NATIONAL AND 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 National and Global Health Law (see below), the LL.M. in Global Health Law and International Governance (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 200180 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 National and Global Health Law

All National and Global Health Law LL.M. candidates are enrolled in the 34-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, National and 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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<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>3-credit Global Health Law Course</td>
<td>3-credit Global Health Law Course</td>
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GPA Requirements

Students must earn a minimum grade point average of "B-" (2.67/4.00) in the courses that are counted toward the LL.M. specialization requirements.

Contact Information

To learn more, please contact:
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Email Address: Sarah Roache (sarah.roache@law.georgetown.edu)

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 3091 v00 Addiction and Mental Health Law and Policy (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%203091%20v00)
LL.M Seminar (cross-listed) | 2 credit hours
Addiction and mental health have increasingly become an integral part of the broader policy landscape. This shift has been accelerated by the impact of social issues such as the opioid epidemic, suicide and homelessness. This seminar will explore the framework of laws and policies promoting human rights, dignity, and recovery for people with substance use disorders and mental health conditions. It will highlight systemic and community responses to addiction, mental health, and related social issues as well as the use of litigation, legislation, advocacy and financial incentives as tools for reform.

Discussion will include:

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

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

LAW 1602 v00 Advanced Topics in Torts: Products Liability, Guns, and Drugs (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%201602%20v00)
J.D. Course (cross-listed) | 3 credit hours
This upper level course will cover the law of products liability generally and take a close look at the state of products liability litigation and liability in relation to guns and to opioids. The goal is to combine a survey of the complicated field of products liability law with a sophisticated deep dive into two areas of cutting edge products liability litigation. The first part of the course will familiarize students with major topics applicable to all products manufacturers including: a product distributor’s liability for defect-caused harm, allocating responsibility inside and outside the commercial chain of distribution, causation, affirmative defenses, approaches to design defect litigation, and federal preemption of products liability claims. Later in the course, we will examine gun manufacturer liability, currently and prior to the passage of the Protection of Lawful 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.

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 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.
Globalization has inevitably forced lawyers, public health professionals, health care professionals, and anthropologists alike to rethink the traditional approaches and methods relied upon within their disciplines. As international borders continue to disappear and countries and people throughout the world become increasingly interconnected and interdependent, public health threats can easily become global in scale and can only be properly addressed through multidisciplinary efforts at global, national, and local levels. Time and time again, the implementation of sound public health measures has proven difficult in communities when local culture and ideology are not considered or properly understood. As governments and international organizations increasingly rely on the law as a fundamental tool for solving critical health problems, it is of the utmost importance that the laws and regulations that they adopt with the aim of protecting and advancing population health, as well as their implementation, properly reflect the social and cultural context of those affected.

Through the analysis of case studies from various areas of global health (including non-communicable diseases, infectious diseases, climate change and health, and gender and health), this course aims to underscore the importance both of incorporating anthropological methods into the practice of global health law and of utilizing a multidisciplinary approach when addressing global health challenges.

**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 1536 v00 Bioethics and Social Justice (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%201536%20v00)
J.D. Seminar (cross-listed) | 2 credit hours
This seminar explores legal, ethical, and social issues raised by developments in health, medicine, and the biological sciences at the U.S. and global levels. It first provides an overview of the normative theories that inform the development of the field of bioethics, as well as connects these theories to legal and social dynamics that continue to shape discussions of equity and justice. It then considers a spectrum of priority topics and themes, through both a theoretical and practical lens, such as end-of-life issues, reproductive rights, human subjects research, access to medicines, and vaccines. Students will develop an in-depth perspective on how law and ethics overlap and shape the discourse on these priority topics. This seminar will be especially informative for students looking to obtain a practical view into how the law interacts with ethical dilemmas in health, medicine, and science.

Learning Objectives:

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

LAW 284 v01 Bioethics and the Law Seminar (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20284%20v01)
J.D. Seminar (cross-listed) | 3 credit hours
This seminar investigates legal, ethical, and social problems raised by developments in health, medicine and the biological sciences through the study of selected subjects that vary from year to year. Issues covered might include death and dying, genomics, reproductive technologies, fetal treatment and research, experimentiation 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 370 v02 Business and Human Rights in the Global Economy
(http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20370%20v02)
J.D. Seminar (cross-listed) | 2 credit hours
Corporations today have a global scale as well as an impact that matches or sometimes exceeds that of governments. Their activities -- from sourcing of raw materials, to processing and production of intermediate or finished goods, to distribution and sale -- have major consequences not only for the human rights of their employees but also for the rights of the individuals and communities impacted by their operations. In many countries, government regulation and oversight are either absent or largely ineffective. Companies in turn struggle to define their responsibilities in the face of these “governance gaps” -- particularly where requirements under national law fall short of international standards in areas such as hours of work and safety and health.

A robust and often contentious debate over these issues culminated in the development of the U.N. Guiding Principles on Business and Human Rights (the “UNGPs”) under the leadership of Special Representative John Ruggie. These Principles establish a framework for considering the respective roles of governments and corporations and outline core concepts of human rights due diligence and effective remedy. In doing so, the UNGPs also inform and to some extent refocus efforts that have emerged over the past 20 years to address these governance gaps and have brought together stakeholders from business, labor, civil society, the investment community, and academia.

At the same time, in recent years there has been an increased push from civil society groups and certain governments to go beyond these "voluntary" efforts and develop a binding business and human rights treaty mechanism; this has met with strong opposition from business and many other governments, including the United States.

Even as "non-regulatory" approaches remain the predominant means of addressing various business and human rights challenges, there also has been a growing focus in recent years on tools through which national governments and international institutions could exercise greater leverage. This includes advocacy for stronger labor and other human rights language in trade agreements, one-way trade preference programs, procurement standards, and the rules and guidelines applied by international financial institutions -- coupled with more aggressive enforcement of those criteria. Expanded efforts to advance that "regulatory" approach in trade policy and elsewhere in some cases has been met with resistance from governments and business, but there also have been examples of emerging consensus among a diverse range of stakeholders.

This course introduces students to this quickly-evolving business and human rights landscape, including the diverse set of multi-stakeholder initiatives -- some, but not all, of which include government participation. We will discuss the guidance provided by the UNGPs and other instruments, the range of stakeholders and how they engage with one another, tools utilized by governments and corporations to implement human rights standards, and how all of these interact in the context of both sector-specific and cross-cutting legal and policy challenges.

Among the questions the course will examine are:

• Which human rights standards are most relevant to business?
• What are the appropriate linkages between business policies and practices and the promotion of human rights?
• Which business and human rights approaches are emerging as "best practices" and perhaps even as recognized norms?
• What tools to support those are being used by governments and corporations?
• Who are the principal stakeholders and what are their roles and objectives?

LAW 3060 v00 Business, Human Rights and Sustainability (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%203060%20v00)
LL.M Course (cross-listed) | 1 credit hour
The relationship between business, human rights, and sustainability has gained momentum in recent years with the private sector, governments, civil society, and international organizations, owing largely to the passage of the United Nations Guiding Principles on Business and Human Rights (UNGPs) in 2011, the 2012 UN Rio + 20 Sustainable Development Conference and the UN Sustainable Development Goals (2015). These developments were preceded and followed by a series of multi stakeholder (governments, private sector, investors, civil society networks and organizations) and specific industry driven initiatives looking at how to integrate these international standards into both self and binding regulatory processes. As a result, many of these initiatives led to an emerging international soft law system of business, human rights and sustainability that is based in the internationally acknowledged body of hard law principles.

Regardless of being industry, sector specific or multi stakeholder in nature, the regulation, de-regulation, policy, practice and ever growing global litigation is multifaceted, dynamic, interactive, complex and challenges business leaders, markets and even lawyers to think outside the box in order to address a challenging relationship between business, markets and society. This is where business strategy meets risks. Or instead, this is where risks eat a business strategy. As a result, business leaders, shareholders and their advisors are now required to integrate a 3D internal and external view and assessment on how to address, prevent, mitigate and remediate the social and environmental impacts (risks) of private sector operations in complex environments and with a collaborative and systems thinking approach.

Bar Associations in America and abroad have begun issuing specific guidance on how corporate lawyers should advice their clients incorporating human rights and sustainability standards. For instance, in a Mergers and Acquisitions (M&A) transaction, corporate lawyers are most likely to encounter questions dealing with social, environmental, human rights and environmental concerns. Those advocating on behalf of environmental and human rights organizations will find their work directly intersects with company law, securities law, investment law, governance, compliance, company law and alternative dispute resolution mechanisms to name a few sub areas.

In practice, these global and ever growing litigation trends are also challenging traditional company-led corporate social responsibility (CSR) and ethics programs that have been associated with both philanthropic, corporate citizenship and company-sponsored activities that give back to societies. While many of these programs have achieved several levels of success, for many sectors in society they remain as corporate public relations or green wash exercises and demand more transparent, accountable and remediation responses. The stakes are high.

Litigation and other types of social demands are challenging companies to be very purposeful and accountable on how they address the environmental, social and governance negative impacts (for some) or violations (for others) of their operations globally and domestically. Stakeholders are asking companies to integrate ongoing due diligence processes that address materiality concerns when it comes to managing supply chains and making sure they are free of child labor, modern slavery and human trafficking. They are also asking companies to address the social and environmental impacts of extraction of natural resources above and below ground, to name a few.

Furthermore, stakeholders are not alone on this. The emerging and growing movement of shareholder advocacy is leading the way across industries and pushing the way through different strategies for more corporate engagements that drive responsible business conduct and leadership.
LAW 3120 v00 Communicating Public and Global Health Law (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%203120%20v00)
LL.M Seminar | 1 credit hour
This course explores how stakeholders understand and communicate the impacts of law on individual and public health outcomes. Many stakeholders, including law-makers, public health experts, regulated industries, health and human rights advocates, and the public, offer unique perspectives and narratives. Through class discussions and participatory exercises, we analyze the tensions that emerge between public health objectives and other legal rights and interests, such as freedom of speech, freedom of movement, and personal choice and responsibility. We imagine how different stakeholders approach health issues, including tobacco control, healthy diets, sexual and reproductive health and infectious disease outbreaks, and how these different approaches inform health law and policy-making and adjudication of contested issues.

The course is designed to teach substantive health law knowledge and practical skills, including legal reasoning, communication, and advocacy. Our analysis and discussions will draw on a wide range of materials, including public comments, advertisements, media, judgments, and legal scholarship. Students will be assessed based on class participation (20%) and presentation of a case study (in pairs or small groups).

Note: Compulsory for National and Global Health Law LL.M students and Global Health Law and Governance LL.M students (if in residence at Georgetown Law).

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; reproductomics; 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, 2020 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.

LAW 754 v01 Epidemiology for Lawyers (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW %20754%20v01)
LL.M Seminar (cross-listed) | 1 credit hour
Increasingly, lawyers and policymakers are confronted with the need to evaluate scientific research about causes of good or ill health. Should the family of a person who was exposed to asbestos and later died of lung cancer sue? At what level should mercury in tuna violate regulatory standards? What measures can be employed to control the spread of an Ebola outbreak or to prevent obesity? Will mandatory quarantines save lives if a bioterrorist releases anthrax in a major city?

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

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

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

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

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

WEEK ONE COURSE. This course will meet for one week only on the following days: Monday, January 6, 2020 through Friday, January 10, 2020, 1:30 p.m. - 4:05 p.m.
This course is mandatory pass/fail and will not count toward the 7 credit pass/fail limit for J.D. students. ATTENDANCE IS MANDATORY AT ALL CLASS SESSIONS. Enrolled students must be in attendance at the start of the first class session in order to remain enrolled. Waitlisted students must be in attendance at the start of the first class session in order to remain eligible to be admitted off the waitlist. All enrolled students must attend each class session in its entirety. Failure to attend the first class session in its entirety will result in a drop; failure to attend any subsequent class session in its entirety may result in a withdrawal. Enrolled students will have until the beginning of the second class session to request a drop by contacting the Office of the Registrar; a student who no longer wishes to remain enrolled after the second class session begins will not be permitted to drop the class but may request a withdrawal from an academic advisor in the Office of Academic Affairs. Withdrawals are permitted up until the last class for this specific course.
LAW 1345 v00 Farm Law and Policy Seminar (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%201345%20v00)
J.D. Seminar (cross-listed) | 2 credit hours
Rules governing agriculture have a dramatic impact on the cost, availability, nutritional quality, and safety of food, the fate of farmers and farm workers, and the environmental impacts of crop and livestock production. This course will cover the policies, rules, and laws that govern agriculture, including laws and regulations related to farm subsidies, farm stewardship, biotech regulation, food safety, food labeling, food assistance, farm labor, animal welfare, agricultural trade, and antitrust issues related to crop and livestock production.

The Farm Law and Policy Seminar complements other courses offered by the Law Center, including courses on Food Law and Environmental Law.

Recommended: A course in food law or environmental law.

LAW 1202 v01 Food and Drug Law (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%201202%20v01)
LL.M Seminar (cross-listed) | 2 credit hours
This course will introduce students to the foundational laws and policies governing the production and distribution of foods, drugs and medical devices in the United States, focusing on the Federal Food, Drug, and Cosmetic Act (the “Act”) and the role of the Food and Drug Administration in enforcing the Act. The course will cover key concepts and definitions – e.g., “food,” “drug,” “labeling” – and federal statutory provisions designed to assure that such products are not adulterated or misbranded. Students will also receive an overview of the different agencies that have jurisdiction over foods, drugs and devices on the state and federal levels, as well as an introduction to the ways in which such agencies exercise their authority through rulemaking, guidance and enforcement activity.

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

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

Note: FIRST CLASS ATTENDANCE IS MANDATORY. Enrolled students must be in attendance at the start of the first class session in order to remain enrolled. Waitlisted students must be in attendance at the start of the first class session in order to remain eligible to be admitted off the waitlist.

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 rights, 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 reimagine and critique prevailing legal rules and cultural norms. In short, the class 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

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

Recommended: Prior Enrollment in Food and Drug Law

LAW 493 v01 Global Health Law

LL.M Seminar | 3 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, and the WHO Framework Convention on Tobacco Control.

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 LL.M.

Class will meet for two hours each week, with third hour of weekly course content delivered asynchronously.

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) H5N; an intentional introduction of a lethal pathogen such as anthrax; and/or major chronic diseases caused by obesity or tobacco use. Students should come to this course with a basic level of understanding of global health law, including the major international health treaties and governing structures. When studying and role playing these kinds of problems, students will be asked to construct innovative methods of global health governance, drawing upon existing international health law and institutions, along with a vision for more ideal models. The course will also capitalize on materials developed in collaboration with faculty from the School of Nursing and Health Studies for use in the “health care situation room”.

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

Note: The first weekend of the course will be held at the Law School and the second weekend will be on the Main Campus at St Mary’s at the School of Nursing and Health Studies.

A student will be permitted to drop a course that meets for the first time after the add/drop period, without a transcript notation, if a student submits a written request to the Office of the Registrar prior to the start of the second class meeting. Withdrawals are permitted up until the last class for this specific course. ATTENDANCE IS MANDATORY AT ALL CLASS SESSIONS. Enrolled students must be in attendance at the start of the first class session in order to remain enrolled. Waitlisted students must be in attendance at the start of the first class session in order to remain eligible to be admitted off the waitlist. All enrolled students must attend each class session in its entirety. Failure to attend the first class session in its entirety will result in a drop; failure to attend any subsequent class session in its entirety will result in a withdrawal. Enrolled students will have until the beginning of the second class session to request a drop by contacting the Office of the Registrar; a student who no longer wishes to remain enrolled after the second class session begins will not be permitted to drop the class but may request a withdrawal from an academic advisor in the Office of Academic Affairs. Withdrawals are permitted up until the last class for this specific course.
LAW 1028 v00 Health Care Fraud and Abuse Seminar (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%201028%20v00)
J.D. Seminar (cross-listed) | 2 credit hours
One-fifth of the U.S. economy centers around health care industry sectors. This seminar examines criminal, civil and administrative tools used by federal and state enforcement authorities to police the U.S. healthcare system. We will focus on cases brought under federal and state False Claims Acts (FCA), the Anti-Kickback Statue (AKS), Stark laws, Federal Food Drug and Cosmetic Act (FDCA), and Foreign Corrupt Practices Act (FCPA). The seminar provides a survey of the enforcement activities of the U.S. Department of Justice (DOJ), the Office of Inspector General at Department of Health and Human Services (OIG), and state Medicaid Fraud Control Units (MFCUs) in matters against pharmaceutical and medical device manufacturing companies, physicians, hospitals, clinical practices, nursing homes, laboratories, and others. The seminar materials thoroughly cover the statues, safe-harbors, and regulations that govern the health care industry. We will also discuss risk mitigation strategies and compliance program best practices across industry sectors to provide insight into the impact enforcement has on (1) clinical decision-making, (2) costs to providers, payers, and patients, (3) patient safety, and (4) quality of care. In an effort to maintain a broad perspective with the diverse and frequently changing legal landscape in the area, in addition to the case book, materials discussed and presented in this course draw from news reports, trade publications, and U.S. government agency materials.

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

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

LAW 2037 v00 Health Information Technology and the Law (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%202037%20v00)
LL.M Seminar (cross-listed) | 2 credit hours
Health care decision-making and innovation are increasingly driven and made 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 technology, including where data comes from, how it is and should be protected, how it can be used, and risks to its integrity and security. In doing so, this course will cover a range of topics including health information privacy, future use of data assets, and conflicts of interest.

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

COVID-19 has put a spotlight on our medical care system's shortcomings, as well as the social inequities that shape Americans' health and well-being. Our nation's response to COVID will thus play a substantial role in this year's edition of the course - as both a matter of national urgency and a window onto these shortcomings.
LAW 2076 v00 Health Law and Regulation (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%202076%20v00)
LL.M Course (cross-listed) | 3 credit hours
Beyond health insurance and the delivery of health care, goods and services related to individual and public health are highly regulated in the United States, and often serve as a basis for international regulations. These goods and services are a large and growing part of the U.S. and world economy, with some estimates being that more than one-quarter of U.S. food and medical products are regulated by the FDA alone. This regulation is carried out directly by a variety of State and Federal agencies (such as the FDA, the CDC, and the NIH) as well as indirectly through the purchasing power of federally financed programs, such as Medicare.

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

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

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

Note: This is a required course for the US Health Law Certificate.

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:

1. What are international human rights standards that relate to health?
2. What does it mean in practice to set out a "right to health," and how might such a right be implemented?
3. What is (and should be) the role of courts in enforcing health rights?
4. What are the key elements of 'rights-based approaches' in programs and policies, with reference to specific health issues and affected populations?
5. How might adopting a rights-based approach to global health issues challenge traditional human rights assumptions and practices?
6. 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 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?

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5. How might adopting a rights-based approach to global health issues challenge traditional human rights assumptions and practices?
6. How can human rights be used to create meaningful social change in health, and what are the limitations to using human rights frameworks?
LAW 1408 v00 Human Genetic Engineering: Law and Policy (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%201408%20v00)

J.D. Seminar (cross-listed) | 2 credit hours
This two-credit seminar will open a window into the fast-developing world of human genetic engineering. It begins with a review of international and regional efforts to ban or restrict human germline modification (HGM), along with a brief world overview of relevant laws and trends. It then focuses on cutting-edge techniques like CRISPR/Cas9 and organized research efforts, particularly in China, that may nonetheless spark a race to create designer babies within a decade or less, as regulation lags behind technology and human affairs. Next, we examine two more well-established reproductive technologies, mitochondrial replacement and pre-implantation genetic diagnosis (PGD), to identify forces that are likely to guide HGM regulation as relevant technologies become safer and more efficient. We'll study the U.K.'s recent adoption of mitochondrial transfer to reduce birth defects or enhance fertility and then learn about evolving U.S. policy. We'll follow the spread of PGD, initially used to identify embryos bearing genes causing incurable childhood diseases, first to other less serious conditions, then to the creation of “savior siblings” and finally to non-medical uses like sex selection. Then we’ll return to HGM and view a sample of public policy proposals and religious views likely to influence the coming debate. Finally, we’ll close with an introduction to futuristic impulses to implement theoretically limitless improvements to human capabilities, sometimes balanced by the desire to use HGM to improve human moral character and tempered by doubts regarding the moral status to be accorded new HGM creations.

LAW 233 v01 Intellectual Property and Medicines (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20233%20v01)

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

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

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

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

LAW 802 v01 International Assistance for Global Health (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20802%20v01)

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

Enrolled students will have until the beginning of the second class session to request a drop by contacting the Office of the Registrar; a student who no longer wishes to remain enrolled after the second class session begins will not be permitted to drop the class but may request a withdrawal from an academic advisor in the Office of Academic Affairs. Withdrawals are permitted up until the last class for this specific course. The take-home exam in this course may be administered mid-semester and the specific exam date will be provided by the professor after the add/drop period.
LAW 3006 v00 International Right to Health (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%203006%20v00)
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: Enrolled students will have until the beginning of the second class session to request a drop by contacting the Office of the Registrar; a student who no longer wishes to remain enrolled after the second class session begins will not be permitted to drop the class but may request a withdrawal from an academic advisor in the Office of Academic Affairs. Withdrawals are permitted up until the last class for this specific course.

LAW 691 v00 International Trade and Health (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20691%20v00)
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 (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20708%20v00)
LL.M Seminar (cross-listed) | 2 credit hours
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.
LAW 2071 v00 Law and Functioning of International Organizations
LL.M Course (cross-listed) | 2 credit hours
Multilateral diplomacy and the international organizations that support much of it have come to play a pervasive role in international relations particularly since the end of World War II. These international organizations serve as instruments of consultation, co-operation and standard setting in almost every sphere of public policy and governmental activity. This may involve broad concerns such the maintenance or restoration of international peace and security, promotion of economic development and stability, advancement of human rights, protection of health, protection of the environment, and the facilitation of trade and investment. Or they may address more specific tasks such as settlement of disputes, codification and progressive development of international law, civil aviation and maritime safety and security, protection of intellectual property, understanding world weather, internet governance, management of the geo-stationary orbit, police cooperation, education and biotechnology. They vary greatly in nature, mission, powers, structure and size. There are inevitable conflicts and frictions in their functioning.

It will examine a number of aspects common to the universe of public, i.e., intergovernmental, international organizations: their legal nature; their need, as the collective instruments of their member states, to remain independent of the individual control of these states, including control through the exercise of some normal state jurisdiction; their immunities and counter-balancing obligations to co-operate; their special body of labor law, including the duties and ethics of the international civil service and the use of international administrative tribunals to adjudicate their employment disputes. The course will examine a sampling of international organizations: how they are governed and financed, how they go about fulfilling their functions, the powers and instruments they use to advance agreed policies, some examples of their output including the development of soft law and hard law instruments and the increasing involvement of civil society in monitoring and influencing their actions. It will also consider the crucial advisory and operational roles lawyers play in a typical international organization, whether as members of the secretariat or of member state delegations.

Students will have the option of preparing a paper that they may elect, after grading, to include in the calculation of their final course grade.

Recommended: Prior enrollment in Public International Law or International Law I.

LAW 199 v03 Law and Regulation of Drugs, Biologics and Devices
J.D. Course (cross-listed) | 3 credit hours
This course explores the legal, regulatory and policy issues that shape the research, development, and commercialization of drugs and biologics in the United States and Europe, with a particular emphasis on public policy issues. We will consider: the role of Federal, State and international regulation; regulatory and ethical issues in the development and testing of new therapies; managing incentives for innovation, including patent, regulatory and data exclusivity; tort liability and its function in the regulation of the pharmaceutical industry; pricing and payment systems and controls; and evolving medical technologies.

Recommended: Prior or concurrent enrollment in Administrative Law.

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

LAW 2010 v01 Law and Regulation of Global Health Technologies
LL.M Seminar (cross-listed) | 2 credit hours
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.
LAW 915 v00 Law, Healthy Lifestyles, and Business Regulation
(http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20915%20v00)
LL.M Seminar (cross-listed) | 1 credit hour
This course is about legal responses to tobacco use, obesity, poor diet, harmful use of alcohol and sedentary lifestyle – the leading causes of preventable disease in the United States, in high-income countries generally, and increasingly, in developing economies. Cancer, heart disease, stroke, diabetes and tobacco-related diseases (known as “non-communicable diseases” or NCDs) are society’s greatest killers, but what can law do – and what should it do – to prevent and manage them?

Unlike other global health threats, NCDs and their risk factors are partly 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 matters for personal responsibility? Does a regulatory approach to the prevention of NCDs imply coercion? Does it signal the emergence of a “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 course will meet for one week only on the following days: Monday, January 11, 2021 through Thursday, January 14, 2021, 9:00 a.m. - 12:20 p.m.

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

LAW 3047 v00 LGBT Health Law and Policy
(http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%203047%20v00)
LL.M Seminar (cross-listed) | 2 credit hours
Despite significant progress in legal protections for (and the visibility of) LGBTQ and non-binary people over the past decade, LGBTQ communities continue to face systemic obstacles to quality health care such as refusals of care, substandard care, and inequitable policies and practices in many health care settings. These experiences of discrimination correlate with significant health disparities, including greater exposure to sexual and gendered violence, higher rates of tobacco and other substance use, mental health concerns, HIV acquisition, and cancer. These disparities are even more pronounced for LGBTQ people who are also members of other groups that face discrimination because of race, ethnicity, or other aspects of identity—such as people of color, young and older people, people with disabilities, low-income people, and immigrants, among others.

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

LAW 275 v01 Medical Judgment, Morals, and Law Seminar
(http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20275%20v01)
J.D. Seminar (cross-listed) | 3 credit hours
"Into each house I go," the Hippocratic Oath promises, "I shall go only for the good of my patients." We think of doctors as devoted to their patients’ well-being, but they increasingly serve social and legal purposes. To control medical costs, physicians ration care, often unbeknownst to their patients. To protect us from foreign enemies, doctors wage war, designing and overseeing the interrogation of terror suspects. When threats to public health loom, physicians make clinical decisions that protect society at their patients’ expense. In our criminal and civil justice systems, medical judgment answers moral and legal questions about the scope of personal responsibility, the reach of civil rights law, and more. And in our politics, medical opinion both masks and imposes moral and cultural beliefs. This Seminar will explore medicine’s myriad social and legal roles, with an eye toward conflict between these roles and physicians’ traditional commitment to their patients’ interests.
LAW 1382 v01 Medical-Legal Partnership: A Collaborative Approach to Health Justice

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

Medical-Legal Partnership (MLP) is a health care delivery model that recognizes that some barriers to good health have legal remedies. In an MLP, doctors and other healthcare professionals work with lawyers to improve the health and lives of vulnerable populations in a way that neither medicine nor law can alone. Thus, for example, the child with asthma who lives in substandard housing may respond more effectively to treatment if her pediatrician and lawyer work together to force her landlord to address the mold, rodent, and roach issues that exacerbate her condition. Beyond direct legal services, MLPs also build institutional capacity to address unmet legal needs and advocate for changes to laws, regulations, practices and policies that impact health.

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

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

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

Required Text
TBA

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LAW 593 v00 National and Global Health Law: O’Neill Colloquium

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.
Proper nutrition is one of the many contributors 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.

Seventy years ago the United Nations (UN) General Assembly adopted the Universal Declaration of Human Rights (UDHR) (1948) and more recently the International Covenant on Economic, Social and Cultural Rights (1966), the International Covenant on Civil and Political Rights (1966), the International Convention on the Elimination of All Forms of Racial Discrimination (1965), the International Convention on the Elimination of All Forms of Discrimination Against Women (1979), and the International Convention on the Rights of the Child (1989). These human rights instruments provide the foundation of what many consider to be the international right to health. While the international right to health is recognized in the Declaration of Tokyo and the Alma-Ata Declaration, and is embedded in the special rights to adequate food (1974) and adequate health (1993), the UN General Assembly did not formally recognize the right to health until 1997.

The definition of the right to health as a universal right is based on the Universal Declaration of Human Rights and the International Covenants on Economic, Social and Cultural Rights, and on Civil and Political Rights. Each of the rights in the UDHR is a foundation upon which other rights are built, while the International Covenants on Economic, Social and Cultural Rights, and on Civil and Political Rights are the primary law-making instruments for the implementation of the human rights described in the UDHR.

Professor: Paul Offit

LAW 1209 v00 Nutrition Law and Policy (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%201209%20v00)

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

Proper nutrition is one of the many contributors 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.
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 (https://oneill.law.georgetown.edu/) 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 Course (cross-listed) | 1 credit hour
The objective of this 1 credit course is to introduce students to the relationship between international laws governing foreign investment and efforts to protect and promote human health. The course will examine the extent to which bilateral investment treaties (BITs) and investment chapters in trade agreements limit domestic regulatory autonomy 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. Enrolled students must be in attendance at the start of the first class session in order to remain enrolled. Waitlisted students must be in attendance at the start of the first class session in order to remain eligible to be admitted off the waitlist. All enrolled students must attend each class session in its entirety. Failure to attend the first class session in its entirety will result in a drop; failure to attend any subsequent class session in its entirety may result in a withdrawal.

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

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

LAW 364 v06 Public Health Law and Ethics (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20364%20v06)

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

This course explores the interwoven dynamics of legal and ethical aspects of public health issues in the United States and abroad, including infectious diseases, tobacco use, obesity, and the environment, among others. This course will be valuable for students interested in global health law, as well as students looking to broaden and deepen their expertise in preparation for a career in health law more generally.

This course will proceed in three movements. First, it will consider the conceptual foundations of public health law in the United States through the lens of governance, ethics, and human rights, affording particular attention to the statutory and regulatory powers and duties of federal and state governmental entities to protect the health and safety of the population. Second, it will examine the sources of tension between the objectives of public health and civil liberties including, among others: labeling and advertising restrictions and free speech; disease surveillance and privacy; and considerations in personal versus population-based conceptions of health. Lastly, this course will conclude by considering emerging public health issues at the intersection of law and ethics, such as biosecurity, vaccine policy, and the role for public health in broader discussions around health care reform in the United States.
Effective PPP lawyers are translators and guides: they 'speak both languages’ thus positioning themselves to propose innovative, non-obvious solutions and can build trust with, and among, partners and stakeholders.

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

To do this, the course uses a mix of lecture, discussion, video, and experiential learning. 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 consortia. 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.

Serving as a lawyer to a PPP provides an exceptional challenge because the tools and strategies that work when counseling in the public sector may be strange or ill fit for purpose in the private sector (and vice versa). Effective PPP lawyers are translators and guides: they ‘speak both languages’ thus positioning themselves to propose innovative, non-obvious solutions and can build trust with, and among, partners and stakeholders.

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

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 the Office of the Registrar (lawreg@georgetown.edu) to request admission.

Evening students who work during the day are encouraged to reach out to the professor to discuss whether this practicum course would be compatible with their schedules. This is a four credit course. Two credits will be awarded for the two-hour weekly seminar and two credits will be awarded for approximately 10 hours of supervised project work per week, for a minimum of 11 weeks. Both the seminar and the project work will be graded. Students who enroll in this course will be automatically enrolled in both the seminar and project components and may not take either component separately. After Add/Drop, a student who wishes
LAW 1445 v00 Reproductive Justice Seminar (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%201445%20v00)
J.D. Seminar | 2-3 credit hours
Reproductive Justice is a concept developed by Black Women activists in the 1990s to provide a different framework to explore how systemic oppression impacts reproductive decision-making. Acknowledging that abortion and contraception were often not the primary reproductive concerns of many marginalized women, including women of color, young women, women with disabilities, undocumented women, and queer women, activists adopted a framework that considers the contexts in which reproductive decisions are made. This approach centers social, racial and economic justice, and focuses as much on women's rights to have and raise children as it does on their right to not have them though access to safe and legal abortion care and contraceptive access.

This course will focus on the rights to not have a child, to have a child, and to raise a child. While abortion will be discussed in several of the units in which it is relevant, due to the truncated semester, the course will not focus on abortion or contraception. Students may, however, focus their writing requirement on abortion or contraception. The course will take an interdisciplinary approach to the issues, incorporating various bodies of law (family law, welfare policy, criminal law) along with an historical analysis, social science, and current events.

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

This course will be enrolled via waitlist.

LAW 3090 v00 Reproductive Rights (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%203090%20v00)
LL.M Course (cross-listed) | 2 credit hours
This course will explore the history and law of reproductive rights in the United States. The majority of the semester will be spent analyzing the constitutional framework, jurisprudence and federal and state regulations governing forced sterilization, contraception and abortion from the 1920s until today. We will consider the historical, social and religious context of the regulation of reproduction; gender, race and socioeconomic class issues; and the practical impact of the regulations in effect today. This course is primarily focused on reproductive rights in the United States, but we may consider comparative international perspectives.

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

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

Grading: Class participation, including oral presentations, will represent 35% of the final grade. A take-home exam will account for the remaining 65%.

Recommended: Constitutional Law I

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.
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.

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 Course (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.

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LAW 1511 v00 The Battle over “Obamacare”: Lessons for Health Policy & American Governance
(http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%201511%20v00)
J.D. Seminar | 3 credit hours
Since the Affordable Care Act became law eight years ago, it has come under unrelenting legal and political attack. It’s been subject to multiple court challenges, and President Trump and congressional Republicans have sought to “repeal and replace” it. Some Democrats, meanwhile, have doubled down, marshalling support for their own, “single-payer” replacement. Meanwhile, some of America’s most bitter cultural conflicts – over sex, gender, and the beginning and end of life – have played out within the framework of the ACA and within the health-care sphere more generally. This seminar will examine the oft-bitter battles over “Obamacare” with an eye toward lessons for health law and policy and for American governance more generally. We’ll examine some of the problems that the ACA and rival Republican and Democratic approaches aim to address, the failings of both markets and regulation in the health sphere, and the politics of health reform.
The Doctors Trial provides a significant and important example of human law 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 3085 v00 The Nuremberg Trials, the Doctors Trials (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%203085%20v00)
LL.M Seminar (cross-listed) | 2 credit hours
The Doctors Trial considered the fate of twenty-three German physicians who either participated in the Nazi program to euthanize persons deemed "unworthy of life" (the mentally ill, mentally retarded, or physically disabled) or who conducted experiments on concentration camp prisoners without consent. The Doctors Trial lasted 140 days. Eighty-five witnesses testified and almost 1,500 documents were introduced. Sixteen of the doctors charged were found guilty. Seven were executed.

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

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