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Newly Filed Free Speech Case May Set Up Off-Label Court Fight

By Christopher R. Hall and Gregory G. Schwab

Par Pharmaceutical filed suit last month against the federal government, seeking to preserve its First Amendment right to provide information to doctors about its prescription drug Megace ES. The suit calls to mind a similar case brought by Allergan in 2009 against the government regarding its right to promote its drug Botox. Allergan dropped that suit as part of a \$600 million settlement with the government in September 2010, so the constitutional issues were never reached. But unlike the Allergan suit, Par seeks to challenge government regulations that it contends criminalize its truthful and non-misleading speech about FDA-approved uses – not just *unapproved* or off-label uses.

In 2005, the FDA approved Megace for the treatment of anorexia, cachexia, and significant weight loss in patients with AIDS. Physicians often prescribe Megace off-label to treat wasting in non-AIDS, cancer and geriatric patients. Par would like to share useful information it has developed about Megace with physicians who work in long-term care facilities. But sharing that useful information with physicians who treat patients with both on-label and off-label indications could result in civil – and even criminal – liability.

Par Pharmaceutical contends that FDA's theory of "misbranding," coupled with FDA's "intended use" and labeling regulations, ban Par from speaking about approved uses of Megace with physicians who may also prescribe the drug for unapproved uses. Misbranding, pursuant to 21 U.S.C. § 352, occurs if a manufacturer alters the FDA-approved labeling to include statements that are "false or misleading in any particular." It may also occur when a drug's label did not contain "adequate directions for use." According to the government, a drug promoted for an off-label indication or use does not contain "adequate directions for use" and therefore misleads.

Under the "intended use" regulations of 21 C.F.R. §§ 201.100 and 201.128, a manufacturer's speech (in the form of communications to prescribing physicians) may demonstrate a manufacturer's intent to promote a drug for off-label use if it concerns indications not explicitly approved by the FDA.

Par alleges in its complaint that the FDA interprets the FDCA and its regulations to prohibit manufacturers from providing instructions for off-label uses. The FDA instead requires manufacturers to treat an approved drug as a new drug and to apply for approval for the new use. Manufacturers that do not submit a new drug application (NDA), but which nonetheless provide instructions for unapproved uses, run afoul of the misbranding rule. Par describes this as an untenable Catch-22. The threat of criminal prosecution chills its right to commercial free speech, which, in Par's view, will benefit patients currently left bereft by the FDA's wooden stance. Par seeks to overturn FDA's "intended use" and labeling regulations as unconstitutional violations of its First Amendment rights.

Par's suit coincides with other efforts to overturn FDA's longstanding promotional rules. The Second Circuit will soon decide the appeal of Alfred Caronia, a former Jazz Pharmaceuticals sales representative, who allegedly promoted the narcolepsy drug Xyrem to treat drowsiness and chronic fatigue. His appeal was boosted by the U.S. Supreme Court's decision in June in *Sorrell v. IMS Health*, which concluded that Vermont could not prohibit the sale of prescription pattern information by pharmacies to anyone, including drug companies that may target specific physicians for marketing.

The Department of Justice has been investigating Par's marketing of Megace since 2009. We will continue to monitor the developments in these cases.

Recent New Jersey Putative Class Action Names Wells Fargo and its Foreclosure Firm in Connection with New Jersey and Pennsylvania Foreclosures

By Francis X. Riley, III and Ryan L. DiClemente

A putative class action was recently filed in the United States District Court for the District of New Jersey against Wells Fargo Bank, N.A. ("Wells Fargo"), its foreclosure firm, Phelan Hallinan & Schmeig LLP, some of its individual partners and attorneys, and Phelan's allegedly related companies that provide foreclosure and mortgage services (collectively, "Phelan"). While putative class actions alleging misconduct against a lender in connection with foreclosures are nothing new, the allegations against the foreclosure firm that was retained by the lender add an additional layer of potential liability for financial service companies and their service providers.

Specifically, Plaintiffs seek to represent a class of New Jersey and Pennsylvania residents who were defendants in foreclosure actions prosecuted by Phelan during the past six years. Plaintiffs

allege Phelan, on behalf of Wells Fargo, executed and notarized fraudulent court documents and property records in an effort to initiate and prosecute foreclosure actions in the names of entities without legal standing to sue. Plaintiffs also contend that Phelan imposed inflated or fabricated fees for "default management services," including improper attorneys' fees and costs, title search fees and property appraisals. Plaintiffs' claims include violations of the federal Racketeer Influenced and Corrupt Organizations ("RICO") Act, the New Jersey Consumer Fraud Act, and Pennsylvania's Unfair Trade Practices and Consumer Protection Law, as well as common law claims for breach of contract and negligence.

While the ultimate success or viability of this putative class action is in question, this case is an example of how the target

on financial service companies' backs can be enlarged by holding them potentially liable for actions with which they seemingly had little direct connection. It is important that financial service companies work with their risk managers to take the appropriate steps to ensure that their service providers comply with applicable laws and regulations. Such protective measures can include mandating audits of and establishing vendor guidelines with concomitant routine reporting requirements for the service providers' policies, procedures and fees. These are just a few examples of the steps financial service companies can take to insulate themselves from potential liability for the actions of their service providers.

Further, many of these suits arising out of the foreclosure process stem in part from the failure to ensure that automated loan foreclosure processes account for the legal requirement of individual and personal review of each file. The laws of many states permit banks to foreclose only based on personal knowledge of the terms of the borrower's loan, the facts surrounding the default, and the amounts due and owing. While we recognize that computerized systems produce more accurate data than the human file review required by most state laws can achieve, we urge our clients to ensure that they incorporate as part of their automated services all legal requirements so as to safeguard against the risk of non-compliance.

Wiretapping Assists Government in Developing Evidence of Insider Trading

By Nicholas J. Nastasi and Amy L. Piccola

On October 26, 2011, the United States Attorney for the Southern District of New York indicted Rajat K. Gupta, a member of the Boards of Directors of The Goldman Sachs Group, Inc. ("Goldman Sachs") and the Procter & Gamble Company ("P&G"), with five counts of securities fraud and one count of conspiracy to commit securities fraud. Gupta, like several recent defendants in insider trading cases, was caught on tape sharing alleged confidential business and financial information.

The charges against Gupta stem from his interactions with Raj Rajaratnam, a hedge fund manager sentenced last month to 11 years in prison for trading on illegal stock tips. According to the six-count indictment, from 2008 through January 2009, Gupta disclosed to Rajaratnam inside information that Gupta had learned in his capacity as a member of the Boards of Directors of Goldman Sachs and P&G with the understanding that Rajaratnam would use the inside information to purchase and sell securities. The indictment includes information on three phone calls Gupta

made to Rajaratnam in which Gupta shared nonpublic information. Each of these phone calls was recorded by the FBI.

WHEN AND HOW THE GOVERNMENT CAN RECORD PHONE CALLS

Title III of the Omnibus Crime Control and Safe Streets Act of 1968 (the "Wiretap Act") establishes procedures for obtaining judicial orders to authorize wiretapping by government officials. 18 U.S.C. § 2518. A federal district court judge may issue an order authorizing interception of communications for up to 30 days upon a showing of probable cause that the interception will reveal evidence that "an individual is committing, had committed, or is about to commit a particular offense." 18 U.S.C. § 2518.

Until recently, the use of wiretap evidence was limited primarily to drug cartel, alien smuggling and organized crime cases. The

Wiretap Act specifically enumerates crimes for which wiretap evidence may be used. 18 U.S.C. § 2516. While the statute enumerates several fraud related crimes under Title 18 (the general crimes Title), it does not include commodities or securities fraud, or insider trading under Title 15. Recent rulings suggest, however, that reliance on wiretap evidence may be allowed in any case in which the wiretap was authorized in the investigation of an enumerated crime, even if that crime is not itself prosecuted. This broader interpretation of the Wiretap Act has changed the face of insider trading cases by permitting the government to obtain stronger evidence. Without the use of wiretap evidence, the government most often relies on circumstantial evidence, usually pointing to telephone calls, emails or meetings that occurred around the time of a significant corporate development and subsequent suspicious trading activity. Circumstantial evidence of this type allows a defendant to create reasonable doubt about the content of the allegedly illegal communications because the actual substance of the communications is rarely available. As the trials

of Rajaratnam and former Galleon Group trader Zvi Goffer demonstrated, real-time recordings of phone calls are irrefutable evidence to juries and are nearly impossible for a defendant to overcome.

The face of financial crimes prosecutions has been dramatically altered by the introduction of wiretap evidence into such cases. In the view of the U.S. Attorney for the Southern District of New York, "Today, tomorrow, next week, the week after, privileged Wall Street insiders who are considering breaking the law will have to ask themselves one important question: Is law enforcement listening?" Individuals in all highly regulated industries should take note. The government has demonstrated its appetite to tape wires for non-conventional crimes, and may well extend the application of the Title III statute even further. In this new environment, it is more important than ever to train employees on rules governing nonpublic information and permissible competition tactics.

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