

**MED. TECH. - Course Information**

Professor Lars Noah

Please be aware that this document does not qualify as a “syllabus” under university rules as it includes only essential information about this course; non-essential boilerplate crafted by others can be found elsewhere.

This class meets Mondays & Wednesdays, 10:30-11:55, in Rm. 355D (or via Zoom for those enrolled in the remote section). Unless otherwise announced, virtual office hours will take place on Fridays @ 12:30-2:30 p.m. (or you can try and make an appointment for a different time). I’ll post any PowerPoint slides and other misc. items after each class on our Canvas site (I’m a first time user on that incoherent platform, so please bear with me), which I have also used to set up Zoom links.

We will be using my casebook, Law, Medicine & Medical Technology (Foundation Press 4th ed. 2017)—as I receive paltry royalties on sales of new copies, the Dean’s office first had to approve my selection of this text, and UF policy requires that I disclose to you this potential conflict of interest. As I’ve started preparing the new edition, occasional assignments may be replaced with new material posted separately (I’ve already done so for our 3rd, 4th & 10th classes, designated as “Supp.”).

The dates indicate when you should be prepared to discuss the assigned readings. 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).

**GOVERNMENT REGULATION**

- Jan. 20 (Wed):        *Introduction/Definition of “Drug”*: v-viii, 3-22, 1209-10  
Video: “Supplements & Safety” (PBS Frontline, 2016) [straddle next class]
- Jan. 25 (Mon):        *Dietary Supplements*: 22-39
- Jan. 27 (Wed):        *Medical “Devices”/“New Drugs”/“Labeling”*: 40-50, Supp. 1-6, 57-69
- Feb. 1 (Mon):        *Misbranding/Practice of Med.*: 69-83, Supp. 7-13, 90-93, 1234-38, 1245-47
- Feb. 3 (Wed):        *Adjudicatory Procedures/Sanctions/Rulemaking*: 93-119
- Feb. 8 (Mon):        *Informal Mechanisms/Access Restrictions/Controlled Substances*: 119-46
- Feb. 10 (Wed):        *State Requirements and Federal Preemption*: 146-70, 429-32

**Product Licensure**

- Feb. 15 (Mon):        *Drug Discovery/Access to Unapproved Products*: 181-84, 251-67  
Video: “Can Alzheimer’s Be Stopped?” (PBS Nova, 2016) [straddle next class]
- Feb. 17 (Wed):        *Demanding Access (cont’d)*: 267-84

Feb. 22 (Mon): *Premarket (& Postapproval) Review of New Drugs: 285-88, Supp. 14-15, 295-310, 373-80*

Feb. 24 (Wed): *Premarket Review of Medical Devices: 325-54*

Mar. 1 (Mon): *Postmarket Surveillance: 354-73*  
Video: "Dangerous Prescription" (PBS Frontline, 2003) [straddle next class]

Mar. 3 (Wed): *Professional Responsibility Issues: 380-98*

**Controlling Access and Information**

Mar. 8 (Mon): *Rx vs. OTC Status: 399-429*

Mar. 10 (Wed): *Rx Drug (and Device) Labeling: 432-55*  
(example of a package insert: 547-53)  
Video: "Money Talks: Profits Before Safety" (2006) [straddle next class]

Mar. 15 (Mon): *Rx Drug (and Device) Advertising: 455-79, 482-84, 493-95*

Mar. 17 (Wed): *Constitutional (First Amendment) Issues: 496-528*

**PRODUCTS LIABILITY**

Mar. 22 (Mon): *Unavoidably Unsafe Products/Compliance Defense: 557-76, 580-92*

Mar. 24 (Wed): *Federal Preemption Defense: 593-606, 612-26*

Mar. 29 (Mon): *Preemption (cont'd)/Causation Issues: 626-31, 637-64*

**Production Defects**

Mar. 31 (Wed): *Manufacturing & Design Defects: 677-703*

Apr. 5 (Mon): *Design Defects (cont'd): 703-33*

**Informational Defects**

Apr. 7 (Wed): *Triggering the Duty to Warn: 739-59, 773-80*

Apr. 12 (Mon): *Learned Intermediary Rule and Exceptions: 780-806*

Apr. 14 (Wed): *Measuring Adequacy: 806-830*

Apr. 19 (Mon): *Unintended Uses/Med. Mal.: 759-73, 831-32, 836-49*

May 3 (Mon): **Final exam:** Open book, 3 essay-style questions (probably given 2½ hours),  
8:30 a.m. with strict word limits to discourage use of canned, nonresponsive answers).