



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

Hope Foster and Bridget Rohde

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Introduction of Panelists

Hope Foster



*Chair, Health Care
Enforcement Defense Group*

HSFoster@mintz.com
202.661.8758

Bridget Rohde



*Member, Health Care
Enforcement Defense Group*

BMRohde@mintz.com
212.692.6883

What We Will Cover

Topic 1

Criminal Prosecutions

Topic 2

Significant Joint Criminal/Civil Matters

Topic 3

Civil Matters

Topic 4

Concluding Thoughts

Criminal Prosecutions

High-level US DOJ Officials State Continuing Focus on Health Care Fraud

- In April 2011, the U.S. Attorney for the Eastern District of New York, and pending nominee for U.S. Attorney General, Loretta E. Lynch unequivocally stated that "fighting health care fraud is a priority of the Department of Justice."
- In her testimony before the House Oversight & Government Reform Subcommittee, U.S. Attorney Lynch, further stated that the Department of Justice 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")

High-level US DOJ Officials State Continuing Focus on Health Care Fraud

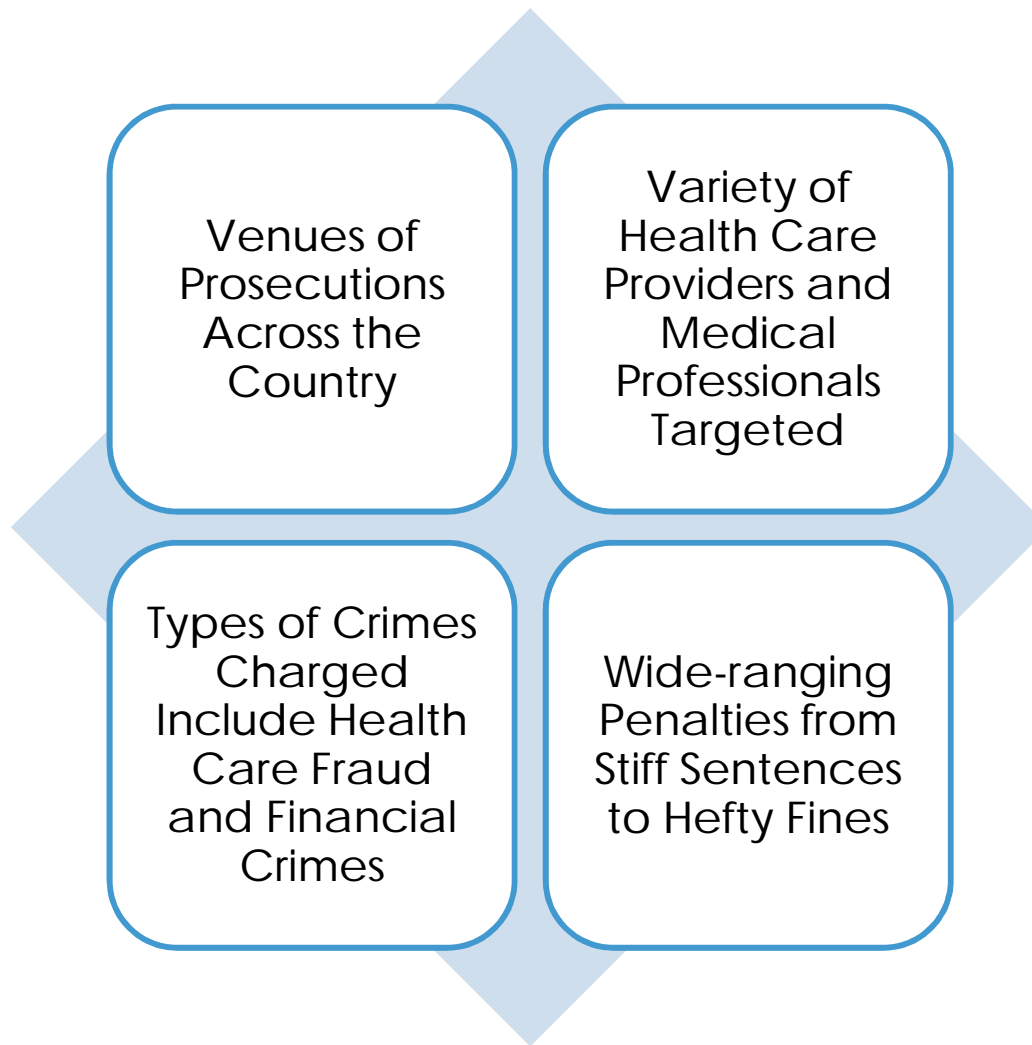
- This past September, at the Taxpayers Against Fraud Education Fund Conference, the newest Assistant Attorney General for the Criminal Division, Leslie R. Caldwell, demonstrated how DOJ is currently seeking to maximize health care fraud enforcement, announcing that there is:

"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."

Medicare Fraud Strike Force Remains Incredibly Active

- The Strike Force is a team of prosecutors and investigators from DOJ, HHS-OIG and state and local law enforcement agencies dedicated to reducing Medicare fraud
- It operates in nine “hot spots” of Medicare fraud
- At the end of 2014 DOJ reported that since its inception in March 2007, the Medicare Fraud Strike Force had charged nearly 2,000 defendants who collectively billed Medicare program more than \$6 billion
- Charges have so far resulted in 1,400 convictions, with stiff penalties

Takeaways from 2014 Strike Force Prosecution



The Strike Force Approach: Conducting Annual Nationwide Takedowns

- May 2014: Medicare Fraud Strike Force conducted the 7th nationwide takedown in its history
 - Alleging numerous Medicare fraud schemes collectively totaling approximately \$260 million in false billings
 - Charging 90 individuals, 27 of whom were doctors, nurses and other medical professionals
 - From Miami to Houston, Los Angeles, Detroit, Tampa, and Brooklyn
- Annual initiative that varies very little. Last year:
 - Alleged approximately \$233 million in fraud schemes
 - Charged 89 individuals in eight cities (six of the same as 2014)

The Strike Force Approach: Obtaining Maximum Impact From Health Care Fraud Investigations

Example 1: Louisiana and Texas Community Health Centers

- In 2011, the government began an investigation of three community health centers – two in Baton Rouge and one in Houston – reviewing conduct over a several year period
- The Centers allegedly
 - Billed Medicare for partial hospitalization program services that were unnecessary or never provided
 - Submitted more than \$258 million in claims
 - Caused Medicare to pay approximately \$43.5 million

The Strike Force Approach: Obtaining Maximum Impact From Health Care Fraud Investigations

Example 1: Louisiana and Texas Community Health Centers (cont'd)

- Outcome
 - 17 individuals convicted, including owners, medical director, administrators, therapists, and marketers
 - Harsh sentences (e.g., 102 months in prison for one owner, 90 months for another) and steep penalties (e.g., \$43.5 million in restitution imposed on these owners)

The Strike Force Approach: Obtaining Maximum Impact From Health Care Fraud Investigations

Example 2: South Florida Partial Hospitalization Program

- Several years ago, the government began investigating American Therapeutic Corporation (ATC), which operated partial hospitalization programs, and its management company, Medlink Professional Management Group, Inc. , allegedly uncovering a \$205 million Medicare fraud scheme
- Crimes alleged include:
 - Paying and receiving bribes in connection with a health care program
 - Money laundering
 - Aggravated identity theft

The Strike Force Approach: Obtaining Maximum Impact From Health Care Fraud Investigations

Example 2: South Florida Partial Hospitalization Program (cont'd)

- Outcome
 - Many individuals were convicted, including owners, managers, doctors, therapists and patient brokers
 - Harsh penalties were imposed, with an ATC owner being sentenced to 50 years in prison
- Notably, U.S. Attorney Lynch and AAG Caldwell have both highlighted the ATC case in public remarks

The Strike Force Approach: Corporations and Health Care Professionals Will be Held Responsible

- In her September 2014 speech, AAG Caldwell said, DOJ would be "stepping up" its prosecutions of corporations involved in health care fraud
- It is also clear that DOJ views professionals as gatekeepers responsible for preventing – and not perpetrating – crime
 - Louisiana and Texas Community Health Centers: A Louisiana psychiatrist was sentenced to approximately 7 years in prison and \$43.5 million in restitution
 - ATC: a physicians assistant received a 15-year sentence and a patient recruiter who was a licensed nursing assistant, received a 12-year sentence

Securities Fraud

Example: ArthroCare Corporation

- January 2014: DOJ announced that ArthroCare, a medical device manufacturer, had agreed to pay \$30 million to resolve charges that senior executives had engaged in a securities fraud scheme. Key components included:
 - DOJ's filing of a criminal information against the company, charging conspiracy to commit securities and wire fraud
 - ArthroCare's entry of a Deferred Prosecution Agreement ("DPA"), and, in addition to payment of the \$30 million, cooperation with the continuing investigation and prosecution of its executives and implementation of an enhanced compliance program and internal controls

Securities Fraud

Example: ArthroCare Corporation (cont'd)

- Spring 2014: former CEO and CFO were convicted of conspiracy, securities fraud, and wire fraud (CEO also convicted of false statements to the SEC)
 - Former CEO sentenced to 20 years in prison
 - Former CFO sentenced to 10 years in prison
- In announcing the sentences, 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."
- C-level executives, like licensed medical professionals, are on notice that they may become a focus of prosecution

Global Anti-Corruption

Example: Bio-Rad Laboratories, Inc.

- November 2014: DOJ announced that Bio-Rad, a medical diagnostics and life sciences manufacturing and sales company, agreed to pay a \$14.35 million penalty to resolve allegations that it violated the FCPA by falsifying books and records and failing to implement adequate internal controls in connection with sales it made in Russia. (Bio-Rad also agreed to disgorgement of \$40.7 million to the SEC). A key component was that:
 - DOJ permitted Bio-Rad to enter a Non Prosecution Agreement ("NPA")

Global Anti-Corruption

Example: Bio-Rad Laboratories, Inc. (cont'd)

- In announcing the 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."
- Bio-Rad's cooperation and remediation included:
 - 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
 - Conducting extensive training

Takeaways

DOJ continues to reward companies for self-disclosure, cooperation and remediation

At the very least, 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, provide extensive training, and monitor compliance

Significant Joint Criminal/Civil Matters

AAG Caldwell Has Specifically Addressed Joint Criminal/Civil Enforcement

- In announcing the new *qui tam* process, she emphasized that criminal prosecutors would immediately review filed *qui tam* actions to determine whether to file a parallel case and that they have a "wealth of experience successfully bringing parallel investigations"

Global Resolution of Criminal & Civil Matters

Example: Endo Health Solutions

- 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
- Criminal resolution
 - Endo Pharmaceuticals entered into a DPA with respect to a misbranding charge in connection with marketing Lidoderm for unapproved uses
 - Forfeiture of \$20.8 million
 - Agreement to implement and maintain enhanced compliance measures

Global Resolution of Criminal & Civil Matters

Example: Endo Health Solutions (*cont'd*)

- Civil settlement
 - Endo Pharmaceuticals paid \$171.9 million to resolve alleged FCA violations by the U.S., a number of states, and the District of Columbia
 - The subsidiary also entered a Corporate Integrity Agreement ("CIA") with HHS-OIG requiring it to implement measures to avoid or promptly detect similar conditions
 - The settlement resolved three *qui tam* lawsuits in the Eastern District of Pennsylvania

Pursuit of Criminal Charges Despite Civil Settlement

Example: Vascular Solutions, Inc. ("VSI")

- November 2014: DOJ obtained an indictment charging VSI and its CEO with:
 - 8 counts of introducing adulterated and misbranded medical devices into interstate commerce
 - Conspiracy to commit these offenses against the U.S. and to defraud the U.S. in connection with allegedly illegal sales activity
- July 2014: VSI agreed to pay \$520,000 to resolve allegations raised in a *qui tam* complaint without admitting liability
- Implication: DOJ and VSI could not reach agreement on related criminal violations, which are being hotly contested by the company

Takeaways

DOJ's preferred approach has been to structure a global resolution that includes a corporation:

Entering into a NPA or DPA

Paying large financial penalties

Having a subsidiary and/or C-level employees plead guilty and bear collateral consequences

Pledging an enhanced compliance program

DOJ is clearly willing to indict a corporation if it believes it has not obtained the appropriate global criminal/civil resolution

Civil Matters

The Headlines and The Numbers

- The FCA remains the government's primary civil remedy to redress false claims for government funds
- In FFY 2014, the government secured civil health recoveries under the FCA of \$2.3 billion for federal losses
- This marks the fifth year in a row that DOJ has recovered more than \$2 billion under the FCA
- Federal enforcement officials were instrumental in recovering additional billions of dollars for consumers and state treasuries

Role of Whistleblowers, the Headlines, and the Numbers

- More whistleblowers are coming forward
- This has caused the government to open more investigations
- And has led to a surge in civil recoveries
- In 2014, more FCA cases were filed under the whistleblower provisions than in any prior year

Role of Whistleblowers, the Headlines, and the Numbers

- The number of qui tam cases has grown steadily since 1986

Year	Number of <i>qui tam</i> cases filed
1987	30
2008	300
2009	400
FFY 2014	700

- Relator's share has grown, too:
 - From January 2009 - September 30, 2014, the government paid \$2.47 billion in relator's share

DOJ's Civil Division Has Reiterated Its Focus On Health Care Fraud

- In a press release last November, DOJ's Civil Division reported its successes for the prior fiscal year and highlighted cases involving:
 - Hospitals
 - Home health services
 - Cardiac procedures

Hospitals

Total fiscal year 2014 Settlements: \$333 million

Example: Community Health Systems (CHS)

- DOJ has showcased its settlement with CHS, describing CHS as "the nation's largest operator of acute care hospitals."
- Allegations included:
 - Deliberate corporate-driven scheme to increase patient admissions
 - Stark violations arising from referrals by a physician who was offered a medical directorship

Hospitals

Example: Community Health Systems (CHS) (cont'd)

- Resolution
 - CHS agreed to pay \$98 million to settle seven FCA lawsuits filed by *qui tam* relators around the country
 - Entered into a five-year CIA with HHS-OIG, requiring significant compliance efforts

Other examples:

- Halifax Hospital System: \$85 million settlement
- King's Daughters Medical Center: \$41 million settlement
- Dignity Health: \$37 million settlement

Home Health Services

Example: Amedisys Inc.

- DOJ described Amedisys as one of the nation's largest providers of home health services
- Allegations
 - Billing of Medicare for nursing and therapy services that were medically unnecessary or for services for patients who were not homebound
 - Violation of the Anti-Kickback Statute and the Stark Law
- Resolution
 - Agreed to pay \$150 million to resolve lawsuits from *qui tam* relators
 - Agreed to be bound by CIA with HHS-OIG requiring implementation of compliance measures to avoid, or promptly detect similar conduct

Predictions for 2015

- FCA will continue to be a powerful tool
- Numerous USAOs will be working together on single cases
- Whistleblowers will file more than 700 cases
- Qui tam avoidance efforts will become even more important
- More criminal investigations will be opened
- Data will be a more important tool in the government's efforts to identify potential fraud and abuse
- Increasingly, the government will use settlements to deter
- The number of settlements that include non-monetary requirements governing conduct will grow

Takeaways

DOJ, as AAG Caldwell has stated, is "stepping up" prosecution of corporations involved in health care fraud

Robust compliance efforts should be undertaken at all levels of a health care provider's corporate structure

Relators can come from any part of a health care organization

Degree of Specificity Required in *Qui Tam* Complaints

Example: Takeda Pharmaceuticals North America, Inc.

- Fourth Circuit Court of Appeals dismissed an FCA case for failing to allege the presentment of a false or fraudulent claim to the government for payment
- Issue: Does Rule 9(b) of the Federal Rules of Civil Procedure require that a complaint under the FCA allege that specific false claims were presented to the government for payment *OR* is it sufficient to allege particular details of a scheme together with reliable indicia leading to a strong inference that claims were actually submitted?
- US argued that the inconsistencies could be sorted out by the circuits without the Supreme Court's intervention

Degree of Specificity Required in *Qui Tam* Complaints

Example: Takeda Pharmaceuticals North America, Inc. (cont'd)

- March 31, 2014: Supreme Court declined wading into the debate over the degree of particularity
 - Government, relators and potential defendants in *qui tam* actions should keep in mind which jurisdiction the complaint was filed in

Concluding Thoughts

Concluding Thoughts

- More parallel investigations
- More qui tam cases subject to criminal investigations
- Whistleblowers will file more than 700 sealed cases
- More cooperation between relators and criminal and civil prosecutors
- More data initiated and driven investigations
- More litigation of declined cases

Concluding Thoughts

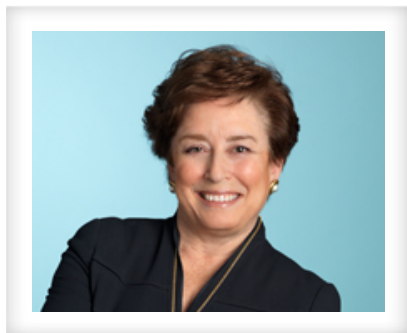
- More enforcement of alleged kickback recipients as well those allegedly offering or paying them
- More use of settlements and resolutions for their deterrence value
- More non-monetary requirements in settlement agreements
- More need to avoid qui tam cases in the first place
- A broadening array of defendant-types

Questions?

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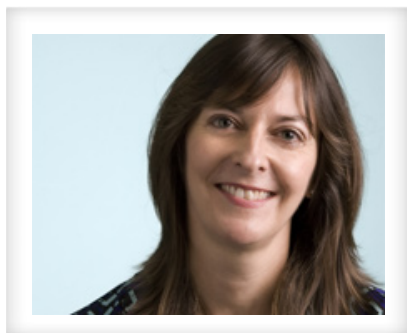
Panelist Biographies



Hope Foster, Member

202.661.8758 • HSFoster@mintz.com

- Chair of the Health Care Enforcement Defense Practice, and serves on the firm's Policy Committee and Pro Bono Committee
- Represents health care providers, product manufacturers, payors, and investors
- Specializes in statutory and regulatory issues affecting the provision of health care services
- Practice includes counseling, structuring, and litigating fraud and abuse issues as well as reimbursement matters
- Defends and resolves large, multifaceted federal and state investigations arising under criminal and civil statutes barring the submission of false claims and the provision of remuneration to induce referrals
- Negotiates and structures global settlements with the US Department of Justice and its US Attorneys' Offices and state Attorneys' General Offices as well as corporate integrity agreements with the Department of Health and Human Services Office of Inspector General



Bridget Rohde, Member

212.692.6883 • BMRohde@mintz.com

- Practices primarily in the areas of white collar criminal defense, corporate compliance and investigations, and monitorships
- Counsels corporate and individual clients in investigations conducted by the U.S. Department of Justice, Securities and Exchange Commission, and other federal, state and local law enforcement agencies
- Conducts internal investigations and provides guidance on creating and improving compliance initiatives
- Previously Chief of the Criminal Division for the U.S. Attorney's Office for the Eastern District of New York