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What *Wyeth v. Levine* Means To The Pesticide Industry

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On March 4, 2009 the Supreme Court held in *Wyeth v. Levine* that the Federal Food, Drug, and Cosmetic Act (FDCA) does not preempt personal injury claims alleging that the warnings on a prescription drug's FDA-approved labeling were inadequate. (A copy of the *Wyeth* decision is available on the Supreme Court's website at http://www.supremecourtus.gov/opinions/08pdf/06-1249.pdf.)

What impact, if any, will *Levine* have on FIFRA preemption of pesticide-related product liability claims for inadequate labeling or failure to warn? The short answer—which cuts both ways—is "not much."

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Levine Holding

Levine focuses on the doctrine of "implied conflict preemption." This is because the FDCA's prescription drug provisions (in contrast to that statute's over-the-counter drug and medical device provisions) do not contain an express preemption clause. Writing for a five-Justice majority, Justice Stevens adhered to the Court's analytical framework for deciding conflict preemption issues. But he concluded that the injured plaintiff's state-law failure-to-warn claims do not conflict with the FDCA because FDA regulations would have allowed the drug manufacturer to add warnings to its product labeling without prior governmental approval. Further, Justice Stevens, who is generally opposed to federal preemption of product liability claims, adopted public interest group arguments that common-law damages suits against drug manufacturers complement the FDCA's goal of bolstering consumer protection rather than undermine FDA regulation of drug safety. Justice Thomas concurred in the Court's judgment, but wrote a separate opinion explaining why he "cannot join the majority's implicit endorsement of far-reaching implied pre-emption doctrines," namely what he considers to be the "inherently flawed," but long established, principle that state law is preempted if it obstructs or interferes with the purposes and objectives of a federal law. Only Chief Justice Roberts and Justice Scalia joined Justice Alito's dissenting opinion that "drug labeling by jury verdict undermines both our broader pre-emption jurisprudence and the broader workability of the federal drug-labeling regime."

Why FIFRA is Different

There are at least two reasons why the Court's opinion in *Levine* should not affect FIFRA preemption of pesticide-related claims for failure to warn or inadequate labeling.

First, unlike the FDCA prescription drug provisions, FIFRA *does* contain an express preemption provision, § 24(b), which is entitled "Uniformity" and prohibits a State from imposing "any requirements for labeling" that are "in addition to or different from" those imposed under FIFRA. According to the *Levine* majority opinion, "[i]f Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history." But that is exactly what Congress did in the case of FIFRA when it enacted § 24(b) in 1972. Contrary to the impression that "victims' rights" attorneys and anti-pesticide groups have tried to create, the Supreme

Court's decision in *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005), which addresses the preemptive scope of § 24(b), does not foreclose all preemption of pesticide-related product liability claims. Instead, *Bates* (whose majority opinion also was authored by Justice Stevens) holds that § 24(b) expressly preempts failure-to-warn and fraud claims, provided that the FIFRA-registered pesticide product at issue is not misbranded. The main source of unresolved confusion surrounding *Bates* involves the Court's holding that § 24(b) only bars failure-to-warn or fraud claims which are based on state-law duties that "diverge" from, and are not "equivalent" to, federal labeling requirements (primarily, if not exclusively, the requirement that the product not be misbranded).

Second, unlike the FDCA situation, there are no EPA regulations or policies allowing pesticide registrants to add health or safety warnings to their product labeling without EPA's prior review and approval. Indeed, doing so would be unlawful under FIFRA. *See* FIFRA § 12(a)(2)(A). Thus, unlike the regulatory regime governing certain prescription drugs, it may be physically impossible for a pesticide manufacturer to comply simultaneously with FIFRA's prohibition against unilaterally adding or revising label warnings and a state tort requirement to add or revise warnings prior to EPA review and approval. In particular cases, such a state vs. federal conflict could support a FIFRA-based implied conflict preemption argument that would not be inconsistent with *Levine.*

***Levine*'s Impact On Pesticide Suits**

The 6-3 *Levine* decision was a major disappointment not only to drug manufacturers, but also to other industries that produce federally regulated products. *Levine* makes it clear that failure-to-warn and other safety-related product liability claims will not be impliedly preempted merely because a federal regulatory agency has reviewed a product's safety, regulated the warnings on a product's labeling, or granted pre-market approval. *Levine* thus dashed the pesticide industry's hopes that the Court would reopen the door to a robust, labeling-related implied preemption defense that pesticide manufacturers and distributors could assert in addition to express preemption of the types of failure-to-warn claims that the Court in *Bates* held are expressly encompassed by § 24(b).

On the other hand, *Levine* leaves *Bates* intact. In fact, in his separate opinion in *Levine*, Justice Thomas quotes his own statement in *Bates* that he has "become 'increasing[ly] reluctan[t] to expand federal statutes beyond their terms through doctrines of implied pre-emption' " (quoting *Bates*, 544 U.S. at 459 (Thomas, J., concurring in judgment in part and dissenting in part). As a result, *Levine* neither widens nor narrows the FIFRA § 24(b) express preemption door kept open by the Court in *Bates.*

What the Pesticide Industry Should Do Now

Neither *Levine* nor *Bates* is a reason for pesticide manufacturers or distributors to refrain from pursuing the FIFRA express preemption defense, as circumscribed by *Bates*, when confronted with failure-to-warn or other claims for inadequate labeling. In most cases, the key to successfully asserting the defense will be to establish as a factual as well as legal matter that the product at issue is *not* misbranded. As Justice Stevens stated in *Bates*, "[i]f a defendant so requests, a court should instruct the jury on the relevant FIFRA misbranding standards, as well as any regulations that add content to those standards . . . a manufacturer should not be held liable under a state labeling requirement subject to [§ 24(b)] unless the manufacturer is also liable for misbranding as defined by FIFRA." 544 U.S. at 454. In other words, *Bates* holds that § 24(b) preempts failure-to-warn claims unless the product is misbranded. Because a product is misbranded under FIFRA if, *inter alia*, its label fails to include warnings that are adequate to protect human health and the environment, establishing that a product is not misbranded may help to rebut failure-to-warn claims on the merits as well as establish that they are preempted.

Further, as suggested above, even in light of *Levine*,implied preemption of pesticide-related failure to warn claims still may be viable under certain circumstances in particular cases where it would be physically impossible for a pesticide registrant to comply with both federal and state requirements.

In any event, it is essential that pesticide manufacturers and distributors, through the vigilance of trade associations such as CropLife America/RISE and the Consumer Specialty Products Association, continue to protect § 24(b). That preemption provision is more than the basis for what continues to be limited, but viable, product liability defense. It also establishes EPA's regulatory primacy over the content

and format of each pesticide product's nationally uniform pesticide labeling. For this reason, preservation and enforcement of § 24(b) should be as important to EPA—Congress' designated pesticide labeling regulatory expert—as it is to industry.

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