

FOOD, DRUG & SAFETY LAWS 2010

307 Mon. 9-11:30 Prof. Jim O'Reilly 556-0062

Rm. 2M28 Droege Ctr., James.oreilly@uc.edu

Text: Hutt, Merrill, Grossman, Food & Drug Law Cases 3d Ed.

Class participation is 20% of final grade; paper is 80%

Why Take This Class? RELEVANCE, INTERESTING MATERIAL, GREAT JOBS.

Since 1982, this course has prepared many new lawyers to understand the federal government's consumer protection activities and to integrate interesting case law with potential employment opportunities. The course is taught in an interactive style with fact-pattern problems and lots of participation. Parts will be very grossly disgusting (food sanitation), others uplifting (cancer drugs), others challenging to your assumptions (biotechnology risks and promises). If litigating product liability cases or managing international trade or serving inside government will be in your future, this class makes a positive addition to your resume – and an intriguing discussion with potential employers. Our alumni and friends have used these learnings to great advantage in many cities.

Class 1 8/23 - SELECT DATE/TIME OF CLASS VISIT TO US FDA OFFICES

Introduction, Hutt/Merrill 1-60 & 21 USC 321, 333-336

Structure, Enforcement tools of the FDA, Rulemaking & Judicial Review

Class 2 8/30 Food, 30-33, 302-321, 344-354, 381-386 & 21 USC 342

Definitions, Safety Issues, Filth, Contamination

Class 3 9/13 Food Economics and DSHEA 203-216, 268-297 & 21 USC 343

Marketing, Dietary supplements and nutrition claims

Class 4 9/20 Food Additives & Biotechnology 397-424, 450-464 & 21 USC 348

Food materials, direct and indirect additives, biotech agriculture

Class 5 9/27 Drugs -- Defined, classes, comparisons 469-474, 520-523, 590-606, 21

USC 352; What are drugs, types of drugs, legal factors in evaluating new drugs

Class 6 10/4 Drugs – Approvals, NDAs and generics, testing, research, 620-651, 674-

697, 754-772 & 21 USC 355

Class 7 10/18 Drugs – Marketing, economics, labeling, advertising, 532-566, 778-788,

21 USC 353

Class 8 11/1 Medical Devices -- Definitions and approvals 991-1019, 21 USC 360

Class 9 11/8 Medical Devices -- Marketing and enforcement, 1033-44, 21 USC 353

Class 10 11/15 FDA's Other Products: Vaccines, Blood, Cosmetics, Body Parts 1082-

1105, 918-952

Class 11 11/22 Malpractice, Drug Abuse, Preemption & Insurance issues 815-834, 1464-1506

Class 12 11/29 Criminal Penalties, Recalls, and Enforcement, 1309-1342, 1378-91

[Date of our 2-hour FDA Visit is To Be Determined]

Papers Due **Monday Dec.6, no later than 4:00 pm** at Registrar's Office; 30 page original research, bluebook cite format, suggested topics circulated in early class periods

OPTIONAL REFERENCE MATERIALS

21 CFR Parts 1-899, 21 USC 321-399

www.fda.gov

www.fda.gov

Food & Drug Law Journal

O'Reilly, Food & Drug Administration (West 3d Ed. 2007)

O'Reilly, Administrative Rulemaking (West 2d Ed. 2010)

O'Reilly, Food Crisis Management (fdli.org)

O'Reilly, Product Warnings, Defects & Hazards (Aspen 2d Ed.)

NOTE: The annual essay contest sponsored by the national association in this field carries a large prize, see www.fda.gov and the top papers in this class are likely to be competitive for prizes.