



Panel: Managing High Volume And Pattern Litigation

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Pliva, Inc. v Mensing: Pre-Emption of Failure-To-Warn Claims Against Generic Manufacturers Leads to Attempts to Contort Product Liability Law

Stephen Imbriglia - June 2012

INTRODUCTION

In 2011, generic drug manufacturers 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. 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 led to attempts by plaintiffs to re-shape the contours of product liability law, both by imposing liability on brand-name manufacturers for products they neither manufactured nor sold and by re-casting claims against generics as something other than failure-to-warn claims.

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. The Eighth Circuit held that *Mensing's* claims against generic manufacturers are not pre-empted by federal law. *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009).

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. The Fifth Circuit held that Demahy's failure-to-warn claims are not pre-empted. *Demahy v. Actavis, Inc.*, 593 F. 3d 428 (5th Cir. 2010).

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 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 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 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."

CONTE, INNOVATOR LIABILITY, AND 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); *Guarino v. Wyeth LLC*, 2012 WL 1138631 (M.D. Fla. April 4, 2012). 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.

EVADING MENSING: ATTEMPTS TO RE-DEFINE CLAIMS AGAINST GENERICS

Mensing pre-empts warning claims. Plaintiffs have, therefore, attempted to describe their claims as something else. For example, some plaintiffs are advancing fraud/misrepresentation claims, but the courts are rejecting those claims. See, e.g., *Metz v. Wyeth LLC*, 2012 WL 1058870 at *5 (M.D. Fla. March 28, 2012); *Bell v. PLIVA, Inc.*, 2012 WL 640742, at *3 (E.D. Ark. February 16, 2012). Attempts to turn warning claims into warranty claims have met with limited success. Most courts have held that implied

How litigation time capsules can help a company minimize legal risk

Kevin M. Zielke

Understandably, the company mindset is always to be looking forward. So, when a company hits a milestone with a product it has had in the development pipeline for a lengthy period of time, the natural inclination is to pause (briefly) to celebrate the accomplishment, before turning attention to the next product. This pattern of constantly looking to the next and the newest challenge is essential to continued growth and innovation, but it is also the source of major problems when, after several years have passed since approval, a product becomes the focus of litigation that has the potential to sprawl into hundreds, even thousands, of cases.

This puts the company into "panic mode" as it is confronted with the need to make critical strategic decisions in a highly compressed period of time based on an overwhelming amount of fragmented and incomplete information — often with no reliable guide to explain the company mindset during the approval process and to shed light on why certain actions were taken while others were not. Litigation "time capsules"

and express warranty claims are pre-empted. *Cooper v. Wyeth, Inc.*, 2012 WL 733846 at *9 (M.D. La. March 6, 2012); *Bell*, supra. Some courts have declined to dismiss warranty claims. *Sacks v. Endoscopy Center*, 2011 WL 4915174 (D. Nev. 2011). Plaintiffs have also advanced consumer fraud claims without success. In *re Fosamax Litigation*, 2011 WL 5903623 at *8-9 (D.N.J. November 21, 2011); *DelValle v. PLIVA, Inc.*, 2011 WL 7168620 at *5 (S.D. Tex. December 21, 2011).

The trend appears to favor the application of pre-emption to the re-labeled theories designed to circumvent *Mensing*. Applying a different name to what is, at its core, a failure-to-warn claim should not be a means to evade *Mensing*.

The legislature may accomplish what the plaintiffs' bar has so far been unable to. Earlier this year, Senator Patrick Leahy (D-VT) introduced the Patient Safety and Generic Labeling Improvement Act, which would amend the Hatch-Waxman amendments to allow generic manufacturers to petition the FDA for a labeling change. By doing away with the rigid "sameness" requirements imposed by Hatch-Waxman, generics would lose the protection of federal pre-emption.

are a proactive step intended to help address this problem.

"Litigation time capsules are designed to capture relevant information and key documents, and to identify and clarify the mindset of decision-makers at the point when product milestones were achieved," says Kevin M. Zielke, a member and the practice group leader for the Pharmaceutical and Medical Device Litigation practice group at Dykema Gossett PLLC. "All of this information would be captured while memories are fresh and documents are close at hand, and then would be stored away such that, if the product faced litigation down the line, the company would have ready access to it. Armed with this information, the company is in a much better position to make the important strategic decisions necessary so that it has the best prospects for litigation success."

Smart Business spoke with Zielke about litigation time capsules and how they can help a company minimize litigation risk.

Why are litigation time capsules so useful and why don't more companies utilize them?

The problem is that when something good happens — a new product has made it through the development pipeline to approval, for example — no one wants to spoil the party by raising the possibility of future litigation. That, however, is precisely the time when undertaking this effort is imperative. The ounce of prevention that a company gains by taking the additional time and effort necessary to work with its attorneys to develop these time capsules has the potential to provide pounds of cure when, in the event of litigation, the company can avoid being caught flat-footed by the informational disadvantage that often exists at the outset of litigation.

While these time capsules can prove enormously helpful in the products liability context, where the company faces the prospect of many lawsuits being brought relating to a particular issue, they can also be used when significant corporate transactions or real estate deals are concluded. Essentially, they provide a snapshot of the then-existing facts, circumstances, key players and driving forces at the time the product was approved or the deal was done.

Why are litigation time capsules so important for businesses to have now?

Today, the need for ready access to key information years after the milestone has been achieved is made all the more critical by two fairly recent developments. First, the ready availability of inexpensive and potentially limitless electronic storage means that those tasked

with responding when litigation has been brought are confronted with a veritable ocean of potentially relevant materials that may be stored on hard drives, servers, backup discs, external drives, flash drives, cloud storage and the like. Second, the increasingly rootless nature of company personnel frequently means that those who were responsible for key decisions or who possess information necessary to effectively respond to the litigation are no longer with the company and not readily available to discuss these issues. As a result, capturing the most relevant materials and having immediate insight into the thinking at the time are essential.

What are the consequences of not appreciating these risks?

Now, perhaps more than ever, successful companies have to confront the fact that the litigation target is on their backs at all times, and have to build this sensibility into their culture by making it part of standard operating procedure. The failure to do so means the company will find itself forced to make key strategic decisions based on whatever information those charged with formulating the response were able to cobble together in the often highly compressed time frames found in the litigation context — after that the company will be largely locked into those early strategic decisions. That's why litigation time capsules work so well: you can wrap your head around lawsuits and respond to them as quickly and efficiently as possible.

About Amy Sorenson

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Amy Sorenson is a regional civil litigator, defending business litigation matters in the Utah, California and Nevada courts. Her practice focuses on complex commercial litigation, including general business litigation, financial services litigation, intellectual property, and professional liability and business tort litigation in federal and state court and arbitration. Her financial services litigation experience includes the representation of lenders in a wide variety of litigation matters, including False Claims Act litigation and SEC receivership matters, as well as defending claims made under the Truth in Lending Act, the Real Estate Settlement Procedures Act, and a wide variety of other state and federal lender liability claims.

Professional Recognition & Awards

- Utah Legal Elite, Civil Litigation, Utah Business Magazine (2007-2009, 2012-2013)
- Mountain States Super Lawyers®, Civil Litigation Defense - Rising Stars Edition (2012)
- Litigation Counsel of America, Fellow (2009)

Representative Presentations & Publications

- Debriefing: Utah Residential Foreclosure Litigation, Speaker, Utah State Bar Convention, Sun Valley, ID (July 2012)
- Professionalism for Inhouse Counsel: An Overview, Speaker, Association of Corporate Counsel Ethics at the End CLE, Salt Lake City, UT (December 2011)
- Rantings of a Partner ... and Pushback from the Associate, Chapter Author: Moving the Court, First Chair Press (July 15, 2011)

Community Involvement

- Legal Aid Society of Salt Lake, President, Board of Directors, Executive Committee (2004-present)
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- University of California, Berkeley, Boalt Hall School of Law (J.D., 1997)
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- Recipient, American Jurisprudence Award, White Collar Crime (1996)
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