

TECH 495: The FDA: Science, Health Policy, and Regulation in an Uncertain Environment

The FDA is a science-based regulatory agency whose mission is to protect and promote the public health. It exists at the interface of science, law, and policy—and some would say, increasingly, politics. This course explores the complex scientific and policy issues the FDA must address in regulatory decisions that affect all Americans and cover products that account for approximately one-fifth of the American economy. It reviews some of the major forces that have shaped the FDA, surveys the broad range of FDA's regulatory mandate, explores the FDA's role as gatekeeper for emerging medical technologies, and examines the current state of the agency in a rapidly changing environment. This course is an elective for Advanced Studies in Technology Transfer.

Learning Objectives

- Understand the FDA's mission, how that mission has evolved, and how science informs the FDA's policy and product decisions
- Explore potential career paths at the FDA and in industries that produce FDA-regulated products
- Appreciate the importance of effectively communicating FDA's decisions on a multitude of complex scientific, medical, and public health matters
- Identify the various forces and interests that confront the FDA, and evaluate their potential impact on the agency in an uncertain and evolving political environment

Credits: 2

Class Type: Graduate Course

Program: Technology Transfer, Business, and Industry