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Evolving Fraud and Abuse Issues

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Criminal Enforcement

2

Criminal Enforcement – HEAT Task Force

- Health Care Fraud Prevention and Enforcement Team (HEAT)
  - Established May 20, 2009
  - Joint DOJ-HHS Collaboration Led by Deputy Attorney General and HHS Deputy Secretary
- Expanded data sharing and improved information sharing procedures to track patterns of fraud and abuse and increase efficiency in investigating and prosecuting complex health care fraud cases.
- Cross-government health care fraud data intelligence sharing workgroup to share fraud trends, new initiatives, ideas, and success stories to improve awareness across the government of issues relating to health care fraud.
- Provide training to federal prosecutors
- Medicare Strike Force effort

3

Criminal Enforcement – HEAT Task Force

- Medicare Strike Force
  - Began in Miami in 2007
  - Now Also in
    - LA
    - Detroit
    - Houston
    - Brooklyn
    - Baton Rouge
    - Tampa
    - Dallas
    - Chicago
- Seeks to Prevent and/or Prosecute Aggressively Health Care Fraud

4

Criminal Enforcement – HEAT Task Force (cont'd)

- By September 2012, the Strike Force had cumulative total of more than 724 cases charging 1,476 defendants, who billed Medicare for more than $4.6 billion
  - 918 defendants pleaded guilty
  - 105 others were convicted in jury trials
  - 745 defendants were sentenced to imprisonment for an average term of more than 45 months

5

Criminal Enforcement – HEAT Task Force (cont'd)

- Examples:
  - 2/11/13 sentencing of former registered nurse in Miami in $63 million scheme involving defunct health provider Health Care Solutions Network Inc. (HCSN)
    - Pleaded to conspiracy to commit health care fraud and conspiracy to commit money laundering.
    - HCSN operated 3 community mental health centers (CMHCs) in Miami area, 1 CMHC in Hendersonville, NC.
    - Former RN allegedly participated in admitting patients who were ineligible for PHP services, routinely fabricating patient medical records that were used to support false and fraudulent billings to Medicare and Medicaid.
    - Allegedly also routinely submitted fraudulent PHP claims for Medicare patients who were not present at the CMHC on days PHP services were purportedly rendered, including days the CMHC was closed due to snow.
    - Also president of separate shell corporation used by HCSN to launder health care fraud proceeds.
  - Owner of same chain sentenced on 2/25/13 to 14 years and $28 million in restitution.

6

Criminal Enforcement – HEAT Task Force (cont'd)

Examples:

- 2/4/13 guilty pleas by two patient recruiters for Miami home health agency for recruiting home health patients for Serendipity Home Health in exchange for kickbacks. Medicare allegedly was billed for home health care and therapy services on behalf of these beneficiaries that were medically unnecessary and/or not provided.
- May 2012, coordinated Strike Force teams in 7 cities executed nationwide operation
  - Resulted in charges against 107 individuals, including doctors, nurses and other medical professionals for alleged participation in Medicare fraud schemes involving approximately $452 million in false billings
  - In related effort, HHS suspended or took other administrative action against 52 providers.
- 7/12, Detroit-area rehabilitation agency owner was sentenced to 84 months in prison for leading role in $3 million Medicare fraud scheme
  - Convicted by jury of one count of conspiracy to commit health care fraud and siz counts of health care fraud
  - Defendant owned fraudulent rehabilitation agency that purchased falsified PT and OT files from more than 30 therapy and rehab companies and used them to fraudulently bill Medicare for more than $3 million.
  - Excluded by OIG for 25 years.

7

Criminal Enforcement – HEAT Task Force (cont'd)

Key areas of prosecution:

- Mental health, especially Community Mental Health Centers (kickbacks, medically unnecessary services, medically ineligible patients, falsification of documentation)
- Home health (kickbacks, fraudulent certifications, other falsification of eligibility)
- DME (equipment medically unnecessary and/or not provided)
- Physical therapy (kickbacks, services not provided)

8

Criminal Enforcement Beyond HEAT

- FCPA (e.g., Orthofix International, N.V., 7/2012 DPA and $2.2 million fine for alleged improper payments to Mexican officials to influence purchases of Orthofix's medical devices by Mexican government-operated hospitals; arose out of self-disclosure)
- Off-label promotion (Abbott Laboratories Inc.'s May 2012 guilty plea and civil settlement of off-label investigation relating to promotion of Depakote, including $700 million criminal fine and forfeiture plus $800 million in civil settlements with the federal government and the states)
  - *But see United States v. Caronia*, 703 F.3d 149 (2nd Cir. 2012): FDCA does not prohibit accurate speech about off-label uses
- Organized crime (e.g., individual sentenced 2/8/13 in SDNY for involvement with Mirzoyan-Terdjanian Organization, an Armenian-American organized crime enterprise engaged in a wide range of criminal activity, including a $100 million Medicare fraud billing ring)

9

Civil Enforcement – False Claims Act

10

Background

- 31 U.S.C. §3729 *et seq.*
- Civil statute
- Initially enacted in 1863 to combat fraud, waste and abuse in Civil War effort
- Revised significantly in 1943, 1986, 2009 (FERA), 2010 (PPACA)
- *Qui Tam* provisions enable private persons to initiate, recover percentage of proceeds
- Department of Justice has responsibility for investigating *qui tams*, enforcing FCA generally (Civil Frauds, USAOs)

11

Conduct Prohibited By FCA

- Submitting a claim for payment, OR causing claim to be submitted for payment, by Government funds. § 3729(a)(1)(A)
- Making or using, or causing to be made or used, false records or statements material to a false claim, §3729(a)(1)(B)
- Making or using, or causing to be made or used, false records or statements material to an obligation to pay money or property to the Government, or knowingly concealing or improperly avoiding or decreasing an obligation to pay money to the Government, §3729(a)(1)(G)
- Conspiring to commit a violation of the FCA, §3729(a)(1)(C)
- All require "knowledge" and link to Government funding
- Also prohibits retaliation against potential or actual whistleblowers, §3730(h)

12

Key Terms

- Knowledge
  - Actual knowledge that the claim or statement was false, OR
  - Deliberate ignorance of truth or falsity of the claim or statement, OR
  - Reckless disregard of the truth or falsity of the claim or statement
- Materiality: having a tendency to influence or be capable of influencing payment or receipt of money or property
- Obligation: established duty, including that arising out of retention of any overpayment

13

Qui Tam Provisions

- A person may bring a civil action for a violation of § 3729 "for the person and for the United States Government."
- The case is filed under seal to give the Government time to investigate and decide whether to "intervene."
  - Seal provision often extends up to two years, or longer.
- The "relator" receives 15% - 25% of the "proceeds of the action of settlement of the claim" or, if the government declines, 25% to 30%.
- Private right of action for individual against whom employer has retaliated for lawful acts in furtherance of a FCA claim or for trying to stop FCA violations.
- Relators have received over $3.4 billion from the "proceeds" of False Claims Act cases since 1986.
- Certain jurisdictional bars, such as the "public disclosure" bar and the "first to file" bar, have been the subject of significant litigation.
  - *Rockwell v. United States* (Supreme Court 2007).

14

Consequences of Liability

- Statutory provisions:
  - Treble the "amount of damages which the government sustains because of the act" giving rise to liability.
  - A civil penalty of $5,500 to $11,000 for each false claim.
- Collateral consequence: exclusion from federal health care programs.
- Result: Particularly high settlement rate.

15

FCA and SSA 60-Day Rule

- Statutory 60-day rule (SSA § 6402)
  - Requires specifically that all providers report and return overpayments within the later of sixty days of identifying the overpayment or the date the corresponding cost report is due, "if applicable." 42 U.S.C. § 1320a-7k(d).
  - Defines "overpayment" to mean "any funds that a person receives or retains under [a FHCP] to which the person, after applicable reconciliation, is not entitled under such title." 42 U.S.C. § 1320a-7k(d)(2).
  - Defines an overpayment retained after such deadline as an "obligation" under the FCA. 42 U.S.C. § 1320a-7k(d)(3).
  - Defines terms "knowing" and "knowingly" as having the same meaning given under the FCA, but the statute otherwise does not employ those terms, leaving definitions for terms that otherwise are not used. 42 U.S.C. § 1320a-7k(4)(A).

16

FCA and SSA 60-day Rule, cont'd.

- Proposed 60-day rule regulations
  - If an overpayment is claims-related, the provider must report and return the overpayment within sixty days of identifying the overpayment.
  - If the overpayment is the type that ordinarily would be reconciled through the cost reports, then the provider can report and return the overpayment either within sixty days after identifying the overpayment or on the date that the cost report is due.
  - Receipt of information by a provider or supplier regarding a potential overpayment "creates an obligation to make a reasonable inquiry" to determine whether an overpayment has, in fact, occurred. Then, "[i]f the reasonable inquiry reveals an overpayment, the provider then has 60 days to report and return the overpayment."
  - If the provider or supplier fails to make a reasonable inquiry, or fails to conduct such an inquiry "with reasonable speed," then the provider or supplier could be viewed as having knowingly retained the overpayment on the grounds that it had "acted in reckless disregard or deliberate ignorance" of an overpayment.

17

FCA and 60-day Rule, cont'd.

- Proposed 60-day regulations, cont'd.
  - Fails to specify whether quantifying the overpayment is inherent in the definition of "identifying" the overpayment.
  - 10-year look-back period (through extension of time to re-open claims)
  - Intersection with self-disclosure protocols:
    - Under SRDP with CMS (limited to Stark), still need to self-report under SRDP but repayment is tolled
    - Self-reporting under SDP (OIG) tolls repayment obligation until settlement or discloser withdraws/removed from Protocol

18

Civil Investigative Demands

- In furtherance of investigation of potential FCA violations, DOJ may issue CIDs for:
  - Documents
  - Interrogatory responses
  - Depositions
- DOJ may share information gathered through CIDs with criminal division, other agencies, and even relator

19

Predicates for FCA Liability

- Factually false claims: services were not provided as represented
- Legally false claims: The claims are false due to the violation of a separate statute or regulation
- The underlying violation renders the claim false or fraudulent, thus giving rise to the FCA violation
  - "Express certification"
  - "Implied certification"
- *See U.S. ex rel. Hutcheson v. Blackstone Medical*, 647 F.3d 377 (1st Cir. 2011) for discussion of these categorizations

20

"Express Certification" Theory

- FCA liability arises when:
  - the person submitting the claim expressly certifies in writing that the items or services at issue comply with the law, knowing that in fact they do not, and
  - compliance with the law is a condition of payment by the government
- Often arises in the cost report context in conjunction with Antikickback Statute violations
  - Cost reports contain certifications that the individual signing it is aware of relevant statutes and regulations and that the services provided complied with all such statutes and regulations
  - Some cost reports even contain language directly referencing the AKS
- *U.S. ex rel. Jones v. Brigham and Women's Hosp.*, 678 F.3d 72 (1st Cir. 2012).

21

"Implied Certification" Theory

- FCA liability arises even in the absence of an express certification of compliance with relevant statutes or regulations when:
  - the claimant knows it did not comply with the statute or regulation but nevertheless submits the claim (or causes it to be submitted)
  - again, compliance with that statute or regulation is a condition of payment
- Applies more often in context of health care claims for individual patients (UB-92s, CMS 1500s), which implicitly represent that the submitter is in compliance with applicable law and regulations and is, therefore, entitled to payment
- Initially more controversial theory than express certification, but becoming well-established now in AKS and Stark context.
  - PPACA revised AKS to provide that claims resulting from AKS violations are false under the FCA. 42 U.S.C. § 1320a-7b(g).

22

Civil Enforcement through FCA

- Hot areas of enforcement (and examples of significant settlements)
  - Pharmaceutical manufacturers, esp. off-label promotion and kickbacks
  - Devices, esp. kickbacks
  - Inpatient/outpatient hospital
  - Financial relationships with physicians (kickbacks and Stark Law, esp. in Medicaid)
  - Individuals
  - ACA amendment to the AKS provides that a claim for items/services resulting from a AKS violation creates liability under the FCA

23

Significant FCA Settlements

- GlaxoSmithKline, July 2012, $3B combined FCA and criminal
- Abbott Laboratories Inc., May 2012, $800M
- Tenet Healthcare Corporation, April 2012, $42.75M to resolve allegations its inpatient rehabilitation facilities unlawfully admitted Medicare patients who did not meet Medicare standards for IRF admissions.

24

Significant FCA Settlements, cont'd.

- Walgreens, April 2012, $7.9M to US and participating states to resolve allegations that Walgreens offered illegal inducements to beneificaries of federal health care programs in the form of gift cards, gift checks, ad other similar promotions, to transfer their prescriptions to Walgreens pharmacies.
- August 2012, prominent Houston radiologist paid $650K to resolve claims he paid illegal compensation to physicians to induce them to refer patients to imaging center he owned and operated. Agreed to voluntary suspension under Medicare and Medicaid for 6 years.
- February 2013, prominent Florida dermatologist agreed to pay $26.1 million to resolve allegations that he improperly accepted remuneration from clinical laboratory. Agreed to 5-year exclusion.

25

OIG Enforcement Through Exclusion and CMPs

26

OIG Enforcement Through Exclusion and CMPs

- Civil Monetary Penalty Statute – 42 U.S.C. § 1320a-7a
  - Up to 3 times damages based on claims filed or remuneration paid
  - Penalties assessed per claim or per incident
- Commonly Enforced CMPs
  - False or fraudulent claims
  - Kickbacks
  - Employment of an excluded individual
  - EMTALA violations (through 42 U.S.C. § 1395dd(d)(1))

OIG Enforcement Through Exclusion and CMPs

- Exclusion Statute – 42 U.S.C. § 1320a-7
- Mandatory
  - Convictions for offenses related to delivery of items or services under Medicare or Medicaid, or patient neglect or abuse
  - Convictions for certain other felonies, including those related to health care fraud and controlled substances
- Permissive
  - Misdemeanor convictions for certain offenses, including those related to health care fraud and controlled substances
  - Licensure actions
  - False claims and kickback violations
  - Other grounds

OIG Enforcement Through Exclusion and CMPs

- Pursue Responsible Individuals for Exclusion and CMPs
- Pursue Conduct Across the Spectrum
  - Disabuse providers of the notion they can fly below the radar.
- Pursue CMPs for employment of or contracting with excluded persons

29

OIG Enforcement Through Exclusion and CMPs

CMP Examples – Pursuing individuals

- Physician practice and four physicians for overcharging beneficiaries -- $170,260
- Nine settlements with physical therapists, for reassigning claims in exchange for a medical directorship and then not performing services, with penalties ranging from $25,500 to $133,000

30

OIG Enforcement Through Exclusion and CMPs

CMP Examples – "Across the Spectrum" Cases

- Settled case with five related entities
  - Medical technology company provided physicians all-expense paid trip to Masters for five years
  - OIG determined this was prohibited remuneration intended to induce referrals.
  - Company paid $126,249.30 in CMPs.
- Pharmacy Grocery chain
  - Pharmacy billed for branded drug while dispensing generic
  - Company paid $56,994 in CMPs.

31

OIG Enforcement Through Exclusion and CMPs

CMP Examples – Employment of Excluded Persons

- Hospital paid $406,030 for employing excluded person for four years.
  - Knew of individual's 4 criminal convictions, but <u>never checked</u> OIG's exclusion list.

32

OIG Enforcement Through Exclusion and CMPs

Exclusion Examples

- 3 former Purdue executives excluded for misdemeanor misbranding based on failure to detect or prevent fraudulent OxyContin misbranding
  - Exclusion under 42 U.S.C. § 1320a-7(b)(1) upheld by Court of Appeals for the D.C. Circuit, remanded for reconsideration of length
- 4 former Synthes executives excluded for misdemeanor misbranding based on failure to detect or prevent fraudulent misbranding and illegal human trials of Norian bone cement
  - Currently on appeal before an administrative law judge

33

Emerging Trends in CIAs

OIG held two roundtables in 2012

- Pharmaceutical Compliance Roundtable
- CIA Roundtable
- White papers available here:

https://oig.hhs.gov/compliance/corporate-integrity-agreements/resources.asp

34

Emerging Trends in CIAs

New Pharma CIAs

- GlaxoSmithKline
  - Compensation not based on volume of sales
  - Recoupment of bonuses and incentives for executive misconduct
- Amgen
  - Annual Risk Assessment
    - Annual Risk Assessment focusing on activities governed by policies and procedures
    - Risk Assessment on a Product-Specific basis ("Ra3")
    - IRO review of Ra3

35

Emerging Trends in CIAs

- GGNSC, Inc. – quality of care CIA
  - Focus on evaluating compliance and quality systems
- Christ Hospital
  - Claims review population based on 1 of 3 risk areas identified by the hospital
- Atrium Medical Center
  - IRO Compliance Audit Review

36

CIA Enforcement

- Enforcement of CIA Terms: enforcement of agreement between OIG and entity
- Resolution of Reportable Events: combination of notification and mandatory Self-Disclosure Protocol with benefits of the Protocol.

37

CIA Enforcement

Stipulated Penalties:

- Failure to submit report
- Failure to screen Covered Persons
- Failure to report a Reportable Event
- Failure to appoint IRO/Monitor
- False Certification

Exclusion:

- Hospital was excluded for complete failure to implement the CIA.

38

Reportable Events

- Substantial Overpayments
- Probable violation of law applicable to Federal health care program for which penalties or exclusion is authorized
- Employment or contracting with an Ineligible Person
- Filing of a bankruptcy petition

39

Reportable Events

- Substantial Overpayments
  - Notice
  - Explanation of cause
  - Proof of repayment
  - Root cause analysis and steps to avoid recurrence, if applicable
- Filing of bankruptcy petition
  - Notice

40

Reportable Events

- Probable violation of law applicable to Federal health care program for which penalties or exclusion is authorized and Employment or contracting with an Ineligible Person:
  - Notice
  - Explanation of cause
  - Root cause analysis
  - Damages calculation, if applicable
- If we determine that a CMP is appropriate, we will apply same standards as in the Self-Disclosure Protocol

41

Self-Disclosures

42

Whether and When to Consider Self-Disclosure

- 60-day reporting and repayment requirement under ACA, FCA triggered whenever provider identifies an overpayment
- More than mere repayment may be advisable when:
  - Evidence of knowing/intentional misconduct
  - Pattern of false/inaccurate claims
  - Stark Law violation (with or without knowledge)
  - Likelihood of whistleblower activity

43

Potential Benefits to Self-Disclosure

- Opportunity to be the first to introduce the situation to enforcers (versus defending later)
- Greater control over process
- Reduce defense expenses
- Reduce financial exposure
  - FCA multiplier reduced
  - Stark Law resolved at less than overpayment amounts
  - Reduce criminal penalty if applicable under USSGs
- Obtain FCA release, eventually barring relator actions

44

(Perceived) Drawbacks to Self-Disclosure

- Lack of predictability
  - Reaction of govt entity to which disclosure is made
  - What agencies will become involved
  - Resolution amount

45

Self-Disclosure Options

- HHS-OIG Self-Disclosure Protocol
- CMS Self-Referral Disclosure Protocol
- DOJ (Main)
- USAO
- State (for Medicaid)
- Report and Repay to Contractor

46

Self-Disclosure Options - OIG

- HHS-OIG Self-Disclosure Protocol (SDP)
  - Federal Register notice, 10/30/1998 (63 FR 58399)
  - Open Letter to Health Care Providers from Daniel R. Levinson, 4/24/2006
  - Open Letter to Health Care Providers from Daniel R. Levinson, April 15, 2008
  - Open Letter to Health Care Providers from Daniel R. Levinson, March 24, 2009

Available at: https://oig.hhs.gov/compliance/self-disclosure-info/index.asp

47

Self-Disclosures - OIG

- HHS-OIG Self-Disclosure Protocol
  - Intended for use to resolve potential violations of federal criminal, civil or administrative laws
  - Not intended for use for mere overpayments
  - Can be used to resolve potential kickbacks under CMPL authority, but not intended for use for pure Stark violations
  - Provider may request involvement of DOJ to obtain concurrent FCA release
  - Disclosure would constitute a report under the 60-day rule and would toll repayment obligations under proposed regulations

48

Self-Disclosures- CMS

- CMS Voluntary Self-Referral Disclosure Protocol (SRDP)
  - Mandated by PPACA
  - Issued 9/23/2010, revised 5/6/2011
  - Establishes process to self-disclose actual or potential violations of the Stark Law ONLY
  - Disclosure tolls 60-day rule's repayment obligations

49

Self-Disclosures - DOJ

- FCA Provisions
  - No DOJ protocol for self-disclosing FCA violations
  - FCA provides cap on damages multiplier at doubles instead of trebles
  - Must report within 30 days of discovering misconduct

50

Questions?

51

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52

***Coronia*: The Anticipated Effect on Off-Label Cases**

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For more than a decade, the Department of Justice ("DOJ") has focused significant resources on pursuing pharmaceutical and device manufacturers who allegedly promoted their products for indications other than those for which the Food and Drug Administration ("FDA") had approved the products. It has brought a number of these cases under the Food Drug and Cosmetic Act ("FDCA"), on the basis that the FDCA prohibits the misbranding of drugs and devices, which it in turn construes to prohibit the "off-label promotion" of drugs and devices, the term "off-label" referring to brought against and settled with pharmaceutical manufacturers based on allegations of off-label promotion of their drugs. Neither the FDCA or any other federal law provision generally prohibits the prescription or use of any drug or device for off-label uses; but the promotion of them for such uses has been interpreted by DOJ and FDA to be prohibited under the statute's misbranding prohibitions.

DOJ's application of the FDCA under this theory has led to dramatically large recoveries against major pharmaceutical manufacturers. DOJ also , however, has applied the False Claims Act (FCA) to off-label promotion to pursue damages against manufacturers who allegedly engaged in off-label promotion and thus allegedly caused physicians to prescribe the drugs for off-label purposes, when those off-label purposes were not reimbursable under Medicare and Medicaid. Many prosecutions have involved joint action by the Criminal and Civil Divisions under both statutes and, as a result, have resulted in negotiated resolutions requiring payment by the manufacturers of significant criminal fines and/or restitution and civil settlement amounts. Just last May, for example, the federal government recovered $3 billion from GlaxoSmithKline LLC in a joint criminal and civil settlement focused primarily on allegations of off-label promotion of Paxil and Wellbutrin, of which $1 billion represented criminal fines and forfeitures and the remaining $2 billion represented payments to the United States and states under the FCA. Around the same time, Abbott Laboratories entered into a joint FCA settlement and guilty plea under the FDCA, resolving allegations of off-label promotion of the drug Depakote for $800 million and $700 million respectively.

But in a court decision that will impact future FDCA cases brought in the Second Circuit, as well as potentially FDCA cases brought in other circuits and even FCA cases predicated on alleged off-label marketing activities, the Second Circuit recently held that a drug manufacturer's off-label promotion of a drug is not prohibited under the FDCA because such a prohibition would unconstitutionally restrict free speech. *United States v. Caronia*, 703 F.3d 149 (2nd Cir. 2012). In *Caronia*, where the Second Circuit's decision finally was issued two years after oral argument, the defendant pharmaceutical sales representative had argued that he was convicted in violation of his First Amendment right of free speech for promoting the FDA-approved drug Xyrem for off-label uses. The drug was manufactured originally by Orphan Medical, Inc., which then was acquired by Jazz Pharmaceuticals, which continued to manufacture and promote the drug. *Id.* at 155. At trial, the jury convicted the sales representative, Alfred Caronia, of conspiracy to introduce a misbranded drug into interstate commerce, a misdemeanor violation under the FDCA.

Xyrem contains the active ingredient gamma-hydroxybutryate ("GHB"), which has been federally classified as the "date rape drug." *Id.* Nevertheless, FDA had approved the drug to treat narcolepsy patients who experience cataplexy (a condition associated with weak or paralyzed muscles) and excessive daytime sleepiness. *Id.* Because of concerns about the drug's safety, however, FDA had required a "black box" warning to be placed on the drug's labels, warning among other things that the drug's safety and efficacy were not established in patients under 16 years of age, and had allowed only one centralized Missouri pharmacy to distribute Xyrem nationally. *Id.*

The evidence presented at trial indicated that Caronia and Peter Gleason, M.D., who had been hired to promote Xyrem through Jazz's speaker programs, had promoted the drug for off-label uses, i.e., for indications other than those for which the FDA expressly had approved the drug. An audio tape presented at trial reflected Caronia informing another physician of the drug's approved indications but also noting that it also could be used to treat insomnia, fibromyalgia, periodic leg movement, Parkinson's disease, restless leg, and other sleep disorders. *Id.* at 156. He directed the other physician to list the diagnosis codes of the actual disease being treated when prescribing Xyrem, for insurance purposes. *Id.* Caronia and Dr. Gleason also explained to other physicians that Xyrem could be used with patients under age 16 and over 65, though they acknowledged that the drug was not approved for those categories of patients. *Id.* at 156-57. Thus, none of the information provided by Caronia or Gleason appeared intended to or likely to mislead the physicians as to the intended uses or scientific evidence, nor did it direct them to submit inaccurate diagnosis information on their prescriptions for the drug.

The Second Circuit agreed with Caronia's argument that he had been convicted for his speech, but rejected his broader argument that the FDCA's misbranding provisions prohibit off-label promotion and thus violate the First Amendment's free speech protections. *Id.* at 161-62. The court applied the two-part analysis set forth by the Supreme Court in *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653 (2011), which involved a First Amendment challenge to speech restrictions imposed by a state statute on pharmaceutical marketing by manufacturers using prescriber-identifying information. *Id.* at 163. Under the first prong of *Sorrell*, the *Caronia* court considered whether the government's construction of the FDCA's misbranding provisions imposes content- and speaker-based restrictions on speech. *Id.* at 164-65. The court found that it did, and therefore the restrictions were subject to heightened scrutiny. *Id.* at 165.

Under the second heightened scrutiny prong of *Sorrell*, the appeals court applied the four-prong test set forth under the Supreme Court's *Central Hudson* decision. *See Cent. Hudson Gas & Elec. Crop. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980). The first *Central Hudson* prong was easily satisfied: the off-label drug use being promoted was lawful activity, and promoting off-label drug use was not inherently false or misleading. *Id.* at 165-66. The second prong also was easily satisfied: the government's asserted interests in drug safety and public health were substantial. *Id.*at 166.

The government's construction of the FDCA did not, however, withstand scrutiny under the third *Central Hudson* prong, which requires that the restriction directly advance the government's interest. *Id.* Off-label prescription is legal, yet the off-label promotion restriction prohibits the free flow of information that would inform such legal prescriptions. *Id.* So long as the off-label use of drugs is lawful, prohibiting promotion does not directly advance the stated governmental interest in reducing patient exposure to off-label drugs or in preserving the efficacy of the FDA's drug approval process. *Id.* at 166-67.

In addition, the criminalization of off-label promotion failed to satisfy the fourth *Central Hudson* prong. That fourth prong requires that the restriction be narrowly drawn. *Id.* at 167. The court found that "a complete and criminal ban on off-label promotion by pharmaceutical manufacturers is more extensive than necessary to achieve the government's substantial interests." *Id.* Instead, the government could simply impose less speech-restrictive alternatives or non-criminal penalties. *Id.* Indeed, the government even could prohibit off-label use entirely. *Id.* at 168.

The court then applied the principle of constitutional avoidance to construe the FDCA not to define the simple promotion of a drug's off-label use as tantamount to misbranding (so as to avoid striking down the misbranding provisions of the statute). *Id.* at 162. Because the court found, based on the trial record, that the government prosecuted Caronia for "mere off-label promotion" and instructed the jury it could convict on that theory, the Second Circuit vacated the conviction. *Id.*

The government had argued in the appeal that Caronia was not prosecuted for his speech but, instead, his off-label promotion of the drug "served merely as 'evidence of intent,' or evidence that the 'off-label uses were intended ones [ ] for which Xyrem's labeling failed to provide any directions.'" *Id.* at 160 (quoting Govt. Brief at 52). The Circuit Court rejected that argument, finding it to be "belied by" the Government's "conduct and arguments at trial." *Id.* at 161. The trial transcript, as quoted by the Second Circuit, clearly reflected that the prosecutors had focused on Coronia's statements to physicians regarding the use of the drug for medical issues other than those for which it was approved and for patient populations beyond those for which it was approved, and that "the government prosecuted Caronia for mere off-label promotion."

Reportedly, the Food and Drug Administration ("FDA") has decided not to appeal or retry the case against Caronia. *See* http://online.wsj.com/article/SB10001424127887324539304578260323575925896.html (last visited 3/11/2013). Thus at least for now, this holding constitutes the law the Second Circuit with respect to off-label marketing.

The language of the *Caronia* focused exclusively on the interpretation of the misbranding provisions of the FDCA in the context of the First Amendment. And since the FDA has chosen not to appeal the Second Circuit's decision in this case, this significant decision will stand as Second Circuit law on the issue of off-label promotion under the FCA. Surely this decision will limit the number of cases that the government brings under the FDCA in the Second Circuit, anyway, where the information provided by the defendant was lawful and not misleading.

Many of these cases, however, involve allegations that the defendant manufacturer or physician provided misleading information to other physicians, which in turn misled them into prescribing the drugs for uses for which they were not approved by the FDA. Given the Second Circuit's emphasis on the fact that this case did not involve misleading information, the government presumably would try to distinguish such a case from *Caronia* and still would try to rely on a misbranding theory of liability under the FDCA.

As noted above, however, whistleblowers and the DOJ have brought a number of civil FCA cases predicated on off-label marketing. Under the theory of those cases, the defendants (typically the manufacturers) violated the FDCA by promoting the drug at issue for off-label uses, as Caronia allegedly did. Although physicians legally may prescribe FDA-approved drugs for off-label uses, the Medicare and Medicaid programs generally do not reimburse for off-label prescriptions, unless the drugs meet certain criteria. Specifically, the off-label uses must be recognized in statutorily-identified

compendia. 42 U.S.C. § 1395x(t); 42 U.S.C. §§ 1396r-8(k)(6), 1396r-8(g)(1)(B)(i). Claims submitted to Medicare and Medicaid for reimbursement for uses not recognized in the compendia are therefore, under the Government's theory, false claims in violation of the FCA. Thus, by promoting drugs for an off-label use not recognized in the compendia, the manufacturer causes false claims to be submitted to Medicare and Medicaid, even though the claims are submitted by unwitting pharmacists rather than by the manufacturer. *See, e.g., U.S. ex rel. Franklin v. Parke-Davis*, 147 F. Supp.2d 39, 53 (D. Mass. 2001).

The impact that the *Caronia* case will have on these FCA off-label cases is unclear. At least in the Second Circuit, the government can no longer argue that the mere off-label promotion of a drug constitutes an FDCA violation. Thus, FCA liability cannot be predicated on a FDCA violation.

On the other hand, the government likely will argue that establishing a FDCA violation is unnecessary for establishing FCA liability. Medicare and Medicaid payment do not turn on whether the manufacturer complies with the FDCA; it turns instead on whether the use for which it is prescribed for the particular patient at issue is scientifically accepted so as to be reflected in a recognized compendium. When a manufacturer promotes a drug off-label, it "knows" within the meaning of the FCA (actual knowledge, reckless disregard or deliberate ignorance) that the drug will be prescribed to patients who are Medicare and Medicaid beneficiaries, even if the primary intent of the promotion is not aimed at increasing federal health care program reimbursement.

Under this FCA approach to liability, the offending conduct still would be the manufacturer's speech, through its employees. But the *Caronia* court left open the possibility that so long as the government stopped short of criminalizing the conduct, it could restrict off-label promotion in other ways. It found, for example, that the case before it was subject to more careful scrutiny than the statutory scheme at issue in *Sorrell* because the FDCA is a "criminal regulatory scheme." *Id.* at 165. Under the FCA, the government would be arguing simply that the manufacturer's accurate sharing of information regarding the drug's off-label uses caused Medicare and Medicaid claims to be submitted on behalf of beneficiaries for the off-label uses that do not fall within the uses identified in the compendia. 42 U.S.C. §3730(a)(1)(A). The element of causation would become the challenge in such cases.

The government also might limit its FCA focus to cases that involve allegedly false or misleading promotion, which again, the Second Circuit explicitly found that *Caronia* did not. *Id.* at 167. Establishing that such false or misleading promotion caused the prescription of the drug for unapproved, non-compendia-cited uses, and thus the submission of false Medicare and Medicaid claims, would avoid First Amendment implications.

As a practical matter, we expect that some government attorneys will back away from off-label promotion FCA cases, particularly those brought in the Second Circuit and those involving the provision of purely accurate information regarding off-label uses. Nevertheless, we also expect that many prosecutors will continue to bring these cases under both the FDCA and the FCA, particularly outside of the Second Circuit and in situations that allegedly involve false or misleading promotion.