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DOJ URGED TO REMOVE FDCA OVERSIGHT FROM OFFICE OF CONSUMER LITIGATION

The Washington Legal Foundation (WLF) today urged the U.S. Department of Justice to remove the Office of Consumer Litigation ("OCL," a branch of DOJ located within the Civil Division) from its oversight and supervisory role in criminal cases arising under the Food, Drug, and Cosmetics Act (FDCA) involving alleged improper promotion of pharmaceuticals and medical devices.

WLF charged that OCL has failed in that role and has done little to develop a coherent federal government policy regarding when such criminal investigations are warranted. WLF said that OCL has simply rubber-stamped whatever criminal investigation local U.S. Attorney Offices have sought to initiate. WLF asked that the coordination role be reassigned to an office within DOJ's Criminal Division, which has far more expertise and experience in addressing the issues inherent in any criminal investigation.

WLF said that it is particularly concerned about the need for effective DOJ coordination in this area because criminal investigations of promotional activities have the potential to adversely affect the nation's health care delivery system. Free flow of truthful information about FDA-approved medical products is essential if consumers are to have the means to make intelligent decisions about the health care needs, WLF said.

While conceding that the health care industry needs to conform its promotional activities to the requirements of federal law, WLF charged that there has been considerable confusion in recent years over precisely what those requirements are -- with the result that medical product manufacturers have been reluctant to provide consumers with a full range of truthful information about their products. For that reason, WLF said, it is absolutely crucial that federal prosecutors speak with one voice and articulate clear standards regarding what sorts of promotional activities merit criminal prosecution. WLF added that some of the more expansive theories of local prosecutors undertaking criminal investigations of pharmaceutical industry promotional practices appear to violate First Amendment norms.

WLF said that to date, OCL has failed to provide clear guidance and coordination. Indeed, WLF's letter said, OCL has left senior FDA officials largely in the dark regarding criminal investigations that it has approved. Health-care consumers will benefit greatly if the guidance and coordination function is shifted to the Criminal Division, WLF said.

WLF is a public interest law and policy center with supporters in all 50 states. It devotes a substantial portion of its resources to defending the rights of individuals and businesses to go about their affairs without undue interference from government regulators. WLF has for many years been actively involved in efforts to decrease federal government restrictions on the flow of truthful information about such off-label uses. For example, WLF filed suit against FDA in 1994 in U.S. District Court for the District of Columbia; the suit sought a determination that FDA's policies regarding manufacturer dissemination of enduring material containing off-label information, and regarding manufacturer support of CME, violated the First Amendment. The district court ruled in WLF's favor on those issues in 1998 and 1999 and granted a permanent injunction against FDA violation of First Amendment rights.

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For further information, contact WLF Chief Counsel Richard Samp, 202-588-0302. A copy of WLF's letter to FDA is posted on its web site.