

Food and Drug Law

Winter term, [Block Winter](#)
M,T,W,Th,F 9 AM - 12 PM

Mr. Peter B. Hutt
3 classroom credits LAW-37300A Winter

This course explores the full range of federal regulation of products subject to the jurisdiction of the Food and Drug Administration (FDA). These products include food, human prescription and nonprescription drugs, animal feed and drugs, biologics and blood products, medical devices, and cosmetics, which together comprise approximately 25% of the gross national product. The course examines the public policy choices underlying the substantive law, FDA enforcement power, and agency practice and procedure. The course covers such contemporary issues as protecting against unsafe or mislabeled food, controlling carcinogens, expediting approval of AIDS and cancer drugs, importing drugs from abroad, switching drugs from prescription to nonprescription status, balancing the benefits and risks of breast implants, compassionate use of experimental products, control of such biotechnology techniques as gene therapy, requiring adequate consumer and professional labeling for FDA-regulated products, and the relationship among international, federal, and state regulatory requirements. A prior course in Administrative Law is desirable but not a prerequisite.

Enrollment in this course is limited to seventy-two students. Sixty students will be enrolled through the Pre-Registration General Lottery. The remaining twelve places will be reserved for students who are not selected for the course by the lottery but who choose to combine the course paper with the third-year Written Work Requirement.

The required course paper may be combined with the Written Work Requirement. This applies to students who take the course as a 2L or a 3L. Students who know that they wish to choose this option should inform the Registrar and e-mail the instructor at phutt@cov.com.

Text: Hutt and Merrill, *Food and Drug Law* (2nd ed. 1991) and Statutory Supplement (1996).