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Federal Preemption of Failure to Warn Claims Against Generic Drug Companies

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Three recent district court decisions – from Minnesota, California and Florida – have created a division in the federal courts on whether products liability claims against generic pharmaceutical manufacturers are preempted by federal law. In *Mensing v. Wyeth, Inc.*, Judge Donovan W. Frank in the District of Minnesota found that the plaintiff's failure to warn claims involving generic versions of Reglan, which treats certain gastrointestinal disorders, were barred because generic drug manufacturers are required by the Hatch-Waxman Act ("Act") to use the same labeling as the brand or innovator drug. Similarly, in a decision from the Northern District of California in *Gaeta v. Perrigo Pharmaceuticals Co.*, Judge James Ware concluded on the same basis that claims against the manufacturer of a generic over-the-counter ibuprofen, a pain medication, were implicitly preempted by the Act. In *Masterson v. Apotex, Corp.*, the Southern District of Florida dismissed the plaintiffs' failure to warn claims concerning the generic version of Paxil, which allegedly caused birth defects to the minor plaintiff. Specifically, Judge James I. Cohn held that conflict preemption applied insofar as the Act mandated generic manufacturers to have identical labeling as the brand drug. Judge Cohn also reasoned that preemption was applicable because generic manufacturers have limited ability to even suggest a label change. In all of the decisions noted above, the courts rejected attempts by the plaintiffs to argue that the FDA's labeling regulations allow both brand and generic drug manufacturers to unilaterally modify warnings under a Changes Being Effected ("CBE") supplement, finding that federal law does not permit such changes by a generic drug manufacturer.

In contrast, several state and federal district courts and the Fourth Circuit weighed in on the issue by either holding or stating in dicta that following marketing approval, a generic drug manufacturer could strengthen drug warnings independent of changes to the innovator drug label. See *Barnhill v. Teva Pharmaceuticals USA, Inc.* (S.D. Ala.); *Laisure-Radke v. Par Pharmaceutical, Inc.* (W.D. Wash.); *Barhoum v. Barr Pharmaceuticals, Inc.*, (N.J. Law. Div.); *McKenney v. Purepac Pharmaceutical Co.* (Cal. App. 5th Dist.); *Foster v. American Home Products Corp.* (4th Cir.; dicta); *Goldych v. Eli Lilly and Company*, (N.D. N.Y.; dicta). These courts did not find any distinction between brand and generic pharmaceutical companies in their ability under FDA regulations to initiate changes to product labeling.

Generic drug manufacturers are not required to duplicate the cost, time and effort already expended by the innovator manufacturer in establishing a product's safety and efficacy. This is consistent with the Act's primary goal of simplifying generic drug approvals to make less expensive prescription pharmaceuticals quickly and widely available to the public. Once a generic drug manufacturer has satisfied all of the requirements of the Act and related federal regulations, and has received marketing approval, it cannot alter or revise product labeling without risking agency enforcement action and the FDA's withdrawal of its Abbreviated New Drug Application ("ANDA").

Frequently, following the FDA's approval of a brand pharmaceutical, the innovator manufacturer may request the FDA's consent to make changes in product labeling because of additional information received through post-marketing safety data collection, advances in medical science, additional studies and/or clinical trials. In submitting its ANDA to the FDA, a generic manufacturer is required to incorporate in its proposed labeling all of the changes, including the most recent ones, approved by the FDA for the brand drug or risk the rejection of its ANDA.

Earlier this year, the FDA proposed certain regulatory changes for brand drugs approved under New Drug Applications ("NDA"). Similar amendments were also proposed affecting medical devices and biologics reviewed under the FDA's specialized procedures. These changes, in the FDA's view, codify existing practice and are intended to reiterate important policies regarding changes to product labeling. Following the comment period for the proposed regulatory changes, the FDA published its final rule on August 22,

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2008, which was entitled "Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics and Medical Devices." The final rule emphasizes that a CBE supplement should be used to amend the labeling of an approved drug "only to reflect newly acquired information." Furthermore, the FDA notes changes to labeling may be used only to implement changes regarding contraindications, warnings, precautions or adverse reactions in circumstances when there is sufficient evidence of a causal association with the drug, biologic or medical device.

Generic manufacturers, however, are and have been excluded by the FDA from the ability to utilize a CBE supplement to effect changes in product labeling. Presaging the holdings in *Mensing, Gaeta and Masterson* in its explanation of the proposed amendments, the FDA reiterated its view that "CBE changes are not available for generic drugs approved under an abbreviated new drug application . . . a generic drug manufacturer is required to conform to the approved labeling for the listed [brand] drug."

In the absence of evidence that a generic drug company has withheld important health safety information from the FDA, and because of the unique constraints imposed upon generic drug manufacturers by the federal regulatory scheme, the federal preemption defense remains a viable option for generics manufacturers. Juries should not be allowed to second-guess the FDA by finding that generic drug warnings different from those prescribed by the FDA for the brand equivalent should have been furnished to a plaintiff's physician.

In the current term, the U.S. Supreme Court in *Wyeth v. Levine* will consider for the first time the preemption of state law-based claims in pharmaceutical products liability cases. Although this case involves a brand, not generic, pharmaceutical, the Court's decision will be important in determining the parameters of the preemption defense available to both generic and brand drug manufacturers.

For Further Information

If you have questions about this Alert or would like more information, please contact Alan Klein, Sharon L. Caffrey, Karen Shichman Crawford, any other member of the Products Liability and Toxic Torts Practice Group or the attorney in the firm with whom you are regularly in contact.