



***Mensing* and Its Impact on State-Law-Based Claims Against Generic Drug Manufacturers**

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Following the U.S. Supreme Court’s five–four decision in *PLIVA, Inc. v. Mensing*,¹ it appears doubtful that many state-law-based claims against generic drug manufacturers remain viable. In *Mensing*, the Supreme Court held that state law claims based upon a failure-to-warn theory against generic drug manufacturers are federally preempted by the U.S. Constitution’s Supremacy Clause. In framing the issue, Justice Clarence Thomas, writing for the Court, asked “whether federal drug regulations

applicable to generic drug manufacturers directly conflict with, and thus pre-empt . . . state-law claims.” Ultimately, the Court found conflict preemption existed insofar as it was impossible for the defendant generic drug manufacturers to simultaneously comply with both the federally-imposed duty to warn and duties imposed by state laws.

The *Mensing* Decision

The *Mensing* case analyzed the inherent tensions between state-law-based failure-to-warn claims of risks inherent in



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prescription drugs and federal regulations implementing the Hatch-Waxman amendments to the federal Food, Drug and Cosmetic Act (FDCA). Those regulations require a generic drug's warnings to be "the same as" those of its bioequivalent branded pharmaceutical counterpart. To attain Food and Drug Administration (FDA) approval of abbreviated new drug applications (ANDAs) permitted by Hatch-Waxman and federal regulations, generic drug companies always needed to ensure that their drug labeling mirrored the brand's label. Recognizing this, the Court in *Mensing* extended the inquiry further: "What is in dispute is whether, and to what extent, generic manufacturers may change their labels *after* initial FDA approval." The Court concluded that under existing federal regulations generic warning labels must always be "the same as" their branded counterparts' labels—both before and after ANDA review and FDA's marketing approval.

Wyeth v. Levine Distinguished

In contrast to the Court's March 2009 *Wyeth v. Levine* decision,² which focused upon preemption in branded pharmaceuticals, the Court in *Mensing* held that the FDA's "changes being effected" (CBE) regulation³ was not available to defendant generic drug manufacturers to unilaterally effect labeling changes.

Likewise, the Court found that generics, unlike innovators, could not utilize "Dear Doctor" letters to advise prescribing physicians of newly ascertained drug risks. In *Levine*, the Court rejected the defendant brand drug manufacturer's federal preemption defense, largely based upon the availability of the CBE regulation to strengthen label warnings. There, the Court concluded that the CBE regulation afforded Wyeth and other brand

drug manufacturers with an ability to comply with both federal and state law requirements by independently strengthening drug warnings subject to the FDA's ultimate approval. There simply was no need in *Levine* for the Court to consider the regulatory scheme for generic as opposed to innovator drugs.

The Influence of the Government's Amicus Brief in *Mensing*

A seminal moment occurred in the briefing prior to oral argument when the U.S. Solicitor General, speaking for FDA, acknowledged in an *amicus* brief that both the CBE regulation and "Dear Doctor" advisory letters were not available to generic drug companies under FDA's regulations. These regulations, the government conceded, applied only to brand drug companies. Instead, the government, citing a 19-year-old *Federal Register* FDA commentary⁴ to then-proposed regulations, asserted that generics "could have proposed—indeed were required to propose—stronger warning labels to the agency if they believed such warnings were needed."

Assuming FDA agreed with the proposed label changes, the government argued, FDA would then work with the innovator manufacturer to craft new label warnings applicable to both the brand drug and its generic equivalents.

Rejecting this argument, the Court said that "[a]lthough requesting FDA assistance would have satisfied the [generic] Manufacturers' federal duty, it would not have satisfied their state tort-law duty to provide adequate labeling." The Court reasoned that while "[s]tate law demanded a safer label[,] it did not instruct the [generic] Manufacturers to communicate with FDA about the possibility of a safer label." Therefore, the Court found that it would be "impossible for the [generic] Manufacturers to comply with both their

state-law duty to change the label and their federal law duty to keep the label the same." Conflict preemption would be rendered impotent, the Court stated, if generics were required to prove that "FDA would not have allowed compliance with state law." Although the Court recognized that it was possible that FDA may have agreed to strengthen generic drug warnings under such circumstances, a hypothetical scenario such as this would not suffice "to prevent federal and state law from conflicting for Supremacy Clause purposes..." To that end, the Court found it unacceptable to imagine that generic drug manufacturers would be "required continually to prove the counterfactual conduct of FDA and brand-name manufacturer in order to establish the supremacy of federal law."

Conflict Preemption Finding Compelled by Differing Regulatory Schemes

Though the *Mensing* Court recognized that its prior *Levine* decision could be seen as conflicting with the approach taken relative to generic drugs, it emphasized that Hatch-Waxman established a different federal regulatory scheme for generic drug manufacturers than exists for brand drug companies. Accordingly, the Court refused to distort the Supremacy Clause in an effort to have similar federal preemption results in the context of dissimilar statutory and regulatory schemes. The Court, however, recognized that Congress and FDA always retain the authority to change the legislative and regulatory framework for generic drugs, and perhaps such efforts now will be undertaken.

The Products Liability Landscape Post-*Mensing*

Failure-to-warn claims are clearly preempted by the primary thrust of the

Mensing decision, leaving plaintiffs to assert alternative claims against generic drug companies under theories of negligence, misrepresentation, breach of express and implied warranties, design defect and strict liability. It is doubtful, however, that any such claims will be successful given the unique legislation under which generics operate, as well as the legal underpinnings of the *Mensing* decision itself.

Similar efforts were made by plaintiffs following the Supreme Court's decision in *Riegel v. Medtronic, Inc.*,⁵ preempting state-law-based tort claims for medical device manufacturers of products undergoing the intensive pre-market approval (PMA) process. Those efforts have been, in the main, notably unsuccessful, and so-called "parallel" claims seeking to revive affected suits or begin new ones frequently were met with effective challenges by the industry.

The results post-*Mensing* may well be similar. Warranty and negligent misrepresentation claims against prescription drug manufacturers would not seem to fit easily within a regulatory scheme in which FDA carefully monitors and controls the labeling, promotional materials, advertising and other information disseminated by generic drug manufacturers relating to their products. Also, drug companies generally do not guarantee outcomes, as each pharmaceutical's pharmacological effect on patients depends upon a host of variables that frequently are difficult to predict or control. Labeling, too, is an integral part of the "design" of a drug dispensed by physicians as learned intermediaries, so defective design claims encompassing generic drug warnings could run afoul of the Court's decision. Insofar as *Mensing* has made plain the inability of generics to have altered or modified the refer-

ence listed drug's labeling, the decision's holdings would appear to foreclose *all* claims premised on the need for stronger or different generic drug warnings than those given.

The implied warranty of merchantability, insofar as it subsumes elements of adequate packaging, labeling and affirmations of fact made in the marketing of a product, does not seem to be a fruitful avenue for plaintiffs' counsel after *Mensing* in the absence, for example, of the over-promotion of a generic pharmaceutical for off-label use. Similarly, any claims based on a breach of the implied warranty of fitness for a particular purpose are weakened by FDA's finding of safety and effectiveness of the brand drug, and the approval of its generic equivalents based on the results of prescribed bench tests, as well as bioequivalence studies on human subjects under regulations promulgated pursuant to Hatch-Waxman. By carefully reviewing preclinical and clinical studies by the innovator, post-approval adverse event reports, periodic reports and scientific literature, sometimes for decades during the innovator's patent exclusivity period, FDA has already determined and prescribed the indicated uses for which the molecule or compound remains safe and effective—in other words, for which it is "fit." When generics enter the market, they do and should rely upon this often-lengthy history of the innovator drug in preparing their ANDAs and in the post-approval marketing and use of their products.

Strict products liability, likewise, does not appear to be a viable approach for plaintiffs post-*Mensing* insofar as section 402A of the Restatement (Second) of Torts requires, in many jurisdictions not adopting blanket immunity for prescription pharmaceuticals, a risk-utility balancing test to determine product defect. In those jurisdictions, a drug's labeling

and product warnings remain an integral consideration in determining whether the product was avoidably unsafe and unreasonably dangerous. For example, under comment k to the Restatement, relating to prescription drugs, "a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous."

Section 6(c) of the Restatement (Third) of Torts offers little solace to plaintiffs and provides an approach that even more highly favors the pharmaceutical industry. Drug manufacturers are subject to liability only in circumstances in which "the foreseeable risks of harm posed by the drug . . . are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug . . . for any class of patients." Under comment b to section 6(c) of the Restatement, "a drug is defectively designed only when it provides no net benefit to any class of patients." As highlighted in the section's comment f, "[g]iven this very demanding objective standard, liability is likely to be imposed only under unusual circumstances." As comment f also notes: "A prescription drug . . . manufacturer defeats a plaintiff's design claim by establishing one or more contexts in which its product would be prescribed by reasonable, informed health-care providers."

Other post-*Mensing* claims of defective design against generic drug companies likewise will be difficult to prosecute insofar as plaintiffs seek to assert that a drug could have been more safely designed. It will be difficult to establish the existence of a practical and technically feasible alternative design preventing the alleged harm without substantially impairing the reasonably anticipated or intended function of the

product. Although such claims have been permitted in a few cases primarily involving vaccines, it would require a plaintiff, through expert testimony, to invent a new molecule or compound achieving the same therapeutic benefits without the side effects experienced by the plaintiff or others similarly situated: not an easy burden to assume or prove by a preponderance of the evidence. Moreover, Hatch-Waxman, and its overriding purpose to bring less-expensive drugs to market quickly under accelerated product approval procedures, furnishes generic drug companies with a more-than-credible argument against having to redesign a drug found safe and effective by FDA. Such costly and time-consuming efforts may well provide generics with a legitimate basis to claim that any such state law requirement obstructs the primary purposes of Hatch-Waxman and is preempted under traditional conflict preemption principles.

In her dissenting opinion, Justice Sonia Sotomayor notes that generics have always had the same pharmacovigilance obligations as brand manufacturers “to monitor the safety of their products,” and to “approach FDA to propose a label

change when they believe a change is required.” While on its face the failure of a generic drug company to comply with these obligations may seem a sure way to avoid the preemption barriers of *Mensing*, upon closer analysis it becomes less clear. Assuming a generic was faulty in its pharmacovigilance obligations or neglected to share important health and safety information with FDA, a plaintiff must establish that the generic’s failures were a proximate cause of his or her injury. To do so, a plaintiff would need to demonstrate that, had the generic been both diligent and compliant in its reporting obligations, FDA would have taken some action to warn or alert prescribing doctors or the public to a newly realized risk or hazard of the drug in question. If, however, it stands for anything, *Mensing* is clear that reliance on such speculative action by FDA is impermissible in a conflict preemption analysis, or, as Justice Thomas called such hypotheses, they are “conjectures.” Moreover, insofar as a generic’s surveillance or reporting failures amount to a violation of FDA regulations, the principles of *Buckman Co. v. Plaintiffs’ Legal Comm.*⁶ likely would imply the preemption of causes

of action premised upon such conduct. Private enforcement actions are barred under *Buckman*.

Conclusion

Undoubtedly, *Mensing* exemplifies a “sea change” in conflict preemption analysis by the Court. It will obviously provide a foundation for new constitutional challenges to state-law-based actions that are claimed to conflict with and be preempted by federal statutes or regulations. The seas ahead are choppy for the plaintiffs in such cases, including generic drug products liability litigation; and it will be interesting to see which claims, if any, survive and can be pursued in pending and future suits. Of equal interest will be efforts undertaken in Congress and at federal agencies, as well as in state legislatures, to address the legal and policy implications of *Mensing*. ▲

1. *PLIVA, Inc. v. Mensing*, 2011 U.S. LEXIS 4793 (U.S. June 23, 2011).
2. *Wyeth v. Levine*, 555 U.S. 555 (2009).
3. 21 C.F.R. § 314.70(c)(6)(iii).
4. 57 Fed. Reg. 17950, 17961 (Apr. 28, 1992).
5. *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).
6. *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341 (2001)