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Why *Wyeth* Matters To The Pesticide Industry

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The "FIFRA preemption defense" was enormously successful from the late 1980s until the Supreme Court's April 2005 decision in *Bates v. Dow AgroSciences*, 544 U.S. 431 (2005). Summary judgments based on FIFRA preemption saved pesticide manufacturers and distributors hundreds of millions of dollars that juries otherwise might have awarded to plaintiffs who claimed that they were injured, or that their crops or property were damaged, due to inadequate labeling or warnings about a pesticide's risks. *Bates*, which focused on the scope of FIFRA's express preemption provision, 7 U.S.C. § 136v(b), practically eviscerated the defense. But the Supreme Court's forthcoming opinion in *Wyeth v. Levine*, No. 06-1249, which was argued on November 3, 2008 and raises the question of whether personal injury claims based on inadequate drug labeling are *impliedly* preempted, may pave the way to at least a limited revival of the FIFRA preemption defense.

From *Ferebee* to *Bates*

FIFRA's preemption provision, entitled "Uniformity," prohibits a state from imposing "any requirements for labeling" that are "in addition to or different from" those imposed under that EPA-administered statute. 7 U.S.C. § 136v(b). In the beginning, the D.C. Circuit held that the preemptive scope of § 136v(b) is limited to state laws that directly require alteration of EPA-approved pesticide labeling and does not apply to state common-law damages claims alleging inadequate labeling or warnings. *See Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529 (D.C. Cir. 1984). But several years later, and despite *Ferebee*, pesticide producers began to argue successfully that FIFRA *impliedly* preempts failure-to-warn and other labeling-related product liability claims because they undermine EPA's statutory mandate to regulate a pesticide product's labeling on a nationally uniform basis. *See, e.g., Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc.*, 959 F.2d 158 (10th Cir. 1992); *Papas v. Upjohn Co.*, 926 F.2d 1019 (11th Cir. 1991).

Implied preemption of pesticide labeling and warning claims was beginning to build momentum when the Supreme Court issued its opinion in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), involving a Federal Cigarette Labeling and Advertising Act preemption

provision analogous to § 136v(b) of FIFRA. *Cipollone* quickly became a watershed in the world of express preemption. In a nutshell, the Supreme Court held that when a federal statute expressly bars a State from imposing particular types of "requirements," that prohibition is not limited to state statutes and regulations, but also encompasses the duties (i.e., requirements) underlying state tort claims. The Court has repeatedly reaffirmed *Cipollone*'s principle that "[a] bsent other indication, reference to a State's 'requirements' includes its common-law duties." *Riegel v. Medtronic, Inc.*, 128 S.Ct. 999, 1008 (2007).

Promptly after issuing *Cipollone*, the Supreme Court sent the *Papas* and *Arkansas-Platte* implied preemption decisions back to the courts of appeals for further consideration. The Eleventh and Tenth Circuits then held, in light of *Cipollone*'s interpretation of the term "requirements," that FIFRA's § 136v(b) preemption provision *expressly* preempts pesticide failure-to-warn claims. *See Papas v. Upjohn Co.*, 985 F.2d 516 (11th Cir. 1993); *Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc.*, 981 F.2d 1177 (10th Cir. 1993). During the ensuing twelve years, federal and state court decisions finding express preemption of personal injury and crop damage claims that directly or indirectly challenged the adequacy of warnings or other information on EPA-approved pesticide labeling proliferated. By the time the Supreme Court rendered its opinion in *Bates*, express preemption of pesticide failure-to-warn and inadequate labeling claims had been upheld by each of the nine federal circuit courts of appeals that considered the subject in light of *Cipollone*, along with numerous state supreme courts and scores of federal and state trial courts.

Then came *Bates*. Although FIFRA preemption always has been limited to product liability claims that implicate a pesticide's labeling, most courts held prior to *Bates* that labeling and warning claims embedded within causes of action for design defect, inadequate testing, breach of express warranty, and oral misrepresentation were expressly preempted by § 136v(b). Justice Stevens' majority opinion in *Bates*, however, seemingly swept away express preemption of such "disguised" failure-to-warn claims. *See Bates*, 544 U.S. at 444. Even more troublesome, while *Bates* held that failure-to-warn (and fraud) claims do impose "requirements for labeling" within the meaning of § 136v(b), the Court read into that preemption provision a vague and potentially gaping "parallel requirements" loophole excluding failure-to-warn claims based on state common-law duties that are "equivalent to, and fully consistent with, FIFRA's misbranding provisions." *Id.* at 447.

The net result of *Bates* is that in most cases express preemption of pesticide failure-to-warn claims has ceased to function as an effective tool for achieving pre-trial dismissal. But *Wyeth v. Levine*, a prescription drug case, now offers the pesticide industry some hope.

Wyeth v. Levine

Plaintiff Diane Levine, a musician, developed gangrene and lost her arm as a result of a health center's negligent intra-arterial injection of an anti-nausea drug. The drug's FDA-approved labeling warned about the dangers of accidental intra-arterial injection when using an "IV push" method of administration. Ms. Levine settled with the health center but sued Wyeth, the drug's manufacturer, on the theory that the drug's labeling failed to explicitly prohibit the IV push method and/or adequately warn of that method's potential catastrophic risks. The Vermont Supreme Court rejected Wyeth's federal preemption defense, and the U.S. Supreme Court granted review.

The prescription drug provisions of the Federal Food, Drug, and Cosmetic Act do not contain an express preemption clause. Thus, the issue before the Court is whether Ms. Levine's claims are barred under principles of implied conflict preemption. FDA, through the Solicitor General, is squarely on the side of preemption in this case. The Solicitor General's argument essentially is that where the FDA has weighed the benefits of a drug against its risks, and has determined what information (including warnings and contraindications) should be presented on the drug's labeling, common-law damages claims based on a different balancing of the same risk and benefit information undermine FDA regulation and are impliedly preempted.

At the November 3 Supreme Court hearing, many of the Justices seemed skeptical that Ms. Levine's claims would avoid preemption if FDA had been fully informed by Wyeth of all relevant risks regarding the IV push method. For example, Justice Alito asked Ms. Levine's attorney "suppose the record showed that the FDA clearly considered whether IV push should be contraindicated and concluded it should not be and prescribed the label that now appears on the drug . . . would [Ms. Levine] still have . . . a non-pre-empted claim?" Ms. Levine's attorney conceded "[t]hat [would] be pre-empted. And the reason it would be pre-empted is because the FDA would have considered and rejected on the basis of the same information or similar information the very duty that underlies the State claim." Tr. at 33-34. This and similar questions asked by other members of the Court suggest that whether a drug manufacturer has provided FDA with all relevant information regarding the specific risk at issue, and whether FDA has considered such information in regulating the drug's labeling, are the key determinants for implied preemption of damages claims that challenge the adequacy of the labeling. A copy of the Supreme Court hearing transcript in *Wyeth* is available at http://www.supremecourtus.gov/oral_arguments/argument_transcripts/06-1249.pdf.

Implications For Pesticide Producers

If the Supreme Court rules in favor of preemption in the *Wyeth* case, that could bolster renewal of a FIFRA *implied preemption* defense, at least in personal injury cases, where there is no issue that EPA carefully considers risk information in regulating label warnings and precautionary measures. *Bates* is an express preemption case limited to the scope of § 136v(b). Furthermore, inclusion in a federal statute of an express preemption provision such as § 136v(b) "does *not* bar the ordinary working of conflict pre-emption principles." *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869 (2000). Despite some dicta in *Bates* suggesting that there was no need to consider implied preemption, it remains a viable, constitutionally based defense.

In view of the holding in *Bates* that only certain failure-to-warn claims are expressly preempted (i.e., claims that would impose state-law requirements for labeling that diverge from FIFRA misbranding standards), it may not be possible to (re)establish the principle that pesticide labeling and failure-to-warn claims are *categorically* barred by conflict preemption. But particular claims in a given case may be impliedly preempted, even if not clearly expressly preempted, where the manufacturer can demonstrate that EPA either specifically rejected the particular label warnings that a plaintiff alleges should have been provided and/or considered all relevant information pertaining to the alleged risks at issue. This may include "disguised" failure-to-warn claims pleaded as claims for strict liability, breach of warranty, or oral misrepresentation.

Because there are striking similarities between how FDA regulates drug labeling and EPA regulates pesticide labeling, a favorable opinion in *Wyeth* very well may support FIFRA implied preemption. Based on the November 3 Supreme Court hearing, the pesticide industry has reason to be cautiously optimistic that the Court's opinion in *Wyeth*, which is expected next Spring, may help to illuminate a implied preemption path around *Bates*.