

Health Care Enforcement in 2015: A Look Back on 2014 and Forecasting the Year Ahead

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In testimony before the House Oversight and Government Reform Subcommittee on Health Care in April 2011, the now-pending nominee for U.S. Attorney General, Loretta E. Lynch, stated in no uncertain terms that “fighting health care fraud is a priority of the Department of Justice.” She succinctly explained that “[w]ith the rising cost of medical care, every dollar stolen from our health care programs is one dollar too many” and that “Medicare and Medicaid fraud can also corrupt the medical decisions health care providers make with respect to their patients, placing them at risk of harm from unnecessary or unapproved treatments.” Ms. Lynch advised the subcommittee that the Department of Justice (“DOJ”) had “enhanced its efforts to protect the public fisc from health care fraud and to help ensure the integrity of patient care,” providing examples of successful efforts by the Health Care Fraud Prevention and Enforcement Action Team (“HEAT”) and Medicare Fraud Strike Force (the “Strike Force”).



In 2014, DOJ, together with the Department of Health and Human Services’ Office of Inspector General (“HHS-OIG”) and other federal and state agencies, methodically continued this approach, once again exacting steep monetary penalties and settlements from companies and imposing lengthy prison terms, fines, forfeiture, and restitution on individuals.

Ms. Lynch’s words, echoed by DOJ’s new Assistant Attorney General for the Criminal Division (“AAG”), Leslie R. Caldwell, and evidenced by DOJ’s enforcement actions this past year, make plain that health care enforcement remains a top priority. Below, we recap some of DOJ’s words and actions in 2014, and forecast what to expect in 2015.

I. Criminal Prosecutions

A. AAG Caldwell Announces Greater Focus on Health Care Fraud Going Forward and Coordination with *Qui Tam* Relators

In remarks at the Taxpayers Against Fraud Education Fund Conference in September 2014, AAG Caldwell lauded the “courageous efforts by relators to bring criminal and civil misconduct to light [as driving] many of the largest and most important health care fraud investigations over the last several decades,” and promised that the Criminal Division would “redouble [its] efforts to work alongside” *qui tam* relators. See September 17, 2014 comments of AAG Caldwell at Taxpayers Against Fraud conference.

Specifically, AAG Caldwell announced that the Criminal Division had:

recently implemented a new procedure so that all new *qui tam* complaints are shared by the Civil Division with the Criminal Division as soon as the cases are filed. Experienced prosecutors in the Frauds Section are immediately reviewing the *qui tam* cases when we receive them to determine whether to open a parallel criminal case. Those prosecutors then communicate swiftly with the Civil Division and U.S. Attorney’s Offices about the best ways to proceed in the parallel investigations.

AAG Caldwell emphasized that skilled prosecutors and investigators are available to work these cases and that they have a “wealth of experience successfully bringing parallel investigations.” She encouraged relators to reach out to criminal authorities in appropriate cases. See *id.*

In addition to announcing the new *qui tam* process, AAG Caldwell highlighted the kinds of cases the Medicare Fraud Strike Force brought in 2014 and continues to prioritize, including cases against medical professionals like doctors and against “executives at health care providers such as hospitals,” and noted they would be “stepping up [their] prosecutions of corporations involved in health care fraud.” See *id.*

B. Prosecutions of Medicare Fraud and Related Offenses in 2014

As DOJ reported in a recent press release, “[s]ince its inception in March 2007, the Medicare Fraud Strike Force, now operating in nine cities across the country, has charged nearly 2,000 defendants who collectively billed the Medicare program more than \$6 billion. In addition, the

HHS Centers 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 14-1373.

Take-aways from 2014 include:

- *Venues of Prosecution* – DOJ and its partners continued to bring cases across the country in jurisdictions that see a high number of health care enforcement actions, including California, Florida, Louisiana, Michigan, New York, and Texas. The Southern District of Florida (Miami) and the Eastern District of Michigan (Detroit) remain particularly active venues for these cases.
- *Variety of Health Care Providers Targeted* – DOJ and its partners are bringing home the message that doctors, nurses, and other medical practitioners will be prosecuted to the fullest extent of the law for their involvement in these cases.
- *Types of Crimes Charged* – DOJ and its partners are using an expanding array of charges to include not only health care fraud, anti-kickback statute violations, and false statements, but also identity theft, money laundering, tax violations, structuring (e.g., making cash deposits in amounts less than \$10,000 to avoid reporting requirements), and obstruction of justice.
- *Wide-ranging penalties* – Sentences imposed included lengthy prison terms, fines, restitution, and forfeiture. Collateral consequences included exclusion from Medicare, Medicaid, and other federal and state health programs.

Below, we discuss some examples of these trends.

1. Medicare Fraud Strike Force Continues to Conduct Nationwide Takedowns

In May 2014, the Strike Force conducted the seventh nationwide takedown in its history, continuing what appears to be an annual initiative. Specifically, on May 13, DOJ and HHS-OIG announced charges against 90 individuals in six cities for allegedly participating in Medicare fraud schemes involving approximately \$260 million in false billings. The government emphasized that 27 of those 90 individuals were doctors, nurses, and other medical professionals. Summarizing the charges, the government stated:

The defendants charged are accused of various health care fraud-related crimes, including conspiracy to commit health care fraud, violations of the anti-kickback statutes and money laundering. The charges are based on a variety of alleged fraud schemes involving various medical treatments and services, including home health care, mental health services, psychotherapy, physical and occupational therapy, durable medical equipment and pharmacy fraud.

These cases were brought in Miami, Houston, Los Angeles, Detroit, Tampa, and Brooklyn. See DOJ press release 14-503.

The sprawling nationwide takedown of numerous Medicare fraud cases that collectively involve a large dollar amount in false billings has clearly become a staple of the government’s strike force approach. They vary little from year to year – for example, 90 individuals were charged in this year’s takedown compared with 89 in last year’s, the collective dollar amount of the fraud schemes was \$260 million this year as opposed to \$223 million last year, and six of the same eight cities hosted both this year’s and last year’s takedowns. The approach is tried and true, serves to put the public on notice of the government’s continuing enforcement efforts, and adds significantly to its coffers, so we can expect to see another nationwide takedown in 2015.

2. Strike Force Fully Exploits Individual Health Care Fraud Investigations to Interdict All Participants

A number of cases demonstrate how DOJ and its partners are seeking maximum impact from each health care fraud investigation by tenaciously following leads to interdict as many participants as possible. Pertinent examples are discussed below.

a. Louisiana and Texas Mental Health Clinics

In 2011, the government began an investigation of three community health centers – two in Baton Rouge and one in Houston – that yielded evidence of a multi-million dollar Medicare fraud. Specifically, over a period of seven years, the centers allegedly billed Medicare for partial hospitalization program services for the mentally ill that were unnecessary or never provided, submitting more than \$258 million in claims and causing Medicare to pay approximately \$43.5 million. See DOJ Press Release 14-1215. 2014 has seen cases against a number of the individual participants in this fraud scheme come to conclusion. Notably, having

been convicted after trial by a jury in May 2014, an owner and operator of the two mental health clinics in Baton Rouge and a patient recruiter were sentenced to 90 months in prison (for health care fraud conspiracy and substantive counts) and 60 months in prison (for health care fraud conspiracy and conspiracy to pay and receive kickbacks), respectively. At their sentencing in October 2014, the co-owner/operator was also ordered to pay \$43.5 million in restitution, while the patient recruiter was ordered to pay \$3.2 million. See DOJ press releases 14-556, 14-1215. In August 2014, a woman who was an owner of all three centers and a marketer for the two in Baton Rouge was sentenced to 102 months in prison and \$43.5 million in restitution after pleading guilty to health care fraud conspiracy and paying and receiving kickbacks. See USAO MD LA release dated August 18, 2014.

To date, this case has resulted in the conviction of 17 individuals, including owners, a medical director, administrators, therapists, and marketers. See DOJ press release 14-1215.

b. South Florida Partial Hospitalization Program

Several years ago, the government began investigating a Medicare fraud scheme involving American Therapeutic Corporation ("ATC"), which operated purported partial hospitalization programs, and its management company, Medlink Professional Management Group, Inc. ("Medlink"). The government reported in a January 2014 press release that ATC, Medlink and various owners, managers, doctors, therapists, patient brokers, and marketers of ATC and Medlink had pled guilty or been convicted at trial of a \$205 million Medicare fraud scheme. The ATC owner, viewed as the mastermind of the scheme, was sentenced to 50 years in prison. See DOJ press releases 14-098, 14-1156; see also April 5, 2011 Testimony of U.S. Attorney Lynch to House Oversight and Government Reform Subcommittee on Health Care and September 17, 2014 comments of AAG Caldwell at Taxpayers Against Fraud conference (both mentioning ATC case).

The case did not end there. In that January 2014 press release, the government announced the latest stage of the prosecution, specifically, the indictment of additional alleged participants in the scheme, including a physician's assistant, a patient recruiter and the co-owner of a check cashing business who allegedly "had facilitated the payments of bribes and kickbacks from ATC to various patient recruiters." The co-owner of the check cashing business was charged with conspiracy to pay and receive bribes and kickbacks in connection with a federal health care program, as well as money laundering conspiracy, substantive money laundering, and aggravated identity theft. See *id.*

In addition to simultaneous takedowns of unrelated smaller dollar-amount frauds in various cities across the country, we can expect 2015 to continue the trend of deep and thorough investigations of high-profile, multi-million dollar fraud schemes, as well as the prosecution of the individuals allegedly responsible for executing them. As AAG Caldwell remarked, DOJ is no longer pursuing just the "low-hanging fruit." See September 17, 2014 comments of AAG Caldwell at Taxpayers Against Fraud conference. Notably, this approach is increasingly resulting in participants beyond the core group of health care providers, medical professionals, and patient recruiters being investigated and charged. Those providing financial services to the core group will also be interdicted, not only for health care fraud conspiracy but for money laundering and similar crimes as well.

3. Professionals Are Being Investigated and Prosecuted to the Fullest Extent of the Law

The cases from 2014 also demonstrate that DOJ is following through on its stated commitment to prosecute professionals, be they doctors, nurses, or other licensed practitioners, whom DOJ believes should be gatekeepers to prevent – not perpetrate – fraud.

For example, in August 2014, a Louisiana psychiatrist was sentenced to approximately seven years in prison and \$43.5 million in restitution, as well as forfeiture of proceeds, for his role in the above-discussed Medicare fraud scheme involving mental health centers. See Section I.B.2.a., above, for additional information. See also DOJ press release 14-894. This is notable particularly when considered with the seven- and eight-year sentences imposed on owners of the mental health centers and the five-year sentence imposed on the patient recruiter. The psychiatrist's sentence is consistent with DOJ's view that gatekeepers should prevent these types of fraud from being perpetrated.

Also, in October 2014, the physician's assistant in the ATC-related Medicare fraud scheme discussed above at Section I.B.2.b. was sentenced to 15 years in prison following his conviction after trial for health care fraud, wire fraud, and false statements; he was also ordered to pay more than \$85 million in restitution jointly and severally with his co-conspirators. See DOJ press release 1156. In December 2014, a patient recruiter in the same scheme, who was a licensed nursing assistant, was sentenced to over 12 years in prison. See DOJ release 14-1373. Here too, the medical professionals, as gatekeepers, received harsh punishment.

C. Securities Fraud

In our 2013 Year in Review, we reported on the evolving securities fraud prosecution involving ArthroCare Corporation, a publicly traded medical device manufacturer based in Texas.

In 2014, the government pressed forward against both the company and a number of C-level executives. Beginning with the company, on January 7, 2014, DOJ announced that ArthroCare had agreed to pay a \$30 million monetary penalty to resolve charges that senior executives had engaged in a securities fraud scheme that inflated the company's earnings through end-of-quarter shipments to distributors and which resulted in more than \$400 million in shareholder losses. DOJ filed a criminal information against the company, charging one count of conspiracy to commit securities and wire fraud, which the company resolved by entering into a deferred prosecution agreement ("DPA") with the government. In addition to agreeing to pay the monetary penalty, the company agreed to cooperate in the continuing investigation and prosecution of its executives and to implement an enhanced compliance program and internal controls designed to prevent and detect violation of federal laws involving its relationships with health care providers. See DOJ press release 14-013.

In late Spring 2014, ArthroCare's former CEO and CFO went to trial and were convicted of conspiracy, securities fraud, and wire fraud; the CEO was also convicted of making false statements to the Securities and Exchange Commission ("SEC"). See DOJ press release 14-588. In August 2014, the former CEO was sentenced to 20 years in prison and the former CFO was sentenced to 10 years in prison. See DOJ press release 14-923. Two former senior vice presidents, who had previously pled guilty to participating in the scheme, were also sentenced, one to almost seven years in prison and the other to five years in prison. *Id.*

In announcing the sentences, the Principal Deputy AAG, Marshall L. Miller, stated that "[t]he aggressive pursuit of corporate executives who commit fraud is at the core of our mission to pursue justice and protect the American public." So C-level executives, like licensed medical professionals, are on notice that they may become a focus of prosecution.

The following message remains important: companies should undertake periodic review and revision of their compliance programs to ensure that they are fine-tuned to their risks and appropriately tailored to prevent illegal and unethical conduct. Compliance training and monitoring are essential to these efforts.

D. Global Anti-Corruption

In November 2009, then-AAG for the Criminal Division, Lanny Breuer, announced that DOJ would be "intensely focused on rooting out foreign bribery" in the pharmaceutical and medical device industries. The case discussed below suggests that current AAG Caldwell will continue, if not reinvigorate, these efforts, with the full support of Attorney General Nominee Lynch.

1. Bio-Rad

In November 2014, BioRad Laboratories Inc., a California-based medical diagnostics and life sciences manufacturing and sales company:

agreed to pay a \$14.35 million penalty to resolve allegations that it violated the Foreign Corrupt Practices Act (FCPA) by falsifying its books and records and failing to implement adequate internal controls in connection with sales it made in Russia.

See DOJ press release 14-1221. Bio-Rad also agreed to disgorgement of \$40.7 million to the SEC. See SEC release 2014-245. The underlying facts involved a subsidiary of Bio-Rad in France paying commissions to intermediary companies purportedly in exchange for services in connection with government sales in Russia; however, the intermediary companies did not provide the services. Nonetheless, several high-level managers knowingly approved the commission payments and caused the payments to be falsely recorded on the subsidiary's and Bio-Rad's books. Additionally, Bio-Rad failed to implement adequate compliance systems and internal controls. *Id.*

In announcing this resolution, AAG Caldwell said that DOJ:

pursues corruption from all angles, including the falsification of records and failure to implement adequate internal controls. [DOJ] also gives credit to companies, like Bio-Rad, who self-disclose, cooperate and remediate their violations of the FCPA.

See *id.* That credit was to allow Bio-Rad to enter into a non-prosecution agreement (“NPA”), because it not only self-disclosed but also made available for interviews U.S. and foreign employees, voluntarily produced documents from overseas, summarized investigative findings, enhanced anti-corruption policies globally, improved compliance and internal controls, and conducted extensive training. See *id.*

Once again, DOJ is sending a very clear message that it will continue its aggressive FCPA enforcement efforts. However, a company that develops, implements, regularly updates, and enforces a compliance program and related policies and procedures fine-tuned to its risks will be credited by DOJ and will avoid the harshest penalties.

II. Significant Joint Criminal/Civil Matters

While 2014 saw no health care fraud settlements on the same scale as GlaxoSmithKline’s \$3 billion settlement in 2012 or Johnson & Johnson’s \$2.2 billion settlement in 2013, DOJ continued to prosecute health care fraud cases aggressively. One matter, involving Endo Pharmaceuticals Inc., shows DOJ following its tried and true approach of simultaneously resolving criminal and civil matters to obtain headline-grabbing results. Another, involving Vascular Solutions Inc., provides a glimpse of what we might expect from DOJ going forward.

A. Endo Health Solutions and Its Subsidiary Resolve Potential Criminal and Civil Liability with \$192 Million Settlement

On February 21, 2014, Endo Health Solutions Inc. and its subsidiary, Endo Pharmaceuticals Inc., agreed to pay \$192.7 million to resolve criminal and civil liability arising from the marketing of prescription drug Liboderm for uses not approved by the Food and Drug Administration (“FDA”). See DOJ release 14-187.

To resolve its criminal exposure, Endo Pharmaceuticals entered into a DPA with respect to a misbranding charge filed in the Northern District of New York. In connection with the DPA, Endo Pharmaceuticals made certain admissions. Among the other terms were forfeiture of \$20.8 million and an agreement to implement and maintain a number of enhanced compliance measures, including making publicly available the results of certain clinical trials and requiring an annual review and certification of its compliance efforts by the CEO of its parent company. See *id.*

The civil settlement resolved alleged False Claims Act (“FCA”) violations by Endo Pharmaceuticals against the U.S., a number of states, and the District of Columbia for a total of \$171.9 million. Endo Pharmaceuticals also agreed to enter into a Corporate Integrity Agreement (“CIA”) with the HHS-OIG requiring the company to implement measures to avoid or promptly detect conditions similar to those giving rise to this matter. The civil settlement resolved three *qui tam* lawsuits in the Eastern District of Pennsylvania. See *id.*

This case, like others before it, reflects DOJ’s and HHS-OIG’s preferred method for resolving cases against major pharmaceutical companies: a guilty plea, NPA, or DPA from a subsidiary; a monetary component composed of some combination of fines, forfeiture, restitution, and a civil settlement; compliance reforms; and a CIA. However, the next matter suggests that, under the new administration, the government may persist with criminal charges if the acquiescence of a parent or subsidiary is not forthcoming.

B. Vascular Solutions Inc. Indicted for Selling Unapproved Medical Devices, Having Earlier Entered a Civil Settlement of False Claims Act Allegations

In November 2014, DOJ’s Civil Division obtained an indictment charging Vascular Solutions Inc. (“VSI”) and its CEO with eight counts of introducing adulterated and misbranded medical devices into interstate commerce in connection with a sales campaign related to the Vari-Lase product line, as well as with a conspiracy to commit these offenses against the U.S. and to defraud the U.S. in connection with the allegedly illegal sales activity. VSI is a public company, with its principal place of business in Minneapolis. The Vari-Lase system was designed to treat varicose veins by sealing them with a laser (“ablation”). See DOJ press release 14-1268.

The indictment, obtained under the Civil Division’s consumer protection criminal authority, specifically alleges that the Vari-Lase system was approved by the FDA only for treatment of superficial veins, not perforator veins (connecting the superficial vein system to the deep vein system). The indictment further alleges that, beginning in 2007, the CEO led a sales campaign to sell the Vari-Lase system for the unapproved use. This allegedly included launching a “Short Kit,” which VSI stated was for treatment of undefined “short vein segments,” but marketed for treatment of perforator veins. See DOJ press release 14-1268.

According to the Acting AAG for DOJ's Civil Division:

[t]hese charges involve a deceptive sales campaign led by the CEO of a publicly traded company...The indictment charges that the sales campaign persisted in the face of FDA warnings, a whistleblower complaint to the CEO and a failed clinical trial showing that the device was less safe and less effective than a product that had already been approved. We will take action to hold corporations and their leaders responsible when they violate laws intended to protect public health.

See *id.*

VSI issued a strong response, stating: "The allegations against us are false and we will contest them vigorously." VSI emphasized that it had cooperated fully during the investigation, "point[ing] out the flaws in the government's theories and evidentiary assumptions," and that it would defend the "improper and false allegations through trial where [it was] confident of prevailing." VSI specifically noted that it did not plan to make any changes to its business operations or personnel as a result of the indictment. See November 13, 2014 Statement of Vascular Solutions on Grand Jury Indictment.

The Chairman of VSI's Board of Directors made a statement supporting management's handling of the matter, the company's defense against the charges, and the decision to keep the CEO in place "throughout this legal process and to its successful resolution at trial." He also noted that VSI has "a complete and detailed compliance program." *Id.*

The VSI matter may signal DOJ's willingness to indict a corporation if DOJ believes it has not obtained the appropriate global criminal/civil resolution. As noted above, DOJ's preferred approach has been to structure a global resolution of its criminal and civil investigations that involves a corporation entering an NPA or DPA, paying large financial penalties, having a subsidiary and/or C-level employees plead guilty and bear any collateral consequences, and pledging an enhanced compliance program. Here, VSI apparently would not accommodate DOJ's preference.

In July 2014, DOJ and VSI entered into a civil settlement, with VSI agreeing to pay \$520,000 to resolve allegations raised in a *qui tam* complaint that that it had caused the submission of false claims to federal health programs by marketing the Vari-Lase devices for treating perforator veins. VSI did not admit liability. See DOJ press release 14-1268. Apparently, DOJ and VSI could not reach agreement on related criminal violations. In civil FCA settlements, DOJ typically reserves all rights to bring criminal proceedings, and requires waiver of double jeopardy claims. DOJ appears to have taken full advantage of such a reservation with VSI.

It will be interesting to watch as DOJ's criminal case against VSI and its CEO proceeds to trial. If DOJ is unsuccessful, additional companies may be emboldened to defend a case through trial. If DOJ is successful, it will likely cause DOJ's preferred approach of simultaneously resolving criminal and civil cases to become further embedded.

III. Civil Matters

A. DOJ's Civil Division Reiterates Its Focus: Hospitals, Home Health Services, and Cardiac Procedures

On November 20, 2014, DOJ's Civil Division announced a summary of its enforcement actions for fiscal year ("FY") 2014, emphasizing its large recoveries and articulating its focus. In FY 2014, DOJ recovered \$2.3 billion from its health care enforcement activities, with \$1.1 billion of that sum coming from its settlement with Johnson & Johnson. See DOJ release 14-1300. Health care fraud continues to be one of the Civil Division's stated priorities, with hospitals, home health services, and cardiac procedures being of particular focus and its enforcement actions bearing that out.

B. A Few Examples

1. Hospitals

DOJ's Civil Division advised in November 2014 that "[c]ases involving hospitals resulted in \$333 million in fiscal year 2014 settlements and judgments, with significant recoveries from two hospital chains." *Id.*

One of those hospital chains was Community Health Systems, Inc. ("CHS"), which was described as "the nation's largest operator of acute care hospitals." *Id.* CHS agreed to pay \$98 million to settle seven FCA lawsuits filed by *qui tam* relators around the country. CHS

also entered into a five-year CIA with the HHS-OIG, requiring CHS to undertake significant compliance efforts. The settlement resolves a number of allegations, including contentions that CHS hospitals:

engaged in a deliberate corporate-driven scheme to increase inpatient admissions [of patients] who originally presented to the emergency departments at 119 CHS hospitals; ...the inpatient admissions of these [patients] was not medically necessary, and the care needed by, and provided to, these [patients] should have been provided in a less costly outpatient or observation setting.

DOJ press release 14-822. The case also involved alleged Stark violations arising from referrals from a physician who was offered a medical directorship.

In addition to the sizeable settlement amount, the CHS settlement is notable for hospital systems and hospital management companies for a number of reasons.

- The breadth of corporate entities and number of hospitals covered by the settlement suggests that robust compliance efforts should be undertaken at all levels of a health care provider's corporate structure – the hospitals, management company, and the parent. As noted above, DOJ asserted in its press release that CHS allegedly engaged in a "deliberate corporate-driven scheme," and the settlement agreement covers not only 119 CHS-operated hospitals, but also parent corporate entities, including CHS, the indirect owner of these hospitals, and Community Health Systems Professional Services Corporation, a CHS subsidiary that provides management services to CHS hospitals. *Id.*
- DOJ continues to vigorously pursue allegations that inpatient hospital admissions should have been for outpatient or observation services. Hospitals and health systems should reexamine their policies in this regard, especially with respect to both admissions from their emergency departments and the specific DRG and MS-DRGs that were involved in this case.
- Relators can come from any part of a hospital's organization. The relators who filed seven related *qui tam* cases around the country against CHS included former nurses, billing personnel, emergency room physicians, and a Director of Health Information Management.
- The government's declination followed by a later request to intervene in one relator's case suggests the significant impact that a national, coordinated investigation resulting from several related *qui tam* complaints in multiple districts could have had on the government's assessment of the merits of an individual case against subsidiaries. In these seven cases, many health care enforcement agencies coordinated their investigation, including DOJ's Civil Division; the United States Attorneys' Offices for the Middle District of Tennessee, Southern District of Texas, Northern and Southern District of Illinois, Northern District of Indiana, and Western District of North Carolina; HHS-OIG; and the Office of Audit Services for the Office of Investigations.

The other hospital case cited by DOJ in its November 2014 summary of its enforcement activities involved Halifax Hospital Medical Center and Halifax Staffing, Inc., a hospital system based in Florida, that agreed in March 2014 to pay \$85 million to resolve alleged Stark Law violations. *See id.*; *see also* DOJ release 14-252. Other cases against hospitals resolved last year include (1) a settlement in May 2014 with King's Daughters Medical Center, which agreed to pay almost \$41 million to resolve "allegations that it submitted false claims to the Medicare and Kentucky Medicaid programs for medically unnecessary coronary stents and diagnostic catheterizations and had prohibited financial relationships with physicians referring patients to the hospital," DOJ release 14-567, and (2) an October 2014 settlement with Dignity Health, which agreed to pay \$37 million to resolve FCA "allegations that 13 of its hospitals in California, Nevada and Arizona knowingly submitted false claims to Medicare and TRICARE by admitting patients who could have been treated on a less costly outpatient basis," DOJ release-1210.

2. Home Health Services

Another notable case from 2014 involved Amedisys Inc., described as one of the nation's largest providers of home health services, and said to operate in 37 states, the District of Columbia, and Puerto Rico. *See* DOJ release 14-422 and 14-1300. Amedisys agreed to pay \$150 million to resolve seven FCA lawsuits filed by *qui tam* relators, six in the Eastern District of Pennsylvania and one in the Northern District of Georgia. Amedisys also agreed to be bound by a CIA with HHS-OIG requiring the implementation of compliance measures to avoid, or promptly detect, the kind of conduct giving rise to this matter. Amedisys allegedly had billed Medicare for

nursing and therapy services that were medically unnecessary or were for services to patients who were not homebound. Amedisys also allegedly violated the Anti-Kickback Statute and the Stark Law.

C. An Update on the Degree of Specificity Required in *Qui Tam* Complaints

In our 2013 Year in Review, we discussed a *qui tam* case against Takeda Pharmaceuticals North America, Inc., with potential precedential effect. In October 2013, the Supreme Court had requested that the Solicitor General “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 a petition for *certiorari* by the relator, specifically regarding whether to grant review of a decision by the Fourth Circuit Court of Appeals dismissing 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 N. Am., Inc.*, 707 F.3d 451 (4th Cir. 2013), *cert. denied*, 2014 WL 1271321 (U.S. March 31, 2014) (No. 12-1349).

Specifically, the issue was whether Rule 9(b) of the Federal Rules of Civil Procedure requires that a complaint under the FCA allege that specific false claims were presented to the government for payment, as the Sixth, Eighth, Tenth, and Eleventh Circuits had ruled, or whether it is sufficient to allege “particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted,” as the First, Fifth, Seventh, and Ninth Circuits had ruled. See Brief for the United States as *Amicus Curiae* at 11-12, *U.S. ex rel. Nathan v. Takeda Pharmaceuticals N. Am., Inc.* (No. 12-1349).

The United States, which had declined to join the underlying FCA case in the federal district court, urged the Supreme Court to deny the relator’s petition for *certiorari*. While acknowledging inconsistent rulings among the circuits on the necessary specificity to plead an FCA case, the U.S. argued that the inconsistencies could be sorted out by the circuits without the Supreme Court’s intervention and, if not, the Supreme Court could address the issue in the future. See *id.* at 16.

It may be that the U.S. was less concerned about inconsistencies between the circuits than bad law possibly being made for FCA plaintiffs and relators due to the lack of specifics in the *Takeda* case.

On March 31, 2014, the Supreme Court denied *certiorari*, declining to wade into the debate over the degree of particularity with which a relator must plead a violation of the FCA. See 2014 WL 1271321 (U.S. March 31, 2014) (No. 12-1349). Since then, other courts have addressed the issue, with the Third Circuit joining the First, Fifth, Seventh and Ninth Circuits in adopting the less rigid position. See *Foglia v. Renal Ventures Management, LLC*, 754 F.3d 153 (3rd Cir. 2014). Thus, the government, relators and potential defendants in *qui tam* actions will have to continue to keep in mind the jurisdiction in which the complaint was filed in assessing the level of pleading specificity required and the likelihood of successful 9(b) dismissal motions.

IV. Conclusion

The vigor with which the DOJ, HHS-OIG, other federal and state agencies and *qui tam* relators brought health care enforcement actions in 2014 reflects their continuing commitment to aggressive prosecution of criminal and civil violations. These cases involved alleged health care fraud, anti-kickback statute violations, false statements, false claims, identity theft, money laundering, tax violations, structuring, and obstruction of justice. New charges were leveled against a wide array of companies and individuals, including corporate executives as well as medical practitioners. Corporations found liable received substantial monetary penalties, while individuals were sentenced to lengthy prison terms and received large fines.

To avoid enforcement actions and associated penalties in 2015, health care executives and companies, and those who provide services to them, should review and, if appropriate, revise their compliance programs and internal procedures—taking proactive measures to prevent fraudulent activity and reduce potential liability.