



Legal Considerations in Drug Development

Course Description

More than 4.7 million Americans work in the pharmaceutical industry and more than 16 million work in healthcare. This course looks at the landscape of how the drug development process is regulated and at some of the most important regulations. Drug development and marketing is, of course, the lifeblood of the pharmaceutical industry.

Course Learning Outcomes

At the completion of this course, students will be able to:

- Analyze the legal and ethical considerations involved in drug development;
- Characterize some of the scientific and commercial features inherent in the pharmaceutical industry that may present legal and/or ethical challenges;
- Identify improper pharmaceutical promotion and marketing practices;
- Describe the mechanisms the FDA has developed by which drugs that treat serious illnesses can be made available to consumers.

Final Exam

Grades and credit recommendations are based solely on a final exam. When students are ready to take the final exam, they should register for a LawShelf account (or simply log in, for those with existing accounts). Go to the video-course page and click “Take the Final Exam” and pay the exam fee, where applicable. Students will be given instructions on how to take the exam. All exams are proctored by the Voice Proctor® proctoring system. An overview of the system is [provided here](#) and it requires no training or learning curve. Grades of 70% or above are considered passing grades and qualify for recommended transfer credit.

The final exam is based on the video course modules. Additional resources detailed in this syllabus are helpful for background and for building greater understanding of the course materials. Inquiries can be made through the LawShelf Contact form on our website by clicking the “email us” button that appears at the bottom of most LawShelf pages. Transcripts can be ordered via Parchment, as detailed on our website.

Case Studies

Many LawShelf video courses include case studies. These do not necessarily teach new material but are meant to demonstrate how the materials covered in the course are applied by various courts. Concepts covered in the case studies are covered on the final exam, so make sure to watch the case studies before taking the exam. However, it is unnecessary to memorize the facts and details of the cases covered in these case studies.

Self-Quizzes

Video-course modules and case studies feature self-quizzes that consist of practice questions on the materials covered in the videos. These questions are presented for the benefit of the student and are **important to review before taking the final exam** because they are similar in style and substance to the questions on the final exam. These quizzes are not graded or monitored and there is no record of how students answer these questions. Students may answer these questions as many times as they like and are encouraged to keep re-taking the quizzes until they have mastered all the questions.

Study Guide

Introductory Videos

These videos provide background to help students better understand the main parts of the course, which are the [video-course modules](#) below.

Health Law: How a New Drug Is Approved, Part 1

<https://lawshelf.com/shortvideoscontentview/health-law-how-is-a-new-drug-approved-part-1/>

Health Law: How a New Drug Is Approved, Part 2

<https://lawshelf.com/shortvideoscontentview/health-law-how-is-a-new-drug-approved-part-2/>

Can Government Mandate the COVID Vaccination?

<https://lawshelf.com/blogentryview/can-government-mandate-the-covid-vaccination>

Courseware Readings

These courseware readings provide background to help students better understand the main parts of the course, which are the video-course modules below.

Drug Development and Ethical Considerations, **Evolve Resources for Pharmacology**
https://www.elsevier.com/data/assets/pdf_file/0003/1104168/original-McCuistion-Ch-1.pdf

Practical, Legal, and Ethical Issues in Expanded Access to Investigational Drugs, **The New England Journal of Medicine**
<https://www.nejm.org/doi/full/10.1056/nejmhle1409465>

Video Course Modules

These videos constitute the main part of the course and are they sources of the questions on the final exam.

Legal Considerations in Drug Development Course Overview Video
<https://lawshelf.com/videocoursescontentview/drug-development>

Legal and Ethical Considerations in Drug Development - Module 1 of 5
<https://lawshelf.com/videocoursesmoduleview/legal-and-ethical-considerations-in-drug-development-module-1-of-5>

Promotion of Pharmaceutical Products - Module 2 of 5
<https://lawshelf.com/videocoursesmoduleview/promotion-of-pharmaceutical-products--module-2-of-5>

Drug Pricing - Module 3 of 5
<https://lawshelf.com/videocoursesmoduleview/drug-pricing-module-3-of-5>

Exceptions to the Rule Part 1 - Module 4 of 5
<https://lawshelf.com/videocoursesmoduleview/exceptions-to-the-rule-part-1-module-4-of-5>

Exceptions to the Rule Part 2 - Module 5 of 5
<https://lawshelf.com/videocoursesmoduleview/expectations-to-the-rule-part-2-module-5-of-5>

Supplemental Suggested Reading

These materials enable students to achieve a deeper understanding of the course materials and in applying the course to real-life situations.

Development & Approval Process for Drugs, U.S. Food & Drug Administration
<https://www.fda.gov/drugs/development-approval-process-drugs>

NACDA Guidelines for Administration of Drugs to Human Subjects, National Institute on Drug Abuse
<https://www.drugabuse.gov/research/clinical-research/nacda-guidelines-administration-drugs-to-human-subjects>

INSIGHT: Legal Battles Extend to Failures in Drug Development, Bloomberg Law
<https://news.bloomberglaw.com/pharma-and-life-sciences/insight-legal-battles-extend-to-failures-in-drug-development>