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United States Sentencing Commission
Attention: Public Affairs
One Columbus Circle, NE
Suite 2-500
Washington, D.C. 20002-8002

Re: Comments Concerning January 19, 2011 Federal Register Notice Regarding Sentencing Guidelines for United States Courts

INTRODUCTION

The law firm of Hyman, Phelps & McNamara, P.C. ("HPM") is pleased to submit this comment in response to the United States Sentencing Commission's January 19, 2011 *Federal Register* notice ("Notice"). 76 Fed. Reg. 3193. This comment relates to the proposed amendment to § 2B1.1 (Theft, Property Destruction, and Fraud) "to implement the directive in section 10606 of the Patient Protection and Affordable Care Act, Public Law 111-148," ("PPACA"), which was enacted by Congress on March 23, 2010. 76 Fed. Reg. at 3194.

In an effort to increase penalties for persons convicted of health care fraud offenses, the Commission proposes that the term "Federal health care offense" should have the same meaning as in 18 U.S.C. § 24, which includes all "prohibited acts" under the Federal Food, Drug, and Cosmetic Act ("FDC Act"), 21 U.S.C. § 331. 76 Fed. Reg. at 3203. As discussed in detail below, this proposal, without refinement, could drastically increase sentences against persons convicted of "strict liability" offenses under the FDC Act, offenses that have nothing to do with health care fraud.

HPM represents many individuals whose activities are regulated by the United States Food and Drug Administration ("FDA") under the FDC Act. Many of these individuals hold positions within management that exposes them to potential liability for the company's actions simply due to their position of responsibility. The sentences that could be imposed against these individuals are affected directly by the Commission's proposal.

The Commission should not adopt the change to the definition of "Federal health care offense," as it proposes. Because of the wide breadth of the FDC Act's criminal sanctions, which can be applied to offenses not involving any fraud or intent (i.e., strict liability offenses), it is particularly important that the Commission avoid the potential consequences of its proposed amendment to the § 2B1.1 fraud guidelines. HPM fears that an unintended result of the proposal would be to impose harsh sentences against persons convicted of strict liability offenses under the FDC Act, when they should be charged instead under the regulatory guidelines contained at § 2N2.1.

A. The *Park* Doctrine and Strict Liability

The FDC Act imposes misdemeanor penalties against a person who commits *any* "prohibited act" contained at 21 U.S.C. § 331, even if the person did not act with fraudulent intent. These are strict liability regulatory offenses for which the United States Supreme Court established a low bar for the government to meet to prove its case. *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 the business entity itself) have an affirmative duty to ensure that the products they sell are safe. Therefore, a person 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 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.

Misdemeanor convictions brought under the *Park* Doctrine are now sentenced under Guideline 2N2.1, just like any other misdemeanor violation of the FDC Act. The unintended impact of the Commission's proposed amendment is that these offenses could be sentenced at the same levels as felony violations under the FDC Act. This equal consideration of strict liability and felony crimes undermines the purpose of the two-tiered approach contained in the FDC Act.[1]

The Commissioner of the FDA has recently publicly stated that it intends to employ the *Park* Doctrine in appropriate cases. As a result, any changes to the sentencing scheme

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[1] The FDC Act provides for a "felony elevation" if a prohibited act is committed with "an intent to defraud or mislead." 21 U.S.C. § 333(a)(2).

for such violations could have a dramatic negative and inappropriate impact on persons regulated by FDA.

B. Problems With The Commission's Proposal

The Commission's proposed changes are intended to implement the directive contained in PPACA § 10606, titled "Health Care Fraud Enforcement." PPACA directed the Sentencing Commission to amend the Guidelines to ensure that the Guidelines and policy statements:

- Reflect the serious harms associated with health care fraud and the need for aggressive and appropriate law enforcement action to prevent such fraud; and
- Provide increased penalties for persons convicted of health care fraud offenses in appropriate circumstances.

From the number of times the word "fraud" is used in this short section, it should be clear that the PPACA contemplates that any amendments to the Sentencing Guidelines should affect only those cases involving fraud. In other words, PPACA intended to address conduct that involves a level of behavior that rises to the level of fraud on the government health care programs. In effect, however, the Commission's proposed changes could go well-beyond raising the penalties for only fraud cases.

The Commission's proposal would amend the Guidelines with regard to "persons convicted of Federal health care offenses involving Government health care programs." 76 Fed. Reg. at 3203. As proposed, there would be no limitation with regard to the types of health care offenses involving health care programs that would be subject to the increased sentencing levels. As a result, if adopted, prosecutors could argue that this language applies to strict liability misdemeanor cases, including those cases brought under the *Park* Doctrine.

The proposed Amendments contain one important limitation. They would only apply to health care offenses "involving Government health care programs." Recent criminal prosecutions of many companies regulated by FDA show that the government considers the "off-label use" cases to involve "Government health care programs." But there is nothing in the Guideline restricting the government from applying it to more traditional FDC Act violations under the description of an offense involving a government health care program. Thus, the proposed change could increase penalties for conduct that has nothing directly to do with the provision of health care services, such as those involving

current Good Manufacturing Practice ("cGMP") violations, failing to report adverse events, or refusing to produce certain records during an FDA inspection. Not to diminish the importance of complying with the law in these areas, but because the FDC Act's prohibited act section covers almost all aspects of regulatory authority vested in FDA, prosecutors could argue that sentencing for any FDC Act violation must be calculated under the "fraud" guidelines when in fact no fraud is involved, or even when there is no direct impact on government health care programs.

C. Alternative Language to Clarify the Scope of § 2B1.1

In light of the above, HPM recommends that the Commission include additional language in § 2B1.1 and the Commentary specifying that the Guideline applies only to "Federal health care offenses" involving fraud. This could be done simply and cleanly by adding the words "involving fraud" after each reference in the Guideline to the words "Federal health care offense." In addition, the Commentary to § 2B1.1 should include discussion that the Guideline does not apply to the strict liability offenses contained in the FDC Act, 21 U.S.C. § 331, and that those violations are addressed at § 2N2.1.

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,

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