FDA Law
Spring 2020
5297 FDA Law
Professor(s): Mark S. Armstrong
Credits: 2
Course Areas: *Health Law*
Time: Thursday, 5:30 – 7:30 p.m.
Course Areas: Health Law

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Office Hours: Th (after class) or other times if you have conflicts then.

Overview: Pharmaceutical products account for a significant portion of healthcare services, so a basic understanding of FDA/Pharmacy law is essential for any student wishing to work in, or to represent clients in the healthcare sector. This course provides a manageable introductory survey of the major substantive topics in FDA Law, particularly relating to drugs, biologics and biosimilars, and the interaction of state pharmacy laws relating to dispensing and distribution of those products. After providing a basic tour of FDA law and applicable state pharmacy laws, the course will turn to discussion of hot topics in FDA/Pharmacy laws, which students will select in consultation with Professor Armstrong.

Assessment: **There is no final exam.** 60% of students' grades will be based on an in-class "midterm" exam to be administered on a date to be determined, based on student input, during weeks 8-10 of the semester. The midterm will cover the substantive FDA and state pharmacy law concepts covered during the first part of the course and will be administered by an anonymous "exam number". The other 40% of students' grades will be based on a short (3,000 to 6,000-word) medical-journal or bioethics-journal-length paper that students will write on an FDA/Pharmacy hot topic that they will choose in consultation with Prof. Armstrong. Those papers will be due on or before the scheduled final exam time at the end of the term.

Because the midterm is a graded assignment, the Office for Student Services will assist students who have a *bona fide* work, healthcare, or school-related conflict (e.g., such as an illness or a moot course competition) that conflicts with the scheduled midterm date. Every effort will be made to select a midterm date that works for all students, but students who nevertheless have a conflict will be able to reschedule their midterms to a date within one week of the scheduled date, on the same basis they would be able to reschedule a final exam.

Participation: Students are expected to stay current on the readings and participate during class. Participation can affect your final grade insofar as habitual lateness or disengagement can cause your grade to be reduced by 1 notch (e.g., A minus to B plus).

Course Text and Materials:

- Textbook: Food and Drug Administration, 4th, 2019-1 ed. Access via Westlaw subscription at https://www.westlaw.com/Browse/Home/SecondarySources/HealthLawSecondarySources/HealthLawTextsTreatises/FoodDrugAdministrationFourthEdition?transitionType=Default&contextData=(sc.Default)&VR=3.0&RS=cblt1.0
- Statute (FDCA/21 U.S.C.) -- Access via FDA website, at http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/default.htm
- Regulations (21 C.F.R.) -- Access via FDA website, at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
- Texas Pharmacy Act (Tex. Occ. Code §§551 – 569) – Access via https://www.pharmacy.texas.gov/Rules_Pharmacy_Act.asp
- Texas Pharmacy Rules (22 TAC §§281 - 385) – Access via https://www.pharmacy.texas.gov/Rules_Pharmacy_Rules.asp
- Additional materials will be distributed and noted in the syllabus.

Learning Outcomes:

1. Understand the institutional framework and scope of authority of the U.S. Food and Drug Administration (FDA) relating to prescription drugs and biologics.
2. Learn and analyze key statutory provisions, regulations, case law, and policy in major FDA areas of regulation concerning drugs and biologics.
3. Learn and analyze key state statutory provisions and regulations regarding the practice of pharmacy and the dispensing and distribution of prescription drugs.
4. Develop insight into how the FDA responds to new scientific and technological advancements with prescription drugs and biologics.
5. Develop practical skills in: (1) how to interpret statutes; (2) how to read regulations; and (3) how to research regulatory materials; and (4) how to represent clients in front of agencies and handle enforcement actions.

Message from the University: Counseling and Psychological Services (CAPS) can help students who are having difficulties managing stress, adjusting to the demands of a professional program, or feeling sad and hopeless. You can reach CAPS (www.uh.edu/caps) by calling 713-743-5454 during and after business hours for routine appointments or if you or someone you know is in crisis. No appointment is necessary for the "Let's Talk" program, a drop-in consultation service at convenient locations and hours around campus. http://www.uh.edu/caps/outreach/lets_talk.html

Attendance The Law Center attendance policy applies. You do not need to notify me if you are going to miss a class here or there. But if you anticipate missing several classes, please let me know beforehand. I reserve the right to deduct from your participation grade if I notice that you are not attending regularly or are habitually late.

Computers Laptops, tablets, and smartphones may be brought to class but should be used only for class-related purposes (taking notes, accessing the blackboard and statutes, etc.). I reserve the right to restrict your use of these devices at my discretion and without notice if your use of them creates a distraction for yourself or for others.

Preferred Name / Pronoun: I will gladly honor your request to address you by an alternate name or gender pronoun. Please advise me of this preference early in the semester so that I may make appropriate changes to my records.

Exam/Grading: See "Assessment" on page 1.