Sills Cummis & Gross P.C.

Client Alert **Product Liability Law**

Pliva, Inc. v. Mensing–
United States Supreme Court Holds That Failure To Warn Claims Against Generic Pharmaceutical Manufacturers Are Pre-Empted By Federal Law

Pliva, Inc. v. Mensing, No. 09-993 (U.S. Sup. Ct. Jun. 23, 2011) represents a landmark victory for generic pharmaceutical manufacturers on the issue of federal pre-emption. The *Mensing* decision is in stark contrast to the Court's most recent pre-emption decision in the pharmaceutical arena, *Wyeth v. Levine*, 555 U.S. 555 (2009), in which the Court held that plaintiffs' state law failure to warn claims against brand-name pharmaceutical manufacturers did not conflict with federal law. In *Mensing*, the United States Supreme Court, by a 5-4 majority, held that state law failure to warn claims against generic pharmaceutical manufacturers are impliedly pre-empted by federal law. In reaching this decision, the Court accepted the Food and Drug Administration's ("FDA") interpretation of its own regulations that generic manufacturers are legally prohibited from unilaterally changing or strengthening their product labeling without prior FDA approval. This deference to the FDA paved the way for the Court's holding. The Court held that because it was impossible for a generic manufacturer to unilaterally add or strengthen warnings without violating FDA regulations, all state law failure to warn claims are pre-empted.

Mensing involved two consolidated cases in which the plaintiffs, Gladys Mensing and Julie Demahy, alleged that they developed tardive dyskinesia, an often irreversible movement disorder, as a result of their ingestion of metoclopramide. Metoclopramide is the generic form of Reglan, which is used to treat various digestive track problems.

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Plaintiffs pursued state law failure to warn claims against the generic manufacturers of metoclopramide alleging that the warnings for the product failed to adequately disclose that prolonged use could cause tardive dyskinesia. The generic manufacturers moved to dismiss on implied pre-emption grounds arguing that: (1) FDA regulations require the warnings on generic pharmaceuticals to be the same as those of the brand-name product; and (2) they had no ability to unilaterally add or strengthen warnings without FDA approval. As a result, the manufacturers argued that plaintiffs' failure to warn claims were pre-empted because it was impossible for them to unilaterally add the plaintiffs' proposed warnings without violating FDA regulations. The trial courts reached opposite results on the manufacturers' motions to dismiss. On appeal, both the Fifth and Eight Circuit Court of Appeals disagreed with the manufacturers and ruled that the claims were not pre-empted.

The United States Supreme Court reversed, holding that plaintiffs' failure to warn claims were pre-empted by federal law. The Court began its analysis by discussing the 1984 Hatch-Waxman Amendments, the statutes that allow the FDA to approve generic pharmaceuticals based on a showing that they are equivalent to a product already approved by the FDA. The Court explained that although manufacturers of brand-name pharmaceuticals are responsible for ensuring the accuracy and adequacy of the warnings on their products, the Hatch-Waxman Amendments only require generic manufacturers to ensure that their warnings are the same as the brand-name product's warnings.

Against this backdrop, the Court addressed the parties' dispute over a generic manufacturers' ability to add or strengthen warnings. The Court rejected plaintiffs' argument that generic manufacturers were free to utilize the FDA's Changes Being Effected ("CBE") regulation. The CBE regulation allows manufacturers to unilaterally add or strengthen warnings before receiving FDA approval. In reaching this conclusion, the Court relied on the FDA's position that the CBE process was unavailable to generic manufacturers because allowing generic manufacturers to unilaterally change their warnings would violate the requirement that the generic products' warnings match those of the brand-name products. The Court also rejected plaintiffs' argument that the defendants were free to send additional warnings to physicians through "Dear Doctor" letters. Again, the Court's position was based on the FDA's interpretation that "Dear Doctor" letters constitute labeling under FDA regulations, and generic manufacturers cannot unilaterally add or strengthen warnings without prior FDA approval.[1]

[1] The *Mensing* Court's deference to FDA's interpretation of its own regulations was quite different from *Wyeth*, where the Court showed no deference to statements made in an FDA Guidance preamble that FDA regulations were both a ceiling and a floor for pharmaceutical products.

Lastly, plaintiffs argued that the defendants could not show impossibility because generic manufacturers that become aware of safety issues potentially associated with their products have a duty to propose that FDA add or strengthen warnings on both the generic and brand-name products. FDA regulations require that labeling be revised to "include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug." 21 CFR § 201.80(e). Since approval of the Hatch-Waxman Amendments, FDA has construed this regulation to require generic manufacturers to contact FDA when they believe that additional risks should be added to the product label. FDA is then responsible for deciding whether the label for the brand-name and generic drug should be changed. The manufacturers disputed that any such duty existed.

Ultimately, the Court did not decide whether such a duty exists because it held that even if generic manufacturers had a duty to propose labeling changes to the FDA, it did not alter the fact that generic manufacturers can not unilaterally change, add or strengthen warnings without violating federal law. The Court explained that plaintiffs' state law claims were based on inadequate warnings – not on the defendants' failure to propose additional warnings to the FDA. The Court also rejected plaintiffs' argument because it held that an "impossibility" analysis should only consider the defendant's independent ability to comply with state and federal law. Application of the pre-emption defense should not turn on whether a third party – in this instance, the FDA – took action on a label change or not. Because the defendants could not independently change their labels without convincing the FDA to undertake a "special effort permitting them to do so," the Court held that it was impossible for the defendants to add the label plaintiffs proposed without violating FDA regulations. Therefore, plaintiffs' failure to warn claims were pre-empted.

Four members of the Court joined in a blistering dissent, accusing the majority of "reinventing" the test for impossibility pre-emption. According to the dissent, the manufacturers should not be able to successfully assert impossibility pre-emption if there is a mechanism to effect a label change. The dissent agreed with the majority that a generic manufacturer could not avail itself of the CBE process or a "Dear Doctor" letter to make a change in product labeling. But the dissent argued that a generic manufacturer did have a duty to ask FDA for a label change if the manufacturer determined that additional risks should be included in the product label. Under these circumstances, a generic manufacturer could establish "impossibility" by showing that FDA had rejected the manufacturer's labeling proposal or that FDA had not yet responded to the manufacturer's request for a label change at the time of plaintiff's

injury. But in the absence of attempting to bring a safety issue to FDA's attention, a generic manufacturer cannot show that a label change was impossible.

The dissent chastised the majority for a decision which produced "absurd consequences." According to the dissent, whether a consumer has a state law remedy for failure to warn now turns on the pharmacist's decision to fill a prescription with a brand-name or generic drug. With 75% of all prescriptions being filled with generic drugs, the dissent argued that under *Mensing*, many consumers will be left without a state law remedy. The majority opinion acknowledged this result, noting that from plaintiffs' perspective, "finding pre-emption here but not in *Wyeth* makes little sense." Nevertheless, the Court found that it was "not this Court's task to decide whether the statutory scheme established by Congress is unusual or even bizarre …. Congress and the FDA retain the authority to change the law and regulations if they so desire."

What Does This Case Mean?

Mensing is a tremendous victory for generic pharmaceutical manufacturers in that it effectively immunizes them from state law failure to warn claims. The decision, however, may have left open the door for plaintiffs to bring negligence and other non-failure to warn claims against generic manufacturers who become aware of safety issues with their products but do not propose that the FDA add or strengthen warnings. As noted above, the Court assumed but did not decide whether generic manufacturers have a duty to propose additional warnings to the FDA. Given the FDA's position, and the Court's extreme deference to the FDA's interpretation of its own regulations, courts in future decisions may ultimately find that such a duty exists. As a result, generic manufacturers may encounter state law claims alleging that they breached this duty to propose a label change. It is unclear whether such a claim is cognizable as an independent cause of action under state law, especially in light of *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), in which the Court held that state law claims alleging violations of FDA reporting requirements were pre-empted.

Given the inconsistent "consequences" of this ruling on consumers of brand-name and generic drugs discussed above, we would expect some members of Congress to propose legislation overruling *Mensing*. Following the *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008) decision, in which the Court held that certain state law claims against medical device manufacturers were expressly pre-empted by the 1976 Medical Device Amendments, Congress introduced The Medical Device Safety Act in an effort to nullify

its effects. To date, however, that legislation has not yet passed. Even if Congress considered legislation to overturn *Mensing*, it would likely take years to wind its way through the legislative process.

For the time being, *Mensing* is the law of the land. Practitioners defending generic manufacturers are now well positioned to move for dismissal of failure to warn claims.

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