CORPORATE COUNSEL

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From the Experts: Brave New (Post-Mensing) World

Generic manufacturers may not be liable for failures to warn, but what about brand-name innovators?

Kelly Savage Day

Michael Healy

The U.S. Supreme Court recently confirmed in *Pliva, Inc. v. Mensing* that the Hatch-Waxman amendments to the federal Food, Drug, and Cosmetic Act (FDCA) categorically preempt state failure-to-warn claims brought against manufacturers of generic drugs. As a result, generic drug manufacturers are not held liable for failing to provide safety warnings on their products—even if they obtain information about new safety risks—if the "new" warning differs from those found on the brand-name equivalent.

Although the 5-4 decision marks a significant win for generic companies and clarifies the scope of the Court's *Wyeth v. Levine* decision—which held that failure-to-warn claims against brand-name drug manufacturers (also known as the innovators) were not automatically

preempted—many brand-name manufacturers are concerned that the Court's recent *Pliva* ruling may adversely affect their businesses by making it more likely that other courts will adopt the theory of liability set forth in California's *Conte v. Wyeth* decision. Under *Conte*, brand-name manufacturers may be liable for injuries suffered by those plaintiffs who take a generic version of their brand-name drug. This article examines the potential legal risks brand-name manufacturers face and offers some concrete suggestions for proactively mitigating these risks both now and in the future.

Conte's Improper End-Run around Generic Preemption Has Not Gained Significant Acceptance Outside of California

Three years ago in *Conte*, California's First District Court of Appeal inexplicitly ruled that brand-name drug manufacturers could be liable for harm to individuals who take generic versions of their brand-name products for alleged deficiencies in the generic drug's labeling. Implicit in the decision was the idea that injured users of generic drugs should not be left remediless. Thus, if state failure-to-warn claims against generic manufacturers are preempted under federal law, the *Conte* court reasoned that injured generic users should be able to recover against the manufacturer of the brand-name equivalent.

The court noted that brand-name manufacturers (unlike the generic manufacturer) can change their labels to provide stronger warnings without violating the FDCA. The court believed that these warnings would ultimately make their way onto generic labeling and protect generic drug users. Brand-name manufacturers (and the attorneys that represent them) viewed *Conte* as an improper end-run around generic preemption and feared that the wayward decision would dramatically shift liability on to them for their generic competitors' defective products.

Generally, their fear has proved unfounded. Although *Conte* remains good law in California, at least 21 states—including Alabama, Arkansas, Colorado, Florida, Georgia, Kentucky, Louisiana, Maryland, Massachusetts, Minnesota, Nevada, New Jersey, New York, North Carolina, Oklahoma, Oregon, Pennsylvania, South Carolina, Texas, Utah, and West Virginia—have expressly rejected its holding. Brand-name manufacturers are understandably concerned that *Pliva* could change the legal landscape for innovators nationwide because courts may feel more pressured to provide a remedy to blameless plaintiffs. But it is unlikely that the jurisdictions that have considered the issue will reverse themselves simply because generic manufacturers are definitively (as opposed to theoretically) not liable for failures to warn.

Innovators Should Anticipate and Prepare for *Conte* Claims

Although *Pliva* should not be viewed as a harbinger of never-ending, ever-expanding liability for brand-name manufacturers, innovators should expect and prepare for an increase in product liability suits seeking to hold them liable for harm stemming from their generic competitors' products, especially in California, where *Conte* remains binding precedent on all state trial courts. (See *Auto Equity Sales, Inc. v. Superior Court* [1962].) To mitigate the potential impact of future claims, innovators should strengthen existing compliance programs and have a strong litigation plan in place to deal with future *Conte* claims.

Avoid and Mitigate Product Liability Risks to Avoid Future Claims

Developing and implementing strong compliance programs to manage legal risks from the outset is crucial. Innovators should consider strengthening existing pharmaco-vigilance programs to identify and address health (and in turn potential litigation) risks throughout the product lifecycle to avoid future claims. These programs should, at a minimum, include standard operating policies and procedures that ensure strict compliance with the FDA's current requirements for the manufacture and sale of drugs. At the same time, brand-name manufacturers should create regulatory and labeling processes to avoid potential lawsuits and bolster future preemption arguments should they be sued. Finally, innovators should assess whether adequate product liability insurance is in place and whether the current coverage extends to all *Conte* exposures and liabilities they may face.

Formulate a *Conte* Litigation Strategy to Deal with Future Claims

Because *Conte* remains binding precedent on all California trial courts until another appellate court rejects its holding, savvy plaintiffs' counsel will file their *Conte*-styled suits in California state courts. Thus, it is important for brand-name manufacturers to identify and retain counsel intimately familiar with California practice and procedure.

Defense counsel should (1) be familiar with various jurisdictions' decisions regarding *Conte*; and (2) be prepared to evaluate all important procedural mechanisms, such as removal, change of venue, assertion of choice-of-law principles, and dismissal, as soon as a complaint is filed. Ideally, innovators will have grounds to (1) remove the case to federal court (and preferably to transfer the action to a court outside California that has previously rejected *Conte*); (2) seek application of a more favorable jurisdiction's laws; and then (3) move for dismissal under Federal Rule of Civil Procedure 12(b)(6). (See *Chemstar, Inc. v. Liberty Mut. Ins. Co.* [1994].) Under the *Erie* doctrine, *Conte* is not binding on California federal district

courts; instead the decision is merely "persuasive" precedent, which the court is not bound to follow if it believes that the California Supreme Court would decide otherwise. Alternatively, counsel will hopefully have grounds to attempt to have the laws of another state apply (again, preferably one that has rejected *Conte*) under established California choice-of-law principles and then to seek dismissal (or "demurrer," as California courts refer to motions to dismiss in state courts) as a matter of law.

In those cases where the case is properly venued in California state court and its laws apply, innovators should assert the preemption defense if appropriate, and if not, then focus on developing a strong causation case.

Conclusion

The tide of product liability actions against brand-name manufacturers will continue to rise. But if companies take the right steps now, there's no need for them to be among those who get their feet wet. With a little planning, innovators can manage the risk of being sued while also enhancing potential defenses in the event of litigation.

Kelly Savage Day is a senior associate and Michael F. Healy is the managing partner of the San Francisco office of Sedgwick. For additional information on this topic, please contact Ms. Day at kelly.savageday@sedgwicklaw.com or Mr. Healy at michael.healy@sedgwicklaw.com.