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# Law Enforcement Targets Pharmaceutical and Medical Device Executives

*Contributed by Kirk Ogrosky, Arnold & Porter LLP*

Senior executives at pharmaceutical and medical device companies are on notice from the Office of Inspector General of the U.S. Department of Health and Human Services (OIG), Food and Drug Administration (FDA), and Department of Justice (DOJ) that the government intends to aggressively pursue them for violations of the False Claims Act (FCA), Food, Drug, and Cosmetic Act, and Anti-Kickback Law, and to exclude them from participation in federal health care programs for violations of those laws. While repeating mantras of recidivism and failures of compliance, the government has made a number of aggressive moves to show that it is moving from rhetoric to a multifaceted attack designed to achieve both punitive and deterrent impact.

The government is sending a clear message that it intends to exclude senior executives through the release of OIG's new guidance on the use of permissive exclusion, the recent exclusion of KV Pharmaceutical's former chief executive officer (CEO), and the exclusion of three Purdue Pharmaceuticals' executives. Individuals with authority to prevent or mitigate harm resulting from non-compliance must understand that the government will look to them as the responsible parties. These enforcement actions may end careers, cause bankruptcy, and lead to incarceration.

In many ways, the government has been forced into its position by the huge sums collected from the pharmaceutical and medical device industries in FCA cases. The billions of dollars in settlements and the lack of DOJ prosecution has raised the ire of Congress. OIG's initiative to expand its use of the permissive exclusion provisions in Section 1128(b)(15) of the Social Security Act is part of a response to congressional pressure to hold individuals accountable. Congress is asking the government's enforcement apparatus to explain why corporations pay billions in fines and penalties while relatively few of the responsible individuals are held accountable. Congress's concern appears to be that FCA settlements, corporate plea agreements and corporate integrity agreements resulting from failures of compliance have become the norm and simply a cost of doing business. At the end of the day, however, it is DOJ that should cause the most concern because its criminal prosecutors may give in to pressure from Congress.

## *Permissive Exclusion Guidance*

On October 20, 2010, OIG released its Guidance for Implementing Permissive Exclusion Authority (the Guidance), in which it expressed its intent to more aggressively exercise its exclusion authority against executives.

The OIG's exclusion authority has traditionally functioned as a remedial tool to protect the Medicare program from individual bad actors. The Guidance signals a shift to proactively use exclusion as a punitive tool to achieve deterrence. Unfortunately, this shift means that OIG will be making an example out of certain executives, irrespective of whether remedial goals have already been achieved. Even where executives have not been convicted of misconduct, they should brace for the possibility of exclusion proceedings.

*Presumption of Exclusion*

The Guidance focuses on the rarely used (b)(15) permissive exclusion provision. According to OIG, it issued the Guidance (a) to improve investigations, (b) to establish a framework for exclusions, and (c) to "positively influence individuals' future behavior and compliance with Federal health care program requirements" – in other words, motivate executives to deter fraud.

The (b)(15) provision imposes a type of strict liability exclusion on (1) those who have an ownership interest in a sanctioned entity and knew or should have known of the conduct giving rise to sanctions, or (2) executives and managers who are deemed responsible parties by virtue of their positions within a sanctioned entity, irrespective of actual knowledge of the conduct giving rise to sanctions. Where there is evidence that an owner, officer, or manager knew or should have known of the sanctioned conduct, OIG will apply a rebuttable presumption of exclusion. Although OIG states that the presumption may be overcome when it finds that "significant factors weigh against exclusion," it does not attempt to describe those factors.

In total, the Guidance signals OIG's intention to focus on executives who "knew or should have known" of the sanctioned conduct. Unfortunately, even executives without knowledge are not spared exclusion under (b)(15). The Guidance lists four factors that OIG claims it will consider in determining whether to exercise its exclusion authority:

First, OIG will examine the circumstances surrounding the misconduct and the seriousness of the sanctioned offense, including the nature and scope of the misconduct, the level at which the conduct occurred, the sanctions leveled against the entity, the harm to beneficiaries and federal health care programs, and whether the misconduct was an aberration or part of a greater pattern. Importantly, OIG will factor-in the conduct of related entities, a corporate parent or subsidiary, and the scope of its review will include "all allegations in criminal, civil, and administrative matters." Second, OIG will consider the executive's role in the company. More specifically, OIG is concerned with an individual's degree of control or authority at the time of the underlying misconduct. Third, OIG will evaluate the individual's response to the misconduct. That is, OIG will look to what steps the individual took to mitigate the harm caused by the violation and to whether the individual disclosed the misconduct to the appropriate authorities. Finally, OIG will consider characteristics of the entity, including its size, corporate structure, and past conduct.

Permissive exclusion under (b)(15) may become even more powerful if Congress extends OIG's authority under terms similar to those in H.R. 6130, which sought to expand the reach of (b)(15) to individuals that no longer work for the sanctioned entity. This type of expansion would allow OIG to seek exclusion of former executives. Executives would be wise to monitor whether Congress moves forward with this provision in the upcoming months.

*Failure to Take Corrective Action*

On November 18, 2010, OIG issued its notice to exclude the former CEO of KV Pharmaceutical under (b)(15). When asked about the exclusion, the second in command within OIG office of counsel said that it was a sign of more exclusion actions to come.

The KV Pharmaceutical exclusion dates back to the summer of 2008, when KV Pharmaceutical and Ethex Corporations allegedly received reports that two of its drugs were being distributed in irregular tablet sizes. *See United States v. Ethex Corp*., Case No. 4:10-CR-00117-ERW (E.D. Mo. Mar. 2, 2010). After receiving initial complaints of oversized morphine sulfate tablets, the companies conducted an investigation and submitted a field alert to FDA. The companies also issued recalls for specific lots of morphine sulfate.

The companies discovered that its tablet press machines were responsible for the irregularities, and subsequently discovered similar irregularities with two other drugs. According to the government, one option presented to the former CEO was to take no action. Despite protests from certain employees, the executive elected to take no action because the probability of harm was so low. Shortly after that decision, the Audit Committee retained independent counsel to conduct an internal investigation and advise them regarding FDA regulatory matters and compliance issues. During that investigation, the former CEO allegedly instructed employees to minimize written communications about tablet manufacturing problems, and sought to limit the Audit Committee investigation. *Id.* ¶ 10.

Ultimately, the Audit Committee investigation led to further disclosures to FDA and product recalls. On December 19, 2008, KV Pharmaceutical and Ethex voluntarily suspended all shipments of FDA-approved drugs in tablet form and implemented remedial improvements to the companies' operations.

On March 2, 2009, the companies entered into a Consent Decree of Permanent Injunction. The Consent Decree came on the heels of repeated warnings by FDA that KV Pharmaceutical, its subsidiaries, and certain of its officers and directors were in non-compliance with the Food Drug and Cosmetic Act's (FDCA) manufacturing and recordkeeping requirements, including cGMPs. *See Consent Decree*, Case No. 4:09-CV-00334-RWS (E.D. Mo. Mar. 2, 2009). On March 2, 2010, Ethex pleaded guilty to two felony counts of failing to file required field reports pursuant to 21 U.S.C. 333(e) and agreed to pay $27.4 million in fines, forfeiture, and other penalties, including $2.34 million in restitution to Medicare and Medicaid programs. Citing his failure to take action to correct problems, OIG notified the former CEO of its intention to exclude him from the programs pursuant to (b)(15) based on his position in the company.

*Off-Label Promotion & Park Doctrine Misbranding*

On December 13, 2010, the U.S. District Court for the District of Columbia affirmed OIG's 12-year exclusion of three Purdue Frederick Company (Purdue) executives. After the executives had pleaded guilty to misbranding OxyContin as responsible corporate officers, a misdemeanor under the FDCA, OIG notified the executives of its intention to exclude.

While OIG used permissive exclusion provision (b)(1) and (b)(3), the case is instructive given that the executives were convicted under the *Park* doctrine, which like (b)(15) does not require actual knowledge. Subsection (b)(1) allows OIG to exclude individuals convicted of a misdemeanor related to health care fraud. Subsection (b)(3) allows exclusion of individuals convicted of a misdemeanor related to the manufacture, distribution, prescription, or dispensing of a controlled substance.

On appeal, the executives argued that their pleas under the responsible corporate officer or Park doctrine did "not reflect any personal wrongdoing," and that excluding them was inconsistent with the remedial purpose of the exclusion statute.

The underlying allegations in Purdue were that supervisors within the company engaged in a scheme to promote OxyContin off-label. The government argued that Purdue illegally promoted OxyContin as "less addictive, less subject to abuse and diversion, and less likely to cause tolerance and

withdrawal than other pain medications." In May of 2007, the government filed criminal charges against Purdue and the three executives for misbranding. Ultimately, the case against Purdue and the executives was resolved by plea, and OIG notified the executives of its intention to exclude.

Upon considering the executives' responses to the exclusion letters, OIG elected to exclude the executives for 20 years based on two aggravating factors. First, the duration of the conduct exceeded one year. Second, the government argued that the conduct resulted in significant financial harm to program beneficiaries. The Administrative Law Judge (ALJ) hearing the case agreed with OIG. Pending appeal to the Departmental Appeals Board (DAB), OIG reviewed additional mitigating evidence and reduced the exclusion period from 20 to 15 years. The DAB further reduced the length of exclusion from 15 to 12 years. On October 29, 2009, the executives appealed the agency's decision to the district court.

The court rejected the arguments that the executives were not guilty of personal wrongdoing and that application of the exclusion penalty was inappropriate where it failed to serve a remedial purpose. The court reasoned that the failure to know and the failure to act where the law imposes a duty constitutes wrongdoing, and that application of the exclusion provision to the executives was consistent with the provision's ultimate purpose of protecting federal health care programs and program beneficiaries. Importantly, the court noted that the statute was intended "'to provide a clear and strong deterrent against the commission of criminal acts.'" *Friedman, et al., v. Sebelius*, Civil Action No. 09-2028 (ESH) (D.C. Dec. 13, 2010). With respect to the duration of the exclusion period, the court concluded that the aggravating factors cited by the Secretary were supported by the admission during the prior pleas. In its conclusion, the court noted that it "defers to an agency's exercise of its remedial discretion, particularly where, as here, the agency's factual findings are amply supported by the record." *Id.* at 29 (citations omitted).

*FDA Referral Criteria*

On February 2, 2011, FDA published non-binding criteria for *Park* doctrine referrals in its Regulatory Procedures Manual (RPM) (the Criteria). *See Special Procedures and Considerations for Park Doctrine Prosecutions*, FDA Regulatory Procedures Manual, Section 6-5-3 (2011). The new provisions in the RPM come almost a year after FDA notified Senator Charles Grassley by letter dated March 4, 2010, of its intention to put forth definitive referral criteria.

Publication of the Criteria signals FDA's intention to move forward with referrals to DOJ in the upcoming months. The extent to which DOJ accepts cases for misdemeanor prosecution remains an unanswered question. Given the increased funding to DOJ and the U.S. Attorney's offices that was enacted as part of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), it is highly likely that DOJ will move quickly to accept case referrals.

While the Criteria provides that actual knowledge of and participation in a violation are relevant facts to be considered for purposes of evaluating whether a referral for prosecution is merited, the Criteria once again reiterates that knowledge and participation are not prerequisites to *Park* doctrine prosecution.

The key considerations listed by FDA include the following: (1) the executive's position and relationship to the alleged violation; (2) whether the executive had authority to correct or prevent the alleged violation; (3) whether the alleged violation itself posed actual or potential public harm; (4) the extent to which the alleged violation was obvious to the executive; (5) whether the alleged violation reflects a pattern of behavior and whether there had been prior warnings; (6) the extent and breadth of the alleged violation; (7) the seriousness of the alleged violation; (8) the quality and quantity of the available evidence; and (8) whether prosecution is a prudent use of government resources. One noteworthy omission from the Criteria is any contemplation that efforts

by executives to discovery and prevent misconduct should be countervailing considerations that favor a declination of referral.

The government has made clear its intention to use its exclusion authority and misdemeanor misbranding prosecution to deter future violations. Senior executives need to be mindful that this is the most challenging enforcement environment faced by any industry and they are the targets. Going forward, counsel representing the interests of an entity will need to assess the impact of potentially losing key and high-level managers to exclusion, even in cases devoid of individual wrongdoing.

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