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ALERT

First Amendment Defense Prevails Against FDA Prosecution for Off-Label Marketing

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In an important 2-1 decision overturning the criminal conviction of a pharmaceutical sales representative, a panel of the U.S. Court of Appeals for the Second Circuit in *U.S. v. Caronia*, today reset the legal boundaries between the Food and Drug Administration's (FDA) regulatory authority and pharmaceutical manufacturers' rights to disseminate "off-label" information about approved drug products. This decision, which the dissenting judge argued "calls into question the very foundations of our century-old system of drug regulation," holds that "the government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug." This decision may be the most significant commercial free speech decision in many years and may well ultimately be taken up by the Supreme Court.

The facts, in brief, are that Alfred Caronia, in the course of his work as a sales representative of Orphan Medical, Inc., was tape-recorded in an FDA sting operation promoting certain uses of the company's drug product, Xyrem, that the FDA had not specifically approved. Caronia's (and Orphan Medical's) promotion of such off-label uses, FDA charged, was a criminal violation because such statements caused Xyrem to be "misbranded" in violation of the Federal Food, Drug, and Cosmetic Act (FDCA). Caronia was convicted after trial and sentenced to one year of probation and 100 hours of community service. He then appealed.

The basis of Caronia's appeal was that the misbranding provisions of the FDCA, under which he was convicted based on his off-label promotion of Xyrem, unconstitutionally restrict speech and "that the First Amendment does not permit the government to prohibit and

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criminalize a pharmaceutical manufacturer's truthful and non-misleading promotion of an FDA-approved drug to physicians for off label use where such use is not itself illegal and others are permitted to engage in such speech."

Thus, the key to Caronia's successful appeal was highlighting the uneven playing field that exists under federal law with respect to speech concerning off-label uses of FDA-approved drugs. Physicians, patients, and indeed anyone other than the manufacturer who markets the drug, have always been unfettered in their right to discuss off-label drug uses with whomever they please. In contrast, pharmaceutical companies and their employees have been subject to FDA policies, regulations, and *in terrorem* enforcement actions specifically designed to suppress their ability to discuss off-label uses of their drug products. That the Second Circuit has now rejected FDA's position regarding manufacturer dissemination of off-label information is both dramatic but also consistent with a judicial trend that has been evolving for at least the last 20 years.

In 1994, Wiley Rein brought suit against the FDA on behalf of the Washington Legal Foundation. In that case, the U.S. District Court for the District of Columbia struck down on First Amendment grounds certain FDA policies restricting manufacturer dissemination of off-label information, *see* http://www.wileyrein.com/newsroom.cfm?sp=newsreleases&id=185, but intervening legislative enactments and a last-minute change of position by the FDA resulted in the case being vacated by the Court of Appeals without a final determinative decision on the merits. The Washington Legal Foundation case, however, showed industry a viable pathway for challenging the FDA's increasingly aggressive efforts to regulate pharmaceutical company speech, and several more cases followed.

Indeed the *Caronia* court also relied upon one of the Wiley Rein progeny, the recent Supreme Court decision, *Sorrell v. IMS Health Inc.*, which held that a Vermont law unconstitutionally restricted disfavored speech with a particular content(marketing) when expressed by certain disfavored speakers (pharmaceutical manufacturers). As Wiley Rein advised the Court in *Sorrell* in a brief on behalf of two leading patient advocacy organizations, the First Amendment does not countenance selectively disparate speech restrictions on different classes of speakers about lawful activities. *See* http://www.wileyrein.com/newsroom.cfm?sp=newsreleases&id=627. The Court in *Sorrell*, and now the court in *Caronia*, have further solidified the judicial recognition that when it comes to free speech, uneven playing fields are inherently suspect, if not presumptively invalid.

The full impact of *Caronia* remains to be seen. The FDA is unlikely to accept the split panel decision and will likely seek *en banc* review and, if necessary, Supreme Court review. However, if the Second Circuit's reasoning survives in essentially its current form, the majority decision will be cited with great frequency by a wide range of FDA-regulated companies – in the pharmaceutical, medical device, biotechnology, and food and dietary supplement industries – who engage in marketing and promotion of their FDA-regulated products and are subject to governmental enforcement action.

The FDA, for its part, may be forced to rethink its legal theories for going after off-label promotion or other marketing approaches with which it disagrees. One approach that has always been available and remains available for the FDA even after *Caronia*, is to prosecute off-label cases on the basis that the information at issue is actually false. For a variety of reasons the agency has avoided this approach, but mainly because it

was simply easier to rely on the heavy-handed presumption that information that the FDA has not approved is unlawful for companies to disseminate, even if truthful. The era of that way of thinking may be out the window under the logic of *Caronia*.

Moreover, while this decision addresses commercial speech issues under the doctrine of constitutional avoidance, its analysis of the commercial free speech issue raised by FDA's effort to criminalize off-label promotion that is neither false nor misleading significantly constrains FDA's ability to limit the flow of off-label information in a way that may also call into question the promotion-based False Claims Act campaign the government has waged against the pharmaceutical industry to extract massive legal settlements. Whether this leads to the Department of Justice targeting doctors and medical practice groups for False Claims Act violations involving their otherwise legal off-label prescribing is an interesting question that would have serious ramifications for health care in this country.

Congress too may be induced to weigh in with new regulatory approaches to drug marketing and reimbursement policy. Finally, doctors and consumers can expect to receive much more information about FDA-regulated products which may lead to better informed health care decision making.

Wiley Rein's involvement in First Amendment issues in the health care regulatory space goes back decades, and our Food & Drug, White Collar, Appellate and Health Care practice groups collectively and collaboratively advise clients in matters involving governmental regulation of therapeutic products and the promotional and marketing activities supporting those products.