**Washington Legal Foundation**
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March 24, 2005

James B. Comey
Deputy Attorney General
U.S. Department of Justice
10th & Constitution Ave., NW
Washington, DC 20530

**Re: Office of Consumer Litigation Oversight of Criminal Investigations Into Allegedly Improper Promotion of FDA-Approved Medical Products**

Dear Mr. Comey:

The Washington Legal Foundation (WLF) has become increasingly concerned by what it views as a lack of centralized Department of Justice coordination and supervision of criminal investigations being conducted by various United States Attorneys' offices into allegedly improper promotion of FDA-approved medical products. The Office of Consumer Litigation (OCL) within the Civil Division ostensibly is undertaking that coordination role. However, WLF has received information from multiple sources indicating that OCL is not up to the task and has done little to develop a coherent federal government policy regarding when such criminal investigations are warranted. WLF respectfully suggests that the coordination role be re-assigned to an office within the Criminal Division, which has far more experience and expertise in addressing the sensitive issues inherent in any criminal investigation.

WLF 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 their health care needs. While the health care industry obviously needs to conform its promotional activities to the requirements of federal law, 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, it is absolutely crucial that federal prosecutors speak with one voice and articulate clear standards regarding what sorts of promotional activities merit criminal prosecution. To date, OCL has failed to provide clear guidance and coordination; indeed, 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.

## I. Interests of WLF

WLF is a public interest law and policy center with members and 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. Among WLF's members are doctors and medical patients who wish to receive information about off-label uses of FDA-approved drugs and medical devices, as well as medical patients who wish their doctors to receive such information.

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. *Washington Legal Found. v. Friedman,* 13 F. Supp. 2d 51 (D.D.C. 1998); *Washington Legal Found. v. Henney*, 56 F. Supp. 2d 81 (D.D.C. 1999), *appeal dism'd,* 202 F.3d 331 (D.C. Cir. 2000).

## II. OCL's Coordination Role

DOJ regulations assign to the Civil Division "all civil and criminal litigation and grand jury proceedings" arising under numerous consumer-oriented statutes, including the Federal Food, Drug, and Cosmetics Act (FDCA), 21 U.S.C. § 301 *et seq.* *See* 28 C.F.R. § 0.45(j). The Civil Division has assigned its FDCA responsibilities to OCL, which was formed in 1971 for the purpose of centralizing in a single office the DOJ role in consumer-related issues.

OCL has recognized that because most pharmaceutical products are marketed nationwide, issues arising under the FDCA tend to be national in scope -- and therefore should be addressed by a single entity applying uniform standards:

> The complex nature of these statutes [including the FDCA], along with a variety of other factors, have led OCL to remain a central repository of technical expertise. The issues that arise under these statutes are commonplace nationally, but arise only infrequently in any single jurisdiction. Moreover, the violations usually have regional or national, rather than local, impact.

*See* Office of Consumer Litigation, "Role of Office of Consumer Litigation" (available online

at http://www.usdoj.gov/civil/ocl/home.cont.htm).

OCL's view of its role in coordinating FDCA enforcement is set out most comprehensively in a monograph posted on the DOJ web site. *See* Office of Consumer Litigation, "Monograph" (available at http://www.usdoj.gov/civil/ocl/monograph.htm). Section II of the Monograph addresses the FDCA at length; it makes clear that OCL views referrals from FDA as the principal means by which FDCA matters will come to its attention.[1] In other words, DOJ has traditionally viewed OCL's FDCA-enforcement role as one of serving the needs of its "client," the FDA.

Section II(B) of the Monograph catalogues a laundry list of acts potentially subject to criminal prosecution under the FDCA, and outlines prosecutions OCL has initiated to punish entities that have engaged in such activities. Notably absent from the list are FDCA prosecutions based on improper promotion of FDA-approved products. To the extent that the Monograph mentions promotional practices at all, it focuses on fraudulent sales pitches designed to deceive consumers:

> **Felony Behavior: Fraud on Consumers.** The most obvious application of the felony provision of the FDCA is to situations in which a supplier does not provide customers or consumers the product purportedly sold. Such activity constitutes monetary fraud under any definition and has traditionally satisfied the "intent to defraud" requirement for felony behavior. *See, e.g.,* the cases

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[1] Section I of the Monograph, entitled "Case Referrals Generally," recognizes that sometimes a United States Attorney's Office (USAO) will receive a matter directly from FDA or other "client agency" without OCL's involvement. OCL cautions, "USAOs that receive cases directly under any of the statutes discussed in this Monograph should contact OCL when the case is received to obtain advice and assistance, and *to procure authorization to file the case.*" Monograph § I (emphasis added). In other words, the Monograph contemplates that in those instances when a USAO becomes involved in an FDCA enforcement matter without having been solicited by OCL, it generally will be because it has been contacted directly by FDA. The Monograph does not appear to contemplate criminal investigations into alleged FDCA violations arising on a USAO's own initiative. Section I underscores the importance of OCL's coordination role in FDCA cases in particular, noting the need for close coordination because FDCA litigation has "important public health implications," is often "of significant interest to the media, Congress, or both," and "can create disagreement among concerned parties" because "these cases involve a mix of scientific, medical, and public health issues not present in most fraud cases." *Id.*

involving the substitution of cheap undeclared ingredients in food.

Monograph, § II(B)(1). The Monograph does not appear to contemplate FDCA criminal investigations of the type that USAOs are initiating with increasing frequency: investigations of manufacturers of FDA-approved products who provide truthful product information to doctors and consumers.

## II. Effective Health Care Delivery Requires the Free Flow of Truthful Information About FDA-Approved Medical Products

WLF applauds DOJ's determination to protect consumers by prosecuting those responsible for making fraudulent claims about their products for the purpose of promoting sales. It is important that the stream of commercial speech flow cleanly as well as freely. But unless government officials have reason to challenge the truthfulness of manufacturer speech, any effort to regulate such speech raises significant First Amendment concerns. More importantly, any effort to regulate such speech threatens to undermine effective health care delivery by denying consumers potentially life-saving information. It is for this reason that coordination of FDCA enforcement efforts is so critical; in the absence of such coordination there is a serious danger that FDCA investigations of promotional practices, mounted by individual U.S. Attorney Offices, will interrupt the free flow of truthful information about FDA-approved products.

The advantages of such information flow are so well known and universally supported by the medical community, that WLF will not dwell on them here at length. Those advantages apply regardless whether the truthful information relates to one of the labeled uses of an FDA-approved product. Physicians who regularly work with FDA-approved drugs and devices, and researchers who study their utility in treating diseases or patient populations that are not included in the existing labeling, often learn that the products can be used safely and effectively for purposes outside the labeling. Given the widespread acceptance within the medical community of such "off-label" uses, patients in many cases would receive sub-optimal care were their doctors limited to using FDA-approved products only as labeled -- or deprived of information on scientific and medical developments regarding new treatment alternatives. Indeed, as the U.S. Supreme Court recently noted, FDA itself fully recognizes the crucial role of truthful off-label information in effective health care delivery. *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 351 n.5 (2001).

Dissemination of this information takes both effort and resources. Manufacturers -- who have both the necessary resources and the incentive to exert the necessary effort -- have traditionally played a large and beneficial role in supporting the dissemination of information

about new uses of marketed products. For example, they have arranged for the distribution of textbooks and reprints from medical journals. They have helped support continuing medical education (CME) programs. They have helped sponsor scientific seminars and symposia at which peers discuss their cutting-edge research. Following WLF's 1999 victory over FDA in *Washington Legal Found. v. Friedman*, which established manufacturers' First Amendment rights to engage in such activities, manufacturers became increasingly willing to exercise those rights, and consumers greatly benefited.

That willingness has been tempered in the last several years, however, by a spate of high-profile investigations by several USAOs into product promotion practices within the pharmaceutical industry. Perhaps the best well-known of these investigations is the one that resulted in the criminal conviction of Warner Lambert for promotional activities undertaken with respect to the drug Neurontin. WLF does not mean to suggest that the First Amendment excuses manufacturers from complying with any and all federal laws governing drug promotion. Clearly, for example, bribing doctors to prescribe a drug to a Medicaid recipient can and should be prosecuted under the anti-kickback statute. But some federal prosecutors have been taking the position that any and all manufacturer speech about off-label uses of an FDA-approved product: (1) transforms all distribution of that drug into the distribution of an unapproved new drug, in violation of § 505(a) of the FDCA, 21 U.S.C. § 355(a); (2) constitutes a new intended use for the product, and thereby violates § 502(f) of the FDCA, 21 U.S.C. § 352(f), which requires a drug or device to be adequately labeled for its intended use; and (3) violates the False Claims Act, 31 U.S.C. § 3729(a), because it causes others to present false claims for payment to the federal government (based on the theory that at least some small portion of off-label uses of an FDA-approved product are not reimbursable under Medicaid). Such claims are fraught with First Amendment difficulties and, at least in some instances, may violate the terms of the injunction entered against the federal government in *Washington Legal Found. v. Friedman.* If the federal government intends to pursue such novel interpretations of the FDCA and the False Claims Act, it is very critical that it do so on a uniform basis -- so that manufacturers can know precisely what is expected of them and so First Amendment advocates such as the Washington Legal Foundation can determine whether federal policy is adhering to constitutional norms. In the absence of a uniform national policy, constitutionally protected speech will be chilled as manufacturers err on the side of caution, and health care delivery will suffer.

## III. OCL Has Not Been Up to the Task of Coordinating Federal Regulation of Promotional Activities, and Its Responsibilities Should Be Transferred to the Criminal Division

Unfortunately, OCL has failed to adequately perform its coordination function. In

particular, despite the large number of on-going USAO investigations into pharmaceutical marketing practices, OCL has failed to bring together relevant federal officials to hammer out a uniform interpretation of the FDCA and False Claims Act provisions cited above. The broad interpretations of those statutes being pushed by some USAOs appear to be inconsistent both with congressional intent and with First Amendment contours as outlined by the federal courts in *Washington Legal Found. v. Friedman*. But however that issue is finally resolved, continued effective delivery of health care requires that *some* uniform interpretation be announced.

OCL's performance in this area differs markedly from DOJ's oversight of health care fraud. In April 1997, DOJ issued comprehensive guidelines designed to ensure coordination among HHS, the Civil Division, the Criminal Division, and USAOs in health care fraud investigations. Part 9-44.000 of the *United States Attorneys' Manual*, entitled "Health Care Fraud," sets out numerous prosecutorial policies to guide prosecutors and to inform the public. The absence of similar guidance from OCL regarding truthful promotional activities is particularly disheartening.

WLF respectfully suggests that OCL's inability to function effectively in its coordination role derives from its orientation as a group designed to serve various federal "clients." The Monograph and other OCL documents cited above suggest that OCL views itself as the representative of the federal agencies charged with enforcement of federal consumer protection laws -- in the case of the FDCA, that agency is FDA. OCL traditionally has taken actions to enforce the FDCA only in response to FDA requests. And enforcement actions against manufacturers of FDA-approved products based on their promotional activities has not been among the actions it traditionally has been asked to undertake by FDA.

The result has been that when USAOs have informed OCL of their planned investigations of manufacturer promotional activities, OCL routinely has granted its approval -- apparently without detailed consideration of First Amendment and statutory construction issues. Most disturbingly, our information indicates that this approval is being granted *without any input from FDA*. This failure to provide a meaningful role to FDA cannot be squared with DOJ's January 20, 2003 *Principles of Federal Prosecution of Business Organizations*, which provides that the most important consideration in deciding whether to bring criminal charges against a corporation is "the nature and seriousness of the offense, including the risk of harm to the public." With its expertise in health care issues, FDA is in a far better position than are federal prosecutors to evaluate the ramifications of undertaking a criminal investigation of a company's promotional activities. FDA broadly supports widespread dissemination of truthful information about off-label uses of FDA-approved products (including, in some instances, manufacturer dissemination); given the chilling effect that criminal investigations are having

on manufacturer support of such dissemination, OCL has been derelict in its duty in failing to seek detailed guidance from FDA before approving investigations in this area. As § 4-8.200 of the *United States Attorneys' Manual* emphasizes, it is especially important for the federal government to "Maintain critical consistency in enforcement decisions" in FDCA litigation. Such "critical consistency" has not been possible to date in light of OCL's failure to seek guidance from FDA in promotional activity cases, or to ensure uniform interpretation of the relevant statutes.

## IV. Conclusion

WLF respectfully requests that DOJ eliminate OCL's oversight function in FDCA criminal enforcement actions. That function should be given to some group within the Criminal Division, which is likely to have considerably more expertise in addressing relevant criminal law issues. WLF recommends that, if necessary to effectuate this transfer, DOJ amend 21 C.F.R. § 0.45(j).

Sincerely,

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Daniel J. Popeo
General Counsel

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Richard A. Samp
Chief Counsel

cc: Peter D. Keisler, Ass't Atty Gen'l, Civil Division
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