

HEALTH LAW (HEGL)

HEGL 0113. R3. Law and Regulation in Biotechnology. (3 Credits)

This course serves as an introduction to the intricate legal and regulatory landscape governing the biotechnology industry. Students will explore the various legal frameworks that shape the entire life cycle of biotechnological products, from early-stage research to post-approval marketing and safety. The course will delve into essential topics, including the clinical trials process, good manufacturing practices, FDA approval requirements, and regulations concerning generics and biosimilars. Additionally, the course will survey the legal considerations on the business and financing side of biotechnology, covering intellectual property, funding mechanisms for research, material transfer agreements, other contractual arrangements, and various corporate structures.

HEGL 0203. Food Policy, Advocacy, and the Law. (2 Credits)

This class will explore the broad range of legal and policy issues that currently shape our food system through a series of readings, films and discussions. Topics will include the legal and policy underpinnings of the United States' and global food systems, the economic and social conditions giving rise to the inequities of access to adequate healthy food among certain sectors of the population, and the public health crisis that has ensued as a result. Class discussions will examine a range of current issues and explore ways to mobilize legal and policy tools in order to strategically respond to the issue identified in that week's readings. The goal of this class is for students to gain an understanding of the legal and policy underpinnings of the food system and to learn to creatively and collaboratively develop effective approaches to address the many complex issues that characterize—and threaten—it. Coursework will include assigned reading, legal and non-legal research and writing, and simulation exercises from which students will gain proficiency in the practical skills required to become effective food systems advocates. Student evaluation will be based on class participation, a short mid-term writing assignment and a final written submission. There will be no exams in this class.

Attributes: CORC, INLJ, LLM, PIE.

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 FFDC. 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 0221. Healthcare Law Affecting Physicians, Hospitals & Ancillary Healthcare Providers. (2 Credits)

The healthcare industry is one of the most significant components of the U.S. GDP, dominates political discussion and the national budget, and is regulated by a myriad of state and federal law. The class will reflect a survey of these legal and policy considerations, with particular emphasis on the primary healthcare providers in the marketplace: physicians, hospitals and ancillary providers. Students will gain an appreciation for the diversity of legal regulation applicable to healthcare providers, and the policy concerns that drive the applicable state and federal regulation. Course Structure: A two credit, seminar-sized course, meeting one day per week, with a final paper of 20 pages constituting 80% of the grade. The other 20% will be based on class participation (10%) and presentation of the final paper topic during last class session (10%). Guest speakers with applicable specialty knowledge and experience in the various subject matter will be invited to several classes.

Attributes: CRCP, LLM.

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 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 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 individuals' 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-aid in 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: HECH, 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, LIDR, LLM.

Prerequisites: EDGL 0202 and (CLGL 0419 or CLGL 0423).

HEGL 0290. Health Care Law. (2 Credits)

This course presents an in-depth overview of the US Health Care System, focusing on landmark cases, statutes, and policies, as well as key stakeholders in the system. Comprising an estimated one fifth of the nation's economy, the system impacts virtually every sector of contemporary society – from employers to government entities to insurers to biotechnology innovators, as well as patients, physicians, and hospitals – in the massive undertaking of providing for the health of the American people. <p> The course introduces students to a comprehensive approach for understanding, analyzing, and resolving the myriad legal issues related to health care practice and administration. Initial sessions examine the evolution of US health care and the historical forces that converged to bring about this unique system, as well as the challenges of access, price, quality, and equity that continue to plague the system. In addition, this semester we will spotlight the challenges of health care disparities and the controversy surrounding the recent Supreme Court Dobbs decision. The course next analyzes the major legislation and landmark cases that distinguish American health care, while highlighting the role of key stakeholders such as physicians, hospitals, and pharmaceutical companies in shaping the health care landscape. Specifically, we will evaluate the Affordable Care Act ("ACA"), explore "conscience clauses" through the Hobby Lobby case, and discuss HIPAA, HITECH, and GINA. Finally, imminent changes – hospital consolidation, physicians in 21st Century America, telehealth, the promise of genetic medicine and pharmaceutical breakthroughs, the impact of public health challenges such as COVID-19, and the role of private equity in health care services – will be analyzed. Upon successful completion of the coursework, students will have attained skills enabling them to successfully navigate the legal challenges associated with health care cases, to draft policies and legislative recommendations, and to devise effective strategies for addressing these complex issues. The class will be graded based on class participation and discussion, a presentation on a topical health care issue (35%), and a final paper providing a critical legal analysis of a topical health law issue (65%). Students may use the course to satisfy the Writing Requirement.

Attributes: INLJ, LLM, LWR, PIE.

HEGL 0292. Health Law and Biomedical Ethics. (3 to 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 healthcare law, public health law, and biomedical ethics. This course provides a foundation for legal practice in these three important fields. <p> Healthcare law focuses on the relationship between health care providers and their patients. It is shaped by concerns about the obligation to provide care; the liability of healthcare institutions and providers; health insurance and regulatory responses; informed consent and confidentiality; and issues of access, equity, choice, cost, and quality. <p> Public health law centers the tension between the state's regulatory powers to promote and protect the collective health, safety, and well-being of its citizens. It also addresses individuals' rights to liberty, autonomy, and property as implicated by state actions, including compulsory quarantine, testing, immunization, and organ donation. <p> Biomedical ethics is concerned primarily with the legal, political, and ethical issues that emerge from medicine, the life sciences, biotechnology, and biomedical research. These include reproductive technology, genetic screening, human research, and organ transplantation and allocation. This portion of the course will therefore cover the legal and regulatory ramifications of such subjects as defining death, "test tube babies," genetic screening and gene editing technologies, gestational surrogacy, human experimentation, and the right to die. <p> Classes will involve multimedia presentations, discussion of legal cases and academic articles, and presentations by practicing attorneys engaged in the fields of bioethics, public health, and health law.

Attributes: INLJ, JD, LLM, LWR, PIE.

HEGL 0299. Law and 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 0305. Pharmaceutical Law - Key Cases, Legislation & Regulations . (2 Credits)

The pharmaceutical industry is one of the most complex in America – evoking both high praise (e.g., rapid vaccine development during the COVID-19 crisis) and high criticism (e.g., ever-escalating prices for essential drugs) at the same time. Behind the complexity is a vast body of law designed to promote safe and effective medicines for the public. The goal of this course is to provide students with a foundation for understanding the scope of pharmaceutical law, by introducing them to key cases, major legislation and regulatory schemes that will enable them to practice in the industry. <p> This course is divided into three (3) units, each focusing on a particular area of Pharmaceutical Law. First, the spotlight is on the Drug Development Process, with focus on the Common Rule (45 CFR 46) and the Belmont Report, as well as the FDA regulations and the Food, Drug & Cosmetic Act. We will also examine key legal cases, including *Moore v. Regents* and *Abigail Alliance*, with its legacy of “Right to Try” laws. Next, the course will turn to key pieces of pharmaceutical legislation, including the Bayh-Dole Act, the Orphan Drug Act, and the Hatch-Waxman Act relating to generic drugs. The role of patent law will be explored through the *Myriad Genetics* case. Finally, the topic of approved drug products, marketing, pricing and products liability litigation will be studied through case law and statutes exploring “off-label use,” “advertising” and “patent bundling,” including the *Parke-Davis* and *Actavis* cases. <p> Upon successful completion of the coursework, students will have acquired a comprehensive understanding of the legal issues and challenges involved in the area of pharmaceutical law and will have developed skills and strategies for practicing in this area. The class will be graded based on class participation and discussion, final paper presentation (35%), as well a final paper analyzing a topical pharmaceutical law issue (65%). Students may use the course to satisfy the Writing Requirement.

Attributes: IPIE, LWR.

HEGL 0363. Law and 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 and 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, CETH, HECH, INLJ, JD, LLM, PIE.