

HAMLIN UNIVERSITY SCHOOL OF LAW
HEALTH LAW INSTITUTE

**INDUSTRY SPOTLIGHT:
DRUGS, DEVICES AND THE FALSE CLAIMS ACT**

1 Credit

Thursday, June 11, 2009 – 9:00 a.m. – 1:30 p.m.

Friday, June 12, 2009 – 9:00 a.m. – 1:30 p.m.

Saturday, June 13, 2009 – 9:00 a.m. – 1:00 p.m.

SYLLABUS

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www.falseclaimsact.com**

Please do not hesitate to contact me with any questions or concerns you may have before, during or after the course. Due to my travel and court schedule, the best and fastest way to contact me is on my BlackBerry at the Email address listed immediately above.

COURSE DESCRIPTION AND BASIC OBJECTIVES

Welcome to Industry Spotlight: Drugs, Devices and the False Claims Act! This course will explore and examine the legal, practical, strategic and even political uses of the federal and state false claims acts in the civil and criminal prosecutions of pharmaceutical and medical device fraud. Examples of issues that will be examined during class will include, but certainly not be limited to, an examination of the Food, Drug, and Cosmetic Act, a review of the *PhRMA* and *AdvaMed* Codes, a thorough examination of the federal and state false claims acts, its whistleblower provisions and a practitioner's overview as to how these statutes have been utilized, and will be utilized in the future, in the area of pharmaceutical and medical device prosecutions.

The approach will be a practical one driven by an engaged practitioner, who has been involved in every aspect of the investigation, prosecution and litigation of these cases under the federal and state false claims acts throughout the United States. The objectives of this course shall include:

a working understanding of these statutes, especially the *qui tam* or whistleblower provisions, and the significant exposure that they extend to manufacturers, distributors and wholesalers of pharmaceutical and medical devices throughout the country, as well as to all executives, sales and marketing individuals, who are part of this distribution fabric.

COURSE MATERIALS

Your course reading materials will include:

- (1) The Federal False Claims Act;
- (2) All 22 State False Claims Acts;
- (3) *Temple Law Review*: "Current Practice and Procedure Under the Whistleblower Provisions of the Federal False Claims Act;"
- (4) *Tulane Law Review*: "States, Statutes, and Fraud: An Empirical Study of Emerging State False Claims Acts;"
- (5) *AHLA Health Lawyers News* Article: "Modern False Claims Act Liability: Cradle to Grave Liability? – Part I;"
- (6) *AHLA Health Lawyers News* Article: "False Claims Act Damages: 'One Size Doesn't Fit All';"
- (7) *AHLA Health Lawyers News* Article: "Modern False Claims Act Liability: Cradle to Grave Liability? – Part II;"
- (8) "Compliance and Governance for Health Care Organizations and Marketing and Sales Activities;"
- (9) Federal Anti-Kickback Statute, 42 U.S.C. Sec. 1320a-7b;
- (10) *ABA Health Law Litigation* Article: "Healthcare Providers' Use of Non-FDA Approved Drugs: A Treacherous Course Regardless of Intent;"
- (11) Current *PhRMA* Code on Interactions with Healthcare Professionals;
- (12) Federal Food, Drug, and Cosmetic Act;
- (13) *AdvaMed* Code of Ethics on Interactions with Health Care Professionals;
- (14) *MDMA* Guidelines for Interactions with Customers;
- (15) Department of Health and Human Services Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers;

(16) Title 42. The Public Health and Welfare Chapter 7. Social Security Act Title XI. General Provisions, Peer Review, and Administrative Simplification Part A. General Provisions, 42 USC § 1320a-7b (2005);

(17) Health Chapter 151 Pharmacy Wholesale Drug Distribution Licensing Act, Minn. Stat. § 151.461 (2004);

(18) Eleven Key Opinions of Judge Saris in the "off-label marketing" area from the District of Massachusetts; and,

(19) "How Best to Get Paid After a Successful Qui Tam Case."

Please contact Marcia Miller at mmiller14@hamline.edu or 651-523-2625 to obtain a copy of the materials.

I will be utilizing some PowerPoint presentations but will probably not post them prior to class so that I can utilize the latest information on decisional caselaw throughout the country. I also recommend you take a look at the website that my law firm has set up for the false claims act, which may be of value to you. Go to www.falseclaimsact.com prior to our course. This will give you some additional background on various theories of liability.

COURSE READINGS

There will be no textbook utilized in this course, but the instructor will use a very simple and straightforward 'question and answer' dialogue approach to present the various issues that will be examined during the three days of the course. I will expect all students to have reviewed the materials that I have provided and be generally familiar with the federal and state false claims acts so that we can have a meaningful dialogue as we move forward in the course. This syllabus will be updated with specific page numbers at least a week before class. In general, the topics will be discussed as follows:

Thursday, June 11, 2009 – 9:00 a.m. – 1:30 p.m.

Overview of the Food, Drug and Cosmetic Act with particular emphasis on labeling, drug approval and the off-label marketing restrictions. An overview of the PhRMA Code. Primer on the False claims Act including review of elements of claim, defenses and relationship to the Anti-Kickback Statute.

Friday, June 12, 2009 – 9:00 a.m. – 1:30 p.m.

Finish overview of False Claims Act. Discuss Qui Tam lawsuits and damage calculations under the False Claims Act. Review Advertising, Promotion and Post Approval Controls and surveillance after drugs and devices are brought to market. We will discuss the emergence of off-label marketing cases.

Saturday, June 13, 2009 – 9:00 a.m. – 1:00 p.m.

We will review the emergence of state false claims acts, state prosecutions, and how these newly empowered attorney generals will, and are, changing the prosecutorial landscape.

TECHNOLOGY POLICY

In order to facilitate focused interactive class and small group discussion, there will be occasions when the class will be asked to close their notebook computers and/or turn off technology they have been using. At other times, students may use laptops for note taking. If a student uses classroom time to read or send e-mail messages, visit web sites or engage in any other online or technology based activities (including cellular telephones) that student will have his or her grade lowered by one-half of a letter. If this occurs a second time, that student will be asked to drop the course and will not receive academic credit for the class.

COURSE EVALUATION

Your course grade will be based on two grading criteria: (1) 25% of your grade will be based on your class participation throughout the class and level of preparedness; and, (2) The remaining 75% will be based on an anonymous paper. The paper topic will be assigned on the last day of class. It will be due within two (2) weeks of receipt of the topic. I will try to arrive at least 15 minutes early for class each day to discuss any issues which may arise.

COURSE ATTENDANCE

At the beginning of each class session, I will distribute a class roster for students to sign. Students who are absent for more than eighty percent (80%) of our total in-class minutes, your absence will be treated as "excessive" in accordance with Hamline University School of Law Academic Rules. This will be an interactive course filled with practical dialogue; therefore, course attendance is a must.