

Where Drugs Come From: How They are Discovered, Developed, Regulated and Marketed

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Type of course: UC Davis School of Medicine, Fourth Year Elective

Course format: This is a 2-week clinical didactic (classroom only; no patient contact). The course includes 12 class hours (6 class meetings of 2 hours each). Self-study is required.

Pre-requisites: UC Davis School of Medicine Year 4 in good standing, or with approval of instructor.

Course objectives: All physicians with direct patient care responsibilities prescribe or use medications. The correct selection and use of medications is critical to providing optimal patient care and avoiding harm. In order to properly prescribe and use medications, physicians must be able to locate, assimilate and critically evaluate scientific evidence pertaining to the safety and efficacy of drug products. Acquiring and properly evaluating information on which to base the selection and use of medications is becoming increasingly difficult as the amount of information available to physicians increases and the quality of information becomes more variable. Forces within the health care system that seek to mandate or limit prescribing also increasingly challenge physicians, particularly in an environment where the cost of medications is rising dramatically. The goal of this course is to educate medical students on the many facets of the process by which drugs are discovered, developed, regulated and marketed, and to raise awareness of the economic, political and social factors that shape the process.

Topics: The course curriculum includes the following topics: Overview of the Drug Discovery Process; Drug Regulation in the United States; Patents and Other Forms of Exclusivity; Drug Targets and Pharmacology; Identification of Lead Candidates; Preclinical Assessment; ADME Including Basic Pharmacokinetic Principles; Principles of Drug Toxicity; Principles of Drug Safety; Clinical Trials; Generic Drugs; Pharmaceutical Industry; Drug Distribution and Marketing; Dietary Supplements; Controlled Substances

Course project: Students will participate in a course research project where they will select a specific topic, and do a deep dive into the topic. Some sample topics are shown below. Students will present their findings and lead a class discussion on their chosen topic. In some cases the topic may be on a specific drug or biological therapy, with consideration of how the drug was discovered and developed, and how it is regulated and marketed.

Relevance to clinical medicine: The course is intended to provide fourth-year medical students with habits of thought that will be of immediate use to them in the practice of clinical medicine, whether in training or in their eventual careers. Any physician who prescribes drugs should be familiar with the broad concepts to be taught in this course. Additionally, any such physician should be familiar with the information resources to which students will be exposed in the course. An understanding of how to find relevant information and critically evaluate it will enhance the student's eventual medical practice. The instructor is a practicing physician. During lectures and class discussions, the instructor will give real world examples from clinical practice to illustrate didactic points and to bring the discussion to life.

Sample Student Project Topics

- How much does the U.S. spend on health care, where does the money go, and why is the spending much more than in other nations?
- How much do drugs cost? Why are prescription drugs so expensive? Does the cost of research explain the high prices? What proposals are being considered to bend the cost curve?
- How are prescription drugs marketed in the U.S.? What is “direct to consumer” advertising and why does it exist in the U.S. and almost nowhere else?
- Why are there shortages of some critical drugs in the U.S.? Which drugs are most affected? What proposals have been made to solve this problem?
- What are pharmacy benefit managers and what roles do they play in the distribution of drugs to patients in the U.S.?
- How are drugs regulated outside of the U.S.? How are drug prices regulated outside of the U.S.?
- What is the opioid crisis? In addition to opioids, what other drugs are abused and what is the extent of the problem in the U.S.? How does the FDA and DEA interact to schedule controlled substances?
- Are cannabis products effective as drugs? What is industrial hemp? How are cannabis and cannabis products regulated?
- What are psychedelics? Do they have potential in clinical medicine? What are the barriers to their adoption?
- What is a medical device and how are medical devices regulated?
- How are vaccines discovered, developed and regulated? How does the economics of vaccines differ from drugs?
- What are the different types of antivirals? How are antivirals discovered and tested? How do they work?
- What are biologicals and how are they discovered, developed and regulated? What is a “biosimilar”?