Rx for Fraud

The Feds Get Personal

BY THOMAS E. ZENO AND KIMBERLY J. DONOVAN

The federal government opened a new front in its war against health care fraud by proposing to ban Howard Solomon from participating in all federal health care programs simply because he was a long-time corporate chairman. Solomon, 83 years old and the chief executive officer of Forest Laboratories since 1977, presided over the company's transformation from a maker of vitamins into a $4 billion global pharmaceutical company. Solomon was not convicted of a health care fraud offense. He was not charged with a health care fraud offense. In fact, Solomon had not even been notified by the government that he was a target of the proposed ban. Rather, the government waited to announce the ban until *after* a wholly-owned subsidiary of Forest Laboratories entered guilty pleas related to marketing its medications.

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As part of the pleas, Forest Laboratories paid the government $313 million and agreed to a corporate integrity agreement (a sort of corporate probation).

The government wanted to make it personal. The government wanted to use its administrative authority to exclude Solomon despite the fact that he had *no* individual involvement in the criminal conduct of the subsidiary. This article will explore how and why the government got to this point and what you can do to protect your executive and corporate clients from exclusion. In addition, this article will identify the hidden dangers that may be lurking behind a civil investigative demand and how you can address them. Finally, this article will emphasize the importance of an effective corporate compliance program in identifying, limiting, and resolving health care fraud problems that your clients may face.

Moving Beyond Corporate Integrity Agreements

In its battle against health care fraud, the government wants to force corporations to take compliance more seriously. The prosecution of fraud in the pharmaceutical industry is a notable example of this effort. The government has garnered an impressive array of convictions and monetary settlements in the past few years by employing 21 U.S.C. § 331, the off-label marketing statute that prohibits promoting medications for a use not approved by the United States Food and Drug Administration (FDA). For instance, in 2009, the government concluded its investigation of Pfizer Inc. and its subsidiary Pharmacia & Upjohn Company Inc. with the largest health care fraud settlement in history—a total of $2.3 billion in criminal fines and civil penalties for intentionally marketing the drugs Bextra, Geodon, Zyvox, and Lyrica for off-label uses. Pharmacia & Upjohn Company Inc. agreed to plead guilty to a felony. The company also agreed to an expansive corporate integrity agreement (CIA) with the Office of the Inspector General (OIG) of the Department of Health and Human Services. The CIA required the company to implement procedures and reviews designed to detect and avoid similar conduct.

In its *Semi-Annual Report to Congress* covering the period October 2010 through March 2011, the OIG reported substantial settlements resulting from prosecutions pursuant to the off-label marketing statute. In one of the touted settlements, Allergan Inc. and Allergan USA Inc. (Allergan) agreed to pay $600 million and enter into a global criminal, civil, and administrative settlement for off-label marketing of the drug Botox. As part of this settlement, Allergan agreed to a comprehensive five-year CIA with the OIG. Among other things, the CIA required that Allergan post information on its website such as honoraria and travel provided to doctors, and that Allergan have certain executives annually certify compliance of their departments with the requirements of federal health care programs. The CIA also provided that Allergan could be excluded from federal health care programs for a material breach of the CIA.

These settlements highlight the OIG's effort to change corporate culture by negotiating CIAs with companies seeking to resolve health care fraud investigations. Under the terms of a CIA, the OIG requires the company to adopt a compliance and ethics program designed to discover existing fraudulent conduct and to prevent future fraudulent conduct. Although CIAs have been hailed as a way to change corporate culture, there is a lingering concern that executives view CIAs as merely a cost of doing business and do not take the detection and prevention of fraud seriously. Even an investigation that results in a corporate guilty plea to a felony may not be considered a significant deterrent in preventing future fraud because the company cannot go to jail. It merely pays a fine.

Both Inspector General Daniel R. Levinson and Lewis Morris, chief counsel to the inspector general, expressed this concern to Congress on March 2, 2011, when they testified that settlements in the billions of dollars are not a sufficient deterrent to change corporate culture and that large companies rarely are excluded from federal and state health care programs because of the potential negative impact on patient care. As a result, the OIG intends to exclude corporate executives from federal health care programs by using the delegated administrative authority of 42 U.S.C. § 1320a-7 "under a broader range of circumstances." Levinson and Morris explained that the OIG wants:

> to attempt to alter the cost-benefit calculus of the corporate executives who run these companies. By excluding the individuals who are responsible for the fraud, either directly or because of their positions of responsibility in the company that engaged in fraud, we can influence corporate behavior without putting patient access to care at risk.

(Testimony of Daniel R. Levinson, Inspector Gen., before U.S. Senate Comm. on Fin. Hearing on Prevent-

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ing Health Care Fraud: New Tools and Approaches to Combat Old Challenges 7 (Mar. 2, 2011), http://tinyurl.com/4fuabkq; Testimony of Lewis Morris, Chief Counsel to Inspector Gen., before Subcomm. on Oversight of U.S. House Comm. on Ways & Means Hearing on Improving Efforts to Combat Health Care Fraud 6 (Mar. 2, 2011), http://tinyurl.com/79dwjez.)

Permissive Exclusion of Corporate Executives Under the *Park* Doctrine

According to its *Semi-Annual Report to Congress*, the OIG excluded 883 individuals and organizations during the period October 2010 through March 2011. Many of these individuals were subject to "mandatory exclusion" because they were convicted of a felony. (42 U.S.C. § 1320a-7(a).)

In addition to mandatory exclusion, the statute provides 16 reasons that the OIG can exercise its discretion to impose "permissive exclusion" for a number of years, which are described in 42 U.S.C. § 1320a-7(b)(1) through (b)(16). This article will discuss the OIG's reliance upon paragraph (b)(1), which was used as the basis to exclude executives of the Purdue Frederick Company, and paragraph (b)(15), which was used as the basis to propose the exclusion of Howard Solomon of Forest Pharmaceuticals. The OIG's expanded use of these subsections is based on the doctrine established in *United States v. Park*, 421 U.S. 658, 667–76 (1975).

In *Park,* the US Supreme Court upheld the conviction of an executive who had "responsibility and authority either to prevent in the first instance, or promptly to correct" a violation of certain provisions in the Food, Drug, and Cosmetic Act, regardless of whether the executive intended to cause the violation or even was aware of it.

Defendant Park was the chief executive officer of Acme Markets Inc., a national retail food chain with approximately 874 retail outlets, 16 general warehouses, and 36,000 employees. The government charged Acme and Park with five counts of holding food in the company warehouse in Baltimore that became adulterated when it was contaminated by rodents. Acme pled guilty, but Park went to trial.

The FDA had notified Park, who worked in Acme's Philadelphia headquarters, that there were unsanitary conditions in Acme's Philadelphia warehouse. The FDA subsequently informed Park that there were also unsanitary conditions in a Baltimore warehouse. At trial, the government proved that Park was the president and chief executive officer of the company. Park delegated "normal operating duties," including sanitation, but retained responsibility for "the big, broad, principles of the operation of the company" and seeing that all of the parts of the company "work together." As the only defense witness, Park testified that, although all of Acme's employees were, in a sense, under his general direction, certain employees were responsible for sanitation. After receiving the second FDA letter, Park conferred with the vice president for legal affairs, who informed him that the Baltimore division vice president "was investigating the situation immediately and would be taking corrective action and would be preparing a summary of the corrective action to reply to the letter." Park testified that he believed he could not have done anything more. Park was convicted and fined $250. (*Id.* at 660–64.)

The Supreme Court upheld Park's convictions stating that, in the area of food, drugs, and cosmetics:

> [t]he requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding, and perhaps onerous, but they are no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them.

(*Id*. at 672.)

This precedent, establishing what amounts to strict liability for "responsible corporate officers," has grown substantially during the past 40 years.

Purdue Executives Excluded for Misdemeanor Fraud

Because of the dire consequences they face today, modern corporate executives, such as those of Purdue Frederick Company (Purdue), can only marvel with envy at the $250 sentence imposed upon Park. Purdue pled guilty to an off-label marketing felony because of misrepresentations made to health care providers that the drug Oxycontin was less addictive and less likely to be abused than other pain medications. As a result of the felony conviction, the company paid what was, at the time, one of the largest settlements by any pharmaceutical company: a total of $600 million in criminal fines and civil monetary sanctions.

In addition to the company's guilty plea, the government demanded that three of the company's executives—the president and CEO, the executive vice president of medical and scientific affairs and former

OIG EXCLUSIONS

The OIG tracks and publicizes exclusions in an online database at http://exclusions.oig.hhs.gov.

executive vice president of worldwide research and development, and the executive vice president and chief legal officer—plead guilty to misdemeanor off-label marketing as "responsible corporate officers" under the *Park* doctrine. These executives agreed to the plea, but none of the executives admitted to personal knowledge of the misconduct. Under the *Park* doctrine, no criminal intent was required for the conviction and none was admitted by the executives. The executives pled guilty solely because their positions made them ultimately responsible for preventing the misbranding or promptly correcting it.

Four months *after* the three executives were sentenced, the OIG informed them of its intent to exclude them from participating in any capacity in any federal health care program, pursuant to 42 U.S.C. § 1320a-7(b)(1). The permissive exclusion authorized by paragraph (b)(1) allows the OIG to exclude an individual convicted of a "misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct."

Recognizing that their established careers in the health care industry were at stake, the executives opposed exclusion vigorously. The OIG considered the submissions of the executives, but decided to exclude them for 20 years. The executives pursued administrative appeals, which upheld the OIG's decision but reduced the exclusion term to 12 years.

The executives appealed to the US District Court for the District of Columbia, arguing that exclusion is not permitted where the convictions are based solely on their positions within the company rather than on their personal conduct. (*See* Friedman v. Sebelius, 755 F. Supp. 2d 98 (D.D.C. 2010).) The district court rejected their argument because the executives were properly convicted under the *Park* doctrine as responsible corporate officers for failing to prevent or correct the fraud of off-label marketing. The district court found that personal knowledge of the false marketing was not required. Using the substantial evidence standard of review, the district court upheld the permissive exclusion because the convictions were related to the fraud detailed in the statement of the offense adopted at the time of the guilty pleas. As of the submission of this article for publication, the decision of the district court is pending appeal to the District of Columbia Circuit Court of Appeals. (*See* Friedman v. Sebelius, No. 11-5028 (D.C. Cir. filed Feb. 8, 2011).)

OIG's Preparation to Exclude Executives Based on Their Positions

The Purdue executives probably felt whipsawed. They agreed to plead guilty to a misdemeanor as responsible corporate executives pursuant to the *Park* doctrine, not knowing that the government would use its permissive discretion pursuant to paragraph (b)(1) to exclude them from working in the health care industry. More was on the way, however. The government was laying the groundwork to use 42 U.S.C. § 1320a-7(b)(15) to exclude executives and officers even if they had not pled guilty.

In their congressional testimony in March 2011, Inspector General Levinson and Chief Counsel Morris emphasized the OIG's discretion to exclude corporate officers responsible for corporate misconduct pursuant to paragraph (b)(15). The OIG has relied upon this paragraph only approximately 30 times since 1996, mostly against individuals who controlled small businesses. Both men testified that the OIG intended to expand the application of paragraph (b)(15) to exclude "executives of large complex organizations like a drug or device manufacturer." (Testimony of Lewis Morris, supra, at 6; see Testimony of Daniel R. Levinson, supra, at 7.)

Paragraph (b)(15) applies to two categories of individuals: (i) owners who knew or should have known of the corporate misconduct and (ii) officers, managers, directors, or administrators who have managerial or operational control or who have a direct or indirect role in the day-to-day operations of the entity. (*See also* 42 C.F.R. § 1001.1051.) As to the second category, there is no requirement that the officers or managing employees with operational control knew or should have known about the corporate misconduct, which is consistent with the *Park* doctrine.

The OIG will consider the following factors when deciding whether to exclude officers or managing employees with operational control:

GOVERNMENT SEEKS PUBLIC'S AID TO FIGHT FRAUD

The government is recruiting individual citizens to help detect and report health care fraud. Some of its current tactics include:

- Interstate billboards to raise awareness about health care fraud and encourage beneficiaries to report fraud.
- "Senior Medicare Patrol," a well-organized group of volunteers, many of whom are senior citizens, charged with educating beneficiaries on how to detect and report health care fraud.
- A website—www.stopmedicarefraud.gov—that provides citizens and media with current information on health care fraud and several easy methods to report suspected Medicare fraud, including a toll-free number, an email address, a link on the website, a fax number, and a mailing address, along with a short training video on the website demonstrating a fraudster trying to get a beneficiary's Medicare information.

- **circumstances of the misconduct and seriousness of the offense**, including the nature and scope of the misconduct and any related misconduct; whether high-level management was involved in the misconduct; the sanctions imposed on the entity; whether individuals were potentially harmed by the misconduct; whether federal programs incurred financial losses; whether this is an isolated incident or pattern of wrongdoing; and whether the entity is a repeat offender;
- **individual's role in the company**, including the individual's current and former positions with the company; the individual's current managerial authority; and whether the misconduct was within the individual's chain of command;
- **individual's actions in response to the misconduct**, including any remedial or mitigating steps taken by the individual; whether these steps occurred before or after the individual suspected an investigation; whether it was impossible to prevent the misconduct; whether the individual exercised "extraordinary care" but still could not prevent the misconduct; and whether the individual cooperated with investigators and prosecutors; and
- **information about the company**, including any previous sanctions or convictions by any federal or state government; and the size and corporate structure of the company.

(*Guidance for Implementing Permissive Exclusion Authority under Section 1128(b)(15) of the Social Security Act*, Off. Inspector Gen. (Oct. 19, 2010), http://tinyurl.com/3mgep8t.)

Proposed Exclusion of Solomon

Less than two months after the congressional testimony of Inspector General Levinson and Chief Counsel Morris, the OIG used paragraph (b)(15) to propose to exclude Solomon. The potential significance of the attempt to exclude Solomon from federal health care programs pursuant to this paragraph is difficult to overstate. Unlike the executives in the *Friedman* case who had admitted to misdemeanor criminal conduct pursuant to the *Park* doctrine, Solomon had not admitted to any criminal intent or failures. The *Wall Street Journal* reported that the attempt was "raising alarms in that industry and beyond about a potential expansion of federal involvement in the business world." (Alicia Mundy, *U.S. Effort to Remove Drug CEO Jolts Firms*, Wall St. J., Apr. 26, 2011, http://tinyurl.com/63p58de.)

The case against Forest Pharmaceuticals was a textbook example of the government's antifraud efforts in the pharmaceutical industry. The terms of the settlement revealed that the government had used an array of weapons in its arsenal, beginning with qui tam relators and ending with a CIA. Forest Pharmaceuticals pled guilty to two misdemeanors: one for illegal promotion of Celexa for use in children and one for illegal distribution of Levothroid because it was an unapproved drug. The company also pled guilty to a felony for lying to the FDA during a regulatory inspection when managers reported that a portable humidifier had not been used to control humidity during the manufacturing process. Forest Pharmaceuticals paid a total of $313 million to resolve the criminal fine, civil violations of the False Claims Act, and forfeiture claims. The qui tam relators were paid approximately $14 million of the settlement proceeds, with the federal government and the states dividing the remainder of the money. The OIG required that Forest Pharmaceuticals sign a five-year CIA mandating an outside expert to monitor compliance and various other elements of a vigorous compliance program. (Press Release, Dep't Justice, Drug Maker Forest Pleads Guilty (Sept. 15, 2010), http://tinyurl.com/ctceppr.)

The OIG wanted more. Accordingly, *following* the sentencing of Forest Pharmaceuticals, the OIG notified Solomon of its intent to exclude him from federal health

MFCUS PROSECUTE PROVIDERS

The states and the District of Columbia also actively fight health care fraud. Throughout the country, Medicaid Fraud Control Units (MFCUs) concentrate exclusively on prosecuting providers who defraud the Medicaid program in their jurisdictions. Comprised of attorneys, investigators, and auditors, MFCUs generally are organized under the direction of the state attorney general or the state Office of the Inspector General.

Because of their effectiveness, MFCUs have been authorized to investigate fraud in any federal health care program if their investigation is primarily related to Medicaid. MFCUs, which operate under administrative oversight of the OIG, often team up with federal investigators and prosecutors. As the large settlements in the pharmaceutical industry demonstrate, close coordination between the federal government and MFCUs is necessary in order to reach a global settlement resolving fraud claims against Medicare and Medicaid. For instance, in the Pfizer settlement, the state Medicaid share of the civil settlement was $330 million.

MFCUs coordinate their activities on a national scale through the National Association of Medicaid Fraud Control Units (NAMFCU). Learn more at http://www.namfcu.net.

care programs. The OIG wanted to exclude Solomon as an example of its plan to alter the "cost-benefit calculus of corporate executives," a term used during the congressional testimony of Inspector General Levinson and Chief Counsel Morris. Although Solomon had not been charged with, let alone convicted of, any wrongdoing, the OIG relied upon paragraph (b)(15) and the *Park* doctrine to exercise its permissive exclusion authority based solely on Solomon's position as a "responsible corporate officer." When Solomon resolved to fight exclusion, the matter seemed poised for a showdown on the scope of the *Park* doctrine.

Suddenly, in early August 2011, the OIG dropped the exclusion action against Solomon. The letter to Solomon's counsel gave no indication of what factors influenced the OIG's decision. The OIG's letter merely said: "Based on a review of the information in our file and consideration of the information that your attorneys provided to us, both in writing and during an in-person meeting, we have decided to close this case. We anticipate no further action related to this matter. (Letter from Peter Clark, Exclusions Director, OIG, to Howard Solomon, Forest Laboratories Inc. (Aug. 5, 2011), http://tinyurl.com/d3x22q2.) The OIG website, which typically provides a treasure chest of information about activities of the OIG, did not provide any information about the closing of the case against Solomon.

Little solace can be taken by corporate officers and managers from the OIG's terse letter merely saying that it has closed the case to exclude Solomon. Because the letter does not give any indication that the OIG has changed its carefully-evolved policy to exclude responsible corporate executives, counsel should proceed as if your client may be the next target of the OIG. In fact, the government has indicated its intent to continue to exclude corporate executives beyond the pharmaceutical industry. The DOJ and FDA have announced that they will target biologics, biotechnology, and medical devices for future enforcement efforts, with executives themselves in the crosshairs. (John T. Aquino, *Prosecutors See Case Shift from Pharma to Devices, Park Doctrine Cases Coming*, BNA Health L. Resource Center (June 15, 2011), http://tinyurl.com/cld2awm.)

The FDA prepared for this new offense in February 2011 by strengthening its guidance about whether to recommend criminal prosecution for violation of FDA statutes. In section 6-5-3 of its 2011 *Regulatory Procedures Manual*, the FDA set forth its view of the *Park* doctrine:

> The Park Doctrine, as established by Supreme Court case law, provides that a responsible corporate official can be held liable for a first time misdemeanor . . . without proof that the corporate official acted with intent or even negligence, and even if such corporate official did not have any actual knowledge of, or participation in, the specific offense. . . . Misdemeanor prosecutions, particularly those against responsible corporate officials, can have a strong deterrent effect on the defendants and other regulated entities. In some cases, a misdemeanor conviction of an individual may serve as the basis for debarment by FDA. . . . Knowledge of and actual participation in the violation are not a prerequisite to a misdemeanor prosecution but are factors that may be relevant when deciding whether to recommend charging a misdemeanor violation.

(*Available at* http://tinyurl.com/bp5l7vc.)

Defending Your Clients from Exclusion

Counsel engaging in settlement negotiations with the government about a health care fraud investigation need to be acutely aware of the potential risk of exclusion. Executives should be advised of the option to obtain advice from counsel separate from the company's counsel. Because a corporate guilty plea can potentially lead to exclusion of uncharged officers and managers, counsel for the executives and the organization need to evaluate the impact of a guilty plea. Before an organization pleads guilty, all counsel should scrutinize language in the statement of the offense to reduce the quantity as well as the quality of admissions that could be used against an executive in a future administrative proceeding. Counsel for executives, even those who will not be charged, should attempt to coordinate with counsel for the organization about the scope of admissions in a corporate plea agreement in order to minimize the potential that admissions will be used not only at sentencing but also in an exclusion proceeding.

Before entering into a guilty plea, nonprosecution agreement, or civil settlement, counsel for both the organization and executives should make it standard practice to ask the government whether it will pursue permissive exclusion against anyone or the company. As evidenced by the delayed actions to exclude the Purdue executives and Solomon, a global settlement does not mean your client is safe. The request for a decision about exclusion should be made before any individual or organization pleads guilty. This request should be made even when an investigation is closed without a guilty plea because the OIG's authority to seek permissive exclusion does not require a criminal conviction. For example, under 42 U.S.C. § 1320a-7(b)(7), the OIG can seek permissive exclusion of an individual based on an administrative determination by a preponderance of the evidence that an individual committed "fraud, kickbacks, or other pro-

THE HEAT IS ON

Many recent health care fraud investigations and prosecutions are connected to HEAT (Health Care Fraud Prevention and Enforcement Action Team), the heavily publicized joint task force that coordinates interagency exchange of information, identifies trends in health care fraud, and strategizes on how to prevent and prosecute health care fraud and abuse. Medicare Strike Force Teams (strike forces) are the combined effort of the OIG, FBI, DOJ prosecutors, and state and local law enforcement. Strike forces target fraud claims submitted for particular medical equipment, drugs, or services that have unusually high billing patterns in a particular city. Operating in Miami, Baton Rouge, Brooklyn, Detroit, Houston, Los Angeles, Tampa, Dallas, and Chicago, strike force investigations have resulted in charges against more than 1,000 individuals alleged to have drained more than $2.4 billion from Medicare. Consisting of a core group of agents and AUSAs trained and specifically assigned to health care fraud investigations and prosecutions, strike forces cut in half the average time from the start of an investigation to prosecution.

Facing losses estimated from $75 to $250 billion a year, the government is significantly increasing funding to stop health care fraud in government programs. For every dollar the government spends on programs to control health care fraud and abuse, it receives an average return on its investment of $6.80. In its *Semi-Annual Report to Congress* covering the period October 2010 through March 2011, the OIG said it anticipated receiving $3.2 billion in recoveries arising from 349 criminal and 197 civil actions that were concluded during the period. In the FY 2012 proposed budget, the president proposed a $270 million increase for health care fraud and abuse control. (*See*, Testimony of Lewis Morris, Chief Counsel, OIG & Peter Budetti, Deputy Adm'r & Dir. Program Integrity, Ctrs. Medicare & Medicaid Servs., before Subcomm. on Fed. Fin. Mgmt., Gov't Info., Fed. Servs & Int'l Sec. Hearing on Harnessing Technology and Innovation to Cut Waste and Curb Fraud in Federal Health Programs (July 12, 2011), http://tinyurl.com/65nlc9t.)

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hibited activities" such as knowingly contracting with an excluded person.

Counsel should argue that a timely decision about exclusion is a matter of due process because the parties need to evaluate the true impact of a proposed agreement with the government. Although the OIG almost certainly will resist the request for an advance decision about exclusion by claiming that it cannot exercise its discretion until after the resolution of criminal and civil matters, this is not correct. When the OIG is ready to settle an investigation and accept the terms of a CIA, the OIG must know enough about the investigation to make other important decisions.

Further, the case of Michael Dinkel is precedent that the OIG will make a decision about exclusion before accepting a settlement. Dinkel was excluded under 42 U.S.C. § 1320a-7(b)(7) without a criminal conviction. As noted in the OIG press release, "Prior to the civil settlement, OIG notified Dinkel that OIG intended to exclude him." (Press Release, OIG, Law Judge Upholds HHS OIG's Exclusion of Owner of Orlando, Florida, Diagnostic Imaging Services Company (July 21, 2011), http://tinyurl.com/cd4m5qu.)

Counsel should demand that the OIG do the same in every case. If the OIG remains indecisive, it may be possible for counsel for an organization to gain other concessions. The OIG may limit the number of individuals or the types of positions that might be considered for permissive exclusion. At a minimum, the OIG should be asked to agree to render its decision about exclusions within a certain period of time so that the organization and the individuals can plan their futures accordingly.

The topic of exclusion should be discussed early so that the client clearly understands the implications of a guilty plea in a health care fraud investigation. Although exclusion might be considered a collateral consequence of conviction, it can result in the devastating loss of livelihood for an individual. In order to defuse possible collateral proceedings, counsel should put on the record during a guilty plea that exclusion has been discussed with your client. Although the exclusion discussion may not be necessary under Federal Rule of Criminal Procedure 11, possible elimination of a person's ability to earn a living would seem to be as worthy of mention as some other warnings given to defendants, such as being unable to own a firearm, being unable to vote, or being subject to deportation.

Civil Investigative Demands

In addition to exclusions, counsel should be aware of the potential implication of a civil investigative demand (CID). Despite its name, the issuance of a "civil" investi-

gative demand is not necessarily limited to civil actions, and it cannot be treated that way. In light of the decision in *United States v. Stringer*, 521 F.3d 1189 (9th Cir. 2008), a CID should be viewed as the spearhead of a secret criminal investigation that may be contemporaneously using undercover techniques such as trash runs, tape recordings by informants, or even wiretaps.

In *Stringer*, the Ninth Circuit upheld coordination between a preexisting civil investigation by the Security and Exchange Commission (SEC) and a criminal investigation in the US Attorney's Office (USAO) in Portland, Oregon. Often referred to as a parallel proceeding, this coordination is better understood as a concurrent or a joint proceeding. The government used the deposition power of the SEC to require the defendants to testify about alleged false statements being examined by the SEC that were also under consideration for indictment by the USAO. To their detriment, the defendants were not aware of the criminal investigation when they were deposed. Because the SEC forms contained boilerplate references to the possibility of an indictment and no misleading answers were given by SEC attorneys in response to defense counsel's questions about potential criminal consequences, the Ninth Circuit found that the SEC attorneys did not mislead the defendants about whether a criminal investigation also was underway. (*Id.* at 1191–94, 1196–98.)

CIDs can be used by federal civil attorneys to demand the production of documents as well as to require a witness to testify or to answer interrogatories without having to wait for formal discovery. (31 U.S.C. § 3733(a)(1).) When used in combination with a complaint filed by a qui tam relator, which remains under seal initially for 60 days but often much longer if the government obtains extensions, CIDs allow a civil government attorney to operate much like a criminal prosecutor in a grand jury investigation. A civil government attorney can use CIDs to assemble evidence before deciding whether to initiate litigation under the False Claims Act, while the person or organization being investigated may not know the investigation exists or can only surmise details about the investigation.

Prior to March 2010, each CID had to be approved by the attorney general, a requirement that severely limited the use of CIDs because of the paperwork required to get approval all the way up the chain from a line assistant US attorney into the leadership in Department of Justice (DOJ). Now, each of the 93 US attorneys has authority to approve the issuance of a CID. Thus, a line AUSA handling a civil case has a practical mechanism to conduct civil health care fraud investigations secretly and thoroughly.

As soon as a CID is received, counsel should contact the AUSA to ask specifically whether a related criminal investigation is underway. The response will likely be noncommittal as it was in *Stringer*. However, even a flat denial cannot be taken as the end of the matter because the government civil attorney may make a subsequent, and genuinely independent, decision to refer incriminating information to a criminal attorney at a later time. As long as this decision is made without deceit, the evidence obtained through the CID will be fully admissible in a criminal trial. Thus, the Fifth Amendment implications of a CID should be weighed in the same manner as if the CID were a grand jury subpoena.

Compliance Identifies, Limits, and Resolves Health Care Fraud

An effective and comprehensive compliance program is the best way to protect a client from a health care fraud investigation. This is not only because a compliance program has been mandated by the Patient Protection and Affordable Care Act for all Medicare and Medicaid providers and suppliers as a condition of enrollment. (Pub. L. No. 111-148, § 6401(a)(7)(A), 124 Stat. 119, 751 (2010).) A compliance program can, among other things, help (1) limit exposure by identifying improper payments before the government finds them; (2) reduce the quality and quantity of qui tam actions; and (3) lessen the punishment if there is a criminal violation.

Sophisticated data mining increases the need to implement compliance programs to detect inaccurate billing before the government does. The government has ended the era of "Pay and Chase" in favor of preventing and detecting fraud so that fraudulent claims are not paid in the first place. The Centers for Medicare and Medicaid Services (CMS) use predictive modeling technology (similar to the technology used by credit card companies) so that they can simultaneously analyze multiple data sources for a large volume of claims on a national basis. Through algorithms and analytical processes, Medicare claims are reviewed for suspicious billing patterns and scored with the risk that they are fraudulent. Claims identified as high-risk receive immediate attention and additional review by data analysts.

CMS will soon have more searchable information because it is in the process of implementing a centralized database that contains claims data from Medicare, Medicaid, Veterans Affairs, secretary of defense, disability insurance benefits, and Indian Health Services.

Both the OIG and DOJ are provided access to the central database. The OIG has new authority to obtain additional information directly from providers and beneficiaries of services or supplies payable by any federal health care program. This authority, combined with data mining of the central database, will significantly increase the ability of the government to detect fraudulent payments before they are paid. Once suspect claims are

QUI TAM AND CHANGES TO THE PUBLIC DISCLOSURE BAR

With lottery-sized success stories such as the $14 million paid to the qui tam relators in the Forest Pharmaceuticals case, it is no wonder that qui tam actions have increased dramatically. Recent legislation has made it even easier to bring a qui tam action.

In a qui tam action, a private person (known as a relator) files a lawsuit under seal on behalf of the government, alleging a violation of the Federal False Claims Act. In the context of health care fraud, the relator often alleges that a company submitted a false claim to one of the federal health care programs for payment. The relator notifies the government of the action and the government has a certain amount of time to decide whether to intervene in the action. If the action is successful, the relator is entitled to share in any proceeds recovered by the action, including through settlement, which can range from 15 to 30 percent depending on factors such as whether the government intervenes.

Because the qui tam concept encourages new information that the government did not previously have, qui tam actions based upon information already in the public domain are generally barred unless the relator is the "original source" of the information. This public disclosure bar, found at 31 U.S.C. § 3730(e)(4), was recently and significantly amended, which will most certainly allow for more qui tam actions. The amendment limited the defined sources constituting public disclosure and expanded the definition of "original source." For example, a relator will likely be permitted to bring a qui tam action based upon information discovered from state or local criminal, civil, or administrative hearings, reports, audits, or investigations, provided the federal government was not a party to the action and the information was not disclosed in the media.

—Thomas Zeno & Kimberly Donovan

identified, CMS may withhold payment on the claims until they are verified. In the event of a credible fraud allegation against a particular provider, all payments to that provider may be suspended pending investigation.

Before implementation of new technology, it was difficult for the government to detect improper billing due to the volume and speed at which claims were processed. The new technology, coupled with the increased use of electronic claims, means improper payments will be detected at a much higher rate. Because CMS is going to stop paying first and ask questions later, providers who submit claims flagged for investigation may be deprived of anticipated cash flow while the government conducts its investigation. Even if it is later determined that the claim was proper, companies on minimal profit margins may find themselves cash strapped for potentially long periods of time. (Testimony of Lewis Morris & Peter Budetti, *supra*, http://tinyurl.com/65nlc9t.)

Qui tam actions are expected to increase because the government will continue to encourage them, the potential rewards are enormous, and recent statutory changes make it easier to file them. For example, the government is now able to save a qui tam action, even though it would have otherwise been dismissed pursuant to the public disclosure bar. (31 U.S.C. § 3730(e)(4)(A).) In order to defend against this trend, companies must ensure that they have a program that provides effective and comprehensive compliance. A compliance program will not prevent all qui tam actions, but it can lessen the prospect of them. It can even give an early warning that a disgruntled employee is likely to become a qui tam relator.

An effective compliance program also provides the option of resolving fraudulent conduct by making a self-disclosure to the OIG. The OIG website explains the self-disclosure process and posts examples of advantageous agreements that organizations have made with the OIG following self-disclosure. Not surprisingly, the OIG requires that self-disclosure result in creation of a compliance program capable of detecting and preventing such conduct in the future.

Because the government continues to obtain convictions, no article for *Criminal Justice* would be complete without mentioning relevant changes to the *United States Sentencing Guidelines Manual*. The Sentencing Commission has been active in the area of health care fraud in each of its last two amendment cycles.

Amendments in 2010 focused on the requirements for an organization to qualify for a three-point reduction in its culpability score when it has committed an offense despite instituting a compliance and ethics program. One amendment clarified that an appropriate response to the criminal conduct requires "reasonable steps" *both* to "respond appropriately to the criminal conduct" *and* to prevent "further similar criminal conduct"; this may include, for example, paying restitution to identifiable victims as a response and hiring an outside professional advisor to prevent future misconduct. (U.S. SENTENCING

Guidelines Manual § 8B2.1(b)(7) cmt. n.6.)

Another amendment created section 8B2.5(f)(3)(C) as a narrow opportunity for an organization to receive the three-point reduction even when the "high-level personnel" or "substantial authority personnel," as described in section 8A1.2 cmt. n.3 participated in the crime. To be eligible for the exception, the compliance program must have the following safeguards:

- individuals in the program must report directly to the organization's governing authority; an individual with "direct reporting obligations" must have "express authority to communicate personally" and promptly to the governing authority about potential criminal conduct, and this identified individual must report at least annually about the status of the compliance and ethics program;
- the offense must be detected by the compliance and ethics program before outside discovery, including by the government;
- the organization must promptly report the offense; and
- no one in the compliance and ethics program can participate in, condone, or be willfully ignorant of the offense.

(U.S. Sentencing Guideline Manual § 8C2.5(f)(3)(C) & cmt. n.11.)

As an emphasis to the value of an effective compliance and ethics program, amendments effective November 1, 2011, create three changes directed at increasing punishment. First, a new guideline contains tiered enhancements for large losses caused during commission of a federal health care offense involving a government health care program. The enhancements are two levels for loss of more than $1 million, three levels for loss of more than $7 million, and four levels for loss of more than $20 million. (U.S. Sentencing Guidelines Manual § 2B1.1(b)(8).) Second, loss will be larger because of the broad definition of a government health care program that includes Medicare, Medicaid, and any program funded in whole or in part by federal or state government. (U.S. Sentencing Guidelines Manual § 2B1.1 cmt. n.1.) Third, the commission created a rebuttable presumption that the amount of intended loss is the total of the fraudulent bills submitted to the government, regardless of the amount actually paid. (U.S. Sentencing Guidelines Manual § 2B1.1 cmt. n.3(F)(viii).) This definition, required by statute, places the burden on the defendant to prove a lack of intent to obtain the total of the claims submitted.

What Counsel Should Do

Although exclusion is a hot button topic in discussions of health care fraud, compliance is the fundamental issue. In the face of increasingly aggressive tactics taken by the government to stop health care fraud, organizations and individuals run a tremendous risk unless they are proactive in establishing effective and comprehensive compliance programs that satisfy the many statutory and regulatory guidelines. Counsel can greatly assist clients by ensuring that compliance programs are in place and working. The program should ensure training of the employees on correct practices, internal reviews to ensure that improper claims are not submitted to the government and are corrected promptly if they occur, and encouragement for employees to inform the company of any potential false claim violations. Counsel should consult with general counsel of your clients to impress upon the client the importance of an effective compliance program. Counsel should know every aspect of the organization's compliance program and regularly evaluate the compliance program. This robust approach to compliance can prevent problems for your clients in the long run and blunt the damage caused by conduct leading to a government investigation. ■