HAMLINE UNIVERSITY SCHOOL OF LAW HEALTH LAW INSTITUTE

INDUSTRY SPOTLIGHT: DRUGS, DEVICES AND THE FALSE CLAIMS ACT

1 Credit

Thursday, June 17, 2010 – 9:00 a.m. – 1:30 p.m. Friday, June 18, 2010 – 9:00 a.m. – 1:30 p.m. Saturday, June 19, 2010 – 9:00 a.m. – 1:00 p.m.

PROPOSED SYLLABUS

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Please do not hesitate to contact us with any questions or concerns you may have before, during or after the course. Due to our travel and court schedule, the best and fastest way to contact us is via the Email addresses listed immediately above. Please direct all questions to Professor Raspanti at his contact information 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. Issues that will be examined during class will include, but not be limited to, a review of the Food, Drug, and Cosmetic Act, an examination of the current PhRMA and AdvaMed Industry Codes. Moreover, we will closely examine the federal and state false claims acts, the whistleblower provisions of these laws and provide a practitioners' overview of how these statutes have been utilized in the past and may be used in the future, in the area of pharmaceutical and medical device prosecutions.

The approach will be a very practical one driven by engaged and focused practitioners, who have 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 include: a working understanding of these statutes, especially the *qui tam* or whistleblower provisions; and the significant legal 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 chain.

COURSE MATERIALS

Your course reading materials will include and are suggested to be reviewed in the following sequence. Many of these materials have been posted for your convenience to our false claims act "website" at: www.falseclaimsact.com. The documents are easy to download. Others will be posted on the Hamline University School of Law website (Hamline). Please let us know if you have any problems accessing them. The list below outlines the materials we wish you to read.

- 1. The Federal False Claims Act as amended by the Fraud Enforcement and Recovery Act of 2009, 31 U.S.C. 3729 et seq.; (See website)
- 2. Feel free to review all 27 State False Claims Acts, however, be prepared to compare, contrast and discuss the following State False Claims Acts: New York, New Jersey, Texas and Minnesota (See website);
- 3. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. (Hamline website);
 - 4. Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b (Hamline website);
- 5. Current PhRMA Code on Interactions with Healthcare Professionals (Hamline website);
- 6. Current AdvaMed Code of Ethics on Interactions with Health Care Professionals (Hamline website);

- 7. Tulane Law Review: "States, Statutes, and Fraud: An Empirical Study of Emerging State False Claims Acts;" (See website);
- 8. *Temple Law Review*: "Current Practice and Procedure Under the Whistleblower Provisions of the Federal False Claims Act;" (See website);
- 9. "The Minnesota False Claims Act: Is It Minnesota Nice?" *Bench & Bar of Minnesota*, April 2010 (See website);
- 10. "The Employment Protection and Anti-Discrimination Provisions of the New Jersey State False Claims Act," New Jersey Law Journal, August 10, 2009 (See website);
- 11. "The 'New' New Jersey False Claims Act: It was Born to Run," *The Legal Intelligencer* (4 part series), July 6-9, 2009 (See website);
- 12. AHLA *Health Lawyers News* Article: "Modern False Claims Act Liability: Cradle to Grave Liability? Part I;" (See website);
- 13. AHLA *Health Lawyers News* Article: "False Claims Act Damages: 'One Size Doesn't Fit All';" (See website);
- 14. Department of Health and Human Services Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers (See website);
 - 15. Some selected Opinions on "off-label marketing" (Hamline website);
- 16. ABA *Health Law Litigation* Article: "Healthcare Providers' Use of Non-FDA Approved Drugs: A Treacherous Course Regardless of Intent;" (Hamline website);
- 17. Health Chapter 151 Pharmacy Wholesale Drug Distribution Licensing Act, Minn. Stat. § 151.461 (2004) (Hamline website);
 - 18. "How Best to Get Paid After a Successful Qui Tam Case." (See website);

We will be utilizing some PowerPoint presentations and/or handouts but will probably not post them prior to class so that we can utilize the latest information of relevance to our course from throughout the country.

REQUIRED COURSE READINGS

There will be no textbook utilized in this course, but the instructors will use a straightforward "question and answer" dialogue approach to present the various issues that will be examined during the three days of our course. We expect all our students to have carefully reviewed the materials that we have provided and outlined in our syllabus. All students should be very 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 may be updated with subject areas we intend to cover each day. In general, the topics will be discussed as follows. Your thoughtful preparation should track the materials we hope to cover each day. Obviously, class discussion may alter the manner in which our materials are covered. Above all, we will have some fun tackling an interesting area of the law.

Thursday, June 17, 2010 - 9:00 a.m. -1:30 p.m.

Overview of the Food, Drug and Cosmetic Act with particular emphasis on labeling, drug approval and off-label marketing issues and restrictions. An overview of off-labeling practices and relevant case law. A discussion of the strengths, weaknesses and significant differences between the PhRMA Code and the AdvaMed Code. We may begin our review of the False Claims Acts, including review of elements of claim and defenses.

Friday, June 18, 2010 – 9:00 a.m. – 1:30 p.m.

We will finish our overview of the Federal False Claims Act and review and contrast the growing number of state false claims acts, including a special emphasis on the Minnesota False Claims Act, which will become effective on July 1, 2010. We will discuss Qui Tam lawsuits and damage calculations under the False Claims statutes.

Saturday, June 19, 2010 – 9:00 a.m. – 1:00 p.m.

We will review the influence of money, "Corporate America," physician prescribing habits, and the juxtaposition of some of the statutes which we previously discussed in class. We will review and discuss the Federal and State Anti-Kickback Statutes. We will touch upon the Sunshine Acts and discuss private and public litigation in the Pharma and Medical Device industries, as well as newly enacted health care reform initiatives. Your final paper topic will be discussed and handed out at the end of this class. Your course materials and our discussions will provide you with everything you will need to complete your paper.

TECHNOLOGY POLICY

In order to facilitate focused interactive class and small group discussion, there will be occasions when the class may 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 or for Internet accessing of documents. If a student uses classroom time to read or send e-mail messages, visit non-authorized 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) 30% of your grade will be based on your class participation throughout the class and level of preparedness; and, (2) The remaining 70% 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. We will try to arrive at least 10 minutes early for class each day to discuss any issues which may arise, and/or stay after class to discuss any issues you may have. Of course, we can arrange for other times that are mutually convenient.

COURSE ATTENDANCE

At the beginning of each class session, we 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 and spirited course filled with practical dialogue; therefore, course attendance is a must and is mandatory for such a limited course.

We look forward to a stimulating few days!

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