



A Warning To In-House Counsel and Compliance Officers: *U.S. v. Sulzbach*

Presenters:

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Today's Presenters



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Overview

- **The Headlines**
 - "Lawsuit Spotlight's GC's Risk of Personal Liability" (*Compliance Week*)
 - "Federal Action on Tenet's Ex-Lawyer Seen As Warning Signal to Compliance Officers" (*BNA Health Care Daily*)
- **Purpose of Web Conference**
 - To provide information to in-house counsel and compliance officers using *U.S. v. Sulzbach* as the backdrop
 - Legal issues
 - Ethical Backdrop
 - We express no opinion on the merits of the allegations made by the government against Christi Sulzbach
 - We recognize that this case is fact-specific and arises from a unique and lengthy history
 - The case, however, presents broader issues involving the operation of compliance programs, reporting under corporate integrity agreements, and government enforcement initiatives that impact upon in-house counsel and compliance officers



What We Will Cover

- The Current Enforcement Environment
- The Legal Framework Applicable To *U.S. v. Sulzbach*
 - The False Claims Act
 - The Stark Law
 - Corporate Integrity Agreements
 - Model Rules of Professional Conduct
- *U.S. v. Sulzbach*
 - The Factual Setting
 - The Government's Claims
 - The Procedural Status
 - The Pending Motion To Dismiss
- Lessons Learned So Far
- Addressing Issues and Questions



The Current Enforcement Environment

- Health Care Enforcement Actions Are Big Business
 - In FY 2006, the federal government recovered approximately \$2.2B in judgments and settlements
 - The Medicare Trust Fund received approximately \$1.5B as a result of these recoveries in FY 2006
 - Since the Health Care Fraud and Abuse Control Program was created in 1997, over \$10.4B has been returned to the Medicare Trust Fund



The Current Enforcement Environment (cont'd)

■ The Number of Enforcement Actions are on the Rise

- In FY 2006, the USAOs opened 836 new criminal health care fraud investigations involving 1,448 potential defendants, in addition to the 1,677 criminal health care fraud investigations already pending
- In FY 2006, criminal charges were filed in 355 cases involving 579 defendants. A total of 547 defendants were convicted of health care fraud crimes that year
- In FY 2006, DOJ opened 915 new civil health care investigations and had pending 2,016 civil investigations at the end of the year
- The number of administrative proceedings initiated by OIG is also on the rise



The Current Enforcement Environment (cont'd)

- Outside of the Voluntary Disclosure Context, the Vast Majority of Civil and Administrative Settlements involve the Imposition of a Corporate (Individual) Integrity Agreement
- Settlements by health care entities are more frequently followed by enforcement actions against responsible individuals
- Government views attorneys as the “first line of defense” against fraud and abuse
- DOJ has never shied away from charging lawyers or compliance officers
 - *United States v. Anderson* (D. Kan.) (2 outside counsel)
 - *United States v. Altieri* (N.D. Ohio) (in house counsel)
 - *United States v. Caputo* (N.D. Ill.) (compliance officer)



The Current Enforcement Environment (cont'd)

9

■ *U.S. v. Anderson* (D. Kan.):

- Federal jury convicted two doctors and two hospital executives for violation of the anti-kickback statute (42 U.S.C § 1320a-7b(b)(1))
- Remuneration disguised under sham consulting contracts that paid each doctor \$75,000 per year for little to no services
- 2 health care transactional lawyers indicted for their part in drafting the sham consulting agreements
- District court acquitted the 2 lawyers at trial based on a finding that the attorneys relied in good faith on representations of their clients and that they used their best efforts to provide sound advice in an ambiguous area of law



The Current Enforcement Environment (cont'd)

10

■ *United States v. Altieri* (N.D. Ohio):

- In-house lawyer for chain of chiropractic clinics charged with conspiracy to commit health care billing fraud
- Clinics allegedly submitted false claims for non-covered chiropractic services representing that they had been performed by medical doctors when in fact the services were provided by licensed chiropractors
- Only claimed financial benefit of lawyer was a modest bonus plan offered by the company
- Good Faith: While legal advice was disputed, on advice of the in-house lawyer, a company employee sent a letter to the AMA asking about proper use of billing codes
- Acquitted after a 3 week jury trial in which he was represented by Foley & Lardner LLP



The Current Enforcement Environment (cont'd)

11

- *United States v. Caputo* (N.D. Ill.):
 - VP of Regulatory Affairs and Chief Compliance Officer convicted for false statements in marketing a surgical sterilizer that was not FDA approved
 - At sentencing, court rejected mitigation arguments based on the company's compliance program finding that it was defective and in some cases even a sham
 - Chief Compliance Officer not independent
 - Chief Compliance Officer had no training in compliance
 - No proactive compliance efforts emphasizing corporate ethics
 - Compliance program failed to recognize or react to other known violations

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The Legal Framework Applicable to the Sulzbach Case

12

- False Claims Act (31 U.S.C. § 3729 et seq.)
 - Purpose: Provide restitution and penalties for money taken from the government by fraud
 - Its Scope:
 - Any person who –
 - Knowingly presents or causes to be presented...a false or fraudulent claim for payment or approval
 - Knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government
 - Knowingly makes, uses or causes to be made or used, a false record or statement to conceal, avoid, or decrease
 - The term “knowingly” in this context means that a person has (a) “actual knowledge” or (b) “acts in deliberate ignorance of the truth or falsity of the information,” or (c) “acts in reckless disregard of the truth or falsity of the information.”

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The Legal Framework Applicable to the Sulzbach Case (cont'd)

13

- In some jurisdictions, the false or fraudulent claim must be material. (See e.g. *U.S. ex rel A+ Homecare Inc. etc.*, 400 F.3d 428,442 (6th Cir. 2005))
- Some cases also require the additional element of damages. (See e.g. *U.S. ex rel. Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 785 n.7 (4th Cir. 1999))
- But, an FCA claim premised on a false certification of compliance also requires that the certification of compliance be a requirement for payment to be received. (See e.g. *U.S. ex rel. Gross v. AIDS Research Alliance – Chicago*, 415 F.3d 601, 604 (7th Cir. 2005))
- There is also a series of cases that adopt a “natural tendency” standard for liability – Does the false statement have a natural tendency to influence the decision to make payment. (See e.g. *U.S. ex rel. A+ Homecare, supra*; *U.S. ex rel. Harrison, supra*.)

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The Legal Framework Applicable to the Sulzbach Case (cont'd)

14

- Liability under the FCA includes fines of not less than \$5,500 nor more than \$11,000 per claim, plus treble damages. FCA liability can also form the basis for administrative sanctions, including exclusion from the Medicare program.
- Stark violations can give rise to FCA liability based on claims submitted for services rendered to tainted patients under either express or implied certification theories
 - *U.S. v. Rogan*, Case No. 06-4144 (7th Circuit, Feb. 20, 2008)

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The Legal Framework Applicable to the Sulzbach Case (cont'd)

15

- The Stark Law (42 U.S.C. § 1395nn)
 - Prohibits financial relationships between physicians and the entities to which they refer Medicare patients for certain “designated health services” (DHS)
 - Inpatient and outpatient services are DHS under the Stark Law such as (as of January 1, 1995):
 - Inpatient and outpatient hospital services
 - Physical therapy, occupational therapy
 - Radiology and radiation therapy
 - DME POS
 - If a financial relationship exists between the physician and the DHS entity and that relationship does not meet an enumerated exception under the statute or implementing regulations, then the physician may not refer Medicare patients to the DHS entity for DHS services and neither the physician nor the DHS entity may bill Medicare for any services provided pursuant to the referral
 - “the entity may not present or cause to be presented a claim...or bill...” 42 U.S.C. §1395nn

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The Legal Framework Applicable to the Sulzbach Case (cont'd)

16

- Many Stark exceptions require compensation at fair market value
 - Personal Services rendered by a physician to a hospital if the remuneration paid is:
 - (a) Consistent with fair market value
 - (b) Would be commercially reasonable in the absence of referrals
 - (c) Is not determined in a manner that takes into account (directly or indirectly) the value or volume of any referrals by the referring physician
 - The Stark law is a strict liability statute containing no intent or even knowledge element

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The Legal Framework Applicable to the Sulzbach Case (cont'd) 17

- Corporate Integrity Agreements –
<http://oig.hhs.gov/fraud/cias>
 - Negotiated as a part of investigations arising under civil false statutes

 - In exchange for an agreement not to seek exclusion from participation in government programs (e.g. Medicare, Medicaid)

 - Typical terms
 - 5 years
 - Compliance officer/compliance committee
 - Comprehensive employee training program
 - Establish a confidential disclosure program
 - Required reports to the OIG
 - Certification requirements
 - Required training attendance by Covered Persons



The Legal Framework Applicable to the Sulzbach Case (cont'd) 18

- Typical terms (cont'd)
 - Certification by the Compliance Officer that:
 - Required policies and procedures in place
 - Required training has been completed
 - All plans of correction have been implemented

 - Certification by the President and CEO “under penalty of perjury” that:
 - Provider is in compliance with all of the CIA requirements “to the best of his or her knowledge”
 - They have reviewed the Implementation Report, and “have made reasonable inquiry regarding its content and believe that, upon such inquiry, the information is accurate and truthful”



The Legal Framework Applicable to the Sulzbach Case (cont'd)

19

- Certificate of Compliance Agreement (CCA) may also be negotiated
 - A requirement to certain compliance obligations
 - Includes reporting overpayments, reportable events and ongoing investigations and legal proceedings

- Factors in CIA Negotiation
 - Severity and extent of underlying misconduct
 - Existing compliance infrastructure
 - Resources available for such efforts
 - Deference to self-disclosing provider



The Legal Framework Applicable to the Sulzbach Case (cont'd)

20

- Model Rules of Professional Conduct – The Ethical Backdrop
 - Do not provide in house counsel with clear guidance on counsel's obligation or ability to report wrongdoing to third parties

 - Model Rule 1.13(b): "If a lawyer for an organization knows that an officer, employee or other person associated with the organization is engaged in action, intends to act or refuses to act in a manner related to the representation that is a violation of a legal obligation to the organization, or a violation of law that reasonably might be imputed to the organization, and that is likely to result in substantial injury to the organization, then the lawyer shall proceed as is reasonably necessary in the best interest of the organization."



The Legal Framework Applicable to the Sulzbach Case (cont'd.)

21

- Model Rules are silent as to the tension between what a lawyer deems “reasonably necessary in the best interest of the organization” under Model Rule 1.13 and the duty of confidentiality that a lawyer owes a client under Model Rule 1.6
- Options afforded by model Rules to in-house counsel who believes a client intends to engage in fraud are: (a) asking the constituents to reconsider the matter; (b) advising the constituents to seek a separate legal opinion; and (c) referring the matter to a higher authority within the organization



The Legal Framework Applicable to the Sulzbach Case (cont'd)

22

- Model Rules do not authorize or require in-house counsel to disclose to law enforcement authorities about potential or ongoing fraud
- In face of ongoing or potential fraud, particularly if counsel’s work product is used to further the fraud, only option is to make a “noisy withdrawal”
- If counsel resigns, can document the measures taken to notify wrongdoing members of the organization of the illegality of the conduct, the consequences of the conduct, and counsel’s attempts to deter the conduct



United States v. Sulzbach

23

■ The Factual Setting

- NME as a target for investigations
 - Fraud and illegal kickbacks conducted by NME subsidiary
 - Investigation involving DOJ, OIG, States
 - Settles with fines and a CIA
 - \$379 million civil and criminal fines
 - 5 year CIA
 - Executed by Ms. Sulzbach – Associate General Counsel and Corporate Integrity Program Director (Resigned September 2003)



United States v. Sulzbach (cont'd)

24

- The CIA
 - Requirements regarding outside counsel approval of contracts with payments to physicians
 - Corporate Integrity Program to ensure legal compliance
 - To file annual compliance reports with certifications that the company “is either in compliance or non compliance with...federal program legal requirements” and the “status of any ongoing investigation of...NME’s compliance with federal program legal requirements”
 - Government inspection rights
 - Required reports of credible evidence of misconduct that management had reasonable grounds, after appropriate inquiry, to believe constituted a material violation of the civil law or federal program rules
 - To take appropriate corrective action of problems identified in its internal investigations, including prompt restitution



United States v. Sulzbach (cont'd)

25

■ The Government's Allegations

- DOJ filed a 40 page civil complaint alleging violation of the False Claims Act with Stark violations as the predicate
- False Claims Act Causes of Action– Presentation of False Claims
 - Making or Using False Record or Statements To Cause False Claim To Be Presented
 - Making or Using False Record or Statement To Avoid An Obligation To Refund
- DOJ alleges that certifications submitted by Sulzbach in 1997 and 1998 pursuant to Tenet's CIA to the effect that Tenet was in compliance with federal law, were knowingly false and "allowed Tenet to bill Medicare for millions of dollars that it [could not under Stark]"
- DOJ alleges that the purported false certifications facilitated payment on 70,000 claims totaling \$18 million

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United States v. Sulzbach (cont'd)

26

- Government alleges Stark law violations in connection with employment contracts entered into by North Ridge Medical Center in Fla. and 12 physicians which government believes (1) provided for compensation above fair market value, and (2) compensation was set in relation to laboratory outpatient referrals
- Sulzbach's 1st motion – Some interesting factual claims and the Statute of Limitations
 - The Government Was Aware of the Facts
 - The Claims Are Time Barred

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Lessons Learned

27

- Addressing Certifications, declarations and attestations
- Negotiating CIA's
 - Addressing Privilege Issues
 - The 2006 Tenet CIA Model
- Service as Lawyer and Compliance Officer
- Reports from Outside Counsel
 - Content and Format
 - The Privilege May Be Waived!
- Internal Investigations
 - Start Up and Follow Through
 - Reports To Be Made



Some Issues And Questions

28

- Should one person be the Corporate Integrity Officer, the Corporation's Counsel, and a CIA Signatory/Certifier?
- How can an entity minimize the risks stemming from the work of outside counsel and outside consultants? What does the case tell us about how results of investigations should be communicated?
- When should an investigative report be presented to an audit committee or compliance committee of the Board?
- How should CIA performance issues be addressed, without triggering notice obligations?





Some Issues And Questions (cont'd)

- How can those certifying documents, such as CIA reports, cost reports, Medicare Advantage/Part D certifications and etc., minimize the risks of a false certification?
- Who is affected by certification of compliance agreement requirements?
- What does this case mean for CIA's and their negotiation?
- When does the compliance officer or in-house lawyer need their own lawyer? How should such a request be pursued?



Questions & Answers

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