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Via First Class U.S. Mail
Eric M. Blumberg
Deputy Chief for Litigation
Office of the Chief Counsel
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852

RE: Public remarks made about FDA's future criminal prosecution of corporate officers for off-label promotion

Dear Mr. Blumberg,

On behalf of the Washington Legal Foundation (WLF), I am writing to express deep concern about recent remarks you made at the Food and Drug Law Institute (FDLI) Enforcement Conference in Washington, D.C. on October 13, 2010. According to multiple press accounts, you announced your 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 you urge federal prosecutors "to criminally charge individuals at all levels in the company."

These comments are irresponsible. Among other things, they ignore the fact 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. But WLF is especially concerned 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. This is especially true with respect to recent efforts to exclude corporate officials from participation in federal health care programs for strict liability convictions under the responsible corporate officer doctrine. Such strict vicarious liability also undermines the due process rights of corporate officials to have minimal notice of criminal culpability.

Interests of WLF

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's members and supporters include corporate executives who are directly threatened by the government's use of the responsible corporate officer doctrine to impose strict criminal liability, which can result in lengthy exclusion from participation in essential government programs.

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 to seek a determination that FDA's policies covering manufacturer dissemination of enduring material containing off-label information violated the First Amendment. In 1998 and 1999, the U.S. District Court for the District of Columbia ruled in WLF's favor on those issues and granted a permanent injunction against FDA's future violation of First Amendment rights. *See Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998); *Wash. Legal Found. v. Henney*, 56 F. Supp. 2d 81 (D.D.C. 1999), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 2000).

WLF does not condone the dissemination of false or misleading information about FDA-approved medications, and it applauds FDA efforts to prevent such dissemination. But WLF also seeks 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. Accordingly,

WLF opposes the use of criminal laws to punish corporate executives for misconduct that they neither condoned nor were even aware of.

The Responsible Corporate Officer Doctrine and the FDCA

Our legal system rarely permits the imputation of liability from one individual to another—even in civil cases. The responsible corporate officer doctrine, first announced by the Supreme Court nearly 70 years ago, is a rare exception. And Section 333(a)(1) of the FDCA creates one of the few "strict liability" crimes in federal criminal law. Under this misdemeanor provision, the executives and managers of companies that make, distribute, and sell pharmaceuticals can be convicted for violating the FDCA without having personally participated in the misconduct or having knowledge of it. Further, the statute does not require the corporate officer to actually exercise any authority over the wrongdoing. Rather, it is sufficient that the defendant was somewhere within the corporate chain of command with "authority and responsibility" for the area in which the violation occurred.

It is unlikely that any pharmaceutical CEO or COO exists who cannot be convicted under the responsible corporate officer doctrine, since there is little if anything within the company's operation that is not, at least on paper, within their authority and responsibility. As one federal court has commented, "The line . . . between a conviction based on corporate position alone and one based on a 'responsible relationship' to the violation is a fine one, and arguably no wider than a corporate bylaw." *United States v. New Eng. Grocers Supply Co.*, 488 F. Supp. 230, 234 (D. Mass. 1980). Because it is such a blunt instrument, the responsible corporate officer doctrine has been used sparingly, especially against legitimate pharmaceutical companies.

In the past fifty years, there have been only a handful of reported decisions in which the government charged a corporate executive with a misdemeanor FDCA violation based merely on the officer's status. Rather, the overwhelming majority of the cases brought against executives under the FDCA provision are based on the executive's own personal wrongdoing or at least actual knowledge of wrongdoing, not the executive's mere position or title in the company. *See, e.g., United States v. Park*, 421 U.S. 658, 662-64 (1975) (affirming conviction of company president where company had

been notified repeatedly by FDA of infestation problems, and the president had personally received notice of at least one failed inspection).

This restrained approach under the FDCA is consistent with longstanding FDA enforcement policy. FDA's *Regulatory Procedures Manual* states that any FDA recommendation for criminal prosecution "should ordinarily contain proposed criminal charges that show a continuous or repeated course of violative conduct." FDA, REGULATORY PROCEDURES MANUAL, § 6-5-1 (Mar. 2007). This is because "the agency ordinarily exercises its prosecutorial discretion to seek criminal sanctions against a person only when a prior warning or other type of notice can be shown." *Id.*

Exclusion from Participation by HHS

Exclusion is the process by which the Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) prohibits individuals 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. Entities that employ an excluded individual for providing items or services to federal program beneficiaries are subject to monetary penalties, making exclusion a *de facto* ban on working in the health care industry.

OIG has recently released a guidance document that indicates a desire to exclude even more individuals from participation in federal health care programs under 42 U.S.C. § 1320a-7(b)(15). The new guidance creates a presumption in favor of exclusion and even endorses a new strict liability exclusion standard in many cases. OIG's proposed bootstrapping of a strict liability misdemeanor offense in order to exclude program participation imposes draconian consequences on corporate executives by effectively depriving them of their livelihoods for more than a decade.

Coupled with your recent public statements, the OIG's new guidance threatens to make it intolerably risky to be a pharmaceutical executive. In such a context, subjecting every manager and executive in the industry to potential criminal liability every time an off-label promotion occurs is extremely shortsighted. 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. Because of the breadth of the FDCA's prohibitions, a real danger exists that the FDCA misdemeanor, coupled with the threat of exclusion, will be seen by federal prosecutors as leverage to allow them to obtain convictions or extract pleas in vindications of suspicions that cannot be proven.

Exclusion is Contrary to the Supreme Court's Justification for Strict Liability Crimes

Although the basis for allowing a strict liability crime has broadened over the years, two crucial considerations have remained: the size of the penalty and the impact on the individual's reputation. *See, e.g., United States v. Freed*, 189 Fed. App'x 888, 891-92 (11th Cir. 2006). The Supreme Court has justified the existence of strict liability crimes only in certain narrowly defined cases where penalties are small and there is no grave damage to the person's reputation. *See, e.g., Morissette v. United States*, 342 U.S. 246, 296 (1952) (emphasizing that the penalties "are relatively small and conviction does no grave damage to an offender's reputation").

In the FDCA context, the Supreme Court has reinforced the narrow confines established to permit criminal convictions for strict liability offenses by applying the responsible corporate officer doctrine only in FDCA cases where the penalties were extremely small. *See Park*, 421 U.S. at 666 (affirming a $250 fine); United *States v. Dotterweich*, 320 U.S. 277 (1943) (affirming a $500 fine and 60 days probation). Exclusion was never threatened, imagined, or even possible in either of these two cases, since HHS only began its exclusion program in 1977.

A lengthy exclusion will effectively end an executive's career and ruin his or her reputation. Courts have long recognized the serious harm of denying individuals the right to employment. If strict liability convictions of executives under the responsible corporate officer doctrine can trigger lengthy exclusions, the penalties available will far exceed the limits recognized by *Dotterweich* and *Park* and thereby frustrate the Supreme Court's intention to limit such convictions to cases where penalties are small and conviction does no grave danger to reputation.

Conclusion

The position advanced by your recent public statements, in tandem with the new OIG guidance on exclusion, uncouples exclusion from individual responsibility and pushes the responsible corporate officer doctrine well beyond what the Supreme Court intended when the doctrine was announced almost 70 years ago. If HHS is permitted to impose lengthy exclusions on executives convicted without evidence of individual culpable conduct, the Supreme Court's rationale for permitting conviction without traditional proof of *mens rea* will be eviscerated. Under such circumstances, application of the responsible corporate officer doctrine will be unlikely to survive a due process challenge in federal court.

Sincerely,

Cory L. Andrews
Senior Litigation Counsel