

Seton Hall University School of Law
HEALTH CARE FRAUD & ABUSE
Fall – 2009

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Syllabus

This course reviews the prevailing legal and practical issues relating to prosecuting and defending against alleged misconduct within the US health care system. These cases are brought against health care providers including hospitals, physician practices, nursing homes, other health care entities such as clinical laboratories, pharmaceutical and medical device manufacturing companies. The course materials will cover the essential features of the major statutes in the area, principally those dealing with false claims, kick-backs and self-referrals.

The field of health care law is often a dense and technically complex area. Indeed the statutes, cases and other materials "...are among the most completely impenetrable texts within human experience.¹" Thus, it is often helpful to take a step back and ask whether the alleged or contemplated activity raises potential issues regarding:

- Impact on clinical decision-making by physicians and others who prescribe treatments and therapies
- Cost to health care programs or beneficiaries
- Over-utilization or inappropriate utilization of treatments or therapies
- Patient safety or quality of care
- Established or recognized laws, regulations, "safe harbors," government or private standards

In an effort to maintain this necessarily broad perspective and in keeping with the diverse and frequently changing landscape in the area of US fraud and abuse legal practice, the materials discussed and presented in this course draw from a variety of sources including statutes, cases, texts, news reports, trade publications, US government agency materials and the like.

I am grateful to Professors Michael Shaw and John Jacobi, each of whom have taught this course for several years at Seton Hall and to James Sheehan, formerly Associate US Attorney for the Eastern District of Pennsylvania, currently Medicaid Inspector General for the State of New York, who has taught a number of Health Care Fraud and Abuse courses at various law schools over the years. The materials and course work we will discuss this semester are drawn in significant part from prior courses taught by these three gentlemen.

¹ See *Rehabilitation Association of Virginia, Incorporated v. Kozlowski*, 42 F.3d 1444, 1450 (4th Cir 1994).

COURSE OBJECTIVES:

At the conclusion of this course, you should be familiar with:

1. The False Claims Act 31 U.S.C. 3729, et seq.
2. The Anti-Kickback Act 41 U.S.C. 51, et seq.
3. The Medicare Medicaid Anti-Kickback Act 42 U.S.C. 1320a-7b(b)
4. The Stark Laws 42 U.S.C. 1395nn
5. The mail, wire, and health care fraud statutes 18 U.S.C. 1341 -1347, 18 U.S.C. 1035
6. The False Statement and False Entry in Public Record Act, 18 U.S.C. 1001
7. The fraud implications of violations of state law (fiduciary duty, commercial bribery, state licensing statutes)

You should be able to apply these laws (and applicable standards) in the following contexts:

- Choosing and investigating cases (prosecution)
- Responding to investigations (defense)
- Identifying and preventing violations of these laws (compliance)
- Allocating risks of fraudulent or violative acts among parties (transactions)
- Representing a whistleblower under the qui tam provisions of the False Claims Act, 31 U.S.C. 3730

This course will examine use of these statutes (and as well as other governing standards) in a number of health care contexts, for example:

- Hospitals and health systems
- Nursing homes and skilled nursing facilities
- Health maintenance organizations, third party payors and their subcontractors
- Physicians, dentists
- Pharmacists, pharmacy benefit management companies
- Pharmaceutical and medical device manufacturing companies
- Laboratories

CLASS SCHEDULE & READING ASSIGNMENTS (subject to change)

OVERVIEW OF MEDICARE AND MEDICAID FRAUD AND ABUSE

Class 1

August 25, 2009

Reading Assignments

- Please read each of the listed statutes, 1-3 and 5 above
- Overview materials from the Kaiser Family Foundation on Medicare and Medicaid programs
- *Alice Gosfield, Medicare and Medicaid Fraud and Abuse (2008)* – 1:1 – 1:16

Class 2

September 1, 2009

Reading Assignment

- *USA v. Rutgard*, 116 F. 3d 1270 (9th Cir., 1997)
- *USA v. McClatchey* 217 F. 3d 823 (10th Cir., 2000)
- *USA v. Calhoon*, 97 F.3d 518 (11th Cir. 1996)
- *Alice Gosfield, Medicare and Medicaid Fraud and Abuse* § 5:11 – § 5:21 (2009)

HOSPITALS & HEALTH SYSTEMS

Class 3

September 8, 2009

Reading Assignment

- *USA v. Kensington Hospital* 760 F.Supp. 1120
- *USA, ex reI. Thompson v. Columbia/HCA* 125 F. 3d 899 (5th Cir. 1997)
- *USA, ex. reI. Thompson v. Columbia/HCA*, (on remand) 20 F.Supp. 2nd 1017 (S.D. Tex. 1998)
- Kickbacks as False Claims: The Use of the Civil False Claims Act to prosecute Violations of the Federal Health Care Program's Anti-Kickback Statute, L. Rev. Mich. St. U. Det C.L. 1 (2001)

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- The Empire Strikes Back: A Critique of the Backlash Against Fraud and Abuse Enforcement. 51 Ala. L. Rev. 239 (Fall, 1999)

PHYSICIANS, DENTISTS, OTHER PROVIDERS

Class 4

September 15, 2009

Reading Assignment

- *USA v. Lorenzo* 768 F. Supp. 1127 (E.D. Pa. 1991)
- *USA v. Krizek* 909 F. Supp. 32 (D.D.C. 1995)
- *USA ex. Rel. Swafford v. Borgess Medical Ctr*, 98 F. Supp 2d 822(WD Mich., 2000)
- *US v. Pogue*, 238 F. Supp. 2d 258
- *US v. Starks*, 157 F.3d 833

QUALITY OF CARE AS A FRAUD ISSUE

Class 5

September 22, 2009

Reading Assignment

- *United States, ex rel. Aranda v. Community Psychiatric Center of Oklahoma*, 945 F. Supp. 1485 (1996 W.D. Okla.)
- "First Nursing Homes, Next Managed Care: Limiting Liability in Quality of Care Cases Under The False Claims Act," 26 Am. J. L. & Med. 69 (2000)
- "When Neglect Becomes Fraud: Quality of Care And False Claims," 43 St. Louis Law Journal 27 (Spring, 1999)
- Application of the Federal False Claims Act to Regulatory Compliance Issues in the Health Care Industry Ala. L. Rev. 105

**DENIAL OF CARE/RATIONING OF CARE/QUALITY OF CARE IN MANAGED
CARE ORGANIZATIONS**

Class 6

September 29, 2009

Reading Assignment

- *Maio v. Aetna U.S. Healthcare* 221 F.3d 472 (3d Cir. 2000)
- *Humana v. Forsyth*, 525 U.S. 299, 119 S. Ct. 710. 142 L. Ed. 2d 753 91999)
- From Tobacco to Health Care and Beyond - a Critique of Lawsuits Targeting Unpopular Industries; *86 Cornell L. Rev. 1334 (September 2001)*

STARK STATUTE

Class 7

October 6, 2009

Reading Assignment

Guest Lecture – Reading to be assigned

PROSECUTING HEALTH CARE FRAUD CASES

Class 8

October 13, 2009

Reading Assignment

Guest Lecture – Reading to be assigned

- US Attorney's Manual and Related Sources
 - *False Claims Act Cases: Government Intervention in Qui Tam (Whistleblower) Suits* (<http://www.usdoj.gov/usao/pae/Documents/fcprocess2.pdf>)

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- *Provisions for the Handling of Qui Tam Suits Filed Under the False Claims Act* (http://www.usdoj.gov/usao/eousa/foia_reading_room/usam/title9/crm00932.htm)
- *Anti-Kickback Act of 1986* (http://www.usdoj.gov/usao/eousa/foia_reading_room/usam/title9/crm00927.htm)
- 9-28.000 Principles of Federal Prosecution of Business Organizations, (http://www.usdoj.gov/usao/eousa/foia_reading_room/usam/title9/28mcrm.htm#9-28.800)

Class 9

October 20, 2009

Reading Assignment

- "False Claims Act and Ethical Pharmaceuticals" OIG Fraud Alert, Prescription Drug Schemes 59 F.R. 65327,65376 (1994)
- *US ex rel Franklin v. Parke-Davis*, 147 F.Supp2d 39 (D. Mass 2001)
- *US ex rel Franklin v. Parke-Davis* 96-11651-PBS – 2003
- *Franklin v. Parke-Davis* – United State’s Statement of Interest in Opposition to Defendant Parke-Davis’ Motion for Summary Judgment
- *United States v. Norian Corporation Synthes, Inc.* – Indictment (2009)

DEFENDING HEALTH CARE FRAUD CASES

Class 10

October 27, 2009

Reading Assignment

Guest Lecture – Reading to be assigned

Class 11

November 3, 2009

Reading Assignment

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- 2005 Federal Sentencing Guidelines. Chapter 8 – Part B – Remedying Harm from Criminal Conduct, and Effective Compliance and Ethics Program § 8B2.1
(http://www.ussc.gov/2005guid/8b2_1.htm)
- Holder, Thompson, McNulty Memos
- 9-28.000 Principles of Federal Prosecution of Business Organizations,
(http://www.usdoj.gov/usao/eousa/foia_reading_room/usam/title9/28mcrm.htm#9-28.800)
- *United States v Stein*, 435 F.Supp.2d 330 (S.D.N.Y. 2006).

COMPLIANCE PROGRAMS

Class 12

November 10, 2009

Reading Assignment

- **OIG Model Compliance Programs**
 - Department Of Health and Human Services Office of Inspector General OIG Compliance Program Guidance for Pharmaceutical Manufacturers; 68 FR 23731 (2003)
 - Department of Health and Human Services Office of Inspector General OIG Supplemental Compliance Program Guidance for Hospitals, 70 FR 4858 (2005)
- American Health Lawyers Association and the Department of Health and Human Services Office of Inspector General, Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors (2003)
- American Health Lawyers Association and the Department of Health and Human Services Office of Inspector General An Integrated Approach to Compliance: A Resource for Health Care Boards of Directors (2004)

NEW AND EVOLVING THEMES IN HEALTH CARE FRAUD PROSECUTION

Class 13

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Reading Assignment

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- Pharmaceutical Marketing Practices: Balancing Public Health and Law Enforcement Interests; Moving Beyond Regulation-Through-Litigation Spring 2006 Volume 39, No. 2.
- Drug and Device Promotion – Charting a Course for Policy Reform, A White Paper by The Center for Health & Pharmaceutical Law & Policy, Seton Hall University School of Law. Tracy Miller, Kathleen Boozang, Kate Greenwood, Kara McCarthy Perry, Cathy Finizio
- Compliance Officer Liability
 - *US v. Caputo*, 374 F. supp. 2d 632 (2006)
 - *US v. Christi Sulzbach* Complaint (2007)
- The Voice of Reason: The Corporate Compliance Officer and the Regulated Corporate Environment. Ashoke S. Talaukdar; 6 UC Davis Bus. L.J 3 (2005)
- Zimmer DPA
- Monitoring" Corporate Corruption: DOJ's Use of Deferred Prosecution Agreements in Health Care, Kathleen M. Boozang + & Simone Handler-Hutchinson, 35 *Am. J. L. and Med.* 89 (2009)

CLASS 14

November 24, 2009

Final Class

Distribution of Take-Home Exam/Summary of Course.