Syllabus version: Oct. 23, 2017

Hot Topics in FDA Law

Spring 2018

5497 Hot Topics in FDA Law - EVANS- 24527

Professor(s): Barbara Evans (FACULTY)

Credits: *4*

Course Areas: *Health Law*

Time: *2:30p-4:10p TTH*

Course Areas: Health Law, Consumer Product Safety Law, Administrative Law

Contact: Barbara Evans, Office BLB 214
Phone: 713-743-2993 (office) 713-446-7576 (Cell or Text)
Email: bjevans@central.uh.edu

Office Hours: T-Th (after class) or other times if you have conflicts then.

Overview: FDA-regulated products account for 25% of the gross domestic product of the United States, so a basic understanding of FDA law is essential for any student wishing to work in, or to represent clients in, the consumer-products sector. This course provides a manageable introductory survey of the major substantive topics in FDA Law, including regulation of food products, food additives, dietary supplements, cosmetics, tobacco, drugs (human and animal drugs), biologics, biosimilars, and medical devices (including genetic and diagnostic tests). After providing a basic tour of FDA law, the course will turn to discussion of hot topics in FDA law, which students will select in consultation with Professor Evans.

Assessment: **There is no final exam.** 60% of students' grades will be based on an in-class "midterm" exam to be administered on a date to be determined, based on student input, during weeks 8-10 of the semester. The midterm will cover the substantive FDA law concepts covered during the first part of the course. The other 40% of students' grades will be based on a short (3,000 to 6,000-word) medical-journal or bioethics-journal-length paper that students will write on an FDA hot topic that they will choose in consultation with Prof. Evans. Those papers will be due on or before the scheduled final exam time at the end of the term.

Because the midterm is a graded assignment, the Office for Student Services will assist students who have a *bona fide* work, healthcare, or school-related conflict (e.g., such as an illness or a moot course competition) that conflicts with the scheduled midterm date. Every effort will be made to select a midterm date that works for all students, but students who nevertheless have a conflict will be able to reschedule their midterms to a date within one week of the scheduled date, on the same basis they would be able to reschedule a final exam.

Participation: Students are expected to stay current on the readings and participate during class. Participation can affect your final grade insofar as habitual lateness or disengagement can cause your grade to be reduced by 1 notch (e.g., A minus to B plus).

Course Text and Materials:

- Textbook: HUTT, MERRILL, & GROSSMAN, FOOD AND DRUG LAW: CASES AND MATERIALS (WEST ACADEMIC/FOUNDATION PRESS, FOURTH ED., 2014).
- Statute (FDCA/21 U.S.C.) -- Access via FDA website, *at* http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/default.htm
- Regulations (21 C.F.R.) -- Access via FDA website, *at*

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

- Additional materials will be distributed and noted in the syllabus.

Learning Outcomes:

1. Understand the institutional framework and scope of authority of the U.S. Food and Drug Administration (FDA) and its relationship to other federal agencies.

2. Learn and analyze key statutory provisions, regulations, case law, and policy in major FDA areas of regulation (food and dietary supplements, cosmetics, drugs, medical devices, biteologics, and tobacco).

3. Develop insight into how the agency responds to new scientific and technological advancements and their integration into consumer products.

4. Develop practical skills in: (1) how to interpret statutes; (2) how to read regulations; (3) how to research regulatory materials; (4) how to represent clients in front of agencies and handle enforcement actions; and (5) how to represent government agencies. FDA law is a case study in regulatory practice of a major federal agency. These same skills and principles have application when representing clients in matters involving many different regulatory agencies.

Message from the University: Counseling and Psychological Services (CAPS) can help students who are having difficulties managing stress, adjusting to the demands of a professional program, or feeling sad and hopeless. You can reach CAPS (www.uh.edu/caps) by calling 713-743-5454 during and after business hours for routine appointments or if you or someone you know is in crisis. No appointment is necessary for the "Let's Talk" program, a drop-in consultation service at convenient locations and hours around campus. http://www.uh.edu/caps/outreach/lets_talk.html

Attendance The Law Center attendance policy applies. You do not need to notify me if you are going to miss a class here or there. But if you anticipate missing several classes, please let me know beforehand. I reserve the right to deduct from your participation grade if I notice that you are not attending regularly or are habitually late.

Computers Laptops, tablets, and smartphones may be brought to class but should be used only for class-related purposes (taking notes, accessing the blackboard and statutes, etc.). I reserve the right to restrict your use of these devices at my discretion and without notice if your use of them creates a distraction for yourself or for others.

Exam/Grading See "Assessment" on page 1

READINGS

HMG = Hutt, Merrill, and Grossman Casebook

I. Introduction and History

Class 1 **HMG: 3-27**

Supplements:
NY Times, "Advisers Say FDA's Flaws Put Lives at Risk"
Washington Post, "FDA told US Drug System is Broken"
CNN, "FDA Scientists Allege Mismanagement at the Agency"
Discuss: Frontiers of FDA Law (e.g., human gene editing, precision medicine, big data, robotics, neurotechnology, and FDA's place in regulating the larger biotechnology industry and its relation to other agencies)

Unit 2 **Basic mechanisms through which FDA operates**

R-2 **Focus your reading on the following pages:**

- HMG pages 29 – 49 (stop at "4. Formal Rulemaking")
- HMG page 55 - 56 (Start at "C. Decline of N&C rulemaking, stop at the Rakoff excerpt)
- At HMG pages 58-61: Read the last two paragraphs of Rakoff (about FDA's good guidance practices); stop at "E. Legislative Rule or Interpretive Rule."
- Pages 62-64: Start at F (Judicial Review of Agency Action); review the APA standards of review on p. 63; refamiliarize yourself with Chevron/Skidmore/Auer deference concepts on page 64.
- Read the two paragraphs about exhaustion of remedies on pages 68-69
- Quickly scan Section G (Judicial review of agency inaction) on 69-73 – the take-away is that it is hard but not impossible to challenge an agency for failing to take action.

Cases to notice:
Abbott Labs v. Gardner (p. 34)
Nat'l Assn for Pharma Mfrs. v. FDA (p.37)
Nat'l Petroleum Rfrs. Assn. v. FTC (p. 39)
Nat'l Nutritional Foods v. Weinberger (p. 40)
Nova Scotia Food Products (p. 44)
Sections 701(a), 701(e) of the Food, Drug, and Cosmetic Act
Skill: How do you find the statutory text?

Unit 3 **FDA's Jurisdiction: The Products FDA Regulates**
Major jurisdictional definitions: Food, Food Additive, Dietary Supplement, Drug, Device, Cosmetic, Biologic, Tobacco Product

R-3 **HMG: 77-90**

Cases to notice:

Bacto-Unidisk (77-79)
US v. Tuente Livestock (p. 80)
Nutrilab (p. 85)
Nutritional Foods v. Mathews (p. 93)
US v. Travia (p. 97)

R-4 **HMG 90-121**
Nutritional Foods v. Mathews (p. 93)
US v. Travia (p. 97)
US v. … SensorPad (p. 99)
US v. Sudden Change (p. 111)
In class problems: Problems on Classifying Products

R-5 **HMG 121 - 151**
US v. 23 Articles… (p. 131)
US v. Undetermined Quantities… (p. 132)
Note also: p. 135 Biologics
FDA v. B&W Tobacco Corp. (p. 141)
Sottera e-cigarette case (p. 146)

Unit 4 **Labeling; FDA Enforcement**
R-6 **HMG 151- 173**
Labeling:
Kordel v. US (p. 152)
US v. 24 Bottles "Sterling Vinegar & Honey" (p. 154)
US v. Undetermined Quantity of Exachol (p. 168)
FDA Enforcement
US v. Nutricology (p. 170)
Heckler v. Chaney (p. 171)
Supplements: 21 USC § 331 (prohibited acts); § 342 (adulterated food); FDA guidance on misbranded drugs and devices.

R-7 **HMG 176-79, 193 – 211**

R-8 **HMG 211-237**

R-9 **HMG 237-251, 262-270**

R-10 **Genzyme materials**
R10-Supp1: Fabrazyme article
R10-Supp2: Consent Decree
R10-Supp2a: (Class Handout) March-in rights
R10-Supp3: Petition
R10-Supp4: NIH Response

Unit 5: **Regulation of Food, Food Additives, and Dietary Supplements**

R-11 http://www.theatlantic.com/health/archive/2016/09/gmo-food-crispr-cabbage/500528/

Regulating Food Labeling

Introduction: Food vs. Supplements (HMG 317-325)
Development of FDA food regulation: (HMG 325-332)
Scope of Labeling and Identity (HMG 332-338, note 1)

Relevant cases from earlier classes:
Kordel v. U.S. – involving misbranded drugs
US v. Urbeteit – involving misbranded devices

Key cases this class:
Carolene Products v. US
Milnot Co. v. Richardson
Preview of R-12 cases

R-12 **Protecting Food Quality**

1. Economic Adulteration (HMG 375 - 379)
2. Identity Standards (HMG 379-388)

China Cracks Down on Food Safety Violators (NY Times)
China Arrests 774 in Crackdown on Tainted Products (NY Times)

Key statutes and regulations:
FDCA §§ 402, 403 (adulteration and misbranding)
Identity Standards: See, e.g., 21 CFR § 164.150
Mandatory Disclosures (see 21 CFR § 101.1 on pages 389-90)

Cases to notice
US v. 88 cases of … Bireley's Orange Beverage
US v. 95 Barrels of … Apple Cider Vinegar
US. v. 423 Cartons … Candy Lollipops
US v. Farinella

R-13 **Health and Other Claims about Food and Dietary Supplements**

Hot topics presentations on food-related topics

Review nutrient and health claims readings assigned last time:
HMG 409 – 413 (stop at "B. Nutrient Content Claims")
HMG 418 (start at "C. Disease Prevention Claims) – 420 (stop at "Food Labeling; general requirements)

Cheerios Warning letter and constitutional limits on FDA's powers:
HMG: 426 (start at Warning Letter) – 441

Also look at the Del-Immune Warning Letter and Response:
http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm07577

6.htm
http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm172332.htm

Cases to notice
Pearson v. Shalala
Whitaker v. Thompson
Fleminger v. HHS

R-14 Hot topics presentations on food-related topics
HMG: 443-447 (structure and function claims, stop at 21 CFR § 101.93)
HMG: 451-454 (claims about "natural," "fresh," "organic" food)
HMG 627 – 633 (Section 10 on dietary supplements)

Readings about dietary supplements to be e-mailed to you:
What You Don't Know Might Kill You (Sports Illustrated)
The FDA's Burden (Sports Illustrated)
Rogues Gallery (Sports Illustrated)
The Vita Myth (Slate)

Unit 6 Regulation of Drugs

This course will not provide detailed coverage of FDA's premarket study requirements and new drug approval process, which are covered in Biotechnology & Law. Instead, it provide a quick overview of these requirements but will focus on set of rights-related issues surrounding FDA's impact on patients' and physicians' autonomy and other hot topics.

R-15 **FDA's Regulatory Powers and Impacts on Patient Autonomy**
HMG 641 - 669
Cases to notice
American School of Magnetic Healing v. McAnnulty
Research Laboratories Inc. vs. US
Rutherford v. US/US v. Rutherford
Abigail Alliance v. von Eschenbach
Weinberger v. Hynson, Wescott & Dunning
Weinberger v. Bentex Pharmaceuticals

R-16 **Basics of FDA's Premarket Processes**
This reading is a little complicated, to try to spare you having to read so many pages:

- Start on page 669 (at "C. Drug Development…") and read to the bottom of page 676
- Start on 678 (middle of page, at "Guidance for Industy, Investigators…") and read to middle of page 682 (stop at "21 CFR sec. 314.126")

- Start on 707 (at "3. The New Drug Application") and read to 709 (stopping at "a. Purpose and Form of the NDA")
- Start on 722 (at "Bernadine Healy, MD") and read to bottom of 726
- Start at 729 (at "g. Balancing Benefit and Risk") and read up to the start of the Notes on page 732.

R-17 Bradley v. Weinberger and notes, pages **867-870** (stop at "Labeling: Failure to Reveal Material Facts)
New Drug Application, pages **707-714**
Ubiotica case: pages **738-740** (read through the end of Note 3)
Alternatives to NDA: pages **751-top of 757** (stopping before "CDER Manual") and **758-61** (Orphan drug intro and Genentech v. Bowen)

R-18 **FDA's Relationship to Physicians**
802 – 806 (to the end of note 4): El-O-Pathic case & Durham-Humphrey amendments
814 -830 (Off-label prescribing)

R-19 **Advertising and Promotion of Prescription Drugs**
907-916 (advertising to physicians and DTC ads)
925 – 928 (to "Squeeze Play"); **934 – 947**

R-20 **Guest lecturer visit**

Unit 7 **Regulation of Medical Devices**

Basics of FDA's Regulation of Medical Devices
HMG 1193 – 1218

Regulation of Market Entry for Devices
HMG 1218 – 1250

Special and General Controls; In Vitro Devices; Mobile Devices
HMG 1251 – 1280

Hot Topics in Device Regulation – The LDT Controversy, National Evaluation System for health Technologies

Unit 8 **Regulation of Biologics**

Basic FDA Regulation of Biologics and Vaccines
HMG 1123 – 1153

Regulation of Cellular & Tissue Products, Gene Editing
HMG 1164-1184

National Academy of Sciences Gene Editing materials

Generic Biologics & Hot Topics presentations (e.g., Clinical Trial Data Sharing; Problems with FDA's Postmarketing Surveillance System)

Remaining Units will be chosen to emphasize topics tailored to students' paper topics.