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Mintz Levin Cohn Ferris Glovsky and Popeo PC

Health Care Enforcement in 2013: A Year in Review

BY HOPE FOSTER, TRACY MINER, AND BRIDGET ROHDE

In 2013, the U.S. Department of Justice ("DOJ"), Health and Human Services Office of Inspector General ("HHS-OIG"), and other federal and state agencies continued to aggressively prosecute health care fraud and related offenses through criminal, civil, and parallel proceedings. Following the approach it has utilized to combat financial crime, DOJ is entering deferred prosecution and non-prosecution agreements with corporate defendants, but prosecuting individual officers and key employees; employing electronic surveillance techniques; and, overall, using the strike force approach developed and implemented to eradicate organized crime and other gangs. This approach resulted in steep monetary penalties for companies and lengthy prison terms, as well as fines, forfeiture and restitution, for individuals. And, as in the past, the government reached civil resolutions, including multi-million dollar settlement amounts and Corporate Integrity Agreements, with a number of health care providers.

Criminal prosecutions, civil enforcement actions, and parallel proceedings are discussed below, as are a number of issues to be on the alert for in 2014.

I. Criminal Prosecutions

A. Medicare Fraud and Related Offenses

DOJ, HHS-OIG, and their partners, through the Medicare Fraud Strike Force ("MFSF" or the "Strike Force"), continued to bring numerous high-impact cases in 2013, employing law enforcement techniques in use since 2007. As DOJ reported in a recent press release, "Since its inception in March 2007, [MFSF], now operating in nine cities across the country, has charged more than 1,700 defendants who collectively have billed the Medicare program for more than $5.5 billion. In addition, HHS's Center for Medicare and Medicaid Services, working in conjunction with HHS-OIG, is taking steps to increase accountability and decrease the presence of fraudulent providers." *See* DOJ press release 13-1283.

Notable take-aways from 2013 include the many venues of prosecution, the variety of health care providers targeted, the types of crimes charged and the wide-ranging penalties imposed.

Many Venues of Prosecution — DOJ and its partners brought cases across the country, including in California, Florida, Illinois, Louisiana, Michigan, New York, Pennsylvania, Texas and Utah. Some federal districts had a particularly high concentration of the Strike Force cases, including the Southern District of Florida, Eastern District of Michigan and Central District of California.

Variety of Health Care Providers Targeted — Cases targeted executives of a health maintenance organization ("HMO"); the owner/operator of an oncology center; the medical director of a hospice; the owner and program coordinator of an adult day care center; owners and others associated with partial hospitalization programs ("PHPs"); owners and others associated with home health care agencies; owners and others

associated with durable medical equipment companies ("DMEs"); owners of ambulance services; and doctors, registered nurses and other medical professionals.

Types of Crimes Charged — Charges included health care fraud for submitting false and fraudulent claims to Medicare, violations of the anti-kickback statute, and, in some recent cases, money laundering.

Wide-ranging Penalties — Sentences included the imposition of lengthy prison terms; fines, restitution, and forfeiture; exclusions from Medicare, Medicaid and other federal and state health programs; and compliance requirements.

Other important take-aways include the following:

1. MFSF Nationwide Takedown Demonstrates Continuing Commitment to Strike Force Approach

In May 2013, the Medicare Fraud Strike Force conducted its sixth nationwide takedown. Specifically, on May 14, DOJ and HHS announced arrests in eight cities of 89 individuals including health care company owners, doctors, nurses and other licensed medical professionals for allegedly participating in Medicare fraud schemes involving approximately $223 million in false billings. This takedown represents a microcosm of Strike Force cases, with individuals in Miami, New Orleans, Houston, Los Angeles, Detroit, Tampa, Chicago and Brooklyn being charged for healthcare-related offenses, including allegedly participating in schemes to submit claims to Medicare for services that were medically unnecessary or never provided. Sometimes, the cases involved patient recruiters or the alleged payment or receipt of kickbacks.

The importance of these periodic national takedowns is not so much the ground-breaking nature or size of the individual cases as the continuing multi-agency law enforcement commitment to bringing them. Indeed, in announcing the May takedown, DOJ's Acting Assistant Attorney General in charge of the Criminal Division stated that it is part of the department's "core mission" to hold accountable those who commit health care fraud. *See* DOJ press release 13-553. In addressing health care fraud, the government will continue using the strike force approach that it historically used to combat organized crime and has more recently used to combat financial crimes like insider trading.

2. Prosecutors Permitted HMO to Enter a DPA, but Charged Individual Executives

In June 2013, the former Chief Executive Officer and Chief Financial Officer of an HMO and the former Vice President of a subsidiary of the HMO were convicted of health care fraud, while another executive of the HMO was convicted of making false statements to law enforcement. The former General Counsel of the HMO awaits trial. The scheme allegedly included the submission of inflated expenditure information in annual reports to the Florida agency that administers the Medicaid program to reduce payback obligations for certain behavioral health services. See DOJ release 13-659.

This case is a good example of the approach utilized for some time now in financial fraud cases. A few years ago, in May 2009, the HMO entered a Deferred Prosecution Agreement ("DPA"), which it has successfully completed according to the government. Especially since the days of Enron and the ruination of Arthur Anderson, DOJ has utilized DPAs as well as Non Prosecution Agreements ("NPAs") in resolving potential criminal charges with corporations. Typically, in situations where the government is amenable to entering into such an agreement and the corporation agrees, it can avoid prosecution if it makes restitution or other monetary payments, undertakes remedial steps to address the problem that drew prosecutorial attention, and adopts or refines compliance measures to avoid and detect similar problems in the future within a designated time frame. However, individuals at the company, including those viewed as gatekeepers, such as C-level executives and attorneys, may not be so fortunate.

3. Investigators Utilized Electronic Surveillance in Multi-Million Dollar Medicare Fraud Case

As of November 12, 2013, 13 individuals had been convicted in connection with a $77 million Medicare fraud scheme involving a Brooklyn, New York clinic. The owner of the clinic was sentenced to 15 years in prison and ordered to pay

approximately $36 million in forfeiture and $51 million in restitution. Another participant — an individual described as a no-show doctor who allegedly let the clinic use his Medicare billing number and rarely visited the clinic except to pick up his check — was sentenced to over 12 years in prison following his conviction for health care fraud, was ordered to pay over $50 million in restitution and another half-million dollars in forfeiture, and was excluded from Medicare, Medicaid and federal health programs; additionally, New York State revoked his medical license. The individual who "impersonated" the doctor was sentenced to eight years in prison, ordered to make restitution and forfeiture payments and was excluded from the federal health care programs. Among those awaiting sentencing is an individual who pled guilty to laundering the proceeds of the health care fraud through a number of shell companies and bank accounts. *See* DOJ press releases 13-837, 13-865, 13-1032, and 13-1207.

In addition to the dollar amount of the fraud scheme, the inclusion of money laundering charges and the variety and size of penalties, this case is notable because the government utilized investigative techniques historically used to investigate organized crime and, in more recent years, insider trading. Specifically, the government stated in press releases regarding this case that it had employed a court-authorized audio/video device concealed in a room at the clinic where conspirators gave cash to Medicare beneficiaries. This case suggests that law enforcement may increase its use of electronic surveillance in health care fraud investigations.

4. Trend of Prosecuting Home Health Care Providers and DMEs Continues; PHPs Draw Sustained Prosecutorial Attention

Continuing the now longstanding trend reported in our 2011 and 2012 annual reviews, in 2013, the government once again brought numerous cases targeting home health care providers and DMEs. These types of prosecutions were well-represented in the MFSF takedown discussed above. Numerous additional prosecutions involving home health care providers were brought in the Southern District of Florida, the Eastern District of Michigan and elsewhere. Cases involving DMEs were also brought, with several of those emanating from the Central District of California. Partial Hospitalization Programs ("PHPs") were also the subject of cases in 2013. A few additional examples illustrate this prosecutorial focus.

a. HCSN

Throughout 2013, there was a steady beat of arrests, guilty pleas, trials and sentencings in connection with a multi-million dollar health care fraud scheme being prosecuted in the Southern District of Florida. The focal point of this prosecution was the activity of now defunct Health Care Solutions Network ("HCSN"), which operated in Florida and North Carolina and purportedly provided a form of intensive treatment for severe mental illness known as PHP services.

According to the government, from 2004 through 2011, HCSN billed Medicare and the State of Florida's Medicaid program approximately $63 million for purported services resulting in $28 million in payments. In announcing the sentence of a former owner of HCSN, the government said that he orchestrated a scheme that "centered on the recruitment and admission of patients who could not benefit from PHP services" and that he utilized patient recruiters to pay cash kickbacks in exchange for referrals from assisted living facilities' patients. The government also alleged that records were then fabricated and used to support false billings to the government. *See, e.g.,* DOJ press release 13-234.

To date, at least 15 individuals have been prosecuted in connection with this scheme. The former owner pled guilty to conspiracy to commit health care fraud and conspiracy to commit money laundering and was sentenced to 14 years in prison as well as $28 million in restitution. *Id.* Other stiff sentences include 10 years in prison for the director of medical records who was convicted by a jury of conspiracy to commit health care fraud based on evidence allegedly showing that she oversaw the "alteration, fabrication and forgery of thousands of documents that purported to support the fraudulent claims" submitted to Medicare and Medicaid (13-763); approximately nine years in prison for a former registered nurse who pled guilty to conspiracy to commit health care fraud and conspiracy to commit money laundering and whose role was described as participating in admissions, records fabrication and

money laundering (13-181); almost six years in prison and approximately $19 million in restitution for a therapist and program coordinator who pled guilty to conspiracy to commit health care fraud and whose role was described as participating in records fabrication (13-552); and over five years in prison for a receptionist/office manager said to have actively concealed the fabrication of medical records (13-981). Notably, several additional arrests — of a medical director and a number of therapists — were made this past summer in this matter (13-795).

b. Biscayne Milieu

Another sprawling case focusing on a PHP prosecuted in the Southern District of Florida involved the Miami-based mental health clinic, Biscayne Milieu. The owners and operators were convicted after a jury trial on charges arising from what the government described as a $55 million fraud involving the submission of false and fraudulent claims to Medicare, kickbacks to recruit patients, bribes to silence patients and money laundering. The most notable events in that case in 2013 were the sentencings of the owners and operators of the clinic — a father, as well as his son and daughter — to 30, 25 and 22 years in prison, respectively, and a former therapist to 10 years in prison. Convicted co-defendants are joint and severally liable for over $11 million in restitution. According to the government, more than 25 individuals charged in connection with this matter have pleaded guilty or been convicted at trial. See DOJ releases 13-387, 13-1188.

B. Securities Fraud

It is important to remember the potential for, and to protect against, other sources of criminal, civil, and regulatory exposure, in addition to Medicare fraud.

On July 16, 2013, DOJ brought securities fraud, wire fraud and conspiracy charges against the former CEO and CFO of a Texas-based, publicly traded, surgical device company, ArthoCare Corp. The former CEO was also charged with making false statements to the U.S. Securities and Exchange Commission ("SEC") during a sworn deposition. *See* DOJ release 13-805; *see also U.S. v. Baker, et al.,* 1:13-cr-00346 (SS) (W.D.Tx). A number of other senior executives have pleaded guilty. See DOJ releases 13-535, 13-827.

For a three-year period from December 2005 through December 2008, the former CEO and CFO allegedly orchestrated a $400 million scheme to defraud investors by falsely inflating the company's earnings through end-of-quarter shipments to distributors. According to the indictment, they, along with other senior executives of the company, allegedly:

- Arranged transactions to park sufficient numbers of medical device products with distributors to meet ArthroCare's end-of-quarter sales expectations;
- Offered, as incentives for the distributors' agreement to the transactions:
  - Substantial up-front cash commissions;
  - Extended payment terms for the devices; and
  - Ability to return the product; and
- Undertook measures to conceal the nature and extent of the company's relationships with distributors.

ArthroCare's revenues were allegedly falsely inflated by *tens of millions of dollars* — potentially inducing investors to engage in trades or to hold company shares based on the falsely generated sales data. The CEO and CFO allegedly certified the accuracy of annual and quarterly filings for the period in question. Trial has been scheduled for May 2014. *See* DOJ release 13-805 and *U.S. v. Baker, et al.,* 1:13-cr-00346 (SS) (W.D.Tx (Austin)).

In public filings, for example, its 10-Q for the quarter ending September 30, 2013, ArthroCare stated that it is being investigated by DOJ and is cooperating with the investigation. It additionally revealed its belief as to possible components of a resolution, given discussions it had with the government: a DPA, an estimated financial component

of approximately $30 million and continuation of compliance and reporting systems. Additionally, ArthroCare and former executives were also subject to other collateral actions, including private securities actions in the Western District of Texas that were settled.

This case serves as a powerful reminder, especially with the new SEC Chair's announced focus on accounting fraud, insider trading and other financial crimes, that a company should consider periodic review and revisions of its financial compliance and ethics program to ensure that it is fine-tuned to the company's risk and appropriately tailored to prevent illegal and unethical conduct. Compliance training and monitoring are essential to these efforts.

C. Global Anti-Corruption

Pharmaceutical and medical device companies have been the focus of an industry-wide DOJ and SEC FCPA inquiry since 2010. Because the DOJ and the SEC generally consider doctors who are employees of state-owned hospitals and health care organizations to be "foreign officials" under the FCPA, pharmaceutical and medical device companies are *particularly* at risk for any direct or indirect sales or marketing activities directed at these foreign doctors.

Most recently, in October 2013, Stryker Corporation, a Michigan-based manufacturer of medical devices, agreed to pay $13.2 million to settle FCPA charges by the SEC, which alleged that Stryker's subsidiaries made improper payments to foreign officials in several countries and booked those payments as legitimate legal, travel, and charitable expenses. This past year, however, also saw several multi-year investigations against medical device companies conclude in prosecutorial declinations, including for Zimmer in February 2013 and Medtronic in June 2013.

Over the course of 2013, the most widely publicized global anti-corruption efforts toward the health care industry involved not the U.S. Foreign Corrupt Practices Act or the U.K. Bribery Act, but Chinese anti-corruption efforts. In early July 2013, news sources reported that Chinese authorities had announced an investigation of senior managers of GlaxoSmithKline (GSK) for economic crimes. That weekend, Chinese authorities in the cities of Shanghai, Beijing, and Changsha also detained GSK employees as part of their investigation. Chinese investigators have said that GSK participated in a widespread bribery and corruption scheme that used travel agencies to funnel $492 million to doctors and government officials to increase pharmaceutical sales. *See, e.g., New York Times* articles of July 1 and October 23, 2013.

On July 22nd, after meeting with the Chinese Ministry of Public Security, GSK stated that "Certain senior executives of GSK China who know our systems well, appear to have acted outside of our processes and controls which breaches Chinese law" and the company further stated that it has "zero tolerance for any behaviour of this nature." GSK sent several senior executives to China to address the crisis, including its president for emerging markets; he told Chinese police GSK will review and reform its business model in China in an effort to reduce drug prices. *See* GSK Statement of July 22, 2013.

In a related action, Chinese authorities ordered a travel agency used by GSK — Shanghai Linjiang International Travel Agency — to stop doing business due to "illegal activities," including fake billing. Linjiang's legal representative in China told Chinese state television that Linjiang arranged cash payments of $6,500 to $81,000 for GSK. Other pharmaceutical companies based in the U.S. and Europe have also have used Linjiang in the past, but all of the companies have since terminated their relationships with the travel agency. *See South China Morning Post* article of July 19, 2013.

In addition, the Chinese Health Ministry announced that 39 employees at a hospital in southern Guangdong Province, the vice chairman of the hospital's trade union and two people in charge of the hospital's relationship with drug companies would be punished for taking illegal kickbacks of $460,000 from two unnamed drug companies between January 2010 and December 2012. Moreover, an unnamed American citizen has been detained in China in connection with the wider Chinese investigation into that country's drug company corruption scandal. It is not known which drug company employed the American citizen. *See Reuters* article of July 23, 2013.

The investigation into GSK is ongoing, although it appears that Chinese authorities are more likely to charge individuals associated with GSK than the company itself. *See The Telegraph* article of Nov. 4, 2013. The DOJ, which has been investigating GSK's sales practices for at least three years, has also expanded its probe to include the Chinese bribery allegations. *See Reuters* article of Sept. 6, 2013.

The investigation marks one of the first instances in which Chinese authorities appear to have independently enforced China's anti-bribery laws against employees of non-Chinese companies. The arrests serve as a reminder that enforcement of anti-corruption laws is not limited to U.S. government actions. Multinational companies operating on foreign soil should understand the potential consequences of alleged violations of foreign anti-bribery laws, regularly assess their risk profiles, and update their compliance programs to account for local variations in enforcement standards.

II. Significant Joint Criminal/Civil Resolutions

The largest U.S. health care fraud settlement of 2013 and a second substantial health care fraud settlement stemmed from four *qui tam*, or whistleblower, complaints that alleged illegal marketing of drugs for uses that were not approved by the FDA. Two major pharmaceutical companies were called to answer for acts alleged to be in violation of criminal provisions of the Federal Drug and Cosmetic Act ("FDCA") as well as the civil False Claims Act ("FCA"). Each of these cases involved criminal guilty pleas by pharmaceutical company subsidiaries together with criminal fines and forfeiture as well as substantial civil settlements. Beyond the continuing threat of criminal prosecution and large monetary penalties, the government used other measures, such as injunctions and Corporate Integrity Agreements ("CIAs"), to foster compliance with federal drug regulations.

A. U.S. and J&J Reached One of the Largest Health Care Fraud Settlements in U.S. History

On November 4, 2013, DOJ announced a deal requiring Johnson & Johnson ("J&J") and three of its subsidiaries to pay more than $2.2 billion to resolve criminal exposure and civil liability arising from marketing prescription drugs for uses not approved as safe and effective by the FDA, as well as for paying kickbacks to doctors and the country's largest long-term care pharmacy provider for prescribing and promoting these drugs. *See* DOJ release 13-1170. The monetary penalty appears to be exceeded only by the $3 billion paid by GSK as a result of its 2012 settlement of False Claims Act allegations.

To address its criminal exposure, on November 7, J&J subsidiary Janssen Pharmaceuticals Incorporated ("Janssen") pled guilty to a misdemeanor charge of misbranding, in violation of the FDCA, in the United States District Court for the Eastern District of Pennsylvania. Specifically, from March 2002 through December 2003, Janssen is alleged to have introduced the drug Risperdal into the market for unapproved uses, namely treating behaviors of elderly, non-schizophrenic patients suffering from dementia, when Risperdal had been approved only for the treatment of schizophrenia; the criminal fines and forfeiture component of the criminal resolution was $400 million. *See U.S. v. Janssen,* Criminal No. 13 – cr- 00605 (TJS) (E.D. Pa).

Civil lawsuits similarly claimed that from 1999 through 2005, J&J and Janssen promoted Risperdal to doctors and nursing homes for unapproved uses in the elderly, children, and mentally disabled. A complaint in the Eastern District of Pennsylvania alleged that the FDA repeatedly advised Janssen that marketing Risperdal as safe and effective for the elderly would be misleading. It also alleged that Janssen downplayed health risks to the elderly posed by Risperdal and improperly promoted its use in children. Speaker fees were allegedly paid to doctors to encourage them to write prescriptions. In addition, J&J and Janssen allegedly engaged in off-label promotion of a newer anti-psychotic drug, Invega. *See* DOJ release 13-1170; *see also U.S. ex rel. Barry v. Janssen, et al.*, Civil Action 10-cv-0098).

J&J and Janssen agreed to pay over $1.2 billion to resolve civil liability under the False Claims Act in relation to Risperdal and Invega. In addition, J&J agreed to pay another $149 million in connection with kickbacks that were allegedly paid to the large long-term care pharmacy. *See* DOJ release 13-1170; Holder Remarks of November 4, 2013; *see also U.S. ex rel. Lisitza and Kammerer,* Civil Action Nos. 07-10288 and 05-11518 (D. Mass.).

An additional component of the resolution is a five-year CIA, described as requiring major changes to the way J&J's pharmaceutical subsidiaries do business. The CIA also requires annual compliance certifications by certain management employees and board members. As the government stated, "[t]his agreement is designed to increase accountability and transparency and prevent future fraud and abuse." *See* DOJ release 13-1170.

A telling remark by U.S. Attorney General Holder Eric Holder is that pharmacists who were supposed to be "gatekeepers" providing independent review of patient medications instead recommended the drugs for unapproved uses at the companies' request. *See* Holder Remarks of November 4. Attorney General Holder's remarks echo a sentiment expressed by the government in financial fraud prosecutions that gatekeepers, for example, professionals including attorneys and accountants, are expected to be a hedge against fraud and certainly not a facilitator. In the health care industry, this sentiment would include lawyers, doctors and pharmacists.

B. Government and Wyeth Achieved Significant Criminal/Civil Resolution

On July 30, 2013, DOJ announced that Wyeth Pharmaceuticals, Inc. ("Wyeth") agreed to pay approximately $490 million to resolve its criminal exposure and civil liability arising from marketing the prescription drug Rapamune, an immunosuppressive drug, for unapproved uses. *See* DOJ release 13-860. While Wyeth had received FDA approval for use of Rapamune in renal transplant patients, the company allegedly trained its sales force to promote the drug's use in non-renal transplant patients and provided financial incentives to its sales force for promoting the unapproved uses. The government viewed this conduct as violative of criminal misbranding prohibitions under the FDCA as well as of the False Claims Act. *Qui tam* relators included former sales representatives.

To resolve its criminal exposure, Wyeth pled guilty to misbranding in violation of the FDCA and agreed to pay a criminal fine of approximately $157 million and forfeiture of $66 million. *See U.S. v. Wyeth Pharmaceuticals, Inc.,* 5:13-cr-00129 (W.D. Okla.). Wyeth also agreed to pay $257.4 million to settle potential civil liability under the False Claims Act for its off labeling promotion of Rapamune, with the settlement proceeds to be shared by the federal government and the states and a portion of the federal government's share going to the whistleblowers. (Note that while Wyeth pled guilty to the criminal charge, there was no determination of liability with respect to the civil claims). *See* DOJ release 13-860; *U.S. ex rel. Sandler et al. v. Wyeth Pharmaceuticals, Inc.,* 05-6609 (E.D. Pa.); *U.S. ex rel. Campbell v. Wyeth Inc.,* 07-00051 (W.D. Ok.).

C. Government Reached Largest Settlement Ever with a Generic Drug Manufacturer, Ranbaxy

On May 13, 2013, DOJ announced what it described as "the largest drug safety settlement to date with a generic drug manufacturer." The resolution had both criminal and civil components, including guilty pleas to multiple felony counts, agreement to criminal fines and forfeiture of $150 million, and federal and state civil claims settlement of approximately $350 million.

With respect to the criminal component of the resolution, on May 13, Ranbaxy USA Inc. pled guilty to felony counts relating to the manufacture and distribution of certain adulterated drugs made at two of the company's manufacturing facilities in India. Three of these felony counts arose under the FDCA and charged introduction of adulterated goods into interstate commerce and failure to file timely reports; four of the felony counts charged false statements to the FDA. Ranbaxy acknowledged that FDA inspections at the company's facilities identified issues with regard to incomplete testing and inadequate stability programs. Ranbaxy also acknowledged that consultants it hired to do audits at the facilities informed it of current good manufacturing practice (or "cGMP") violations and that those violations resulted in the introduction of some adulterated drugs into interstate commerce. Ranbaxy also admitted making false statements to the FDA in annual reports regarding the dates of stability testing of certain drugs. *See* DOJ release 13-542; *U.S. v. Ranbaxy USA, Inc.,* 1:13-CR-0238 (JFM)(D. Md.).

As to the simultaneous civil resolution, Ranbaxy agreed to pay the additional $350 million to resolve allegations that, from April 2003 through September 2010, it caused false claims to be submitted to government health care programs for certain drugs manufactured at the Indian facilities whose strength, purity or quality differed from the drugs'

specifications or that were not manufactured according to the FDA approved regulation. (This agreement was not an admission of liability by Ranbaxy, except to the extent that Ranbaxy USA made admissions in its plea agreement). The federal government and states participating in the agreement shared the civil settlement proceeds with the *qui tam* relator, a former Ranbaxy executive who received approximately $48 million of the federal government's share. *See* DOJ release 13-542; *U.S. ex rel. Thakur v. Ranbaxy Laboratories Limited,* 1:07-962 (JFM)(D. Md.).

Finally, the government also utilized an injunction, with requirements including establishment and documentation of management control over quality assurance and control at the two Indian facilities in question and establishment of an office of data reliability with responsibility for review of applications to the FDA and certification as to the accuracy and completeness of the data in the applications. *See* DOJ release 13-542; *U.S. v. Ranbaxy Laboratories Limited,* JFM-12-250 (D. Md.).

III. Civil Matters

DOJ together with its partners also aggressively pursued numerous civil matters during 2013. These cases were filed in federal districts across the country, often alleged the submission of false claims related to improper Medicare billings, and were initiated by *qui tam* whistleblowers, often referred to as "relators." Some of these cases involved allegations of kickbacks. Many of the cases were resolved with multi-million dollar settlements. In its press releases on civil matters, DOJ often attributed the resolutions to its partnership with HHS and the HEAT initiative announced in May 2009. DOJ has referred to the False Claims Act as one of its most powerful tools to combat health care fraud and has stated that, since January 2009, it has used the act to recover approximately $12 billion for fraud involving federal health care providers. *See, e.g.,* DOJ Release 13-1352 (release from 12/20/13).

A. A Few Notable Cases

1. Numerous Hospitals Across the Country Settled False Claim Allegations Regarding Kyphoplasty

On July 2, 2013, DOJ announced that it had reached a settlement with 55 hospitals located in 21 states for over $34 million to settle allegations that they had submitted false claims to Medicare for kyphoplasty procedures. Kyphoplasty is a minimally invasive procedure used to treat certain spinal fractures and can often be performed safely and effectively on an out-patient basis. The settling hospitals frequently billed Medicare for kyphoplasty on a more expensive in-patient basis. DOJ noted that all but four of these settling hospitals had been named as defendants in a *qui tam* complaint and that the whistleblowers would receive approximately $5.5 million as relators' share. *See* DOJ Release 13-745; *U.S. ex rel. Patrick and Bates v. Kyphon Inc.,* docket no. 6:05-cv-6568 (Western District of New York). DOJ advised that it had reached settlements with over 100 hospitals for a total of approximately $75 million to resolve allegations that they mischarged Medicare for kyphoplasty. *See* DOJ Release 13-745.

2. U.S. Reached One of the Largest False Claims Act Settlements with an Individual in U.S. History

On February 11, 2013, DOJ announced what it billed as "one of the largest [settlements] ever with an individual under the False Claims Act in U.S. history." *See* DOJ Release 13-183. Specifically, a Florida dermatologist agreed to pay approximately $26 million to resolve allegations that he accepted kickbacks from a pathology laboratory to which he sent biopsy specimens and that he billed Medicare for medically unnecessary skin surgeries. In addition to the staggering settlement amount, the dermatologist was excluded from Medicare, Medicaid and other government health care programs. (The laboratory and its owner had previously reached a settlement of the same lawsuit). The whistleblower received over $4 million. *See* DOJ Release 13-183; *U.S. ex rel. Freedman v. SuarezHoyos et al.,* 04-933 (M.D. Fl).

B. Important Limitations on *Qui Tam* Relators

1. False Claims Act Is Not a License to Divulge Employer (or Client) Confidences

A September 2013 decision out of the Northern District of Illinois serves as a reminder that health care companies should take proactive steps to protect themselves against misuse of confidential information by former employees in *qui tam* lawsuits under the False Claims Act.

In *United States ex rel. Wildhirt v. AARS Forever, Inc., et al.,* 2013 WL 5304092 (N.D. Ill. Sept. 19, 2013), the court granted in part and denied in part a motion by the *qui tam* relators seeking dismissal of several counterclaims filed against them by the defendants, relators' former employers, AARS Forever, Inc. and THH Acquisition LLC 1. The relators had signed "Employee Confidentiality, Non-Compete and HIPAA Agreements," stating, among other things, that the relators:

- Would not copy or disclose confidential information except with permission and in connection with their employment;
- Would indemnify defendants from loss, claim, or damages (including attorneys' fees) for the unauthorized disclosure of confidential information;
- Would not receive any monetary reimbursement for involvement or assistance in a *qui tam* lawsuit against defendants (and disclose and turn over any *qui tam* award to defendants); and
- Would immediately notify defendants in writing of any "suspect practices" of which they became aware.

See id. at *5-6. Additionally, the relators had executed "Confidential Acknowledgement of No Known Suspect Practices" statements and had not reported any. *See id.* at *7-8.

After their employment ended, relators sued alleging that defendants violated the FCA and its Illinois counterpart by falsely billing Medicare and Medicaid for patients in the Veterans Administration hospital system. One of the relators retained company documents after her employment ceased and, in connection with the *qui tam* lawsuit, allegedly disclosed the documents to counsel, to the government, and to the public. Relators also allegedly disclosed the contents of company-related verbal communications. *See id.* at 8.

The defendants filed counterclaims alleging, among other things, that relators: (1) breached their agreements with the defendants through unauthorized disclosures of confidential information and (2) breached their agreements by failing to report suspect practices to the company before filing the *qui tam* lawsuit. The defendants also sought indemnification under those agreements for damages suffered as a result of relators' disclosure of confidential information. *See id.* at *11-12.

The relators sought to dismiss defendants' counterclaims on a number of grounds, including public policy. They identified the policy interest to be "the detection and exposure of potential fraud against the United States" and said that the confidentiality agreement thwarted the interest in having *qui tam* relators come "forward with evidence of fraud, thereby hindering government investigations." Id. at 12-13.

Reviewing the "well-developed jurisprudence that addresses these policy interests in the context of counterclaims brought against relators in FCA litigation," the court explained that a *qui tam* defendant may bring counterclaims "for independent damages" that are "not dependent on a finding that the *qui tam* defendant is liable." There are two categories of these independent claims: (1) when the conduct at issue in the counterclaim is distinct from the conduct underlying the FCA case; or (2) when a counterclaim is "bound up in the facts of the FCA case" and the defendant is not liable in the FCA case. The court decided that defendants' counterclaims fit "comfortably in at least one of the two categories" and thus could not be dismissed on the pleadings as contrary to public policy. The court did, however, dismiss counterclaims to the extent that defendants sought damages or indemnification if relators prevailed. *See id.* at *13-15.

The decision highlights the benefits of requiring employees to report potentially unlawful conduct internally and utilizing robust employee confidentiality agreements. In addition, internal reporting is an important part of an effective compliance program. Furthermore, because *qui tam* relators often take and disclose confidential company information in support of their claims, requiring employees to sign confidentiality agreements may both dissuade employees from misappropriating confidential information and give the company recourse if they do.

2. What Degree of Specificity Is Required in *Qui Tam* Complaints?

In October 2013, the U.S. Supreme Court made an interesting request of the Solicitor General, inviting him "to file a brief…expressing the views of the United States" on the issue of the level of specificity about false claims that must be alleged in a complaint under the False Claims Act. *See U.S. ex rel. Nathan v. Takeda Pharmaceuticals North America, Inc.,* 2013 U.S. LEXIS 5280 (U.S. Supreme Court, October 7, 2013). This request arose in the context of the high court's consideration of whether to grant review of a decision by the Fourth Circuit Court of Appeals, which dismissed an FCA case against the pharmaceutical company for failing to allege the presentment of a false or fraudulent claim to the government for payment. *See U.S. ex rel. Nathan v. Takeda Pharmaceuticals North America, Inc.,* 2013 U.S. App. 765 (4th Cir., January 11, 2013).

As the Fourth Circuit framed the issue, "[t]he parties dispute the proper application of *Rule 9(b)* [of the Federal Rules of Civil Procedure] in this case. In Relator's view, to meet the requirements for pleading a fraud claim under the Act, a relator need only allege the existence of a fraudulent scheme that supports the inference that false claims were presented to the government for payment. In contrast, Takeda argues that *Rule 9(b)* requires that a relator plead facts plausibly alleging that particular, identifiable false claims actually were presented to the government for payment." Id. at *8-9.

The Fourth Circuit rejected the relator's contentions, noting along the way "the multiple purposes of *Rule 9(b)*, namely, of providing notice to a defendant of its alleged misconduct, of preventing frivolous suits, of 'eliminat[ing] fraud actions in which all the facts are learned after discovery,' and of 'protect[ing] defendants from harm to their good will and reputation.'" *Id.* at *9 (citations omitted). The Circuit held that "when a defendant's actions, as alleged and reasonably inferred from the allegations *could* have led, but *need not necessarily* have led, to the submission of false claims, a relator must allege with particularity that specific false claims actually were presented to the government for payment. To the extent that other cases apply a more relaxed construction of *Rule 9(b)* in such circumstances, we disagree with that approach." *Id.* at *14. Acknowledging that relators face practical challenges, the Circuit stated that "[n]evertheless, our pleading requirements do not permit a relator to bring an action without pleading facts that support all elements of a claim." *Id.* at *15.

As of the end of the year, the Solicitor General had not yet made a submission on the issue. That submission, and the Supreme Court's ultimate decision, if any, hold the possibility of more uniform adherence to stringent pleading requirements in FCA cases and the further possibility of reigning in the explosion of these cases and the associated huge monetary penalties. It is an issue worth monitoring.

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