

In a significant ruling that may have wide implications for the FDA's authority to regulate the marketing of pharmaceutical products, the United States Court of Appeals for the Second Circuit recently vacated the conviction of a pharmaceutical sales representative for promoting the off-label use of a prescription drug on the ground that the sales representative's free speech rights under the First Amendment had been violated.

In *United States v. Caronia*, 2nd U.S. Circuit Court of Appeals, No. 09-cr-5006, Alfred Caronia, a sales representative for Orphan Medical Inc., was convicted in 2008 of conspiracy to introduce a misbranded drug into commerce by promoting the narcolepsy medication Xyrem for unapproved uses. Caronia appealed, arguing that the conviction violated his free speech rights. In vacating the conviction, Judge Denny Chin, writing for the Court, held that “the government cannot prosecute pharmaceutical manufacturers and their representatives under the [U.S. Food, Drug and Cosmetic Act] for speech promoting the lawful, off-label use of an FDA-approved drug.” The Court further held that, “in the fields of medicine and public health, ‘where information can save lives,’ it only furthers the public interest to ensure that decisions about the use of prescription drugs, including off-label usage, are intelligent and well-informed.”

The Court in *Caronia* rejected the government's contentions that those restrictions on off-label promotion were needed to stop the non-approved use of drugs, and preserve the efficacy of the FDA drug approval process. Quoting an earlier Supreme Court opinion, the Court wrote: “The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.” (Judge Chin made clear in a footnote that off-label promotion that is false or misleading does not get First Amendment protection.)

In a vigorous dissent, Judge Debra Ann Livingston wrote: “[T]he majority calls into question the very foundations of our century-old system of drug regulation. I do not believe that the Supreme Court's precedents compel such a result.”

The *Caronia* decision raises serious questions about the scope of the FDA's authority to regulate the marketing of pharmaceutical products, and specifically, the limits imposed on the FDA's authority by the First Amendment. It remains to be seen whether courts in other Circuits adopt the *Caronia* holding and whether the matter is ultimately considered by the United States Supreme Court.