Exclusion of individuals: Taking it to the top

By Virginia Gibson, Esq., Eliza Andonova, Esq., and Danielle Drissel, Esq.
Hogan Lovells

> If writing a check for $200 million isn't enough to have a company change its ways, then maybe we have got to have the individuals who are responsible for this held accountable. The behavior of a company starts at the top.
>
> — *Lewis Morris, chief counsel to the inspector general of the Department of Health and Human Services*[1]

The pharmaceutical industry's ear is tuned to the questions "Who's next?" and "How far will it go?" With the recent "notice of intent to exclude" Forest Laboratories' CEO, the quickening tempo of the Office of Inspector General's use of exclusion authority has sounded deep notes of alarm that "new" and seemingly random risks face pharmaceutical industry executives. In 2007 the OIG excluded three senior pharmaceutical executives who had been convicted of strict-liability misdemeanor offenses.

In 2010 it issued a notice of intent to exclude a pharmaceutical industry executive who had not then been charged with a crime and was not charged until four months later. More recently, this year the OIG issued a notice of intent to exclude an executive of another pharmaceutical company convicted of criminal charges despite the fact that he was not charged, and there are no facts of public record showing he acted criminally or had knowledge of criminal acts of others in his corporation.

In light of the potentially career-ending exposure facing individuals who work for a convicted corporation, executives and directors of companies under investigation have to ask "Who is sufficiently disinterested in the outcome to decide whether the corporation can or should plead guilty?" The OIG's new path creates an unprecedented level of personal risk for executives and managers as well as for the corporations they manage and the shareholders who own them.

EXCLUSION AUTHORITY AND ITS IMPACT

The Social Security Act gives the secretary of the Department of Health and Human Services and, by delegation, the OIG, the authority to exclude individuals and entities from participation in federal health care programs, or FHCPs, which means no FHCP may pay for any items or services furnished directly or indirectly by the excluded individual or entity.[2] Exclusion can be the "death penalty" for companies and individuals who rely on Medicare or Medicaid revenues for their livelihood. The payment prohibition applies to the excluded person or entity or to anyone who employs or contracts with the excluded person or entity.

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An OIG guidance issued in 1999 set out an expansive view of the ramifications of exclusion for individuals, explaining that they could not work in the health care industry unless their work is wholly separate from any item or service (including administrative and management services) reimbursable by an FHCP; and their salary (or consulting fee) is paid from funds wholly separate from any monies that can be tied to, or are comingled with, direct or indirect FHCP funds.[3]

That guidance, untested to this day in any federal court, extended the OIG's reach well beyond persons or entities who bill health care programs and their employees, to manufacturers and others whose goods and services health care entities buy and use to treat FHCP beneficiaries, and to the employees of those downstream entities. The practical difficulty that excluded individuals, especially senior-level managers, can have finding employment in the pharmaceutical industry that avoids both of the OIG's prohibitions means the exclusion of pharmaceutical industry executives could be the end of their careers.

EXCLUSIONS BASED ON SANCTIONS AGAINST INDIVIDUALS

The OIG's first efforts to pursue pharmaceutical industry representatives relied on its authority under Section 1128(b)(1) of the Social Security Act to exclude an individual convicted of a misdemeanor "relating to fraud, theft, embezzlement, breach of fiduciary responsibility or other financial misconduct."[4]

In 2007 the Department of Justice prosecuted Purdue Frederick Co. for felony misbranding of OxyContin with intent to mislead and entered into a nonprosecution and civil settlement with its parent corporation. The DOJ also prosecuted three executives for strict-liability misdemeanor misbranding violations of the Food, Drug and Cosmetic Act, reviving the long-dormant "responsible corporate officer" doctrine established in *United States v. Park*.[5]

Under this doctrine, an individual can be held liable for a strict-liability FDCA violation even absent criminal conduct by the individual or knowledge of or intent to cause the violation, if at the time of the misconduct the individual "had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance or promptly to correct the violation complained of, and that he failed to do so."[6]

The OIG followed after the DOJ and used its permissive exclusion authority against

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the Purdue executives solely on the basis of their conviction for holding positions of authority in a company that admitted to felony misbranding "with intent to mislead," arguing that a strict liability *Park* doctrine conviction was, in essence, inherently blameworthy.

In *Friedman v. Sebelius*,[7] the U.S. District Court for the District of Columbia reviewed the OIG's decision and upheld its authority to exclude the executives, applying a highly deferential "substantial evidence" test. The court described its role in reviewing the OIG's decision as limited to determining whether "more than a mere scintilla" of evidence supported it.

EXCLUSIONS BASED ON SANCTIONS AGAINST CORPORATE EMPLOYERS

Not wanting to rely solely on DOJ charges and convictions as the basis for its enforcement efforts, in October 2010 the OIG issued new guidance announcing its intention to make greater use of its existing but seldom-used discretionary authority to exclude individuals who themselves were not convicted of or had not pleaded guilty to a crime.[8]

The OIG is authorized under Section 1128(b)(15) of the Social Security Act to exclude individuals who have a direct or indirect ownership interest in or who are officers or managing employees of any entity that is excluded or has been convicted of or pleaded guilty to particular health care offenses. Within such a sanctioned company, the new guidance claims the OIG has the authority to exclude individuals with operational or managerial control over the entity or who directly or indirectly conduct day-to-day operations.

The OIG announced it will apply a presumption in favor of exclusion if it concludes the officer or managing employee "knew or should have known" of the misconduct forming the basis for the company's sanction. This presumption may be overcome if the OIG finds that "significant factors weigh against exclusion," but the guidance does not describe what such significant counterweights might be.

Even if the OIG concludes there is no evidence that a responsible officer or managing employee knew or should have known of the misconduct for which his employer was sanctioned, its guidance announces it may still exclude that officer or employee after considering four categories of factors:

- Information about the entity such as its size, corporate structure and whether there were previous sanctions or convictions.
- The individual's position in the entity and the relationship of the position to the underlying misconduct.
- The circumstances of the misconduct and seriousness of the offense, including the terms of the resolution and whether there was actual or potential harm to FHCPs or beneficiaries.
- The individual's actions in response to the misconduct, such as whether the individual took steps to stop or mitigate the misconduct. (The OIG "may consider" whether the individual can demonstrate either that preventing the misconduct was impossible or that he or she exercised extraordinary care but could not prevent the misconduct.)

conduct OIG considers relevant."[9] The OIG specifically identifies allegations in criminal, civil or administrative matters against entities or individuals other than he who is to be excluded as relevant in its consideration.

THE OIG FOLLOWS THROUGH

Within weeks after issuing the guidance, the OIG used its Section (b)(15) authority to exclude the former chairman of the board and CEO of KV Pharmaceutical. At the time of his exclusion, KV's CEO was uncharged and KV's subsidiary, Ethex Corp., had pleaded guilty to a felony failure to inform the Food and Drug Administration about manufacturing problems that led to misbranded drugs entering commerce.

Several months after his exclusion, however, charges against the CEO were unsealed, and he pleaded guilty to two misdemeanor violations of the FDCA. The public record stated that KV's CEO had personal knowledge of and made the decision not to inform the FDA of the sanctioned conduct.

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The OIG's plans for excluding even those individuals who neither knew nor should have known of the illegal conduct stand incongruously against the purpose for exclusion. Congress intended exclusion to be remedial — a way to protect FHCPs and beneficiaries from harm the excluded person could cause. Yet the OIG's guidance focuses almost exclusively on the conduct and character of the convicted corporation and not the individual facing exclusion.

Specifically, the OIG's first and third categories of factors look at the company, its compliance history, the harm from the corporate actions and the remedy for that harm. The second and fourth view the individual, first as he is positioned in the organization and as *his position* relates to the sanctioned conduct. Only the fourth category looks at the individual's *actions in response to* the company's misconduct.

Notably, the OIG has interpreted "misconduct" to include not only the factual basis for the corporate sanction but also "any other

The allegations in the unsealed charges that KV's CEO played an integral role in the misconduct underlying the criminal charges against Ethex Corp. caused some to believe that the OIG would not impose Section (b)(15) exclusion unless there was evidence of criminal misconduct by the individual facing exclusion. But such conjecture, or hope, was proved wrong and misplaced when in April the OIG sent a notice of intent to exclude to the CEO of Forest Laboratories after his company settled civil allegations and entered into a nonprosecution agreement and its subsidiary entered felony guilty pleas.

In a fact sheet about the proposed exclusion, a public statement on a pending exclusion which is itself unprecedented, the OIG said Forest's CEO faced exclusion because he was the CEO when wholly owned subsidiary Forest Pharmaceuticals Inc. pleaded guilty to three criminal offenses: distributing a misbranded drug, distributing an unapproved new drug and felony obstruction of an agency proceeding.[10] The CEO was and remains uncharged in the matter, and there

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are no public criminal or civil allegations that the CEO was personally involved in the misconduct giving rise to the company's sanction.[11]

The government's sentencing memorandum filed in connection with the penalty phase of the case against the Forest Laboratories subsidiary contains the most factual allegations of any government pleadings yet made public. The DOJ alleged that the FDA issued many notices to the public and to all makers of levothyroxine, best known under the Synthroid and Levoxyl brand names, about its plan to require approval of thyroid drugs previously distributed without such approval and its plan to require the phase-down of distribution in cases in which FDA approval was not attained.

The agency made known in these notices its concern with continued problems in maintaining the stability of the dosages, with consequent patient harm. Yet, the government makes no reference to Forest's CEO or any role he played in the corporate response to the FDA. Instead, it alleged activities by people to whom he delegated authority in Forest.

For example, it alleges that Forest filed a new drug application seeking approval for the levothyroxine product of its subsidiary, conducted all other regulatory activity for the subsidiary and submitted data gathered by the subsidiary to the FDA in support of the NDA. The DOJ alleges that both Forest and its subsidiary received FDA notice of a distribution phase-down schedule, yet "a senior manager" of the subsidiary decided to continue distributing the unapproved drug in quantities exceeding the FDA's schedule.

Later, when the FDA inspected the subsidiary's manufacturing plant, it found problems with test conditions, and employees gave false statements about equipment that they then corrected the following day with inspectors. Two days after the inspection, Forest notified the agency that it was withdrawing the NDA because stability data that the subsidiary gathered could not support it.

Shortly thereafter, Forest and its subsidiary received notice that the subsidiary's production should halt. It did so, but only after rushing through some final orders until after midnight on the day the notice was received.

A CEO of a parent corporation reasonably and necessarily relies upon executives in subordinate corporations to exercise proper judgment and to follow regulatory processes and comply with regulatory notices, directives on testing and distribution of its drugs. To find that a CEO "knew or should have known" of such facts as the day-of-notice rush to get the product out the door, or use of a humidifier in a test room in a subsidiary manufacturing plant, or that employees in that subsidiary would respond untruthfully to initial questions from FDA inspectors stretches logic.

Indeed, it appears a practical impossibility for a CEO to require such details to be cleared through him. It remains to be seen whether the OIG will make public its own reasoning behind the notice to exclude and any evidence upon which it relies to exclude the CEO. Whether the OIG applied its presumptive test that he "knew or should have known" or whether it applies the non-presumptive exclusion factors outlined in the guidance will make this record of decision very closely watched.

LEGAL, ETHICAL AND BUSINESS CONSIDERATIONS AT THE TOP

Decision-making for the corporation

The new exclusion paradigm presents profound new challenges in the resolution of corporate investigations or charges. The individuals who make corporate decisions now face a significant conflict of interest with their employer.

Agreeing to plead the company presents personal risk of exclusion for the company's leadership, even if those individuals do not face criminal or civil sanction themselves. Now that the OIG has articulated how broadly it intends to use its Section (b)(15) authority, it will be increasingly difficult to identify individuals who can make impartial decisions for the company.

Can only managers and executives who joined the company after the conduct in question make decisions about resolving it? Must boards of directors have a committee of only independent or outside members to approve such decisions?

The degree to which individuals are willing to make decisions for their corporate employers around resolving investigations and threatened or actual prosecutorial action will present serious questions for companies until the OIG clarifies its standards for pursing individuals.

Notifying individuals of their risk

The new risks for individual citizens of the corporate world raise questions of the extent to which a company should help its executives and managers understand and manage that risk. When an investigation arises or charges are brought, does a company have an obligation to inform managing employees of their potential exclusion risk? Do corporate executives and managers now need counsel at an earlier stage in the case and before they participate in decisions to investigate internally and resolve matters on behalf of the company?

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The answers to these questions will require an analysis of many of the same factors the OIG will examine. Which corporate positions had authority over the conduct in question? What did the individuals who held those positions at the time of the conduct do to prevent and actively supervise those who acted wrongly? And, if they learned of the conduct, what steps did they take in response?

All these inquiries will strain corporate resources since the need for support will extend not only to those individuals most directly involved in the conduct at issue but also to those above them in the chain of authority.

From outward appearances, the notice of intent to exclude Forest's CEO was a surprise to him and his company. If this is the case, pressure may be brought upon the OIG to develop a system in which individuals and their counsel may learn well in advance of any official public notice that they are under examination so that they may take appropriate steps to gather information relevant to the exclusion factors, prepare a defense and begin negotiations with the OIG.

Navigating the exclusion process

The exclusion process presents substantial challenges to those seeking to defend individuals whom the OIG targets for

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exclusion. Individuals have no formal process for challenging exclusion under Section (b)(15) until after a notice of intent to exclude has been issued. At present, the only formal opportunity to create a record is during the 30 days after this notice, when the individual may submit written evidence that exclusion is not appropriate. Indeed, this process does not include mechanisms to develop the individual's records of defense.[12]

How does individual counsel acquire information when witnesses and internal investigations are controlled by the company? What would be effective substantive defenses to a Section (b)(15) exclusion under the new guidance factors? It is not clear what is sufficient to demonstrate that misconduct was "impossible to prevent" or that the individual facing exclusion exercised "extraordinary care."

The only defense that may be readily provable by the individual is that his authority in the corporation does not rise to the level of a managing employee. In short, the exclusion process offers small comfort to those within the penumbra of the OIG's new shadow.

CONCLUSION

Pharmaceutical industry executives now face an unprecedented level of personal exposure for corporate conduct. The limited available defenses to the senior leadership of a sanctioned company will loom large for executives considering resolution of allegations against the corporation.

So long as the OIG appears willing to use its exclusion authority to end the careers of individuals who had no reason to know of corporate misconduct, the agency's efforts to take it to the top may leave pharmaceutical industry executives nowhere to go but down. WJ

NOTES

[1] Ricardo Alonso-Zaldivar, *Feds Now Target Execs, Not Just Companies, in Health Frauds,* Associated Press, May 31, 2011.

[2] 42 C.F.R. § 1001.10.

[3] *See* HHS-OIG Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs (September 1999), *available at* http://www.oig.hhs.gov/fraud/alerts/effect_of_exclusion.asp.

[4] 42 U.S.C. § 1320a-7(b)(1).

[5] *See United States v. Park*, 421 U.S. 658 (1975).

[6] *Id.* at 673-74.

[7] 755 F. Supp. 2d 98 (D.D.C. 2010).

[8] *See* Guidance on Implementation of Permissive Exclusion Authority (October 2010) *available at* http://www.oig.hhs.gov/fraud/exclusions.asp.

[9] *See id*.

[10] *See* OIG fact sheet on Forest Laboratories Inc. and the inspector general's exclusion, *available at* http://oig.hhs.gov/publications/docs/press/2011/factsheet_051011.asp.

[11] Although many have expressed surprise at the "delay" in issuing the notice of intent to exclude in light of Forest Pharmaceuticals' guilty pleas in November 2010, the OIG's general practice is to initiate exclusion proceedings only after sentencing. Forest's CEO received his notice shortly after Forest Pharmaceuticals was sentenced in March 2011.

[12] *See* generally, 42 C.F.R. Section 1001.2001.

Virginia Gibson (left), a trial lawyer at **Hogan Lovells** in Philadelphia, focuses on health care fraud and abuse litigation and counseling, federal and state False Claims Act litigation, and white-collar criminal defense. **Eliza Andonova**'s (center) practice at the firm in Washington focuses on white-collar criminal defense, government investigations, civil False Claims Act litigation, and health care fraud and abuse. **Danielle Drissel**'s (right) practice at the firm in the Washington office focuses on health care issues, with an emphasis on fraud and abuse law and regulatory compliance.

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