

Syllabus version: August 7, 2023

FDA Law

Fall 2023

5297 FDA Law

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/FDCAct/default.htm>
- Regulations (21 C.F.R.) -- Access via FDA website, at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/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.

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.

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.

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.

Honor Code.

The UHLC Honor Code applies to all aspects of this course. You are responsible for knowing all Honor Code provisions and for complying with the Honor Code. Please inquire if you have any questions regarding how the Honor Code's provisions apply to specific activities or situations related to this course. Your continuing enrollment in this course is deemed to be a pledge by you under the Honor Code to comply with the Honor Code in relation to this course and to comply with the instructions in the course syllabus.

AI Generated Text.

The software technology known as artificial intelligence has recently expanded its capability to generate text (AI Generated Text). Examples of the technology include what are known as "generative" large language models (LLMs), and a specific implementation what is well known in the general public is ChatGPT. These systems can generate text in response to prompts and/or input of other text/documents/code/images. The output, the AI Generated Text, appears to have human-mimicking "intelligence" and is thus potentially usable as a substitute for written work product one might generate themselves. AI Generated Text can include computer code or programs as well as human language content.

Your continuing enrollment in this course is deemed to be a pledge by you under the Honor Code to not prompt, generate, obtain, read, or use any AI Generated Text in relation to any activity or assessment in this course. This applies to AI Generated Text from yourself or others. This pledge includes that your assessment work product in the course is without any contribution from AI Generated Text. This specifically extends to the plagiarism policy and unauthorized aid/materials parts of the Honor Code: AI Generated Text will be treated as from another/other in applying the plagiarism policy to this course. The term "assessment" means any work product generated for this course that is submitted to the instructor or presented in a class session, regardless whether it is graded content or not. Assessments include mid-terms and final exams. AI Generated Text may not be used in the development or drafting of any assessments created by you in a non-proctored environment, such as a "take-home" final examination unless specified as an exception below. The parts of the Honor Code that refer to unauthorized materials or aid are specifically prohibited from any use of AI Generated Text in this course unless specified as an exception below.

The following activities are exceptions to the immediately preceding paragraph; the intent of these exceptions is to allow use of AI Generated Text for specifically and narrowly defined activities in relation to this course:

- Creating content for an outline that you use to summarize the course content
- "conversing" with the AI Generated Text software system to create hypotheticals to better understand course content, alone or with others
- checking text drafted by you for misspellings, grammar and punctuation errors, strength and clarity of prose, verbosity, effective transitional language and thesis sentences, word choice, excessive passive voice, and like things

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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.