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COURT UPHOLDS CONVICTION IN CASE RAISING FIRST AMENDMENT ISSUES

(United States v. Caputo)

The U.S. Court of Appeals for the Seventh Circuit this week upheld the criminal convictions of business executives alleged to have marketed an unapproved medical device. The decision was a partial setback for the Washington Legal Foundation (WLF), which had filed a brief expressing concern that the convictions could be viewed as upholding restrictions on the right of manufacturers to speak truthfully regarding off-label uses for their FDA-approved product (that is, a use of the product not strictly conforming to the uses specified on the FDA-approved labeling).

WLF was gratified that although the appeals court upheld the conviction, it went out of its way to make clear that it was not condoning government efforts to suppress truthful off-label speech. Rather, the court held, it did not need to reach the First Amendment issue because the trial court had made clear to the jury that it could not convict the defendants unless the jury found both that the defendants had lied to the FDA and that their medical device had never been approved by FDA.

WLF's brief in *United States v. Caputo* 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 argued that if there was any chance at all that the jury might have convicted the defendants based solely on their having made constitutionally protected statements, the First Amendment required that the convictions be overturned. 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 reviewing the Court's decision. “We are not convinced that the appeals court correctly interpreted the jury charge regarding the circumstances under which the jury was permitted to return a jury verdict, but at least the appeals court decision does not create any sort of precedent in favor of government suppression of truthful speech about off-label drug use. 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 involved Ross Caputo and Robert 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. 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 false or misleading.

The district court denied the defendants' pre-trial 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 and/or unapproved sales of the Plazlyte sterilizer), Caputo and Riley appealed.

In its brief in support of Riley's appeal, WLF argued that his conviction should be overturned because his truthful statements regarding off-label uses of the medical device were constitutionally protected commercial speech. WLF argued 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, Riley's conviction could not stand because he 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 improved health care. In a landmark federal lawsuit, WLF successfully challenged FDA restrictions on manufacturer dissemination of truthful speech about off-label uses of FDA-approved products.

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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.