GLOBAL HEALTH LAW LL.M.

Georgetown’s Global Health Law LL.M. programs train lawyers to apply their specialized legal skills to improve population health in the United States and globally. The innovative full- or part-time courses of study explore the intersections of health and law, including global health governance, health and human rights, food and drug law, access to health care, and legal interventions to prevent and control infectious and non-communicable diseases.

Created in 2007 as part of the O’Neill Institute for National and Global Health Law (http://oneill.law.georgetown.edu), our programs include the LL.M. in Global Health Law (see below), the LL.M. in Global Health Law and International Institutions (https://curriculum.law.georgetown.edu/llm/llm-joint-degree-programs/joint-degrees/jd-llm-global-health-law-international-institutions) with the Graduate Institute of International and Development Studies in Geneva, Switzerland, and certificate programs in Food and Drug Law (https://curriculum.law.georgetown.edu/llm/llm-certificate-programs/llm-food-drug-law-certificate) and U.S. Health Law (https://curriculum.law.georgetown.edu/llm/llm-certificate-programs/llm-us-health-law-certificate). We have more than 180 graduates from 30 countries working to improve the public’s health in the private sector, academia, non-government organizations, international organizations, and all levels of government.

LL.M. in Global Health Law

All Global Health Law LL.M. candidates are enrolled in the 4-credit Global Health Law course, which explores the roles that the law, lawyers, and legal institutions play in public health across the globe. Working with their academic advisor, candidates select additional courses from Georgetown Law’s unparalleled health law curriculum, with more than 35 courses addressing domestic and global health law.

As part of their program, Global Health Law students have the unique opportunity to engage with the O’Neill Institute, a premier research institution working at the intersection of health and the law. Candidates may work on O’Neill Institute projects as research assistants, enroll in its practicum courses, attend symposia and events, and participate in career and professional development programs including a mentorship program that partners students with O’Neill Institute staff and program alumni.

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<thead>
<tr>
<th>Requirement</th>
<th>U.S.-Trained Students</th>
<th>Foreign-Trained Students</th>
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<tbody>
<tr>
<td>Total Credits Required</td>
<td>24</td>
<td>20</td>
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<tr>
<td>Specialization Credits Required</td>
<td>16</td>
<td>14</td>
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<tr>
<td>Program Course Requirements</td>
<td>4-credit Global Health Law Course</td>
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<td>GPA Requirements</td>
<td>Students must earn a minimum grade point average of “B-” (2.67/4.00) in the courses that are counted toward the LL.M. in Global Health Law specialization requirements</td>
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Contact Information
To learn more, please contact:

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Please address any questions about admissions the Office of Graduate Admissions (https://www.law.georgetown.edu/admissions-aid/graduate-admissions).

Search LL.M Global Health Law Courses (http://curriculum.law.georgetown.edu/course-search/?program=program_83)

LAW 534 v01 Access to Health Care and Coverage: Law and Policy (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20534%20v01)
J.D. Course (cross-listed) | 3 credit hours
The law governing access to health care has been in flux and in legal dispute in recent years. This course will examine America’s programs for health care access and finance, including employment-based private insurance, Medicare, Medicaid, CHIP, and VA. The course will also examine the enactment, implementation, and litigation of the Affordable Care Act. In addition to these payment systems, the course will also at laws affecting non-comprehensive systems such as emergency rooms, public hospitals, and community health centers. No previous knowledge of health law is required.

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

This is a required course for the U.S. Health Law Certificate.

LAW 1602 v00 Advanced Topics in Torts: Products Liability, Guns, and Drugs (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%201602%20v00)
J.D. Course (cross-listed) | 3 credit hours
This upper level course will cover the law of products liability generally and take a close look at the state of products liability litigation and liability in relation to guns and to opioids. The goal is to combine a survey of the complicated field of products liability law with a sophisticated deep dive into two areas of cutting edge products liability litigation. The first part of the course will familiarize students with major topics applicable to all products manufacturers including: a product distributor’s liability for defect-caused harm, allocating responsibility inside and outside the commercial chain of distribution, causation, affirmative defenses, approaches to design defect litigation, and federal preemption of products liability claims. Later in the course, we will examine gun manufacturer liability, currently and prior to the passage of the Protection of Lawful Protection in Arms Act, which reshaped the landscape of gun litigation. Finally, we will end with a consideration of the growing litigation related to the opioids, litigation inflected by doctrines peculiar to prescription drug manufacturer liability. The final examination will be a self-scheduled 48 hour take home exam. Attendance and participation are crucial to the course, and significant credit will be given to those students who contribute thoughtfully and constructively to class discussion of cases and issues.
LAW 277 v02 Aging and Law Seminar (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20277%20v02)
J.D. Seminar | 3 credit hours
This seminar explores, through lecture, discussion, role playing, 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; 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.

LAW 369 v01 AIDS Law and Ethics Seminar (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20369%20v01)
J.D. Seminar (cross-listed) | 2-3 credit hours
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. 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.
This development, of course, is raising legal issues. There is a growing but still unsettled body of law on this subject. Some but not all CAM modalities are now licensed and regulated by at least some states. Federal regulatory bodies, such as the FDA and FTC are trying, within the limits of their statutory authority, to protect what they perceive to be the interests of the public. Yet, they come at the problem through conventional, rather than alternative, eyes. Conventional law is based upon protecting the public from purveyors of the proverbial "snake oil" frauds. And to an extent this law is being used to keep out alternatives to the established health-care modalities. This seminar studies the tensions, legal, economic, and social, of this struggle as it unfolds. This seminar covers several areas of law including administrative law, medical malpractice, informed consent, FDA/FTC law, among others. A paper meeting the upperclass legal writing requirement is required.

Global Health Law LL.M.

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

This J.D. 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.

Recommended: Prior enrollment in Global Health Law and any coursework in public health, public health law, and cultural anthropology.

Note: This class will meet on the following Summer 2017 Wednesdays: 6/21, 6/28, 7/5, 7/12, and 7/19.

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 (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 (cross-listed) | 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 examine the fundamental elements of ART law and practice so that students have a foundation to 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; reprogenetics; 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%201101%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

LAW 1102 v00 Drug Law and Policy Seminar: A Critical Perspective on the War on Drugs in the Americas (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%201102%20v00) J.D. Seminar (cross-listed) | 2-3 credit hours

This seminar will explore the policy of prohibition on drug production, distribution and consumption that embodies the long-standing hemispheric “war on drugs”. It will examine the legal regime that underpins current policies on drug trafficking (international, transnational and domestic regulations) related to criminalization but also to arms’ sale and money laundering. We will reflect on the economic and social consequences that drug-trafficking prohibition has had in countries and communities situated on different sides of the global drug trade. Our focus will be primarily on the United States, Mexico and Colombia. The seminar will explore the dominant “law and order” criminalization paradigm and contrast it with other potential approaches that focus on public health and economic development. We will conclude by considering a range of potential policy alternatives to the current model.

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 3003 v00 Employee Benefits: Health & Welfare Plans (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW %203003%20v00) LL.M Seminar (cross-listed) | 2 credit hours

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

Prerequisite: Federal Income Taxation (formerly Taxation I).

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

Note: This course is required for the Employee Benefits Certificate.

This course is open to J.D. students by professor permission. Interested students should contact Ellis Duncan via email at ged5@law.georgetown.edu no later than August 1, 2018 for permission to take this class. Students may not withdraw from this class after the add/drop period ends without the permission of the professor.
The Farm Law and Policy Seminar complements other courses offered by the Law Center, including courses on Food Law and Environmental Law. Students will have until the beginning of the second class session to 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.

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.

Recommended: A course in food law or environmental law.
LAW 1272 v00 Gender and Sexuality (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%201272%20v00)

J.D. Course (cross-listed) | 3 credit hours
This course will provide an introduction to the legal contexts and theoretical debates surrounding sex, gender, sexuality, and their intersections. We will explore the way gender and sexuality have been debated, defined, and redefined in the contexts of gender identity and performance, sexual pleasure, reproductive right, sexual violence, marriage, family organization, and work. In each context we will canvas the evolution of the law as well as consider how feminist and queer theorists have conceptualized gender and sexuality in order to rethink and critique prevailing legal rules and cultural norms. In short, this course will probe the ways that law is gendered, sexualized and raced, and with what overall effects on social institutions and practices.

Key topics will include:
- The influence of identitarian politics on law and vice versa
- Regulation of Sexual Conduct
- Regulation of Reproduction
- The Meanings of Same Sex Marriage
- Sex, Law & Consent
- Gender & Sexuality at Work
- Equality, Stereotypes, and Pregnancy
- Sexual Harassment

Students will be graded primarily on the basis of a take-home exam at the end of the semester with some consideration of class participation. There may also be short response/essay papers or small group projects required.

Strongly Recommended: Constitutional Law II.

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

LAW 3028 v00 Global Drug Law and Regulation (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%203028%20v00)

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

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  
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) H5N1; 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 entirety. This course requires full participation at all class sessions.

LAW 1028 v00 Health Care Fraud and Abuse Seminar  
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 Statute (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 statutes, 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 2037 v00 Health Information Technology and the Law  
LL.M Seminar (cross-listed) | 2 credit hours
Health care decision-making and innovation are increasingly driven and made possible by vast stores of data. The importance of data has created an inevitable push-pull dynamic between concerns for confidentiality and demands for medical progress and cost containment. Data is both a privacy risk and a tremendous asset. This course will explore the legal and ethical issues at the intersection of health information, including where data comes from, how it is used, and risks to its integrity and security. In doing so, this course will cover a range of topics including health information privacy, future use of data assets, and conflicts of interest.

LAW 206 v03 Health Law and Policy  
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.
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.

LAW 3054 v00 Health Rights Litigation Intensive (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%203054%20v00)
LL.M Course (cross-listed) | 2 credit hours
This one-week intensive course offers students an opportunity to develop specialist-level knowledge in litigating health-related rights at the national, regional, and international levels.

During the course, globally renowned experts will lecture on a range of topics, including: regulation of private actors; sexual and reproductive health and rights; rights issues arising in health-care settings; approaches to health-care rationing and factors to consider in assessing the equity impacts of judgments; access to medicines and intellectual property; judicial legitimacy in deciding issues with budgetary and policy implications; and judicial effectiveness and impact of judgments.

The course is highly participatory, and uses case-based teaching and group exercises extensively. Students will be evaluated based on their participation in lectures and group exercises throughout the week, as well as their participation in either the moot court competition or the fundraising pitch on the final day of the course.

Recommended: Prior enrollment in International Human Rights; International and Comparative Law on Women’s Human Rights; Gender, Sexual and Reproductive Health and International Human Rights Law; O’Neill Institute Practicum: Health and Human Rights

Note: This class will meet on the following Summer 2017 dates: 6/26, 6/27, 6/28, 6/29, and 6/30.
The course seeks to answer the following questions:

- What are international human rights standards that relate to health?
- What does it mean in practice to set out a “right to health,” and how might such a right be implemented?
- What is (and should be) the role of courts in enforcing health rights?
- What are the key elements of ‘rights-based approaches’ in programs and policies, with reference to specific health issues and affected populations?
- How might adopting a rights-based approach to global health issues challenge traditional human rights assumptions and practices?
- How can human rights be used to create meaningful social change in health, and what are the limitations to using human rights frameworks?

The class will explore the conceptual and practical implications of adopting human rights frameworks relating to health policymaking and programming, including emphases on accountability, participation and non-discrimination. We will examine how human rights discourses are shaped and contested, and how this determines the relevance of ‘human rights-based approaches’ to addressing the health needs of different populations. Throughout the course, as we discuss specific issues, we will examine potential limitations as well as strengths of using human rights to improve global health.

The course seeks to answer the following questions:

- What are international human rights standards that relate to health?
- What does it mean in practice to set out a “right to health,” and how might such a right be implemented?
- What is (and should be) the role of courts in enforcing health rights?
- What are the key elements of ‘rights-based approaches’ in programs and policies, with reference to specific health issues and affected populations?
- How might adopting a rights-based approach to global health issues challenge traditional human rights assumptions and practices?
- How can human rights be used to create meaningful social change in health, and what are the limitations to using human rights frameworks?
**LAW 802 v01 International Assistance for Global Health**

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

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 3006 v00 International Right to Health**

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

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

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

**Note:** 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.

**LAW 691 v00 International Trade and Health**

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

The objective of this 2 credit seminar is to introduce students to the relationship between international laws governing trade and efforts to protect and promote human health. The course will focus on the impact of the law of the World Trade Organization (WTO) on domestic health measures as well as on international efforts carried out under the auspices of the World Health Organization. Students will learn, and be asked to think critically about, how the international trade regime affects national regulation in the interests of human health.

The course will address the following subject matter:
1. Introduction to ‘trade and health’: issues and underlying theories.
2. The prohibitions and exceptions of the General Agreement on Tariffs and Trade in a health context.
3. Risk regulation, the precautionary principle and sanitary measures (such as import safety measures).
4. International standards and technical barriers to trade, such as labeling measures.
5. Trade in health services, health worker migration and the General Agreement on Trade in Services.
6. Access to essential medicines under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) and TRIPs plus agreements.
7. The fragmentation of international law: cross-fertilization between international trade law and global health law.
8. Policy coherence, legitimacy and participatory governance at the WTO.

**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.
LAW 708 v00 International Trade, Intellectual Property Rights, & Public Health

This course will cover the interface between the intellectual property rights, international trade and public health, focusing in particular on the WTO TRIPS Agreement and subsequent decisions. It will provide an introduction to the provisions of WTO agreements relevant to public health (other than TRIPS), and to the law and economics relating to IPRs and public health; it will cover the provisions of the TRIPS Agreement relevant to public health, and discuss the relevant disputes settled in the WTO. It will examine the background, content and implications of the Doha Declaration on the TRIPS Agreement and Public Health and of the subsequent TRIPS amendment implementing compulsory licensing for exports. It will also discuss the relevance of bilateral or regional free trade area agreements to the subject.

The course would study relevant national/regional implementing legislation, for example on compulsory licenses, and discuss use of the WTO export compulsory license provisions, namely the Rwanda-Canada case. In addition to the final paper, students will be graded on class participation, individual presentations and group exercises, an example of the last being a hypothetical case study of exports, with students taking up the role of legal advisors based in either the importing country or the exporting country.

Finally, the course will also cover recent work on trade, intellectual property and public health in other intergovernmental organizations, in particular in the World Health Organization.

Recommended: Coursework in International Trade, Intellectual Property Rights, or Public Health.

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. Students may not withdraw from this class after the start of the second class session without the permission of the professor.

LAW 2071 v00 Law and Functioning of International Organizations

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 enrollment in Public International Law or International Law I.

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

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.
Technological advances in diagnostics and therapeutics have the potential to revolutionize health care and improve the lives of millions of people. However, many of these technologies remain out of reach to those who need them, particularly the poor in low- and middle-income countries.

With increased investment and global attention over the last decade, there has been tremendous progress in building a pipeline of candidate medical technologies to meet the health needs of the world's poorest people. This course will explore the legal, regulatory and policy issues that are shaping the research, development, and delivery of those drugs, vaccines, and diagnostics. Part I of the course will provide an overview of the burden of neglected diseases in low- and middle-income countries and the new institutions and initiatives that have arisen to address that burden. Part II will examine the incentives for global health innovation, including intellectual property management, regulatory and tax incentives, and prizes and advance market commitments. Part III will consider the role of national and international regulation, international clinical trials and the globalization of research, and World Health Organization's policy processes for ensuring drug and vaccine safety and recommending their use. Part IV of the course will explore the legal, regulatory and policy issues that arise in the delivery and use of global health technologies, particularly supply chain contracting, drug resistance, and post-market surveillance in low- and middle-income countries.

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, then, from the regulation of those businesses that all too frequently have a vested interest in unhealthy lifestyles.

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

During the course, we will confront some important over-arching questions. What are the global determinants of NCDs, and how are these diseases being managed, globally? What do the global solutions look like? To what extent should law intervene to influence the behavior of populations – as distinct from treating lifestyle-related risk factors as the personal responsibility of each individual? Does a regulatory approach to the prevention of NCDs imply coercion? Does it signal the emergence of 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 “legislating the recipe for tomato ketchup?”

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

Note: WEEK ONE COURSE. This seminar will meet for one week only on the following days: Monday, January 6, 2020 through Friday, January 10, 2020, 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.
Despite significant progress in legal protections for — and the visibility of — LGBT people over the past decade, LGBT communities continue to face systemic obstacles to quality health care such as refusals of care, substandard care, and inequitable policies and practices in health care settings. These experiences of discrimination correlate with significant health disparities, including greater exposure to violence, higher rates of tobacco and other substance use, mental health concerns, HIV, and cancer. These disparities are even more pronounced for LGBT people who are also members of other groups that face discrimination because of race, ethnicity, or other aspects of identity — such as people of color and immigrants, among others.

In this seminar, students will learn about LGBT health law and policy issues from a variety of perspectives — including medicine, public health, women's studies, and U.S. foreign policy — and gain a better understanding of the social mistreatment and ostracism of LGBT people at both the individual and community level. Topics covered will include international human rights law, LGBT-inclusive data collection, clinical and cultural competency, and health issues facing LGBT young people and elders. This course will also examine the ways in which LGBT individuals and families are treated under federal, state, and international (U.S. foreign policy) law and how these policies impact access to health care and contribute to health disparities.

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 2099 v00 Nutrition Law and Policy**
(http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%202099%20v00)

LL.M Course (cross-listed) | 2 credit hours
Proper nutrition is one of the many contributor’s to overall health and could be one of the most cost-effective approaches to address many of societal, environmental and economic challenges facing the world today. Increasingly, law and policy has been recognized as a high-impact and robust approach for accelerating progress toward reducing and managing nutrition-related chronic diseases such as obesity, cardiovascular disease, type 2 diabetes mellitus and certain types of cancer. In various jurisdictions, policymakers enact courses of action, regulatory measures, laws and policies, and set funding priorities designed to address food insecurity, hunger, obesity prevention, chronic diseases, among other health and well-being concerns. This course focuses on policies, programs and practices across the globe—at the national, tribal, state and local levels—that improve or hinder healthy eating. Students will examine the evidence informing these courses of action, along with the historical and contemporary legislative, regulatory and judicial aspects. Topics and themes include dietary guidance, food and nutrition assistance programs, food and nutrition labeling, and other environmental and policy strategies to improve access to healthier foods and beverages.

**Student Learning Goals:**

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

**Recommended:** Constitutional Law, Property, Contracts, Torts, as well as Food and Drug Law, Introduction to Health Law, and Land Use and Planning.
LAW 1209 v01 O'Neill Institute Practicum: Health and Human Rights
(http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%201209%20v01) (Project-Based Practicum)
J.D. 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 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. Case 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
(http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%201209%20v02) (Project-Based Practicum)
J.D. 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 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 concurrently enroll in this practicum course and an externship.
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*, 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 3073 v00 Public Health Emergencies: Enabling Preparedness and Response through Law and Policy (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%203073%20v00)
LL.M Seminar (cross-listed) | 1 credit hour

Increasing globalization compounds the complexity in preparing for and responding to public health emergencies. Identifying the numerous stakeholders, legal and policy considerations, and authorities in the midst of responding to a potential or declared public health emergency is a difficult endeavor. Fragmented or siloed preparedness activities and efforts before the public health emergency or after the response to the emergency or event inevitably result in duplicative or even confounding efforts, initiatives, authorities, or mandates. In spite of this, governments, international organizations, and non-government organizations continue to combat waning prioritization and urgency to initiate, maintain, and enable preparedness and response activities, capabilities, and functionality. Now more than ever, coordinated integration and implementation of national and international law and policy is critical to ensuring and enabling effective operationalization of stakeholders and resources globally during a response as lives hang in the balance.

Through the analysis of case studies from various global events (including infectious diseases, chemical and radiological events, and natural disasters), this course aims to establish a better understanding of the various global and national legal and policy fora, considerations, and influences and how they have (or have not) been applied in preparedness and response various efforts.

LAW 3057 v00 Public Health Law & Policy in Global Perspective (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%203057%20v00)
LL.M Seminar (cross-listed) | 1 credit hour

This course will focus on four core issues: quarantine and criminal penalties, access to affordable medicines and intellectual property, the international and constitutional right to health, and how political institutions and race intersect and condition the effect of law on population health. By looking at these issues in both the United States and abroad, particularly in low- and middle-income countries, students will gain a comparative perspective about how law works in practice.

Utilizing HIV and tuberculosis as core case studies, students will explore how law and policy tools can have a significant impact on population health. Today, state actors continue to use law to address public health issues—with examples of both great successes and significant failures.

As public health law embodies both thorny ethical issues and empirical questions about the power of the state to affect health, examining the intersection of law and social science will reveal substantive issues in key health policy issues as well as the conditions under which law and legal advocacy affects wellbeing. HIV and TB, the world’s biggest infectious killers, provide a lens through which to better understand central issues in public health law and policy, which will then be linked to other health concerns in infectious, non-communicable, and environmental health.

This one-week class will be a blend of lectures, discussion, and small group work. Readings will include case law and legal theory as well as texts from political science, economics, and public health. At the end, students will have a better understanding of how and when the law matters for health—which will be of particular interest to students interested in litigation, lawmaking, and public health regulation.

Note: WEEK ONE COURSE. This seminar will meet for one week only on the following days: Monday, January 7, 2019 through Friday, January 11, 2019, 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.
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 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 would 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 1600 v00 Public Interest Advocacy: Government Regulation of Food and Personal-Care Products (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%201600%20v00) (Fieldwork Practicum) J.D. Practicum | 4 credit hours

In a fieldwork practicum course, students participate in a weekly seminar and conduct related fieldwork at an outside organization. This practicum course will focus on regulation of food and personal-care products by the Food and Drug Administration (FDA) under the Food, Drug, and Cosmetic Act. Students will participate in a two hour/week seminar and also undertake 10 hours/week of fieldwork at the Environmental Working Group (EWG), a public-interest nonprofit that advocates on behalf of consumers of both food and personal-care products, and other non-governmental organizations.

SEMINAR: The FDA’s authority to regulate the safety and nutritional aspects of food products dates back to 1906, and has evolved as food production has become increasingly industrialized and affected by an array of new technologies. On the other hand, FDA’s authority over the safety of personal-care products has remained rudimentary, and presents unique challenges in the face of both long- and short-term risks linked to their use. This seminar will utilize legislative and administrative materials as well as case law to enable students to become acquainted with the processes by which the federal government regulates food and personal-care products, will compare FDA’s regulatory authorities with regulatory schemes for consumer products, and will critique both the statutory framework and the performance of FDA in carrying out its duties. The course will also touch on related topics such as the role of the Federal Trade Commission in the regulation of trade practices related to food and cosmetics, the roles of the Environmental Protection Agency and the Consumer Product Safety Commission in the regulation of chemicals in consumer products, and the interaction of federal and state regulation.

FIELDWORK: In the fieldwork component of this course, students will be assigned to projects at the Environmental Working Group or a similar non-governmental organization. They will have an opportunity to learn how such institutions play a role in representing consumer interests in product safety issues being debated in both the administrative and legislative processes, and in matters subject to litigation.

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, as well as food and drug law-related courses, are recommended but not required.

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

Note: This practicum course is open to L.L.M. students, space permitting. Interested L.L.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 class and working 10 hours/week (during business hours) on site at their field placements. This is a four credit course. Two credits will be awarded for the two-hour weekly seminar and two credits for approximately 10 hours of fieldwork per week, for a minimum of 11 weeks, to be scheduled with the faculty. The fieldwork must be completed during normal business hours. The two credit seminar portion of this practicum will be graded. The two credits of fieldwork are mandatory pass/fail. Students will be allowed to take another course pass/fail in the same semester as field work. Students who enroll in this course will be automatically enrolled in both the seminar and fieldwork components and may not take either component separately. After Add/Drop, a student who wishes to withdraw from a practicum course must obtain permission from the faculty member and the Assistant Dean for Experiential Education.
LAW 3067 v00 Public-Private Partnerships: Law and Governance
(http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%203067%20v00)
LL.M Seminar (cross-listed) | 2 credit hours
Public-Private Partnerships (PPPs) are a modern means for pursuing social and policy outcomes. When they work, they mobilize the comparative advantages of the public and private spheres to address key challenges. When they fail, critics cite their worst aspects and argue for a retreat into more traditional roles. Their prevalence means that everyone is likely to come across, and be affected by, such a partnership at some point in their careers.

Bridging theory and practice, students will have the opportunity to understand why PPPs have emerged and the theoretical basis under which they operate. They will also receive practical tools and knowledge to allow them to work with or within a PPP and discuss and debate sophisticatedly how they should be managed and governed.

To do this, the course uses a mix of lecture, discussion, video, and experiential learning. It will start by examining and contrasting the key organizational, legal, and governance components of public-sector institutions and corporate entities. Students will then analyze several kinds of PPPs including global health partnerships, innovative finance institutions, and biomedical research consortiums. In particular, they will examine applicable international, corporation, and regulatory law and seek to understand the choices these partnerships make in applying a particular mix of public-sector and corporate norms. A key feature is a simulation that provides students the opportunity to experience the formation of a PPP using the tools they develop during the semester.

LAW 1071 v00 Reproductive Health and International Human Rights Law
(http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%201071%20v00) (Project-Based Practicum)
J.D. 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 reproductive health and rights. 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 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 and coerced sterilization. Analyzing recent decisions emerging from regional and international human rights bodies, such as the European Court of Human Rights, the Inter-American Commission and Court on Human Rights and the CEDAW Committee (UN Committee on the Convention on the Elimination of All Forms of Discrimination against Women), the seminar component will provide a 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 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 reproductive health rights. In the past, external partners have included organizations working on women’s rights issues, such as: 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 per week, for a minimum of 11 weeks. Both the seminar and the project work will be graded. Students who enroll in this course will be automatically enrolled in both the seminar and project components and may not take either component separately. After Add/Drop, a student who wishes to withdraw from a
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.

LAW 3017 v00 Survey of Employee Benefits Law
(http://curriculum.law.georgetown.edu/course-search/?keyword=LAW %203017%20v00)
LL.M Course (cross-listed) | 2 credit hours
This course provides a general overview of the federal labor and tax law policies and principles that apply to employment-based retirement plans, health care plans, and executive compensation arrangements. Students will examine the principles of the Internal Revenue Code and ERISA that govern the form and operation of employer-sponsored plans, especially tax-qualified pension plans, executive compensation arrangements and welfare plans (with a focus on health care). This class will concentrate on the structure and basic rules that govern such arrangements. In the context of tax-qualified and nonqualified plans and health and welfare programs, this course will explore plan administration, fiduciary duties, claims appeals and litigation.

Prerequisite: Federal Income Taxation (formerly Taxation I).


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

LAW 2080 v00 The Affordable Care Act: Law and Policy Governing Private Health Insurance
(http://curriculum.law.georgetown.edu/course-search/?keyword=LAW %202080%20v00)
LL.M Seminar (cross-listed) | 3 credit hours
The Patient Protection and Affordable Care Act has significantly impacted the health care system. Through changes to the regulation of private health insurance, federal subsidies for low-income people, individual and employer mandates, and expansion of the Medicaid program, millions of Americans have gained health insurance. Yet, implementation of the law’s most significant reforms has been challenging, and its provisions have been subject to extensive litigation and continued threats of repeal.

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. The course will explore regulatory changes such as new market reforms and health insurance marketplaces; the impact of federal and state approaches to implementation; and legal and regulatory challenges. Guest lectures by speakers—including insurance industry representatives, legal experts, and regulators—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.

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 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 implementation, and likely areas of changes to the law given real-time debates.

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 869 v00 The Role of WHO in Global Health Law and Governance**

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

WHO is the sole global health organization and, as such, has been traditionally considered the lead actor in this domain at the center and the forefront of technical, policy and normative developments in global health governance. Its Constitution and institutional structure represent both the embodiment of a new way of thinking about global health and its governance at the time of creation of the UN system as well as the outcome of political compromises that have affected the life of the organization and its positioning in the global health landscape. The historical development of WHO's functions and activities are also an emblematic reflection of the changing role of health in the global economic, political and development agendas, and, as such, can shed light on broader issues of international law and relations. WHO's role and significance as the central actor in global health governance has been the object of contestation and much critical reflection starting in the 1990s and culminating with the organization's role in responding to the Ebola crisis. At the same time, global health governance has become more complex, fragmented and politicized and the future role of WHO has to be seen in the context of those developments and the search for a coherent global health architecture.

The course will focus on four broad areas covering the most important aspects of WHO as an international organization, an actor in global health governance, and a forum for policy and legal developments: 1) Historical, constitutional and institutional aspects; 2) normative functions and the role of WHO in the development of international law; 3) directing and coordinating functions, both in terms of how to address the most important health challenges as well as with regard to WHO's interaction with a number of political and economic regimes; 4) the position of WHO in the current global health landscape, both with regard to the role of other actors as well as to how the organization should look to its own future. The course will allow students to gain not only an in-depth knowledge and appreciation of WHO from an institutional and structural perspective, but also most importantly to appreciate the main contemporary challenges in global health as well as the role of health in a number of critical policy and normative regimes. The approach of the course will be based on lecturing, class discussions and at least one class exercise. Prof. Burci's former tenure as the Legal Counsel of WHO and a long-term senior lawyer in the organization will allow him to contribute real-life examples and experiences that will better root the course in the realities of the life of an international organization.

**LAW 3020 v00 Zika, Ebola, MERS, and the One Health Model of Global Outbreaks**

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.

**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.