PRE-EMPTION DOUBLE STANDARD?

Manufacturers of Identical Products Are Not Equal

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In this era of spiraling health care costs, especially for pharmaceuticals, consumers are more interested than ever in having their prescriptions filled with less expensive generic drugs instead of their brand name equivalents. In fact, each state has a law permitting pharmacists to substitute a generic for its counterpart, and generics constituted 75 percent of all dispensed prescription drugs in 2009. Until now, whether you should insist on receiving the generic form of a prescription drug involved a relatively simple financial calculation, because you were receiving the same product and saving money. Based on the June 23, 2011 decision of the United States Supreme Court in *Pliva, Inc. v. Mensing*, 131 S.Ct. 2567 (2011), however, such savings may come with a high cost: your ability to pursue a state-law failure to warn claim against the manufacturer.

Although Supreme Court jurisprudence has long recognized a presumption against pre-emption absent a clear and manifest purpose of Congress, manufacturers of federally regulated products argue, with varying degrees of success, that state law tort claims are necessarily pre-empted where they appear to conflict with federal law. Specifically, manufacturers argue that it is impossible to comply with both federal and state law and/or that subjecting the products to the tort law of individual states would obstruct the objectives and purposes of the federal law. In the pharmaceutical context, its is typically the manufacturers' position that once the Food and Drug Administration ("FDA") accepts labeling for a particular drug, those warnings should not be subject to litigation under state law.

In *Pliva*, the Supreme Court agreed, holding that federal drug regulations applicable to generic drugs pre-empt state law warning claims. Although the decision might appear to be a relatively straightforward application of federal law and regulations when viewed in a vacuum, the Court had previously ruled, in *Wyeth v. Levine*, 129 S.Ct. 1187 (2009), that such failure to warn claims against brand name pharmaceutical manufacturers are generally *not* pre-empted. The decisions seem difficult to reconcile, because they create different liability postures for manufacturers of identical products. More importantly, the import of the decisions is that whether consumers can pursue state law tort claims may rely on the fortuity of their pharmacist's choice in filling prescriptions.

WYETH: NAME-BRAND MANUFACTURERS ARE SUBJECT TO STATE LAW TORT CLAIMS

The plaintiff in *Wyeth* had her arm amputated after developing gangrene as the result of the administration of Phenergan, an antihistamine used to treat nausea, using an IV-push methodology directly into her vein. The FDA first approved injectable Phenergan in 1955. Although Wyeth and the FDA subsequently communicated about adding a warning against IV-push administration due to the known risk of developing gangrene if it enters a patient's artery, the FDA approved a Phenergan label without such a warning in 1998. The trial court instructed the jury that it could consider Wyeth's compliance with the FDA requirements, but that such compliance was not determinative of the adequacy of the warnings. The jury found in favor of plaintiff, and the decision was affirmed by the Vermont Supreme Court.

The Supreme Court found that the state law warning claims against Wyeth were not pre-empted by FDA approval of the Phenergan label in 1998. The Court found meaning in the fact that although Congress had specifically enacted an express pre-emption provision for medical devices under the Federal Food, Drug, and Cosmetic Act ("FDCA"), no such provision was enacted for prescription drugs. Thus, the Court rejected Wyeth's claim that the FDCA was both a floor and a ceiling for drug regulation, i.e., that FDA approval of the labeling precluded a state court finding that the labeling was inadequate. Importantly, the Court further held that it was not impossible for Wyeth to comply with both the FDA regulations and state law requirements, since drug manufacturers are required by the FDCA to change their labels based on information learned after the drug's initial approval, and Wyeth could have unilaterally changed its label to include a warning against IV-push administration and sought FDA approval of the amended label.

PLIVA: STATE LAW CLAIMS AGAINST GENERIC DRUG MANUFACTURERS ARE PRE-EMPTED

Plaintiffs in the trilogy of cases decided in *Pliva* developed tardive dyskinesia, a severe neurological disorder, due to long term use of the generic form of Reglan, which is commonly used to treat digestive tract problems. The risks of such use were well known and, subsequent to plaintiff's ingestion of the generics, the name brand manufacturer requested, and the FDA approved, a label change adding a warning against use of Reglan for more than twelve weeks. The trial and appellate courts had reached different conclusions on the issue of whether the state-law tort claims were pre-empted.

The Supreme Court began its decision by noting that Congress had changed the duties of generic manufacturers in 1984 by enacting the Drug Price Competition and Patent Term Restoration Act, otherwise known as the "Hatch-Waxman Amendments." Under that Act, generic drugs can gain FDA approval by showing equivalence to an FDA-approved drug. This serves the purpose of developing generic drugs inexpensively, as duplication of the costly clinical trials performed on the brand name drugs was not necessary. However, the Act requires, *inter alia*, that a generic drug application must show that the proposed labeling is the same as the labeling approved for the name brand drug. Thus, although Congress imposes on name brand manufacturers a continuing duty to ensure that its label is both accurate and adequate, the generic manufacturer has no such duty. In fact, federal law prevents the generic manufacturers from independently changing their labels. Accordingly, the Court held that it was impossible for the generic drug manufacturers to comply with both federal and state law, and found that the state law warning claims were pre-empted.

In so holding, the Court noted that, given the *Wyeth* decision, the *Pliva* holding seemed to make "little sense." However, the majority explained that the different statutory duties and regulatory schemes were created by Congress and the FDA, and that it was simply applying them to the controversy before it. If a different result was desired, those entities had the power to change the laws and regulations.

CONCLUSION

It would be easy to interpret the decisions in *Wyeth* and *Pliva* in terms of ideology. The *Wyeth* decision, which seemingly expands tort liability, was written by Justice Stevens, joined by Justices Kennedy, Souter, Ginsburg, Breyer and Thomas (concurring in the judgment only). *Pliva*, which appears to limit liability claims, was written by Justice Thomas, joined by Justices Roberts, Scalia, Alito and Kennedy. But such a facile conclusion would ignore the reality that the differing liabilities faced by brand name and generic drug manufacturers were the result of Congressional action, done for the otherwise laudable purpose of bringing generic drugs quickly and inexpensively to market.

The Court could not disregard the express provisions of federal law in order to fashion favorable result for the plaintiffs in *Pliva*. Despite a favorable result and the fact that whether a person has a state law tort claim may be decided by the happenstance of who is filling their prescriptions, the problem was created by Congress and the FDA and the ball is now in their court. Until they choose to act, *Pliva* is a significant victory for generic drug manufacturers, who should be able to seek dismissal of state law failure to warn claims.

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