

Syllabus version: May 20, 2026
FDA Law
Fall 2026
5237 FDA Law 26157
Professor(s): Mark S. Armstrong
Credits: 2
Course Areas: *Health Law*
Time: Wednesday, 4:00 – 6:00 p.m.
Course Areas: Health Law

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Office Hours: W (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, medical devices 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 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.

Instruction Mode: Face-to-Face

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 Law – Cases and Materials, 5th Edition
Authors: Peter Barton Hutt, Richard A. Merrill and Lewis A Grossman
ISBN-10: 1636596959
ISBN-13: 978-1636596952
- Statute (FDCA/21 U.S.C.) -- Access via FDA website, at <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCA/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 and medical devices.
2. Learn and analyze key statutory provisions, regulations, case law, and policy in major FDA areas of regulation concerning drugs, biologics and medical devices.
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 medical devices.
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.

Counseling and Psychological Services (CAPS):

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. See: http://www.uh.edu/caps/outreach/lets_talk.html.

Mental Health and Wellness Resources.

The University of Houston has a number of resources to support students' mental health and overall wellness, including CoogsCARE and the UH Go App. UH Counseling and Psychological Services (CAPS) offers 24/7 mental health support for all students, addressing various concerns like stress, college adjustment and sadness. CAPS provides individual and couples counseling, group therapy, workshops and connections to other support services on and off-campus. For assistance visit uh.edu/caps, call 713-743-5454, or visit a Let's Talk location in-person or virtually. Let's Talk are daily, informal confidential consultations with CAPS therapists where no appointment or paperwork is needed.

Need Support Now? - If you or someone you know is struggling or in crisis, help is available. Call CAPS crisis support 24/7 at 713-743-5454, or the National Suicide and Crisis Lifeline: call or text 988, or chat 988lifeline.org.

Title IX/Sexual Misconduct.

Per the UHS Sexual Misconduct Policy, your instructor is a "responsible employee" for reporting purposes under Title IX regulations and state law and must report incidents of sexual misconduct (sexual harassment, non-consensual sexual contact, sexual assault, sexual exploitation, sexual intimidation, intimate partner violence, or stalking) about which they become aware to the Title IX office. Please know there are places on campus where you can make a report in confidence. You can find more information about resources on the Title IX website at <https://uh.edu/equal-opportunity/title-ix-sexual-misconduct/resources/>.

Reasonable Academic Adjustments/Auxiliary Aids.

The University of Houston is committed to providing an academic environment and educational programs that are accessible for its students. Any student with a disability who is experiencing barriers to learning, assessment or participation is encouraged to contact the Justin Dart, Jr. Student Accessibility Center (Dart Center) to learn more about academic accommodations and support that may be available to them. Students seeking academic accommodations will need to register with the Dart Center as soon as possible to ensure timely implementation of approved accommodations. Please contact the Dart Center by visiting the website: <https://uh.edu/accessibility/> calling (713) 743-5400, or emailing jdcenter@Central.UH.EDU.

The Student Health Center offers a Psychiatry Clinic for enrolled UH students. Call 713-743-5149 during clinic hours, Monday through Friday 8 a.m. - 4:30 p.m. to schedule an appointment.

The A.D. Bruce Religion Center offers spiritual support and a variety of programs centered on well-being.

The Center for Student Advocacy and Community (CSAC) is where you can go if you need help but don't know where to start. CSAC is a "home away from home" and serves as a resource hub to help you get the resources needed to support academic and personal success. Through our Cougar Cupboard, all students can get up to 30 lbs of FREE groceries

a week. Additionally, we provide 1:1 appointments to get you connected to on- and off-campus resources related to essential needs, safety and advocacy, and more. The Cougar Closet is a registered student organization advised by our office and offers free clothes to students so that all Coogs can feel good in their fit. We also host a series of cultural and community-based events that fosters social connection and helps the cougar community come closer together. Visit the CSAC homepage or follow us on Instagram: @uh_CSAC and @uhcupbrd. YOU belong here.

Recording of Class.

Students may not record all or part of class, livestream all or part of class, or make/distribute screen captures, without advanced written consent of the instructor. If you have or think you may have a disability such that you need to record class-related activities, please contact the Justin Dart, Jr. Student Accessibility Center. If you have an accommodation to record class-related activities, those recordings may not be shared with any other student, whether in this course or not, or with any other person or on any other platform. Classes may be recorded by the instructor. Students may use instructor's recordings for their own studying and notetaking. Instructor's recordings are not authorized to be shared with anyone without the prior written approval of the instructor. Failure to comply with requirements regarding recordings will result in a disciplinary referral to the Dean of Students Office and may result in disciplinary action.

Security Escorts and Cougar Ride

UHPD continually works with the University community to make the campus a safe place to learn, work, and live. The security escort service is designed for the community members who have safety concerns and would like to have a Security Officer walk with them, for their safety, as they make their way across campus. Based on availability either a UHPD Security Officer or Police Officer will escort students, faculty, and staff to locations beginning and ending on campus. If you feel that you need a Security Officer to walk with you for your safety, please call 713-743-3333. Arrangements may be made for special needs.

Parking and Transportation Services also offers a late-night, on-demand shuttle service called "Cougar Ride" that provides rides to and from all on-campus shuttle stops, as well as the MD Anderson Library, Cougar Village/Moody Towers and the UH Technology Bridge. Rides can be requested through the UH Go app. Days and hours of operation can be found at <https://uh.edu/af-university-services/parking/cougar-ride/>.

Syllabus Changes.

Please note that the instructor may need to make modifications to the course syllabus. Notice of such changes will be announced as quickly as possible through (specify how students will be notified of changes).

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.