Arnall Golden Gregory LLP

Client Alert

Contact Attorney
Regarding This Matter:

Alan G. Minsk
404.873.8690 - direct
404.873.8691 - fax
Alan.Minsk@agg.com

Recent Ruling Favors Federal Preemption of State Tort Claims against Generic OTC Drug Companies

A United States District Judge in California has ruled recently that the Food and Drug Administration's (FDA) labeling requirements for generic over-the-counter drugs preempt failure to warn claims based in state tort law. The case, Gaeta v. Perrigo Pharmaceuticals Co., represents a growing trend an important move in favor of federal preemption of state tort claims for drug and device companies.[1] As Bill Kitchens recently wrote in *Regulatory Focus*, a current series of cases are further defining the scope of the preemption defense:

- In February 2008, the Supreme Court held in Riegel v. Medtronic that FDA's premarket application (PMA) approval process preempts suits challenging the safety or effectiveness of class III devices.[2] The 8-to-1 holding in Riegel sets clear precedent for class III device companies, but the applicability of this precedent beyond devices is limited. The Riegel Court relied heavily on the fact that the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (FDCA) contain an express preemption clause for devices. Riegel, therefore, did not define the scope of the preemption defense with respect to a wider range of products.
- The Gaeta ruling in California comes at a time when the question of the scope of the preemption defense is on the national agenda. The U.S. Supreme Court will soon hear a case that addresses a broader preemption issue: whether the new drug approval procedures under the FDCA preempt state tort claims against prescription drug companies. The upcoming case, Wyeth v. Levine, will better define the applicability of the preemption defense for pharmaceutical companies that do not have an express preemption clause in the FDCA.[3]
- Gaeta, while not a national precedent, suggests a continued move in the direction of a broader preemption defense to include a wider range of products. The court ruled in favor of Perrigo Pharmaceuticals on summary judgment. It held that making "Perrigo liable…for failing to warn…on the labeling of its drug" conflicted with the company's obligations under FDA's abbreviated new drug application (ANDA) process, which includes governs labeling requirements.

[1] No. C 05-04115, slip op. (N.D. Cal. June 13, 2008)

[2] 128 S. Ct. 999 (2008)

[3] 944 A.2d 179 (Vt. 2006), cert. granted, 128 S. Ct. 1118 (2008)

Arnall Golden Gregory LLP
Attorneys at Law
171 17th Street NW
Suite 2100
Atlanta, GA 30363-1031
404.873.8500
www.agg.com

A Trend in Favor of Preemption?

The recent cases seem to indicate a trend in favor of a broader preemption defense. But other developments might temper the trend:

- In March 2008, the Supreme Court split 4-4 in Warner Lambert v. Kent over whether federal law preempts state statutes providing a "fraud on the FDA" exception to protection from state tort liability.[4] Warner Lambert Company argued in favor of preemption based on the Supreme Court's 2001 holding in Buckman Co. v. Plaintiff's Legal Committee.[5] In Buckman, the Court held that claims alleging a company had committed fraud on FDA by intentionally withholding or misrepresenting information were preempted because "fraud on the FDA" suits interfere with federal regulation of pharmaceuticals.
- The split vote in Kent fails to extend the Buckman reasoning to state legislation with a fraud on FDA exception to preemption. The Michigan statute at issue in Kent permits judges and juries to determine whether the company facing tort claims committed fraud on FDA and whether FDA would have approved the drug but for that fraud. The ruling at the Second Circuit level does not set national precedent and the Supreme Court's split vote on appeal renders unpredictable its future rulings in similar cases.
- Bill Kitchens' *article* observed that key Democratic legislators, such as Senators Edward Kennedy (D-MA) and Representative Henry A.Waxman (D-CA), have heavily criticized the Riegel precedent in favor of preemption for devices. Both legislators have publicly committed to working on legislation that will undo the Riegel holding.
- Representative Waxman, Chairman of the House Oversight and Government Reform Committee, and Representative Frank Pallone, Jr. (D-NJ), Chairman of the House Energy and Commerce Subcommittee on Health, have proposed legislation that would overrule the Supreme Court's holding in Riegel. The pending legislation is called the Medical Device Safety Act of 2008 (HR 8381). Also, Representative Waxman's Committee on Government Oversight and Reform held hearings in May on whether FDA regulation should bar liability claims. Following the hearings, he sent a letter on June 26 to FDA requesting documents explaining its position on preemption. The Committee website states that the FDA's position in favor of preemption under the Bush Administration is a reversal of previous long-standing policy.

[4] 128 S. Ct. 1168 (2008)

[5] 531 U.S. 341 (2001)

The Bottom Line

Regardless of scope, the preemption defense is available only to companies whose products fully comply with the applicable safety and effectiveness requirements under the FDCA and the greater FDA regulatory scheme. Regulatory compliance is an implied threshold question in all of the recent cases that ruled in favor of preemption. If the companies in question had failed to comply with FDA regulations, the court holdings may not have been in their favor.

- The Riegel Court relied on the fact that the devices at issue had received PMA approval. The Court reasoned that when FDA grants PMA approval to a device, it has already reasonably assured the safety and effectiveness of that device. In order to receive approval, device companies must not deviate from the exact specifications of the application. Thus, the Court reasoned that state tort laws were in conflict with the PMA scheme because they impose additional requirements on companies in excess of what FDA requires.
- Gaeta is no exception to this rule. In this most recent case, the court found that the ibuprofen manufacturer "complied with the labeling requirements that the FDA has set" under its process for approval of generic products. The court relied on this finding of compliance to hold that the state law causes of action were preempted. The court reasoned that the warnings the Plaintiff sought would put "Perrigo's ANDA in jeopardy for failing to conform to the FDA's approved labeling" for the product.
- Until the Supreme Court decides Levine, we will likely continue to see inconsistent rulings on the preemptive effect of federal drug law and regulations on state tort claims. We will follow this case and provide a future update when the case is argued in the fall.