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Third Circuit Upholds Landmark Win For Preemption Defense Against Drug Lawsuits

The U.S. Court of Appeals for the Third Circuit has become the first federal appellate court to hold that federal law preempts state-law product-liability suits against manufacturers of prescription drugs. The court decided that product-liability lawsuits are barred when they seek to hold the manufacturer liable for failing to include a warning that the FDA has determined is scientifically unsupported. The decision, *Colacicco v. Apotex*, provides an important precedent for stemming the flow of product-liability lawsuits that ask juries to second-guess the scientific determinations of the FDA.

Colacicco reviewed two district court decisions. In each lawsuit, a plaintiff sought to hold the manufacturer of an SSRI anti-depressant liable for failing to warn that the drug increased the risk of suicide. Though the Court acknowledged that the lack of a warning in the labeling approved by the FDA could reflect either the FDA's conscious decision or "mere inertia," the Court recognized that in this case it "need not speculate on the rationale of the FDA for its failure to require the adult suicidality warnings. Not only has the FDA filed an amicus brief in the Colacicco action but it has repeatedly rejected the scientific basis for the warnings that [the plaintiffs] argue should have been included in the labeling."

The Court also rejected the plaintiffs' argument that the defendants could have added a supplemental warning through the "changes being effected" regulation, notwithstanding the FDA's prior scientific determination. "Because the standard for adding a warning to drug labeling is the existence of 'reasonable evidence of an association of a serious hazard with a drug,' 21 C.F.R. § 201.57(e), and the FDCA authorizes the FDA to prohibit false or misleading labeling, a state-law obligation to include a warning asserting the existence of an association between SSRIs and suicidality directly conflicts with the FDA's oft-repeated conclusion that the evidence did not support such an association."

Finally, the Court rejected the plaintiffs' argument that preemption could not occur unless the specific defendants had formally petitioned to add the warnings at issue and the FDA had formally rejected such a petition. Agreeing with an argument advanced by the American Tort Reform Association, which filed an amicus brief prepared by Covington & Burling LLP, the Court refused to "encourage regulated parties to submit [proposed supplemental warnings] for the sole purpose of insulating themselves from potential liability."

Because the Court specifically applied its rule to situations in which the FDA had rejected the scientific basis of the warning sought by plaintiffs, the broader implications of the decision, including its influence on the Supreme Court's ruling next term in *Wyeth v. Levine*, remain to be seen. On the one hand, the *Colacicco* court suggested (whether correctly or not) that the case before it was factually different from the *Levine* case. On the other hand, the *Colacicco* court's rationale for holding that FDA regulation preempts contrary state requirements applies equally to *Levine*. For example, *Colacicco* recognized the tremendous burden placed on companies from disparate state-court judgments on the adequacy of their labeling: "Absent a determination that the FDA-approved labeling and the FDA's refusal to require the warnings suggested by plaintiffs in this case preempt state tort

actions, the manufacturers may be subjected to considerable liability based on varying standards, with no benchmark that they should follow." And as discussed above, the *Colacicco* court recognized the undesirability of a legal regime like that urged by both the *Colacicco* and *Levine* plaintiffs, under which companies are forced to submit endless variants of label changes and have them rejected by the FDA before advancing a preemption defense.

The *Colacicco* court's agreement with the FDA regarding when preemption exists also applies equally to *Levine*. The FDA (represented by the Solicitor General) has argued that the *Levine* claims should be preempted, suggesting that preemption occurs whenever plaintiffs "challenge labeling that FDA approved, after being informed of the relevant health risk, based on its expert weighing of the risks and benefits of requiring additional or different warnings."

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