HEGL 0204. FEDERAL FOOD, DRUG, AND COSMETIC LAW. (2 Credits)

This course is designed to examine legal and policy issues associated with the Food and Drug Administration's regulation of drugs and medical devices, foods and dietary supplements, cosmetics, and tobacco products. The class will review the statutory provisions of the Federal Food, Drug and Cosmetic Act, implementing regulations, and administrative actions that govern the development/formulation, product positioning and approval/clearance, and labeling/marketing of this broad range of products. We will also analyze governing case law and administrative decision-making by examining a variety of actions taken by the FDA in implementing the FFDCA. Students who are interested in life sciences will obtain a comprehensive overview of the historical background and current state of FDA, and will explore FDA's expanding authority over novel technologies, enforcement and inspection powers, and post marketing surveillance to address safety concerns.

HEGL 0206. LEADING AND DESIGNING HIGH PERFORMING AND TRUSTWORTHY ORGANIZATIONS. (2 Credits)

Course Goals
This course will cover various perspectives on leadership and how effective leaders balance trust and control and use elements of organization design to enhance performance defined more broadly to include economic, relational and moral dimensions. This course will focus on understanding the nature and function of the trustworthy organization to economic and social progress. A key element in the course will be to understand how leaders, who are educated in a new paradigm concerning how we define performance can make a difference to create trustworthy institutions. We will define trust, define stakeholders and seek to understand how trust is earned and sustained by various organizational actors and by the system as a whole. The course design will be structured and we will retain flexibility to bring in various guest speakers who are experts in one or more areas of trust.

Course Methods
The primary method of pedagogy in this class will be to combine readings covering various aspects of trust with application exercises to make the concepts usable and real. This will start with asking students to discern their own processes of discerning trust in their roles as investors, employees, customers and citizens. We will then explore research on trust and trustworthiness and concentrate on a model of the trustworthy organization. We will then apply this model to real organizations in teams to diagnose and make prescriptions for enhancing trust. The course will end with a series of “live cases” where we seek to understand and enhance trust in different companies. The degree of learning in the course will be evaluated (tested) as follows:

1. Team papers/projects (70% of grade).
2. Class participation (30% of grade).

HEGL 0230. DRUG REGULATION. (2 or 3 Credits)

This course critically examines how drugs and drug users are regulated in the United States by examining the laws and regulations employed to govern drug consumption and sale. Today, drug laws touch upon nearly every segment of society and every aspect of modern life, from regulations that prohibit smoking in public spaces and laws that allow for the consumption of marijuana for medicinal purposes, to laws that mandate long prison sentences for those convicted of certain drug offenses. Moreover, individuals of all income levels, from rural, suburban and urban areas, and from virtually every racial and ethnic group are subject to a dizzying array of drug laws. However, these laws differ in many critical respects, as do their social and demographic effects. This course explores the various regulatory mechanisms used to control consumption and sale of drugs, including criminal laws and penalties, the FDA drug approval process, civil litigation against drug manufacturers, patent laws, tobacco mass-tort litigation, and market-based strategies such as production subsidies and taxation.

Attribute: LAW J.

HEGL 0232. INTRODUCTION TO HEALTH LAW. (3 or 4 Credits)

Ensuring the health and welfare of citizens is one of the foundational aims of government, and this goal is facilitated by the enactment and enforcement of individual health law, public health law, and biomedical ethics. This course provides a basic foundation for legal practice in these important fields.

Health Law
Health law focuses on the relationship between health care providers and their patients and is shaped by concerns about: the obligation to provide care, the liability of healthcare institutions and providers; managed care and regulatory responses; informed consent and confidentiality; as well as issues of access, equity, choice, cost, and quality.

Public Health Law
Public health law focuses on the central tension between the state's regulatory powers to protect and promote the collective health, safety and well-being of its citizens; and an individual's constitutionally-protected rights to individual liberty, autonomy and property. Thus, this portion of the course examines such topics as compulsory testing and immunization; and the regulation of drugs and biotechnology.

Biomedical Ethics
A central focus of bioethics is the effect of new technology on the human body. This portion of the course will therefore cover the legal and regulatory ramifications of such topics as: physician-assisted dying, the right to refuse life-sustaining treatment, assisted reproductive technologies, genetic screening and technologies, human experimentation and research, organ transplantation and allocation, and reproductive surrogacy.

Attributes: INLJ, PIE.
HEGL 0262. MEDICAL MALPRACTICE LITIGATION PRACTICUM. (3 Credits)

This advanced practicum will give students the experience of handling a medical malpractice case from start to finish. Partnering with the Emergency Medicine Residency Program at St. Barnabas Hospital, the class will offer a unique interdisciplinary approach to litigation simulation by creating a realistic experience for law and medical students. The class will be structured around a single medical malpractice lawsuit with students acting as both plaintiff and defense counsel. Students will engage in all facets of the litigation process including client counseling, witness interviews, case evaluation, medical investigation, expert report development, pleadings, depositions, and, finally, a full mock trial. Real doctors, residents, and nurses will act as fact and expert witnesses. The defendant will be a current St. Barnabas resident and the plaintiff will be portrayed by a professional actor. Class time will include guest speakers, demonstrations, student performance, critique, and reflection. For exceptions to prerequisite, contact Professor Adam Shlahet directly.

Attributes: EXP, JD, LAW, LLM.
Prerequisites: EDGL 0202 and (CLGL 0419 or CLGL 0423).

HEGL 0290. HEALTH CARE LAW. (2 Credits)

The Patient Protection and Affordable Care Act signed into law in 2010 is set to transform health care in America and continues to foster intense debate. What are the social, fiscal, legal and political implications of PPACA and other health care initiatives? This course will take a comprehensive look at health care policy in this country, examining whether health care is a right, how differing views on this issue impact policy, the evolution of the health insurance system, the common problems associated with health insurance, PPACA’s sweeping changes to the system and whether the law will survive constitutional scrutiny. Students will review ERISA, COBRA, HIPAA, WCHRA, GINA and sections of PPACA. The course will include several guest speakers.

Attributes: INLJ, LLM, PIE.

HEGL 0292. HEALTH LAW AND BIOMEDICAL ETHICS. (3 Credits)

Bioethics focuses on issues that arise at the intersection of medicine, technology, science, and ethics. The law and policy are implicated by virtually all bioethics issues from the central tension between the state’s regulatory powers and individual autonomy, to issues of privacy, personhood, and the just and equitable distribution of scarce resources among members of the population. This course offers a broad survey of the legal and ethical issues that can arise in the state’s attempts to regulate personal behavior and the application of medical and biotechnological innovations. Thus, a central focus of this class will be the effect of new technology on the human body, as with reproductive technology, drug regulation, or genetic research. This course, therefore, covers the legal and regulatory ramifications of such subjects as: defining death, “test tube babies,” genetic technologies (including CRISPR gene editing), reproductive surrogacy, clinical trials, and human experimentation and research; along with the race, gender, sexuality, class, and ability status implications. Bioethics law is complicated by the fact that it lacks the same type of common law tradition that one finds in Torts, Contracts, or Constitutional Law. Indeed, this area of the law is replete with problems in need of solutions. Thus, we will examine whether the various issues emerging from biotechnology conflicts are best resolved by regulation, judicial intervention, or private negotiation.

Attributes: JD, LLM, PIE.

HEGL 0299. LAW & NEUROSCIENCE SEMINAR. (2 to 3 Credits)

This seminar examines a variety of cutting-edge, at times controversial, linkages between law and neuroscience, ranging from social and environmental influences on the brain and behavior to the interpretations of neuroimaging to the prediction of criminality and predispositions towards mental illnesses and addictions. Students will learn how discoveries in neuroscience intersect with societal responses, legal decision-making, the punishment of criminals, and the development of innovative rehabilitation strategies. The seminar’s primary format consists of a speakers series comprising some of the leading experts in the country – neuroscientists, psychologists, medical researchers, and lawyers – who will come and discuss their work and research so that the class can interact with them directly by way of questions or commentary. These discussions are aimed at helping students understand the neuroscientific basis for behavioral patterns that often have legal implications.

Attribute: PIE.

HEGL 0363. LAW & MEDICINE. (2 Credits)

This course combines the presentation of legal and scientific theory with practical examples and discussions. The legal theory of medical malpractice, is reviewed including such topics as physician’s standard of care, informed consent, current issues in physician malpractice, strategic approaches of plaintiffs as well as defendants to malpractice actions, discovery techniques, effective use of medical experts, and key elements of a medical malpractice trial. The course also will deal with the preparation and presentation of medical proof in civil and criminal cases. Study is also given to legal, medical, social and moral issues involved in the areas of right to treatment, human experimentation, organ transplants, allocation of scarce resources, euthanasia, and right to life.

Attributes: INLJ, LLM.

HEGL 0368. PSYCHOLOGY & CIVIL LAW. (2 or 3 Credits)

The role of psychologists and other mental health professionals in civil litigation is both diverse and important. This course covers a number of the areas in which psychologists consult on matters related to civil practice law forensic matters outside of the criminal arena. This course brings psychology graduate students and law students together in a broad overview of issues related to mental health law and civil practice. The semester will be divided relatively evenly between reviewing the case law and legal standards and the clinical issues that bear upon these legal issues. Through this course, law students will gain expertise understanding, utilizing, and responding to mental health testimony in civil litigation and psychology students will develop skills evaluating mental health issues that arise in these contexts. Specific legal issues discussed include the concept of torts and malpractice, causation, standards of proof, and expert testimony. We will focus on several of the areas of civil law in which psychologists play a significant role, including personal injury, sexual harassment, and disability law, as well as a number of issues that arise in elderly or medically ill individuals such as informed consent and decision-making competence, involuntary treatment and the right to refuse medications, physician-assisted suicide, testamentary capacity, and psychological autopsies. Issues such as psychological testing, report preparation and expert testimony are discussed in the context of these issues and the legal standards that apply.

Attributes: INLJ, PIE.
HEGL 0369. PSYCHOLOGY AND CRIMINAL LAW. (2 or 3 Credits)
This course is designed to provide an overview to the interaction between psychology and the criminal law. The focus will be primarily on the three major aspects in which psychologists are involved in the criminal justice system: competence to stand trial evaluations, mental state at the time of the offense (mens rea and the insanity defense), and the assessment of risk/prediction of future dangerousness. One of the guiding principles in forensic psychology, which will be reflected in this course, is the need to understand legal standards in order to tailor psychological knowledge and practice to the courts. As such, the content of the course will be evenly divided between understanding the legal issues involved and the practical application of psychological principals and knowledge. Likewise, readings and class time will be divided reviewing legal standards and case law and the psychological research, theories and techniques related to these issues. In addition, specific topics such as forensic psychological assessment, report writing, and expert testimony will be discussed.
Attributes: CEED, INLJ, JD, LLM, PIE.

HEGL 0371. ADVANCES IN HEALTHCARE LAW. (2 Credits)
Health Law has been a diverse, dynamic and growing field for many years. Since the change in administration and the proposed changes to the ACA along with rapidly evolving healthcare delivery models, new reimbursement methodologies, technological and biomedical innovation and the recognition of the role of social determinants of health the need for skilled healthcare attorneys well versed in these factors is essential. In addition a new practitioner in the field would also need to understand bioethical issues including reproductive health, human studies research and end-of-life care. The class will also focus on the medical-legal partnership movement. The Health Law field offers a diverse array of opportunities for attorneys interested in both the for profit and not for profit sector. In order to be well positioned for a career in Health Law, the student must be able to navigate this new healthcare landscape.
Attributes: INLJ, PIE.