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March 17, 2010

United States Sentencing Commission
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Re: Comments Concerning January 21, 2010 Federal Register Notice Regarding Organizational Guidelines

INTRODUCTION

The law firm of Hyman, Phelps & McNamara, P.C. (HPM) is pleased to submit this comment in response to one aspect of the United States Sentencing Commission's January 21, 2010 *Federal Register* notice (Notice). This comment relates to the proposed amendment to "the Commentary to § 8B2.1 (Effective Compliance and Ethics Program) to clarify the remediation efforts required to satisfy subsection (b)(7) (the seventh requirement for an effective compliance and ethics program). The proposed amendment adds a new application note that describes the reasonable steps to respond appropriately after criminal conduct is detected, including remedying the harm caused to identifiable victims and payment of restitution." 75 Fed. Reg. 3534 (Jan. 21, 2010). Elsewhere in the Notice, the Commission explained that those remedial steps would include self-reporting to the government and cooperating with government officials. *Id.* at 3535.

As discussed below, there are a number of federal statutes that subject an offender to criminal prosecution based on a "strict liability" theory. A prime example is the Federal Food, Drug, and Cosmetic Act (FDC Act). In those instances, an organization has theoretically engaged in "criminal conduct" whenever it commits a "prohibited act" as defined in the statute, regardless of whether the organization intended to violate the law.

HPM represents many companies and individuals whose activities are regulated by the United States Food and Drug Administration (FDA) under the FDC Act and other statutes, the Federal Trade Commission under the Federal Trade Commission Act[1], the United States

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[1] The Federal Trade Commission Act contains a provision that subjects food, drug, device or cosmetic manufacturers which disseminate a false advertisement to criminal sanctions. 15 U.S.C. § 54(a). That provision appears to permit a conviction in the absence of "wrongful intent" as long as the products involved may be injurious to health.

Consumer Product Safety Commission under the Federal Hazardous Substances Act and other statutes[2], and the Drug Enforcement Administration under the Controlled Substances Act. This Comment is applicable to organizations regulated by those federal agencies. It may be equally applicable to organizations regulated under other federal statutes.

In sum, the Commission should not adopt the proposed Commentary discussed above. Because of the wide breadth of the FDC Act's criminal sanctions, which can be applied to "no intent" offenses of the FDC Act, it is particularly important that the Commission understand the consequences of amending the Commentary to § 8B2.1. As shown below, if the proposed amendment is adopted it would require organizations to consider making restitution every time they learn they have committed a prohibited act under the FDC Act (even when the violation was unintentional). This would impose costly analyses by organizations regulated by FDA and other federal agencies on a daily basis. Moreover, no matter how much the new Commentary is publicized once it is adopted, organizations around the country, particularly those that are small, will not know of the Commentary and will therefore make no effort to comply. The Commission should not seek to mandate conduct by organizations that will lack the knowledge to comply.

Finally, HPM fears that adoption of the proposed Commentary will result in unintended collateral consequences for organizations. Plaintiffs filing product liability and other litigation against organizations will deem the Commentary to be the expected norm for organizations, if not the applicable legal *requirements*. Plaintiffs may cite an organization's failure to consider making restitution or take other remedial steps upon discovery of routine FDC Act violations as the organization's unwillingness to undertake what the government has mandated.

A. The *Park* Doctrine and Strict Liability

Persons who commit *any* "prohibited act" under the FDC Act are subject to criminal liability even if the person did not intend to violate the law. These are strict liability regulatory offenses for which the United States Supreme Court established a low bar for the government to meet in order to prove its case.[3] *See United States v. Park*, 421 U.S. 658 (1975). In *Park*, the Supreme Court upheld misdemeanor convictions based on the premise that persons who manage FDC Act-regulated businesses (and of course the business entity itself) have an affirmative duty to ensure that the products they sell are safe. Therefore, a person, including an organization, responsible for FDC Act compliance can be convicted even though the person did not know about the organization's illegal activity. The Court stated that the FDC Act criminally punishes

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[2] The Federal Hazardous Substances Act contains a provision that subjects any person who violates that Act to criminal sanctions. 15 U.S.C. § 1264(a). That provision also does not, on its face, require wrongful intent as an element of an offense.

[3] Of course, organizations and others can have a number of proper defenses to a criminal prosecution alleging that such offenses have occurred.

neglect where the law requires care or inaction, and imposes a positive duty to seek out and remedy violations when they occur, and also a duty to implement measures that will ensure that violations will not occur.

B. Common Remedial Steps Undertaken by Organizations Regulated by FDA

Organizations regulated by FDA and other agencies are expected, if not required, to conduct frequent audits of their own systems to ensure that they are complying with complicated regulatory schemes such as the FDC Act. It is hardly surprising, and indeed laudatory, that companies will routinely discover that they have committed a violation of the FDC Act, and then take unilateral steps to correct the violation. However, we doubt that many companies, if any, do or will routinely consider making immediate restitution or self-reporting those violations to FDA. Nor do we believe that FDA expects that organizations will take such actions every time a company determines that it has violated the FDC Act. Indeed, unlike some other federal agencies, FDA has not implemented a Voluntary Disclosure Program that announces what will happen to organizations which self-report violations.[4]

As noted above, most violations of the FDC Act are considered to be criminal conduct. However, FDA brings criminal actions with regard to a very small percentage of those violations. Instead, once FDA becomes aware of an FDC Act violation, FDA commonly undertakes one of a number of regulatory steps to encourage the organization to correct the violation.

These steps include an FDA investigator's issuance of an FDA Form 483. At the conclusion of an FDA inspection, the agency investigator issues a Form 483 to advise the organization of the FDC Act violations that the FDA investigator believes he or she has observed during a regulatory inspection. In Fiscal Year 2008, FDA issued just under 5000 Form 483s.[5] Of course, issuance of a Form 483 does not necessarily mean that an organization has in fact violated the FDC Act. It means that an FDA inspector has expressed his or her opinion that the Act was violated.

FDA also issues "Warning Letters" to organizations, in addition to, or in place of, a Form 483. In those letters, FDA officials advise organizations that FDA believes the organization has violated the FDC Act. In Fiscal Year 2008, FDA issued 445 such letters.[6]

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4 *See* John R. Fleder, *"A Voluntary Disclosure Program for FDA-The Time Has Come,"* 54 Food and Drug Law Journal 389-399 (1999).

5 FDA, The Enforcement Story, at 10-2 (2008), *available at* http://www.fda.gov/downloads/ICECI/EnforcementActions/EnforcementStory/UCM129823.pdf

6 *Id.*

FDA has many other tools available in its enforcement arsenal to advise organizations that certain practices violate the FDC Act. For most legitimate manufacturers, FDA's inspection observations, Warning Letters, and other administrative actions are taken extremely seriously. However, we doubt that legitimate companies do, will, or can, undertake a review to determine if they should make restitution or take other remedial steps each time an organization learns, either on its own or based on a meritorious FDA statement, that the organization has violated the FDC Act.

C. The FDC Act is Comprehensive in its Coverage

A product regulated by FDA may be deemed "adulterated" or "misbranded" (and thus in violation of the FDC Act) for numerous reasons set forth in the FDC Act. Some of those reasons result in products that are deemed "adulterated" or "misbranded" but are not dangerous or misleading to consumers in any respect, and often are no less safe and effective because of the violation. To provide concrete examples, consider the following regulatory and statutory requirements and the consequences of violating them:

- Under 21 U.S.C. § 351(a)(2)(B), a drug is adulterated if the methods used in manufacturing drugs are not operated in conformance with current good manufacturing practice. "Adulteration" occurs under the FDC Act even if a organization can establish that the cGMP violation did not affect product safety or quality. FDA has issued implementing regulations for this statutory provision in 21 C.F.R. Part 211. 21 C.F.R. § 211.34 states that a drug manufacturer violates the cGMP requirements if it does not have adequate records identifying the address of all of its consultants. Thus, a determination by an organization that this practice has occurred with regard to records kept in a drug manufacturer's facility is a finding that it is in violation of current good manufacturing practices, which causes the drugs manufactured at, or distributed from, that facility to be legally "adulterated." It is a criminal offense to introduce adulterated drug products into interstate commerce. 21 U.S.C. §§ 331(a), 333(a). In such a case, distribution of the product may violate the FDC Act, even though the product is safe and effective.

- A drug is "misbranded" if it does not conform to a number of requirements set forth in 21 U.S.C. § 352. For example, a product is misbranded if its packaging does not bear a label containing, among other things, the place of business of the manufacturer. 21 U.S.C. § 352(b). Thus, a safe and effective drug product is "misbranded" if the manufacturer inadvertently lists the incorrect street address ("1600 Pennsylvania Avenue" instead of "1500 Pennsylvania Avenue") on the labels of the drug products manufactured at a particular facility. Again, this is arguably "misbranding" even if no consumer was misled or harmed by this inadvertent mistake.

- Similarly broad regulatory requirements exist for food products, medical devices, dietary supplements, and cosmetic products regulated by FDA.

D. Other Points

We appreciate that the Commission has acknowledged that it would not expect organizations to make restitution in all instances where an organization has engaged in criminal conduct. Instead, the proposed restitution "expectation" would apply only where there is "an identifiable victim or victims." 75 Fed. Reg. at 3535 (column two). However, this limitation provides little consolation or help to businesses regulated by FDA and other federal agencies. Will the Commission expect those organizations to do an analysis of whether there *are* identifiable victims each time the organization learns (from its own audits or outside notification) that it has engaged in unlawful activity? If so, the Commission could be expecting these organizations to undertake costly analyses of potential victims every time the organization learns that it has violated the FDC Act. The Commission surely would not intend to impose such a costly burden on organizations.

The Notice also states that the organization should "otherwise remedy the harm resulting from the criminal conduct. Other appropriate responses may include self-reporting, cooperation with authorities, and other forms of remediation. Second, to prevent further similar criminal conduct, the organization should assess the compliance and ethics program and make modifications necessary to ensure the program is more effective." 75 Fed. Reg. at 3535 (column two).

For the reasons set forth above, the Commission should not expect organizations regulated by FDA and other federal agencies to automatically undertake these other "responses" as soon as the organization learns it has committed criminal conduct. For instance, a mandate that organizations self-report each "violation" to FDA would inundate FDA with daily reports of trivial violations by the few organizations even aware of the requirement to be imposed by the Commission. Moreover, the absence of an FDA-issued Voluntary Disclosure Program leaves organizations at the mercy of the FDA to determine what sanctions should be imposed on the organization that does self-report.

We also appreciate that the Commission believes that the proposed commentary to require restitution upon discovery that criminal conduct has occurred "is already a significant remediation step considered under current Department of Justice guidelines in determining whether to prosecute business organizations. *See* U.S. Attorney's Manual, Chapter 9-28.300(A)(6) and Chapter 9-28.900(A) & (B)." 75 Fed. Reg. at 3534 (column three). But, it is true that restitution is just cited in an expansive list of factors that a prosecutor can consider in determining the "proper treatment of a corporate target" in U.S.A.M. Chapter 9-28.300. The commentary acknowledges that the listed factors may or may not be relevant.

Also, the Manual's comment to Chapter 9-28.900, which deals more specifically with restitution, is certainly not an unequivocal statement that an organization must make restitution when it discovers it has engaged in criminal conduct. Instead, it merely contemplates that "[a] corporation's efforts to pay restitution even in advance of any court order" as "evidence of [the

corporation's] acceptance of responsibility and...may be considered in determining whether to bring criminal charges."

Regardless of the wording or meaning of these provisions of the United States Attorney's Manual, we submit that the Commission should not adopt language which would create any type of binding norm or even an expectation regarding what organizations should do in terms of making restitution or taking the other "responses" set forth in the Notice.

CONCLUSION

HPM appreciates the opportunity to present our views and would be happy to provide any additional information that may be helpful to the Commission as it considers these important issues.

Respectfully submitted,

John R. Fleder