Client Alert

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Off-Label Marketing Conviction Violates First Amendment

Narrow Construction of Food & Drug Act Undermines FDA Regulation, Class Actions

A divided panel of the Second Circuit Court of Appeals in New York overturned on First Amendment grounds the conviction of a pharmaceutical sales representative for conspiracy to introduce a misbranded drug into interstate commerce, an offense more commonly referred to as off-label marketing.

The decision, *United States v. Caronia,* No. 09-5006-cr (2d Cir. Dec. 2, 2012), likely will touch off a firestorm of controversy over the scope of FDA's authority in regulating drug marketing and promotion, which has been the basis for many class actions and enforcement actions against drug makers.

The drug at issue in the *Caronia* litigation is Xyrem, a powerful central nervous system depressant manufactured by Jazz Pharmaceutical. Its active component, gamma-hydroxybutryate, has been federally classified as the "date rape drug."

Judge Denny Chin, writing for himself and Judge Reena Raggi, avoided deciding whether the misbranding prohibition of the Food, Drug & Cosmetic Act is unconstitutional by construing the Act narrowly. He held the Act should not be regarded as criminalizing the truthful promotion of off-label drug use because this would render the Act unconstitutional. He also held, however, that the conviction itself could not stand because the government had prosecuted Caronia for mere off-label promotion and the jury had been instructed that it could convict on that theory.

Judge Chin grounded his ruling in *Sorrell v. IMS Health Inc.,* 131 S. Ct. 2653 (2011), a decision rendered a year and a half after Alfred Caronia's conviction in November 2009. Hunton & Williams LLP represented IMS Health in that case and persuaded the Supreme Court that a Vermont law violated the First Amendment by prohibiting the use of truthful information about doctors' historical prescribing practices in drug marketing. *Sorrell* inspired immediate predictions that the government no longer would be able to prohibit truthful off-label marketing, *see* Lisa Blatt, Jeffrey Handwerker, John Nassikas, and Kirk Ogrosky, *Does Sorrell v. IMS Health Mark the End of Off-Label Promotion Prosecution?, 9 Pharm. L. & Ind. Rep. (Bloomberg BNA)* Issue No. 28 (July 15, 2011). The Second Circuit's decision is the first confirmation of the prediction.

In *Sorrell* the Supreme Court held the Vermont law had to be subjected to "heightened" judicial scrutiny, but declined to specify the precise level of the scrutiny because the law could not survive even intermediate scrutiny generally applied to commercial speech. Judge Chin similarly held the he need not decide whether strict scrutiny applied because the government's construction of the Act failed intermediate scrutiny.

Under intermediate scrutiny, a law or regulation is invalid if it prohibits non-misleading speech about a lawful activity without directly and materially advancing important government interests or if it is not narrowly tailored to do so. Judge Chin noted that doctors are not prohibited from prescribing off-label uses and scientific journals are not prohibited from promoting off-label use and reasoned that a restriction on sales reps promoting off-label uses could be nothing more than "an indirect and questionably effective means" of deterring harmful off-label drug uses. In the prosecution of Caronia, the government had not claimed the promotion was misleading or that doctors could not prescribe the drug for the promoted uses. It argued only that the law prohibited promoting those uses.

Judge Chin also held the FDA's construction of the law was broader than necessary because the government could deter harmful off-label uses directly by communicating with physicians itself or by requiring manufacturers to make certain disclosures. He rejected the contention that the government's own speech or required disclosures would be ineffective because the government offered no evidence to support the contention.

Judge Debra Ann Livingston, who had voted to uphold the law that was the subject of the *Sorrell* decision when that case went through the Second Circuit, dissented in *Caronia* on the basis of her view that the government had convicted Caronia not because it disagreed with his message, but rather because he had engaged in a conspiracy to misbrand the drug. She reasoned that his promotion of the drug had been merely evidence of the act of misbranding. She interpreted the majority's decision as "call[ing] into question the very foundation of our century-old system of drug regulation."

Indeed it could. While courts lately have struggled with whether off-label promotion can be regarded as the cause of consumer harm, *see In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235 (3d Cir. 2012), claims that it does have driven huge settlements such as Pfizer Inc's $2.3 billion settlement in 2009. The proceeds were divided among the federal government, the states, and civil litigants.

Expect now that the government will ask the Second Circuit to reconsider its *Caronia* decision. If that fails, the government will have no choice other than to seek review by the authors of *Sorrell*. Persuading them that *Sorrell* is distinguishable may be an impossible task. *Sorrell* broadly states a pro-speech, anti-regulation First Amendment philosophy which bodes ill not only for restrictions on the pharmaceutical industry, but in our view many types of regulation on truthful speech. *See* Thomas R. Julin, Jamie Z. Isani & Patricia Acosta, *The Dog that Did Bark: First Amendment Protection of Data Mining,* 36 Vt. L. Rev. 881 (2012).

Contacts

Thomas R. Julin
tjulin@hunton.com

Terence G. Connor
tconnor@hunton.com

Jamie Zysk Isani
jisani@hunton.com

Patricia Acosta
pacosta@hunton.com

Gary C. Messplay
gmessplay@hunton.com

Sheldon T. Bradshaw
sbradshaw@hunton.com