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WLF Encourages New FDA “Payor Communications” Guidance to Come into Compliance with Federal Law

(In re: FDA Payor Communications Guidance)

“FDA needs to revise this guidance to bring it into full compliance with both the First Amendment and the statutory ‘safe harbor’ that Congress created for such communications.”

—Richard Samp, WLF Chief Counsel

WASHINGTON, DC—Washington Legal Foundation filed formal comments with the Food and Drug Administration today in response to the agency’s request for input on its January 2017 draft Payor Communications Guidance. WLF’s comments encourage FDA to revise that guidance, which purports to govern the sorts of health care economic information (HCEI) that drug and medical device manufacturers may share with payors, formulary committees, and similar entities.

WLF argues in its comments that permitting manufacturers to disseminate truthful HCEI is critical to delivery of health care in this country. Without this information, healthcare providers and payors cannot make economically rational decisions regarding which medical products to include in their formularies.

Congress adopted a statute in 1997 that provides a “safe harbor” for manufacturers. Those that disseminate HCEI in compliance with the statute are not subject to FDA sanctions. But for nearly 20 years, FDA issued no rules governing how it would implement the safe harbor. As WLF points out, this failure chilled truthful speech because manufacturers proved reluctant to disseminate HCEI without FDA assurances that their actions would not subject them to sanctions. WLF’s comments applaud FDA for providing long-overdue guidance to manufacturers in January. But WLF also argues that the document restricts speech more severely than is permitted under either the First Amendment or the statutory “safe harbor.”

In particular, WLF notes that Congress barred FDA restrictions on disseminating truthful HCEI that in any way “relates to” an FDA-approved indication for a drug, even if the HCEI includes information about an off-label use of the drug. WLF argues that FDA’s interpretation of the “relates to” clause is far too restrictive.

Celebrating its 40th year, WLF is America’s premier public-interest law firm and policy center advocating for free-market principles, limited government, individual liberty, and the rule of law.

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