

PRESS RELEASE

Bert Rein, in *Bloomberg BNA* Column, Says First Circuit Ruling May Signal Change in Prescription Drug Preemption Landscape

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In a column published online yesterday by *Bloomberg BNA's Pharmaceutical Law & Industry Report*, Wiley Rein founding partner Bert W. Rein says a recent federal appeals court ruling concerning the drugs Celexa and Lexapro may have significantly altered the litigation landscape for preemption of state law actions that challenge branded drug labels.

In a February 25 decision, the U.S. Court of Appeals for the First Circuit ordered the dismissal of the class action case *In re: Celexa and Lexapro Marketing and Sales Practice Litigation* on federal preemption grounds. The lawsuit alleged that Celexa and Lexapro labels, approved by the U.S. Food and Drug Administration (FDA), exaggerated the drugs' efficacy in treating adolescent depression. The plaintiffs had sought to hold the drugs' manufacturer, Forest Laboratories, liable and force label changes under California consumer protection laws.

The plaintiffs contended that Forest could have made the labeling changes they sought without prior FDA authorization under FDA's so-called Changes Being Effectuated (CBE) regulation. Invoking the Supreme Court's 2009 decision in *Wyeth v. Levine*, the plaintiffs argued that the availability of CBE enabled Forest to comply both with its federal law duty to use only an FDA-approved label and its state law duty to modify its originally approved label to eliminate unwarranted efficacy claims. The First Circuit rejected the plaintiffs' argument.

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Practice Areas

Food & Drug

According to Mr. Rein's article, the First Circuit's *Celexa/Lexapro* ruling may signal that the post-*Levine* drug preemption pendulum is now swinging toward affording branded manufacturers a greater area of federal preemption protection from state-law based claims premised on labeling inadequacies. To read the article, "*In Re: Celexa and Lexapro Marketing and Sales Practice Litigation-A Harbinger of Change in the Prescription Drug Preemption Landscape*," [click here](#).

Mr. Rein has been recognized as a Washington "Visionary" by *The National Law Journal* and a "Leading Food and Drug Lawyer" by the *Legal Times*.