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Generic Drug Preemption Cases Give Supreme Court Opportunity to Revisit and Refine *Wyeth v. Levine*

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Wiley Rein's FDA Practice Group partners Bert Rein, James Czaban, and Karyn Ablin have published an article in *The National Law Journal* analyzing the implications and possible outcomes of three consolidated pending Supreme Court cases involving federal preemption of state products liability claims based on inadequate labeling against generic drug makers. The cases are a follow-on to the Court's two-year-old *Wyeth v. Levine* decision, where the Court held that such claims against branded drug makers were not preempted by FDA's authority to regulate drug labeling unless the manufacturer could clearly establish that FDA would have barred it from making the labeling change assertedly required under state law. The generic drug makers argue that they meet this standard because they operate under a different federal regime that bars them from deviating from the labeling of the drug that they imitate.

The cases offer the Supreme Court a golden opportunity to provide important and much-needed guidance concerning the operation of impossibility conflict preemption principles in cases involving prescription drug injuries. The article suggests that these cases highlight the need for the Court to re-think its recent decision in *Wyeth v. Levine* in order to promote consistency and predictability in pharmaceutical tort litigation and to guard against intruding on FDA's ability to fulfill its congressionally mandated role as the nationwide regulator of prescription drugs and their labeling.

You can read the article in its entirety **HERE.**

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Practice Areas

Food & Drug