HEALTH LAW, POLICY, AND BIOETHICS

Health law is a broad and exciting field that is not easily defined. There are, at least, three different, but overlapping, components to health law. First, the field is concerned with the provision of health care within the American health care system—the delivery, financing, and organization of personal medical services. Health care services consume a substantial part of the nation’s Gross National Product. The study of the health care system involves complex judgments about how to allocate health care services: access, equity, justice, quality, and cost. The United States has a highly eclectic health care system involving both private health care (e.g., managed care and fee-for-service) and public health care financing (e.g., Medicare and Medicaid).

Second, the field is concerned with bioethics—the ethically and legally appropriate way to structure myriad relationships among health care professionals and patients. Bioethics is concerned with micro-relationships between professionals and patients and concerns itself with enduring issues such as informed consent, confidentiality, and physician fidelity. Bioethics is also concerned with many interesting, emerging issues at the interface of law and society such as the human genome project.

Third, the field is concerned with public health. Public health law is concerned with the powers and duties of the state to assure the conditions for populations to be healthy. As a result, public health law is concerned with constitutional powers such as the police power and issues of federalism. Public health discusses many topics that are important to assuring healthy populations including tobacco, infectious diseases, and firearms.

The study of health law, policy and ethics, therefore, involves many subjects in a general legal education such as constitutional law, administrative law, local and government law. Scholars in health law also are also interested in specialized legal topics such as disability discrimination law and international law (notably human rights).

Georgetown has the most well regarded faculty and resources devoted to health law of any elite law school in the United States. Founded in 2007, the Linda and Timothy O’Neill Institute for Global and National Health Law aims to find innovative solutions for the most pressing health concerns facing the nation and the world through research, scholarship, and reflective engagement with partners in the public and private sectors. In addition to our own faculty, students can benefit from rich resources on our main campus: the Kennedy Institute of Ethics, the Program in Clinical Ethics, and the Institute for Health Care Research and Policy. Additionally, the joint degree program in law and public health with Johns Hopkins University is widely regarded as the best such program. The two Universities offer a combined J.D. and MPH. All in all, there is a world of opportunities for students interested in the related fields of health law, policy and ethics at Georgetown.

The Law Center has a vast array of courses in the fields of health law, policy and ethics. We have separated our offerings much as described above: health care financing, organization and delivery; bioethics; and public health. The upper class students will want to take the core classes in each of the respective areas of health law: Health Law and Policy and Public Health Law and Ethics.

Search Health Law Policy and Bioethics Courses (http://curriculum.law.georgetown.edu/course-search/?cluster=cluster_60)

LAW 3165 v00 Health Care Privacy and Security (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%203165%20v00)

LL.M. Seminar (cross-listed) | 1 credit hour
This course will explore the primary legal and policy principles surrounding the use and disclosure of personal data across the healthcare industry — the key privacy and security laws, regulations and principles that govern how the healthcare industry operates. We also will focus on the concepts surrounding the privacy of health information, and evaluate why this information should be treated differently than other personal information (if at all). We will learn through understanding the relevant legislative and regulatory provisions, and by applying a series of case/situation examples for class discussion. The overall goal of the course is to provide both an understanding of the relevant legal principles for health care privacy in general and to develop an ability to address how these issues arise in legal practice.

This course will emphasize the primary privacy and information security principles set out in the Health Insurance Portability and Accountability Act ("HIPAA") as a baseline framework for compliance, and will explore how these rules apply in theory and in practice. We will discuss the best approaches for overall HIPAA compliance. We also will explore emerging areas for privacy and information security, including new enforcement principles, issues related to security breaches and breach notification, and the emergence of "non-HIPAA" data as a new challenge to the privacy and data security regulatory structure (including important developments connected to the Dobbs decision and the COVID-19 pandemic). We will spend some time on issues related to privacy and medical research. We also will assess how these issues affect the business of healthcare, including a broad range of strategic and compliance issues affecting healthcare companies and others that use personal data. We will conclude with an analysis of these issues going forward — how the law and the health care system are changing and how the regulation of the privacy of personal health data can impact these developments.

Recommended: Information Privacy Law (recommended but not required)

LAW 534 v01 Access to Health Care and Coverage: Law and Policy (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20534%20v01)

J.D. Course (cross-listed) | 3 credit hours
The law governing access to health care has been in flux and in legal dispute in recent years. This course will examine America's programs for health care access and finance, including employment-based private insurance, Medicare, Medicaid, CHIP, and VA. The course will also examine the enactment, implementation, and litigation of the Affordable Care Act. In addition to these payment systems, the course will also at laws affecting non-comprehensive systems such as emergency rooms, public hospitals, and community health centers. No previous knowledge of health law is required.

Note: The course will not focus on biomedical ethics, medical malpractice, or pharmaceutical regulation.

This is a required course for the U.S. Health Law Certificate.
LAW 3166 v00 Access to Reproductive Healthcare Under the Law (How We Got to Dobbs and What’s Next?)

LL.M. Seminar (cross-listed) | 2 credit hours

The course will look at the treatment of reproductive rights in early America through the mid-1800’s and to the legalization of abortion. We will examine how we got from Roe v. Wade to Dobbs v. Jackson Women’s Health Care and discuss the legal and practical impact of the Supreme Court’s reversal of Roe, as well as state attempts to ban or restrict abortion. The course will directly address Institutional Learning Objective 8 by requiring students to think critically about the law’s claim to neutrality and its differential effects on subordinated groups, including those identified by race, gender, indigeneity, and class and consider whether one person’s moral or ethical position should prevail when that position has disparate negative impacts on marginalized communities.

We will look at how the law is intersecting with issues of race, sex, class, religion, sexual orientation, and politics to shape the culture of the country and our individual lives. The course will conclude with a review of the current legal battles relating to abortion, emergency contraception, assisted reproduction and gender affirming care, and discuss the legal theories at play, which are being used by both sides of the debate in competing iterations.

Prerequisite: Constitutional Law.

LAW 3091 v01 Addiction and Mental Health Law

LL.M Seminar (cross-listed) | 2 credit hours

According to a U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA) 2021 survey, nearly 1 in 3 adults had either a substance use disorder or a mental illness in the prior year, and 46 percent of young adults 18-25 had either a substance use disorder or a mental illness. Due to the increased prevalence of these chronic disorders, and their nexus to the public health crisis of suicide, opioid addiction, and homelessness, it is critically important for lawyers and advocates to have a strong understanding of behavioral health law from the constitutional to local regulatory level.

This course is a practice-based seminar that is designed to improve the students’ practical legal skills – writing, analysis, oral communication, issue spotting, and attention to detail – while examining key laws, legal decisions, and policies in Addiction and Mental Health Law. This seminar will explore the framework of laws and policies promoting human rights, dignity, and recovery for people with substance use disorders and mental health conditions. It will highlight systemic and community responses to addiction, mental health, and related social issues as well as the use of litigation, legislation, advocacy, grants and financial incentives as tools for prevention and reform.

Discussions will include:

- Institution-based issues such as the involuntary detention and civil commitments of individuals with a serious mental illness, restraint and seclusion, the right to appropriate treatment under Youngberg v. Romeo, institutional reform under 42 U.S.C. § 1983 and Monell v. Department of Social Services of the City of New York, and the Department of Justice’s authority under the Civil Rights for Institutionalized Persons Act;
- Forensic issues such as pretrial competency, Not Guilty By Reason of Insanity, and forced medication for competency purposes under Sell v. United States;
- Community-based issues such as deinstitutionalization, rights of an individual to receive services in the most integrated setting appropriate to their needs, housing discrimination, Medicaid, rulemaking and administrative adjudications under the Administrative Procedure Act, behavioral health provider licensure and regulation, and the False Claims Act;
- Federal and state/local initiatives such as 911 diversion programs and co-responder law enforcement teams, mental health courts and diversion, harm reduction strategies, e.g. decriminalization of fentanyl testing paraphernalia, federal State Opioid Response grants, rapid rehousing initiatives, and liberalization of 42 CFR Part 2 to facilitate increased information sharing for Substance Use Disorder treatment records;
- Understanding the Triple Aim in healthcare, data, outcome measures, and healthcare finance structures for behavioral health, including Medicaid and commercial insurance;
- Role of the health care and criminal justice systems and trends in reforms; and
- Cultural competence in legal advocacy and practice.

Guest lectures and discussion will provide real world case studies on laws and policy reforms impacting addiction and mental health.

Mutually Excluded Courses: Students may not receive credit for this course and Addiction and Mental Health Law and Policy.
LAW 3091 v00 Addiction and Mental Health Law and Policy (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%203091%20v00)
LL.M Seminar (cross-listed) | 2 credit hours
Addiction and mental health have increasingly become an integral part of the broader policy landscape. This shift has been accelerated by the impact of social issues such as the overdose epidemic, suicide and homelessness. This seminar will explore the framework of laws and policies promoting human rights, dignity, and recovery for people with substance use disorders and mental health conditions. It will highlight systemic and community responses to addiction, mental health, and related social issues as well as the use of litigation, legislation, advocacy and financial incentives as tools for reform.

Discussion will include:

- Evolution of responses to addiction, mental health, and related social issues;
- Human rights, deinstitutionalization and the rights of an individual to receive services in the most integrated setting appropriate to their needs;
- Statutory and regulatory frameworks promoting access to treatment, including the Patient Protection and Affordable Care Act;
- Understanding data, outcome measures, and healthcare finance structures for behavioral health, including Medicaid and commercial insurance;
- The role of litigation to promote accountability and protect civil rights;
- The impact of stigma, the dignity of risk, and harm reduction philosophy;
- Role of the health care and criminal justice systems and trends in reforms;
- The impact of globalization and comparative analysis of international drug policy;
- Cultural competence in legal advocacy and practice.

Guest lectures and discussion will provide real world case studies on laws and policy reforms impacting addiction and mental health.

LAW 1602 v00 Advanced Topics in Torts: Products Liability, Guns, and Drugs (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%201602%20v00)
J.D. Course (cross-listed) | 3 credit hours
This upper level course will cover the law of products liability generally and take a close look at the state of products liability litigation and liability in relation to guns and to opioids. The goal is to combine a survey of the complicated field of products liability law with a sophisticated deep dive into two areas of cutting edge products liability litigation. The first part of the course will familiarize students with major topics applicable to all products manufacturers including: a product distributor's liability for defect-caused harm, allocating responsibility inside and outside the commercial chain of distribution, causation, affirmative defenses, approaches to design defect litigation, and federal preemption of products liability claims. Later in the course, we will examine gun manufacturer liability, currently and prior to the passage of the Protection of Lawful Commerce in Arms Act, which reshaped the landscape of gun litigation. Finally, we will end with a consideration of the growing litigation related to the opioids, litigation inflicted by doctrines peculiar to prescription drug manufacturer liability. The final examination will be a self-scheduled 48 hour take home exam. Attendance and participation are crucial to the course, and significant credit will be given to those students who contribute thoughtfully and constructively to class discussion of cases and issues.

LAW 277 v02 Aging and Law Seminar (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20277%20v02)
J.D. Seminar (cross-listed) | 2 credit hours
This seminar explores, through lecture, discussion, role playing, and problem solving, the range of legal challenges and public policy issues affecting older adults. Subject areas include health care benefits (Medicare, Medicaid); long-term services and supports (nursing homes, home and community-based services, long-term care insurance, state-based programs); income security programs (Social Security, SSI); aging and autonomy, including elder abuse, neglect and exploitation and advance planning related to incapacity (powers of attorney, guardianship and its alternatives, choices regarding life-sustaining medical treatment); housing and consumer issues affecting older adults; and ethical issues in representing older adults. Coursework will address systemic inequities faced by older adults of color, older women, LGBTQ older adults, older adults with disabilities, and older adults who are immigrants or have limited English proficiency. The seminar is both practice- and policy-oriented and integrative with respect to other coursework and related disciplines.

Recommended: Prior or concurrent enrollment in one or more of the following courses: Administrative Law; Family Law I: Marriage and Divorce; Constitutional Law II: Individual Rights and Liberties; Professional Responsibility.
LAW 065 v02 Alternative, Complementary, and Integrative Medicine, The Legal Issues Seminar (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20065%20v02)
J.D. Seminar (cross-listed) | 3 credit hours
Alternative, Complementary, and Integrative Medicine (“non-traditional medicine”) (“CAM”) is the fastest-growing sector of American Health Care and is one of the fastest growing fields in the United States. Presently, at least 50 percent of Americans are using some form of alternative and complementary therapy such as acupuncture, nutritional supplementation, herbs, massage, yoga, chiropractic or homeopathy. According to the Journal of the American Medical Association in 1997, visits to alternative health care practitioners exceeded total visits to all conventional primary care physicians. The number of clinics and hospitals that integrate some modalities of CAM alongside conventional medicine is growing rapidly. The Institute of Medicine, a part of the National Academy of Sciences, has held recent conferences on the values of both CAM and Integrative Medicine. The NIH is using significant resources to fund research in this area.

This development, of course, is raising legal issues. There is a growing but still unsettled body of law on this subject. Some but not all CAM modalities are now licensed and regulated by at least some states. Federal regulatory bodies, such as the FDA and FTC are trying, within the limits of their statutory authority, to protect what they perceive to be the interests of the public. Yet, they come at the problem through conventional, rather than alternative, eyes. Conventional law is based upon protecting the public from purveyors of the proverbial “snake oil” frauds. And to an extent this law is being used to keep out alternatives to the established health-care modalities. This seminar studies the tensions, legal, economic, and social, of this struggle as it unfolds. This seminar covers several areas of law including administrative law, medical malpractice, informed consent, FDA/FTC law, licensure, among others.

A paper meeting the upperclass legal writing requirement is required.

LAW 1107 v00 Analytical Methods (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%201107%20v00)
J.D. Course (cross-listed) | 3 credit hours
Lawyers in every type of practice (corporate, litigation, government, public interest, etc.) routinely deal with problems that require a basic understanding of concepts and methods from economics and statistics. This course provides an introduction to these subjects and their application and relevance to law and legal practice. Topics covered include decision analysis, game theory, probability, and statistics. Grades will be based on a graded problem set and a take-home final examination. No prior background in economics or statistics is required; however, we will regularly use elementary algebra and geometry. Students with strong backgrounds in economics, mathematics, or statistics should consult with the professor before enrolling in the course.

Course Objective and Learning Outcomes: The objective of the course is to enhance students’ ability to give sound legal advice and make effective legal arguments by introducing them to selected concepts and methods from economics and statistics that are relevant to numerous areas of law and legal practice. These concepts and methods include: decision trees, expected value, sensitivity analysis, risk aversion, present value; Nash equilibrium, game trees, backward induction, subgame perfection, moral hazard, adverse selection; probability, conditional probability, independence, Bayes’ rule; descriptive statistics (including measures of central tendency and variability), hypothesis testing, confidence intervals, statistical significance, type I and type II errors, and regression analysis.

By the end of the course, I expect students to have a good understanding of these concepts and methods and to be able demonstrate a basic proficiency in applying them to: (i) unpack complex decisions of the kind that lawyers and their clients often encounter in litigation and transactions; (ii) analyze situations involving strategic interactions (i.e., situations where the outcome depends on the strategies and actions of multiple parties) of the kind that lawyers and their clients often encounter in litigation and transactions; and (iii) engage in probabilistic and statistical reasoning and evaluate probabilistic and statistical evidence of the kind that courts and lawyers often encounter in litigation.
**LAW 2028 v01 Assisted Reproductive Technologies and the Law**  
LL.M Seminar (cross-listed) | 2-3 credit hours  
This 2 or 3 credit seminar will provide an overview of the underlying and competing laws and policies arising from the assisted reproductive technologies (ARTs) that continually make front page news. Since the 1980 opening of the country’s 1st IVF clinic amidst protests and pickets, courts and legislatures have struggled to create laws and policies in response to continually evolving reproductive advances. Topics will include: the legal status of the IVF embryo in the context of procreative rights (highlighted by the currently changing and challenging legal context); embryo cryopreservation, storage, disposition and mix-ups; legal implications of advances in egg freezing, reproductive genetics and oncofertility; posthumous reproduction; egg and sperm donation; traditional/genetic and gestational surrogacy; unique issues for single and same-sex couples, including the impact of legally recognized same-sex marriage; and professional and regulatory aspects of the ARTs.

Two classes that will examine selected legal and policy aspects of comparative ART law perspectives on “third-party ART” and the impact these differences have on cross-border reproductive practices, with a particular focus on surrogacy.

National experts in their respective fields will provide guest lectures on: medical advances in ART; psychosocial aspects of donor egg and 3rd party ART; reproductive genetics; and potentially other emerging developments.

**Note:** This seminar requires a paper. J.D. students must register for the 3 credit section of the seminar if they wish to write a paper fulfilling the Upperclass Legal Writing Requirement for JD students. The paper requirements of the 2 credit section will not fulfill the Upperclass Legal Writing Requirement for JD students.

**LAW 1536 v00 Bioethics and Social Justice**  
J.D. Seminar (cross-listed) | 2 credit hours  
This seminar explores legal, ethical, and social issues raised by developments in health, medicine, and the biological sciences at the U.S. and global levels. It first provides an overview of the normative theories that inform the development of the field of bioethics, as well as connects these theories to legal and social dynamics that continue to shape discussions of equity and justice. It then considers a spectrum of priority topics and themes, through both a theoretical and practical lens, such as end-of-life issues, reproductive rights, human subjects research, access to medicines, and vaccines. Students will develop an in-depth perspective on how law and ethics overlap and shape the discourse on these priority topics. This seminar will be especially informative for students looking to obtain a practical view into how the law interacts with ethical dilemmas in health, medicine, and science.

**Learning Objectives:**

- Describe the normative theories that inform the development of the field of bioethics and the role that the law has played in this evolution
- Describe practical examples of legal and ethical dilemmas that arise across multi-disciplinary topics in health, medicine, and the biological sciences
- Articulate the ethical arguments on often opposing sides of priority bioethical issues, understanding the varied levels of nuance involved
- Analyze the role of legal institutions and law and in creating a framework to address the ethical, legal, and social issues that arise in the fields of health, medicine, and the biological sciences
LAW 1536 v01 Bioethics and Social Justice (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%201536%20v01)
J.D. Seminar (cross-listed) | 1 credit hour
This seminar explores legal, ethical, and social issues raised by developments in health, medicine, and the biological sciences at the U.S. and global levels. It first provides an overview of the normative theories that inform the development of the field of bioethics, as well as connects these theories to legal and social dynamics that continue to shape discussions of equity and justice, including on the global stage. It then uses several in-class simulations to explore the practical challenges—both legal and ethical—that arise for counsel practicing in this field. The simulations are designed for students to “step into the shoes,” as it were, of different actors, from in-house counsel at an academic medical center to the United States Ambassador to the United Nations, to gain practical insight into real-world situations. This seminar will be especially informative for students looking to obtain a practical view into how the law interacts with ethical dilemmas in health, medicine, science, and politics.

Learning Objectives:

• Describe the normative theories that inform the development of the field of bioethics and the role that the law has played in this evolution
• Describe practical examples of legal and ethical dilemmas that arise across multi-disciplinary topics in health, medicine, and the biological sciences
• Articulate the ethical arguments on often opposing sides of priority bioethical issues, understanding the varied levels of nuance involved
• Analyze the role of legal institutions and law and in creating a framework to address the ethical, legal, and social issues that arise in the fields of health, medicine, and the biological sciences

Note: Withdrawals are permitted up until the last class for this specific course.

LAW 3038 v00 Biosecurity and the Law (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%203038%20v00)
LL.M Seminar (cross-listed) | 2 credit hours
This course is designed to provide students an understanding of current and emerging issues concerning biosecurity and relevant law. Recent global acts of terrorism coupled with sophisticated advances in biotechnology present a host of complex issues driving biosecurity analysis and discussion. We will examine both the history and current state of bioterrorism threats with an emphasis on the legal and ethical challenges as we “sort out” best methods for moving forward. Our analysis will explore the recent Zika and Ebola threats as well as the threats posed by prior H1N1, SARS, anthrax, smallpox, SARIN, Ricin, and even the possibilities stemming from genetically engineered once thought “dead” bio-threats. Our method of instruction will focus on significant legal challenges each week. We will however, use past examples of quarantine and cordon sanitaire applications to instruct as how best to legally address future possible pandemics. Within our course exercises, students will be assigned healthcare and legal roles in order to gain insight as to management of a true healthcare crisis. Guest speakers with knowledge of crisis management will be invited to share personal experiences and advice concerning future pandemics. We will also examine recent legislation, both domestic and international, with a view toward a better understanding of the complex challenges within biosecurity.

LAW 1789 v00 Biotechnology and the Law Seminar (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%201789%20v00)
J.D. Seminar (cross-listed) | 3 credit hours
This is a survey class, examining issues ranging from drug regulation, clinical trials, assisted reproductive technology, telemedicine, and stem cell development/regulation to the commercialization of the human body. For this class we will use the Biotechnology, Bioethics, & The Law Casebook (Goodwin, et. al., eds). This course requires substantial reading, preparation, organization, and the ability to analyze subtle nuances between various judicial decisions, legislative enactments, ethics, and legal rules, which sometimes may seem in conflict.

In this class, we will examine whether emerging biotechnological conflicts are best resolved by regulation, judicial intervention, or private negotiation. Professor Goodwin encourages robust dialogue. As such, students should come to class prepared with their ideas, intuitions, and opinions. Their analysis should demonstrate a grasp of the materials. Students are expected to discuss the materials, act responsibly toward their peers, as well as conduct themselves in a professional manner. There are no prerequisites for this course. However, students must be prepared for rigorous discussions and substantial reading assignments. This course is a building block for the other courses in ethics, health law, and a law and science curriculum, including Patents, Food & Drug Law, Health Regulations, and Bioethics. The core competencies expected in this class are critical thinking and the application of social, legal, moral, and economic reasoning.

Much of the reading assigned for class will be covered during discussion. However, some assigned readings may not be covered given limited class time. Nonetheless, students are responsible for all reading materials. The readings include excerpts from medical journals, regulations, cases, newspapers, and social science periodicals.

Course Goals

The goals of this course are to:

• Introduce students to the study of biotechnological developments, health policy, and ethics;
• Familiarize students with the medical and legal literature on the topic;
• Engage students with practical as well as theoretical ideas in biotechnology law;
• Stimulate intellectual curiosity about the subject matter;
• And inspire critical thinking and thoughtful analysis.
The course will take a pragmatic approach to exploring the rights and activities provided by government entities, and public accommodations. Against people with disabilities in employment, the programs, services, or health infrastructures in colonized lands were subverted and colonial health services were designed primarily to protect the health of European and American personnel who were essential to upholding the colonial economy. (Zeinabou Niamé Daffé et al, 2021)

COVID-19 has demonstrated that the modern global health systems, built on the foundations of colonialism, continue to perpetuate practices and laws that often result in inequitable access to health services and products, and unequal enjoyment of the right to health. Created on the foundations of tropical medicine. The Special Rapporteur on the Right to Health, Dr. Tlaleng Mofokeng, has made decolonizing human rights in global health an integral part of her mandate and to that end has proposed the idea of a forthcoming Lancet O’Neill Commission on Racism and Structural Discrimination in Global Health Law.

The course will provide a historical context to students of the impact of racism and colonization on modern day global health. It will examine the historical role of the law in entrenching racially discriminatory health law and policies, and examine the opportunities for reform through the work of the forthcoming Lancet O’Neill Commission on Racism and Structural Discrimination in Global Health, co-chaired by Dr. Tlaleng Mofokeng and Dr. Ngozi Erondu.

This course covers the Americans with Disabilities Act, its amendments, regulations, and interpretive guidance as they relate to discrimination against people with disabilities in employment, the programs, services, or activities provided by government entities, and public accommodations. The course will take a pragmatic approach to exploring the rights and responsibilities arising from this law and will focus on such issues as defining disability, the concept of qualified persons with a disability, reasonable accommodations, medical exams and disability-related inquiries, program access, and public accommodations.

This course focuses on the tax and ERISA aspects of employer-sponsored health and welfare benefit plans. The tax discussion will concentrate on the conditions for favorable tax treatment of health and welfare benefits (and other statutory fringe benefits), the cafeteria plan rules, the applicable nondiscrimination requirements, and the special rules applicable to funded welfare benefits. The ERISA discussion will focus on plan design, reporting and disclosure, claims procedures, and fiduciary duty rules. The course will integrate the tax, labor and public policy aspects of the Affordable Care Act and other health care reforms.

Prerequisite: Federal Income Taxation.

Mutually Excluded Courses: Students may not receive credit for this course and Health and Welfare Benefit Plans: Tax & ERISA Aspects.

Note: This course is part of the following graduate programs: Health Law LL.M. Taxation LL.M.

This course is required for the Employee Benefits Certificate. Students may not withdraw from this class after the add/drop period ends without the permission of the professor.

This course surveys the law regulating the fundamentals of the employee-employer relationship and examines a variety of public policy questions relating to employment standards regulation. The subjects covered may include: the common law doctrine of at-will employment and the development of contract and tort exceptions to that doctrine; statutory efforts to protect employees from wrongful discharge; the law of work-related invasions of privacy (e.g., drug-testing, genetic screening, polygraphs, etc.); the National Labor Relations Act; the regulation of employment compensation (e.g., Fair Labor Standards Act, prevailing wage laws); the regulation of workplace health and safety (e.g., Occupational Safety and Health Act). This course may also cover the Worker Adjustment and Retraining Notification Act, the Family Medical Leave Act, and workers compensation.

This course covers the key laws developed to control pollution. The main focus of the course is on current statutes, including the National Environmental Policy Act, the Clean Water Act, the Resource Conservation and Recovery Act, the Superfund Act (CERCLA and SARA), and the Clean Air Act. Other statutes, such as the Oil Pollution Act, as well as climate change, are addressed briefly. Common law and pre-1970s efforts to develop law to obtain control are also reviewed. Relying on their practical experience, the instructors address application and interpretation of the statutes, Congressional actions to extend and modify the statutes, regulatory implementation of the statutes by executive agencies, enforcement policy and practice, the role of states, citizens’ groups and industry, and private efforts at clean-up. The professors use problems to help students understand the practical application of the statutes in real-world contexts.

Strongly Recommended: Prior or concurrent enrollment in Administrative Law.
LAW 146 v08 Environmental Law
This course focuses on legal strategies to regulate and remedy environmental harms. The course is designed to prepare transactional lawyers, regulatory lawyers, government counsel and litigators, as well as students interested in specializing in environmental law. A major goal of the course is to introduce students to the analytical skills necessary to understand and work in this and other predominantly statutory and regulatory fields. The course starts by reviewing economic, ecological and historical perspectives on protection of the environment. We also briefly cover common law environmental claims. We then turn to several cross-cutting public environmental law issues, namely discussion of regulatory design choices, federalism issues, a brief introduction to important administrative law concepts, cases, and doctrine, and analysis of the role of citizens as enforcers under US environmental laws. We then turn to in-depth analysis of key portions of several of the most significant federal environmental laws, including hazardous waste cleanup laws, the National Environmental Policy Act (NEPA), the Endangered Species Act, the Clean Air Act, and the Clean Water Act. We will also look at the developing body of law regarding climate change.

LAW 146 v10 Environmental Law
Between New Year’s Day in 1970 and December of 1980, Congress enacted virtually all of our major federal environmental statutes. To this day, these laws form the core of this country’s approach to addressing environmental problems. All of the laws aim to achieve cleaner water, air, and land, while at the same time taking very different approaches to doing so. This course will introduce you to the major federal statutes on environmental protection, including but not limited to the Clean Air Act, the Clean Water Act, and the Superfund law. You will come to understand the basic regulatory goals and mechanisms of these laws. You will also learn how one might choose among these goals and mechanisms in fashioning environmental policy. Ideally, you will come away with an informed judgment about how far we have come in protecting the environment and how far we still have to go.

Recommended: Administrative Law or a first-year elective on legislation and/or regulation.

LAW 754 v01 Epidemiology for Lawyers
Increasingly, lawyers and policymakers are confronted with the need to evaluate scientific research about causes of good or ill health. Should the family of a person who was exposed to asbestos and later died of lung cancer sue? At what level should mercury in tuna violate regulatory standards? What measures can be employed to control the spread of an Ebola outbreak or to prevent obesity? Will mandatory quarantines save lives if a bioterrorist releases anthrax in a major city?

This class will provide students with a basic toolset in public health’s empirical methods. Disciplines such as epidemiology, risk assessment, and biostatistics provide ways to systematically evaluate proposed policy and search for answers in the quest for better health. To illustrate how these methods are deployed in practice, we will discuss case studies from the Ebola epidemic in West Africa, Zika virus, Middle East Respiratory Syndrome (MERS), and novel avian influenza, among others. We will also examine US domestic health issues that engage questions of law, policy, and democracy.

Students who successfully complete this class will not be trained to be professional scientists. However, students will be able to:

1. Understand fundamental epidemiological concepts;
2. Interpret health data and research;
3. Critically evaluate empirical claims;
4. Identify when assistance from health experts is required; and
5. Apply learnings to the development of policy and laws.

Lawyers with training in epidemiology will be able to more effectively respond to emerging and persistent issues in our complex society, whether they practice in health law, torts, environmental regulation, law enforcement, or human rights.

Note: In the Spring 2022 semester, this course will take place online via Zoom.

Not intended for MPH students. No prior knowledge of Epidemiology is assumed. WEEK ONE COURSE. This course will meet for one week only on the following days: Monday, January 10, 2022 through Thursday, January 13, 2022, 1:30 p.m. - 4:50 p.m. This course is mandatory pass/fail and will not count toward the 7 credit pass/fail limit for J.D. students. ATTENDANCE IS MANDATORY AT ALL CLASS SESSIONS. Enrolled students must be in attendance at the start of the first class session in order to remain enrolled. Waitlisted students must be in attendance at the start of the first class session in order to remain eligible to be admitted off the waitlist. All enrolled students must attend each class session in its entirety. Failure to attend the first class session in its entirety will result in a drop; failure to attend any subsequent class session in its entirety may result in a withdrawal. Enrolled students will have until the beginning of the second class session to request a drop by contacting the Office of the Registrar, a student who no longer wishes to remain enrolled after the second class session begins will not be permitted to drop the class but may request a withdrawal from an academic advisor in the Office of Academic Affairs. Withdrawals are permitted up until the last class for this specific course.
LAW 530 v00 Federal Legislation Clinic (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20530%20v00)
J.D. Clinic | 10 credit hours
Please see the Federal Legislation Clinic website (https://www.law.georgetown.edu/experiential-learning/clinics/federal-legislation-clinic) for more detailed information about the program.

For registration-specific supplemental materials, please see the Federal Legislation Clinic PDF (https://georgetown.app.box.com/s/rtxa9wd6240fjkQ7anfuq6zm4e6bpzy).

For information about clinic registration, please see the Clinic Registration Handbook (https://georgetown.app.box.com/s/0ehc9a8928jpbteghs0uz7s6j9e5y8).

Mutually Excluded Courses: Students may not concurrently enroll in this clinic and an externship or a practicum course.

LAW 1844 v00 Federal Regulation of Biopharma: Commercial Considerations, Risk Identification and Mitigation (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%201844%20v00)
J.D. Seminar (cross-listed) | 2 credit hours
This seminar provides an overview of the principal legal issues impacting the commercialization, sale and marketing of biopharmaceutical products. It:

- Provides an overview of the structure and operation of the biopharmaceutical industry, including manufacturers of innovator and generic products;
- Explores the principal laws governing the sale and marketing of biopharmaceuticals, including relevant portions of the Federal Food, Drug, and Cosmetics Act, the False Claims Act, and the Federal Anti-Kickback Statute;
- Explores how these laws create liability for both biopharmaceutical companies and their executives for the manner in which such companies price, report prices on, communicate about, and interact with regulators and health care providers about their products;
- Addresses industry-specific government investigations, risk assessment, and compliance efforts; and
- Concludes with a table-top exercise in which students role play a government investigation.

LAW 1834 v00 Follow the Science? Medicine in the Law’s Crossfire (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%201834%20v00)
J.D. Seminar (cross-listed) | 2-3 credit hours
More than ever, parties to bitterly-contested legal and political questions invoke medicine to support their side. Abortion, LGBTQ rights, criminal responsibility, racial equity, and vaccines and other measures against COVID-19 are among the areas of conflict that have drawn medical science and judgment into the mix. Often, physicians have been eager participants, sometimes going beyond what science shows. Such participation has a long, oft-troubling history: biomedical expertise has been invoked to identify witches, “prove” the inferiority of racial and ethnic groups, and block women’s access to educational and professional opportunity. This seminar will explore advocates’ use and abuse of medical science and judgment from America’s founding to the present, with an eye toward distinguishing between what courts, political leaders, and parties to conflict should and shouldn’t call upon medicine to do. Students can take this seminar for 3 credits (to satisfy the Upper Class Writing Requirement), or 2 credits (by writing a shorter, unsupervised paper).

Note: This seminar requires a paper. J.D. students must register for the 3 credit section of the seminar if they wish to write a paper fulfilling the Upperclass Legal Writing Requirement. The paper requirements of the 2 credit section will not fulfill the J.D. Upperclass Legal Writing Requirement.

LAW 1208 v00 Food Law Seminar (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%201208%20v00)
J.D. Seminar (cross-listed) | 2-3 credit hours
This seminar introduces students to the laws and regulations that govern our food. The seminar will focus mostly, but not exclusively, on the federal regulatory framework for food. Topics will include the legal definition of food, rules on food labeling, standards for food safety, provisions for food security, and regulation of the environmental consequences flowing from the agricultural practices that produce our food. Beyond the law itself, we will consider the scientific, economic, and ethical principles implicated by legal decisions concerning food.

Note: This seminar requires a paper. J.D. students must register for the 3 credit section of the seminar if they wish to write a paper fulfilling the Upperclass Legal Writing Requirement. The paper requirements of the 2 credit section will not fulfill the J.D. Upperclass Legal Writing Requirement.
This course will provide an introduction to the legal contexts and theoretical debates surrounding sex, gender, sexuality, and their intersections. We will explore the ways in which gender and sexuality have been debated, defined, and redefined in the contexts of gender identity and performance, sexual pleasure, reproductive rights, sexual violence, marriage, family organization, work, and education. In these contexts, we will consider the evolution of the law, the discursive effects of law, and the ways in which feminist and queer theorists have challenged and reimagined prevailing legal rules and cultural norms. In short, the class will probe the ways in which law is gendered, sexualized, and raced, and with what overall effects on social institutions and practices.

Key topics will include:

- The Mutual Influence of Identitarian Politics and Law
- Constitutional Law of Sex Equality, Liberty, and Religious Objection
- Regulation of Sexual Conduct
- Regulation of Reproduction
- The Evolving Meanings of Marriage & Family
- Sexual Harm & Consent
- Gender & Sexuality at Work, School and other Institutions

Strongly Recommended: Constitutional Law II.

Mutually Excluded Courses: Students may not receive credit for this course and Sexual Orientation and the Law: Selected Topics in Civil Rights.

LAW 3028 v00 Global Drug Law and Regulation (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%203028%20v00)
LL.M Seminar (cross-listed) | 2 credit hours
Globalization and the international trade of drugs and medical products have progressed beyond any single regulatory authority’s ability to effectively ensure the quality, safety, and effectiveness of these products. In the U.S., the importation of foreign sourced products has increased tremendously, accounting for over 80% of the active pharmaceutical ingredients. However, varying drug regulations have resulted in gaps in oversight causing differing views on the acceptable level of risk in public health leading to drug quality related deaths and other serious harms. One clear reason for this compromised system is the differences in how these products are regulated from country to country. Nevertheless, the pharmaceutical and related industries are thriving in the global marketplace. This course is intended to be the first comparative survey into the regulatory frameworks of certain key countries, both developed and developing markets, along with international institutions, such as the World Health Organization, involved in promoting the access and development of safe, effective and quality medical products. This course will also identify the major international non-governmental stakeholders, and the multi-lateral schemes and treaties in which they operate that are intended to assist in the convergence of pharmaceutical laws and regulations.

LAW 493 v01 Global Health Law (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20493%20v01)
LL.M Seminar (cross-listed) | 2 credit hours
Global Health Law is the flagship course offered by Georgetown University Law Center’s O’Neill Institute for National and Global Health Law. This course is open to both Georgetown JD and LLM students and is compulsory for students in the National and Global Health Law LLM and the Global Health Law and Governance LLM.

The survey course explores the roles that the law, lawyers, and legal institutions play in public health across the globe. Global health law encompasses international law and policy that directly or indirectly affects health, including treaties, regulations, strategies, and expert guidelines. This course provides a strong foundation in these instruments, laws and policies, including topics such as governance of the World Health Organization, Universal Health Coverage, the International Health Regulations, the role of the UN Special Rapporteur on Health, and the proposed accord on global pandemic preparedness. The course also explores comparative national approaches to health governance, law, and policy.

The course is divided into three modules. Module 1 covers the foundations of global health law, providing overviews of public international law, international human rights law, international trade law, and the intersections between intellectual property law and health. Module 2 covers health systems and governance, including the World Health Organization, and public health ethics and principles. Module 3 addresses the human right to health and other key emerging topics in health law such as environmental law and health, the global campaign for Universal Health coverage, and the use of litigation to advance the right to health. The course culminates in students presenting proposals to reform international law to better protect and promote global and public health outcomes.

Students will hear from leading voices in global health law and benefit from the expertise of the O’Neill Institute for National and Global Health Law, as well as other resources at Georgetown University and in the broader Washington, DC community.

Course Goals/Student Learning Outcomes

1. Knowledge of the substantive foundations of global health law, including public international law; human rights law; global health governance; the interface between international trade and intellectual property law and health; and principles of public health law.
2. Knowledge of the legal issues related to a range of global health challenges, including access to health care and prevention and control of non-communicable diseases and infectious diseases.
3. Knowledge of the various roles that lawyers can play in advancing global health, including legal drafting, negotiating, litigation, and advocacy for law reform.
4. Ability to use various skills relied upon by global health lawyers, including legal research, analysis and writing, strategic thinking, and communication.

Recommended: Prior enrollment in International Law I.

Note: Required for the Global Health Law LL.M.
In this intensive course, students will work with faculty and fellows at the O'Neill Institute for National and Global Health Law to gain an in-depth understanding of global health law through intensive examination and role play of one or more major problems in global health. Potential problems could include a naturally occurring infectious disease epidemic such as extensively drug resistant tuberculosis; a future epidemic such as pandemic Influenza (A) H5N; an intentional introduction of a lethal pathogen such as anthrax; and/or major chronic diseases caused by obesity or tobacco use. Students should come to this course with a basic level of understanding of global health law, including the major international health treaties and governing structures. When studying and role playing these kinds of problems, students will be asked to construct innovative methods of global health governance, drawing upon existing international health law and institutions, along with a vision for more ideal models. The course will also capitalize on materials developed in collaboration with faculty from the School of Nursing and Health Studies for use in the “health care situation room”.

Full attendance and participation is required at all sessions. Class sessions will consist of a combination of lecture, case simulations, and discussion. Grades are based on student participation, a daily journal to be kept by students, and a final paper.

**Note:** A student will be permitted to drop a course that meets for the first time after the add/drop period, without a transcript notation, if a student submits a written request to the Office of the Registrar prior to the start of the second class meeting. Withdrawals are permitted up until the last class for this specific course.

**ATTENDANCE IS MANDATORY AT ALL CLASS SESSIONS.** Enrolled students must be in attendance at the start of the first class session in order to remain enrolled. Waitlisted students must be in attendance at the start of the first class session in order to remain eligible to be admitted off the waitlist. All enrolled students must attend each class session in its entirety. Failure to attend the first class session in its entirety will result in a drop; failure to attend any subsequent class session in its entirety will result in a withdrawal. Enrolled students will have until the beginning of the second class session to request a drop by contacting the Office of the Registrar; a student who no longer wishes to remain enrolled after the second class session begins will not be permitted to drop the class but may request a withdrawal from an academic advisor in the Office of Academic Affairs. Withdrawals are permitted up until the last class for this specific course.

This course analyzes the subject matter of global health security as it is shaped by international agreements and national implementation and preparedness laws. As societies and economies are increasingly interwoven and interdependent, new forms of health security threats have arisen, and nations are now contending with such implications through established agreements like the International Health Regulations (2005), a draft new pandemic agreement, and various forms of “soft power” diplomacy to mitigate infectious disease risks. In recent years, the realm of health security has expanded greatly with more governments, companies, and NGOs working to solve problems and pursue opportunities. Most prominently, the COVID-19 pandemic has shattered existing paradigms of stability and security, with ramifications from the global perspective down to that of nearly every world citizen. Over an immersive weekend of overview and interaction, this course highlights prominent threat categories, namely the “3-D threats” of Disaster, Disease, and Disorder. This seminar will be devoted as an active legal laboratory in which student ideas are solicited and shaped with the participation of the class.

The objective of the course is to crystallize student understanding at the international, national, and local legal level, the perspective viewed by national and organizational leaderships, and to frame student thinking by developing a broad, contextual understanding of the situation of health security. The course will draw connections between direct experience with purposeful intent through class exercises. Practical frameworks will be employed to simplify the dynamics within complex situations, and to organize student thinking about actions and options. An overnight simulation activity assessing a humanitarian crisis between the first and second day invites analysis about cause-effect, goals-intentions, and interventions-consequences. Two special guest speakers will share experiences on the policy frontlines, further enriching classroom dialogue. The course relies on active participation that feeds a mutual learning environment and that catalyzes and reveals students’ ideas as they occur, thereby fostering an at-the-ready style of nimble thinking and conversing.
LAW 183 v03 Health and Human Rights (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20183%20v03) (Project-Based Practicum)
J.D. Practicum | 4 credit hours
This course explores the potential of using the law, and specifically, the human rights legal framework, to improve health. Students will be exposed to real life projects at the domestic level in a number of different jurisdictions, especially but not exclusively from Latin-America and Africa; as well as at the regional and international level, including the Inter-American Human Rights System and the United Nations Human Rights System. With this approach, students will strengthen not only their knowledge of the human rights framework within their familiar jurisdictions, but will also have the opportunity to develop comparative legal research skills.

The human rights framework that students will learn in depth in this practicum is not limited to the right to health but involves other related human rights that are also social determinants of health or that are instrumental to the effective realization of the right to health. Therefore, students will be exposed to the substantive expertise needed to successfully practice the strategic use of the integrity of the human rights framework in the specific context of health. Students will also be required to consider the use of other legal frameworks that have the potential of having a positive impact on health outcomes.

The variety of projects will take into consideration the complexity and different dimensions of the right to health as well as the nature of the legal obligations that it imposes in different contexts. We will offer projects that respond to current and pressing global challenges with respect to health, for example, projects exploring the right to health and other rights in the context of public health emergencies, the link between health and the environment, the structural disadvantage that specific groups face with respect to their health and the role of private actors, to name a few.

For the execution of their projects, students will work with external partners of the O’Neill Institute for National and Global Health Law, in particular, the Health and Human Rights Initiative. (“HHRI”).

Prerequisite: J.D. students must complete the required first-year program prior to enrolling in this course (part-time and interdivisional transfer students may enroll prior to completing Criminal Justice, Property, or their first-year elective).

Mutually Excluded Courses: Students may not concurrently enroll in this practicum course and a clinic or another practicum course. Students may concurrently enroll in this practicum course and an externship.

Note: This practicum course is open to LL.M. students, space permitting. Interested LL.M. students should email the Office of the Registrar (lawreg@georgetown.edu) to request admission.

Evening students who work during the day are encouraged to reach out to the professor to discuss whether this practicum course would be compatible with their schedules. This is a four-credit course. Two credits will be awarded for the two-hour weekly seminar and two credits will be awarded for approximately 10 hours of supervised project work per week, for a minimum of 11 weeks. Both the seminar and the project work will be graded. Students who enroll in this course will be automatically enrolled in both the seminar and project components and may not take either component separately. After Add/Drop, a student who wishes to withdraw from a practicum course must obtain permission from the faculty member and the Assistant Dean for Experiential Education. The Assistant Dean will grant such withdrawal requests only when remaining enrolled in the practicum would cause significant hardship for the student. A student who is granted permission to withdraw will be withdrawn from both the seminar and project components. Default attendance rule for all practicum courses (unless the professor indicates otherwise).

LAW 1028 v00 Health Care Fraud and Abuse Seminar (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%201028%20v00)
J.D. Seminar (cross-listed) | 2 credit hours
One-fifth of the U.S. economy centers around health care industry sectors. This seminar examines criminal, civil and administrative tools used by federal and state enforcement authorities to police the U.S. healthcare system. We will focus on cases brought under federal and state False Claims Acts (FCA), the Anti-Kickback Statue (AKS), Stark laws, Federal Food Drug and Cosmetic Act (FDCA), and Foreign Corrupt Practices Act (FCPA). The seminar provides a survey of the enforcement activities of the U.S. Department of Justice (DOJ), the Office of Inspector General at Department of Health and Human Services (OIG), and state Medicaid Fraud Control Units (MFCUs) in matters against pharmaceutical and medical device manufacturing companies, physicians, hospitals, clinical practices, nursing homes, laboratories, and others. The seminar materials thoroughly cover the statues, safe-harbors, and regulations that govern the health care industry. We will also discuss risk mitigation strategies and compliance program best practices across industry sectors to provide insight into the impact enforcement has on (1) clinical decision-making, (2) costs to providers, payers, and patients, (3) patient safety, and (4) quality of care. In an effort to maintain a broad perspective with the diverse and frequently changing legal landscape in the area, in addition to the case book, materials discussed and presented in this course draw from news reports, trade publications, and U.S. government agency materials.

The class requires a paper of approximately 20-25 pages in length.

Recommended: Criminal Justice (or Democracy and Coercion) or Criminal Procedure.

LAW 206 v03 Health Care Law and Policy (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20206%20v03)
J.D. Course (cross-listed) | 4 credit hours
This course is Georgetown Law’s introduction to the law and policy of health care provision and financing. No single course can serve as a comprehensive introduction, and this class won’t try. Rather, we’ll consider central themes and selected topics, with an eye toward the larger questions that drive legal, political, and ethical conflict in the health sphere. We’ll begin with some context – the non-medical determinants of health, which have much greater influence on population-wide health than does clinical care. We’ll then turn to the idea of a right to health care, then to the roles of markets and government in making care available and containing medical costs. Next up will be an introduction to the Affordable Care Act, with an eye toward its conceptual framework, its critics’ core objections, and the main problems that it has left unresolved. We’ll examine some of the legal conflicts that have arisen over the ACA, then turn to brief introductions to several other areas of health care law, including medical malpractice, antitrust, and the role of for-profit v. non-profit institutions. We’ll finish with consideration of racial disparities in health care and tension between medicine’s clinical and social roles.

COVID-19 has put a spotlight on our medical care system’s shortcomings, as well as the social inequities that shape Americans’ health and well-being. Our nation’s response to COVID will thus play a substantial role in this year’s edition of the course – as both a matter of national urgency and a window onto these shortcomings.
LAW 3140 v00 Health Equity and Social Justice (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%203140%20v00)

LL.M Seminar (cross-listed) | 2 credit hours
This course will examine the social, legal, and economic systems in the United States that have precipitated health inequities for different populations throughout history. Students will develop an intense understanding of U.S. public health law and policy constructs and the varied social determinants of health that affect public health outcomes by exploring how past and current U.S. law and policy perpetuate disparities. This course will also explore how legal and policy reform can be utilized to promote health equity and eliminate injustices across populations. Topics covered in the course include health disparities in the U.S. among LGBTQ, immigrant, rural, and minority populations; substance use policy; maternal and child health; and environmental health. The course will utilize various learning modalities such as research review, discussion, case studies, and guest lecturers. By the conclusion of the semester, students will be equipped with tools to leverage the law to improve health outcomes and the skills necessary to become successful practitioners working at the intersection of public health administration and law.

LAW 2037 v00 Health Information Technology and the Law (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%202037%20v00)

LL.M Seminar (cross-listed) | 2 credit hours
Health care decision-making and innovation are increasingly driven and made possibly by vast stores of data. The importance of data has created an inevitable push-pull dynamic between concern for confidentiality and demands for medical progress and cost containment. Data is both a privacy risk and a tremendous asset. This course will explore the legal and ethical issues at the intersection of health information, including where data comes from, how it is used and should be protected, how it can be used, and risks to its integrity and security. In doing so, this course will cover a range of topics including health information privacy, future use of data assets, and conflicts of interest.

Note: This course is part of the following graduate programs: Master of Law and Technology Technology Law & Policy LL.M.

LAW 627 v00 Health Justice Alliance Law Clinic (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20627%20v00)

J.D. Clinic | 10 credit hours
Please see the Health Justice Alliance Law Clinic website (https://www.law.georgetown.edu/experiential-learning/clinics/health-justice-alliance-clinic) for more detailed information about the program.

For registration-specific supplemental materials, please see the Health Justice Alliance Law Clinic PDF (https://georgetown.app.box.com/s/e40877jbidxouzrd4hm80w7tk7yc).

For information about clinic registration generally, please see the Clinic Registration Handbook (https://georgetown.app.box.com/s/0ehca9a8928phq5gsh0uz7s60j9e5y88).

Mutually Excluded Courses: Students may not concurrently enroll in this clinic and an externship or a practicum course.

LAW 2076 v00 Health Law and Regulation (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%202076%20v00)

LL.M Course (cross-listed) | 3 credit hours
Beyond health insurance and the delivery of health care, goods and services related to individual and public health are highly regulated in the United States, and often serve as a basis for international regulations. These goods and services are a large and growing part of the U.S. and world economy, with some estimates being that more than one-quarter of U.S. food and medical products are regulated by the FDA alone. This regulation is carried out directly by a variety of State and Federal agencies (such as the FDA, the CDC, and the NIH) as well as indirectly through the purchasing power of federally financed programs, such as Medicare.

This course will include an introduction to the basic legal and regulatory frameworks within public health and an overview of the Constitutional limits and policy choices that have led to current law. The course will then move to a review of several major fields of regulation. From a high-level, this includes the regulation of health professionals, health systems, and medical or food products impacting human health. The course will then conclude with an examination of several contemporary problems, such as the safe and effective use of human drug products, infectious-disease prevention and control, ethical research practices, and rationing and allocation of limited resources.

The primary objective of the course is to teach students about the regulation of public health at the intersection of state and federal levels, recognizing that such regulatory frameworks often become the template for international policies. Students will be called on to learn the basics of two fundamental statutes—the Public Health Service Act (PHSA) and the Food, Drug and Cosmetic Act (FDCA). Students will also be called upon to follow examples of administrative change under these statutes, each year analyzing a new set of proposed regulations and sub-regulatory guidance documents. By the end of the course, students will be able to describe the major means by which goods and services used in both personal and public health are controlled, as well as areas in which future changes are likely.

Currently, there is no text or case book on this subject. The primary readings will be assigned by the professor.

Note: This is a required course for the US Health Law Certificate.
Health Law, Policy, and Bioethics

LAW 1828 v00 Health, Law and Islam
LL.M Seminar (cross-listed) | 2 credit hours
The Muslim view is that the origins of Islamic legal code are rooted in the Muslim holy text (the Quran) and Sunna (the portion of Muslim law based on the prophet Mohammed's words or acts), and it is this jurisprudence that gives Islamic religious practice its connection and sustainability in everything including health law and policy. This seminar provides an overview of where Islam as a rule of law and global health intersect through subject specific segments. The seminar will start by exploring Islamic law and the history of healthcare under Islamic law and move into segments that discuss food hygiene jurisprudence, prophetic medicine as Sunna, bioethics and Islam, mental health and Islamic law, migrant health and Islamic law, and finally sexual, reproductive and human rights under Islamic law. It presupposes the Quran and Sunna as the legal documents and where relevant, the seminar will discuss comparative aspects to western perspectives. This seminar supports the notion that global health law is part of a growing health diplomacy where it becomes vital to understand key aspects of how culture and religion can influence health, policy and the law locally and globally.

LAW 1286 v00 Human Trafficking and Modern Slavery in the 21st Century: Legal Perspectives
J.D. Seminar (cross-listed) | 2 credit hours
Slavery has been a phenomenon that has existed since before written history, yet it is only in the last 200 years that efforts to abolish it have gained traction. Today, increasing mobility, global supply chains, and continued social discrimination have created the environment for ongoing human exploitation, even though the formal practice of chattel slavery, or the legal ownership of one human being by another, is illegal virtually everywhere. Indeed, some estimate that there are more slaves today than at any other time in human history. Most recently, efforts to eliminate severe forms of human exploitation are being made under the banner of ending human trafficking (or more formally, trafficking in persons).

This course will provide students an overview of the multiple legal perspectives on combating human trafficking and modern slavery. This will include the definitional tensions between different perspectives, alternative approaches to addressing severe human exploitation, and an overview of the current U.S. legal framework for eradicating human trafficking and modern slavery and its weaknesses. Attention will be paid to commonly recognized principles in human rights, criminal and labor law, but also in such areas as corporate responsibility and immigration law. The class will use a range of materials, including international treaties, decisions of international and foreign tribunals, and more familiar U.S. statutory materials and legislative history (such as committee reports).

Learning Objectives:
At the conclusion of the class, students should be able to

• recognize many of the forms of and pervasive nature of human trafficking and modern slavery;
• identify risks of human trafficking and modern slavery in most areas of practice they may choose in the future; and
• have familiarity with emerging issues in the area of human trafficking and modern slavery.

Recommended: A prior course in public international law or international human rights.

Mutually Excluded Courses: Students may not receive credit for both this seminar and Human Trafficking in International and Transnational Law.
**LAW 3145 v00 Indigenous Health Law and Access to Health Care**

(http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%203145%20v00)

LL.M Seminar (cross-listed) | 1 credit hour

Internationally the United Nations recognizes indigenous peoples and their special rights associated with identity and culture. Many countries have formal systems intended to support indigenous peoples with instruments of law, policy, and custom. This course will examine those international instruments, treaties, court cases, and Congressional acts to explore what it means for the Right to Health to exist, the ways that right is recognized among indigenous peoples, and major shortfalls in achieving equity through these paths. American Indians and Alaska Natives (AIAN) experience serious health disparities in key morbidity/mortality indicators. AIANs are also a bell-weather subgroup in the US for unusual disease such as bubonic plague or the rapid dissemination of novel infectious disease such as happened among tribes in the covid-19 pandemic. In addition to risk and vulnerability that contribute to health disparities, sovereign nation status of the 573 federally recognized tribes in the US and the Indian Health Service that serves them are particular structures shown to mitigate despair and promote future well-being in remarkably difficult circumstances. There are unique laws, operations, and tensions that undergird these structures. Recent actions to strengthen treaty obligations and extend equity movements to indigenous peoples are gathering energy to address health and justice disparities.

This course focuses on the laws and systems foundational to access to care and health services for Indigenous peoples in the US. The course will include discussions on self-determination, sovereignty, funding, social determinants of health, inter-generational trauma and additional elements of Indigenous health law in the US and the Indian Health Service that serve these other Indigenous health systems particularly those in Canada, Australia and New Zealand.

The course is designed to provide practical skills for students interested in health equity and justice, Indigenous access to care, Indigenous health law, and policy implementation. The course illuminates, in particular, outcomes of shared American history and distinctive obligations, systems, and opportunities to address ethnic disparities.

**Learning Objectives:**

By the end of this course, students will be able to:

- Identify and interpret relevant authorities and limitations that underpin Indigenous access to health care
- Identify and understand specific regulations, guidance, and laws applicable to providing health care to US tribal governments
- Gain knowledge on the right to self-determination
- Master vocabulary and terminology associated with Indigenous rights and health law
- Understand the linkage of national health systems to the United Nations including the UN Permanent Forum on Indigenous Issues; and UN Declaration on the Rights of Indigenous Peoples
- Compare and analyze legal instruments and structures from other countries, including New Zealand, Australia, and Canada with the United States

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**LAW 3114 v00 Industry Epidemics: NCDs, Commercial Risk Factors and the Law**

(http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%203114%20v00)

LL.M Seminar (cross-listed) | 2-3 credit hours

This seminar will examine the role of law and policy in addressing modifiable risk factors that contribute to the rising prevalence of non-communicable diseases (NCDs). Risk factors to be addressed include: tobacco use, unhealthy diets, and the harmful use of alcohol. Materials and discussions will probe questions such as: What are the best regulatory practices to deal with NCDs risk factors? How do transnational corporations contribute to the spread of non-communicable diseases? How different international legal regimes come into play in addressing risk factors? What are the opportunities and challenges of using law & policy to address NCDs’ commercial risk factors? Throughout this course we will have opportunities to consider how law and policy shape contemporary legal discussions related to NCDs, such as tobacco plain packaging, alcohol sponsorship, childhood obesity, commercial speech and food labelling, and targeted marketing strategies.

The course will take a global approach grounded in constitutional law and different international legal regimes (WTO, Human Rights Systems – Regional & Universal—, among others). The course will explore how the rise in NCDs prevalence in both developed and developing countries is mainly driven by transnational corporations, globalization and foreign direct investment. Additionally, case studies will explore a variety of examples from jurisdictions spanning the United Kingdom, South Africa, and Latin American countries, including taxes to discourage consumption of unhealthy products, laws restricting advertising and promotion, and laws and policies to promote access to information to consumers.

Students will be equipped with an understanding of specific issues, such as the role of law compared with policy, the strengths and weaknesses of different regulatory strategies and the role and responsibilities of the relevant industries in promoting the right to health. After exploring a series of foundational themes and issues through the first half of the course, the remainder will focus on in-depth case studies and experiences in regulating the risk factors from a comparative perspective and future challenges.

This seminar requires attendance and participation in seminar discussions, preparation for class, writing response posts, and the submission of a final paper.

**Course goals:**

- Understanding of the various risk factors contributing to non-communicable diseases (NCDs).
- Understanding of various models of regulation of NCDs risk factors.
- Understanding of complex risk factors regulatory issues across various constitutional systems and international legal regimes.
- Understanding the interaction between regulation of NCDs risk factors and issues like gender and freedom of speech.
- Understanding the role of transnational corporations in the increased prevalence of NCDs.

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**Recommended:** Administrative Law; Federal Indian Law.
**LAW 233 v01 Intellectual Property and Medicines**

This course examines the special legal and policy issues arising from the use of intellectual property rights in the pharmaceutical and biotechnology fields. The course will cover: (1) U.S. case law impacting intellectual property, patents, trademarks and copyrights in drugs and biologics; (2) the interplay of the regulatory approval process for therapeutic products with intellectual property rights; (3) the Hatch-Waxman Act and its impact on how patent rights for pharmaceuticals are procured and enforced; and (4) major legislative developments affecting the use of intellectual property rights in the drug, biotechnology and medical device fields, such as the Biologics Price Competition and Innovation Act of 2009 and the America Invents Act of 2011. Other topics may be included depending on current judicial or legislative developments. A background in biologics or pharmaceuticals is not required, although completion of a basic patent law or a food and drug law course is recommended.

Students will have the option of taking this course for either two or three credits. The three credit option will require a paper that satisfies the upperclass legal writing requirement in compliance with Law Center regulations. The two credit option will require completion of a final paper or of several shorter legal writing samples on student-selected or assigned topics.

**Strongly Recommended:** Prior or concurrent enrollment in a basic patent law course or food and drug law course is highly recommended.

**Note:** This seminar requires a paper. J.D. students must register for the 3 credit section of the seminar if they wish to write a paper fulfilling the Upperclass Legal Writing Requirement. The paper requirements of the 2 credit section will not fulfill the J.D. Upperclass Legal Writing Requirement.

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**LAW 145 v00 International Environmental Law**

The course focuses on international law applicable to the leading environmental and natural resource issues. It provides a framework for identifying and addressing the legal issues, links international law with relevant national laws, and focuses on ways to strengthen compliance with international obligations. The course covers climate change, ozone depletion, transboundary pollution and hazardous waste disposal, fresh water (both surface and ground water), marine resources, biodiversity, the links between human rights and environment and between environment and trade, and the financing of sustainable development. Special attention is given to cutting edge issues, such as synthetic biology and ecocide as an international crime.

Learning goals for this course: To enable students to become effective counsel, litigators, negotiators, arbitrators, judges, or legal advisors on a broad range of international environmental problems; to understand international instruments and negotiations; and to be able to apply legal concepts developed in the course within different national settings for implementing international law.

**Recommended:** International Law I: Introduction to International Law

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**LAW 227 v04 International Human Rights**

This course examines the law, institutions, and advocacy strategies designed to protect international human rights. We will analyze civil and political rights and economic and social rights, as well as international humanitarian law, and explore key enforcement mechanisms at the national, regional, and international levels. The evolving role of NGOs and civil society actors in advancing human rights, and the responsibility of corporations, will also be examined. Both progress and enduring challenges in making human rights real "on the ground" will be a focus of this course, together with the need for effective enactment of legal standards, enforcement of those standards, and empowerment of affected communities. Current legal issues and strategies concerning climate change and human rights will also be highlighted.

**Recommended:** International Law I: Introduction to International Law.

**Mutually Excluded Courses:** Students may not receive credit for both this course and the graduate course, International Human Rights Law.

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**LAW 3006 v00 International Right to Health**

The course provides an introduction to the human right to health and its implementation in a few hot topic issues. Issues covered will include criminalization of drug use and sexual and reproductive health, vulnerable groups, HIV/AIDS, the intellectual property regime and access to medicines, and a critique of the current framework and the challenges that impede the realization of the human right.

**Recommended:** Introductory course in public international law or human rights, introduction to public international law and/or introduction to human rights

**Note:** ATTENDANCE IS MANDATORY AT ALL CLASS SESSIONS. Enrolled students must be in attendance at the start of the first class session in order to remain enrolled. Waitlisted students must be in attendance at the start of the first class session in order to remain eligible to be admitted off the waitlist. All enrolled students must attend each class session in its entirety. Failure to attend the first class session in its entirety will result in a drop; failure to attend any subsequent class session in its entirety may result in a withdrawal.

Enrolled students will have until the beginning of the second class session to request a drop by contacting the Office of the Registrar; a student who no longer wishes to remain enrolled after the second class session begins will not be permitted to drop the class but may request a withdrawal from an academic advisor in the Office of Academic Affairs. Withdrawals are permitted up until the last class for this specific course.
This course explores the legal, regulatory and policy issues that shape the government and industry response to the COVID-19 pandemic. We will explore these issues using real-world examples, including innovation, including patent, regulatory and data exclusivity; tort liability and medical devices in the United States. We will consider the history and research, development, and commercialization of drugs, biologics, and medicinal products. We will also examine the role of federal regulation of medical technologies; legal and ethical issues and its function in the regulation of the life sciences industry; and other issues we will explore these issues using real-world examples, including the government and industry response to the COVID-19 pandemic.

**Recommended:** Prior or concurrent enrollment in Administrative Law.

**Note:** This is a required course for the Food and Drug Law Certificate.

**LAW 520 v00 International Women's Human Rights Clinic**

(J.D. Clinic | 10 credit hours)

Please see the International Women's Human Rights Clinic website (https://www.law.georgetown.edu/experiential-learning/clinics/international-womens-human-rights-clinic) for more detailed information about the program.

For registration-specific supplemental materials, please see the International Women's Human Rights Clinic PDF (https://georgetown.app.box.com/s/rg9mhjfda1jrp86a5bvhctvzjgc8lnt).

For information about clinic registration generally, please see the Clinic Registration Handbook (https://georgetown.app.box.com/s/3y9f8w3jvqyqynevij3ytjfl6j9j9v6).

**Mutually Excluded Courses:** Students may not concurrently enroll in this clinic and an externship or a practicum course.

**LAW 199 v03 Law and Regulation of Drugs, Biologics and Devices**

(J.D. Course (cross-listed) | 3 credit hours)

This course explores the legal, regulatory and policy issues that shape the research, development, and commercialization of drugs, biologics, and medical devices in the United States. We will consider the history and role of federal regulation of medical technologies; legal and ethical issues in the development and testing of new therapies; managing incentives for innovation, including patent, regulatory and data exclusivity; tort liability and its function in the regulation of the life sciences industry; and other issues. We will explore these issues using real-world examples, including the government and industry response to the COVID-19 pandemic.

**Note:** This is a required course for the Food and Drug Law Certificate.

**LAW 915 v00 Law, Healthy Lifestyles, and Business Regulation**

(LL.M Seminar (cross-listed) | 1 credit hour)

This course is about legal responses to tobacco use, obesity, poor diet, harmful use of alcohol and sedentary lifestyle – the leading causes of preventable disease in the United States, in high-income countries generally, and increasingly, in developing economies. Cancer, heart disease, stroke, diabetes and tobacco-related diseases (known as “non-communicable diseases” or NCDs) are society’s greatest killers, but what can law do – and what should it do – to prevent and manage them?

Unlike other global health threats, NCDs and their risk factors are partly the result of consumer choices and transactions lived out every day across the country. The challenge of creating healthier lifestyles cannot be separated, then, from the regulation of those businesses that too frequently have a vested interest in unhealthy lifestyles.

Law’s relationship with tobacco, alcohol and food is complex and contested. Nevertheless, governments around the world are experimenting with a wide range of legal strategies to encourage healthier lifestyles. This course places U.S. developments in a global and comparative context, offering comparisons with legal strategies for encouraging healthier lifestyles in Australia and other countries.

During the course, we will confront some important over-arching questions. What are the global determinants of NCDs, and how are these diseases being managed, globally? What do the global solutions look like? To what extent should law intervene to influence the behavior of populations – as distinct from treating lifestyle-related risk factors as the personal responsibility of each individual? Does a regulatory approach to the prevention of NCDs imply coercion? Does it signal the emergence of a “nanny state”? Do legal approaches to reducing NCD risks necessarily depend on motivating people to consciously change their lifestyles, or can laws embody different strategies? Is it possible to regulate business without micro-managing or dictating commercial decisions and “legislating the recipe for tomato ketchup”?

Most people want to live longer and healthier lives. Yet no country can achieve this without addressing the preventable risk factors that drive non-communicable diseases. This course gives students the conceptual tools to think powerfully about law’s role in the prevention of NCDs, and to participate effectively in debates about appropriate, workable, legal interventions.

**Note:** WEEK ONE COURSE. This course will meet for one week only on the following days: Monday, January 08, 2024 through Thursday, January 11, 2024, 9:00 a.m. - 12:20 p.m.

This course is mandatory pass/fail and will not count toward the 7 credit pass/fail limit for J.D. students. ATTENDANCE IS MANDATORY AT ALL CLASS SESSIONS. Enrolled students must be in attendance at the start of the first class session in order to remain enrolled. Waitlisted students must be in attendance at the start of the first class session in order to remain eligible to be admitted off the waitlist. All enrolled students must attend each class session in its entirety. Failure to attend the first class session in its entirety will result in a drop; failure to attend any subsequent class session in its entirety may result in a withdrawal. Enrolled students will have until the beginning of the second class session to request a drop by contacting the Office of the Registrar; a student who no longer wishes to remain enrolled after the second class session begins will not be permitted to drop the class but may request a withdrawal from an academic advisor in the Office of Academic Affairs. Withdrawals are permitted up until the last class for this specific course.
LAW 3047 v00 LGBTQ Health Law and Policy
(http://curriculum.law.georgetown.edu/course-search/?keyword=LAW %203047%20v00)
LL.M Seminar (cross-listed) | 2 credit hours

Course Description

Despite progress in legal protections for LGBTQ+ and non-binary people, and in the face of recent setbacks, LGBTQ+ communities continue to face systemic obstacles to quality health care such as coverage, refusals of care, substandard care, lack of access to culturally competent care, discrimination, and inequitable policies and practices in health care settings. These experiences correlate with significant health disparities, including greater exposure to sexual, institutional, and state violence, higher rates of tobacco and other substance use, mental health concerns, HIV and other infectious diseases, and cancer. These disparities are even more pronounced for LGBTQ+ people who are also members of other groups that face discrimination because of race, ethnicity, or other aspects of identity—such as Black, Indigenous, and other People of Color, young and older people, people with disabilities, people with low incomes, and immigrants, among others.

In this seminar, students will learn about LGBTQ+ health law and policy issues from a variety of perspectives—including medicine, public health, public benefits, health insurance, social determinants of health, and U.S. foreign policy—and gain a better understanding of the legal and social mistreatment of LGBTQ people at both the individual and community level and its impact on health. Topics covered will include health care access, LGBTQ-inclusive data collection, clinical and cultural competency, disability rights, reproductive justice, and health issues facing LGBTQ+ youth and older adults. This course will also examine how LGBTQ+ individuals and families are treated under federal, state, and international law, and how these policies impact access to health care and contribute to health disparities.

Course Goals & Student Learning Outcomes

The primary objective of the course is to teach students about health disparities faced by LGBTQ+ communities, to identify the laws and policies that contribute to these health disparities, identify legal and policy measures to reduce those disparities, and to discuss emerging issues and topics that affect LGBTQ+ peoples’ health. Through this course, students will learn about the impact that federal, state, and international laws and policies have on LGBTQ+ health, including speakers who are actively working in the LGBTQ+ community at nonprofits, Capitol Hill, and government agencies. Past speakers include attorneys from the NAACP Legal Defense and Education Fund, Lambda Legal, National Center for Transgender Equality, the National Immigration Law Center, and the Presidential Advisory Council on HIV/AIDS.

This seminar will help students develop critical thinking skills and will provide a clearer understanding of how federal, state, and international laws and policies impact LGBTQ+ health. The course will also highlight how lawyers can use the tools of law (e.g., litigation, legislation, regulatory action) to advance health justice and equity amid a rapidly changing legal and political environment.

LAW 593 v00 National and Global Health Law: O'Neill Colloquium
(http://curriculum.law.georgetown.edu/course-search/?keyword=LAW %20593%20v00)
J.D. Seminar (cross-listed) | 2-3 credit hours

In this interdisciplinary colloquium, leading national and international scholars in a range of domains will explore fundamental normative and policy problems of contemporary concern in health law. Topics will include health care, public health, global health, science, regulation, politics, ethics, and policy. The colloquium will have participants from across the Georgetown University campus among faculty, senior administration, and students, as well as participants in the Washington health policy and legislative community.

Each seminar session will focus on a presentation by, or structured dialogue with, distinguished guest speakers. Students from the Law Center and other schools within Georgetown University (including Nursing and Health Studies, Medicine, Arts and Sciences, Foreign Service, Business, and other graduate programs) will be expected to prepare for intensive discussions in which experts, faculty and students explore, analyze and deepen their understanding of issues selected for consideration each month. The colloquia will be open to other students and faculty members across Georgetown University as well as interested members of the public, particularly professionals working in health law and policy in Washington.

Mutually Excluded Courses: Students may not receive credit for this course and Pandemics, Global Health, and the Law Seminar.

Note: This seminar requires a paper. J.D. students must register for the 3 credit section of the seminar if they wish to write a paper fulfilling the Upperclass Legal Writing Requirement. The paper requirements of the 2 credit section will not fulfill the J.D. Upperclass Legal Writing Requirement.
Proper nutrition is one of the many contributor's to overall health and could be one of the most cost-effective approaches to address many of societal, environmental and economic challenges facing the world today. Increasingly, law and policy has been recognized as a high-impact and robust approach for accelerating progress toward reducing and managing nutrition-related chronic diseases such as obesity, cardiovascular disease, type 2 diabetes mellitus and certain types of cancer. In various jurisdictions, policymakers enact courses of action, regulatory measures, laws and policies, and set funding priorities designed to address food insecurity, hunger, obesity prevention, chronic diseases, among other health and well-being concerns. This course focuses on policies, programs and practices across the globe—at the national, tribal, state and local levels—that improve or hinder healthy eating. Students will examine the evidence informing these courses of action, along with the historical and contemporary legislative, regulatory and judicial aspects. Topics and themes include dietary guidance, food and nutrition assistance programs, food and nutrition labeling, and other environmental and policy strategies to improve access to healthier foods and beverages.

Student Learning Goals:

- Identify key law and policy approaches used across the globe that have been used or have the potential to improve or hinder healthy eating;
- Discuss and debate the historical and contemporary legislative, regulatory and judicial aspects of the key nutrition law and policy approaches during collaborative in-class exercises; and
- Execute analytical and strategic planning for developing, implementing, evaluating, and sustaining a nutrition law and policy approach during in-class exercises and as part of the mid-term and final projects.

Recommended: Constitutional Law, Property, Contracts, Torts, as well as Food and Drug Law, Introduction to Health Law, and Land Use and Planning.

**LAW 2099 v00 Nutrition Law and Policy**

LL.M Seminar (cross-listed) | 2 credit hours

In a project-based practicum course, students participate in a weekly seminar and work on a project under the supervision of their professors. This course explores the challenges and opportunities of using law to address risk factors that contribute to the rising prevalence of NCDs, such as unhealthy diets, tobacco use, and alcohol consumption. By taking an international and comparative approach, it navigates the theory behind the regulation of risk factors to NCDs in relation to concrete examples from around the world, with a particular emphasis on Latin America, where considerable progress has happened in recent years. Students will participate in a two-hour/week seminar and carry out 10 hours/week of project work under the direction of the course professors.

SEMINAR: In every class, students will learn substantive content and develop lawyering skills, leading to a comprehensive understanding of the role of law in relation to risk factors to NCDs, including in policy, advocacy, and litigation. Specifically, students will be introduced to NCDs (definition, risk factors, and global burden); understand the role of corporations as drivers of NCDs; learn about regulations to address NCDs, such as pricing and taxation, labelling and packaging, and restrictions to marketing and advertising; and explore the strengths and weaknesses of regulatory, advocacy, and litigation approaches to NCDs. In navigating these topics, students will develop a set of lawyering skills, including generating and using evidence, monitoring policy, building coalitions, conducting scenario-planning, engaging decision-makers, segmenting audiences, and framing arguments.

PROJECT WORK: On the experiential/field-work side, students will work with external partners of the O'Neill Institute for National and Global Health Law (and the newly created Global Center for Legal Innovation Food Environments) on legal and policy projects related to NCDs and the law. For example, students may draft alternative reports to UN bodies analyzing compliance with human rights obligations related to unhealthy diets, tobacco use, or alcohol consumption (e.g., “shadow reports”). Such a report could analyze the prevailing legal frameworks in a particular country and highlight strengths and weaknesses in the statutory and regulatory language. By working with the O'Neill Institute and civil society organizations, the course gives students the opportunity to use law to address critical health challenges.

**Prerequisite:** J.D. students must complete the required first-year program prior to enrolling in this course (part-time and interdivisional transfer students may enroll prior to completing Criminal Justice, Property, or their first-year elective).

**Mutually Excluded Courses:** Students may not concurrently enroll in this practicum course and a clinic or another practicum course. Students may concurrently enroll in this practicum course and an externship.

**Note:** This practicum course is open to LL.M. students, space permitting. Interested LL.M. students should email the Office of the Registrar (lawreg@georgetown.edu) to request admission.

Evening students who work during the day are encouraged to reach out to the professor to discuss whether this practicum course would be compatible with their schedules. This is a four-credit course. Two credits will be awarded for the two-hour weekly seminar and two credits will be awarded for approximately 10 hours of supervised project work per week, for a minimum of 11 weeks. Both the seminar and the project work will be graded. Students who enroll in this course will be automatically enrolled in both the seminar and project components and may not take either component separately. After Add/Drop, a student who wishes to withdraw from a practicum course must obtain permission from
LAW 3020 v00 Pan-Epidemics and PHEICs: COVID-19, EBOLA, and What’s Next? (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%203020%20v00)

LL.M Seminar (cross-listed) | 1 credit hour
This course will focus on the legal, public health and medical challenges presented by ongoing pandemics and epidemics, most notably COVID-19, as well as preparedness for future pandemics through the lens of the “One Health” paradigm—an integrated 3-part framework that takes into account the health of humans, animals, and the environment.

The course will address the legal response to epidemic disease, focusing particularly on the World Health Organization’s International Health Regulations (IHR), including the process for deciding whether to declare a Public Health Emergency of International Concern (PHEIC) (including historical examples of COVID-19, Ebola, Zika, MERS, Yellow Fever, polio, pandemic influenza, and more). It will also look at other legal mechanisms for pandemic preparedness, such as the Pandemic Influenza Preparedness Framework and examine reforms to global governance for health emergency preparedness that have been proposed as a result of the COVID-19 pandemic.

Prof. Lucey will provide his personal perspective based on on-the-ground work in responding to Ebola, COVID-19, Zika, MERS, SARS Flu, Plague, and more. This work overseas led to his proposal in 2014 to create an Exhibition on Global Epidemics at the Smithsonian Museum of National History, which opened in 2018 and has been extended to 2022 to add COVID-19. The class will include a tour of this exhibit.

The course will be discussion-focused, including readings, videos, interactive lectures, and classroom outbreak simulation (“tabletop”) exercises. During these exercises students will be given a fact pattern and assigned a role (e.g., the WHO Director-General, US Centers for Diseases Control and Prevention (CDC) officials, NGOs, etc.) and asked to negotiate with others and reach agreement.

Note: ATTENDANCE IS MANDATORY AT ALL CLASS SESSIONS. Enrolled students must be in attendance at the start of the first class session in order to remain enrolled. Waitlisted students must be in attendance at the start of the first class session in order to remain eligible to be admitted off the waitlist. All enrolled students must attend each class session in its entirety. Failure to attend the first class session in its entirety will result in a drop; failure to attend any subsequent class session in its entirety may result in a withdrawal.

Enrolled students will have until the beginning of the second class session to request a drop by contacting the Office of the Registrar; a student who no longer wishes to remain enrolled after the second class session begins will not be permitted to drop the class but may request a withdrawal from an academic advisor in the Office of Academic Affairs. Withdrawals are permitted up until the last class for this specific course. This course is mandatory pass/fail and will not count toward the 7 credit pass/fail limit for J.D. students. Grading is based on participation in the final simulation exercise (no papers or exams).

LAW 1781 v00 Pandemics, Global Health, and the Law Seminar (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW %201781%20v00)
J.D. Seminar (cross-listed) | 2-3 credit hours
This course will cover the pressing threats to global health security, challenges in pandemic preparedness and response, and the law and policy responses required to make us all safer. We will examine the major actors, institutions, and legal frameworks in global health security, question whether they are adequate to meet the task, and discuss how they can be improved to better prepare the world for future health threats. Specifically, this course will offer opportunities to reflect upon the COVID-19 pandemic, including the weaknesses in international systems that allowed an outbreak to spiral into a pandemic, the various mechanisms utilized in the response, the inequities exposed and exacerbated, and the path forward.

The class will examine legal instruments (both “hard” and “soft” law) at both the national and global level, as well as agencies, institutions, and public/private partnerships.

The class format will include a mix of formal lectures, class discussions, and real-life simulations as an experiential component. The course is open to both Georgetown JD and LLM students. Subject to changing public health guidance, the course will be taught in person. Attendance and participation will be recorded.

Learning Objectives:

The goal of this course is to guide students to understand and critically assess national and global health law and governance frameworks, together with tools needed to safeguard health security. In addition to law and governance, the class will use health equity as a lens to understand allocation of scarce resources at the national and global level. Additionally, our aim is for students to actively consider solutions to secure a better future; one in which the world can respond to pandemic threats with science and equity at the forefront. We also expect students to develop high quality research and writing skills, presenting a clear thesis and well-developed arguments in all written assessments.

Reading assignments will include chapters and excerpts from the required course text, which explores the threats to global health security, the legal frameworks, institutions, and actors tasked with responding to these threats, and offers a blueprint for a more secure world. The course textbook will be supplemented with up-to-date readings on the COVID-19 pandemic and beyond. Students should come to each class highly prepared to comment and ask questions.

Mutually Excluded Courses: Students may not receive credit for this seminar and National and Global Health Law: O’Neill Colloquium.

Note: This seminar requires a paper. J.D. students must register for the 3 credit section of the seminar if they wish to write a paper fulfilling the Upperclass Legal Writing Requirement. The paper requirements of the 2 credit section will not fulfill the J.D. Upperclass Legal Writing Requirement.
LAW 508 v02 Policy Clinic (Harrison Institute for Public Law) (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20508%20v02)
J.D. Clinic | 8 or 14 credit hours
Students in the Policy Clinic provide services to make democracy work several policy themes. Recent projects include:

- **Community equity** – Combat gentrification and displacement in low-income communities of color; develop a community support fund; develop a community resilience hub.
- **Health and food** – Organize a consortium to improve working conditions in university food supply chains, expand access to oral health services, reinvent a better food chain for institutions (universities, hospitals, schools, and shelters), analyze social determinants of health (housing, food security, etc.) for state health officials.
- **Labor and human rights** – Organize a consortium to improve working conditions in university food supply chains (same as health above), protect worker rights in global supply chains for the FIFA World Cup and other mega-sporting events.
- **Trade and climate** – Develop mutually supporting climate and trade policies, develop options for international cooperation on climate policies through “climate clubs,” recommend strategies to decarbonize steel production without violating WTO rules, and identify strategies for reducing greenhouse gas emissions while preserving manufacturing jobs.

Please see the Policy Clinic website (https://www.law.georgetown.edu/experiential-learning/clinics/the-policy-clinic-climate-health-food-human-rights-and-trade-harrison-institute) for more detailed information about the program.

For registration-specific supplemental materials, please see the Policy Clinic PDF (https://georgetown.app.box.com/s/s6zpvb37jpc1cza3m5uk4ifv18akcst9).

For information about clinic registration generally, please see the Clinic Registration Handbook (https://georgetown.app.box.com/s/0ehc9a8928jphteghs0uz7s60j9e5y88).

Learning outcomes for this clinic: Students are supervised, evaluated and graded on three skill sets, each of which has specific evaluation criteria in the Policy Clinic Operations Guide. (https://www.law.georgetown.edu/wp-content/uploads/2022/04/2021-22-Policy-clinic-operations-8-12-21-v3.docx)

1. **Management and professionalism** – includes “managing up” with supervision meetings, initiating self-evaluation, managing effort and deadlines, collaborating, and expectations in a professional culture.
2. **Analysis and strategy** – covers legal, policy and strategic analysis. It includes identifying issues that require analysis, learning the context efficiently, using diverse sources to avoid bias, explaining analytic methods, using a logical framework, and drawing conclusions that meet client needs.
3. **Communication, writing and speaking** – includes organizing documents and presentations, meeting audience needs for context and decision-making, relating analysis through stories and examples, presenting visual information, and editing for plain language, clarity, and English style.

**Recommended:** Legislation and Administrative Law. Also, for climate projects: Local Government Law; and for trade or human rights projects: International Law I, International Trade (various titles), World Trade Organization: Law, Policy and Dispute Settlement, and International Human Rights.

**Mutually Excluded Courses:** Students may not concurrently enroll in this course with:

- **LAW 1288 v00 Politics of Litigation and Litigation of Politics** (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%201288%20v00)
J.D. Seminar (cross-listed) | 2 credit hours
Many of the most important and intense political disputes in American history have come before the federal courts. From the controversy about the midnight judges reflected in *Marbury v. Madison*, to the conflict about slavery at the core of *Dred Scott*, to the rise of interest group litigation by civil rights, religious, environmental, and other organizations, those opposed to prevailing laws and policies have taken their grievances to court. In recent years, a new breed of political litigation has proliferated. Increasingly, the losers in legislative and electoral battles have leapt immediately into the judicial arena, challenging the constitutionality of the laws enacted over their objection or the way elections are run. Increasingly, politicians and the entities they control have deployed litigation as another tool in the partisan arsenal. And increasingly, federal courts have become the arbiters of political disputes between the other two branches of the Federal Government, and between the Federal Government and the States, and between political candidates.

This course will use the legal challenges to the Affordable Care Act as an initial case study of how political disputes play out in litigation, from the trial courts to the Supreme Court. We will follow the pattern of political litigation into the Trump and Biden Administrations, and assess the lessons from the partisan shift in the litigation. We will consider how and why partisan disputes generate litigation and discuss the issues this litigation raises regarding the appropriate role of courts in our democratic system. In large part, the perspective will be practical, as we explore the legal, strategic, and tactical choices advocates make in bringing high profile political cases, in framing the legal issues, in harnessing the rules of procedure, and in managing the political features of the case – both offensively and defensively, and both inside and outside the courtroom. We will discuss the hurdles litigants face in seeking to strike down federal laws, the particular challenges of representing the U.S. Government in defending those laws, and the conflicting pressures that bedevil advocates on both sides of the cases. In some of our sessions, students may be asked to strategize or to argue from the perspective of the plaintiffs or the defendant in the cases.

**Prerequisite:** Constitutional Law I: The Federal System (or Democracy and Coercion).

**Recommended:** Prior or concurrent enrollment in Federal Courts and the Federal System.
LAW 995 v00 Public Health and International Investment Law (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20995%20v00)

J.D. Course (cross-listed) | 1 credit hour

The objective of this 1 credit course is to introduce students to the relationship between international laws governing foreign investment and efforts to protect and promote human health. The course will examine the extent to which bilateral investment treaties (BITs) and investment chapters in trade agreements limit domestic regulatory autonomy, particularly in the field of public health.

International investment law is comprised of over 3000 BITs, which govern the acceptance and treatment of foreign investment. BITs impose various rules limiting the freedom of domestic policy-makers, including rules governing national treatment, most-favored-nation treatment (principles of non-discrimination), fair and equitable treatment, and expropriation. Foreign investors, including trans-national corporations, are increasingly using these rules to challenge domestic regulations such as public health measures.

The course will address:

1. the theoretical perspectives underlying the international law of investment and the concept of police powers (particularly the power to protect health);
2. the different types of legal tests used to determine the regulatory legitimacy of a measure as well as the impact of varying standards of proof on analysis of this type;
3. rules governing expropriation of property rights and the circumstances in which health and environmental health measures might be considered equivalent to expropriation;
4. rules governing fair and equitable treatment as used in determining the legitimacy of domestic regulatory measures;
5. rules governing non-discrimination and their potential impact on domestic health measures that are non-discriminatory in form;
6. rules governing arbitrary or discriminatory measures; and
7. procedural issues relating to the participation of civil society in the negotiation of investment treaties and the settlement of investment disputes.

There are no prerequisites for the course, although familiarity with international law or global health law is desirable. The course is ideal for students in the Global Health Law LLM program or for other students wanting a course on international investment law.

Prerequisite: Familiarity with international law or global health law is helpful, but not required.

Note: ATTENDANCE IS MANDATORY AT ALL CLASS SESSIONS. Enrolled students must be in attendance at the start of the first class session in order to remain enrolled. Waitlisted students must be in attendance at the start of the first class session in order to remain eligible to be admitted off the waitlist. All enrolled students must attend each class session in its entirety. Failure to attend the first class session in its entirety will result in a drop; failure to attend any subsequent class session in its entirety may result in a withdrawal.

Enrolled students will have until the beginning of the second class session to request a drop by contacting the Office of the Registrar; a student who no longer wishes to remain enrolled after the second class session begins will not be permitted to drop the class but may request a withdrawal from an academic advisor in the Office of Academic Affairs. Withdrawals are permitted up until the last class for this specific course. The take-home exam in this course may be administered mid-semester and the specific exam date will be provided by the professor after the add/drop period.

LAW 364 v07 Public Health Law and Ethics (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20364%20v07)

J.D. Course (cross-listed) | 3 credit hours

This course explores the interwoven dynamics of law, ethics, and science in public health through examination of core legal theory and practice-based examples. With COVID-19 ushering law, policy, and decision-making around public health into broad public awareness, this class will draw upon current issues in society, enabling students to apply legal and ethical concepts to real-world scenarios. By spotlighting recent and historical examples of public health law in action, including COVID-19, opioids, obesity, tobacco, and the environment, this course will be valuable for students interested in health law and equity, as well as students seeking to deepen their expertise in public policy.

Students will learn the conceptual foundations of public health law in the United States, with particular attention to the statutory and regulatory powers and duties of federal and state governmental entities to protect the health and safety of the population and the judicial decisions that shape them. Sources of tension between public health goals and objectives and civil liberties will be interactively contemplated, including, among others: disease surveillance and privacy; labeling and advertising restrictions and free speech; and considerations around individual versus population-based conceptions of health. Discussions of recent major legislative developments and court decisions impacting jurisprudence, public health authority, and individual rights will be incorporated alongside primary themes. Throughout the course, students will engage with public health law through applied learning—case studies and class exercises—focused on analyzing emerging issues, comparing national and global responses, understanding ethical implications, and developing legal and policy strategies that integrate health equity and address social determinants of health.

LAW 3067 v00 Public-Private Partnerships: Law and Governance (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%203067%20v00)

LL.M Course (cross-listed) | 1 credit hour

Public-Private Partnerships (PPPs) are a modern means for pursuing social and policy outcomes and have recently served as a key vehicle for addressing the COVID-19 pandemic. When they work, they mobilize the comparative advantages of the public and private spheres to address key challenges. When they fail, critics cite their worst aspects and argue for a retreat into more traditional roles. Their prevalence means that everyone is likely to come across, and be affected by, such a partnership at some point in their careers.

Serving as a lawyer to a PPP provides an exceptional challenge because the tools and strategies that work when counseling in the public sector may be strange or ill fit for purpose in the private sector (and vice versa). Effective PPP lawyers are translators and guides: they ‘speak both languages’ thus positioning themselves to propose innovative, non-obvious solutions and can build trust with, and among, partners and stakeholders. Bridging theory and practice, students will have the opportunity to understand why PPPs have emerged and the theoretical basis under which they operate. They will also receive practical tools and knowledge to allow them to work with or within a PPP and discuss and debate sophisticatedly how they should be managed and governed.

To do this, the course uses a mix of lecture, discussion, video, and experiential learning. A key feature is a simulation that provides students the opportunity to experience the formation of a PPP using the tools they develop during the semester.
Health Law, Policy, and Bioethics

**LAW 2080 v01 Regulating Private Health Insurance and Health Care Prices: Legal and Policy Disputes**

Access to affordable and quality health care eludes millions of Americans. Through changes ushered in by the Patient Protection and Affordable Care Act (ACA), millions of Americans have gained health insurance. At the same time, implementation of the law’s reforms have been challenging, and its provisions have been subject to extensive litigation and continued threats of repeal. Health care costs also continue to climb for privately-insured Americans more broadly – leading to calls for further action to regulate health care prices – the main driver of rising costs.

The legal and policy clashes over the ACA’s implementation have also foreshadowed future obstacles facing subsequent major health care reform initiatives - such as the No Surprises Act and Medicare Drug Price Negotiation Program.

This course will examine the regulation of private health insurance and health care prices in commercial insurance and public programs. The course will explore federal regulatory changes under the ACA; subsequent reforms to private insurance under the No Surprises Act and other measures under consideration to address health care pricing; the new authority for Medicare to negotiate the price of prescription drugs; and legal challenges burdening the regulation of private health insurance and efforts to regulate health care prices. This course will also situate health care in the broader context of measures to address public health and population health, interrogate the persistent disparities in health care access and quality and the challenges to addressing those disparities, including what became more visible during the COVID-19 pandemic.

Guest lectures will provide students with a greater, contextualized understanding of former and current legal and policy disputes related to private health insurance regulation and measures to address rising health care prices. The course will also explore what these legal and policy efforts mean for consumers, public health, and broad work to address inequities in health care access and outcomes—as well as where Congress and the White House may push forward with health reform in the future.

**LAW 1071 v00 Reproductive Health and International Human Rights Law**

This fieldwork practicum course, focusing on the interaction between international human rights law and reproductive health and rights. The course will provide an overview of international reproductive health and rights, while affording students an opportunity to work in organizations that are addressing issues in the field in various ways.

As such, students participate in a two-hour weekly seminar and work for 10 hours/week for at least 11 weeks during the semester at an outside organization.

**SEMINAR:** The seminar will begin by providing an overview of international human rights law as it pertains to reproductive rights. The course will then focus on access to reproductive and sexual health from an international perspective, examining States’ obligations on a variety of issues, such as maternal mortality and coerced sterilization. Analyzing recent decisions emerging from regional and international human rights bodies, such as the European Court of Human Rights, the Inter-American Commission and Court on Human Rights and the CEDAW Committee (UN Committee on the Convention on the Elimination of All Forms of Discrimination against Women), the seminar component will provide a necessary foundation for the students to conduct their fieldwork.

Fieldwork: Students will be placed with organizations working in the area of reproductive rights. Most likely, the work will be conducted remotely, as several of these organizations are not based in the Washington D.C. area. The work conducted for this portion of the course will be supervised by the external organization.

Some of the projects may include drafting amicus briefs for cases currently pending before international bodies, and drafting briefs assessing a particular State’s compliance with human rights law regarding sexual and reproductive rights to be filed in front of UN bodies (shadow reports). Through these projects, students will learn how to conduct an analysis of existing legal and regulatory frameworks for sexual and reproductive health from a human rights perspective. By working with external civil society organizations, the course will give students the opportunity to develop practical projects using international human rights law to advocate for the advancement of reproductive health rights. In the past, external partners have included organizations working on women’s rights issues, such as: the O’Neill Institute for National and Global Health Law, the Center for Reproductive Rights, Women’s Link Worldwide, Human Rights Watch (Women’s Rights Division), IPAS, the Women’s Equality Center, and the Southern Africa Litigation Centre, among others.

**Prerequisite:** J.D. students must complete the required first-year program prior to enrolling in this course (part-time and interdivisional transfer students may enroll prior to completing Criminal Justice, Property, or their first-year elective).

**Mutually Excluded Courses:** Students may not concurrently enroll in this course and an externship or a clinic or another practicum course.

**Note:** This practicum course is open to LL.M. students, space permitting. Interested LL.M. students should email the Office of the Registrar (lawreg@georgetown.edu) to request admission.

Evening students who work during the day are encouraged to reach out to the professor to discuss whether this practicum course would be compatible with their schedules. This is a four credit course. Two credits will be awarded for the two-hour weekly seminar and two credits for approximately 10 hours of fieldwork per week, for a minimum of 11 weeks, to be scheduled with the faculty. The two-credit seminar portion of this practicum will be graded. The two credits of fieldwork are mandatory.
LAW 1445 v00 Reproductive Justice Seminar

J.D. Seminar | 2-3 credit hours

Reproductive Justice is a concept developed by Black Women activists in the 1990s to provide a different framework to explore how systemic oppression impacts reproductive decision-making. Acknowledging that abortion and contraception were often not the primary reproductive concerns of many marginalized women, including women of color, young women, women with disabilities, undocumented women, and queer women, activists adopted a framework that considers the contexts in which reproductive decisions are made. This approach centers social, racial and economic justice, and focuses as much on the rights to have and raise children as it does on the right to not have them though access to safe and legal abortion care and contraceptive access.

This course will focus on the rights to not have a child, to have a child, and to raise a child. The course will not focus on abortion or contraception, but will address the impact of Dobbs and forced birth. Students are welcome to focus their writing requirement on abortion or contraception. The course will take an interdisciplinary approach to the issues, incorporating various bodies of law (family law, welfare policy, criminal law) along with an historical analysis, social science, and current events.

Note: J.D. students must register for the 3 credit section of the seminar if they wish to write a paper fulfilling the Upperclass Legal Writing Requirement.

This course will be enrolled via waitlist.

LAW 3090 v00 Reproductive Rights

LL.M Course (cross-listed) | 2 credit hours

This course will explore the history and law of reproductive rights in the United States. The majority of the semester will be spent analyzing the constitutional framework, jurisprudence and federal and state regulations governing forced sterilization, contraception and abortion from the 1920s until today. We will consider the historical, social and religious context of the regulation of reproduction; gender, race and socioeconomic class issues; and the practical impact of the regulations in effect today. This course is primarily focused on reproductive rights in the United States, but we may consider comparative international perspectives.

Please note that this course will not cover regulation of parenting, adoption, foster care, assisted reproductive technologies or related reproductive health topics, or reproductive justice in any meaningful detail.

All students are expected to read the assignments, attend class, and prepare for active discussion every week. Depending on course enrollment, I may assign small groups of students to assist me in leading each week's discussion of the assigned materials. Short oral presentations on current events or topics of particular interest will likely be assigned during the second half of the semester.

Grading: Class participation, including oral presentations, and/or short reaction papers will represent at least 35% of the final grade. A take-home exam will account for the remaining 65%.

Recommended: Constitutional Law I

Note: The course incorporates some international perspectives, and US reproductive jurisprudence is influential globally—but happy to discuss further since the focus is US law.
LAW 1892 v00 Reproductive Rights and Justice Seminar

J.D. Seminar (cross-listed) | 2-3 credit hours

The class will focus on reproductive health and the law. Understanding and learning about the legislative process is essential to this class. Reproductive justice issues span not only constitutional law considerations, but also other aspects of law, society, and the political process. Topics researched and/or discussed will include abortion, assisted reproduction, contraception, treatment of incarcerated pregnant individuals, pregnancy exclusion laws, rape and statutory rape laws, personhood and feticide laws, surrogacy, the use of child endangerment laws to prosecute women for their conduct during pregnant, and parenthood.

Students will learn how to perform in-depth research and analysis involving these subjects and will then learn the process of drafting legislation, understanding the legislative process, and productively working with legislators, policy makers, advocacy groups, and other interested parties to promote reproductive liberties and enact necessary changes.

All students will gain significant exposure to legal research and writing and will work closely with the instructors to develop and hone these critical skills.

Course Goals:
The goals of this course:

- Introduce students to the study of reproductive health law, policy, and regulations
- Familiarize students with the social, medical and legal literature on the topic
- Engage students with practical as well as theoretical ideas in reproductive justice
- Stimulate intellectual curiosity about the subject matter
- Inspire thoughtful analysis
- Encourage and facilitate discussions

Note: This seminar requires a paper. J.D. students must register for the 3 credit section of the seminar if they wish to write a paper fulfilling the Upperclass Legal Writing Requirement. The paper requirements of the 2 credit section will not fulfill the J.D. Upperclass Legal Writing Requirement.

LAW 837 v00 Research with Human Subjects: Law, Policy & Ethics

LL.M Seminar (cross-listed) | 1 credit hour

This course provides an opportunity to explore issues related to the use of humans as research subjects. The course will begin by examining the history of human subject research, including the abuses that led to the creation of our modern legal protections. Following a discussion of the ethical principles of research involving humans, we will carefully explore the legal treatment of human subjects, focusing on US regulations and international instruments. Core sources will include: the Common Rule (45 CFR 46), Belmont Report, Declaration of Helsinki, Nuremberg Code, and CIOMS. After exploring a series of foundational themes and issues through the first half of the week, the remainder of the class will focus on in-depth case studies. Topics may include: international research, research involving vulnerable populations (children, prisoners, and pregnant women), informed consent, research on subjects with impaired decision-making abilities, genetic/genomic research, risk-benefit analysis, coercion/undue inducement, use of placebos, and IRB governance.

Note: WEEK ONE COURSE. This course will meet for one week only on the following days: Monday, January 9, 2023 through Thursday, January 12, 2023, 9:00 a.m. - 12:20 p.m. The course will have a take-home exam that must be completed between January 20 and January 27, 2023.

This course is mandatory pass/fail and will not count toward the 7 credit pass/fail limit for J.D. students. ATTENDANCE IS MANDATORY AT ALL CLASS SESSIONS. Enrolled students must be in attendance at the start of the first class session in order to remain enrolled. Waitlisted students must be in attendance at the start of the first class session in order to remain eligible to be admitted off the waitlist. All enrolled students must attend each class session in its entirety. Failure to attend the first class session in its entirety will result in a dropout; failure to attend any subsequent class session in its entirety may result in a withdrawal. Enrolled students will have until the beginning of the second class session to request a drop by contacting the Office of the Registrar; a student who no longer wishes to remain enrolled after the second class session begins will not be permitted to drop the class but may request a withdrawal from an academic advisor in the Office of Academic Affairs. Withdrawals are permitted up until the last class for this specific course.

NOTE: Mandatory attendance rules will be enforced for this class for the Spring 2023 semester. Graduating students are encouraged to ensure they have enough credits should they be prevented from attending due to COVID-19 symptoms, isolation, quarantine, or other disruptions.
LAW 3017 v00 The Affordable Care Act: Law and Policy Governing Private Health Insurance

This course provides a general overview of the federal labor and tax law policies and principles that apply to employment-based retirement plans, health care plans, and executive compensation arrangements. Students will examine the principles of the Internal Revenue Code and ERISA that govern the form and operation of employer-sponsored plans, especially tax-qualified pension plans, executive compensation arrangements and welfare plans (with a focus on health care). This class will concentrate on the structure and basic rules that govern such arrangements. In the context of tax-qualified and nonqualified plans and health and welfare programs, this course will explore plan administration, fiduciary duties, claims appeals and litigation.

Prerequisite: Federal Income Taxation.

Note: Students enrolled in the Employee Benefits Certificate Program may not register for this course.

LAW 2080 v00 The First 1000 Days: Global Health Law & Policy from Gestation to Age Two

The first 1,000 days between a woman’s pregnancy and her child’s second birthday significantly impacts a child’s ability to grow, learn, and thrive and affects a country’s health and prosperity. This course approaches this period with a Reproductive Justice (RJ) lens, emphasizing social supports, financial assistance and other tools that advance the right to have and raise children. Both in the US and throughout the world, factors such as race, language, income, education, ability, gender identity and sexual orientation all impact one’s ability to carry a healthy pregnancy to term, and the opportunities babies have to grow and thrive.

Increasingly, law and policy has been recognized as a high-impact and robust approach for accelerating progress in supporting women who are pregnant and lactating, along with infants through their first 24 months. In various jurisdictions, policymakers enact courses of action, regulatory measures, laws and policies, and set funding priorities with direct or indirect effects on providing the essential building blocks for families during the 1,000-day window of opportunity. This course focuses on policies, programs and practices across the globe—at the national, tribal, state and local levels—that improve or hinder a mother and child’s health and well-being. Students will examine the evidence informing these courses of action, along with the historical and contemporary legislative, regulatory and judicial aspects. This course applies the RJ framework to an area that has primarily been viewed as one of public health. In doing so, students will build a deeper understanding of the social factors and inequities that impede public health initiatives and widen health disparities. Topics and themes include preconception care, infertility, assisted reproductive technology, maternal and infant mortality disparities, newborn screening, immunizations, maternity and paternity leave policies, breastfeeding relevant policies and practices, dietary and physical activity guidance, social assistance programs, food and nutrition labeling, childcare supports, and other environmental and policy strategies to support maternal and child health.

Note: J.D. students must register for the three-credit section of the seminar if they wish to write a paper fulfilling the Upperclass Legal Writing Requirement for JD students. The special requirements of the two-credit section will not fulfill the Upperclass Legal Writing Requirement for JD students.
LAW 3139 v00 The International Health Law Infrastructure - Building Resilience from the COVID Crisis (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%203139%20v00)
LL.M Seminar (cross-listed) | 2 credit hours
This course will provide an overview of the international and domestic legal and policy frameworks relating to Global Health. It will explore the critical tools used by the international community and donor governments to respond to the COVID crisis. Using the International Health Regulations, Sustainable Development Goals 2030, WTO Doha Declaration, COVAX Agreements, and International and Regional Human Rights Treaties we will provide a foundation of policy deployment at the international level. Against this backdrop we will focus on the challenges and the tension of international organizations to operate in crises and the sovereignty of the country members resulting in a hardening of nationalism and making their citizens a top priority. Cross-border challenges and threats had been a concern before COVID-19; climate change, fragility and conflict, migration and infectious disease are all increasing in frequency. We will address and examine how these tensions impacted the COVID crisis and other global health emergencies.

The course is designed to impart practical skills for students interested in exploring careers focused on these international issues/global health in government, nongovernmental organizations or the private sector, providing a complementary perspective to Preventing, Detecting and Responding to Global Health: The International Health Regulations and the U.S. Government Interagency Process from the international perspective.

By the end of this course, students will be able to:

- Identify and interpret the key relevant authorities and limitations that underpin the global response to the COVID crisis and other global health emergencies in the international community.
- Identify and interpret the key regulations, guidance, and other laws applicable to providing COVID response as well as broader global health assistance by the countries at the national level.
- Draw lessons learned from the international and country-level response to the COVID crisis.
- Predict and explain policy decisions based on knowledge of areas of international organization, donor governments and private actors discretion and restrictions.
- Critically analyze the application of the international global health infrastructure, the IHR and Global Health Security Agenda to COVID and other real life scenarios.
- Identify and recommend changes to the international legal framework for global health to respond more efficiently and effectively to the next global health crisis.
- Differentiate between ideals and goals that are achievable under the relevant legal and regulatory frameworks from activities that are restricted, restrained or prohibited.

Recommended: International Law; Administrative Law; Global Health Law Seminar

LAW 3085 v00 The Nuremberg Trials, the Doctors Trials (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%203085%20v00)
LL.M Seminar (cross-listed) | 2 credit hours
The Doctors Trial considered the fate of twenty-three German physicians who either participated in the Nazi program to euthanize persons deemed "unworthy of life" (the mentally ill, mentally retarded, or physically disabled) or who conducted experiments on concentration camp prisoners without consent. The Doctors Trial lasted 140 days. Eighty-five witnesses testified and almost 1,500 documents were introduced. Sixteen of the doctors charged were found guilty. Seven were executed.

The Doctors Trial provides a significant and important example of human rights violations and serves as a lesson in law and bioethics vital to understanding how law evolved from an initial eugenics policy to and including the horrible examples that framed human atrocities during WW II.

This course will highlight examples from Jeanne Guillemin’s "Hidden Atrocities, Japanese Germ Warfare and American Obstruction of Justice at the Tokyo Trial", Joel Dimsdale’s "Anatomy of Malice" examining the psychological assessments necessary for the trials, and Vivien Spitz's "Doctors from Hell", delving deep into the actual court transcripts from the proceedings. Ben Ferenz’s work, one of the actual prosecutors at the trials, will also be included as insight into this tragic period.
The Role of WHO in Global Health Law and Governance

LAW 869 v00 The Role of WHO in Global Health Law and Governance (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20869%20v00)

LL.M Course (cross-listed) | 1 credit hour

WHO is the sole global health organization and, as such, has been traditionally considered the lead actor in this domain at the center and the forefront of technical, policy and normative developments in global health governance. Its Constitution and institutional structure represent both the embodiment of a new way of thinking about global health and its governance at the time of creation of the UN system as well as the outcome of political compromises that have affected the life of the organization and its positioning in the global health landscape.

The historical development of WHO's functions and activities are also an emblematic reflection of the changing role of health in the global economic, political and development agendas and, as such, can shed light on broader issues of international law and relations. WHO's role and significance as the central actor in global health governance has been the object of contestation and much critical reflection starting in the 1990s and culminating with the organization's role in responding to recent health emergencies such as the 2014-2015 Ebola outbreak in West Africa and most importantly the COVID-19 pandemic. At the same time, global health governance has become more complex, fragmented and politicized and the future role of WHO has to be seen in the context of those developments and the search for a coherent global health architecture.

The course will focus on four broad areas covering the most important aspects of WHO as an international organization, an actor in global health governance, and a forum for policy and legal developments: 1) Historical, constitutional and institutional aspects; 2) normative functions, with particular focus on the International Health Regulations, and the role of WHO in the development of international law; 3) directing and coordinating functions, both in terms of how to address the most important health challenges as well as with regard to WHO's interaction with a number of political and economic regimes; 4) the position of WHO in the current global health landscape, both with regard to the role of other actors as well as to how the organization should look to its own future.

The course will allow students to gain not only an in-depth knowledge and appreciation of WHO from an institutional and structural perspective, but also most importantly to appreciate the main contemporary challenges in global health as well as the role of health in a number of critical policy and normative regimes. The approach of the course will be based on lecturing, class discussions and at least one class exercise. Prof. Burci's former tenure as the Legal Counsel of WHO and a long-term senior lawyer in the organization will allow him to contribute real-life examples and experiences that will better root the course in the realities of the life of an international organization.

Recommended: International law, International organizations, Global Health Law

Note: This course is part of the following graduate programs:
International Legal Studies LL.M.

ATTENDANCE IS MANDATORY AT ALL CLASS SESSIONS. Enrolled students must be in attendance at the start of the first class session in order to remain enrolled. Waitlisted students must be in attendance at the start of the first class session in order to remain eligible to be admitted off the waitlist. All enrolled students must attend each class session in its entirety. Failure to attend the first class session in its entirety will result in a drop; failure to attend any subsequent class session in its entirety may result in a withdrawal. Enrolled students will have until the beginning of the second class session to request a drop by contacting the Office of the Registrar; a student who no longer wishes to remain enrolled after the second class session begins will not be permitted to withdraw.
LAW 611 v04 World Health Assembly Simulation: Negotiation Regarding Climate Change Impacts on Health

J.D. Seminar | 1 credit hour

This Week One simulation will introduce students to the science and impacts of climate change, including effects on health such as heat stress, vector-borne disease, and food security. It will provide students an opportunity to develop positions, advocate, conduct a simulated negotiation, and receive feedback to improve skills. The negotiations will take place as part of the World Health Organization’s World Health Assembly. Students will represent countries and important civil society institutions in negotiating and crafting an international agreement pertaining to climate change and global health. They will have the opportunity to conduct research for their assigned country or organization, interview experts, develop strategy, negotiate, receive and incorporate feedback, and draft resolutions, treaties, or other legislative language. Our approach will allow students to go through not merely an academic negotiation exercise but to develop language that might be useful in the real-world context of the World Health Assembly.

**Note:** This course is mandatory pass/fail, and does NOT count against the 7-credit pass/fail limit for J.D. students.

This optional, elective course is for first-year J.D. students only. Details regarding the registration process will be provided to students during the fall semester via email, information sessions, and on the Week One website (https://www.law.georgetown.edu/experiential-learning/simulations/first-year-week-one-simulations). ATTENDANCE AT ALL CLASS SESSIONS IS MANDATORY. All enrolled students must be in attendance at the start of the first class session in order to be eligible for a seat in the class and must attend each class session in its entirety. For more information, please see the Week One website (https://www.law.georgetown.edu/experiential-learning/simulations/first-year-week-one-simulations). Due to the intensive nature of the course, the small-group, team, and individual work that is involved, and the preparation that is necessary to ensure a positive student experience, students who wish to drop the course after they have accepted a seat must drop by Monday, November 27, 2023 at 3:00 p.m. After that point, students must receive permission from both the course professor and Assistant Dean for Experiential Education to drop the course. Permission will only be granted when remaining enrolled in the course would cause significant hardship for the student. Students who are enrolled but do not attend the first class session will be withdrawn from the course.

**Full-time and visiting Faculty**

Marta Beresin
Maxwell Gregg Bloche
Yael Cannon
Michele Goodwin
Lawrence O. Gostin
David Hyman