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Health Care Enforcement in 2016: A Look Back on 2015 and Forecasting the Year Ahead

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2015 was a year of transition for the U.S. Department of Justice ("DOJ"), with the installation of a new Attorney General, Deputy Attorney General, and several other high-level officials. In January 2015, Andrew Weissmann came on board as Chief of the Fraud Section, filling a key role within DOJ's Criminal Division, and reuniting the leadership of the Enron Task Force. (The task force initially had Leslie R. Caldwell, the current Assistant Attorney General in charge of the Criminal Division, and Mr. Weissmann at its helm). In March 2015, Benjamin R. Mizer became Principal Deputy Assistant Attorney General and Acting Assistant Attorney General in charge of the Civil Division. The reorganization was completed with the installation of Sally Quillian Yates as Deputy Attorney General and, finally, of Loretta E. Lynch as Attorney General, this past spring.

Despite the many officials in transition and the other important law enforcement challenges that the government faced in 2015, based on the cases pursued by DOJ and its partners, health care fraud remains a top enforcement priority. Moreover, there have been policy developments that will impact health care fraud enforcement, as will, we anticipate, DOJ's new compliance counsel.

Below we recap these policy developments as well as some of the notable cases from 2015, and we forecast what to expect in 2016.

I. General Developments

A. The Yates Memo

On September 9, 2015, DOJ Deputy Attorney General Yates issued a memo reaffirming the government's commitment to investigating individuals and prosecuting culpable ones, as well as formally directing its prosecutors to prioritize individual accountability when addressing corporate misconduct. Since then, there has been a lively debate regarding the significance of this development and whether it actually represents a change in policy. Time, of course, will be the best judge. In the meantime, here are the basics from the memo, as well as some additional commentary by high-level DOJ officials.

There are essentially six points in the Yates Memo:

- To be eligible for any cooperation credit, corporations must provide to DOJ all relevant facts about the individuals involved in corporate misconduct.
- Both criminal and civil corporate investigations should focus on individuals from the inception of the investigation.

- Criminal and civil attorneys handling corporate investigations should be in routine communication with one another.
- Absent extraordinary circumstances, no corporate resolution will provide protection from criminal or civil liability for any individuals.
- Corporate cases should not be resolved without a clear plan to resolve related individual cases before the statute of limitations expires, and declinations as to individuals in such cases must be memorialized.
- DOJ civil attorneys should investigate individuals as well as the company and evaluate whether to bring suit against an individual based on considerations beyond the individual's ability to pay.

See the Yates Memo here; *see also* Mintz Levin *Health Law and Policy Matters* blog post, DOJ Issues Memo Directing Prosecutors to Focus on Individual Accountability, September 11, 2015 (discussing the Yates Memo in detail).

On September 10, 2015, at New York University School of Law, Deputy Attorney General Yates gave a speech regarding the memo that strayed little from its text; moreover, she did not take any questions. The public head-scratching then began. Didn't prosecutors always seek to prosecute individuals? Didn't corporations that were cooperating with the government already disclose this type of information? What exactly was new here? Or, contrarily, was a new rigid standard required that corporations would be hard-pressed to meet? Was the government pulling back from its position that corporations need not waive the attorney client privilege? Were joint defense agreements going to be feasible going forward? The questions abounded.

Later in September, at the Global Investigations Review Conference in New York, Assistant Attorney General Caldwell addressed the central tenet of the Yates Memo, stating "companies seeking cooperation credit must affirmatively work to identify and discover relevant information about culpable individuals through independent, thorough investigations. Companies cannot just disclose facts relating to general corporate misconduct and withhold facts about responsible individuals. And internal investigations cannot end with a conclusion of corporate liability, while stopping short of identifying those who committed the criminal conduct." *See* Mintz Levin *Securities Matters* blog post, Assistant Attorney General Caldwell Clarifies Application of Yates Memo on Individual Accountability, September 23, 2015.

Assistant Attorney General Caldwell also offered some answers to practitioners representing corporations, saying "We recognize, however, that a company cannot provide what it does not have. And we understand that some investigations — despite their thoroughness — will not bear fruit. Where a company truly is unable to identify the culpable individuals following an appropriately tailored and thorough investigation, but provides the government with the relevant facts and otherwise assists us in obtaining evidence, the company will be eligible for cooperation credit. We will make efforts to credit, not penalize, diligent investigations. On the flip side, we will carefully scrutinize and test a company's claims that it could not identify or uncover evidence regarding the culpable individuals, particularly if we are able to do so ourselves." (That said, Assistant Attorney General Caldwell acknowledged that sometimes DOJ can obtain evidence that a corporation cannot.) Assistant Attorney General Caldwell also remarked that the Yates Memo does not change existing DOJ policy regarding the attorney client privilege and work product protection. *See id.*

In October, at the Pharmaceutical Compliance Congress and Best Practices Forum in Washington, D.C., Principal Deputy Assistant Attorney General Mizer of the Civil Division provided his thoughts on the Yates Memo. In the context of "current law enforcement efforts that may bear on what the future holds," he focused on a few of the above bullet points. He bluntly paraphrased the first bullet point by saying "this means no partial credit for cooperation that doesn't include information about individuals," and stressed that it applies with equal force to civil investigations and specifically to False Claims Act investigations.

Principal Deputy Assistant Attorney General Mizer also emphasized that DOJ's Criminal and Civil Divisions would focus their investigations on individuals from the outset and that criminal and civil attorneys "have been directed to cooperate [with each other] to the fullest extent permitted by law at all stages of an investigation." The latter is a point that Assistant Attorney General Caldwell made early in her tenure during a speech at a Taxpayers Against Fraud conference. It was at their September 2014 Conference that she announced a procedure whereby *qui tam* complaints would be shared by the Civil Division with the Criminal Division as soon as the cases were filed and that the attorneys in the Fraud Section of the Criminal Division would immediately review them to determine whether a parallel criminal case should be brought. *See* Mintz Levin Securities Matters blog post, Principal Deputy Assistant Attorney General Mizer Sheds Additional Light on Individual Accountability and the Yates Memo, October 23, 2015.

Other high-level officials from DOJ, the SEC and U.S. Attorney's Offices have addressed the Yates Memo, with the usual disclaimers that the

views they are expressing are their own, and not the government's views, but providing some practical considerations. These federal law enforcement officials have emphasized that they want defense counsel to provide the facts, including who was involved in or approved the conduct at issue, and not just statements that mistakes were made.

It might be the case that the Yates Memo is, as advertised, a memo to DOJ criminal and civil attorneys directing them to coordinate better amongst themselves: to amass a complete body of evidence of corporate and individual wrongdoing; to require all available evidence that corporations have regarding their employees' misconduct before awarding cooperation credit; and to obtain supervisory approval and maintain records of actions to best ensure that the procedure is uniformly applied. If such an approach is followed across DOJ and all U.S. Attorneys' Offices, we may see more parallel criminal and civil fraud cases against health care providers and product manufacturers.

B. DOJ's Hiring of Compliance Counsel

In November 2015, Assistant Attorney General Caldwell continued to emphasize the importance of companies having compliance programs fine-tuned to their specific risks, as a hedge against fraud and abuse. She specifically addressed the way DOJ thinks about compliance programs. *See* *Justice News*, "Assistant Attorney General Leslie R. Caldwell Speaks at SIFMA Compliance and Legal Society New York Regional Seminar," November 2, 2015.

AAG Caldwell stated that when DOJ prosecutors are considering whether to charge a corporation criminally, they "look closely at whether compliance programs are simply 'paper programs' or whether the institution and its culture actually support compliance. We look at pre-existing programs, as well as remedial measures a company took after discovering misconduct — including efforts to implement or improve a compliance program." *See id.*

On November 3, 2015, the Criminal Division added a resource for evaluating compliance programs with the hiring of Hui Chen as compliance counsel for the Fraud Section. AAG Caldwell addressed this addition in her remarks at the SIFMA conference, noting that DOJ wanted "the benefit of the expertise of someone with significant high-level compliance experience across a variety of industries." (Previously, Ms. Chen was global head of anti-bribery and corruption at Standard Chartered and Assistant General Counsel at Pfizer focusing on compliance.) In the context of making charging decisions, compliance counsel "will help [DOJ] assess a company's program, as well as test the validity of its claims about its program, such as whether the program truly is thoughtfully designed and sufficiently resourced to address the company's compliance risks, or essentially window dressing." *Id.* Additionally, compliance counsel "will help guide Fraud Section prosecutors when they are seeking remedial compliance measures as part of a resolution with a company." The idea is to require an effective program without being unduly burdensome. *Id.*

AAG Caldwell specifically addressed speculation in the legal community that the hiring of compliance counsel was a precursor to a compliance defense. She said it is not, and that review of a company's compliance program will remain one of the several factors (*i.e.*, the Filip factors) reviewed when DOJ considers whether to charge a company. *Id.*

AAG Caldwell drove home the importance of compliance, stating "[o]ur hiring of a compliance counsel should be an indication to companies about just how seriously we take compliance." *Id.* The Fraud Chief, Mr. Weissmann, has suggested that DOJ hopes to urge organizations to strengthen their internal compliance function to prevent misconduct that can lead to prosecutions. He and Ms. Chen have gone on the road to talk with compliance professionals about DOJ's objectives.

II. Criminal Prosecutions

A. Medicare Fraud and Related Offenses

In 2009, DOJ and Health and Human Services ("HHS") kicked off the Health Care Fraud Prevention & Enforcement Action Team (or "HEAT") initiative "focus[ing] their efforts to prevent and deter fraud and enforce current anti-fraud laws around the country." *See* DOJ press release 15-757. HEAT built upon the Medicare Fraud Strike Force that had been initiated a few years earlier. The strike force approach employs multi-agency cooperation and a variety of investigative techniques harkening back to those used by DOJ's organized crime task force to interdict a large swath of perpetrators for a variety of health care-related crimes in the targeted cities. *See* Rohde, B., *New York Law Journal*, "The Strike Force Approach to Combatting Health Care Fraud," February 10, 2014.

These efforts have been increasingly effective. 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 2,300 defendants who have collectively billed the Medicare program for more than $7 billion. In addition, the HHS Centers for Medicare and Medicaid Services ("CMS"), working in conjunction with the HHS-[Office of Inspector General ("HHS-OIG")], is taking steps to increase accountability and decrease the presence of fraudulent providers." *See* DOJ press release 15-1370. This reflects the charging in 2015 of approximately 300 defendants for collectively billing Medicare approximately $1 billion.

Takeaways from 2015 include:

Hot Spot Venues Targeted — DOJ and its partners continued to bring cases across the country in jurisdictions with allegedly high levels of Medicare fraud, including California, Florida, Louisiana, Michigan, New York, and Texas. The Southern District of Florida (Miami) remained a particularly active venue for these cases. The Central District of California (Los Angeles) remained a locus of durable medical equipment ("DME") fraud prosecutions.

Licensed Health Care Professionals Increasingly Prosecuted — DOJ and its partners regularly prosecuted doctors, nurses, and other medical professionals.

Health Care and Financial Crimes Charged — Cases typically included charges of conspiracy to commit health care fraud, the related substantive offense or anti-kickback statute violations, with other crimes such as money laundering or identity theft sometimes rounding out the alleged criminal conduct.

Long Prison Terms and Other Penalties Obtained — Sentences included lengthy prison terms, as well as fines, restitution, and forfeiture. Collateral consequences included exclusion from Medicare, Medicaid, and other federal and state health programs. CMS suspended a number of providers using its Affordable Care Act authority.

Some examples of these trends included the following.

1. Medicare Fraud Strike Force Conducts Largest Coordinated Nationwide Takedown in DOJ History

In June 2015, the Strike Force conducted its annual nationwide takedown, the eighth in its history. Specifically, Attorney General Lynch and HHS Secretary Sylvia Mathews Burwell announced charges against 243 defendants in 17 federal districts for allegedly participating in Medicare fraud schemes involving approximately $712 million in false billings. The defendants included doctors, nurses, and other licensed medical professionals (46 of the total defendants); home health care providers; pharmacy owners; and patient recruiters. The charges were based on "alleged fraud schemes involving various medical treatments and services, including home health care, psychotherapy, physical and occupational therapy, durable medical equipment (DME) and pharmacy fraud. More than 44 of the defendants arrested [were] charged with fraud related to the Medicare prescription drug benefit program known as Part D," which was described as "the fastest-growing component of the Medicare program overall." *See* DOJ press release 15-757; *see also, e.g., Justice News*, Attorney General Loretta Lynch Delivers Remarks at the Press Conference to Announce a National Medicare Fraud Takedown, June 18, 2015; Assistant Attorney General Leslie R. Caldwell Delivers Remarks at the Press Conference to Announce a National Medicare Fraud Takedown," June 18, 2015.

The 2015 annual nationwide takedown merits careful scrutiny. From one year to the next, the total dollar amount of alleged false billings in the numerous Medicare fraud cases comprising the nationwide takedown typically rises. For example, alleged false billings grew from $223 million in 2013 to $260 million in 2014. Notably, the Medicare fraud cases interdicted as part of the 2015 takedown totaled approximately $712 million, marking an almost threefold increase. The number of individual defendants rose to 243 from 89 in the 2013 takedown and 90 in the 2014 takedown. Forty-six of the 2015 defendants were licensed medical professionals, compared to 27 in 2014. (The press release for the 2013 takedown did not identify the number of licensed medical professionals charged that year.) *Compare* DOJ press release 15-757 to DOJ press releases 14-503 and 13-553.

Viewed another way, the Miami portion alone of the 2015 takedown, with 73 defendants and approximately $263 million in false billings, was on par with the entirety of last year's nationwide takedown. *Compare* DOJ press release 15-757 to DOJ press release 14-503.

Another interesting fact about the 2015 takedown involves the number of participating districts. In addition to the Strike Force districts,

cases were brought by eight other U.S. Attorney's Offices, namely, those for the Districts of Alaska, Connecticut, Maryland, Northern Ohio, Southern California, Southern Georgia, Southern Illinois, and Western Kentucky. *See* DOJ press release 15-757. DOJ has not added any cities to the Strike Force since 2011, and the participation of these additional districts does not necessarily presage a change. More likely, and importantly, the increased breadth and depth of the Strike Force cases and the fact of additional cases from other districts reflect the fruits of the Strike Force's growing expertise, additional resources, and new and more technologically advanced investigative tools.

Aside from remarking on the historic size of the 2015 takedown, high-level officials at DOJ and HHS made other notable comments. Both HHS Secretary Burwell and AAG Caldwell spoke about preventing fraud before it starts, catching fraud at an earlier stage, and better detecting and fighting fraud. They also noted that health care enforcement efforts more than pay for themselves. *See* DOJ press release 15-757. With this measure of success, we can expect to see a continuation and strengthening of these efforts in 2016.

2. Licensed Medical Professionals Are Front and Center in Health Care Fraud Prosecutions.

For the last few years, DOJ's highest-level officials have repeatedly said that doctors, nurses, and other licensed medical professionals will be prosecuted to the fullest extent of the law if they are involved in health care fraud. In connection with the annual nationwide takedown, AAG Caldwell specifically noted that DOJ was "really focusing on bringing corrupt medical professionals in particular, as well as their accomplices, to justice more quickly than ever." *Justice News,* Assistant Attorney General Leslie R. Caldwell Delivers Remarks at the Press Conference to Announce a National Medicare Fraud Takedown, June 18, 2015.

In 2015, the Strike Force pursued a number of cases against licensed medical professionals in addition to those that were part of the annual nationwide takedown. Some representative cases are highlighted below.

Spectrum Care P.A.: In the culmination of a case tried in March 2014, two physician owners of Spectrum Care P.A, a community mental health clinic in Houston purportedly providing partial hospitalization program ("PHP") services, were sentenced in January 2015 for their roles in a $97 million Medicare fraud scheme. According to DOJ, the evidence at trial showed that Drs. Mansour Sanjar and Cyrus Sajadi signed documents certifying that patients qualified for PHP services when they did not, in fact, qualify for or need such services. The evidence allegedly showed that the doctors billed Medicare for these services, as well as for recreational activities that were not covered by Medicare, and that they paid kickbacks to group care operators and patient recruiters. Dr. Sanjar was sentenced to 148 months in prison, and Dr. Sajadi was sentenced to 120 months in prison; both were ordered to pay over $8 million in restitution. Other participants in the scheme have also been prosecuted and sentenced to prison time and financial penalties. *See* DOJ press release 15-033.

In announcing the sentences of Drs. Sanjar and Sajadi, AAG Caldwell observed that: "Doctors are not only bound by oath to serve the health of their patients, they are bound by duty to serve as gatekeepers for Medicare spending. In this case, without the criminal participation of Drs. Sanjar and Sajadi, this fraud simply could not have happened." *Id.*

Hollywood Pavilion: In April 2015, a Miami-area physician, Dr. Barry Kaplowitz, was sentenced to 60 months in prison and $2.9 million in restitution for his role in a $5.5 million Medicare fraud scheme. According to DOJ, the evidence at trial showed that Dr. Kaplowitz, the medical director at Hollywood Pavilion ("HP"), "signed false and fraudulent medical records in order to make it appear that HP patients qualified for and received intensive outpatient services, even though they did not." The records became the basis for more than 2,800 false claims to Medicare for over $5.5 million, in response to which Medicare reimbursed $2.9 million. In addition to Dr. Kaplowitz, HP's former CEO, COO, and other high-level personnel were convicted and sentenced to substantial prison terms and restitution; for example, the former CEO was sentenced to 25 years in prison, the former COO was sentenced to 6 years in prison, and both were ordered to pay over $39 million in restitution. *See* DOJ press release 15-534.

B. Securities Fraud

In an April 2015 speech at New York University regarding the role of criminal law enforcement in addressing conduct that may also be subject to regulatory enforcement, AAG Caldwell drew upon the securities fraud prosecution of ArthroCare Corporation ("Arthrocare"), which we have chronicled in our last two year-in-review reports, to illustrate her view that criminal prosecution is the best way to punish culpable individuals. *See Justice News,* Assistant Attorney General Leslie R. Caldwell Delivers Remarks at the New York University Center on the Administration of Criminal Law's Seventh Annual Conference on Regulatory Offenses and Criminal Law, April 14, 2015.

To briefly recap, Arthrocare is a publicly traded medical device manufacturer based in Texas. In January 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 involved inflating the company's earnings through end-of-quarter shipments to distributors and 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 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 through its relationships with health care providers. *See* Foster, H. and Rohde, B., Mintz Levin alert, Health Care Enforcement in 2015: A Look back on 2014 and Forecasting the Year Ahead (*citing* DOJ press release 14-013).

In 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 false statements to the Securities and Exchange Commission ("SEC"). In August 2014, the former CEO was sentenced to 20 years in prison and the former CFO was sentenced to 10 years in prison. Other former senior executives, who had pled guilty to participating in the scheme, were sentenced to lesser but still significant prison terms. *See id.* (*citing* DOJ press releases 14-588 and 14-923).

Wrapping up her speech at NYU, and punctuating what she believes to be the advantages of criminal prosecution, AAG Caldwell singled out the Arthrocare case. She stated, "[t]hat case — involving egregious accounting fraud and where one of the defendants lied during a SEC deposition — shows the role that criminal prosecution can play in holding individuals accountable for their criminal conduct." *See Justice News*, Assistant Attorney General Leslie R. Caldwell Delivers Remarks at the New York University Center on the Administration of Criminal Law's Seventh Annual Conference on Regulatory Offenses and Criminal Law, April 14, 2015.

Upcoming securities fraud cases in the health care space will likely look like Arthrocare.

C. Global Anti-Corruption

The SEC brought a notable Foreign Corrupt Practices Act ("FCPA") case involving the New York-based pharmaceutical company, Bristol-Myers Squibb, based on conduct by a Chinese affiliate. DOJ did not bring a criminal case against the U.S. company. We discuss the Bristol-Myers Squibb case and DOJ, SEC, and global health care enforcement, below.

1. Bristol- Myers Squibb

In October 2015, the SEC announced that Bristol-Myers Squibb ("BMS") had agreed to pay more than $14 million to settle alleged violations by BMS and its majority owned joint venture operating in China ("BMS China") of the internal controls and record-keeping provisions of the FCPA. BMS did not admit or deny the SEC's findings. *See In the Matter of Bristol-Myers Squibb Company*, Securities and Exchange Act Release No. 76073, October 5, 2015 (the "SEC's Cease and Desist Order" or the "Order"); *see also* SEC release 2015-229.

According to the SEC's Cease and Desist Order, certain BMS China employees provided cash and other inducements to foreign officials such as health care providers ("HCPs") at state-owned and state-controlled hospitals to generate prescription sales.The relevant transactions were then falsely recorded as legitimate business expenses in the BMS/BMS China books and records. *See* the SEC's Cease and Desist Order.

The Order emphasized a number of perceived BMS/BMS China deficiencies, beginning with a failure to respond to red flags indicating that the improper payments were being made. The red flags included documents such as "non-compliant claims, fake and altered invoices and receipts, and consecutively numbered receipts," *id.* at 3, that BMS China had identified through an internal review of travel and entertainment expenses submitted for reimbursement. The results of this internal review, as well as of monthly post-payment reviews of false or unsubstantiated claims conducted by a local accounting firm, were provided to BMS China management and to compliance managers who reported to senior management at BMS. *See id.*

The Order additionally stated that BMS China employees admitted that they submitted false reimbursement claims and used the funds to make the improper payments, and terminated employees sent emails to the BMS China president about the necessity of providing incentives to meet sales targets. BMS China nonetheless did not investigate. *See id.*

The Order also noted BMS's failure to: implement a formal FCPA compliance program until 2006, despite having begun operations in China

many years earlier; have appropriate compliance professionals in place, and training available, until even later; and remediate controls deficiencies in a timely manner. *See id.* at 4.

Despite focusing on these early compliance weaknesses, the Order noted that BMS "implemented significant measures to enhance its anti-bribery and general compliance training and policies and to strengthen its accounting and monitoring controls relating to interactions w/ HCPs…." *Id.* at 6. Examples of these efforts included 100% pre-reimbursement review of all expense claims; implementation of an accounting program to track each expense claim and the retention of a third-party vendor to conduct surprise checks at sales representative-sponsored events. BMS also terminated over 90 BMS China employees, disciplined an additional 90 and replaced certain officers in order to enhance the tone at the top and overall culture of compliance. Notably, BMS revised the compensation structure for BMS China employees to reduce the portion of incentive-based compensation for sales and distribution. *See id.*

Based on all the circumstances, the settlement of the books and records and internal controls related allegations required disgorgement, pre-judgment interest, and a civil penalty totaling over $14 million, prompt reporting of any questionable or corrupt payments or transfers and submission over the subsequent two-year period of three status reports regarding FCPA and anti-corruption remediation and compliance implementation. *See id.* at 7-9.

Following the resolution with the SEC, DOJ advised BMS that it had closed its related FCPA investigation. *See* Form 10-Q filed by Bristol-Myers Squibb Company on October 27, 2015, at page 23. DOJ does not appear to have publicly commented about this decision or its underlying rationale.

Nonetheless, the conduct and remediation by BMS set forth in the SEC Cease and Desist Order, as well as the resolution of the SEC matter with a fine and self-monitoring and the closing of the DOJ's criminal investigation, brings into sharp focus how these government entities expect companies to conduct themselves: (1) identify and heed red flags, investigate them, undertake appropriate remediation and (2) develop and maintain a robust compliance program fine-tuned to the risks presented by a company's business.

The better this self-policing is, the better any resolution with the government will be if misconduct nonetheless occurs. For example, if BMS had instituted an appropriate compliance program earlier and jumped on the red flags, perhaps its resolution with the SEC would have been less onerous, carrying an even more modest financial penalty. On the other hand, had it not undertaken the extensive remediation set forth in the Order, BMS might have faced a stiffer penalty, and perhaps an external monitor, and DOJ might not have closed its investigation without exacting its own penalty. The takeaway is to pay attention to the government's often repeated message that compliance efforts are a key factor in the government's decision-making about the appropriate resolution of corporate wrongdoing.

2. A Note on DOJ, SEC, the FCPA and Healthcare Enforcement

Last year, we reported on the November 2014 agreement by Bio-Rad Laboratories, Inc., a California-based medical diagnostics and life sciences manufacturing and sales company, to pay $14.35 million to DOJ to resolve allegations that it had violated the FCPA's books and records and internal controls provision in connection with a French subsidiary paying commissions to intermediary companies purportedly in exchange for services in connection with government sales in Russia. High-level managers allegedly approved the commission payments even though they knew that the services had not been provided. Bio-Rad also agreed to disgorge $40.7 million to the SEC. *See* Foster, H. and Rohde, B., Mintz Levin alert, Health Care Enforcement in 2015: A Look back on 2014 and Forecasting the Year Ahead (*citing* DOJ press release 14-1221 and SEC release 2014-245).

AAG Caldwell used the announcement of the Bio-Rad resolution early in her tenure as an occasion to explain the circumstances under which DOJ may give credit, such as a non-prosecution agreement, to a corporation. The circumstances that she mentioned included self-disclosure of wrongdoing, making U.S. and foreign employees available for interviews, voluntarily producing documents from overseas, summarizing investigative findings, enhancing anti-corruption policies globally, improving compliance and internal controls, and conducting extensive training. *See id.* She has repeated her message of cooperation and compliance many times in the ensuing year, driving home the importance of these two factors which are within a company's control even after alleged wrongdoing has occurred.

AAG Caldwell has also addressed the question of why DOJ pursues criminal prosecutions to address corporate fraud, given the availability of regulatory enforcement and civil actions. She has said that DOJ prosecutes cases criminally because of the perceived egregious nature and extent of the conduct, its view that the conduct was undertaken knowingly and willfully and, with respect to culpable individuals, the

punitive and deterrent effect of incarceration on others. She also added that cases involving other types of facts and circumstances may be best resolved by means other than criminal prosecution. *See* *Justice News*, Assistant Attorney General Leslie R. Caldwell Delivers Remarks at the New York University Center on the Administration of Criminal Law's Seventh Annual Conference on Regulatory Offenses and Criminal Law, April 14, 2015.

While DOJ did not release a statement as to why it closed its FCPA investigation of BMS, DOJ likely performed this type of analysis and determined that, under all the facts and circumstances, the SEC enforcement action was the appropriate response to BMS's alleged conduct.

Examining FCPA cases brought against health care companies and how they are resolved helps to explain DOJ's decision-making process. Among other things, DOJ appears to consider whether regulatory or other action is sufficient under the circumstances. Moreover, while compliance is not a legal defense, a robust compliance program addressing company-specific risks (or line of business-specific risks for a larger company) that is implemented, enforced, and refined in response to evolving circumstances is likely to go a long way in affecting: (i) whether the government charges a criminal violation, (ii) the type of resolution that the government is willing to agree to, and (iii) the consequences of such resolutions.

III. Significant Joint Criminal/Civil Matters

Perhaps serving as an early example of the Yates Memo in practice, DOJ reached a notable settlement in October 2015 with pharmaceutical company Warner Chilcott to resolve criminal liability and False Claims Act ("FCA") allegations, and DOJ simultaneously announced the indictment of Warner Chilcott's former president.

A. Warner Chilcott Resolution

On October 29, 2015, the United States and Warner Chilcott PLC, together with its subsidiary Warner Chilcott U.S. Sales LLC, reached a global resolution in connection with the allegedly illegal marketing of certain drugs, including Actonel and Atelvia that treat osteoporosis. As further discussed, the settlement included a guilty plea by the subsidiary and a settlement totaling $125 million to resolve criminal liability and civil False Claims Act claims. Additionally, the United States charged a former president of Warner Chilcott's pharmaceutical division, W. Carl Reichel, with one count of conspiring to pay kickbacks to physicians to induce them to prescribe Warner Chilcott drugs. Several other individuals had previously pleaded guilty in connection with related activities. *See* DOJ release 15-1330; *see also U.S. v. W. Carl Reichel*.

To resolve its criminal exposure, the Warner Chilcott subsidiary pled guilty to a felony count of "paying kickbacks to physicians throughout the United States to induce them to prescribe its drugs, manipulating prior authorizations to induce insurance companies to pay for prescriptions of Atelvia that the insurers may not have otherwise paid for and making unsubstantiated marketing claims for the drug Actonel." *See id.* Subsidiary employees, at the direction of management, paid remuneration to physicians through (i) "medical education events," held at expensive restaurants, that offered little, if any, education and (ii) speakers' fees for physicians who often did not speak about clinical topics. Another component of the scheme involved sales representatives filling out and submitting physician prior authorization forms for patients regardless of whether the stated justifications were true. *See* DOJ release 15-1330.

The civil settlement resolved FCA allegations that Warner Chilcott made false claims to government health care programs and violated the federal anti-kickback statute by paying illegal remuneration to physicians through the medical education events and speaker programs and causing the submission of false prior authorization requests.

In announcing the global resolution of the case and Reich's indictment, Principal Deputy Assistant Attorney General Mizer of the Civil Division stated that DOJ was "committed to protecting the integrity of prescribing physician decisions and ensuring that financial arrangements in the healthcare marketplace comply with the law." In a nod to the Yates Memo, he added that DOJ would "continue to hold companies and responsible individuals accountable when they use improper incentives…to promote their products." *See id.* Emphasizing the point, the U.S. Attorney for the District of Massachusetts, where the cases were brought, stated that "Today's enforcement actions demonstrate that the government will seek not only to hold companies accountable, but will identify and charge corporate officials responsible for the fraud." *See id.*

IV. Civil Matters

A. DOJ's Aggressive Enforcement Agenda

On December 3, 2015, DOJ announced that in FY2015 (October 1, 2014 – September 30, 2015) it obtained more than $3.5 billion in settlements and judgments from civil cases involving fraud and false claims against the government. Of the $3.5 billion, DOJ reported that $1.9 billion was from cases involving allegations of health care fraud for "allegedly providing unnecessary or inadequate care, paying kickbacks to health care providers to induce the use of certain goods and services, or overcharging for goods and services paid for by Medicare, Medicaid, and other federal health care programs." *See* DOJ press release 15-1478. DOJ also reported that there were 638 new cases filed under the *qui tam* provisions of the FCA in FY2015, and $2.8 billion of the $3.5 billion was recovered in cases filed under the *qui tam* provisions. From the settlement proceeds of $2.8 billion in these cases, DOJ awarded *qui tam* relators $597 million.

In health care fraud matters in particular, DOJ recovered $1.4 billion in health care cases in which it intervened, and a record $468 million in health care cases in which it declined. Additionally, 423 new *qui tam* matters alleging health care fraud were filed in FY2015.

Looking forward to 2016, DOJ Civil Division Deputy Assistant Attorney General Joyce R. Branda, who had served as the Director of the Civil Fraud Section, discussed the Civil Division's enforcement priorities at an American Health Lawyers Association conference in September 2015. She noted the Department's renewed focus on individual culpability and reminded the bar that the principles outlined in the Yates Memo extend to health care FCA cases.

Deputy Assistant Attorney General Branda also described DOJ enforcement priorities as including the following programs, providers, and predicate acts:

- ***Medicare Advantage Program payments*** — DOJ will be closely scrutinizing allegations of inflated Medicare Advantage plan risk scores.
- ***Hospice claims*** — DOJ will pursue allegations of hospice providers falsely certifying individuals for hospice care when they do not meet hospice admission criteria.
- ***Stark Law violations*** — DOJ is focused on hospital compensation to physicians and is particularly concerned about arrangements with physicians under which they are paid more than fair market value for the services they perform or where compensation from a hospital clearly takes into account the "volume or value" of their referrals.

In addition, Ms. Branda noted such other areas of enforcement priority as skilled nursing facilities to ensure that therapy provided to residents is both medically necessary and beneficial, and she emphasized DOJ and HHS-OIG's increasing use of data analysis in investigations and prosecutions.

B. Notable Settlements

1. Hospitals and Implantation of Cardiac Devices

Taking a page out of the Medicare Fraud Strike Force's playbook, DOJ's Civil Division, on October 30, 2015, announced that it had "reached 70 settlements involving 457 hospitals in 43 states for more than $250 million [to resolve False Claims Act allegations] related to cardiac devices that were implanted in Medicare patients in violation of Medicare coverage requirements." *See* DOJ press release 15-1339. Not surprisingly, DOJ, the U.S. Attorney's Office for the Southern District of Florida, and HHS-OIG were partners in this case, which was triggered by a *qui tam* filing in the Southern District of Florida by a cardiac nurse and a health care reimbursement consultant, who have received $38 million from these settlements.

In announcing the settlements, Principal Deputy Assistant Attorney General Mizer stated the philosophy of the Civil Division under his leadership: "While recognizing and respecting physician judgment, the department will hold accountable hospitals and health systems for procedures performed by physicians at their facilities that fail to comply with Medicare billing rules." He added that the Department was confident that the settlements would lead to "increased compliance" and result in "significant savings." *See id.*

As with the Medicare Fraud Strike Force's annual nationwide takedown of criminal cases, the announcement of these FCA civil settlements

for a cumulative dollar amount in the hundreds of millions enabled the government to get publicity for its message: there was a coordinated effort among federal agencies, based on the whistleblower claims, to bring cases with respect to two of its announced priorities — hospitals and cardiac procedures. This approach is intended to deter violations of Medicare billing requirements in this specific arena and, in what is becoming the parlance of the day, encourage increased compliance. The messages of DOJ's Criminal and Civil Divisions, as well as the Department's various policies, converge here as hospitals and health systems are told that they will be held accountable for individual conduct, including clinical decision making, and they should make every effort to establish compliance protocols that deter physicians from using their facilities to conduct cardiac procedures outside Medicare guidelines.

2. Clinical Laboratories

Not since the 1990's has DOJ been as actively and aggressively pursuing allegations against clinical laboratories, including urine drug testing laboratories, cardiovascular laboratories, and traditional blood testing laboratories. In one significant investigation, triggered by multiple *qui tam* filings, Millennium Laboratories, one of the largest urine drug testing laboratories, agreed in October 2015 to pay $256 million to resolve allegations that it had billed Medicare, Medicaid, and other federal health care programs for medically unnecessary drug testing and genetic testing and had provided kickbacks to physicians to induce referrals. *See* DOJ press release 15-1289. DOJ reported that this resolution included the payment of $227 million to resolve FCA allegations that Millennium caused physicians to order excessive numbers of urine drug tests, in part through the promotion of "custom profiles," which, instead of being customized for individual patients, were in effect standing orders that resulted in physicians ordering large numbers of tests without individualized assessments of each patient's needs. DOJ also alleged that Millennium violated the Stark Law and Anti-Kickback Statute by providing physicians with free drug test cups on the express condition that the physicians return the specimens to Millennium for additional testing.

Likewise, as to cardiovascular disease testing laboratories, DOJ reached some notable settlements. On April 9, 2015, DOJ reported that, in a case stemming from three *qui tam* filings, Health Diagnostics Laboratory Inc. (HDL) and Singulex Inc. agreed to pay $47 million and $1.5 million, respectively, to resolve allegations that they had violated the FCA and the Anti-Kickback Statute by paying remuneration to physicians in the form of processing and handling fees in exchange for patient referrals and by billing federal health care programs for medically unnecessary testing. *See* DOJ press release 15-431.

3. Pharmaceutical Manufacturers and Specialty Pharmacies

On November 20, 2015, in a head start for FY2016, the U.S. Attorney for the Southern District of New York announced that Novartis Pharmaceuticals had agreed to a $390 million settlement (including a $20 million civil forfeiture) and to make factual admissions to resolve allegations under the FCA, the Anti-Kickback Statute, and state statutes that it gave kickbacks to specialty pharmacies in return for recommending two of its drugs, Exjade, an iron chelation drug, and Myfortic, an anti-rejection drug for kidney transplants. *See* United States Attorney's Office for the Southern District of New York press release 15-300. This agreement follows settlements in January 2015 and April 2015 in this case with two specialty pharmacies, Bioscrip, Inc. and Accredo Health Group, that agreed to pay a total of $75 million to resolve federal and state claims against them based on the same allegations. This much-watched case had been litigated heavily by DOJ since April 2013 and involved allegations that Novartis had paid kickbacks in the form of patient referrals and rebates to Bioscrip and Accredo to induce those pharmacies to recommend Exjade refills. With respect to Myfortic, DOJ alleged that Novartis entered into rebate contracts with specialty pharmacies to improperly induce the pharmacies to recommend to doctors that they switch patients to Myfortic from competitor drugs. Consistent with the Southern District's practice and DOJ's initiative to obtain factual admissions in civil cases where appropriate, Novartis agreed to 33 detailed factual admissions about its relationships and interactions with specialty pharmacies in connection with distribution of Exjade and Myfortic, and in the settlement agreement agreed to "accept responsibility" for this conduct.

4. Stark Law Settlements Involving Physician Compensation from Hospitals

Culminating a number of significant investigations and, in the case of Tuomey, years of litigation, DOJ, in September and October of 2015, resolved a cluster of cases involving allegations that hospitals had paid compensation to physicians in violation of the Stark Law, thus giving rise to substantial liabilities under the FCA.

On September 4, 2015, DOJ announced a settlement of $25 million, plus an additional contingent payment of $10 million, with Columbus Regional Healthcare System and a $425,000 settlement with one of its employed physicians to resolve allegations of FCA and Stark Law violations. *See* DOJ press release 15-1089. This settlement resolved allegations that Columbus Regional compensated its employed physician in excess of fair market value and in excess of the revenue received on services he personally performed. This settlement also resolved

allegations that, between 2003 and 2013, Columbus Regional provided excessive salary and directorship payments to a physician that violated the Stark Law.

Shortly after this settlement, on September 15, 2015, DOJ announced a $69.5 million FCA settlement with North Broward Hospital District based on allegations that a hospital engaged in a scheme of over-compensating physicians in violation of the Stark Law and the FCA. *See* U.S. Attorney for the Southern District of Florida press release dated Sept. 15, 2015. This civil settlement resolved allegations that the hospital district paid compensation to nine employed physicians that exceeded the fair market value for their services. In that case, the *qui tam* whistleblower alleged that the compensation to the physicians generated significant losses, which were offset by profits received from those physicians' referrals, and that this compensation arrangement reflected the fact that the hospital district weighed the volume and value of anticipated referrals when setting physician compensation, in violation of the Stark Law. The *qui tam* whistleblower further alleged that the hospital district generated "Contribution Margin Reports," which continually tracked referral profits, for cardiologists, oncologists, and orthopedic surgeons who collected salaries of $1 million and higher.

In short order, on September 21, 2015, DOJ announced that Adventist Health System agreed to pay $115 million to resolve allegations under the Stark Law and the FCA that Adventist maintained improper compensation arrangements with referring physicians and miscoded claims. *See* DOJ press release 15-1146. DOJ alleged that that Adventist submitted false claims to the Medicare and Medicaid programs for services rendered to patients referred by employed physicians who received bonuses based on a formula that improperly took into account the value of the physicians' referrals to Adventist hospitals. Not unlike the North Broward Hospital District matter, the *qui tam* complaints alleged that the overall physician compensation was above fair market value, as evidenced by Adventist's "substantial and consistent losses" on their physician practices, which were tolerated only because Adventist recovered those losses and profited by capturing referrals.

To top off this hat trick, on October 16, 2015, to help kick-off FY2016 recoveries, DOJ announced a $72.4 million settlement to resolve a $237 million judgment against Tuomey Healthcare System for billing the Medicare program between 2005 and 2010 for services referred by 19 physicians with whom the hospital had improper financial relationships under the Stark Law. *See* DOJ press release 15-1285. This settlement resolved litigation that had been ongoing since 2007, when DOJ intervened in this *qui tam* action filed in 2005. Under the terms of the settlement agreement, Tuomey will be sold to Palmetto Health, a multi-hospital health care system. DOJ argued that Tuomey, fearing that it could lose lucrative outpatient procedure referrals to a new freestanding surgery center, had entered into contracts with 19 specialist physicians that required the physicians to refer their outpatient procedures to Tuomey and, in exchange, paid them compensation that exceeded fair market value and included part of the money Tuomey received from Medicare for the referred procedures. DOJ retried this case after the Fourth Circuit vacated the district court's initial post-trial judgment in favor of the United States, and in May 2013 the jury determined that the contracts violated the Stark Law and the FCA and resulted in the submission of false claims in the amount of $39 million. On October 2, 2013, the trial court entered an FCA judgment in favor of the United States for more than $237 million, based on trebling the damages plus civil penalties of $5,500 per claim for over 21,000 claims. The United States Court of Appeals for the Fourth Circuit affirmed the judgment on July 2, 2015.

5. DaVita

In DOJ's year-end press release, it noted the settlement in June 2015 with DaVita HealthCare Partners, Inc., the largest provider of dialysis services in the United States, under which DaVita agreed to pay $450 million in a declined case to resolve allegations that it knowingly generated and billed the government for "unnecessary waste" in administering the drugs Zemplar and Venofer to dialysis patients, see DOJ press release, 15-797. This settlement terminated years of litigation between DaVita and the *qui tam* relators who brought the action and represents one of the most significant recoveries in a declined *qui tam* case. DOJ also noted a settlement with DaVita in the amount of $350 million to resolve allegations under the FCA that it violated the Anti-Kickback Statute with respect to physician ownership in its dialysis centers. *See* DOJ press release, 14-1167.

C. Selected Significant Decisions

1. Wartime Statute of Limitations and First-to-File Bar

Once again, the Supreme Court weighed in this term on FCA issues, this time to clarify a provision of the FCA and decide once and for all what "pending" means in the context of the "first to file" rule, and to determine whether the Wartime Suspension of Limitations Act ("WSLA") has tolled civil actions under the FCA since the Authorization for Use of Military Force Against Iraq Resolution of 2002, as the Fourth Circuit held.

On May 26, 2015, in *Kellogg Brown & Root Services, Inc. v. United States ex rel. Carter*, the U.S. Supreme Court unanimously held that the WSLA does not toll the statute of limitations for civil actions under the FCA. Instead, the Court held that the WSLA, which tolls claims for "any offense" involving fraud against the federal government, applies only to criminal offenses. The FCA has a six-year statute of limitations, with a discovery rule exception that permits claims to be brought for up to ten years. Under the DOJ interpretation, which it argued before the Court, the WSLA's tolling for FCA actions would have been triggered by the Authorization for Use of Military Force Against Iraq Resolution of 2002, and thus would have permitted DOJ or relators to bring actions going back to 1996, or even earlier.

The Court also settled a split between the U.S. Courts of Appeals for the D.C. Circuit and the Fourth Circuit regarding the "first to file" bar in the FCA. The *qui tam* provisions of the FCA provide that "no other person other than the Government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). The Supreme Court considered only the ordinary meaning of the word "pending" and decided that a dismissed FCA case is not a "pending" case. Thus, the Court explained, a later FCA action is not barred simply because an earlier, but now dismissed, FCA action based on the same underlying facts had been filed.

In its decision, the Court flatly rejected the defendants' argument that Congress used "pending" in the FCA as short-hand for any "first-filed action." The Supreme Court acknowledged defendants' concern that lifting the first-to-file bar when the first-filed action ends could have negative practical consequences and noted that "[t]he False Claims Act's *qui tam* provisions present many interpretive challenges, and it is beyond our ability in this case to make them operate together smoothly like a finely tuned machine." Unfortunately, this decision creates an opportunity for parasitic "whistleblowers," and it increases the risk that companies may have to litigate serially similar allegations of misconduct.

2. Statistical Sampling to Prove Liability under the FCA

Perhaps one of the most significant FCA issues percolating in federal courts this year is whether statistical sampling of claims, and extrapolation of that sampling, can be used to prove liability under the FCA. The Court of Appeals for the Fourth Circuit on September 29, 2015, agreed to hear an appeal that will address whether statistical sampling can be used in this fashion. *United States ex rel. Michaels et al. v. Agape Senior Community, Inc.* This appeal is of critical importance to the government's and relator's ability to prove liability in FCA cases that often allege tens of thousands of individual Medicare claims. Recently, a number of district courts have permitted, at least at the motion to dismiss stage, such use of sampling and extrapolation, even though typically these tools have been employed only for proving FCA damages.

If DOJ and relators are permitted to prove FCA liability by taking a relatively small sample of claims, demonstrating "falsity" and "knowledge" as to some of those claims, and then extrapolating the "error rate" to a large universe of claims, defendants in these cases will potentially be subject to enormous liabilities for claims that are never specifically identified and that cannot be individually defended.

DOJ seeks to have the litigation and trial tools to demonstrate that no alleged fraud is "too big to prove," and argues that providers should not have the incentive to submit false claims on a large scale. However, the use of statistical sampling to prove liability under the FCA, a quasi-criminal statute, seems to run counter to the statute's requirements that attach very significant liability for the "knowing" submission of a "false" or "fraudulent" claim, which in cases involving allegations of unnecessary services based on medical records is inherently individualized.

In *Agape*, the relators alleged that Agape, which operated 24 nursing homes in South Carolina, submitted false claims to Medicare, Medicaid, and Tricare for hospice care and general inpatient services. The number of patients and the total number of false claims submitted by those patients was roughly between 10,000 and 20,000 patients and 53,000 to 62,000 claims. Given the magnitude of a full-blown expert review, relators sought to use statistical sampling to determine liability. The district court denied that request and noted that each claim at issue was fact-dependent and wholly unrelated to each and every other claim. The district court also recognized that the parties had access to the relevant files regarding each of the contested claims and a claim-by-claim review was not impossible. Recognizing that courts had reached different conclusions on the permissibility of statistical sampling for these purposes, the district court certified its ruling for immediate appeal to the Fourth Circuit, which the Fourth Circuit granted.

The *Agape* decision, as it recognizes itself, contrasts directly with the important decision in *U.S. ex rel. Martin v. Life Care Centers of America* decided on September 29, 2014. In that case, on a Motion for Summary Judgment, the United States and Life Care Centers fully briefed the core issue of the use of statistical sampling to prove liability. Life Care Centers is an operator of skilled nursing facilities, and DOJ proposed, through expert testimony and statistical analysis, to use a random sample of 400 nursing facility admissions to extrapolate to a total of

over 54,000 admissions and over 150,000 Medicare claims. The district court considered extensively the legal and practical arguments on both sides, and concluded that "[t]he language and the history of the FCA do not suggest that statistical sampling is an improper vehicle by which to litigate FCA claims" in that "there is no explicit prohibition against the use of statistical sampling." The court rejected the argument "that statistical sampling simply cannot be applied to an FCA case involving Medicare overpayment" because "if accepted, it would materially limit the efficacy of the FCA as a tool to combat fraud against the government." The court was concerned that, without the availability of statistical sampling, "large-scale perpetrators of fraud would reap the benefits" of DOJ's practical limitations in proving the allegations. Nonetheless, the court recognized that Life Care made "several compelling arguments regarding the inherent limitations associated with statistical sampling," but that these arguments are best presented at trial as challenges to expert testimony and statistical evidence. Since the *Life Care* decision, a number of district courts have declined to rule, at the early stages of litigation, against the use of statistical sampling to prove liability under the FCA. The Fourth Circuit decision in *Agape* will shape the landscape for this issue, and the briefing in that case by DOJ, the defendant, and interested *amici* will provide that court with robust arguments on both sides.

On a related note, in the recent *AseraCare* case, the district court judge permitted the use of statistical evidence to prove FCA liability, but then over the vigorous objections of DOJ bifurcated the liability phase of the trial into a "falsity" phase and "knowledge" phase. *U.S. ex rel. Paradies v. AseraCare, Inc.* However, after the jury decided in favor of DOJ as to "objective falsity" on claims for 104 of the 121 hospice patients presented to the jury, the district court judge ordered a new trial on the basis of defective jury instructions as to what constituted falsity on these claims.

3. Implied False Certification

Once again, the Supreme Court has taken on an FCA case, this time to consider a core theory of liability under the FCA, as compared to some of the more procedural issues it has ruled on in recent terms. On December 4, 2015, the U.S. Supreme Court granted *certiorari* in *Universal Health Services, Inc. v. United States ex rel. Escobar* to review whether the "implied false certification" theory of legal falsity under the FCA is a viable theory of liability and, if so, whether a claim can be legally "false" under that theory if the provider failed to comply with a statute, regulation, or contractual provision that does not explicitly state that it is a condition of payment.

In *Universal Health Services,* the First Circuit reversed the dismissal of an FCA action against a mental health provider and ruled that a violation of state regulations can form the basis for an FCA action. The Supreme Court also has before it a petition for *certiorari* in a case from the Fourth Circuit that raises the same issue in the context of a defense procurement contract. *See United States v. Triple Canopy, Inc., petition for cert. filed* (June 5, 2015). The issue of whether, and under what circumstances, an "implied false certification" theory is viable has been ruled on by many federal courts of appeals, with some courts requiring that the law, regulation or contract expressly state that compliance is a condition of payment, some courts not requiring that express statement, and another rejecting the theory altogether.

DOJ embraces and relies on this theory in a wide range of cases under the FCA, and it underlies a wide swath of allegations by relators in *qui tam* filings. A decision by the Supreme Court, expected before the end of the term, typically in late June, could have a substantial impact on investigations and litigation in health care matters under the FCA.

V. Conclusion

As in past years, 2015 saw health care enforcement continue unabated. On both the criminal and civil sides, federal prosecutors emphasized their ongoing cooperation with each other, their policy of jointly referring new *qui tam* cases to civil and criminal prosecutors, and their commitment to holding individuals accountable. Since September, defense lawyers have been repeatedly reminded by government lawyers about the Yates Memo, its impact on individuals, what it means for resolving cases, and the fact that it is now being followed throughout DOJ. The combination of these initiatives promises to result in more enforcement in 2016. In addition, as we seem to say every year, the theories underlying investigations and the tools used to conduct them are still becoming more sophisticated, bringing with them new, untested, and often unforeseen allegations of criminal and civil liability. An important counterpoint, however, is the government's views about compliance, which offer important guidance about potential risk reduction. And 2016 could see significant appellate decisions about the scope of the FCA and proving cases under it. These decisions will be important as, at least for now, the FCA and its *qui tam* provisions remain the government's most potent enforcement tool.