SYLLABUS
REGULATION OF FOOD AND DRUGS
310-001 - SPRING 2012
3 CREDITS
THURSDAYS 8-10:40PM
FOUNDERS HALL 477

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DESCRIPTION OF THE COURSE:
This weekly class considers the constitutional, legal, regulatory and public policy issues under the Federal Food, Drug, and Cosmetic Act (FDCA) and related statutes. The class will focus on a range of cutting-edge issues involving the regulation of conventional and biotech foods, drugs, biologics, medical devices and tobacco. This will include identifying and isolating legal theories, such as adulteration and misbranding, which are central to an understanding of the FDCA, as well as identifying the particular set of legal enforcement tools, whether it be injunction, seizure, or criminal penalties, used by the federal government in regulating the interstate traffic of these products, which constitute close to 25% of U.S. gross domestic product. This course does not have any specific prerequisites, though a basic understanding of Administrative Law is helpful.

REQUIRED TEXTS AND MATERIALS:


3. Handouts and reserve materials

When HM&G, or other readings, refer to sections of the Food, Drug, and Cosmetic Act, you are expected to read these sections in the statutory supplement. Also, you are expected to read all of the reading assignments for the classes listed below, including the text marked as “Comments” or “Notes”, unless advised otherwise. Where a reading assignment below references a case with a citation, please obtain the case from Westlaw or LexisNexis and read the assigned pages.

OUTLINE, CLASS SCHEDULE AND TENTATIVE READING ASSIGNMENTS:
Please see weekly reading assignments below. If a particular reading assignment is modified, the
students will be advised a week before the class in question.

**Class 1 - January 12th:** Introduction; History; Food, Drug, Biological Product, Medical Device, and Cosmetic Definitions; and Scope of Definitions.

**Class 2 - January 19th:** Food, Drug, Biological Product, Medical Device, and Cosmetic Definitions (cont.); Scope of Definitions (cont.); Limits on FDA’s Jurisdiction; and Enforcement.
HM&G 48-70, 77-88; 1196-1200, 1203-1217, 1220-21, 1225-26, 1230-33, 1237, 1242-44, 1262-66, 1282-83, 1309-10, 1313-1319, 1339 (paragraph on informal compliance correspondence), 1351-52, and the decision of Smoking Everywhere, Inc., v. FDA, 680 F.Supp.2d 62. There is no need to read beyond page 75 of the Smoking Everywhere decision.

**Class 3 - January 26th:** Food Labeling; Regulation of Food Identity and Quality.
HM&G 91-120, 130-35, 208-16, 140-60, 162-69.

**Class 4 - February 2nd:** Food Standards of Identity; Food Names; Nutrient Content Descriptors; Disease Claims (“Health Claims”).

**Class 5 - February 9th:** The First Amendment and Qualified Disease Claims; Food Sanitation and Safety.

**Class 6 - February 16th:** Food Sanitation and Safety (cont.); Safety of Functional Ingredients in Food.
HM&G 360-83, 393-419, 423-429.

**Class 7 - February 23rd:** Safety of Functional Ingredients in Food (cont.); the Delaney Clause; Dietary Supplements and “Structure/Function” Claims.
HM&G 260-68, 276-84, 450-53.

**Class 8 - March 1st:** Medical Devices
HM&G 967 introductory paragraph, 977-981, 984-990, 991-1002, 1010-1019, 1023-1028.

**Class 9 - March 8th:** Human Drugs – History; Seven Critical Legislative Milestones; The 1962 Premarket Approval Requirements; Effectiveness; Safety; General Recognition of Safety and Effectiveness; Grandfather Clauses; Constitutional Boundaries.

March 15th - Spring recess.

**Class 10 - March 22nd: Human Drugs – Regulation of the Drug Development Process; The New Drug Application Review Process; Post-Approval Obligations; Suspension of Approval for “Imminent Hazard”**.

**Class 11 - March 29th: Human Drugs – Pre-Approval Access to Investigational New Drugs; Expedited Review Processes; Special Incentives for Needed but Commercially Unpromising Drugs; Formal Adjudicatory Proceedings on New Drug Applications; Orphan Drugs; DESI Review.**
HM&G 648-657, 708-713, 639-642, 579-590, 613-620. as well as the decision of Sigma Tau v. Schwetz, 288 F.3d 141.

**Class 12 - April 5th: Human Drugs – Premarket Approval of Generic Drugs; Origins and Overview; The Abbreviated NDA Review Process; Eligibility for the ANDA Process; Non-Patent Marketing Exclusivity; Special Patent Law Provisions Relating to Generic Drugs; Orphan Drugs.**
HM&G 754-771, 700-706, as well as the decision of Serono Labs v. Shalala 158 F.3d, 1313.

**Class 13 - April 12th: Human Drugs – Prescription Requirement; Non-Prescription (OTC) Drug Monographs; Switching from Rx to OTC; Regulation of Physician Prescribing; Controls over Prescription Drug Distribution; Regulation of Drug Product Quality; Regulation of Drug Labeling, Advertising and Promotion; Pre-Approval Promotion/Promotion of Unapproved Uses.**
HM&G 478-493, 520-522, 788-812, 523-531, 815-834, 566-576, 493-520, 532-545, 555-560, 545-555, 722-723, and as well as the decision of Tummino v. Torti, 603 F. Supp. 2d 519. For this decision it is only necessary to read the introduction starting on page 522, the section entitled “Statutory and Regulatory Background” and the conclusion.

**Class 14 - April 19th: Biological Products –**
HM&G 876-900, the decision of U.S. v. Loran Medical System, 25 F. Supp.2d 1082 and a handout on “Biosimilars” legislation..

**OFFICE HOURS:**
I will be available both before and after every class to discuss the class material. I will also be available by appointment, which can be scheduled by emailing me at mark.schwartz@fda.hhs.gov or calling me at 301-796-8716. Please note that I will not be checking my George Mason email account during the semester.
FINAL GRADE:
Final exam 80 percent
Class Participation/Assignments 20 percent

Students are expected to prepare their reading assignments for each class. Class participation means involvement in class discussions by volunteering to discuss reading assignments in class as well as answering questions posed in class and by handing in any written assignments that were assigned in the prior class.