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## FDA Revamps Criminal Prosecution Guidelines and Expands Health Care Fraud-Related Investigations

On January 26, 2011, the Food and Drug Administration (FDA) published revised guidelines for the submission and review of prosecution recommendations.<sup>1</sup> Issued quietly – without FDA announcement or fanfare – the updated guidelines remove prior criteria that encouraged the purposeful and sparing use of FDA’s authority to refer matters for criminal prosecution. FDA appears also to have made an effort to distance itself still further from the procedural safeguards provided by the Food, Drug and Cosmetic Act (FDCA) for those being considered for a criminal referral. In addition, FDA introduced special procedures and considerations for prosecution of senior-level corporate officers under the *Park* Doctrine.

### Top Line Summary

- FDA amends the Regulatory Procedures Manual to provide agency personnel greater discretion in recommending criminal prosecutions.
- FDA’s revisions to the RPM reflect an additional step away from the substantive due process rights guaranteed by the Food, Drug and Cosmetic Act.
- FDA identifies criteria it will consider when recommending *Park* prosecutions and reiterates that knowledge of and actual participation in underlying misconduct are not prerequisites of prosecution.
- FDA introduces Pharmaceutical Fraud Pilot Program, expanding health care-fraud investigations through increased coordination with law enforcement agencies.

A **comparison** of the former versus amended FDA Regulatory Procedures Manual, Section 6-5, is attached as an Appendix to this client advisory.

### Background of FDA Prosecution Guidelines

The FDA Regulatory Procedures Manual (RPM) provides agency personnel – primarily inspectors, investigators and compliance officers – with information on internal procedures used in processing regulatory and enforcement matters. While the RPM neither constrains agency action nor creates any rights for individuals or entities, historically it has provided FDA-regulated companies with a compass for navigating and understanding the process behind agency investigations.<sup>2</sup>

Section 6-5 of the RPM outlines considerations for prosecution recommendations of potential FDCA violations.<sup>3</sup> In order to expedite the case review process, this section provides FDA personnel a variety of procedures based on the distinguishing characteristics of each case. This guidance is important because, depending on the nature of an investigation, substantially similar conduct may result in a recommendation for criminal prosecution in one instance and a FDA Warning Letter or Form 483 in another. FDA updates the RPM periodically to reflect amendments to the FDCA and changes in agency enforcement policy. However, RPM § 6-5 (the Prosecution Guidelines) had remained largely untouched for more than five years, until the recent revisions.<sup>4</sup>

## RPM Revisions Relax Prosecution Guidelines

Perhaps the most conspicuous change to the Prosecution Guidelines is the removal of a prominent notation describing the importance of prior notice in the context of agency enforcement actions. With limited exception, it is established FDA practice to warn individuals and firms of potential regulatory violations before commencing a prosecution.<sup>5</sup> Prior notice includes, for example, issuing an FDA Form 483, an Untitled Letter or a Warning Letter. Providing notice prior serves two primary policy considerations – preserving FDA resources and generating a case record.

In addition to reducing the importance of prior notice, other portions of the guidelines were eliminated altogether. Of the relevant provisions, key substantive revisions include:

- inserting an exception to the prior-notice requirement for undefined situations where notice is inconsistent with “the public protection responsibilities of the agency;” and
- removing requirements that each prosecution recommendation should ordinarily be supported by facts that show a continuous or repeated course of violative conduct – that is, “counts from two or more inspections, or counts from separate violative shipments at different points in time.”

This reduction in preconditions grants investigators and compliance officers greater flexibility in determining how to pursue an enforcement action. FDA personnel are no longer advised to engage repeatedly the target of an investigation via “two or more inspections” before filing a prosecution recommendation, nor are they advised to establish a “repeated course of violative conduct.” These revisions diminish the opportunity for individuals and companies to self-correct potential regulatory lapses; they also yield a corresponding increase in the likelihood of prosecution for an FDCA violation.

FDA also used the revisions to distance the agency from the requirements of 21 U.S.C. 335, a due process provision granting individuals under criminal investigation the right to notice that a recommendation is being considered and an opportunity to be heard. Section 335 mandates:

Before any violation of [the FDCA] is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

The former Guidelines required agency personnel to follow Section 335’s procedural safeguards (commonly referred to as a Section 305 hearing), yet FDA removed from the updated guidelines any reference to this provision. This is not the agency’s first attempt to weaken the Act’s due process protections. Following a contentious notice and comment period, FDA implemented regulations stating notice and an opportunity to be heard are not required if there is any reason to believe a prospective defendant may destroy evidence or flee to avoid prosecution. *See* 21 C.F.R. §§ 7.84(a) (2) & (3). The regulations further state that notice may be withheld where the commissioner contemplates recommending the matter to the Department of Justice for further investigation. These due-process exceptions provide FDA broad discretion to withhold notice, and substantially undercut protections granted to individuals by Congress. FDA’s latest tactic, omitting Section 335 from the guidelines, underscores the agency’s effort to move further away from the Act’s due process requirements.

## FDA Releases *Park Doctrine* Guidance<sup>6</sup>

As most in FDA-regulated industry have been hearing, there has been a chorus of calls for increased individual accountability. In March 2010, FDA Commissioner Margaret Hamburg publicly called for increased prosecution of “responsible corporate officers” under the FDCA. The responsible corporate officer (RCO) doctrine, or so-called *Park Doctrine*, allows senior-level individuals in FDA-regulated companies to be charged for violating the FDCA, even where the individual neither knew of nor participated in the underlying misconduct. The consequences of a *Park* conviction are dramatic. Individuals convicted under the *Park Doctrine* are subject to criminal fines, debarment by FDA and, in some cases, exclusion from participation in federal health care programs.

In furtherance of Commissioner Hamburg’s call-to-action, FDA has issued special procedures and considerations for *Park* prosecution recommendations. Notable among the FDA’s stated considerations is a paradoxical policy statement: “Misdemeanor prosecutions, particularly those against responsible corporate officials, can have a strong deterrent effect on the defendants and other regulated entities.” A hallmark of *Park* liability is that RCOs can be held liable without proof of intent, without proof of negligence or without proof of knowledge. It seems difficult to imagine that prosecutions of individuals who have no intent or knowledge of an underlying FDCA violation could inhibit culpable conduct by other similarly situated individuals.

Policy considerations notwithstanding, FDA instructs agency personnel to consider three primary factors when determining whether to recommend a *Park* prosecution: (i) an individual’s position in a company; (ii) an individual’s relationship to the violation and (iii) whether the official had the authority to correct or prevent the violation. The guidelines reiterate that knowledge of and actual participation in a violation are not prerequisite factors to a *Park* prosecution, but are merely two relevant factors in considering whether to recommend an enforcement action. The guidelines identify additional factors for consideration, including:

- whether the violation involves actual or potential harm to the public;
- whether the violation is obvious;
- whether the violation reflects a pattern of illegal behavior and/or failure to heed prior warnings;
- whether the violation is widespread;
- whether the violation is serious;
- the quality of the legal and factual support for the proposed prosecution; and
- whether the proposed prosecution is a prudent use of agency resources.

The guidelines note these factors do not create or confer any rights on any person, do not bind the FDA and are intended solely to provide guidance to agency personnel. Viewed in this light, FDA’s *Park* factors are analogous to the United States Attorneys’ Manual’s Principles of Federal Prosecution.<sup>7</sup> Like the Principles of Federal Prosecution, the *Park* factors offer an authoritative list for potential defendants to reference in preliminary discussions with agency personnel. Targeted individuals have an opportunity to marshal exculpatory evidence and demonstrate they are, in the conventional sense, *responsible* corporate officers.

## Pharmaceutical Fraud Pilot Program

Released on January 26, 2011, the Department of Health and Human Services' Health Care Fraud and Abuse Control Program Report<sup>8</sup> boasts numerous high-profile accomplishments: recovery of more than \$4 billion in FY 2010; expansion of HEAT, the Health Care Fraud Prevention & Enforcement Action Team, partnerships; and a return on investment of almost \$7 for every \$1 spent. Buried in the 88-page report, however, is a little known and modestly funded program, the FDA Pharmaceutical Fraud Pilot Program (PFPP).

Billed as an effort to detect, prosecute and prevent FDA-related health care fraud, the PFPP promises to focus on fraudulent marketing schemes, application fraud, clinical trial fraud and manufacturing-related FDCA violations. Predictably, the report highlights among the "anticipated schemes" PFPP will handle the investigation and prosecution of off-label promotion of pharmaceuticals and medical devices. Receiving a mere \$1.7 million in funding for FY 2010, the FDA PFPP has opened significant criminal investigations, including:

- two off-label promotion matters involving different manufacturers of brand name prescription drugs;
- two matters involving manufacturing fraud associated with current Good Manufacturing Practice issues, one of which also involves potential application and promotional fraud;
- a clinical trial fraud matter where study documents are alleged to have been falsified; and
- a Contract Testing Laboratory company that allegedly falsified data used to support multiple drug applications.

The PFPP is expanding quickly: hiring new personnel, establishing relationships with criminal investigators and regulatory components of the FDA, and reaching out to United States Attorneys' Offices. FDA also has established a training plan to implement the PFPP.

At this point, it is difficult to see how FDA's PFPP differs materially from other fraud enforcement initiatives underway. In 2010, the Department of Justice opened more than 1,100 new criminal health care fraud investigations and federal prosecutors had over 1,750 health care fraud criminal investigations pending. DOJ also opened in 2010 almost 950 civil health care fraud investigations and had more than 1,250 related civil matters pending at the end of the year.<sup>9</sup> The PFPP likely will result in more investigations stemming from FDA inspections and other oversight activities, rather than from whistleblowers and data-mining expeditions. One thing appears to be clear: considering the current regulatory landscape and the success of the U.S. Department of Health and Human Services' fraud prevention efforts as a whole, the PFPP is likely to emerge as an additional weapon in the government's steadily increasing enforcement arsenal.

*(Endnotes on page 5)*

## Endnotes

- 1 <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176738.htm>
- 2 <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm>
- 3 <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176738.htm>
- 4 See generally RPM News, available at <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm093503.htm>
- 5 <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176738.htm#SUB6-5-13>
- 6 For a detailed description of the development of the *Park Doctrine*, see Skadden's recent Client Alert, *FDA Announces New Push to Prosecute Corporate Officers and Executives for No-Intent Crimes*, available at <http://www.skadden.com/Index.cfm?contentID=51&itemID=2003>.
- 7 [http://www.justice.gov/usao/eousa/foia\\_reading\\_room/usam/title9/28mcrm.htm](http://www.justice.gov/usao/eousa/foia_reading_room/usam/title9/28mcrm.htm)
- 8 <http://oig.hhs.gov/publications/hcfac.asp>
- 9 <http://www.justice.gov/dag/pubdoc/hcfacreport2010.pdf>

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