

**MED. TECH. - Course Information**

Professor Lars Noah

This class meets Wednesdays & Thursdays @ 9:00-10:25 a.m. in Rm. 355D. Unless otherwise announced, office hours will take place on Wednesdays & Thursdays @ 11:30 a.m.-1:30 p.m. in Rm. 335 (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.

We will be using the latest edition of my casebook, Law, Medicine & Medical Technology (Foundation Press 5th ed. 2022). I have placed three copies on reserve—to check availability, go to [https://ufl-flvc.primo.exlibrisgroup.com/permalink/01FALSC\\_UFL/175ga98/alma99383998218506597](https://ufl-flvc.primo.exlibrisgroup.com/permalink/01FALSC_UFL/175ga98/alma99383998218506597)

The dates 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).

**GOVERNMENT REGULATION**

- Jan. 18 (Wed):        *Introduction/Definition of "Drug":* v-viii, 3-24  
Video: "Supplements & Safety" (PBS Frontline, 2016) [straddle next class]
- Jan. 19 (Thu):        *Dietary Supplements:* 24-42
- Jan. 25 (Wed):        *Medical "Devices"/"New Drugs":* 42-63, 70-77
- Jan. 26 (Thu):        *"Labeling"/Misbranding/Practice of Med.:* 78-104
- Feb. 1 (Wed):        *Adjudicatory Procedures/Sanctions:* 104-28
- Feb. 2 (Thu):        *Rulemaking/Informal Mechanisms:* 128-50
- Feb. 8 (Wed):        *State Requirements and Federal Preemption:* 150-76

**Product Licensure**

- Feb. 9 (Thu):        *Drug Discovery/Access to Unapproved Products:* 187-90, 257-73  
Video: "Can Alzheimer's Be Stopped?" (PBS Nova, 2016) [straddle next class]
- Feb. 15 (Wed):        *Demanding Access (cont'd):* 274-89
- Feb. 16 (Thu):        *Premarket Review of New Drugs:* 291-94, 301-22
- Feb. 22 (Wed):        *Access Restrictions/Controlled Substances:* 322-44

- Feb. 23 (Thu): *Premarket Review of Medical Devices: 363-89*
- Mar. 1 (Wed): *Postmarket Surveillance: 393-414*  
Video: "Dangerous Prescription" (PBS Frontline, 2003) [straddle next class]
- Mar. 2 (Thu): *Professional Responsibility Issues: 420-38*

**Controlling Access and Information**

- Mar. 8 (Wed): *Rx vs. OTC Status: 439-67*
- Mar. 9 (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. 22 (Wed): *Rx Drug (and Device) Advertising: 494-522, 531-35*
- Mar. 23 (Thu): *Constitutional (First Amendment) Issues: 535-63*

**PRODUCTS LIABILITY**

- Mar. 29 (Wed): *Unavoidably Unsafe Products/Compliance Defense: 595-614, 618-29*
- Mar. 30 (Thu): *Federal Preemption Defense: 632-44, 650-67*
- Apr. 5 (Wed): *Causation Issues: 674-701*

**Production Defects**

- Apr. 6 (Thu): *Manufacturing & Design Defects: 715-40*
- Apr. 12 (Wed): *Design Defects (cont'd): 741-72*

**Informational Defects**

- Apr. 13 (Thu): *Triggering the Duty to Warn: 777-97, 810-20*
- Apr. 19 (Wed): *Learned Intermediary Rule and Exceptions: 820-51*
- Apr. 20 (Thu): [Course evals. (first 15 mins.)]  
*Measuring Adequacy: 851-77*

- May 11 (Thu): **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

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### **Doctrinal content**                      (approximate)

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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%

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

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### **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.