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PLIVA, INC. v. MENSING: PRE-EMPTION OF FAILURE-TO-WARN CLAIMS CREATES POTENTIAL OF LIABILITY FOR ANOTHER'S PRODUCT

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INTRODUCTION

Generic drug manufacturers recently won a huge victory in the United States Supreme Court in *PLIVA, Inc. v Mensing* (No. 09-993, June 23, 2011). The Court held that failure-to-warn claims, the most prevalent type of product liability theory asserted against drug manufacturers, are pre-empted as to generic drug makers. While the Court breathed new life into the defense of implied pre-emption, a defense that appeared nearly moribund after the Court's 2009 decision in *Wyeth v. Levine*, 555 U.S. 555 (2009), the *Mensing* decision has placed state and federal courts in something of a quandary: courts must now decide whether a brand-name manufacturer can be liable for a product that it did not make, sell or profit from, or they may have to deny a plaintiff injured by an allegedly defective drug her day in court when consumers who took the brand-name version of the same drug can recover from the manufacturer. The former course involves a radical revision of one of the basic tenets of product liability law; the latter creates an apparent unfairness and arbitrariness in judicial outcomes.

NATURE OF THE CLAIMS

The Supreme Court's decision in *Mensing* involves two claims that metoclopramide, the generic version of the prescription drug Reglan, caused tardive dyskinesia, a severe neurological movement disorder. In 2001, Gladys Mensing's doctor prescribed Reglan to treat her diabetic gastroparesis. She used metoclopramide for four years before developing tardive dyskinesia. She claimed that despite mounting evidence that long-term 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 were similar. Her physician prescribed Reglan to treat her gastroesophageal reflux. She ingested metoclopramide for four years before developing tardive dyskinesia and contended 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 took 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 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. The district court granted the generic defendants' summary judgment motions on the grounds of federal pre-emption. 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 they were pre-empted. 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.

WYETH v. LEVINE

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 pre-empted 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 pre-emption arguments, though not eliminating those opportunities.

THE EIGHTH AND FIFTH CIRCUITS REJECT PRE-EMPTION

The Eighth Circuit, in Mensing's case, and the Fifth Circuit, in Demahy's case, both held that claims against generic manufacturers were not pre-empted by federal law. See *Mensing v. Wyeth, Inc.,* 588 F.3d 603 (8th Cir. 2009) and *Demahy v. Actavis, Inc*. 593 F.3d 428 (5th Cir. 2010). In both cases, the generic manufacturers attempted to distinguish *Wyeth v. Levine* on the ground that it concerned claims against brand manufacturers, not generics. Emphasizing 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 companies argued that it was impossible for them to comply with both federal law and state law. An ANDA applicant must show the FDA that its drug is essentially the same as the name brand drug and that its 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 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.

The Fifth Circuit rejected the manufacturer's argument that the CBE process is not available to generic companies. It also found nothing in the FDCA or the Hatch-Waxman Amendments explicitly forbidding generic manufacturers from proposing a label change through the "prior approval" process required for "major changes." 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 generic manufacturers petitioned the Supreme Court for review of both the *Mensing* and *Demahy* decisions. The Court granted certiorari and consolidated the two cases.

THE SUPREME COURT: CLAIMS ARE PRE-EMPTED

Justice Clarence Thomas, writing for a 5-4 majority, held that federal law requires generic labeling to be the same as the labeling approved by the FDA for the brand-name drug and that, therefore, it is impossible for a generic manufacturer to comply with federal labeling requirements and state laws requiring a drug manufacturer to enhance warnings on generic labeling if the generic manufacturer believes that the enhancement is necessary. The Supreme Court analyzed three avenues for effecting labeling changes and concluded that none provide a generic the ability to independently modify a label. Unlike brand-name manufacturers, generic manufacturers cannot employ the FDA's changes-being-effected ("CBE") process, which allows brand-name companies to change labeling without prior FDA approval and to write "Dear Doctor" letters that provide physicians with additional warnings and drug information.

The Court also rejected the argument that the third avenue, petitioning the FDA to enhance the labeling, overcame the impossibility pre-emption defense. Even assuming that the generic manufacturer had a duty to propose stronger warnings to the FDA if it believed such warnings are necessary, simply communicating to the FDA about a suggested label change would not have satisfied the state law duty of providing an enhanced label. To comply with state law, the generic would have to change its label before the brand-name product's label was changed, and the generic would then be in violation of the federal law requiring that a generic's labeling be identical to the FDA-approved brand-name label.

Justice Sotomayor authored a dissent (joined by Justices Breyer, Kagan and Ginsburg) that rejects the majority's impossibility pre-emption analysis and notes that, "Until today, the mere possibility of impossibility had not been enough to establish pre-emption. The dissenting opinion agrees with the majority that generic manufacturers are not permitted to unilaterally change their labels through the CBE process or to issue "Dear Doctor" letters, but concludes that the even though the "[g]eneric manufacturers cannot disseminate additional warnings on their own does not mean that federal law permits them to remain idle when they conclude their labeling is inadequate." The dissent would require the generic manufacturer to prove the FDA would not have approved a proposed labeling change to establish pre-emption. If the generic manufacturer proposed a labeling change to the FDA but it was rejected, then it would be impossible to for the defendant to comply with a state-law duty to warn, and impossibility pre-emption would be established.

Both the majority and minority opinions in *Mensing* note the inequitable consequences of insulating generic companies, but not the brand-name companies, from liability. Justice Thomas wrote: "We recognize that from the perspective of Mensing and Demahy, finding pre-emption here but not in *Wyeth* makes little sense. Had Mensing and Demahy taken Reglan, the brand-name drug prescribed by their doctors, *Wyeth* would control and their lawsuits would not be pre-empted… We acknowledge the unfortunate hand that federal drug regulation has dealt Mensing, Demahy and others similarly situated." But, he reasons, it is not for the Court to decide whether the statutory scheme established by Congress is unusual or bizarre, and, "We will not distort the Supremacy Clause in order to create similar pre-emption across a dissimilar statutory scheme." Justice Sotomayor's dissent notes that the result leads to "[s]o many absurd consequences that I cannot fathom that Congress would have intended to pre-empt state law in these cases," one such consequence being that "[a] drug consumer's right to compensation for

inadequate warnings now turns on the happenstance of whether her pharmacist filled her prescription with a brand-name drug or a generic."

POST-MENSING, POTENTIAL LIABILITY FOR ANOTHER'S PRODUCT

The protection afforded generic manufacturers by the pre-emption defense, and the seemingly unfair and arbitrary results that protection creates, provide attorneys representing consumers allegedly injured by inadequate warnings on generic drugs with a platform for proposing a dramatic revision of the most basic tenet of product liability law: that only a company that manufactures or sells a product is liable for any defects in that product. Relying on a negligent misrepresentation theory of liability, a California court has held that a brand-name manufacturer can be liable to a consumer who only ingested the generic version of the product. *Conte v. Wyeth, Inc*., 85 Cal. Rptr. 3d 299(Ct. App. 2008).

The plaintiff in *Conte* developed tardive dyskinesia after taking only a generic version of Reglan, but she sued the brand-name manufacturer on the basis that it was foreseeable that its negligent misrepresentations about the drug would cause harm to those who took only the generic version. The *Conte* court rejected the brand manufacturer's contentions that the claims were product liability claims disguised as claims for fraud and misrepresentation. It therefore found the overwhelming authority requiring that a plaintiff in a product liability action prove that the defendant manufactured or sold the product in question to be of no import. The court engaged in a duty analysis with a particular emphasis on foreseeability, that is, was it foreseeable that a prescriber would rely on statements made by the brand-name manufacturer when prescribing the generic product. Noting that state regulations expressly authorize pharmacists to fill prescriptions for brand drugs with generic equivalents, and that physicians prescribe generic drugs knowing that the FDA has confirmed that the generic versions are therapeutically equivalent to the branded drug, the court found that it was "eminently foreseeable" that the physician might prescribe metoclopramide in reliance on the brand-name manufacturer's representations about Reglan. This foreseeability analysis led to the court's conclusion that there was a duty owed by the brand-name manufacturer to the plaintiff who had consumed only the generic product.

Since *Conte* was decided, many courts have been asked to adopt its reasoning. Many have declined to do so. *See, e.g., Schrock v. Wyeth, Inc*., 601 F.Supp.2d 1262 (W.D. Okla. 2009); *Finnicum v. Wyeth, Inc*., 708 F.Supp.2d 610 (E.D. Tex. 2010). One has adopted the *Conte* reasoning. *Kellogg v. Wyeth, Inc*., 762 F.Supp.2d 694 (D. Vt. 2010). The decisions rejecting *Conte* rely heavily on *Foster v. American Home Products*, 29 F.3d 165 (4th Cir. 1994), which held that the brand-name manufacturer of Phenergan could not be held liable for negligent misrepresentation where the decedent, an infant who had died from sudden infant death syndrome, had been given only the generic version of the product. The *Foster* court rejected the notion that the claim was not a product liability claim: "Although actions for negligent misrepresentation arise in many contexts other than products liability, in this case the allegations of negligent misrepresentation are an effort to recover for injuries caused by a product without meeting the requirements the law imposes in product liability actions." It also rejected the argument that since the generic manufacturer did not create the warnings and is required by federal law to use the same warnings, a plaintiff cannot recover from a generic manufacturer: "We do not accept the assertion that a generic manufacturer is not responsible for misrepresentation on its product labels if it did not initially formulate the warnings and representations itself. When a generic manufacturer adopts a name brand manufacturer's warnings and representations without independent investigation, it does so at the risk that such warnings and representations may be flawed." Lastly, the *Foster* court found that the brand-name manufacturer had no duty to the plaintiffs, since there was no relationship between the parties giving rise to such a duty, stating, "We think that to impose a duty in the circumstances of this case would be to stretch the concept of foreseeability too far."

Courts that are asked to adopt the *Conte* rationale will now do so with the knowledge that if they do not, a plaintiff suffering from a serious condition allegedly caused by an inadequately labeled drug will have no recourse due to the (using Justice Sotomayor's word) "happenstance" that she used a generic drug rather than a name-brand. A major assumption underlying the *Foster* decision - that generic manufacturers could be held liable for inadequate warnings on their products - has disintegrated. The *Foster* decision also relied on the notion that a generic manufacturer, if it did not believe its labeling to be adequate, could take unilateral action to address the problem. The *Mensing* decision's acceptance of the generic companies' arguments that federal law prevents them from taking unilateral action undercuts that premise.

But if Justice Thomas and the *Mensing* majority were unwilling to "distort" the Supremacy Clause to avoid a seemingly unfair result, courts should be equally reluctant to reject long-standing principles of product liability law to correct an unfair result. The *Foster* court, and many other courts, have correctly concluded that claims for negligent misrepresentation against brand-name manufacturers are poorly disguised product liability claims, and the rules of product liability still apply. And *Foster's* conclusion that the existence of a duty requires not just the foreseeability of a possible harm but some relationship between the parties is legally and logically sound. *PLIVA, Inc. v. Mensing* should not be the occasion to undermine all that *Foster* got right.

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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.

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