FOOD & DRUG LAW CERTIFICATE

Program details and eligibility requirements for the Certificate in Food & Drug Law can be found on the Georgetown Law main website *(*https://www.law.georgetown.edu/academics/certificates-of-specialization/food-drug-law/*).*

Below are descriptions for courses currently or previously offered for the Certificate in Food & Drug Law.

For the current list of course offerings, refer to the Curriculum Guide (https://curriculum.law.georgetown.edu/course-search/?program=program_93). To find the list, locate *Courses in a Graduate Program* under the Curriculum Guide *Search Options* menu and select *Food & Drug Law Certificate*.

Search LL.M Food and Drug Law Certificate Courses (https://curriculum.law.georgetown.edu/course-search/?program=program_93)

LAW 065 v02 Alternative, Complementary, and Integrative Medicine, The Legal Issues Seminar (https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 065 v02)
J.D. Seminar (cross-listed) | 3 credit hours
Alternative, Complementary, and Integrative Medicine (CAM) is one of the fastest growing sectors of American healthcare. At least 50 percent of Americans are using some form of alternative and complementary therapy such as acupuncture, nutritional supplementation, herbs, massage, yoga, chiropractic, or homeopathy. According to the Journal of the American Medical Association, visits to alternative healthcare 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, Engineering and Medicine, has held recent conferences on the values of both CAM and Integrative Medicine while The National Institutes of Health is using significant resources to fund research in this area.

These developments, of course, are 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 Food and Drug Administration (FDA) and the Federal Trade Commission (FTC), are trying, within the limits of statutory authority, to protect what officials 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 proverbial "snake oil" frauds. And, to an extent, the law is being used to keep out alternatives to the established healthcare modalities. This seminar studies the tensions -- legal, economic, and social -- of this struggle as it unfolds. This seminar also covers several areas of law, including administrative law, medical malpractice, informed consent, FDA/FTC law, and licensure, among others, and addresses the tension between government paternalism and individual rights in the United States. A paper meeting the upper class legal writing requirement is required.

LAW 2028 v01 Assisted Reproductive Technologies and the Law (https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 2028 v01)
LL.M. Seminar (cross-listed) | 2-3 credit hours
This 2 or 3 credit seminar will provide an overview of the underlying and competing laws and policies arising from the assisted reproductive technologies (ARTs) that continually make front page news. Since the 1980 opening of the country's 1st IVF clinic amidst protests and pickets, courts and legislatures have struggled to create laws and policies in response to continually evolving reproductive advances. Topics will include: the legal status of the IVF embryo in the context of procreative rights (highlighted by the currently changing and challenging legal context); embryo cryopreservation, storage, disposition and mix-ups; legal implications of advances in egg freezing, reproductive genetics and oncofertility; posthumous reproduction; egg and sperm donation; traditional/genetic and gestational surrogacy; unique issues for single and same-sex couples, including the impact of legally recognized same-sex marriage; and professional and regulatory aspects of the ARTs.

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

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

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

LAW 1844 v00 Federal Regulation of Biopharmaceuticals: Issues and Controversies (https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 1844 v00)
J.D. Seminar (cross-listed) | 2 credit hours
This seminar provides an overview of the principal legal issues impacting the development and commercialization of biopharmaceutical products. It:

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

At the end of the course, students will have a foundational understanding of the biopharmaceutical industry, the federal regulatory rules governing the development, distribution, and promotion of biopharmaceutical products, and areas of ongoing legal debate. The primary statute of focus for the course is the Federal Food, Drug, and Cosmetic Act of 1938, as amended. Students will also gain an understanding of the key primary sources in life sciences regulatory law with particular emphasis on legislation regulations, sub-regulatory guidance, and case law applicable to biopharmaceutical products.

Strongly Recommended: Administrative Law; Constitutional Law

LAW 1202 v01 Food and Drug Law (https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 1202 v01)
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.

Mutually Excluded Courses: Students may not receive credit for this course and Food Law Seminar.

LAW 1600 v01 Food Justice Law and Policy (https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 1600 v01) (Fieldwork Practicum)
J.D. Practicum | 4 credit hours
Rules governing food and agriculture can have a dramatic impact on the welfare of farmers, food and farm workers as well as the price of food, access to healthy food, the fate of rural communities, the environment, and animal welfare. This is a fieldwork practicum course that has both 1) a two-credit graded seminar exploring food justice and policy issues and 2) a two- credit fieldwork placement. The fieldwork credits are mandatory pass-fail.

SEMINAR: This seminar portion of the course will advance the Law Center's institutional learning outcomes by covering the policies, rules, and laws that govern food and agriculture, including laws and regulations related to farm subsidies, farm stewardship, pesticide safety, food safety, food labeling, food and farm labor, and animal welfare. The extent to which these policies have discriminated against farmers of color and food and farm workers and limited access to healthy food choices will be a major theme of this practicum. Students will have pervasive opportunities to think critically about the law's claim to neutrality and its differential effects on subordinated groups.

FIELDWORK: In the fieldwork component of this course, students will be assigned to projects with the Environmental Working Group, the Environmental Defense Fund, the Center for Science in the Public Interest, Earthjustice, or other food, farm, worker, environmental justice, and animal justice organizations working on these issues. They will have an opportunity to learn how such institutions play a role in advancing food justice issues being debated in both the administrative and legislative processes, and in matters subject to litigation. Students must work 10 hours per week for 11 weeks for two credits.

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 Constitutional Criminal Procedure (formerly Criminal Justice), Property, or their first-year elective.

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

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

Note: This course is suitable for evening students who can commit to attending class and working 10 hours/week (during business hours) on site at their field placements.

This is a four-credit course. Two credits will be awarded for the two-hour weekly seminar and two credits for approximately 10 hours of fieldwork per week, for a minimum of 11 weeks, to be scheduled with the faculty. The fieldwork must be completed during normal business hours. The two-credit seminar portion of this practicum will be graded. The two credits of fieldwork are mandatory pass/fail. Students will be allowed to take another course pass/fail in the same semester as the field work. Students who enroll in this course will be automatically enrolled in both the seminar and fieldwork components and may not take either component separately. After Add/Drop, a student who wishes to withdraw from a practicum course must obtain permission from the faculty member and the Assistant Dean for Experiential Education. The Assistant Dean will grant such withdrawal requests only when remaining enrolled in the practicum would cause significant hardship for the student. A student who is granted permission to withdraw will be withdrawn from both the seminar and fieldwork components. Default attendance rule for all practicum courses (unless the professor indicates otherwise): Regular and punctual attendance is required at all practicum seminars and fieldwork placements. Students in project-based practicum courses are

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

Mutually Excluded Courses: Students may not receive credit for this course and Food and Drug Law.

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

LAW 2037 v00 Health Information Technology and the Law (https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 2037 v00)
LL.M Seminar (cross-listed) | 2 credit hours
Health care decision-making and innovation are increasingly driven and made possibly by vast stores of data. The importance of data has created an inevitable push-pull dynamic between concerns for confidentiality and demands for medical progress and cost containment. Data is both a privacy risk and a tremendous asset. This course will explore the legal and ethical issues at the intersection of health information, including where data comes from, how it is 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 2076 v00 Health Law and Regulation (https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 2076 v00)
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 233 v01 Intellectual Property and Medicines (https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 233 v01)
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 patents and other intellectual property in drugs and biologics; (2) the interplay of the regulatory approval process for therapeutic products with intellectual property rights; (3) the Hatch-Waxman Act and its impact on how patent rights for pharmaceuticals are procured and enforced ; and (4) major legislation affecting the use of intellectual property rights in the drug, biotechnology and medical device fields, such as the Biologics Price Competition and Innovation Act of 2009 and the America Invents Act of 2011. Other topics may be included depending on current judicial or legislative developments. A background in biologics or pharmaceuticals is not required, although completion of a basic patent law or a food and drug law course is recommended.

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

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

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

LAW 708 v00 International Trade, Intellectual Property Rights, & Public Health (https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 708 v00)
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, including on the Covid-19 vaccines waiver. 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 TRIPS-plus provisions in bilateral or regional free trade area agreements. The course would study relevant national/regional implementing legislation, for example on compulsory licenses, and discuss use of the WTO export compulsory license provisions. Finally, the course will also cover recent work on trade, intellectual property and public health in other intergovernmental organisations, in particular in the World Health Organization, including negotiations on the pandemic agreement. In addition to the final paper, students will be graded on class participation, individual/group class presentations.

The learning objectives and outcomes of this course are to be able to:

- Identify the legal and policy implications of international trade rules, particularly those on intellectual property rights (IPRs), for public health, and critically evaluate proposals for changes to these rules;
- Understand past and current legal work of international institutions in this field, particularly the WTO and the WHO, and evaluate the way forward;
- Improve the basic skill of communicating effectively, both in writing and orally, on a legal topic covered by the course, for example by explaining clearly how the provisions of TRIPS could be used to promote both the innovation of and access to needed medicines;
- Improve the skill of independently conducting legal and policy research;
- Demonstrate the basic value of being respectful of the different views in this area, including during group work and in class.

Recommended: Coursework on the basics of International Trade/ Intellectual Property Rights/ Public Health is recommended.

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 199 v03 Law and Regulation of Drugs, Biologics and Devices (https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 199 v03)
J.D. Course (cross-listed) | 3 credit hours
This course explores the legal, regulatory and policy issues that shape the research, development, and commercialization of drugs, biologics, and medical devices in the United States. We will consider the history and role of federal regulation of medical technologies; legal and ethical issues in the development and testing of new therapies; managing incentives for innovation, including patent, regulatory and data exclusivity; tort liability and its function in the regulation of the life sciences industry; and other issues. We will explore these issues using real-world examples, including the government and industry response to the COVID-19 pandemic.

Recommended: Prior or concurrent enrollment in Administrative Law.

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

LAW 915 v00 Law, Healthy Lifestyles, and Business Regulation (https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 915 v00)
LL.M Seminar (cross-listed) | 1 credit hour
Everyone wants to live a long and healthy life, but what are the impediments to a longer lifespan, and a longer healthy life expectancy? 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, also in low and middle-income countries. 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 law be permitted to do – to prevent and control them?

Unlike other global health threats, NCDs and their risk factors are partly the result of consumer choices and transactions lived out every day across the country. The challenge of creating healthier lifestyles cannot be separated from debates about the regulation of those businesses that have a vested interest in the promotion of harmful products and unhealthy lifestyles. Law's relationship with tobacco, vaping, 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 context and offers 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 leaving lifestyle-related risk factors to the personal responsibility of each individual? Does a regulatory approach to the prevention of NCDs imply coercion? Does it signal the emergence of a "nanny state"? Do legal approaches to reducing NCD risks necessarily depend on motivating people to consciously change their lifestyles, or can laws embody different strategies? Is it possible to regulate business without micro-managing individuals or "legislating the recipe for tomato ketchup?" Most people want to live longer and healthier lives. This course gives students the conceptual tools to think powerfully about law's role in the prevention of NCDs, and to participate in debates about effective, appropriate legal interventions.

Note: UPPERCLASS WEEK ONE COURSE. 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 2099 v00 Nutrition Law and Policy (https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 2099 v00)
LL.M. Seminar (cross-listed) | 2 credit hours
Proper nutrition is one of the many contributor's to overall health and could be one of the most cost-effective approaches to address many of societal, environmental and economic challenges facing the world today. Increasingly, law and policy has been recognized as a high-impact and robust approach for accelerating progress toward reducing and managing nutrition-related chronic diseases such as obesity, cardiovascular disease, type 2 diabetes mellitus and certain types of cancer. In various jurisdictions, policymakers enact courses of action, regulatory measures, laws and policies, and set funding priorities designed to address food insecurity, hunger, obesity prevention, chronic diseases, among other health and well-being concerns. This course focuses on policies, programs and practices across the globe—at the national, tribal, state and local levels—that improve or hinder healthy eating. Students will examine the evidence informing these courses of action, along with the historical and contemporary legislative, regulatory and judicial aspects. Topics and themes include dietary guidance, food and nutrition assistance programs, food and nutrition labeling, and other environmental and policy strategies to improve access to healthier foods and beverages.

Student Learning Goals:

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

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

LAW 1209 v02 O'Neill Institute Practicum: Regulating Alcohol, Tobacco & Food in International and Comparative Law (https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 1209 v02) (Project-Based Practicum)
J.D. Practicum (cross-listed) | 4 credit hours
In a project-based practicum course, students participate in a weekly seminar and work on a project under the supervision of their professors. This course explores the challenges and opportunities of using law to address risk factors that contribute to the rising prevalence of Non-Communicable Diseases (NCDs), such as unhealthy diets, tobacco use, and alcohol consumption. By taking an international and comparative approach, it navigates the theory behind the regulation of risk factors to NCDs in relation to concrete examples from around the world, with a particular emphasis on Latin America, where considerable progress has happened in recent years. Students will participate in a two-hour/week seminar and carry out 10 hours/week of project work under the direction of the course professors.

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

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

Prerequisite: J.D. students must complete the required first-year program prior to enrolling in this course. Part-time and interdivisional transfer students may enroll prior to completing Constitutional Criminal Procedure (formerly 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: Evening students who work during the day are encouraged to reach out to the professor to discuss whether this practicum course would be compatible with their schedules.

This is a four-credit course. Two credits will be awarded for the two-hour weekly seminar and two credits will be awarded for approximately 10 hours of supervised project work per week, for a minimum of 11 weeks. Both the seminar and the project work will be graded. Students who enroll in this course will be automatically enrolled in both the seminar and project components and may not take either component separately. After Add/Drop, a student who wishes to withdraw from a practicum course must obtain permission from the faculty member and the Assistant Dean for Experiential Education. The Assistant Dean will grant such withdrawal

LAW 995 v00 Public Health and International Investment Law (https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 995 v00)
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 that allow for investor-State dispute settlement limit domestic regulatory autonomy, particularly in the field of public health.

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

The course will address:

1. the theoretical perspectives underlying the international law on foreign investment;
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 the expropriation of property rights and the circumstances in which health measures might be considered equivalent to expropriation;
4. rules governing the concept of 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; and procedural issues relating to the participation of civil society in the negotiation of investment treaties and the settlement of investment disputes through international arbitration.

The course is ideal for students in the Global Health Law LLM program or for students wanting a course on international arbitration or international investment 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 1600 v00 Toxic Chemical Law and Advocacy (https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 1600 v00) (Fieldwork Practicum)
J.D. Practicum | 4 credit hours
In a fieldwork practicum course, students participate in a weekly seminar and conduct related fieldwork at an outside organization focused on toxic chemical law. For example, have you ever wondered what is in the food and drink we consume besides the raw agricultural products such as coffee beans or milk? In this course, students will explore the how the Food and Drug Administration (FDA) under the Food, Drug, and Cosmetic Act, by the Environmental Protection Agency (EPA) under the Toxic Substances Control Act and other statutes, and the the Consumer Product Safety Commission (CPSC) under the Consumer Product Safety Act work together (or don't) to regulate toxic chemical products in consumer products that are consumed or used in the U.S. every day such as coffee, soft drinks and yogurt. Students will develop real-world lawyering skills such as fact gathering, legal research, drafting, developing guidance or advice, crafting advocacy strategy and more. Students will participate in a two hour/week seminar and also undertake 10 hours/week of fieldwork at the Environmental Working Group (EWG), a public-interest nonprofit that advocates on behalf of consumers, and other non-governmental organizations.

SEMINAR: The authority of the FDA, EPA and CPSC to regulate the safety of toxic chemicals in consumer products has evolved as the manufacturing of everyday products has become increasingly industrialized and affected by an array of new technologies that cause the food and drink we regularly consume to contain potentially harmful chemicals. This seminar will utilize legislative and administrative materials as well as case law to enable students to critically evaluate the processes by which the federal government regulates toxic chemicals in consumer products and compare and contrast regulatory schemes for different consumer products. The course will also touch on related topics such as the role of the Federal Trade Commission in the regulation of marketing trade practices related to chemicals in consumer products.

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

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

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

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

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

This course is suitable for evening students who can commit to attending class and working 10 hours/week (during business hours) on site at their field placements. This is a four credit course. Two credits will be awarded for the two-hour weekly seminar and two credits for approximately 10 hours of fieldwork per week, for a minimum of 11 weeks, to be scheduled with the faculty. The fieldwork must be completed during normal business hours. The two credit seminar portion of this practicum will be graded. The two credits of fieldwork are mandatory pass/fail. Students will be allowed to take another course pass/fail in the same semester as the field work. Students who enroll in this course will be automatically