# LAW 7138: Law of Drugs and Biologics

This course examines how the U.S. Food and Drug Administration (FDA) regulates 25% of the U.S. economy and exerts decisive authority over the availability of new therapeutic drugs and biologics. Activities of the biotechnology and pharmaceutical industrial sectors, from discovery of a potentially life-saving medicine to its approval, are rigidly controlled by FDA regulation and pharmaceutical and biotechnology companies must manage its regulatory risks. Through lecture, reading assignments and discussion, this course will provide background on the legislative authority which underlies FDA activities, the processes and procedures by which the Agency carries out its mandate and the public policy debates that deal with the tension between accelerating approval of new treatments for incurable diseases such as AIDS, cancer, rare diseases, heart and Alzheimer's disease and the demand to improve the safety of marketed drugs. We will also consider the aspects of FDA law which affect intellectual property protection in the biotech and pharmaceutical industries, including the Hatch-Waxman Act which, among other things, provides major support for the U.S. generics drug industry. Finally, we consider the implications of the cost of prescription drugs and biologics in the delivery of the overall heathcare system. Course grading will be determined by class participation and a final examination. This course is offered on an every other year basis. Exam Info: Take-Home Exam
**Credits:** 2.0