IN-HOUSE COUNSEL GUARDING AGAINST EXPANDED LIABILITY

Steve Imbriglia
Gibbons

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SUPREME COURT TO DECIDE WHETHER FAILURE-TO-WARN CLAIMS AGAINST GENERIC MANUFACTURERS ARE PREEMPTED

Stephen J. Imbriglia

simbriglia@gibbonslaw.com

INTRODUCTION

In *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), the Supreme Court held that state-law failure-to-warn claims against a pharmaceutical company are not preempted solely because the U.S. Food and Drug Administration approved the drug's label. The Court rejected Wyeth's argument that requiring the company to comply with a state law duty to provide a stronger warning interfered with Congress' intent to entrust the FDA with labeling decisions. The *Levine* decision narrowed the opportunities for implied preemption arguments, though not eliminating those opportunities.

The Supreme Court is currently considering whether failure-to-warn claims against generic manufacturers are preempted. Why might claims against generic manufacturers be preempted when claims against brand manufacturers are not? The generic companies contend that under the different regulatory scheme applicable to generics, as opposed to brand manufacturers, they have no legal mechanism to update their labeling if the brand companies have not done so first.

Oral argument was held on March 30, 2011.

RESPONDENTS' CLAIMS

The Supreme Court will decide this issue in the context of two claims that metoclopramide, the generic version of the prescription drug Reglan, caused tardive dyskinesia, a severe neurological movement disorder, in two women who used metoclopramide for years. In 2001, Gladys Mensing's doctor prescribed Reglan to treat her diabetic gastroparesis. She used metoclapramide for four years before developing tardive dyskinesia. She claims that despite mounting evidence that long-term metoclopramide use carries a risk of tardive dyskinesia far greater than that indicated on the product's label, the generic manufacturers did nothing to communicate that risk by revising the labeling. Julie Demahy's claims are similar. Her physician prescribed Reglan to treat her gastroesophageal reflux. She ingested metoclopramide for four years before developing tardive dyskinesia and contends that the manufacturer failed to warn of the risks of neurological disorder after long-term use of metoclopramide.

The FDA approved Reglan in 1980. Five years later, manufacturers began seeking approval for generic versions. In 1985, the FDA required an update to Reglan's labeling that warned of the risk of tardive dyskinesia. The label warnings about tardive dyskinesia did not change between

1985 and the years during which Ms. Mensing and Ms. Demahy used the product. The generic drugs' labels have always been in relevant part the same as the Reglan label. Acting on its own initiative, the FDA ordered manufacturers of Reglan and generic metoclopramide on February 26, 2009 to add a boxed warning to their labels about the increased risk of risk of tardive dyskinesia with prolonged use, defined as use for more than 12 weeks.

Mensing sued the manufacturers and distributors of generic metoclopramide in the District of Minnesota. She also sued the manufacturers of Reglan, the "brand" defendants, for fraud and negligent misrepresentation on the theory that the prescribing physician had relied on Reglan's labeling when assessing the risks and proper uses of metoclopramide. *Mensing v Wyeth, Inc*., 562 F.Supp. 2d 1056 (D.Minn. 2008). The district court granted the generic defendants' summary judgment motions on the ground of federal preemption. The court also granted the brand defendants' summary judgment motions, because under Minnesota law, they owed Mensing no duty because she never ingested their product.

Demahy sued Actavis, a generic manufacturer, in the Eastern District of Louisiana. Actavis moved to dismiss the failure-to-warn claims on the ground that they were preempted. The manufacturer also moved to dismiss Demahy's fraud-on-the-FDA claims. The district court granted the motion as to the fraud-on-the-FDA claims but denied it as to the failure-to-warn claims.

MENSING v. WYETH, INC., 588 F.3d 603 (8TH Cir. 2009)

In *Mensing*, the generic defendants attempted to distinguish *Wyeth v. Levine* on the ground that it concerned claims against brand manufacturers, not generics. Pointing to the different regulatory scheme applicable to generics, specifically the abbreviated new drug application (ANDA) procedure legislated in the Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act, the generic defendants argued that it was impossible for them to comply with both federal law and state law. ANDA applicants must show the FDA that their drug is essentially the same as the name brand drug and that their proposed label is in relevant part identical to the name brand drug label. 21 C.F.R. §314.94(a)(8). The parties agreed that generic labels must be substantively identical to brand labels even after they enter the market. The generics argued, accordingly, that they cannot unilaterally revise a label warning, as a brand company may through the "changes being effected," or "CBE," process.

The Eighth Circuit determined that it need not decide whether generic manufacturers may unilaterally enhance a label warning through the CBE procedure, because the generic companies could at least have proposed a label change that the FDA could have received and imposed uniformly on all metoclopramide manufacturers. The court noted that the regulatory framework makes clear that a generic manufacturer must take steps to warn its customers when it learns it may be marketing an unsafe drug and that generic manufacturers are subject to the requirement that their labeling be revised as soon as there is reasonable evidence of an association between a drug and a serious hazard. Relying on comments made by the FDA outside the regulations, the Eighth Circuit found an expectation that generic manufacturers will initiate label changes other than those made to mirror changes to the brand labels. In addition, the court noted that the

generic manufacturers could have suggested that the FDA send out warning letters to health care professionals.

The court also considered, and rejected, the argument that even if compliance with both state and federal law was not impossible, compliance with the state law would obstruct the purposes and objectives of the federal law. Citing *Levine*, the *Mensing* court held that, "The obligation Mensing seeks to impose upon generic manufacturers does not obstruct the purposes and objectives of the Hatch-Waxman Amendments in any way. On the contrary, '[f]ailure to warn actions,' like Mensing's, 'lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times.'"

DEMAHY v. ACTAVIS, INC., 593 F.3d 428 (5th Cir. 2010)

Addressing the "impossibility" argument made by the generic manufacturer in *Demahy*, the Fifth Circuit noted that although the Hatch-Waxman Amendments proscribe the approval of an application to produce a generic drug with labeling that is not the "same as" the listed drug, the regulations do not bar labeling modifications following initial approval: "As for maintaining an adequate label, the regulatory framework makes plain that manufacturers - name brand and generic alike - must act to warn customers when they learn that they may be marketing an unsafe drug. For their part, generic manufacturers are subject to the requirement that their labeling 'be revised . . . as soon as there is reasonable evidence of an association of a serious hazard with a drug.'"

In a lengthy analysis, the Fifth Circuit rejected Actavis' argument that the CBE process is not available to generic companies. It also found that nothing in the FDCA or the Hatch-Waxman Amendments explicitly forbids generic manufacturers from proposing a label change through the "prior approval" process required for "major changes." Like the Eighth Circuit, the Fifth Circuit also determined that a generic company can suggest that the FDA send a "Dear Doctor" letter to medical professionals. Thus, the *Demahy* court identified three ways that a generic manufacturer could comply with both state and federal law. In affirming the district court's denial of the motion to dismiss the failure-to-warn claims, the Fifth Circuit reiterated one of the pillars of the *Levine* decision: "a central premise of federal drug regulation [is] that the manufacturer bears responsibility for the content of its label at all times."

The United States Supreme Court's decision in *Pliva, Inc. v. Mensing* is expected this summer.

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STEPHEN J. IMBRIGLIA

Stephen J. Imbriglia is the Administrative Director in charge of Gibbons' Philadelphia Office. Mr. Imbriglia is a trial lawyer who concentrates his practice in the defense of product liability cases. He defends pharmaceutical and medical-device manufacturers. For more than twenty years, Mr. Imbriglia has also defended companies in toxic tort litigation, such as those involving exposures to asbestos, benzene, beryllium and lead. In addition to defending clients in individual cases, he has extensive experience representing companies in class actions, multidistrict litigation and serial lawsuits. Mr. Imbriglia has served as national and local counsel for companies in mass tort litigation. Mr. Imbriglia also defends professionals, including architects, engineers and accountants, in professional-liability actions. Mr. Imbriglia has authored articles about medical monitoring claims, Daubert issues, class actions and mass tort litigation. A Philadelphia native, Mr. Imbriglia began his career as a prosecutor in the Philadelphia District Attorney's Office before transitioning to civil litigation.

Representative Cases

Defense of pharmaceutical company in multi-million dollar claim involving mistaken administration of a drug to an individual in anaphylaxis and allegation that drug was inadequately labeled.

Defense of manufacturer of products for the dental industry in several mesothelioma cases involving short-term asbestos exposure.

Defense of company that operated lead-processing plant in claim by worker at adjacent facility that he had developed porphyria as a result of exposure to lead.

Defense of product manufacturer in personal injury and property damage claims arising from leaking underground gasoline tank and resulting in exposures to gasoline and benzene.

Defense of fireproofing manufacturer in numerous asbestos property damages cases brought by building owners seeking tens of millions of dollars for asbestos removal costs.

Defense of grinding wheel manufacturer in case brought by purchaser of property for pre-existing lead contamination of ground and water.

Defense of manufacturer of conveyor system for food industry in case involving serious hand injury.

Defense of manufacturers of PPA - containing products in cases brought by individuals who had suffered strokes.

Defense of engineering firm in multiple personal injury and medical monitoring suits arising from beryllium exposure.

Defense of geotechnical engineer in wrongful death suit resulting from pier collapse.

Defense of structural engineer in property damage suit arising from building collapse.

Stephen J. Imbriglia
Administrative Director of the Philadelphia Office

Director
Products Liability

Practice Areas
Pharmaceutical, Medical Device & Lab Defense
Products Liability

Contact Information
1700 Two Logan Square
18th & Arch Streets
Philadelphia, PA 19103-2769

Direct: 215-446-6209
Fax: 215-446-6306
simbriglia@gibbonslaw.com

Education
Boston College Law School (J.D., cum laude, 1980)

Wesleyan University (B.A., cum laude, 1977)