

Food and Drug Law

Fall 2009

Syllabus

Professor Jesson

Hamline University School of Law

General course Information:

Course: Food and Drug Law

Credits: 2

Classroom: Law 103

Time: Thursdays, 4-5:50 p.m.

Professor: Lucinda Jesson
Office 229East Building
Office Hours: one hour before class and by appointment
Email: ljesson01@hamline.edu
Cell: 612.817.3046
Office: 651.523.2519

Description:

Welcome to Food and Drug Law! This course will focus on the regulation of food, drugs and medical devices by the U.S. Food and Drug Administration (FDA). Students will learn about the statutory framework involved with particular emphasis on the Federal Food, Drug and Cosmetic Act. Students will learn FDA's interpretation and enforcement of its statutes and regulations and will gain insight into FDA's decision-making processes and policies. In addition, current food and drug news stories will be discussed throughout the semester.

Course Materials:

All reading assignments are from the required text, FOOD AND DRUG LAW, Cases and Materials by Peter Barton Hutt, Richard Merrill, and Lewis Grossman (Foundation Press 3d Edition). Because of the constantly changing legal environment, new regulations, articles and cases will be assigned and posted on TWEN each week. When PowerPoints are used as part of a class lecture, copies of the PowerPoints will either be provided at the end of class or posted on TWEN. Selections from In Defense of Food and

The Omnivore's Dilemma by Michael Pollan are assigned as well. Copies of each text are on reserve in the library. The books are available in paperback in local bookstores as well.

Course Evaluation:

Subject to the caveat below regarding class preparedness, eighty percent of your course grade will be based on one self-scheduled, anonymous, final examination, which shall include essay and objective questions. Twenty percent will be based on a group presentation regarding a current FDA regulatory issue. Students will select their group and a presentation topic during the second week of class. Fifteen minute presentations will be scheduled throughout the semester. The caveat is that your course grade may be adjusted one-half of a letter (up or down) based on class preparedness in accordance with Hamline University School of Law Academic Rule 105. More specifically, I reserve the right to: 1) raise your course grade by one-half of a letter if you participate substantially when not called on or distinguish yourself when called on; or 2) lower your course grade by one-half of a letter if you are not prepared when called on. Your active participation in small group exercises will be assessed as part of your class preparedness.

Course Attendance:

At the beginning of each class, I will distribute a class roster for you to sign. If you are absent for more than three classes, your absences will be treated as "excessive" in accordance with Hamline University School of Law Academic Rule 108.

Learning Outcomes:

- Interpret statutes, regulations and agency guidance
- Learn how to interact with regulators on behalf of a client
- Understand the structure and enforcement powers of the FDA, with particular attention to the premarket approval processes
- Apply understanding of the regulatory structure and new caselaw to representation of clients involved with preemption and fraud and abuse challenges
- Demonstrate how to counsel clients involving food and drug labeling and promotion issues

Assignments:

This syllabus will be updated throughout the semester, including changes to reflect the small group presentations described above.

Week One: August 20, 2009

Overview history of food and drug regulation, the structure of the FDA and the history of Food and Drug Regulation. Review the difference between the FDCA itself, regulations, and "guidance" documents. Discuss advice to a dietary supplement client based on the

statute and guidance documents posted on TWEN. **Bring a news article on recent food or drug law issue involving the FDA to class.**

Reading: pages 3- 27, materials posted on TWEN and pages 1-60 of In Defense of Food by Michael Pollan on reserve in the library.

Week Two: August 27, 2009

What is food and how would we know? Review the basic components of the Food Label. Begin discussing Nutrition Labeling.

Reading: pages 92-120; 130-143; 171-183; 198-218.

Week Three: September 3, 2009

Consider when food has been adulterated. Does it contain poisonous substances? Unavoidable contaminants? Filthy substances? Or is it the product of Good Manufacturing Practices (GMP)? Look at the FDA's inspection rights as the agency seeks to maintain sanitation practices.

Reading: pages 300-319; 326-334; 344-355; and 1242-1254 and 1261-1262.

Week Four: September 10, 2009

Review verified (and unverified) health claims for foods under the FDCA. Discuss the labeling of "organic" foods in light of selections from The Omnivore's Dilemma. Consider the laws that govern food additives and the regulation of dietary supplements. Should they be regulated as a food, food additive or as a drug?

Reading: pages 393-411; 268-297. The Omnivore's Dilemma pages 134-184, on reserve in the library.

Week Five: September 17, 2009

Finish discussion regarding regulation of dietary supplements. Overview Drug Regulation.

Reading: Continuation from previous week.

Week Six: September 24, 2009

We enter the world of drug law and regulation by examining the new drug approval process, beginning with new drug research and development

Reading: pages 624-637; 642-646; and 648-659 and materials posted on TWEN.

Week Seven: October 1, 2009

Next, consider the new Drug Approval Process including user fees; the obligation to weigh safety and effectiveness; orphan drugs; the use of preapproval inspections and advisory committees; and FDA labeling review. Review the final approval process at the FDA.

Reading: pages 674-698; 701-706; 723-728 and 731-737 and materials posted on TWEN.

Week Eight: October 8, 2009

Consider post approval obligations, including adverse event reporting. Examine the Vioxx controversy. Then move to consider the approval process for generic drugs (the ANDA) and the impact of generics on costs and patent terms. Finish with a discussion of the costs and trade offs involved in our drug approval process.

Reading: pages 745-754; 759-767; 772-788 and materials posted on TWEN.

Week Nine: October 22, 2009

Review the regulation of over the counter (OTC) drugs and how drugs switch from prescription to nonprescription status.

Reading: pages 788-815; 523-530.

Week Ten: October 29, 2009

Overview of the regulation of medical devices including the definition of “device”; the risk classification of devices; market entry requirements for medical devices and postmarket controls and responsibilities. [In the true meaning of “overview”, much of this material will be conveyed by lecture. The reading is limited to the first issues of definition and classification.]

Reading: pages 977-999; 1010-1013.

Mark Duval, guest speaker

Week Eleven: November 5, 2009

Begin the discussion about regulation of drug and device marketing by examining labeling requirements, including the process for approved labeling, the intended use and new drug approval requirement; the use of warnings in labeling; misbranding in labeling, and the distinction between labeling and advertising.

Reading: pages 478-520 and materials posted on TWEN.

Week Twelve: November 12, 2009

Consider the regulation of drug and device advertising including examination of the key principles of advertising and promotion; promotion to professionals; direct to consumer advertising; and the promotion of drugs for unapproved uses (*Washington Legal Foundation vs. Henney*) and other current issues.

Reading: pages 532-560 and materials posted on TWEN.

Week Thirteen: November 19, 2009

Examine the FDA's enforcement jurisdiction including seizure, injunctions, recalls and off labeling marketing efforts. Compare FDA's role to that of the FTC and the Department of Justice.

Reading: Pages 1196-1225; 1262-1294; 1339-1352; and 1303-1309.

Week Fourteen: Tuesday, December 1, 2009

Examine the recent case law on FDCA preemption of state law tort claims involving FDA Approved Drugs and Medical Devices.

Reading: pages 1436-1454 and cases posted on TWEN.

