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WLF OPPOSES INCREASED CRIMINAL PROSECUTION OF CORPORATE OFFICERS

The Washington Legal Foundation (WLF) this week called on the Food and Drug Administration to abandon its announced plans to seek increased criminal prosecution of company executives for promotional activities in instances where the executives never participated in, encouraged, or had knowledge of the alleged violations. WLF expressed its concerns in a letter to Eric Blumberg, Deputy Chief for Litigation in the FDA's Office of Chief Counsel, in response to recent comments Blumberg made calling for increased criminal prosecution of executive officers in pharmaceutical companies.

According to multiple press accounts, Blumberg spoke at the Food and Drug Law Institute (FDLI) Enforcement Conference in Washington, D.C. on October 13, 2010, where he announced the view that large, monetary settlements (such as FDA's recent record-breaking \$2.3 billion settlement with Pfizer) were "not getting the job done" to adequately deter off-label promotion, and that he urged federal prosecutors "to criminally charge individuals at all levels in the company."

Blumberg's remarks follow the recent guidance released by the Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS), which expands the basis for excluding individuals, including pharmaceutical executives, from participating in federal health care programs. When an individual is excluded, federal health care programs like Medicare and Medicaid will not pay for any item or service furnished, ordered, or prescribed by that individual. Because entities that employ an excluded individual for providing items or services to federal program beneficiaries are subject to monetary penalties, such exclusion operates as a *de facto* ban on working in the health care industry.

"Subjecting every manager and executive in the industry to potential criminal liability every time an off-label promotion occurs is extremely shortsighted," WLF Senior Litigation Counsel Cory Andrews wrote in a letter to Blumberg. "In the wake of such an aggressive use of the FDCA misdemeanor, industry executives will have little incentive to continue working in the pharmaceutical sector."

WLF's letter emphasized that the free flow of truthful information about FDA-

approved drugs and medical products is essential if consumers are to have the means to make intelligent decisions about their health care needs. WLF cautioned that increased criminal prosecution of company executives for promotional activities has the potential to adversely affect the nation's healthcare delivery system by labeling responsible corporate officials as criminals—even if they never participated in, encouraged, or had knowledge of the alleged violations.

WLF's letter also took issue with recent efforts by HHS to exclude corporate officials from participation in federal health care programs for strict liability convictions under the responsible corporate officer doctrine. Courts have long recognized the serious harm of denying individuals the right to employment. WLF noted that lengthy exclusion will effectively end an executive's career and ruin his or her reputation. WLF stated that if strict liability convictions of executives under the responsible corporate officer doctrine can trigger lengthy exclusions, the penalties available will undermine the due process rights of corporate officials to receive minimal notice of criminal culpability.

WLF is a public interest law and policy center with supporters in all 50 States. WLF devotes a substantial portion of its resources to defending free enterprise, individual rights, and a limited and accountable government. Among other things, WLF works to ensure that the federal government respects individual rights by not imposing restrictions on individual and economic activity in the absence of evidence of individual blameworthiness, or in any manner not authorized by law.

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For further information, contact WLF Senior Litigation Counsel Cory Andrews, (202) 588-0302. A copy of WLF's brief is posted on its web site, www.wlf.org.