



FOR IMMEDIATE RELEASE

January 3, 2017

Media Contact: Derek Dye | ddye@wlf.org | 202-588-0302

WLF Urges FDA to Abide by First Amendment, Lift Restrictions on Off-Label Communications

(In re: Communications Regarding Off-Label Uses of Approved Medical Products)

“For two decades, federal courts have repeatedly reminded FDA that the First Amendment constrains its power to censor truthful speech by drug and device manufacturers. FDA is to be applauded for agreeing to re-examine its draconian restrictions on manufacturer speech. But public health will continue to suffer unless FDA begins to respect those First Amendment constraints.”

—Richard Samp, WLF Chief Counsel

WASHINGTON, DC—Washington Legal Foundation late Friday urged the Food and Drug Administration (FDA) to ease its restrictions on manufacturer dissemination of truthful information about “off-label” uses of FDA-approved medical products—that is, uses not included on the FDA-approved product labeling. In comments filed in response to FDA’s September 1, 2016 formal request for input, WLF argued that current restrictions prevent doctors from learning of the latest medical advances and violate First Amendment constraints on the government’s power to suppress truthful commercial speech. These comments augment testimony presented by WLF at a public meeting called by the agency in early November.

The medical community’s knowledge regarding the safety and efficacy of FDA-approved drugs and medical devices inevitably outpaces FDA-approved labeling. In fields like oncology, the great majority of medically-accepted treatments involve off-label uses of FDA-approved drugs and devices. FDA recognizes the importance of off-label uses and does not regulate physician use of FDA-approved products for unapproved uses. Yet the agency seeks to prevent product manufacturers (and only manufacturers) from speaking truthfully about such uses.

WLF’s comments argue that doctors and other medical professionals appreciate the difference between FDA-approved uses (which must be validated by medical research whose costs often exceed one billion dollars) and off-label uses, and thus are unlikely to be misled by information that truthfully reports the results of clinical studies regarding the safety and effectiveness of off-label uses. Because of the unlikelihood that professionals could be misled, WLF argues, the First Amendment does not permit FDA to prohibit manufacturers from disseminating truthful off-label information to medical professionals—provided that they provide adequate disclaimers.

After submitting its comments, WLF issued the following statement by Chief Counsel Richard Samp: “For two decades, federal courts have reminded FDA that the First Amendment constrains its power to censor truthful speech by drug and device manufacturers. FDA is to be applauded for agreeing to re-examine its draconian restrictions on manufacturer speech. But public health will continue to suffer unless FDA begins to respect those First Amendment constraints. FDA ought to focus on restricting false or misleading speech, and scientific information can’t be deemed ‘false’ simply because FDA has not yet verified its accuracy.”

WLF is a public interest law firm and policy center that regularly litigates in defense of commercial free speech.

###