

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 Hour) 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 905-0 Regulatory Strategy & Communication (1.5 Credit Hour) 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 Hour) 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 920-0 Data Privacy Management (1.5 Credit Hour) This class will focus on the evolving data ecosystem within the existing legal and regulatory landscape, which is also evolving. It will: 1) explain the technology underlying the tracking, collection and aggregation of consumer data, 2) identify the first and third party data aggregators, and outline what they do, 3) explore how business uses consumer data, particularly for its marketing purposes, and 4) provide the legal and regulatory perspective toward the industry's behavior and practices. The class will cover a number of recent court cases and Federal Trade Commission enforcement actions as a way to enhance understanding of the critical data privacy issues facing business. As part of the evaluation for the course, teams of 3-4 students will work on a project based on a hypothetical situation with students forming interdisciplinary teams representing legal, tech and business operations. Obviously, a bit of role-playing will be required. The project will require the launch of a new product (probably an app) incorporating a "privacy by design" approach and data governance best practices. Teams will demonstrate compliance with relevant statutes and regulations, and address the building of a corporate culture where business, legal and technology collaborate. The project will be assigned day 1, so students will have the entire 6-7 weeks to complete it, with readings and class discussion supporting their efforts. Project deliverables will include a brief "executive" presentation by each team, accompanied by a written plan and recommendations. *Additional Course Information:* MSL Students Only

REGLAW 922-0 Data Privacy & Security: Law & Regulation (1.5 Credit Hour) Privacy and data security law is becoming a more and more important topic for organizations. How can companies legally use personal information? What disclosures do they need to make? Are there restrictions on the type of information that can be collected? Can information be combined? How are "big data" and digital tracking activities regulated? What obligations do companies have to protect information? What happens if things go wrong? This course will provide a global framework of privacy and data security laws. We will examine laws that impact corporate actors with respect to the collection, combination and sharing of personal information. Grading in this practical, hands-on seminar will be based on interactive in-class exercises and a final paper. Readings will be from a treatise being prepared by the professor. *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 925-0 Global Business Regulation & Risk Assessment (1 Credit Hour) Legal/regulatory compliance requirements have seen a sharp increase globally. This increase reflects the rather rapid development of normative values regarding compliance and business ethics of society at large. The proliferation of laws across the globe (and the evolution of existing laws) adds to the complexity of increased compliance

requirements for business conduct in areas such as accounting, anti-bribery, antitrust, data privacy, and intellectual property; this impacts both emerging and established companies. Increased penalties for violations have become substantial and reputational damage to companies that result from liability has become significant. This course will provide the analytical tools necessary to understand the complexities of compliance as part of a business risk analysis and to use compliance in shaping business strategy. Students will be assessed based on their ability to lead discussion on one of the case studies. This includes: an ability to summarize salient features of the case study, analyze what a company did wrong, and suggest improvements for compliance-related performance going forward. *Additional Course Information:* MSL Students Only

REGLAW 930-0 Regulation: Environment and Energy (1 Credit Hour)

This course explores the legal and policy issues involved in the regulation of energy and the environment, through the lens of the topic of climate change. The course will focus on the interplay between Congress, the Executive Branch, and the Courts in the development of climate change law. Special attention will be given to the Clean Air Act and relevant energy laws, including their impact upon efforts to develop new and alternative energy sources. Students will be expected to review selected published opinions and related materials involving climate change issues and will then be asked to apply what they have learned by representing hypothetical clients in a case study developed from a real-life situation. An overriding theme of the course will be the continuing and evolving relationship among nature, science, and the law. Student assessments will be based on (i) class participation (40%) and (ii) participation in the case study (60%). *Additional Course Information:* MSL Students Only

REGLAW 935-0 Regulation: Tech and Telecom (1 Credit Hour) This course, which will be taught in three evening sessions during Power Week, will focus on two issues: net neutrality and universal service. Net neutrality has been the major competition and regulatory issue that has faced telecommunications in recent decades – without the jargon, the issue is whether the law should apply a rule that prevents broadband networks from discriminating among content and applications providers. We will divide our time on net neutrality fairly equally into three parts: (1) understanding the fundamental Internet technologies that enable broadband services and that frame the policy issue; (2) discussing the fundamental business and economic principles that bear on the relationship between carriers and content providers; and (3) addressing the design of regulatory institutions that might address any competition problems. The problem of universal service has similarly plagued communications markets: how does government ensure that everyone has fundamental communications access (and how does government define what “fundamental communications access” is)? Although we will focus on telecommunications and Internet services, we will draw analogies to other utility and transportation markets based on common economic and regulatory principles. We will also draw analogies to other high-technology markets, such as software and Internet search that have confronted similar challenges. *Additional Course Information:* MSL Students Only

REGLAW 940-0 Regulation of Drugs, Devices & Biologics (1 Credit Hour)

This course examines issues in the regulation of drugs, medical devices, and biologics in the United States. With respect to drugs, it explores the process for pre-market approval of these products by the FDA, policy and constitutional issues in the marketing of these products to physicians and to consumers, the relationship between pioneer and generic drugs, the tension between federal regulation and state product liability law, and a variety of other issues. With respect to devices, it examines the various categories of devices, the pre-clearance process, preemption of state

tort law, and other issues unique to devices. With respect to biologics, it covers current regulatory issues in the approval of these products and a variety of issues relating to regulation of blood, organ transplants, and vaccines. It will provide the legal background needed by such students to consider and understand the complex legal and policy issues raised by regulation of the manufacturing, promotion, and distribution of these products. Participation will count in the grading for this class; students will have a choice of a paper or in-class presentation for the final project. Prerequisite: Regulatory Strategy & Communication. *Additional Course Information:* MSL Students Only

REGLAW 942-0 Energy Law & Policy (1 Credit Hour) 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 (including 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. The course will start by building an energy life cycle around the core components of fuel, electric generation, transmission and use. We will flesh out this cycle by looking at core data that describe where we get our energy, how we use it, and how much it costs to use, as well as what the trends in this data foretell for our future. Next we will identify as many of the major legal touchstones raised at each stage of the energy life cycle as the class knows at this time. Having established an overview framework of the intersection of energy and the law, the class will then shift to digging deeper into the major energy legal touchstones by examining energy from the following core legal perspectives: 1) ownership and common law; 2) applicable statutory laws and regulations; 3) transactions; 4) litigation; and 5) current and future policy issues. The course will end by reviewing student presentations relating to the final class projects, revisiting the energy life cycle, and identifying additional legal touchstones missed the first time around. Student assessments will be based on (i) class participation (40%) and (ii) participation in a final project or paper (60%). *Additional Course Information:* MSL Students Only

REGLAW 945-0 Health Data: Classification and Compliance (1.5 Credit Hour) This course will provide students with a basic understanding of health data and practical proficiency of its utility; it is important not only on a personal health level, but also as a lynchpin in seeking professional opportunities. It will cover various issues relevant to uses of data in healthcare, including healthcare informatics and big data analytics. Some other applications include government regulations in managing US healthcare, priorities of healthcare systems in enhancing research, big data challenges for medical device and pharma companies, and solving unique healthcare problems through data in start-up world. The course is distributed in 6 topics with several subtopics and structured to include lectures, cases, demonstrations, and expert appearances. The six topics are: Types of Health Data; Health Data Sources; Use and Accessibility of Health Data; Compliance: Health Data Security, Privacy, and Legal; Data Standards; and Interoperability and Data Sharing. Evaluation Methods: No final exam. Final project and some peer-to-peer evaluations. Class Materials: No required textbook. Material will be posted online. *Additional Course Information:* MSL Students Only

REGLAW 947-0 Health Informatics: Practical Data Applications (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 950-0 Open Data: Implications for Government, Law, and Society (0.5 Credit Hour) In 2014, Congress unanimously passed, and President Obama signed, the most sweeping government management reform in a quarter-century. The Digital Accountability and Transparency Act, or DATA Act, directed the executive branch to transform all of its spending information from disconnected documents into open, standardized data. In May 2017, the DATA Act's main deadline arrived, and the Treasury Department began publishing all executive-branch spending information as a single, searchable open data set. The DATA Act is part of a global move toward standardizing and publishing many domains of government information beyond just spending, a shift referred to as the open data movement. Open data promises to change the way citizens interact with their government by improving the breadth and depth of information available to voters. The transition from documents to data also promises to improve government management: as public-sector leaders gain access to searchable data on spending and operations, it becomes easier to deploy analytical tools to inform decisions. However, the most economically consequential (and still mostly theoretical) impact of the open data movement will be to streamline interaction between government and business. This course will summarize the first decade of the open data movement in the United States and elsewhere, outline significant information domains where the shift from documents toward data has gained momentum, consider potential challenges in security and privacy, and zero in on the current and theoretical consequences for the relationship between government and business. Assessment for this course will take place via an in-class scoping exercise, with brief oral presentations by each participant. *Additional Course Information:* MSL Students Only

REGLAW 951-0 Regulatory Internship (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 960-0 Data Security & Breach: Identification, Investigation, Notification, and Defense (1.5 Credit Hour) 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 Credit Hour) Privacy is becoming a more and more important topic for organizations. How can companies legally use personal information? What disclosures do they need to make? Are there restrictions on the type of information that can be collected? Can information be combined? How are "big data" and digital tracking activities regulated? This course will provide a global framework of privacy laws. We will examine laws that impact corporate actors with respect to the collection, combination and sharing of personal information. No pre-requisites. Grading in this practical, hands-on seminar will be based on interactive in-class exercises and a final paper. Readings will be from a treatise being prepared by the professor. *Additional Course Information:* MSL Students Only

REGLAW 970-0 Health Care Law and Regulation (1 Credit Hour) The delivery of health care items and services is a major commercial enterprise, with national health expenditures accounting for 17.5% of Gross Domestic Product in 2014. As a guardian of the public interest, the government is involved in regulating the delivery of health care, so as to protect patient rights, assure quality, and limit provider conflicts of interest. As the most significant source of payment for health care items and services, the government also has a compelling interest in cost transparency and containment. This course will provide an overview of some of the key state and federal laws that address these public policy goals, with reference to recent events, including, for example, news stories, enforcement actions, and shareholder suits. At the conclusion of the course, you should have sufficient familiarity with the legal landscape to enable you to be an effective contributor to efforts to bring compliant health care products and services to market. By way of example, this course will introduce you to state laws dealing with professional and facility licensing, CON, fee splitting and corporate practice, and to federal laws dealing with kickbacks, civil money penalties, open payments, and false claims. This course will explore the context, substance and purpose of these laws, with a view to identifying the imperatives, obstacles and opportunities that they create. At the conclusion of the course, you should have sufficient familiarity with the legal landscape to enable you to be an effective contributor to efforts to bring compliant health care products and services to market. This course will build on the principles learned in the Legal and Regulatory Process course, and is related to, but not duplicative of, the following courses: Global Business Regulation and Risk Assessment; Regulatory Compliance (distinction: this course is focused on U.S. regulation and compliance rather than on global compliance, and on the substance of the regulation rather than on compliance strategies); Corporate Criminal Law (distinction: this course

will touch on corporate criminal law as just one of many theories of liability and regulation); Regulation: Medicine and Health (distinction: this course may touch on but is not focused on FDA matters); and, Integration of Science and Clinical Care (distinction: this course may touch on but is not focused on the intersection of these two areas). No pre-requisites. No final exam required. No required text. All required readings will be posted in Canvas. *Additional Course Information:* MSL Students Only

REGLAW 972-0 Health Care Law & Regulation: State (1 Credit Hour)

This course is designed to introduce students to the regulatory scheme that governs the US health care system, with an emphasis on matters traditionally regulated by state governments. In addition to other topics, we will explore the manner in which the delivery of health care services and products is regulated to protect significant individual and societal interests such as patient autonomy, the quality of medical care, and market competition. By the end of the course, students will have been introduced to some of the key bodies of state health care regulation, such as: regulating informed consent; requiring professional licensure - including the regulation of telemedicine and the activities of alternative providers; and seeking to assure professional autonomy - such as anti-fee-splitting laws and the prohibition against the corporate practice of medicine. This information will enable students to play an active role in identifying, understanding and navigating the State 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 974-0 Health Care Law & Regulation: Federal (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 Credit Hour) 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. Student presentations will permit in-depth exploration of a topic of interest for each student. Evaluation will be based on class participation, a class presentation, and a series of short writing assignments. *Additional Course Information:* MSL Students Only

REGLAW 980-0 Regulatory Compliance: Product Approval & Life Cycle Issues (1.5 Credit Hour) 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 985-0 Regulatory Compliance at Universities (0.5 Credit Hour)

Like all businesses, higher education is subject to an array of laws and regulations. This course will highlight the regulatory environment in higher education, considered by some to be one of the most heavily regulated businesses. Included in this discussion will be an overview of the regulatory scheme in higher education and how colleges and universities structure themselves to manage their compliance obligations. Completion of Regulatory Strategy & Communication is preferred, but not required. In-class final project ? Higher Education Compliance Alliance Matrix <<http://www.higheredcompliance.org/matrix/>> ? "Government Regulation of Higher Education: The Elephant in the Middle of the Room," by Stephen S. Dunham, published in The Journal of College and University Law, Vol. 36, No. 3 ? "Reforming Regulation of Research Universities," by Tobin L. Smith, Josh Trapani, Anthony DeCraepeo, and David Kennedy, published in Issues in Science and Technology, Summer 2011 ? "The Cost of Federal Regulatory Compliance in Higher Education: A Multi-Institutional Study," published by Vanderbilt University, October 2015 ? Various federal rules and regulations ? Office of Management and Budget memoranda, including: » Executive Order 13563, "Improving Regulation and Regulatory Review;" and » Executive Order 13610, "Identifying and Reducing Regulatory Burdens." *Additional Course Information:* MSL Students Only

REGLAW 990-0 Legal & Regulatory Issues in Emerging Industries (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*