The Impact of 2009 False Claims Act Developments on Compliance

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Introduction

- Health care spending lost to fraud is estimated to be 3–10% of expenditures – or $68 – $226 billion annually.
- The government estimates that for every $1.00 it spends on enforcement, it recoups at least $15.00
- The government has made it a priority to reduce fraudulent spending

The Enforcement Environment

- Increased enforcement activity
  - Increased funding to government enforcement agencies
  - The OIG Work Plan
  - HEAT
  - RACs
  - FERA
- Settlements are increasing in size
- Expanding scope of conduct subject to the FCA
  - Kickbacks
  - FDCA
- Expanding scope of CIAs

What does this mean for you?

- Your role as a compliance officer is more important than ever
- Effective corporate compliance programs are a "must"
- Opportunities to proactively identify areas for improvement and "holes"

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Fraud Enforcement and Recovery Act (FERA)

- Increased funding for attorneys, investigators
- Civil Investigative Demand authority expanded
  - Attorney General may delegate authority to issue CIDs (requests for documents, testimony, interrogatories)
  - DOJ may share the information obtained with qui tam relators or others

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Fraud Enforcement and Recovery Act (FERA)

- Reverse False Claims
  - Imposes liability for "knowingly and improperly avoid[ing] or decreas[ing] an obligation to pay or transmit money or property to the Government."
  - "Obligation" means "an established duty . . . arising from . . . the retention of any overpayment."
  - Senate Report: "retention of overpayment" triggers FCA liability.

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Fraud Enforcement and Recovery Act (FERA)

- Eliminates "presentment" requirement
  - Overrides *Allison Engine v. United States ex rel. Sanders* (2008)
  - Increases risk for subcontractors, sub-grantees
- Codifies definition of "material"
  - Means falsity has a natural tendency to affect government's payment decision
  - Some courts had required an actual impact on government's payment decision

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Health Care Reform

- Stark Law Self-Disclosure Protocol
  - Would authorize HHS to compromise claims
  - Consider severity of violation, timeliness of disclosure and cooperation
- Providers must refund all "known" Medicare and Medicaid overpayments within 60 days, imposing FCA liability if refund does not occur within 60 days

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Health Care Reform

- Limits FCA "public disclosure bar" to apply to federal lawsuits or administrative proceedings in which the U.S. Government is a party
- All claims "resulting" from Anti-Kickback Statute violations are false under FCA
  - Effort to undo *U.S. ex rel. Thomas v. Bailey*, 2008 WL 485360 (E.D. Ark.)

Pfizer Settlement - September 2009

- Global payment of $2.3 billion
  - $1 billion civil settlement.
  - $1.3 billion in criminal fines and forfeitures
- CIA
- This was – and still is – the largest health care fraud settlement in the DOJ's history.

Allegations

- Pfizer – FCA violations for:
  - unlawfully promoting 4 drugs, including Bextra, a painkiller, for unapproved uses
  - paying kickbacks to induce prescriptions for Pfizer drugs
- Pharmacia & Upjohn Company – felony violation of FDCA for misbranding Bextra with intent to defraud or mislead

Criminal Charges

- Pharmacia & Upjohn Company agreed to pay a $1.195 billion criminal fine, the largest criminal fine ever imposed in the US for any matter.
- $105 million forfeiture
- Pfizer allegedly promoted Bextra for uses and dosages that FDA specifically declined to approve due to safety concerns.

Civil Settlement

- $1 billion:
  - Bextra - $502 million
  - Geodon - $301 million
  - Zyvox - $98 million
  - Lyrica - $48 million
  - Kickback allegations - $50 million
- Federal settlement amount - $669 million (relators received 15%)
- Medicaid State settlement amount - $331 million

CIA

- Pfizer is the first biopharmaceutical company to commit to reporting payments for conducting Phase I-IV clinical trials in addition to disclosing payments for speaking and consulting.
- CCO reports directly to CEO with periodic reports to Audit Committee. GC will no longer oversee compliance program.

Quest Diagnostics/NID Settlement - April 2009

- Global payment of $308 million - one of the largest recoveries ever in a case involving a medical device
  - $268 million civil settlement
  - $40 million criminal fine
- Quest Diagnostics:
  - non-prosecution agreement
  - CIA
- NID: felony misbranding violation

Allegations

- NID violated the FCA by manufacturing IVD test kits that produced unreliable results
- Case of first impression:
  - Faulty test kits allegedly "caused" laboratories to submit false claims

Regulatory Background

- Laboratories governed by CLIA
- IVD manufacturer regulated by FDA

CIA

- Focuses on IVD compliance with certain identified portions of FDA's QSR regulations
- Requires CCO to report to CEO
- Recognizes two compliance committees
- Mandates compliance expert review
- Requires IVD products review by IRO

Omnicare Settlement - November 2009

- $98 million civil settlement by Omnicare
- $14 million civil settlement by IVAX
- Most recent of a long line of Omnicare settlements

Allegations

- Omnicare violated the FCA by soliciting and paying kickbacks
- Omnicare paid kickbacks to nursing homes to induce referrals by providing services below cost and below fair market value
- Omnicare solicited, and IVAX paid, $8 million in exchange for Omnicare's purchase of $50 million of IVAX's drugs

Allegations cont'd

- Omnicare solicited and received kickbacks from J&J in return for agreeing to recommend that physicians prescribe Risperdal
- The alleged kickbacks took multiple forms, including:
  - rebates conditioned on an "Active Intervention Program"
  - data purchase fees
  - educational grants

Other Allegedly Culpable Parties

- The government announced in November 2009 that it intervened and filed complaints against Mariner Health Care Inc. and SavaSeniorCare Adminstrative Services LLC and their principals for accepting kickbacks from Omnicare
- The government intervened in an FCA action against J&J in January 2010

Cell Therapeutics Inc. v. Lash Group Inc., 586 F.3d 1204 (9th Cir. 2009)

- Case of first impression
- Bottom line - FCA does not prohibit a defendant who has settled with the government from seeking recovery from a third party for contractual indemnity and independent claims.

Background

- CTI - young company, received FDA approval for cancer drug
- Hired Documedics, who advised that off-label uses were reimbursable under Medicare
- Based on advice, CTI stopped pursuing research/publications that would have supported Medicare reimbursement
- CTI employee filed qui tam suit. CTI settled for $10.6 million.

CTI Claims

- CTI sued Documedics for:
  - Declaratory relief of obligation to indemnify CTI for damages related to investigation and any resulting judgment or settlement
  - Various breach of contract claims
  - Negligence in providing professional services
- District court held CTI's claims were barred, citing *Mortgages*[1/]

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1/ *Mortgages, Inc. v. U.S. Dist. Ct.*, 934 F.2d 209 (9th Cir. 1991)

Precedent

- Under *Mortgages*, no right of indemnity or contribution among scheme participants.
- But, under *Madden*, FCA defendants may bring independent claims against relators.[2/]
  - Claims for independent damages are distinguishable from claims for indemnification or contribution, which "only have the effect of offsetting liability."
  - Two-stage resolution process

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2/ *United States ex rel. Madden v. Gen. Dynamics Corp.*, 4 F.3d 827 (9th Cir. 1993)

Holding

- CTI alleged $12.3 million in damages in addition to the $10.6 million settlement payment
- Court found CTI alleged four types of damages:
  - investigation, litigation, and settlement expenses;
  - lost opportunities to pursue other means of reimbursement;
  - damage to reputation; and
  - increased cost of capital

Holding cont'd

- Only the first type of damages was arguably a claim for indemnification for settlement costs
- District court erred in characterizing the settlement as effectively establishing liability:
  - Disclaimer of liability; no collateral estoppel
  - Chilling of settlement process

Health Care Industry Liability Insurance Program v. Momence Meadows Nursing Center, Inc., 566 F.3d 689 (7th Cir. 2009)

- Former employees filed qui tam suit
- Bottom line - Confirms that insurance carriers generally have no duty to defend or indemnify insureds in connection with qui tam suits.

Allegations

- Claims were false because Momence certified on annual cost reports that it was meeting the required standard of care when it knew it was not. Allegations included Momence's failure to:
  - maintain minimum staffing levels
  - ensure adequate nutrition
  - provide clean, dry beds, clothes, and regular baths

Insurer's Action

- Insurer brought action seeking declaratory judgment that it had no duty to defend or indemnify Momence based on a commercial general liability policy.
- Policy included coverage for
  - bodily injury and property damage; and
  - personal and advertising injury liability
- Policy contained employment-related practices exclusion

Momence's Arguments

- Insurer is obligated to defend if any portion of the suit potentially falls within the scope of coverage.
- Momence claimed allegations of physical harm to residents caused the claims to fall within the scope of coverage for "bodily injury"

Holding

- Alleged statutory damages arose from false cost report filings, not bodily injury.
  - Proof of bodily injury is not required
- Insurers are not obligated to defend FCA suits merely because they would have to defend against suits for damages resulting from the conduct underlying the FCA action.

Cardiac Procedures/Stents

> Maryland Hospital (Towson)
  - Investigation of financial relationships with cardiologists
  - Expands to include medical necessity of procedures to implant coronary stents
  - Hospital's outside experts concluded that 369 procedures by a "marquee" physician were unnecessary
  - Hospital notified 369 patients

The Baltimore Sun (Jan. 15, 2010)

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Cardiac Procedures/Stents

- Two Louisiana hospitals
  - Paid $1.9M and $3.8M to settle qui tam alleging unnecessary coronary stent procedures
  - Hospitals allegedly had deficient peer review
  - CIA focused on quality of care in cardiac cath lab
  - Malpractice settlements ($15M)
  - Cardiologist sentenced to ten years
  - Relator: another cardiologist

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Cardiac Procedures/Stents

- Peninsula Regional Medical Center (MD) informed patients that a cardiologist on staff had performed unnecessary stent implantations
  - Pending federal investigation

  Source: Cardiovascularbusiness.com

- Tenet (Redding, CA)
  - $54 million to settle qui tam allegations of unnecessary cardiac surgery
  - $395 million to settle malpractice claims

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Hospital FCA Settlements based on financial relationships with physicians

- St. John Health System (Tulsa)
  - $13.2M settlement, no CIA
  - Self-disclosure
  - Arrangements with 23 physicians, groups at issue
- Arlington Memorial Hospital (TX)
  - $990,000 settlement, no CIA
  - Self-disclosure
  - Payments for unneeded, not provided interpretations of arterial blood gas tests

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Hospital FCA Settlements based on financial relationships with physicians

- South Texas Health System
  - $27.5 million settlement, 5-year CIA
  - Medical directorships, non-FMV leases
  - *Qui tam*
  - Arrangements with seven doctors reportedly at issue
- UMDNJ - $8.3M (cardiology appointments, directorships)
- Covenant Med. Center (Iowa) - $4.5M (five employed physicians allegedly paid excessive compensation)

Lessons

- Understand your risk areas
  - Industry-specific risks
  - Increasing exposure under the "causes to be presented" provision
  - Increasing number of criminal prosecutions
- Understand your company's marketing and billing practices
- Understand your contracts
  - Insurance policies - what do (and don't) they cover
  - Indemnification provisions

Lessons cont'd

- Ensure appropriate oversight of the company's compliance program by the Board of Directors
- Review internal reporting structure for compliance activities for appropriateness
- Ensure compliance programs are appropriately supported, and address any discrepancies between content and behavior expeditiously

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Thompson v. QHR
Handling Potential Whistleblowers

- Employee contends that hospital management company had conflict of interest
- Cryptic compliance complaint to hospital's outside auditor
- Did not internally report, as required by company policy, and refused to speak with compliance officer, lawyer
- Employee terminated, filed retaliatory discharge case
- *Qui tam* action dismissed

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Thompson v. QHR
Handling Potential Whistleblowers

- Channeling complaints to compliance program
  - Annual certifications (open-ended)
  - Policy requiring notification of compliance concerns and protecting from retaliation
- Investigate and keep employee apprised
  - Two people at interview
  - Must demonstrate response to employee
- Reassignment versus retaliation

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Thompson v. QHR
Handling Potential Whistleblowers

- Severance agreements
  - Representation that employee has informed employer of all compliance issues
  - Identify where and how notice of issues provided
- Employee must return money if in breach of agreement (EEOC issue re ADEA)
- Broad release
- Return of company property
- Cooperation with investigations

Questions?

Thank You!

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