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**COURT URGED TO OVERTURN CONVICTION  
FOR SPEECH ON OFF-LABEL DRUG USES  
(United States v. Caputo)**

The Washington Legal Foundation (WLF) yesterday urged the U.S. Court of Appeals for the Seventh Circuit to overturn the criminal convictions of business executives alleged to have promoted an FDA-approved medical device for an off-label use (that is, a use not strictly conforming to the uses specified on the FDA-approved labeling).

In a brief filed in *United States v. Caputo*, WLF argued 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. WLF noted that the government also alleged that some statements made by the defendants were false. But WLF argued that because the jury returned a general verdict against the defendants and thus might have convicted on the basis of their constitutionally protected statements, the conviction could not be allowed to stand. WLF filed its brief with the *pro bono* assistance of James M. Beck, Arnon D. Siegal, Sean P. Wajert, and Michael E. Planell, attorneys with the law firm of Dechert LLP.

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

The case involves Ross A. Caputo and Robert M. Riley, two executives with AbTox, Inc., a medical device manufacturer located in Illinois. AbTox obtained FDA approval to market the Plazlyte hospital sterilizer, a medical device used for sterilizing surgical and other medical instruments. Federal prosecutors alleged that the Plazlyte sterilizer actually sold by AbTox was not approved by FDA because it had been modified without FDA approval -- an issue not addressed by WLF in its brief. Prosecutors also alleged that the defendants conspired to sell the sterilizer for off-label uses by informing hospital officials about medical studies that described ways of using the sterilizer that had not been approved by FDA. Prosecutors have never alleged that those studies -- which were shown only to trained medical professionals -- were in any way false or misleading.

The district court denied the defendants' motion to dismiss the indictment on First Amendment grounds. Although the judge conceded that the defendants' statements regarding off-label uses were not misleading, he held that prosecuting them for making those statements was constitutionally permissible because it directly advanced the government's interest in encouraging manufacturers to seek FDA-approval for known off-label uses. Following their convictions for conspiracy to defraud the U.S. government (by promoting off-label sales of the Plazlyte sterilizer), Caputo and Riley appealed.

In its brief to the Seventh Circuit in support of Riley's appeal, WLF argued that the convictions should be overturned because the defendants' truthful statements regarding off-label uses of their medical device were constitutionally protected commercial speech. WLF 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. WLF argued that the government's policy on off-label promotion is shot so full of contradictions and exceptions that it cannot be said to materially advance any government interest. WLF also argued 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.

WLF noted that the defendants were convicted on evidence that did not distinguish between allegedly false/misleading speech, speech concerning unapproved devices, and truthful speech about off-label uses of an FDA-approved device. WLF argued that under those circumstances, the convictions could not stand because the defendants may well have been convicted, in whole or in part, for engaging in constitutionally protected commercial speech.

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 landmark federal lawsuit, WLF successfully challenged 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](http://www.wlf.org).