



HEALTH CARE FRAUD REPORT



Reproduced with permission from Health Care Fraud Report, 15 HFRA 105, 01/26/2011. Copyright © 2011 by The Bureau of National Affairs, Inc. (800-372-1033) <http://www.bna.com>

OIG Exclusions and Individual Accountability: Key Developments for Executives in 2010 Will Have a Lasting Impact in 2011 and Beyond



LISA C. DYKSTRA, HOWARD J. YOUNG, AND
M. ERIN RODGERS SCHMIDT

Corporate health care executives, beware. Federal enforcement authorities in 2010 took aim at owners, officers and other health care executives with newfound vigor, and 2011 is likely to be no different.

This article briefly explains some of the more notable statements and developments in this area in 2010 that portend choppy waters ahead for some health care owners and executives, including:

Dykstra is a partner with Morgan Lewis in Philadelphia. She can be reached at (215) 963-5699 or ldykstra@morganlewis.com. Young is a partner in the firm's Washington office. He can be reached at (202) 739-5461 or hyoung@morganlewis.com. Schmidt is an associate in the Philadelphia office. She can be reached at (215) 963.5163 or mrodgersschmidt@morganlewis.com.

- Congressional testimony and other public statements by federal enforcement agency officials that highlight increased focus on individual accountability and exclusions;
- Passage of H.R. 6130, "Strengthening Medicare Anti-Fraud Measures Act of 2010" by the House in September 2010, likely to be reintroduced in the 112th Congress;
- Publication of Office of Inspector General for the U.S. Department of Health and Human Services ("OIG") *Guidance for Implementing Permissive Exclusion Authority* in October 2010; and
- The Dec. 13, 2010, decision of the U.S. District Court for the District of Columbia affirming HHS Secretary Kathleen Sebelius's decision (acting through the OIG) to exclude three Purdue Frederick executives as responsible corporate officers after they were convicted for misdemeanor misbranding.

When taken as a whole, these developments reflect that health care executives and their legal advisors begin 2011 with a shifted landscape full of jagged edges.

Given the current landscape, 2011 will likely be marked by expanded action by various government entities to hold individual owners, officers, and other health care executives individually accountable for fraud and abuse in the health care companies they own and lead.

Government Officials Warned of an Increased Focus on Individual Accountability in Statements and Testimony Throughout 2010

On March 4, 2010, HHS Inspector General Daniel R. Levinson testified before the House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies regarding efforts to combat health care fraud, waste, and abuse in Medicare and Medicaid.

Levinson testified that “OIG is . . . using our administrative authorities to hold responsible individuals accountable for fraud, including . . . responsible corporate officials whose companies have committed fraud.”¹

Levinson amplified his comments in a keynote address to the Health Care Compliance Association Annual Compliance Institute on April 19, 2010. Regarding “Individual Accountability,” Levinson’s statements highlighted OIG’s focus on “holding Responsible Corporate Officials accountable for health care fraud.”² The speech laid out the rationale for individual accountability under the responsible corporate officer doctrine as outlined in *United States v. Park*.³ Levinson specifically highlighted the exclusion of the three Purdue executives—the chief executive officer, the general counsel, and the chief medical officer—as evidence of the responsible corporate officer doctrine being applied “extensively in a variety of criminal cases involving public welfare statutes.”

Similarly, on June 15, 2010, Lewis Morris, chief counsel to the HHS Inspector General, testified at a House Ways and Means Subcommittee on Health hearing on Reducing Fraud, Waste and Abuse in Medicare and discussed executive accountability in response to questions from Rep. Lloyd Doggett (D-Texas).

Morris testified about the OIG’s views on changing the “approach that corporate America takes to the integrity of our system” and stated that a challenge “we need to address is having executives understand that

they will be held personally accountable for schemes that are then hatched and pushed downstream.”

Morris emphasized work by both the OIG and DOJ to “change corporate cultures . . . by focusing on individuals.” Morris specifically referenced Fortune 500 companies in his remarks and noted that these companies should “understand that they will be treated the same way as anyone else who abuses our program.”⁴

Assistant Attorney General Tony West echoed this approach in his Oct. 20, 2010, speech to the Pharmaceutical Regulatory and Compliance Congress in Washington, D.C. West stated that “where the facts and law allow, the civil division [or DOJ] will pursue the individuals responsible for illegal conduct just as vigorously as we will companies.”⁵ West’s comments were delivered the very day that OIG announced its *Guidance for Implementing Permissive Exclusion Authority* for owners, officers, or individuals with a control interest in sanctioned entities.

Perhaps the most direct comments came from Eric Blumberg, Food and Drug Administration litigation chief, in an October 2010 interview in which he confirmed that the FDA is “looking for cases to use what is known as the *Park Doctrine* as a tool to ‘change the corporate culture’ of firms that have thus far shrugged off other penalties.”⁶ Blumberg stated:

I don’t know when, where or how many cases will be brought . . . but if you are a corporate executive—or counsel advising such a client—I would not wait for the first case to decide now is the time to comply with the law. They won’t get a mulligan on their conduct.

Blumberg further advised executives to “take this seriously” and “find out what is going on in the marketing and sales divisions of their companies.”

With respect to the large-dollar settlements by large pharmaceutical companies, Blumberg noted “[i]t is clear that these fines are not working here. . . . We need to put something else on the scale to make people think twice, three times, before they promote drugs for unapproved uses.”

His proposal for getting “executives’ attention”? “A few cases in which we have convicted two-legged defendants.” Indeed, by late 2010, we are starting to see increased use of FDA’s permissive debarment authority against individuals, even though unrelated to off-label promotion.

This focus on individual accountability can be measured by more than these words alone: as reported in OIG’s *Semiannual Report to Congress*, in fiscal year

¹ *Combating Health Care Fraud and Abuse: Hearing Before the Subcomm. on Labor, HHS, Educ. and Related Agencies of the H. Comm. on Appropriations*, 111th Cong. 6 (Mar. 4, 2010) (testimony of Daniel R. Levinson, Inspector Gen. of HHS), available at <http://oig.hhs.gov/testimony/docs/2010/3-4-10LevinsonHAppropsSub.pdf>.

² Daniel R. Levinson, Summary of IG Compliance Keynote Address to the Health Care Compliance Association, at 5-6 (Apr. 19, 2010) at <http://oig.hhs.gov/testimony/docs/2010/HCCAIGKeynoteSummary.pdf>. Specifically, the highlights state: “[u]nder the ‘responsible corporate officer’ doctrine, corporate officers are subject to both civil and criminal liability for corporate violations of statutes affecting public welfare. Liability as a responsible corporate officer does not turn upon a corporate officer’s approval of wrongdoing, but rather on whether the officer had, by reason of his or her position in the corporation, responsibility and authority either to prevent, or promptly correct, the violation at issue, and the officer failed to do so. *United States v. Park*, 421 U.S. 658, 673-674 (1975).”

³ 421 U.S. 658, 673-674 (1975).

⁴ See Press Release, Rep. Pete Stark, Ways and Means Hearing Focuses on Efforts to Combat Fraud, Waste, and Abuse In Medicare (June 15, 2010), http://www.stark.house.gov/index.php?option=com_content&view=article&id=1948.

⁵ See Nina Youngstrom, *New Inspector General Guidance Confirms that Individuals will be Accountable for Organizational Fraud*, AIS HEALTH (Nov. 12, 2010), available at <http://www.aishealth.com/Bnow/hbd111210.html>.

⁶ Christopher K. Hepp, *Big Pharma Executives Facing Legal Threat*, PHILA. INQUIRER, Oct., 31, 2010, available at http://www.philly.com/inquirer/business/homepage/20101031_Big_Pharma_executives_facing_legal_threat.html.

2010, OIG excluded 3,340 individuals and organizations from participation in federal health care programs.⁷

This is an increase by more than 700 exclusions over the 2,556 individuals and organizations excluded by the OIG in fiscal year 2009.⁸

No one who has been heeding public statements and testimony of DOJ, OIG, and FDA officials should be surprised with these increased figures. With an increase in health care criminal prosecutions and convictions comes more mandatory exclusions, but OIG also appears to be exercising its discretionary (permissive) exclusion authorities with greater vigor.

Congress Sought to Expand Exclusion Authority

In a year marked by extensive discussion of health care-related legislation, and the enactment of the Patient Protection and Affordable Care Act (PPACA), Congress acted to expand the authority for excluding certain individuals and entities in two ways.

First, although it was repealed as of Dec. 15, 2010, section 6502 of PPACA would have imposed mandatory exclusion by state Medicaid agencies as of Jan. 1, 2011. Section 6502 would have mandated that state Medicaid agencies exclude individuals or entities who had not returned Medicaid overpayments, had been suspended or excluded from Medicaid, or had been affiliated with an individual or entity excluded from the program.

Section 6502 was repealed because, after its passage, the unintended and potentially crippling consequences of implementing mandatory exclusion were seen as posing a risk to patient access and care as well as to law enforcement's ability to investigate and resolve corporate fraud cases.⁹

Though mandatory exclusion by state Medicaid agencies was not viewed as the best way forward, Congress made other efforts in 2010 toward expanding OIG's authority to exclude individuals and affiliated entities.

On Sept. 22, 2010, with little fanfare or debate, and after advocacy over the summer by the OIG, the House passed H.R. 6130, the "Strengthening Medicare Anti-Fraud Measures Act of 2010."

The bill sought to give the OIG broadly expanded new authority to exclude corporate executives from federal health care programs if a company once managed by the executive was convicted for fraud that occurred on that executive's watch. The legislation would have also conferred upon OIG broad new authority to ex-

clude an "affiliated entity" of a sanctioned (i.e., convicted or excluded) entity.

Under current law, OIG only has the authority to permissively exclude individuals who at the time of the proposed exclusion own, control, or direct a sanctioned entity.¹⁰

Individuals with a direct or indirect ownership or control interest must "know or should know" of the action for which the entity was sanctioned. By contrast, individuals who are officers or managers of the sanctioned entity may be excluded merely on the basis of their status as a current officer or managing employee of the sanctioned entity.

The House bill would have amended the Social Security Act¹¹ to expand markedly the OIG's permissive exclusion authority to individuals and organizations who are, or were, affiliated with "sanctioned entities"¹² during the period in which the sanctioned conduct occurred. The bill would have permitted derivative exclusion of a corporate executive or affiliated entity merely by virtue of their status or relationship to the sanctioned entity.¹³

This new authority would have expanded the OIG's exclusion authority in two critical ways. First, it would have permitted the OIG to exclude organizations (not just individuals) affiliated with the entity that is convicted or excluded, and not just the sanctioned entity.

Second, the new provisions would have allowed the OIG to exclude individuals and affiliated entities even if they are no longer affiliated with the sanctioned entity; rather, it would be sufficient if the individual had been in an executive position or the entity was affiliated at the time of the sanctioned conduct.

The bill was sponsored by Rep. Fortney Pete Stark (D-Calif.), chairman of the House Ways and Means Subcommittee on Health, and co-sponsored by Rep. Wally Herger (R-Calif.), the subcommittee's ranking Republican member, along with twenty other members.

When introducing the bill on Sept. 15, 2010, Stark explained that the bill was designed to "provide the Inspector General with . . . additional tools . . . to better

¹⁰ 42 U.S.C. § 1320a-7(b)(15).

¹¹ Specifically, section 2 of H.R. 6130 sought to amend Section 1128(b)(15) of the Social Security Act (42 U.S.C. 1320a-7(b)(15)).

¹² Under current law, a "sanctioned entity" is an entity convicted of any offense for which mandatory exclusion is required (including program-related crimes, patient abuse convictions, a felony conviction for health care fraud, and felony conviction relating to controlled substances), or for misdemeanor fraud (in health care or any government program), obstruction of an investigation, or misdemeanor conviction for controlled substances, or where the entity has been excluded from Medicaid or a State health care program.

¹³ The bill defined Individuals or Entities Affiliated with a Sanctioned Entity as (i) any individual who: (I) is a person with an ownership or control interest . . . in a sanctioned entity or an affiliated entity of such sanctioned entity (or was a person with such an interest at the time of any of the conduct that formed a basis for the conviction or exclusion . . .); and (II) knows or should know . . . (or knew or should have known) of such conduct; (ii) any individual who is an officer or managing employee . . . of a sanctioned entity or affiliated entity of the sanctioned entity (or was such an officer or managing employee at the time of any of the conduct that formed a basis for the conviction or exclusion . . .); (iii) Any affiliated entity of a sanctioned entity.

⁷ Press Release, OIG News, *OIG Reports \$25.9 Billion in Savings and Expected Recoveries in FY 2010* (Dec. 15, 2010), <http://oig.hhs.gov/publications/docs/press/2010/sar2010press.pdf>. Additionally, the OIG reported 647 criminal actions against individuals or organizations that engaged in crimes against HHS programs and 378 civil actions, including False Claims Act ("FCA") and other suits.

⁸ Press Release, OIG News, *OIG Reports \$20.97 Billion in Savings and Recoveries in FY 2009* (Dec. 3, 2009), <http://oig.hhs.gov/publications/docs/press/2009/SemiannualFall2009PressRelease.pdf>.

⁹ Section 205(a) of the Medicare and Medicaid Extenders Act of 2010, signed into law on December 15, 2010, repealed the affiliate exclusion provision. See *Medicare Doc Pay Fix Would Repeal PPACA Medicaid Exclusion Provision*, BNA's HEALTH CARE DAILY REPORT (Dec. 14, 2010) available at http://news.bna.com/hdln/HDLNWB/split_display.adp?fedfid=18830637&vname=hcenotallissues&fn=18830637&jd=a0c5r1c8y2&split=0.

protect Medicare.”¹⁴ Stark noted the importance of these new changes as protecting “Medicare from executives who circumvent exclusion by moving to another company” and empowering OIG with a “new tool in its arsenal” to combat the issue of parent/shell corporate structures that permit a shell organization to be excluded with no real operational impact on the parent company.

Although the bill was not taken up by the Senate in this past 111th Congress, as recently as Dec. 23, 2010, Stark announced his intention to ensure the bill becomes law in the next Congress.¹⁵

Health care companies and the executives and officers who lead them should pay close attention to this legislative issue in the future as the bill, if enacted, would make it much easier for the OIG to exclude individuals or affiliated entities in the future, even absent evidence of personal knowledge, involvement, or complicity in the misconduct.

Inasmuch as the OIG asserts the exercise of its discretion in permissive exclusion actions is not reviewable (unlike the period of exclusion), congressional efforts to further expand the scope of OIG’s permissive exclusion authority should be monitored as OIG’s “remedial” authority under current law is expansive.

Legal challenges to OIG’s exercise of its exclusion authority have proven difficult to challenge once the OIG elects to initiate an exclusion action given the limited authority of Administrative Law Judges under HHS exclusion regulations and *Chevron* deference applied by federal courts.¹⁶

New OIG Guidance Explains a Rebuttable Presumption of Exclusion for Executives Who Knew or Should Have Known of Fraud or Other Sanctioned Conduct

The legislative developments above must be understood in the broader context of another recent development in this area. On October 20, 2010, OIG published non-binding *Guidance for Implementing Permissive Exclusion Authority*, related to its use of OIG’s existing permissive exclusion authority under 42 U.S.C. § 1320a-7(b)(15) related to individuals with an ownership or control interest in a sanctioned entity or an officer or managing employee of such an entity (“OIG (b)(15) Guidance”).¹⁷

The Guidance signals the OIG’s desire to increase use of its permissive exclusion authority even if that section of the law is not broadened by Congress.

The issuance of the OIG (b)(15) Guidance underscores yet again that the OIG intends to pursue individual corporate executives with zeal.

¹⁴ 156 CONG. REC. E1637-1638 (Sept. 15, 2010) (statement of Rep. Stark).

¹⁵ Press Release, Rep. Pete Stark, Stark Criticizes Anonymous Republican Senators for Holding Up Medicare Anti-Fraud Bill (Dec. 23, 2010), http://www.stark.house.gov/index.php?option=com_content&task=view&id=2111&Itemid=84.

¹⁶ Whether such authority raises constitutional concerns is outside the scope of this article.

¹⁷ OIG, *Guidance for Implementing Permissive Exclusion Authority*, Oct. 20, 2010, available at http://oig.hhs.gov/fraud/exclusions/files/permissive_excl_under_1128b15_10192010.pdf.

Among the clear signals in the OIG (b)(15) Guidance is direction to law enforcement agents to develop, in their investigative plans, evidence that demonstrates individuals, and not just corporations, knew or should have known of the misconduct that gave rise to a conviction or exclusion of the entity.

Additionally, the OIG (b)(15) Guidance advises that the OIG will apply a rebuttable presumption of exclusion where there is “evidence that the individual knew or should have know” of the sanctioned conduct. In assessing the significant factors that weigh against the presumption of exclusion, the OIG will look to (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.

The OIG appears to have applied these principles when it excluded Marc S. Hermelin, former chairman of the board of directors of K-V Pharmaceutical Co., from participation in federal health care programs after a K-V subsidiary (Ethex Corp.) pleaded guilty to two felony counts of failing to report manufacturing problems to the FDA.¹⁸

Hermelin was not convicted of any crime. Nonetheless, the OIG excluded the now former majority shareholder and KV Pharmaceutical director. To avoid having K-V Pharmaceutical itself excluded by OIG, Hermelin voluntarily resigned from the board, resigned from family trusts holding company stock, and has agreed to divest his ownership interests in the company’s voting stock.

This development suggests the very real possibility that current and former executives and officers of health care companies may face not just criminal and civil investigations into and sanctions for alleged health care fraud—but the real potential of losing their own ability to remain in the health care field if they were “on the watch” when the fraud occurred.

OIG’s Exclusion of Purdue Executives Under a Responsible Corporate Officer Doctrine Is Affirmed by DC’s Federal District Court

OIG’s intention to pursue with vigor corporate health care owners and executives was perhaps further buoyed in late December 2010 with the decision by a federal district court in D.C. to affirm OIG’s exclusion of three Purdue Frederick executives.¹⁹

In 2007, Purdue Frederick Company (“Purdue”) pleaded guilty to one count of felony misbranding of OxyContin with intent to defraud or mislead, a violation of the Food, Drug and Cosmetic Act (FDCA).

Three Purdue executives pleaded guilty to the no-fault, strict liability misdemeanor charge of misbranding under the FDCA (21 U.S.C. §§ 331(a) and 333(a)(2)) based on their status as responsible corporate officers. Purdue and the executives were convicted pursuant to their pleas.

In connection with the executives’ plea agreements, the executives disgorged a collective total of \$34.5 mil-

¹⁸ See Former K-V Pharmaceutical Board Chairman Excluded by HHS, Thompson Food & Drug Regulation Newsbriefs (Nov. 17, 2010) available at <http://www.thompson.com/public/newsbrief.jsp?cat=FOODDRUG&id=3237>.

¹⁹ *Friedman v. Sebelius, Sec’y, Dep’t of Health and Human Servs.*, No. 09-2028, Memorandum Op. and Order (D.D.C., Dec. 13, 2010).

lion, paid fines, were sentenced to probation and ordered to do community service. In 2008, however, the executives received an additional punishment: the OIG notified each executive that he was being individually excluded from participation in all federal health care programs for a 20-year period.

The executives appealed OIG's decision but, to date, the HHS Administrative Law Judge, Departmental Appeals Board (DAB) Appellate Division, and federal district court in D.C. have upheld the exclusions (although the 20-year period of exclusion was reduced to 12 years).

The Aug. 28, 2009, decision of the DAB Appellate Division provides a telling picture of the potential for more exclusions of responsible corporate officers—under *United States v. Dotterweich*²⁰ and *United States v. Park*²¹—in the future.

The DAB panel clearly upheld that the OIG's exclusion authority reaches individuals convicted under the responsible corporate officer doctrine.

In other words, the OIG may exclude an individual based on the fraud of his or her company, regardless of whether the individual was convicted of fraud him or herself, as long as the individual had responsibility and authority either to prevent the fraud in the first instance or to promptly correct certain conduct resulting in the fraud.²²

For individual exclusion, the OIG need only establish that an individual's offense was one "relating to fraud"—specifically that there is a nexus or common sense connection between the conduct giving rise to the individuals' offense and the fraud for which the company was convicted.²³

The DAB panel dismissed the Purdue executives' arguments that they were not individually culpable for the fraud or an ongoing threat to the health care system and wrote that their individual convictions—even if only for a misdemeanor—were "as a minimum, a culpable omission."²⁴

The Dec. 13, 2010, federal district court Opinion and Order affirming the DAB decision and the OIG's exclusion of the three executives clearly rejected the executives' arguments that the OIG's exclusion authority does not reach individuals convicted solely by virtue of their status as responsible corporate officers.

In doing so, the court noted that the underpinning of a case based on "responsible corporate officer" status cannot rest on position within corporate hierarchy alone. Instead, the government must have a prima facie case that the individual had the responsibility and authority to prevent (in the first instance) or promptly respond to a violation.²⁵ Attorneys for the three executives have announced that the executives plan to appeal the court's decision.²⁶

Lessons From 2010: Navigating the Exclusion Landscape in 2011

The year 2010 was marked by significant attention to, and developments related to, holding individual health care executives accountable. The palpable shift of enforcement agency focus on health care executives may have two practical results.

First, in connection with "global" resolutions involving health care organizations, no matter what health industry sector, defense counsel may push harder for a release of the (b)(15) exclusion authority for individuals (and if HR 6130 becomes law, affiliated entities) from the OIG.

In the last decade, the OIG has resisted mightily or refused altogether to provide such individual releases in global fraud resolutions. This natural tension may delay global resolutions and may result in pressure on corporations to leave its corporate executives "twisting in the wind" should a corporate resolution become strategically paramount.

Second, corporate executives may proactively pursue more robust compliance controls and accountability, including the use of internal compliance certifications from individuals who report up to them. In doing so, the "not on my watch" efforts may help minimize OIG's use of its (b)(15) permissive exclusion authority as to those individuals.

From a policy perspective, this may be exactly what the OIG hopes to achieve when flexing its 1128(b)(15) exclusion muscle. At a minimum, the developments in 2010 should make corporate executives, owners, and directors sit up and take note—federal authorities are looking to bring cases against individuals and to exclude them from health care programs.

²⁰ 320 U.S. 277 (1943).

²¹ 421 U.S. 658 (1975).

²² See *Goldenheim, et al., v. Inspector General*, DAB No. 2268, 2009 WL 2957956, at 6 & 8 (HHS Aug. 28, 2009).

²³ *Id.* at 8.

²⁴ *Id.* at 17.

²⁵ *Friedman v. Sebelius, Sec'y, Dep't of Health and Human Servs.*, No. 09-2028, Memorandum Op. and Order, 18-19 (D.D.C. Dec. 13, 2010).

²⁶ See Leigh Kamping-Carder, *Purdue Execs Can't Shake Ban From Federal Funds*, LAW 360 (Dec. 14, 2010), available at <http://www.law360.com/web/articles/215110>.