Individual prosecutions

Imminent Exclusion Proceedings for Pharmaceutical Executives Who "Knew or Should have Known" of Sanctioned Conduct

By Kirk Ogrosky

On October 20, 2010, the Office of Inspector General (OIG) unveiled its *Guidance for Implementing Permissive Exclusion Authority* (the "Guidance"), which will further intensify today's challenging enforcement environment. OIG issued the Guidance after years of mounting pressure on the Food and Drug Administration (FDA), the Department of Justice (DOJ), and OIG regarding the alleged lack of individual accountability for off-label promotion and other violations. The Guidance is a bold statement signaling OIG's intention to aggressively pursue pharmaceutical executives.

Rather than wait for DOJ to bring charges against individual wrongdoers, OIG is poised to issue notices to executives after their companies have resolved cases and executed Corporate Integrity Agreements (CIAs). Unfortunately, while highlighting the punitive and deterrent value of making examples out of individual executives, the Guidance ignores the remedial purpose of permissive exclusion authority.

OIG's Focus on Executives Who "Knew or Should Have Known"

Section 1128(b)(15) provides two bases for exclusion: (a) for those that have an "ownership or a control interest," OIG may exclude if the individual "knew or should have known of the conduct that led to the sanction;" or (b) for individuals serving as "officers and managing employees," OIG may exclude based solely on the individual's position within the company. In both cases, OIG advises that it will apply a rebuttable presumption of exclusion where there is "evidence that the individual knew or should have known" of the sanctioned conduct. The OIG will look to non-enumerated "significant factors" that weigh against exclusion to rebut the presumption.

For officers and managing employees who do not fall within the presumption of exclusion, OIG will conduct an inquiry of four areas to determine whether to pursue exclusion: (a) the circumstances and seriousness of the sanctioned conduct, (b) the individual's role at the sanctioned entity, (c) the individual's actions in response to the misconduct, and (d) information about the entity.

For executives wondering how to protect themselves in situations where they did not know, and where there is no reason to believe that they "should have known" of the sanctioned conduct, OIG lays out several questions to consider:

- Did the executive take steps to stop the misconduct and mitigate its impact?
- Did the executive order "appropriate disciplinary action" against the responsible person(s)?
- Did the executive take responsible action prior to learning of the investigation?
- Where preventing the sanctioned conduct was impossible, did the executive exercise extraordinary care?

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Other than a general message that "tone at the top" and maintaining and supporting a strong compliance program will be important factors in permissive exclusion decisions, these parameters suggests that the real targets of OIG's campaign to exclude executives will focus on those that "knew or should have known" the circumstances of a violation.

Finally, in considering the underlying conduct, OIG will consider the conduct of "related" entities such as a corporate parent or subsidiary, and it will not limit its evaluation to admitted wrongful conduct but will consider all "allegations in criminal, civil, and administrative matters."

Risky Proposition to be a Pharmaceutical Executive

OIG states that the Guidance was issued to: (a) improve investigations, (b) establish a framework for (b)(15) permissive exclusions, and (c) deter conduct or as OIG words it: "positively influence individuals' future behavior and compliance with Federal health care program requirements by holding individuals accountable for misconduct within entities in which they are in positions of responsibility." The importance of the Guidance is its advance notice of OIG's intention to use (b)(15) exclusions to deter off-label promotion and other violations.

Notwithstanding these stated reasons, Congress has pressured DOJ, OIG, and FDA to address why companies pay billions in fines and penalties, yet relatively few individuals are held accountable. Since 2006, federal prosecutors have charged approximately 25 individuals with offenses related to pharmaceutical and device sales practices. FDA Commissioner, Margaret Hamburg, told the Senate in March of 2010 that her agency was developing criteria to use in selecting cases to recommend to DOJ for strict liability misdemeanor misbranding prosecutions, and FDA's Deputy Chief for Litigation Eric Blumberg recently echoed these warnings. However, such cases can be difficult to prosecute as a practical matter. OIG's response to the low number of charged individuals is to exclude them. In fact, the Guidance seems to be yet another part of a mounting government effort to punish executives when DOJ does not have sufficient evidence of criminal wrongdoing.

While not part of flexing its permissive exclusion muscle, OIG entered into a notable agreement with Synthes on October 4, 2010, as part of a global settlement with DOJ, whereby Synthes was required to divest Norian Corporation, a U.S. subsidiary, in order to avoid exclusion. This is another example of OIG's expanding role within enforcement.

Expansion From Remedial to Punitive Tool

While issues relating to (b)(15) permissive exclusion have not been litigated at either an administrative or court level since its effective date in 1997, there are several sources to ascertain the purpose of extending the power of exclusion. The grant of authority to permit permissive exclusion was given to allow OIG "to keep [those who commit fraud] out of the Medicare and Medicaid Programs. They deprive patients of needed services or supplies, and they divert taxpayer funds from their intended purposes." 133 Cong.Rec. 14,177 (statement of Chairman Waxman, House Subcommittee on Health and the Environment). Exclusion should be remedial in nature serving to protect the public, as opposed to punitive. See S.Rep. No. 109, 100th Cong., 1st Sess. 1-2 (1987).

The Guidance fails to articulate how excluding a pharmaceutical executive in an off-label promotion type case serves the remedial purpose of protecting Medicare beneficiaries. Instead, the Guidance uses language of deterrence. In situations where executed CIAs serve the remedial purpose of protecting the program, the use of derivative permissive exclusion appears to serve as random punishment with the goal of deterrence.

Courts have also recognized that the purpose of exclusion should be to protect federal programs and their beneficiaries from future harm. See *Hanlester Network v. Shalala,* 51 F.3d 1390, 1401-02 (9th Cir. 1995). The court stated that "[b]ecause liability is strictly vicarious, emanating totally from the conduct of" one wrongdoer that the permissive exclusion of other individuals was not necessary to meet its remedial purposes once the wrongdoer was gone. *Id.* Therefore, "no remedial purpose would be served by excluding" others and the court reversed "the imposition of permissive exclusions." *Id.*

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Conclusion

In keeping with prior governmental warnings, OIG will undoubtedly send notices of its intent to exclude certain executives in off-label promotional matters within the next few weeks. The impact of these exclusions, if successful, will effectively end careers. In the future, counsel representing the interests of an entity will need to assess the impact of potentially losing key and high-level managers to exclusion. This assessment will likely lead to early meetings with OIG in the case resolution process. ■

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