

SYLLABUS

Welcome to Topics in Food and Drug Law.

Format of Class

Two 90' classes per week, T and Th from 6-7:30. If there is a conflict or a class must be cancelled we will arrange to meet at another day and time. This may periodically occur for the Tuesday class.

Our class is relatively small, the topics to be discussed are controversial, and the discussion should be lively. You will not learn to think as attorneys until you start talking about the law and start talking like attorneys. Judges, juries, opposing counsel, and your clients are all going to assess your ability as a lawyer by how you summarize and discuss important issues as well as potential remedies.

This class is designed to help you all develop your own style; do not be shy about speaking up. You may be surprised at how important and complicated the “stupid” question you were reluctant to ask is.

Class participation is encouraged and will only be counted against you in grading if you do not participate *at all*. Absent that, it can only help your grade.

Required Reading

1. Casebook – Food and Drug Law. Cases and Materials. 3rd ed. Foundation Press 2007
Edited by Peter Barton Hutt, Richard A. Merrill, and Lewis Grossman.
All three of the authors are practicing food and drug law attorneys and law professors. The first two are arguably the most famous food and drug law attorneys in the world. The text is comprehensive, exhaustive and is THE book.
2. The New York Times. There is stuff in the NY Times almost every day about food and drug law. Start looking for articles every day.
3. Handouts – will be sent electronically by Nadia
4. Powerpoint slides for each class – will be sent ahead of time. As always, I'll be revising/adding stuff right up to class.
5. Feel free to email me and the rest of the class interesting articles or news items you come across in print or on the web. We'll spend the first 10 minutes of each class talking about what's in the news on food and drug law related topics.

Structure of the Course

There are 14 weeks in the semester for a total of 28 classes.

The first half of the course will be devoted to the basics of food and drug law. This will include a general overview of FDA and FDA enforcement powers under its enabling statute (the 1938 Federal Food, Drug and Cosmetic Act) and its very numerous amendments, as well as an overview of the basic statutory framework and laws governing the regulation of drugs, medical devices, biologics, cosmetics, dietary supplements, and food. We need this foundation for the second half of the course to be as productive as possible and to understand the controversies and nuances of the big topics for discussion in the second half of the course.

The second half of the course will be devoted to an in-depth analysis of the dozen or so most important and controversial topics in food and drug law. A list of these topics will be provided to select from.

There are 22 students and 11 classes. Two students per topic per class. We will try to pair LLM students with LLM students to make it fair.

Each topic will be assigned to two students who will debate the critical regulatory question and pivotal cases on this issue. There will be a “core” question to be discussed, and in most cases one or more critical law cases, to be debated. It is a virtual certainty that we will not agree with the way all of the cases were decided by SCOTUS or the particular Appellate Court.

For those of you who took the Law of Human Research seminar last semester the format will be somewhat familiar. There will be a 20’ discussion by each student in an Appellate Court type setting; I will be the presiding judge. There will be a question and answer period for 10 minutes, and the rest of the class will be devoted to open to discussion.

Grading

90% of the grade will be a function of the student presentation and accompanying 10-page paper. 10% of the grade will be based on class participation; in general I use class participation to adjust grades upward. The oral presentation and paper will serve as the final exam. This means that when the course is over, *it's really over*.

Weekly Schedule of Classes for Topics in Food and Drug Law

Week	Dates	Topic and Reading
1	1/18	Overview of Course and Course description Powerpoint talk: Overview of FDA Basics Reading: Hutt Chapter 1 – Historical Background
	1/21*	FDA Powers: Enforcement and Otherwise FDA’s lack of regulation of medical and pharmacy prof. Reading: the China/Heparin debacle Reading: Hutt Chapter 2 – FDA Jurisdiction: A Matter of Definitions *if I am out of town we’ll start with this on 1/26 and then go right to drugs
2	1/26	Regulation of Prescription and Over the Counter Drugs Reading: Hutt Chapter IV - Human Drugs The Role of CDER and how it makes decisions CDER’s relation to industry: Critical Path Initiative Is FDA regulation an impediment to advances? IND v NDA The New Drug Label – significance?
	1/28	Other agencies and players in drug regulation Narcotics – DEA CMS – independent review Cases: Gonzales v. Raich Adverse Event Reporting: mandatory v. voluntary
3	2/2	Regulation of Medical Devices Reading: Hutt Chapter VII – Medical Devices
	2/4	
4	2/9	Regulation of Biological Drug Products, Vaccines, and Biotechnology Reading: Hutt Chapter VI – Biologics: Vaccines, Blood, Tissue Transplants, and Cellular Therapies
	2/11	Regulation of Gene Therapy
5	2/16	Regulation of Cosmetics and Color Additives
	2/18	Regulation of Dietary Supplements

6	2/23	Regulation of Food and Food Additives Reading: Hutt – Chapter III - Food
	2/25	AIDS and the FDA – accelerated approval; dealing with “grass roots” medical movements
7	3/2	The Delaney Clause and Carcinogens Reading: Hutt Chapter IX – Regulation of Carcinogens
	3/4	Regulation of Animal Drugs and Food Reading: Hutt
8	3/9	FDA and CMS
	3/11	Catch-up on Basics
The Remainder of the Semester – 13 classes – will be devoted to an individual topic		
9	3/16	Spring Break – No Class
	3/18	Spring Break – No Class
10	3/23	Topic #1
	3/25	Topic #2
11	3/30	Topic #3
	4/1	Topic #4
12	4/6	Topic #5
	4/8	Topic #6
13	4/13	Topic #7
	4/15	Topic #8
14	4/20	Topic #9
	4/22	Topic #10
15	4/27	Topic #22
	4/29	Last Class – Wrap Up

List of Controversial Topics in Food and Drug Law.

Note: list is not exhaustive; I am open to suggestions.

1. TOBACCO: Regulation of Tobacco, including advertising and promotion
History of, current status, ongoing litigation
Core Qs: FDA should not be given authority to regulate tobacco products
FDA's regulation of advertising and promotion of tobacco products is unconstitutional
2. DTCA OF DRUGS : FDA and the 1st Amendment:
Q: Should Direct to Consumer advertising of drugs be banned, as it is elsewhere?
Other issues: direct to physician promotion of off-label uses of drugs should be banned
Litigation: Washington Legal Foundation
Core Q: direct to consumer advertising of drugs should be banned
3. DTCA OF DEVICES: Direct to consumer advertising of medical devices
Litigation
My article in FDLJ
4. VACCINE SAFETY AND VACCINE COURTS: Vaccine and Safety Issues:
Childhood vaccines and autism
The respective roles of FDA and CDC in vaccine regulation
Q: parents should be able to sue vaccine manufacturers in state court, regardless of VICP and Vaccine Court decision
Litigation: The Pawling Case
5. HEALTHCARE REFORM AND FDA
Q: should drug costs be part of the drug approval process?
Q: should drug trials be required to compare the efficacy to other drugs? Should the way we approve follow-on drugs be changed?
Q: How does FDA fit into the Comparative effectiveness schema?

6. GENERIC BIOLOGICS: our patent system should be changed

Cases:

7. HOME-BREW GENETIC TESTS:

Q: the regulation of personal genetic tests is totally inadequate and the “home brew” exception should be eliminated

Q: the advertising and promotion of such tests is totally inadequate

Q: One should not be allowed to patent a naturally-occurring gene or its products even if you discover it

8. PREEMPTION – 2 possible classes; one for drugs, and one for medical devices

Q: the 1976 MDA should be revised so that device manufacturers can be sued

Cases: Lohr v. Medtronic, Riegel v. Medtronic

Q: Wyeth v. Levine: the FDA label should protect manufacturers against state tort suits for damages from drugs. The role of the learned intermediary doctrine

9. CONFLICTS OF INTEREST

Q: Conflict of interest rules at NIH and academic medical center physician researchers should be the same as they are at FDA

10. OFF-LABEL USE OF PRESCRIPTION DRUGS

Q: should it be illegal? What is the evidence it is of benefit?

Q: what about off-label use of surgical devices? If it's legal, is there enough oversight? Who regulates it, and how well do they do?

11. FOOD: the current food safety system is inadequate and should be dismantled

12. DRUG SAFETY: our current system is totally inadequate

Case: Vioxx

13. DIETARY SUPPLEMENTS:

Q: DSHEA should be repealed

14. DRUGS AND THE INTERNET

DRUGS AND IMPORTATION FROM OTHER COUNTRIES

Q: FDA needs to do much more to regulate, and has the power to do so. Our current supply chain for raw materials: how can FDA regulate foreign manufacturers and suppliers?

Q: dealing with foreign drug manufacturers: how best to deal with China?
The heparin debacle

15. CANCER THERAPEUTICS

Q: Access to unapproved drugs and life-saving medical devices: is current system good enough?

Case: Abigail Alliance

16. THE PROBLEM OF PRESCRIPTION DRUG COSTS

Q: prescription drug prices in the U.S. are ridiculous and we should adopt price controls. The roles of FDA and CMS