UNIV. OF FLORIDA
COLLEGE OF LAW

Spring 2024

MED. TECH. - Syllabus

Professor Lars Noah

This class will meet on Wednesdays & Thursdays @ 10:30-11:55 a.m. in Rm. 285D. Unless otherwise announced, office hours will take place on Mondays & Thursdays @ 12:30-1:30 p.m. in Rm. 335 (or you can contact me: noah@law.ufl.edu, (352) 273-0923).

We will be using my casebook, Law, Medicine & Medical Technology (Foundation Press 5th ed. 2022). I have placed three copies on reserve: KF3821.N63 2022. I'll post any PowerPoint slides and other misc. items after each class on our Canvas site.

The dates in the syllabus indicate when you should be prepared to discuss the assigned readings, while I'll be showing the specified videos in class. We won't cover every detail mentioned in the readings (there are "citation dumps" that you'll want to skim), but the discussion will highlight what I regard as most important for you to understand.

Regular attendance and occasional participation are expected of everyone (I'll try to keep track of both). If I detect a problem (esp. if on-time attendance slips below 80%), then I'll email you to provide notice of the potential consequences. (Patterns of leaving mid class also arouse my ire.) Otherwise, apart from minor adjustments necessitated by the mandatory curve used at this place, your grades will depend entirely on final exam performance (format noted on the bottom of p.2).

Other information about UF Levin College of Law policies, including compliance with the UF Honor Code, Grading, Accommodations, Class Recordings, and Course Evaluations can be found (on Canvas) at this link: https://ufl.instructure.com/courses/427635/files/74674656?wrap=1. Apart from what already appears in this document and my *Preface* (and what'll become readily apparent in class), I don't supply a course description/objectives, learning outcomes, workload or other such drivel.

GOVERNMENT REGULATION

Jan. 17 (Wed):	*Introduction/Definition of "Drug"*: v-viii, 3-24 Video: "Supplements & Safety" (PBS Frontline, 2016) [straddle next class]
Jan. 18 (Thu):	*"Dietary Supplements"*: 24-42
Jan. 24 (Wed):	*Medical "Devices"/"Tobacco Products"/"New Drugs"*: 42-51, 61-77
Jan. 25 (Thu):	*"Labeling"/Misbranding/Practice of Med.*: 78-104
Jan. 31 (Wed):	*Adjudicatory Procedures/Sanctions*: 104-28
Feb. 1 (Thu):	*Rulemaking/Informal Mechanisms*: 128-50
Feb. 7 (Wed):	*State Requirements and Federal Preemption*: 150-76

Product Licensure

Feb. 8 (Thu): *Drug Discovery/Access to Unapproved Products*: 187-90, 257-73
Video: "Can Alzheimer's Be Stopped?" (PBS Nova, 2016) [straddle next class]

Feb. 14 (Wed): *Demanding Access (cont'd)*: 274-89

Feb. 15 (Thu): *Premarket Review of New Drugs*: 291-94, 301-22

Feb. 21 (Wed): *Access Restrictions/Controlled Substances*: 322-44

Feb. 22 (Thu): *Premarket Review of Medical Devices*: 363-89

Feb. 28 (Wed): *Postmarket Surveillance*: 393-414
Video: "Dangerous Prescription" (PBS Frontline, 2003) [straddle next class]

Feb. 29 (Thu): *Professional Responsibility Issues*: 420-38

Controlling Access and Information

Mar. 6 (Wed): *Rx vs. OTC Status*: 439-67

Mar. 7 (Thu): *Rx Drug (and Device) Labeling*: 471-94 (ex. of a package insert: 586-92)
Video: "Money Talks: Profits Before Safety" (2006) [straddle next class]

Mar. 20 (Wed): *Rx Drug (and Device) Advertising*: 494-522, 532-35

Mar. 21 (Thu): *Constitutional (First Amendment) Issues*: 535-63

PRODUCTS LIABILITY

Mar. 27 (Wed): *Unavoidably Unsafe Products/Compliance Defense*: 595-614, 618-29

Mar. 28 (Thu): *Federal Preemption Defense*: 632-44, 650-67

Apr. 3 (Wed): *Causation Issues*: 674-701

Production Defects

Apr. 4 (Thu): *Manufacturing & Design Defects*: 715-40

Apr. 10 (Wed): *Design Defects (cont'd)*: 741-72

Informational Defects

Apr. 11 (Thu): *Triggering the Duty to Warn*: 777-97, 810-20

Apr. 17 (Wed): *Learned Intermediary Rule and Exceptions*: 820-51

Apr. 18 (Thu): [Course evals. (first 15 mins.)]
Measuring Adequacy: 851-77
Index (skim/just FYI): 1347-52

May 6 (Mon) [in class]: **Final exam**: Open book, 3 essay-style questions (probably given 2½ hours), with strict word limits to discourage use of canned, nonresponsive answers.

Course Facts

MEDICAL TECHNOLOGY AND THE LAW
Prof. Lars Noah 3 credits

Doctrinal content (approximate)

Administrative procedure	5%
Constitutional law (total)	30%
Commercial speech	10%
Substantive due process	5%
Supremacy clause	10%
other	5%
Regulatory (esp. FDA)	25%
Torts (esp. products liability)	35%
other:	
Professional responsibility	4%
Criminal law	1%

Warning: May cause users to lose faith in all FDA-regulated therapeutic products!

Additional statements:

- High 1L course content (> 50%) may help to promote success on the bar exam.
- STEM-certified (heavy dose of science & technology)
- Offers a glimpse at the nature of sophisticated law practice, with specialization based on industry sector (rather than particular skill set or doctrinal category).
- Nutrient dense—short on empty calories (apart from screening a few PBS documentaries).

Rated "M" (mature audiences only) for occasional descriptions of medical gore, sex, and drug use.

In order to comply with UF Law Policy, the following information has been added.

COURSE DESCRIPTION FROM UF LAW WEBSITE

This course considers the many ways that our society manages pharmaceuticals and medical devices. Therapeutic products confront a distinctive regulatory regime, which in turn poses a variety of questions related to administrative procedure, constitutional law, and torts, among other doctrinal subjects.

STUDENT LEARNING OUTCOMES:

At the end of this course, students should be able:

1. To understand administrative procedure.
2. To understand formal and informal rulemaking.
3. To understand state requirements and federal preemption.
4. To understand premarket and postmarket review and surveillance.
5. To recognize constitutional issues in the regulatory regime.

ABA OUT-OF-CLASS HOURS REQUIREMENTS: ABA Standard 310 requires that students devote 120 minutes to out-of-class preparation for every "classroom hour" of in-class instruction.