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. We sometimes offer a special seminar called the Advanced Health Law Seminar which is highly recommended for those interested in pursuing the field seriously.

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

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 examine 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 277 v02 Aging and Law Seminar (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW

%20277%20v02)

J.D. Seminar | 3 credit hours

This seminar explores, through lecture, discussion, and problem solving, the demographics, public perceptions, special legal problems, and public policy issues affecting older persons. Subject areas include income maintenance programs (Social Security, SSI); health and long-term care benefits (Medicare, Medicaid, long-term care insurance, state and federal financing issues); retirement housing and long-term care options and regulation (continuing care retirement communities, nursing homes, home and community-based care, home equity conversion); estate and personal planning issues related to incapacity (powers of attorney, trusts, guardianship and its alternatives, elder abuse, the right to refuse life-sustaining medical treatment, bioethical dilemmas, surrogate decision making, and health care advance directives); and ethical issues in representing the elderly. 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; Employment Discrimination; Family Law I: Marriage and Divorce; Constitutional Law II: Individual Rights and Liberties; Professional Responsibility.

Note: This seminar requires a paper. 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 Upperclass Legal Writing Requirement.
This course examines the social, legal, political, and ethical controversies surrounding the HIV/AIDS pandemic in contemporary society. It covers both domestic and international law and policy. The course is divided into several parts. Part I covers the role of social movements and mobilization in the response to HIV/AIDS. Part II, AIDS in the Courtroom, covers the major court cases related to HIV/AIDS in the United States and in key countries around the world like South Africa, India and Brazil that provide important comparative perspectives to understand the power of law. These cases demonstrate the social impact of AIDS—the effect of litigation on social institutions, constitutional law, and interpersonal relationships. Part III, Rights and Dignity, examines the role of international human rights, privacy, and discrimination. Part IV, Policy, Politics, and Ethics, covers a wide range of the most contentious debates of the HIV/AIDS pandemic, including testing, named reporting, civil and criminal confinement, sex work, drug law and policy, LGBT rights, and gender. Part V, Special Considerations covers a set of particular contexts and realities including sexual assault, HIV-infected health care workers, and perinatal transmission of HIV. The final Part, Governance and Financing, examines the absence of political leadership, the international trade system which militates against access to affordable treatment in low- and middle-income countries, the systems of financing for HIV in the U.S. and around the world, and the ethics of international collaborative research. The AIDS pandemic has reached deeply into all major spheres of modern life—e.g., law, medicine, economics, and politics. The pandemic has transformed society and restructured ethical values. This course provides an account of the major themes of the pandemic during the last three decades and offers an analysis of contemporary and future policy.

Mutually Excluded Courses: Students may not receive credit for this seminar and the course, AIDS Law and Ethics.

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 J.D. Upperclass Legal Writing Requirement. The paper requirements of the 2-credit section will not fulfill the J.D. Upperclass Legal Writing Requirement.
LAW 2028 v01 Assisted Reproductive Technologies and the Law
(http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%202028%20v01)
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; 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 and gestational surrogacy; unique issues for single and same-sex couples, including the rapidly changing impact of same-sex marriage; and professional standards, economic and regulatory aspects of the ARTs.

Three national experts in their respective fields will provide guest lectures on: medical advances in ART (including a field trip to a locally based national IVF clinic); psychosocial aspects of donor egg and 3rd party ART; and regulation and public relations for ART providers.

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 284 v01 Bioethics and the Law Seminar
(http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20284%20v01)
J.D. Seminar (cross-listed) | 3 credit hours
This seminar investigates legal, ethical, and social problems raised by developments in health, medicine and the biological sciences through the study of selected subjects that vary from year to year. Issues covered might include death and dying, genomics, reproductive technologies, fetal treatment and research, experimentation with human subjects, and societal controls on scientific advances.

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 056 v00 Biotechnology and Patent Law Seminar
(http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20056%20v00)
J.D. Seminar (cross-listed) | 2-3 credit hours
This course examines a variety of legal and policy issues associated with the intellectual property protection available to biotechnological innovations, with an emphasis on patents.

Specific issues that will be examined within this framework include legal utility; conception and reduction-to-practice of biological molecules; anticipation and obviousness of nucleic acids; written description and enablement requirements for biological processes and molecules; experimental use; export and import issues; infringement; and potentially developments outside the US.

Course readings rely primarily on cases, statutes, and regulations. A biotechnology background is not necessary.

Prerequisite: Patent Law or patent law experience.

Note: J.D. students must register for the three-credit section of the course if they wish to write a paper fulfilling the J.D. Upperclass Legal Writing Requirement. A take home exam is required for the two-credit section.
LAW 2030 v01 Comparative Reproductive Technologies and "Reproductive Tourism" (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%202030%20v01)

LL.M. Seminar | 2-3 credit hours

The use of reproductive technologies—and crossing national borders to obtain them—has become a burgeoning multi-billion dollar, international industry. While the desire to have children may be universal, legal protections and restrictions on access to reproductive technologies vary immensely from country to country, and often reflect conflicting cultural and religious values. This seminar will explore and compare a diverse number of legal systems’ approaches to selected reproductive technologies with a particular emphasis on the legal implications for “cross-border reproductive care” (“reproductive tourism”). Other topics will include: comparative access to and affordability of IVF, egg and sperm donation, and surrogacy; reprognetics; treatment for same-sex couples; professional liability; and embryonic stem cell research (as it intersects with egg donation and the use of IVF embryos). Guest lectures will provide a medical and an ethical perspective to broaden an understanding of the legal and policy challenges in this unique field.

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 1101 v00 Consumer Advocacy: Public Health Regulation of Tobacco and Personal-Care Products (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20201101%20v00) (Fieldwork Practicum) J.D. Practicum | 4 credit hours

In fieldwork practicum courses, students participate in weekly seminars and conduct related fieldwork at outside organizations. This fieldwork practicum course will focus on federal regulation of tobacco and personal-care products by the Food and Drug Administration (FDA) under the Food, Drug, and Cosmetic Act and how public interest groups advocate greater protections for consumers. Students will participate in a two-hour/week seminar and carry out either 10 or 15 hours/week of fieldwork as interns with one of two national consumer and environmental health organizations: the Campaign for Tobacco-Free Kids or the Environmental Working Group. (Two pass/fail credits will be awarded for 10 hours/week of fieldwork, and three pass/fail credits will be awarded for 15 hours/week of fieldwork.)

SEMINAR: In the two-credit, graded, seminar portion of the practicum, students will utilize legislative and administrative materials as well as case law to become familiar with the processes by which the federal government regulates tobacco and personal-care products, and to critique both the statutory framework and FDA’s performance in protecting consumers. The 2009 Tobacco Act created a new regulatory regime very different from the FDA’s existing authority to regulate other products within its jurisdiction. Examination of the agency’s initial steps to carry out this responsibility provides a chance for students to understand how a federal agency responds to a legislative mandate requiring innovative action to address a major public health problem. On the other hand, FDA has minimal authority to regulate personal-care products, raising real concerns for consumer protection. The course will also touch on related topics such as the role of the Federal Trade Commission in the regulation of trade practices, the Freedom of Information Act, the legislative process and the interaction of federal and state regulation.

FIELDWORK: In the two- or three-credit, mandatory pass-fail, fieldwork portion of the practicum, students will work as interns with the Campaign for Tobacco-Free Kids or the Environmental Working Group on projects aimed at strengthening the legislative or administrative processes, or on matters in litigation, under the supervision of attorneys connected with these organizations. (Students who have completed this course will have priority consideration if they opt to apply for the year-long Toni Stabile Graduate Fellowship at the Environmental Working Group after graduation.)

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).

Recommended: Administrative Law; Food and Drug Law-related courses.

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

Note: LL.M. students must seek professor permission to apply. Evening students who work during the day are encouraged to reach out to the professors to determine whether this practicum course would be compatible with their schedules. This is either a four or a five credit course, depending on the number of fieldwork hours/week. Two credits will be awarded for the two-hour weekly seminar and either two credits (for 10 hours/week) or three credits (for 15 hours/week) for the fieldwork. The fieldwork will be conducted over a minimum of 11 weeks, to be arranged with the faculty members. Students will have the ability to choose the credit option that best fits their schedules. However, the fieldwork must be completed during normal business hours. All students will initially be registered for a total of four credits, which is the two-credit seminar plus the two-credit fieldwork component. After Add/Drop, a student who wishes to withdraw from both the seminar and fieldwork component, he or she must speak to the professor as soon as possible and indicate otherwise): Regular and punctual attendance is required at all seminar and fieldwork components. Students who fail to participate in seminar and fieldwork components will be withdrawn from both the seminar and fieldwork components and may not take either. Students who enroll in this course will be automatically enrolled in the seminar and fieldwork components. 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 a practicum would cause significant hardship for the student. A student who is granted permission to withdraw will be withdrawn from both the seminar and fieldwork components separately. After Add/Drop, students may enroll prior to completing Criminal Justice, Property, or their first-year elective).
LAW 131 v02 Disability Discrimination Law
J.D. Course | 3 credit hours
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.

LAW 263 v02 Employment Law
J.D. Course | 3 credit hours
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.

LAW 146 v08 Environmental Law
J.D. Course (cross-listed) | 3 credit hours
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 an 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 v09 Environmental Law
J.D. Course (cross-listed) | 3 credit hours
This course focuses on legal strategies to regulate and remedy environmental harms. It is designed to prepare transactional, regulatory, and government lawyers, and 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 an in-depth analysis of the key laws developed to control pollution: 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 key topics such as climate change, enforcement policy and practice, and the role of states, citizens’ groups and industry are addressed briefly. The professor will 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.
This course addresses the growing use of empirical methods in health law and policy, as well as in a variety of related fields, such as environmental policy, toxic torts, and biopreparedness. It provides basic training in the methods of epidemiology, risk assessment, and biostatistics. The goal of the class is to produce lawyers, policymakers, and advocates who can critically evaluate study design and analytical methods and who have sufficient scientific literacy to be able to participate effectively in multi-disciplinary teams with scientists and health professionals. In addition to the core methodological components, focus topics—such as tobacco control, documenting human rights violations, and the impact of urban design on obesity—will be examined.

There is no math or science prerequisite; quantitative skills needed for the class will be developed through instruction and exercises.

Note: Not intended for MPH students. No prior knowledge of Epidemiology is assumed.

WEEK ONE COURSE. This seminar will meet for one week only on the following days: Monday, January 7, 2018 through Friday, January 11, 2018, 1:30 p.m. - 4:05 p.m. This course is mandatory pass/fail and will not count toward the 7 credit pass/fail limit for J.D. students. Attendance at all class sessions is mandatory and all enrolled students must attend the first class in order to remain enrolled. Students on the wait list must attend the first class in order to be admitted off the wait list. Enrolled students will have until the beginning of the second class session to request a drop by contacting the Office of the Registrar. Once the second class session begins, students may only seek a withdrawal by contacting their academic advisor in the Office of Graduate Programs. Withdrawals are permitted up until the last class for this specific course.

LAW 1208 v00 Food Law Seminar (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%201208%20v00)
J.D. Seminar (cross-listed) | 3 credit hours
This seminar introduces students to the laws and regulations that govern our food. The seminar will primarily cover law at the federal level, including but not limited to such topics as the legal definition of food, rules on food labeling, standards for food safety, and regulation of genetically modified organisms. Beyond the law itself, we will consider the scientific, economic, and ethical principles implicated by legal decisions concerning food.

Prerequisite: Administrative Law or the first-year course, Government Processes, or the first-year electives, The Regulatory and Administrative State, Congress and the Administrative State, Legislation and Regulation, or The Regulatory State.

Note: FIRST CLASS ATTENDANCE IS MANDATORY. All enrolled and waitlisted students must be in attendance at the start of the first class session in order to be eligible for a seat in the class.

Mutually Excluded Courses: Students may not concurrently enroll in this clinic and an externship or a practicum course.
LAW 1071 v00 Gender, Sexual and Reproductive Health and International Human Rights Law (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%201071%20v00) (Project-Based Practicum) | 4 credit hours

In a project-based practicum course, students participate in a weekly seminar and work on a project under the supervision of their professor. This project-based practicum course will focus on the interaction between international human rights law and sexual and reproductive health. Students will participate in a two hour/week seminar and carry out 10 hours/week of project work under the direction of the course professor.

SEMINAR: The seminar will begin by providing an overview of international human rights law as it pertains to sexual and reproductive rights. The course will then focus on access to reproductive health from an international perspective, examining States’ obligations on a variety of issues, such as maternal mortality. Finally, students will learn through coursework about other sexual and reproductive health issues linked to the right to dignity, autonomy and bodily integrity, such as rape as a means of torture and forced 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 solid legal foundation for students to develop their experiential/field placement projects.

PROJECT WORK: Students will work with external partners on legal and policy projects related to sexual and reproductive health. 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. Students will also learn how to use epidemiological data to support and craft compelling human rights law arguments for advancing public policy on, for example, maternal mortality and sexual violence prevention and eradication. 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 sexual and reproductive health rights. In the past, external partners have included: the Center for Reproductive Rights, Women’s Link Worldwide, Human Rights Watch (Women’s Rights Division), IPAS, and 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 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 Louis Fine (fine@law.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 each week, for a minimum of 11 weeks.

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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.

Recommended: Prior Enrollment in Food and Drug Law
LAW 493 v01 Global Health Law (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20493%20v01)
LL.M Course | 3-4 credit hours
Global Health Law is the flagship course for 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 a compulsory unit in the Global Health LLM.

No longer an emerging field, global health law encompasses international law and policy that directly or indirectly affects global health, including treaties, regulations, global strategies and other non-binding standards, national and international jurisprudence etc. The field of study includes both legal instruments designed to protect public health as well as the interaction between legal instruments from other international legal regimes and public health considerations and concerns. This course provides a strong foundation in these laws and policies, including governance of the World Health Organization, the International Health Regulations, the WHO Framework Convention on Tobacco Control, international trade and investment law, and human rights treaties such as the International Covenant on Economic, Social, and Cultural Rights.

In examining the application and effectiveness of global health law, this course provides a normative foundation for global health issues including infectious diseases (such as Ebola, HIV/AIDS, tuberculosis, malaria, and influenza) and noncommunicable diseases (such as diabetes, cancer and cardiovascular disease and their causes, including obesity, tobacco, and alcohol).

In this course, students will hear from leading voices in global health and the law and benefit from the expertise of Georgetown Law's O'Neill Institute.

Text
The compulsory text for the course is Gostin, “Global Health Law” (2014, Harvard University Press). Additional readings – including key legal instruments – will be assigned for each topic.

Recommended: Prior enrollment in International Law I.

Note: Required for the Global Health Law LL.M.

LAW 594 v00 Global Health Law: An Intensive, Problem-Based Exploration (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20594%20v00)
J.D. Seminar (cross-listed) | 2 credit hours
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: The first weekend of the course will be held at the Law School and the second weekend will be on the Main Campus at St Mary’s at the School of Nursing and Health Studies.

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. All enrolled and waitlisted 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. This course requires full participation at all class sessions.
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 Law and Policy (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20206%20v03)
J.D. Course (cross-listed) | 4 credit hours
Health law is a vast and expanding field. No single course can survey it all. This course focuses on the organization, financing, and provision of medical care, with an eye toward issues not yet resolved by courts, legislators, regulators, and American society. It also considers some related ethical questions. Topics and themes include the economics of health insurance and managed care, regulatory responses to the market’s perceived failures, medical tort law, access to care, consumer choice and patient autonomy, defining and assessing quality, health care providers’ conflicts of interest, privacy and confidentiality, and socio-economic and racial disparities in health and medical care.

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.
This two-credit seminar will open a window into the fast-developing world of human genetic engineering. It begins with a review of international and regional efforts to ban or restrict human germline modification (HGM), along with a brief world overview of relevant laws and trends. It then focuses on cutting-edge techniques like CRISPR/Cas9 and organized research efforts, particularly in China, that may nonetheless spark a race to create designer babies within a decade or less, as regulation lags behind technology and human affairs. Next, we examine two more well-established reproductive technologies, mitochondrial replacement and pre-implantation genetic diagnosis (PGD), to identify forces that are likely to guide HGM regulation as relevant technologies become safer and more efficient. We’ll study the U.K.’s recent adoption of mitochondrial transfer to reduce birth defects or enhance fertility and then learn about evolving U.S. policy. We’ll follow the spread of PGD, initially used to identify embryos bearing genes causing incurable childhood diseases, first to other less serious conditions, then to the creation of “savior siblings” and finally to non-medical uses like sex selection. Then we’ll return to HGM and view a sample of public policy proposals and religious views likely to influence the coming debate. Finally, we’ll close with an introduction to futuristic impulses to implement theoretically limitless improvements to human capabilities, sometimes balanced by the desire to use HGM to improve human moral character and tempered by doubts regarding the moral status to be accorded new HGM creations.
LAW 223 v02 Insurance Law: Litigation and Regulation
This course focuses on the law of insurance, the insurance of business, and the business of insurance. Questions concerning property and casualty insurance, including insurance for mass torts, product liability, directors’ and officers’ liability, and natural disasters are examined. The obligations of insurance companies to conduct their business according to state and, to some extent, federal regulation and the law of insurance bad faith are explored. Particular types of coverages that will be studied include homeowners insurance, comprehensive general liability (CGL) insurance, excess and umbrella insurance, D&O insurance, and property insurance (including business-interruption/lost-profits insurance). Students will develop sophisticated skills in analyzing the applicability of insurance to complex loss situations, the duties of insureds and insurance companies, and the ethical questions faced by lawyers sometimes caught in between.

Learning Objectives:
In this course, you will learn:

1. Business context and objectives for insurance transactions.
2. How to parse and interpret insurance-policy language.
3. How property-casualty insurance responds to “real world” situations, involving losses to property including from natural disasters, mass tort claims, shareholder claims, and other situations.
4. How courts and law makers create incentives for insurance companies to act in positive ways. This includes questions of insurance company “bad faith” or good faith, the obligation of an insurer to accept a reasonable settlement offer from a plaintiff, obligations of insurers to provide lawyers to defend the insured and the ethical limits on the role of the lawyer, including when the lawyer is selected by the insured rather than the insurance company.
5. Through reviewing excerpts from briefs, students will gain a better appreciation of how to articulate insurance-law points and make appropriate argument.
6. The reading material introduces the wide variety of relevant sources that may assist lawyers, such as cases, articles/treatises, attorneys-general opinions, bar-association ethics opinions, and actual insurance policies.

Prerequisite: Torts (or Government Processes), Civil Procedure (or Legal Process and Society), and Contracts (or Bargain, Exchange, and Liability).

Recommended: Corporations.

LAW 802 v01 International Assistance for Global Health
The overall objective of this course is to explore the present and potential role of international human rights law – and the right to health in particular – in international assistance for global health.

During the first class, we will discuss the recent history and present practice of international assistance for global health. We will discuss tensions between the objectives of development and relief, and between the objectives of promoting ‘health security’ and equity in global health. During the second class, we will explore the concept of equity in global health: how it is central to several definitions of global health, what the practice of international assistance for global health should look like, if the predominant objective of that assistance were equity. During the third class, we will examine the meaning of the right to health, the freedoms and entitlements it generates and the corresponding national and international responsibilities. During the fourth class, we will discuss if and how the right to health can be used to modify/improve the practice of international assistance for global health, taking into account that such assistance serves other objectives as well.

Strongly Recommended: Completion of coursework in the area of international human rights law.

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. 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 145 v00 International Environmental Law
This course focuses on international law applicable to the leading environmental and natural resource issues. The course covers climate change, ozone depletion, transboundary pollution, hazardous wastes and chemicals, biodiversity, agriculture, fresh water, human rights and environment, environment and trade intersection, and financing of sustainable development. The course provides a framework for addressing the legal issues, links international law with relevant national laws, and focuses on ways to strengthen compliance with international obligations.

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 and natural resource problems; to understand international negotiations; and to be able to apply legal concepts developed in the course within different national settings for implementing international law.
In the last two centuries, universal human rights have evolved from a utopian philosophical proposal to the dominant ideal of contemporary world politics. Beginning with the U.N. Charter in 1945, an elaborate body of human rights law has emerged. Nevertheless, even today human rights remain utopian for millions, perhaps billions, of people. This course will examine the basics of human rights law: the human rights provisions of the U.N. Charter and the Universal Declaration of Human Rights; the Genocide Convention; the Covenants on civil, political, economic, and social rights; the Torture Convention; and other treaties. The course also examines efforts by regional organizations and NGOs to implement human rights, and human rights successes and failures "on the ground." The course will study the U.S. role in human rights, and the post-9/11 tensions between human rights and the campaign against international terrorism.

**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.

**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 (http://www.law.georgetown.edu/academics/academic-programs/clinical-programs/our-clinics/IWHR) for more detailed information about the program.


For information about clinic registration generally, please see the Clinic Registration Handbook (http://www.law.georgetown.edu/academics/academic-programs/clinical-programs/clinical-applications/upload/Clinic-Registration-Handbook-v2.pdf).

**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 and biologics in the United States and Europe, with a particular emphasis on public policy issues. We will consider: the role of Federal, State and international regulation; regulatory 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 pharmaceutical industry; pricing and payment systems and controls; and evolving medical technologies.

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

**Note:** This is a required course for the Food and Drug Law Certificate.
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 be doing — to prevent and control them?

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

Although the law’s relationship with the lifestyle-related risk factors for NCDs is complex and contested, governments around the world are experimenting with a wide range of legal strategies to prevent their impact and to create healthier societies. This course places U.S. developments in an international context, and offers frequent 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 to what extent are global solutions needed? What do 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 the “nanny state”? Does progress necessarily depend on motivating people to consciously improve their habits and lifestyles? Is it possible to regulate business without micro-managing or dictating commercial decisions and “mandating the recipe for tomato ketchup?”

The overall aim of this course is to give students the conceptual skills to think powerfully about law’s role in the prevention of NCDs, to contextualize emerging developments and to participate effectively in debates about appropriate, workable, legal interventions.

Note: WEEK ONE COURSE. This seminar will meet for one week only on the following days: Monday, January 7, 2018 through Friday, January 11, 2018, 9:00 a.m. - 11:35 a.m.

This course is mandatory pass/fail and will not count toward the 7 credit pass/fail limit for J.D. students. Attendance at all class sessions is mandatory and all enrolled students must attend the first class in order to remain enrolled. Students on the wait list must attend the first class in order to be admitted off the wait list. Enrolled students will have until the beginning of the second class session to request a drop by contacting the Office of the Registrar. Once the second class session begins, students may only seek a withdrawal by contacting their academic advisor in the Office of Graduate Programs. Withdrawals are permitted up until the last class for this specific course.

**Required Text**

LAW 1382 v01 Medical-Legal Partnership: A Collaborative Approach to Health Justice (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%201382%20v01)
J.D. Seminar (cross-listed) | 2 credit hours
Medical-Legal Partnership (MLP) is a health care delivery model that recognizes that some barriers to good health have legal remedies. In an MLP, doctors and other healthcare professionals work with lawyers to improve the health and lives of vulnerable populations in a way that neither medicine nor law can alone. Thus, for example, the child with asthma who lives in substandard housing may respond more effectively to treatment if her pediatrician and lawyer work together to force her landlord to address the mold, rodent, and roach issues that exacerbate her condition. Beyond direct legal services, MLPs also build institutional capacity to address unmet legal needs and advocate for changes to laws, regulations, practices and policies that impact health.

Using readings, discussion, guest lecturers, community-based work in D.C., and case simulations, we will explore:

- social determinants of health and health disparities, as well as the connections between poverty, health, and law.
- barriers to health faced by specific types of populations/disease groups and how law can reduce those barriers.
- how interdisciplinary collaboration can help lawyers more effectively address legal issues that affect health.

As part of this class you will be involved in projects designed to support the establishment of an MLP at Georgetown. The latter part of the semester will also include joint classes with first-year Georgetown medical students enrolled in a medical school "selective" on MLP. Travel to main campus for those classes will be provided, timing and details will be arranged at the start of the semester. Students will be evaluated based on the quality of their class participation, several short written assignments, and their MLP project. There is no end-of-semester exam.

Required Text
TBA

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.

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 1209 v01 O'Neill Institute Practicum: Health and Human Rights

In a project-based practicum course, students participate in a weekly seminar and work on a project under the supervision of their professors. This project-based practicum course will give students the opportunity to work with Georgetown Law's O'Neill Institute (http://www.law.georgetown.edu/oneillinstitute/index.cfm) and its civil society partners to use international human rights law to advocate for positive health outcomes. 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 the seminar, students will explore the connections between global health and human rights. We begin by examining the emergence of health and human rights as a distinct field. Following this, we will carefully consider the meaning of the international right to health, stressing the material differences between civil and political rights, on the one hand, and economic, social, and cultural rights on the other. After exploring a series of foundational themes and issues through the first half of the semester, the remainder of the class will focus on in-depth case studies (e.g., HIV/AIDS, mental health, access to essential medicines, reproductive rights). While we will use the International Covenants on Economic, Social and Cultural Rights, and on Civil and Political Rights as the dominant legal instruments in our analyses, our discussions will also reference other international instruments, as well as a variety of national cases, constitutions and legislation. Class time will be devoted to developing practical advocacy and drafting skills to support students in their project work. Students will also learn how to use epidemiological data to support and craft compelling arguments for advancing the right to health.

PROJECT WORK: Students will work with external partners of Georgetown Law's O'Neill Institute on legal and policy projects related to health and human rights. For example, students may draft alternative reports to UN bodies analyzing compliance with human rights obligations related to tobacco control (e.g., “shadow reports”). A report such as this could analyze the prevailing legal frameworks for ensuring universal access to maternal health services in a particular country and highlight any weaknesses in the statutory and regulatory language. A report such as this would also suggest recommendations for the UN body to consider. By working with the O'Neill Institute, Inter-Governmental Organizations (e.g., PAHO), and civil society organizations, the course will give students the opportunity to use international human rights law to advocate for legal mechanisms 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 Louis Fine (fine@law.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.

LAW 1209 v02 O'Neill Institute Practicum: Regulating Alcohol, Tobacco & Food in International and Comparative Law

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 will give students the opportunity to work with Georgetown Law's O'Neill Institute (http://www.law.georgetown.edu/oneillinstitute/index.cfm) and its external partners in government and civil society to gain experience in using law to prevent non-communicable diseases (NCDs), including cancer, cardiovascular diseases, chronic respiratory diseases and diabetes. Law is a key tool to reduce the prevalence of key NCD risk factors: tobacco and alcohol use, physical inactivity, and unhealthy diets. 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 the seminar, students will explore the challenges and opportunities of using law to address risk factors that contribute to the rising prevalence of NCDs. The course will take a global approach grounded in international law, including international human rights law - the right to health, and World Health Organization (WHO) law and policy instruments, such as the Framework Convention on Tobacco Control and the Global Action Plan for the Prevention and Control of NCDs 2013-2020. Further, case studies will explore a variety of best practice 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 physically active lifestyles.

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 semester, the remainder of the class will focus on in-depth case studies and experiences in regulating the risk factors (e.g., industry litigation challenging NCD-related laws, challenges in monitoring and evaluating the health impacts of NCD-related laws, and civil society's role in NCD law-making). Students will also learn how to use epidemiological data to craft compelling arguments in support of adoption of NCD-related laws and policies and to defend these laws when challenged by industry. Class time will be devoted to developing practical advocacy and drafting skills to support students in their project work.

PROJECT WORK: Students will work with external partners of the O'Neill Institute for National and Global Health on legal and policy projects related to NCDs, law and human rights. For example, students may draft alternative reports to UN bodies analyzing compliance with human rights obligations related to tobacco control and unhealthy diets (e.g., “shadow reports”). A report such as this could analyze the prevailing legal frameworks in a particular country and highlight any weaknesses in the statutory and regulatory language. By working with the O'Neill Institute, Inter-Governmental Organizations (e.g., the Pan American Health Organization, World Health Organization), and civil society organizations (e.g., Campaign for Tobacco Free Kids, Inter-American Heart Foundation), the course will give students the opportunity to use law to advocate for legal mechanisms 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 and the project work will be graded.
J.D. Clinic | 8 or 14 credit hours

Learning outcomes for this clinic: Students are supervised, evaluated and graded on three skill sets, each of which has explicit evaluation criteria in the clinical program design (https://www.law.georgetown.edu/experiential-learning/clinics/the-policy-clinic-climate-health-food-human-rights-and-trade-harrison-institute).

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. **Research and analysis** – covers legal, policy and strategic analysis. It includes identifying issues that require analysis, learning the context efficiently, using diverse sources to learn efficiently and avoid bias, explaining analytic methods, using a logical framework, and drawing conclusions or options that meet client needs.

3. **Communication, writing and speaking** – includes organizing documents and presentations logically, meeting audience needs for context in the introduction and for decision-making in the conclusion, relating analysis through stories and examples, presenting visual information, and using appropriate language in terms of editing conventions, clarity, tone, and jargon.

**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 clinic and an externship or a practicum course.

**Note:** Please see the Harrison Institute for Public Law Policy Clinic website (http://www.law.georgetown.edu/academics/academic-programs/clinical-programs/our-clinics/HIP) for more detailed information about the program.

For registration-specific supplemental materials, please see the Policy Clinic DOCX (http://www.law.georgetown.edu/academics/academic-programs/clinical-programs/clinical-applications). For information about clinic registration generally, please see the Clinic Registration Handbook (http://www.law.georgetown.edu/academics/academic-programs/clinical-applications/upload/Clinic-Registration-Handbook-v2.pdf).

**LAW 508 v02 Policy Clinic (Harrison Institute for Public Law)** (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20508%20v02)

**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 Second Bank of the United States reflected in **McCulloch v. Maryland**, to the conflict about slavery at the core of **Dred Scott v. Missouri**, 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 battles have leapt immediately into the judicial arena, challenging the constitutionality of the laws enacted over their objection. 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.

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 Administration, 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. For the most part, though, 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)
LL.M Seminar (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 in the field of public health. International investment law is comprised of over 2500 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-favoured-nation treatment (principles of non-discrimination), so-called fair and equitable treatment and expropriation of property rights. These rules are increasingly being used by foreign investors, including transnational corporations, to challenge domestic regulations such as public health measures. For example, a major tobacco company recently filed arbitration claims challenging tobacco packaging regulations introduced by health authorities in Australia and Uruguay.

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.

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

Note: ATTENDANCE IS MANDATORY AT ALL CLASS SESSIONS. All enrolled and waitlisted 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.

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. 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 v05 Public Health Law and Ethics (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20364%20v05)
J.D. Course (cross-listed) | 3 credit hours
This course is intended to provoke thought and legal and ethical debate over pressing public policy issues surrounding the major health problems facing America and globally—e.g., infectious diseases, smoking, obesity, violence, injuries, and the environment. First, the course will examine the Constitutional and historical foundations of public health law in the United States. This section will discuss the Constitutional and statutory powers and duties of government to assure the conditions for a healthy and safe population, including the implementation of the Affordable Care Act. Second, the course will examine the conflicts between public health and civil liberties. For example, the course will probe conflicts between: (1) injury and disease surveillance and privacy; (2) labeling and advertising restrictions and freedom of expression; (3) personal control measures (e.g., screening, forced medical treatment and quarantine) and liberty; (4) commercial public health regulation and property rights. Finally, the course will examine the future of public health law. This "Future" includes a careful analysis of biosecurity—both naturally occurring (e.g., Ebola, pandemic influenza, Zika Virus) and intentional (e.g., bioterrorism such as smallpox and the anthrax attacks after September 11, 2001). This course should be important for all students considering careers in health law as well as those simply interested in exploring and debating the state of public health in America. It is a particularly unique opportunity for students given the expertise of Georgetown Law's own O'Neill Institute for National and Global Health Law.

LAW 364 v06 Public Health Law and Ethics (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20364%20v06)
J.D. Course (cross-listed) | 3 credit hours
This course explores the interwoven dynamics of legal and ethical aspects of public health issues in the United States and abroad, including infectious diseases, tobacco use, obesity, and the environment, among others. This course will be valuable for students interested in global health law, as well as students looking to broaden and deepen their expertise in preparation for a career in health law more generally.

This course will proceed in three movements. First, it will consider the conceptual foundations of public health law in the United States through the lens of governance, ethics, and human rights, affording 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. Second, it will examine the sources of tension between the objectives of public health and civil liberties including, among others: labeling and advertising restrictions and free speech; disease surveillance and privacy; and considerations in personal versus population-based conceptions of health. Lastly, this course will conclude by considering emerging public health issues at the intersection of law and ethics, such as biosecurity, vaccine policy, and the role for public health in broader discussions around health care reform in the United States.
LAW 1081 v00 Public Interest Lawyering: Access to Health Care
(http://curriculum.law.georgetown.edu/course-search/?keyword=LAW\%201081\%20v00) (Fieldwork Practicum)
J.D. Practicum | 3 credit hours
In fieldwork practicum courses, students participate in weekly seminars and conduct related fieldwork at outside organizations. This practicum course will focus on public interest lawyering in the context of access to health care. Students will participate in a two hour/week seminar and also undertake 5 hours/week of fieldwork with Whitman-Walker Health.

SEMINAR: This course explores public interest lawyering and the critical role that safety net benefits play in helping low-income people secure access to health care in the United States. As a community health center with a 30 year old a medical-legal partnership, Whitman-Walker Health leverages lawyers to address health harming legal problems and improve social determinants of health for DC's diverse urban community with special focus on people living with HIV, the LGBT community, and individuals facing barriers to health care. Using fundamental lawyering skills – client intake, education, counseling, outreach, negotiation, and advocacy and analytic skills, we will focus on Medicare and Medicaid – the key government programs that provide assistance to economically vulnerable people - and the Affordable Care Act (ACA) as a mechanism for health insurance and improved patient protections. Using the District of Columbia (and its surrounding jurisdictions for comparison), students will examine eligibility rules, the benefits (and coverage) provided by these programs, and legal issues that arise requiring advocacy and influencing access to health care. We will also highlight safety net programs like the DC Healthcare Alliance and prescription drug assistance programs for specialty populations like the AIDS Drug Assistance Programs. The course will incorporate changes to the social safety net posed by the new Presidential Administration.

FIELDWORK: The fieldwork part of this course will focus on assisting low-income area residents navigate their Medicare Part D prescription drug benefit and making changes, if needed, during the annual open enrollment season. Within open enrollment, all Medicare beneficiaries have the opportunity to review their prescription drug needs to confirm that their particular Part D plan will meet their needs for the following year. This review process is complex and without assistance, most enrollees will not complete the process. The Medicare Part D open enrollment season illustrates the technical eligibility and benefits concepts presented throughout the semester, the complex systems that individuals must navigate in order to access care in our country, and the importance of strong client interviewing and counseling skills to educate and advise clients about these issues. Fieldwork will include brief research and writing, client outreach and counseling, Medicare Part D case analysis, preparation for various legal clinics (Transgender Legal Clinic, Healthcare Power of Attorney, Social Security Disability, and Medicare Part D), and staffing Medicare Part D clinics. The course materials and experiential learning will provide a technical and practical foundation for students interested in pursuing a career in legal services and/or public policy affecting low income populations and their ability to access health care.

Prerequisite: 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 and an externship, clinic, or another practicum course.

Note: This practicum course is open to LL.M. students, space permitting. Interested LL.M. students should email Louis Fine (fine@law.georgetown.edu) to request admission.

This course is suitable for evening students who can commit to attending

LAW 1445 v00 Reproductive Justice Seminar
(http://curriculum.law.georgetown.edu/course-search/?keyword=LAW\%201445\%20v00)
J.D. Seminar | 2-3 credit hours
Reproductive Justice is a concept developed by Women of Color 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 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 women's rights to have and raise children as it does on their 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. While abortion will be discussed in several of the units in which it is relevant, due to the truncated semester, the course will not focus 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 837 v00 Research with Human Subjects: Law, Policy & Ethics
(http://curriculum.law.georgetown.edu/course-search/?keyword=LAW\%20837\%20v00)
LL.M Seminar (cross-listed) | 3 credit hours
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 semester, 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.

This seminar provides opportunities for participants to engage in a research and writing project related to humans as research subjects. Participants will conduct independent research and scholarly writing on important problems at the intersection of law, policy and ethics.

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.
The primary objective of the course is to teach students about the regulation of private health insurance at the federal and state level, with the rare opportunity to witness real-time changes to this complex system. Through this course, students will gain practical experience in identifying and analyzing federal and state laws, regulations, and administrative materials. Students will also gain a broader understanding of regulatory advocacy, its significance in administrative law, and how it has affected Affordable Care Act implementation. By the end of the course, students will be able to describe how private health insurance is regulated at the federal and state level, the major reforms ushered in by the Affordable Care Act, federal and state progress in Affordable Care Act implementation, and likely areas of changes to the law given real-time debates.

This course will examine the regulation of private health insurance with an emphasis on the issues that the Affordable Care Act was designed to address. Specifically, the course will explore regulatory changes such as new market reforms and health insurance marketplaces; the impact of federal and state approaches to implementation; legal and regulatory challenges; and areas where changes are anticipated. Guest lectures by speakers including legal experts, health policy experts, state and federal regulators, consumer advocates, and insurers will provide students with an in-depth understanding of how the Affordable Care Act has been implemented and what it means for millions of consumers across the country.

Note: This is a required course for the U.S. Health Law Certificate.
LAW 496 v01 The Mind and the Law (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20496%20v01)
J.D. Course (cross-listed) | 3 credit hours
Developments in neuroscience and the psychological study of cognition and emotion are transforming our understanding of the mind. These developments have large implications for law and lawyering. They challenge some of civil and criminal law's central premises - about people's rationality, free choice, and consistency over time. This course will examine some of these challenges, and it will weigh the law's possible responses. Legal topics to be explored will include health and safety regulation, the idea of the reasonable person, intent and culpability, mental disability, and the roles of revenge, regret, and other motives in civil and criminal justice. Other themes, relevant to lawyering and to the management of conflict, will include the psychology of negotiation, the nature of intuition and judgment, and the roles of trust and social norms. The course will also consider the causes and control of violence and extremism, as well as the use of emerging neuroscience technologies for legal and national security purposes.

LAW 611 v04 World Health Assembly Simulation: Negotiation Regarding Climate Change Impacts on Health (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20611%20v04)
J.D. Course | 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: FIRST-YEAR WEEK ONE COURSE: This course will meet on the following days: Monday, January 7, 2019, through Thursday, January 10, 2019. 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, who are enrolled through a lottery process. ATTENDANCE AT ALL CLASS SESSIONS IS MANDATORY. All enrolled and waitlisted 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 see the Week One website (http://www.law.georgetown.edu/go/weekone). 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 Friday, November 30, at 3:00 p.m. After that point, permission to drop from the course professor and Assistant Dean for Experiential Learning is required. Students who are enrolled but do not attend the first class session will be withdrawn from the course.

LAW 3020 v00 Zika, Ebola, MERS, and the One Health Model of Global Outbreaks (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 the ongoing Middle East Respiratory Syndrome (MERS) and Ebola epidemics within the “One Health” paradigm—a more inclusive and 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 and will cover recent developments, such as the critical findings of an independent panel that examined the WHO’s response to the Ebola epidemic. In addition, Prof. Lucey will provide his personal perspective based on on-the-ground work in responding to Ebola in Sierra Leone, Liberia, and Guinea, as well as to MERS throughout the Middle East and Korea.

The course will be discussion-based, with course materials including online readings, videos, and other materials. The class will consist of interactive lectures, general discussion, 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 come to resolution. Grading will be determined based on a take-home exam along with class participation, including discussion and participation in simulation exercises.

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.

This course is mandatory pass/fail and will not count toward the 7 credit pass/fail limit for J.D. students.

Full-time Faculty
Maxwell Gregg Bloche
Lawrence O. Gostin
Nan Hunter
Timothy Westmoreland