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COURT OVERTURNS CONVICTION FOR SPEECH ON OFF-LABEL DRUG USES

(United States v. Caronia)

The U.S. Court of Appeals for the Second Circuit today overturned the criminal conviction of a business executive alleged to have promoted an FDA-approved pharmaceutical for an off-label use (that is, a use not strictly conforming to the uses specified on the FDA-approved labeling). The decision was a landmark victory for the Washington Legal Foundation (WLF), which handled the briefing and oral argument of all First Amendment issues on the appeal.

The appeals court's 2-1 decision in *United States v. Caronia* agreed with WLF that the First Amendment broadly protects the right of individuals to speak truthfully about off-label uses of FDA-approved products, even in a commercial context. The court noted that the government did not allege that the executive said anything false but was prosecuting him solely because it did not approve of his truthful statements. WLF filed its briefs with the *pro bono* assistance of Michael A. Carvin and Eric E. Murphy, attorneys with the Jones Day law firm. Murphy handled oral arguments on First Amendment issues.

The appeals court threw out charges against an individual convicted of "conspiracy to introduce a misbranded drug into interstate commerce." Judge Livingston dissented, agreeing with the federal government that the case raised no First Amendment issues.

"By prosecuting those engaged in truthful speech about off-label uses of medical products, the federal government has significantly hindering health care delivery in this country," said WLF Chief Counsel Richard Samp following the court's decision. "Off-label use is essential to good medical practice because the medical community's knowledge of the drug effectiveness inevitably outpaces the painstaking FDA approval process for label changes. In many circumstances off-label use is standard-of-care medicine," Samp said.

The now-exonerated defendant is Alfred Caronia, a former salesman for Orphan Medical in the New York area. In 2002, Orphan Medical obtained FDA approval to market the drug Xyrem to treat cataplexy (a sudden loss of muscle tone associated with narcolepsy). Doctors soon discovered, however, that Xyrem was also safe and effective for the treatment of other conditions, and they began prescribing Xyrem for those off-label uses – a practice that is not only legal but also extremely common among health professionals. Caronia was convicted of having (in 2005) encouraged doctors to engage in those off-label uses. The uses in question are now "on-label" because they have all now been approved by FDA, in one instance within a matter of days after Caronia's promotional activities took place. Prosecutors did not contend that anything Caronia said about Xyrem was false, or that any patients were harmed as a result of his actions.

Prosecutors alleged that Xyrem became “misbranded” the moment Caronia started promoting it for off-label uses. A drug is deemed “misbranded” under federal law if its label does not include adequate directions for its intended use, and prosecutors argued that by definition an FDA-approved label will never provide adequate directions for an intended off-label use. Caronia was convicted of violating 21 U.S.C. § 331(k) by conspiring to introduce into interstate commerce a drug, Xyrem, that was misbranded. Caronia then appealed his conviction to the Second Circuit.

The appeals court agreed with WLF that the conviction should be overturned because the defendant’s truthful statements regarding off-label uses of Xyrem were constitutionally protected commercial speech. The court stated that the First Amendment does not permit the government to restrict truthful commercial speech unless it can demonstrate that its restrictions materially advance a substantial government interest and do so in a narrowly tailored manner. The appeals court held that prosecutors met neither standard. In particular, it held that to the extent that the government has legitimate concerns about dissemination of truthful off-label speech, a system of disclaimers (without the need for speech restrictions) would fully address those concerns. For example, the government could require manufacturers to make absolutely clear to the medical professionals to whom they are speaking that the uses being discussed are off-label uses.

The appeals court held that the conviction could not stand, even when judged under the “intermediate” First Amendment scrutiny normally applied in commercial speech cases. But it went much further by holding that Caronia’s prosecution should be subject to “heightened” scrutiny because it imposes content-based and speaker-based restrictions on truthful speech. The court concluded that “heightened scrutiny” (a standard that virtually always results in invalidation of speech restrictions) is required by *Sorrell v. IMS Health*, a 2011 Supreme Court decision that struck down Vermont restrictions on truthful speech about health care delivery.

WLF is a public interest law and policy center with supporters in all 50 States. It devotes a significant portion of its resources to advocating for improvements in health care. In a 1999 decision, WLF won invalidation of certain FDA restrictions on manufacturer dissemination of truthful speech about off-label uses of FDA-approved products. A permanent injunction against FDA interference with such speech remains in place.

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For further information, contact WLF Chief Counsel Richard Samp, (202) 588-0302. A copy of WLF’s brief is posted on its web site, www.wlf.org.