

REGULATORY LAW (REGLAW)

While every effort is made to ensure course lists are accurate, change is inevitable and courses may show alternate program restrictions at the time of scheduling. Courses used to satisfy graduation requirements must be designated as such at the time of registration. Not all courses are offered each year.

REGLAW 901-0 Legal & Regulatory Process (1.5 Credit Hours) This course introduces students to the key elements of the U.S. legal system. We will look at the constitutional structure of government, the sources of lawmaking authority, and the manner in which Congress, the administrative state, and the judiciary collaborate in developing rules of applicable law. Along the way, we will study the judicial and lawmaking system, the regulatory design and implementation process, and, to some degree, mechanisms of dispute resolution. Given the unique focus of the MSL program, we will pay special attention to how the American legal system considers, evaluates, and negotiates matters involving science and technology. *Additional Course Information:* MSL Students Only, Course required for MSL degree

REGLAW 902-0 U.S. Regulation: Design, Implementation, and Enforcement (1.5 Credit Hours) This class explores the different modes of regulation that have been used in the United States to tackle a range of issues, including pollution control, energy production, climate change, food and drug safety, and shareholder protection. We consider the advantages and disadvantages of various modes of regulation, including: prescriptive "command and control" regulation (e.g., drug warning label requirements), market-based regulation (e.g., carbon taxes and tradeable pollution permits as a way to mitigate climate change), informational regulation (e.g., mandatory disclosure of toxic releases and impact assessments), and regulation through common law liability (e.g., tort suit judgments in products liability cases). One focus of the class is the complicated relationships among the federal, state and local governments in the U.S. regulatory system, including federal preemption of state and local regulation and federal/state cooperation in regulatory implementation and enforcement. We also explore the legal issues surrounding the different kinds of enforcement actions companies can face (administrative, civil, and criminal), and the role of whistleblowers and citizen suits in regulatory enforcement. Finally, the role of lawyers and the attorney-client privilege in regulatory compliance and enforcement will be considered, with particular reference to federal regulation of public corporations under the Sarbanes-Oxley Act. Students will be assessed based on their participation in discussion each week, as well as a final paper. *Additional Course Information:* MSL Students Only

REGLAW 904-0 Global Transactions & Compliance (1.5 Credit Hours) This course will examine business, legal and ethical issues that arise when commercial transactions cross national borders, as in today's global economy, they almost always do. Subjects that will be explored include: the political, legal and cultural frameworks of jurisdictions outside of the United States; global macro-economic institutions; international taxation; anticorruption and fraud prevention; cyber security; anti-money laundering/terrorist financing; as well as ethical and organizational decision making and leadership. Subjects will often be explored in the context of specific regions and jurisdictions. *Additional Course Information:* MSL Students Only

REGLAW 905-0 Regulatory Strategy & Communication (1.5 Credit Hours) The Regulatory Communications and Strategy class will examine the legal and business aspects of understanding and complying with regulations, communicating with regulators, communicating with internal and external audiences concerning regulatory activities, developing

regulatory goals and strategies, and understanding and developing strategies for addressing regulatory failures. The course will use a combination of lecture and case study approaches with students reviewing and analyzing recent instances of regulatory successes and failures, including regulatory aspects of product development, introduction and marketing, and communications strategies for all stages of the regulatory process. *Additional Course Information:* MSL Students Only

REGLAW 915-0 Technology Standards: Strategic & Antitrust Considerations (1.5 Credit Hours) Technology standards permeate the modern economy, from WiFi and mobile phones to complex medical equipment to smart thermostats and electric cars. These standards would not exist but for the voluntary, cooperative efforts of numerous companies - often from what would at first appear to be far-flung industries. This survey course will explain the pivotal business strategies related to technology standards, including whether a firm may want to join a cooperative effort or whether instead it may prefer to try for a proprietary solution on its own. We will review the fundamentals of participating in cooperative standard setting organizations, the strategies that firms employ in such participation, and how participation can affect a firm's intellectual property acquisition and licensing decisions - most importantly related to patenting. Finally, we will discuss the basic elements of how firms compete in the multifaceted world of technology standards and will review the primary antitrust risks that come hand-in-hand with aggressive competition. The initial classes will be traditional lecture/discussion and will focus on foundational issues. We anticipate bringing in an industry practitioner for an in-depth interview on how their firm makes strategic decisions regarding standard participation. Another class will involve a standard setting exercise; for this, students will assess the opportunities relating to an emerging standard for their assigned "company," deciding on their optimal strategy and attempting to win other "companies" over to their side. Grade assessments will be based on in-class preparedness and participation (10%), a writing assignment and a presentation, matching skills required in real world jobs. The in-class presentation will comprise 45% of the grade and includes both a group and an individual contribution score. The out-of-class writing assignment is a memo providing an antitrust risk assessment for the student's "company" and is broken down into a first draft and a final draft. *Additional Course Information:* MSL Students Only

REGLAW 917-0 Legal & Policy Issues in College Athletics (1 Credit Hour) This course will survey several issues that have given rise to the current state of disruption in college athletics. Students will learn how key legal concerns - including antitrust restrictions, labor interests, and intellectual property tensions - work alongside business interests and political dynamics in crafting competitive opportunities. Students will be able to identify and evaluate the various interests and issues at play in order to develop their own unique philosophy regarding the appropriate construction of intercollegiate athletics policy. *Additional Course Information:* MSL Students Only

REGLAW 921-0 Emerging Issues in Biotech & Food (1.5 Credit Hours) The advance of technology commonly brings great gains for society; however, those advances often also bring about new societal challenges. These challenges must be met with either the application and adaptation of existing laws and regulations or the development of entirely new legal structures. The study and application of biology - loosely defined as biotechnology - has seen monumental advancements in the last few decades. Impacts of these biological advances have been seen in industries as diverse as pharmaceuticals, food and agriculture, banking, and family law. This course allows students the opportunity to explore recent technological developments in biotechnology and

food technology, concentrating on the social, ethical and legal effects of these developments. The course begins with a professor-led series of discussions centered around new technologies from various industries and their resulting societal challenges. The class will discuss existing and emerging ethical and legal regimes for these technologies. In the second half of the course, students will be required to research a technological topic of their choice (with professor approval) and lead a substantial class discussion on the technology and its social, ethical, and legal effects. *Additional Course Information:* MSL Students Only

REGLAW 923-0 Privacy in Practice (1 Credit Hour) This interactive class will provide students with insights into some of the key issues that face corporate actors under privacy and cyber security laws. This class will not include lectures. Instead it is an active learning experience where students will participate in three four-hour interactive sessions. We will first run a four-hour bootcamp on creating working teams and addressing project management for privacy and cybersecurity within corporate offices. We will then engage in a four-hour data breach bootcamp. Finally, we will run a four-hour compliance bootcamp with a “privacy law hustle” resulting in synthesizing a privacy law development and presenting it to an in-house client. *Additional Course Information:* MSL Students Only

REGLAW 924-0 Data in Society (1 Credit Hour) Technological advances are making data easier to generate, share, access, and use. Many of these new applications are beneficial. With better data, organizations can run more efficiently, governments can make better decisions, and individuals can take advantage of free services. Some of these new applications are troubling. It is so easy to generate and share data that individuals constantly do so without realizing it. Data in Society seeks to introduce the technologies that are speeding the flow of data and explore the applications of these technologies for management, government, daily life, and the law. *Additional Course Information:* MSL Students Only

REGLAW 936-0 Fintech Law & Regulation (0.5 Credit Hour) The Fintech industry has attracted attention for its promise to create efficiencies in financial services, disrupt traditional banking, and bring benefits to consumers. At the same time, the industry has generated new business models that raise questions about how decades-old financial services laws should apply and the approaches regulators should take in overseeing the industry. This course highlights novel Fintech business models, the financial services laws and regulations that may apply, and the regulatory agencies and approaches that provide oversight. *Additional Course Information:* MSL Students Only

REGLAW 937-0 Regulatory Compliance for Consumer Packaged Goods (0.5 Credit Hour) Consumer products can be found anywhere from your medicine cabinet to your backyard to your refrigerator. To ensure consumer safety, there are a myriad of rules, regulations and standards. In this course, we will discuss who regulates these products in the U.S., explore aspects of the “whys” of the regulations, and the outcomes. We will also spend a bit of time discussing the “gray” area of innovative products and regulatory strategy. This course is designed to provide foundational regulatory knowledge as well as practical applications and regulatory strategy. *Additional Course Information:* MSL Students Only

REGLAW 940-0 Medical Devices: Regulation & Compliance (1 Credit Hour) This course will examine the regulation of medical devices and the interplay of statutory law, industry standards, and regulatory agency guidance. We will explore Food and Drug Administration (FDA) regulations; requirements for the development, manufacturing, and distribution of these products; and compliant interactions between industry and physicians (and other healthcare providers). We will also look at healthcare fraud and abuse, including the anti-kickback statute. The course will cover the regulatory and compliance considerations for:

- Bringing a medical device to market for the first time
- Keeping

that medical device product on the market

- Compliance considerations in the sales and marketing of medical devices
- Expanding sales and marketing of the device into other geographies

While the primary focus will be on the US to establish a foundation, the course also will provide insight to medical device regulation and compliance globally. Additionally, where appropriate, a comparison of medical devices to other regulated products such as drugs and biologics will be highlighted. *Additional Course Information:* MSL Students Only

REGLAW 942-0 Climate Change: Law & Policy (1.5 Credit Hours) Energy is at the heart of the modern world's economic and societal progress, without which we could very well likely still be living in caves and grass huts and dying by the ripe age of 21. Energy is also at the heart of the dramatic rise in global warming and the unprecedented damage this warming is causing to our climate, our environment and our selves. This means we are faced with a challenge: how do we continue to support worldwide economic growth and the quality of life for millions it will provide, an economic growth which in large part still must be fueled by energy consumption, yet at the same time significantly reduce the global warming caused by the very GHG emissions such energy consumption has spawned and address and adapt to the adverse climate change impacts that are already baked into our climate system. This class will explore the law's role in meeting this existential challenge. The objective of this course is to provide an overview of the major legal principles, statutes, regulations and policies applicable to the energy area; explore from a legal perspective some of the significant issues in the energy space today, with a focus on climate change; and use the intersection of energy and the law to examine the process by which our society makes major public policy, commercial and individual decisions involving complex issues of science and technology. *Additional Course Information:* MSL Students Only

REGLAW 947-0 Transforming Healthcare: Digital Health & AI (1 Credit Hour) This course focuses on how health information technology (HIT) can be implemented and used in creating positive change in the current healthcare landscape. With the field of healthcare informatics rapidly evolving to become the most important field of study in the healthcare industry, this course will work to provide knowledge of foundational biomedical informatics concepts along with real world applications. This course is distributed into three modules: (1) fundamentals of clinical research informatics, including clinical decision support system, (2) healthcare privacy and standards related to medical information, and (3) innovative health data applications, including the latest trends of mobile health technology. Additionally, students will explore how biomedical information systems are created and managed, while also learning about career strategies for how best to achieve their goals within the field. The course will use a mix of lectures, role-based training and use case scenarios. *Additional Course Information:* MSL Students Only

REGLAW 951-0 Regulatory Internship (0-5 Credit Hours) MSL students may participate in an internship in the field of regulation as part of their MSL academic program. There are a variety of possible placements, including educational institutions, non-profits, government agencies, or companies. The work done in the internship will further the educational goals of the MSL program, develop the MSL student's skills, and provide real world and practical training for the student. Internships are supervised by an on-site supervisor and by an MSL faculty member. A minimum of 45 hours of internship work is required for each credit awarded. Registration Requirement: Once the student has identified and been accepted at an approved placement, the student will apply to the MSL Program Director for permission to enroll in the internship; approved students will be given a permission number to enroll in the course. Evaluation Method: Internship performance will be evaluated by the student's on-site supervisor, in conjunction with the MSL faculty

supervisor, on a credit/no credit basis. The on-site supervisor will complete two written evaluations of the student's work: one mid-way through the internship and a final evaluation. *Additional Course Information:* MSL Students Only

REGLAW 957-0 Clinical Trials Regulation & Ethics (0.5 Credit Hour) The course will explore the intersection of law, ethics, and medicine, providing students with a comprehensive understanding of the rules, principles, and guidelines that ensure the ethical and legal conduct of clinical trials.

We'll then dive further into exploring how pharmaceutical and biotech companies navigate regulatory pathways to build successful clinical development strategies and design clinical trials that ultimately result in product approvals. Students will learn about the various stakeholders, including institutional review boards, biosafety committees, regulatory agencies, pharmaceutical/biotechnology companies, and researchers. *Additional Course Information:* MSL Students Only

REGLAW 960-0 Data Security Regulation: Data Breaches and Beyond (1.5 Credit Hours) This seminar will examine how corporate actors are required to respond and notify around a data breach incident. Students will explore the substantive and procedural requirements that arise from state and federal data breach notification laws, and the requirements placed on corporations to notify impacted individuals when there has been a breach of triggering information, as both of those terms are defined under the laws. Topics include determining the laws applicable to a particular corporate entity (Gramm-Leach-Bliley, HIPAA, state laws, etc.), deciding if an incident constitutes a breach where notice is legally required, practical considerations for investigating a breach within various types of corporate entities, steps required for providing legally-compliant notification, exposure and legal risks after notification, and considerations for providing notification even if not legally required to do so. Registration Requirement: None. Students are recommended (but not required) to take Privacy Management in the Collection and Use of Data. Evaluation Method: No final exam. The grade is based on in-class participation, an in-class presentation, and a series of short reaction papers. Class Materials: Thomas on Data Breach: A Practical Guide to Handling Data Breach Notifications Worldwide, 2015 ed. ISBN: 9780314634184. *Additional Course Information:* MSL Students Only

REGLAW 965-0 Privacy Law and Regulation (1.5 Credit Hours) This course examines the law of information privacy: an individual's ability to control their personal information. The course examines the philosophical roots of privacy and traces the history of American privacy law. We will review the major federal privacy statutes, the role of federal administrative agencies in regulating corporate privacy conduct, and the large gaps that remain in the protection of individual privacy rights. Particular attention will be paid to ongoing efforts to regulate emerging technologies. Evaluation will be based on a series of discussion board posts and a final exam. *Additional Course Information:* MSL Students Only

REGLAW 973-0 Health Law (1.5 Credit Hours) This is a survey course intended to provide students with an overview of the structure, financing and regulation of the U.S. health care system. Specifically, in this course, we will learn to think of the health care system as a three-legged stool comprised of three elements: cost, quality and access. Further, we will consider how health care laws and regulations aimed at these elements (e.g., improving quality, reducing cost, and increasing access) impact the three primary stakeholders in the U.S. health care system: providers, consumers/patients, and payors. *Additional Course Information:* MSL Students Only

REGLAW 974-0 Advanced Healthcare Law & Regulation (1 Credit Hour) Through Medicare, Medicaid and various other health care programs, the Federal government is responsible for a significant percentage of national health care expenditures. Several bodies of law have developed to

protect against the possibility that these expenditures are being exploited through the provision of sub-standard, unnecessary, or overly expensive goods and services. We will focus primarily on the criminal and civil laws that are incidental to Federal government's role in health care finance. By the end of the course, students will have been introduced to some of the key bodies of Federal health care regulation, including the Federal Anti-Kickback Statute, Stark law, Sunshine/Open Payments Act and the False Claims Act. This will enable students to play an active role in identifying, understanding and navigating the Federal regulations applicable to projects with which they will become professionally involved. Grades will be based on a combination of class participation, in-class projects and presentations, and a short written project. *Additional Course Information:* MSL Students Only

REGLAW 975-0 Food Policy and Regulation (1.5 Credit Hours) This course will explore the role of regulation and policy in the contemporary food system. We will examine the local, state, and federal regulation of food, and sample policy topics from selected health, safety, and social issues in the food system. Topics may include: food safety, labeling and marketing, local food, and urban agriculture. *Additional Course Information:* MSL Students Only

REGLAW 980-0 Regulatory Compliance: Drug Approval & Life Cycle Issues (1.5 Credit Hours) In this course, students will be exposed to current Good Manufacturing Practices (cGMPs), which regulate the Biopharmaceutical Industry. Students will learn how companies interpret the regulations to comply with the spirit of the law as well as the legal implications they face when they don't comply. This will be accomplished in a series of lectures that cover: - Biopharmaceutical product development and approval, i.e., how to get a drug commercially approved for sale, - Post-approval, modifications/improvements required to keep pace with changes in regulations, market competition, needs of a diverse patient population, manufacturing costs, i.e. product lifecycle maintenance "LCM", - What it means to operate in compliance with cGMPs and how FDA monitors and enforces cGMP regulations. What happens when companies fall into non-compliance and how non-compliance can escalate; i.e., form 483 observations, warning letters, consent decrees, etc., - A deep dive into understanding the breadth and depth of impact non-compliance both internal and external to the company. On completion of this course students should have: an appreciation for the regulatory landscape for life science product development, an appreciation of factors impacting a company's ability to achieve and maintain compliance and the trade-offs that must be made, an understanding of how you, as a patient or caregiver, are impacted by pharmaceutical non-compliance, and how far reaching the impacts of non-compliance can be. As part of an intensive course project, that runs in parallel with lectures, students will evaluate business trade-offs and the impact of each to maintain compliance while ensuring sustainable drug supply to meet demand. At the end of the course students will present their deep dive assessment of real life, current warning letter situations affecting local biopharmaceutical companies. Prerequisites: Regulatory Strategy & Communication. *Additional Course Information:* MSL Students Only

REGLAW 981-0 Along the Regulatory Frontier: New Issues and Emerging Technologies (1.5 Credit Hours) How does regulation account for new issues and emerging technologies? This has always been a conundrum for lawmakers, agency officials, and the judiciary as well. In this course, we will consider this question by focusing on "frontier" subjects of regulation: artificial intelligence and machine learning; drug policy (including cannabis, psychedelics, & opioids); public health emergencies stemming from novel viruses, such as Covid-19; and new ways of creating more access to justice and furnishing legal services, including by non-lawyers. In considering these rapidly-evolving topics, we will explore

how existing institutions and doctrines can be adapted to meet new demands and what other tools and techniques must be developed to meet upcoming challenges along the regulatory frontier. *Additional Course Information: MSL Students Only*

REGLAW 990-0 Dynamics of the Cannabis Industry: Past, Present & Future (0.5 Credit Hour) On November 5, 1996, California became the first state to legalize medical cannabis, thus starting a two-decade journey where several states enacted laws allowing citizens access to cannabis for medical purposes - creating a legal industry based on a substance that had been federally illegal since the 1930s. Often light on structure, many programs appeared unregulated; basically giving people access to cannabis under the guise that it was "legal" in the state while continuing to be illegal on a federal level. On August 29, 2013, the U.S. Department of Justice announced an update to its federal cannabis enforcement policy. While not a change in federal law, the DOJ memo, often referred to as the Cole Memo, provided states with a framework for establishing regulated cannabis programs (medical and adult-use) that would defer enforcement of cannabis-related matters to the states. Thus began the new generation of the state-legal cannabis industry. As of today, 29 states plus Puerto Rico and Guam have legalized medical cannabis; 8 of those states have legalized adult-use; and an additional 17 states have enacted CBD-only laws (cannabis containing less than .3% THC) - in total 95% of the U.S. population lives in a state where there is some form of legal cannabis. The legalized cannabis markets produced approximately \$7.2B in sales in 2016 and that number is expected to surpass \$24B in 2025. That said, cannabis remains federally illegal - the federal government providing only superficial guidance to states on how they can choose to enforce cannabis laws within their state (but only within their state because the federal government will not allow the product to cross state lines) - presenting some of the most unique legal and regulatory issues that any industry has seen. This course is designed to acquaint students with the legal and regulatory challenges present in the emerging cannabis industry. We'll take a look at the very interesting history of cannabis and cannabis legalization/illegalization in the U.S., the current state of federal law and the various state laws and the unique business issues that such conflicting federal/state laws present; we'll review a case study of a company developing a multi-state operation; and we'll look at the various directions that this industry is likely to go in the future. *Additional Course Information: MSL Students Only*

REGLAW 992-0 RegTech: Transforming the Interaction of Regulators, Regulated Enterprises, and Markets (0.5 Credit Hour) *Additional Course Information: MSL Students Only*

REGLAW 995-0 Regulatory Policy (1.5 Credit Hours) This class builds on the required Legal & Regulatory Process class to enable students to understand how the legal principles of regulatory law translate into actual policies affecting any business operating in America. Almost all major industries are currently subject to some form of regulation. Those managing those businesses-and those introducing new ones-inevitably interact with regulators: courts and administrators. It is thus vital for them to understand the goals these policy-makers are pursuing, their motivations, and the legal tools at their disposal. This course will provide students with the instruments to do so. To achieve that aim we will survey the emergence of American regulatory law, its treatment of specific industries as examples, the economic rationales animating regulatory law, and the most recent controversies affecting it (e.g., the Great Recession of 2008, net neutrality, antitrust and big tech). *Additional Course Information: MSL Students Only*