule, and directly contradicts the government's Ninth Circuit amicus brief in the same case. That court of appeals brief explained that merely comparing the

general FIFRA [misbranding] standard to California's general ... standards that require a manufacturer to warn of known risks ... misses the thrust and full import of FIFRA's preemption provision. ... In order to avoid federal preemption under FIFRA, it is not enough for a state law merely to be advancing similar policies or interests. ... Instead, where California general common-law standards impose any inconsistent labeling or packaging requirement, the California common-law claims are preempted, even if the standard supporting those claims is phrased similarly to the standard imposed by Congress through FIFRA.[26]

The solicitor general's current, constricted view of FIFRA preemption defeats the purpose of FIFRA Section 24(b) by allowing each state to impose its own requirements for health warnings on what Congress intended to be nationally uniform product labeling regulated solely by the EPA on the basis of sound science.

As the Supreme Court cautioned in Bates when emphasizing Section 24(b)'s "narrow, but still important," role: "[I]magine 50 different labeling regimes, each prescribing the ... wording of warnings."[27]

If the solicitor general's most recent interpretation of FIFRA's 50-year-old preemption provision were to prevail, the result would be nationally "uniform" product labeling

encumbered by a multiplicity of potentially conflicting or inconsistent, state-specific warning statements.

Consider, for example, the EPA's recent letter approving the California Environmental Protection Agency's newly proposed, ludicrously ambiguous, California-specific, label warning about glyphosate's supposed cancer risk.[28] An EPA-approved label containing such state-required statements likely would confuse, rather than inform, pesticide users, some of whom may be deterred from using highly beneficial products that the EPA has determined, as in the case of Roundup, do not pose chronic health risks.

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Disclosure: The author submitted an amicus brief on behalf of the Atlantic Legal Foundation in support of the pending petition for a writ of certiorari in Monsanto v. Hardeman.

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- [1] Available at https://www.supremecourt.gov/DocketPDF/21/21-241/222984/20220510154200610_Monsanto.CVSG%205.9.22%20v.2.pdf.
- [2] U.S. Br. in Hardeman at 6.
- [3] Available at https://atlanticlegal.org/wp-content/uploads/2022/05/Hardeman-DOJ-Amicus-Br-9th-Cir.pdf.
- [4] See Hardeman v. Monsanto Co., 997 F.3d 941 (9th Cir. 2021).
- [5] 544 U.S. 431 (2005).
- [6] Available at https://www.justice.gov/sites/default/files/osg/briefs/2004/01/01/2003-0388.mer.ami.pdf.
- [7] U.S. Br. in Bates at 20.
- [8] Transcript of Oral Argument, Bates v. Dow AgroSciences, LLC, 544 U.S. 431 (2005) (No. 03-388), available at https://www.oyez.org/cases/2004/03-388.
- [9] U.S. Br. in Hardeman at 8.
- [10] 555 U.S. 555, 577 (2009).
- [11] U.S. Br. in Hardeman at 8.
- [12] Wyeth, 555 U.S. at 580 n.13.
- [13] U.S. Const., art. VI., cl. 2.

- [14] See EPA glyphosate information page, https://www.epa.gov/ingredients-used-pesticide-products/glyphosate.
- [15] See EPA Letter to Glyphosate Registrants (Aug. 7, 2019), available at https://www.epa.gov/sites/default/files/2019-08/documents/glyphosate_registrant_letter_-_8-7-19_-_signed.pdf.
- [16] Bailey Glasser LLP, U.S. Solicitor General Sides With Cancer Victims In Appeal of \$80 Million Roundup Verdict, https://www.baileyglasser.com/news-us-solicitor-general-sides-with-cancer-victims-appeal-80m-roundup-verdict.
- [17] 7 U.S.C. § 136v(b).
- [18] Bates. 544 U.S. at 452.
- [19] Id. at 446.
- [20] Id.
- [21] U.S. Br. in Bates at 1.
- [22] See U.S. Br. in Hardeman (9th Cir.) at 3.
- [23] H.R. Rep. No. 92-511, at 16 (1971).
- [24] See U.S. Br. in Hardeman at 7 (citing Bates, 544 U.S. at 447).
- [25] See 7 U.S.C. § 136(q).
- [26] U.S. Br. in Hardeman (9th Cir.) at 19-20.
- [27] Bates, 544 U.S. at 452.
- [28] See EPA letter to Cal. EPA (Apr. 8, 2022), available at https://www.epa.gov/system/files/documents/2022-04/letr-to-ca-oehha-on-ca-prop-65.pdf.