

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 Wednesdays & Thursdays, 1:15-2:40, in Rm. 284. I’ll post any PowerPoint slides and other misc. items after each class on our Canvas site. Unless otherwise announced, office hours will take place on Tuesdays @ 12:00-2:00 p.m., Wednesdays & Thursdays @ 12:00-1:00 p.m. (or you can try and make an appointment for a different time), subject to the following caveat: no shirt, no shoes, *no mask*, no service.

We will be using the new edition of my casebook, Law, Medicine & Medical Technology (Foundation Press 5th ed. 2022), but thanks to a delay caused by the publisher, it has not yet come out. Therefore, I will post the first few days of reading assignments and then plan to loan out hardcopies (with the expectation that these will be returned in reasonable condition at the end of the semester; you’ll get an “incomplete” for the course until you return or replace it); in the event of any further publication delays (or if too many students enroll), however, I’ll have to come up with another plan.

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. 19 (Wed): *Introduction/Definition of “Drug”*: v-viii, 3-24
 Video: “Supplements & Safety” (PBS Frontline, 2016) [straddle next class]
- Jan. 20 (Thu): *Dietary Supplements*: 24-42
- Jan. 26 (Wed): *Medical “Devices”/“New Drugs”*: 42-63, 70-77
- Jan. 27 (Thu): *“Labeling”/Misbranding/Practice of Med.*: 78-104
- Feb. 2 (Wed): *Adjudicatory Procedures/Sanctions*: 104-28
- Feb. 3 (Thu): *Rulemaking/Informal Mechanisms*: 128-50
- Feb. 9 (Wed): *State Requirements and Federal Preemption*: 150-76

Product Licensure

- Feb. 10 (Thu): *Drug Discovery/Access to Unapproved Products*: 187-90, 257-73
 Video: “Can Alzheimer’s Be Stopped?” (PBS Nova, 2016) [straddle next class]

- Feb. 16 (Wed): *Demanding Access (cont'd): 274-89*
- Feb. 17 (Thu): *Premarket Review of New Drugs: 291-94, 301-22*
- Feb. 23 (Wed): *Access Restrictions/Controlled Substances: 322-44*
- Feb. 24 (Thu): *Premarket Review of Medical Devices: 363-89*
- Mar. 2 (Wed): *Postmarket Surveillance: 393-414*
Video: "Dangerous Prescription" (PBS Frontline, 2003) [straddle next class]
- Mar. 3 (Thu): *Professional Responsibility Issues: 420-38*

Controlling Access and Information

- Mar. 16 (Wed): *Rx vs. OTC Status: 439-67*
- Mar. 17 (Thu): [cancelled (for speaking gig at Duke)]
- Mar. 23 (Wed): *Rx Drug (and Device) Labeling & Advertising: 483-95, 501-18*
- Mar. 24 (Thu): *Constitutional (First Amendment) Issues: 535-63*

PRODUCTS LIABILITY

- Mar. 30 (Wed): *Unavoidably Unsafe Products/Compliance Defense: 595-614, 618-29*
- Mar. 31 (Thu): *Federal Preemption Defense: 632-44, 650-67*
- Apr. 6 (Wed): *Causation Issues: 674-701*

Production Defects

- Apr. 7 (Thu): *Manufacturing & Design Defects: 715-40*
- Apr. 13 (Wed): *Design Defects (cont'd): 741-72*

Informational Defects

- Apr. 14 (Thu): *Triggering the Duty to Warn: 777-97, 810-20*
- Apr. 20 (Wed): *Learned Intermediary Rule and Exceptions: 820-51*
- Apr. 21 (Thu): *Measuring Adequacy: 851-77*

- May 5 (Thu): **Final exam:** Open book, 3 essay-style questions (probably given 2½ hours), with strict word limits to discourage use of canned, nonresponsive answers).