



January 28, 2013

U.S. ABANDONS APPEAL FROM DECISION AFFIRMING OFF-LABEL SPEECH RIGHTS

(United States v. Caronia)

The federal government announced this week that it would not pursue an appeal from a landmark appeals court decision that affirmed commercial speech rights and 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 to abandon an appeal marked another victory for the Washington Legal Foundation (WLF), which played a lead role in overturning the conviction.

The December 2012 decision by the U.S. Court of Appeals for the Second Circuit 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. Prosecutors initially sought and obtained an extension of time within which to seek a rehearing in the appeals court. However, they later allowed the January 16, 2013 deadline to pass without filing a rehearing petition. Moreover, according to several press reports, FDA announced this week that it has also decided that it will not seek review in the U.S. Supreme Court. The deadline for seeking Supreme Court review is March 4, 2013.

Under the appeals court decision, the federal government has the option of seeking a new criminal trial for Alfred Caronia, a former salesman for Orphan Medical in New York. FDA's announcement this week did not rule out the possibility of a re-trial. Given the appeals court's strong affirmation of Caronia's First Amendment rights, however, the likelihood that prosecutors could obtain another criminal conviction is slim. Caronia had been convicted of "conspiracy to introduce a misbranded drug into interstate commerce."

Caronia was represented on appeal by his court-appointed lawyer, Jennifer McCann of the Long Island, New York-based law firm Thomas F. Liotti, LLC. The Washington Legal Foundation, however, handled briefing and oral argument on all First Amendment issues. 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 presented WLF's oral arguments on First Amendment issues.

In explaining the federal government's decision to drop its appeal, FDA is reported to have said, "FDA does not believe that the Caronia decision will significantly

affect the agency's enforcement of the drug misbranding provisions" of federal drug law.

WLF attorneys said in response that FDA is greatly underestimating the importance of the *Caronia* decision. In that case and other criminal prosecutions, the federal government took the position that *any* time someone affiliated with a drug company engages in speech regarding off-label uses of one of the company's drugs, he is *automatically* deemed to have engaged in an illegal misbranding of the drug, regardless whether the speech is false or misleading. "The *Caronia* decision decisively rejected FDA's 'automatic misbranding' theory, finding that it violated the First Amendment," said WLF Chief Counsel Richard Samp in response to FDA's statement. "The *Caronia* decision, when combined with the permanent injunction entered against FDA in *WLF v. Friedman* that prohibits the agency from violating First Amendment rights, will prevent the agency from conducting business as usual," Samp said.

Samp said that in the future, FDA is unlikely to succeed in off-label speech prosecutions without proving that the challenged speech was false or misleading. Furthermore, Samp said, courts are unlikely to accept FDA assertions (of the sort it has repeatedly made in the past) that speech is by definition "false or misleading" simply because it makes claims that are more-likely-than-not true but that have not been fully substantiated by lengthy, double-blind clinical trials.

Moreover, although the possibility of future off-label prosecutions of drug companies and their top executives for false speech is not foreclosed by *Caronia*, it appears exceedingly unlikely that a "misbranding" prosecution could succeed against an individual salesperson or a doctor who has received payments from the company, none of whom actually sell drugs – all drugs are sold by pharmacies pursuant to prescriptions. Such prosecutions have been based on the theory that one person's statements can cause an entire product line to be "misbranded"; the *Caronia* decision calls that theory into question.

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 v. Friedman*, 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 principal brief in the *Caronia* case is posted on its web site, www.wlf.org.