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Five Take-aways for Pharmaceutical Companies from Recent Supreme Court Activity

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Now that we are near the middle of the Supreme Court's 2011 term, it is worthwhile to look back at the past year to see how last term's remarkable slew of decisions has impacted the pharmaceutical industry. Among other issues, that term addressed the First Amendment, federal preemption, private rights of action, and contingency arrangements between state attorney general offices and private lawyers. The ramifications will be felt for some time to come. This article reviews five take-aways from that term.

The First Amendment Applies to Pharmaceutical Companies

In *Sorrell v. IMS Health*, 131 S. Ct. 2653 (2011), the Supreme Court held that pharmaceutical company promotion is entitled to full First Amendment protection. At issue was Vermont's Prescription Confidentiality Law, Vt. Stat. Ann., Tit. 18, § 4631 (Supp. 2010), which, among other restrictions, prohibited pharmaceutical companies from using a doctor's prescription history in promoting their drugs to that doctor. After a bench trial, the District Court upheld Vermont's law. On appeal, the Second Circuit reversed, holding that the law burdened the speech of pharmaceutical companies without adequate justification. Because of a circuit split involving similar legislation in other states, the Supreme Court granted certiorari. The Court found that Vermont's law violated the First Amendment because it discriminated against pharmaceutical companies based on the content of the message and burdened "disfavored speech by disfavored speakers." *Sorrell*, 131 S. Ct. at 2663.

Sorrell has already (and appropriately) emboldened pharmaceutical companies to protect their right to engage in commercial speech. In October 2011, for example, Par Pharmaceutical Inc. filed a complaint in the U.S. District Court for the District of Columbia challenging FDA regulations that criminalize truthful speech about the FDA-approved uses of prescription drugs to physicians who are more likely to use the drug for off-label uses. *See* Complaint, Civ. No. 1:11-cv-01820 (D.D.C. Oct. 14, 2011). We are likely to see similar suits in the future.

A Win for Generic Manufacturers May Create Challenges for Brand Name Drugmakers

In a 5-4 decision, the Supreme Court continued to shape the scope of federal preemption by holding in *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), that federal drug labeling laws directly conflict with, and thus preempt, state law failure to warn clams against generic drug manufacturers. In *Mensing*, the Court consolidated two state law failure-to-warn cases originating in the Fifth and Eight Circuits against generic manufacturers of the drug metoclopramide. Both appellate courts held that federal drug labeling laws did not preempt state law failure-to-warn claims against generic drug manufacturers. The Supreme Court reversed, finding it "impossible" for manufacturers of generic drugs to comply with state law duties to strengthen generic drug

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labels without violating federal drug labeling laws. *Id*. at 2578. These laws require generic drugs' labels to be "the same as" the labeling approved for their brand-name counterpart. *Id*. at 2574.

Although the full implications of *Mensing* remain to be seen, lower courts have begun dismissing failure to warn claims against generic companies. Order, *Henderson v. Sun Pharmaceuticals Industries, Ltd*., Order, No. 4:11-cv-00060-HLM (N.D. Ga. Aug. 22, 2011). Plaintiffs' lawyers, however, are unlikely to simply abandon product claims when their prospective clients are allegedly injured by generic drugs. They are already seeking ways to distinguish *Mensing*, with some success in some courts. In *Fisher v. Pelstring, C.A*., the U.S. District Court for the District of South Carolina held that *Mensing* did not preempt claims that a generic defendant failed to timely incorporate in its generic labeling FDA-mandated warnings on the brand name labeling. Order, No. 4:09-cv-00252-TLW (D.S.C. Sept. 30, 2011). A Nevada state court recently concluded that *Mensing* does not preempt claims that generic drug manufacturers should have sent Dear Doctor Letters that were consistent and not contrary to brand labels. *Carol Keck v. Endoscopy Center of Southern Nevada, L.L.C.*, No. A575837 (Nev. Dist. Ct., Clark Cty., Aug. 19, 2011).

Plaintiffs' lawyers also will likely invoke the 2009 California Court of Appeal decision, *Conte v. Wyeth*, 85 Cal. Rptr. 3d 299 (Cal. Ct. App. 2009). *Conte* held a brand-name drug manufacturer liable for injuries caused by the generic counterpart because the prescribing physician purportedly relied on the brand-name product's labeling when prescribing the generic drug. While the majority of courts have rejected this theory as stretching the foreseeability doctrine too far, two different federal district courts recently denied a brand-name manufacturer's motion for summary judgment where the plaintiff had received only a generic equivalent. *See, e.g.*, *Weeks v. Wyeth*, 2011 BL 86692 (M.D. Ala. Mar. 31, 2011); *Kellogg v. Wyeth*, 762 F. Supp. 2d. 694 (D. Vt. 2010). Brand name manufacturers for their part will appropriately resist these efforts based on traditional notions of product identification and proximate causation. Ultimately, legislators may come to the scene and attempt to impose liability on generic manufacturers or consider the fairness of requiring brand name manufacturers to foot the bill for generic companies' products.

Rejection of a "Statistical Significance" Test for Disclosure of Adverse Event Reports May Create Uncertainty in the Securities Realm but Help in the Product Space

In *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309 (2011), the Court addressed the pleading requirements for two key elements of securities fraud claims—materiality and scienter—in a case brought against a pharmaceutical company alleging a failure to disclose adverse event reports associated with the company's core brand of products. The defendants argued that the plaintiffs failed to plead both elements adequately because the number of adverse events did not rise to statistical significance.

The Court unanimously rejected the defendant's proposed "bright-line" rule on statistical significance. Rather, the Court held, a careful, fact-specific inquiry is required to determine the sufficiency of the allegations. But, the Court made clear that "the mere existence of reports of adverse events—which says nothing in and of itself about whether the drug is causing the events—will not satisfy [the materiality pleading] standard." *Id*. at 1321. Securities lawyers should note that such reports may be material when coupled with other evidence. *See In re Merck & Co., Inc. Securities, Derivative, & ERISA Litigation*, 2011 BL 204682, at *13 (D.N.J. Aug 08, 2011). Those lawyers who defend companies in product liability cases will appreciate the Supreme Court reinforcing the point that adverse event reports standing alone can be nothing more than reports.

Limitations on the Government's Reach into Pharmaceutical Company Conduct

In *Astra USA, Inc. v. Santa Clara County, CA*, 131 S. Ct. 1342 (2011), the Court considered whether "covered entities" under Section 340B of the Public Health Services Act may bring private actions under the federal common law as third-party beneficiaries of Pharmaceutical Pricing Agreements (PPAs) between pharmaceutical companies and the federal government. Section 340B imposes ceilings on prices that drug manufacturers may charge to specified federally funded health care facilities such as public hospitals and community health centers (340B entities). Santa Clara County, operator of several 340B entities, filed a breach of contract suit alleging that the drug manufacturer defendants were overcharging 340B health care facilities in violation of the PPAs. The District Court dismissed the complaint, but the Ninth Circuit reversed, finding that 34B entities could maintain an action as third-party beneficiaries. *Id*. at 1347. In a unanimous decision, the Court held that suits by 340B entities are not permitted, concluding that the absence of a private right of action under the Act "would be rendered meaningless if 340B entities could overcome that obstacle by suing" under a common law breach of contract theory. *Id*. at 1348.

The biggest practical impact of this decision may be to litigation under the Medicaid Drug Rebate Program (MDRP). Although the Court "took no position" on whether states and other third-parties can sue for breach of the MDRP, the Court's reasoning and language counsel against it. *Id*. at 1349 n.5. The Court frequently likened § 340B PPAs to the Medicaid Rebate Agreement, stating that "Congress made HHS administrator of both the Medicaid Drug Rebate Program and the 340B Program" and concluding that private suits would "undermine the agency's efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis." *Id*. at 1349. The U.S. District Court for the District of Massachusetts recently recognized that the application of *Astra* in litigation involving Medicaid Rebate Agreements was "quite difficult" but found that the decision did not invalidate state common law and statutory fraud claims. *See Massachusetts v. Schering-Plough Corp*., 779 F. Supp. 2d 224, 239-40 (D. Mass. 2011).

More broadly, decisions like *Astra* should embolden pharmaceutical companies to fight back against overreaching, including by governments, like we *see* happening in Takeaway 5.

Challenges to Contingency Fee Prosecutors Will Continue

In *Atlantic Richfield Co. v. Santa Clara*, 131 S. Ct. 920 (2011), the Court denied review of a California Supreme Court ruling that upheld the government's use of contingency fee prosecutors – private plaintiffs' law firms retained on a contingency fee basis to prosecute civil lawsuits against corporations. Atlantic Richfield Co. claimed that contingency fee arrangements violate due process because they interject a financial and personal stake in a public prosecution, interfering with a prosecutor's duty to act solely in the public interest. According to its petition, "this brand of lawyer-sponsored government litigation [has] become[] a cottage industry." Brief for Petitioner at 4, *Atlantic Richfield Co. v. Santa Clara*, No. 10-546 (Oct. 22, 2010).

While the Supreme Court denied this petition, the argument underlying it is gaining momentum. In August 2011, for example, Merck filed suit in federal court alleging that the Kentucky Attorney General's retention of outside counsel to prosecute Vioxx-related civil litigation violated due process. *See* Complaint, Civ. No. 3:11-cv-00051-DCR (E.D. Ky. Aug. 16, 2011). Merck contends that the state AG is not empowered to outsource this type of work and that such agreements result in profit motivation guiding prosecutorial decision-making, rather than the public interest. As states continue to retain outside lawyers for civil litigation against drug manufacturers, Merck's actions likely will encourage other pharmaceutical companies to raise similar due process arguments.

Of course, the decisions cited above could end up being isolated one off decisions or the beginning of trends. It will be fascinating and instructive to see how these principles play out in federal and state courts in the years to come.

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