
Masters of Science in Jurisprudence in Health, Science and Technology at Seton Hall University School of Law



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Associate Director of the Health, Law and Policy Program: John V. Jacobi, J.D.

Acting Director, Institute of Law, Science and Technology: R. Erik Lillquist, J.D.

Faculty: Barnes; Bernstein; Boozang; Coleman; Denbeaux; Gilhooley; Huberfeld; Jacobi; Jennings; Lillquist; Opderbeck; Risinger; Sullivan.

Master of Science in Jurisprudence in Health, Science and Technology

Seton Hall Law School offers a Master of Science in Jurisprudence (M.S.J.) Degree in Health, Science and Technology. The M.S.J. program provides professionals working in health care, information technology, telecommunication, pharmaceuticals and biotechnology with a solid foundation in the legal and regulatory aspects of the industry.

The M.S.J. degree is an extension of the Law School's nationally ranked Health Law & Policy Program (HeLPP), and the Institute of Law, Science & Technology (ILST). Recently, more than ever before, the legal profession and the health, science and technology industries have become inextricably intertwined. Frequently professionals in health, science and technology feel as if they need a lawyer in order to competently and efficiently perform their job. The M.S.J. degree provides these professionals with a solid foundation in legal aspects of their respective industries so that they have a better understanding of the laws that affect their everyday lives.

Armed with this knowledge, professionals working in the health care, information technology, telecommunications, pharmaceutical, biotechnology and related industries will perform their jobs with much less frustration and confusion, and with more confidence and reliability. Courses are conveniently scheduled to accommodate working students. The Law School is conveniently located one block west of Newark Penn Station.

Admission Requirements

A candidate seeking admission to the M.S.J. Program must have at least a bachelor's degree from a regionally accredited college or university, or the foreign equivalent. The Admissions Committee prefers candidates who have professional experience in the health, technology, pharmaceutical, biotechnology, communications or related industries. Decisions are based on quality of undergraduate performance and, if applicable, graduate school academic records, ability to do superior work, and writing skills. Candidates are not required to take pre-admissions tests such as the LSAT, GRE or GMATS. Any applicant whose pre-college education was in a language other than

English will be required to take the Test of English as a Second Language (TOEFL).

Enrollment in the program begins each June with a summer class, *The Legal System, Research and Writing*, followed by a course of study beginning in the Fall. Students who do not successfully complete the summer course are not invited to continue in the program.

Admissions Procedures

Interested applicants must apply directly to the Law School. Contact (973) 642-8871 and request a M.S.J. application. Completed M.S.J. applications should be mailed to the Office of Graduate Programs, Seton Hall Law School, One Newark Center, Newark, N.J., 07102, along with:

- \$60 application fee payable to Seton Hall University;
- personal statement (as described in the application);
- resume;
- official transcript from all colleges/universities attended; and
- two or three letters of recommendation.

Financial Assistance

Financial aid may be available through the Federal Loan Program. For more information, please call (973) 642-8744.

Course of Study

The M.S.J. candidate must complete 30 credit-hours of coursework at the Law School. The M.S.J. candidate's curriculum is substantially made up of required courses. The program begins each summer with a 4-credit legal method and research and writing course to orient the M.S.J. student to the tools of legal reasoning. Additionally, the M.S.J. candidate must take two survey courses of 3 credits each, *Business Law Survey* and *The Legal System: Research and Writing II*, which are designed specifically to provide an overview of basis areas of legal study.

Upon completion of the second semester in the program, candidates must select the track they will follow: health law or intellectual property. The health law track will focus on legal, regulatory and ethical issues related to traditional healthcare industries and medical professions. The intellectual property track will focus on legal, regulatory and ethical issues related to science, information technology and telecommunications. Professionals working in the pharmaceutical or biotechnology industry are permitted to create a combined curriculum with the permission of the Director of Graduate Programs.

Students choosing the health law track will be required to take Health Law for MSJS I and II and either Constitutional Law Survey or Intellectual Property Survey and either Health Law for MSJs or Institutional Law. Students choosing the Intellectual Property track will be required to take Intellectual Property and one of the following seminars: Copyright, Trademark and Unfair Competition or Patent Law. All students are required to take the 3 credit capstone seminar entitled *Advanced Topics in Health, Science and Technology* in their final semester.

Course Descriptions

Core Courses

HLTH 7390 The Legal System, Research & Writing I

This course provides M.S.J. students with an introduction to the legal system as well as basic legal research and writing skills, with a focus on topics relevant to the health and pharmaceutical industries. Students will receive LEXIS, WESTLAW and Internet research training. *4 credits*

HLTH 7391 The Legal System, Research & Writing II

This course introduces M.S.J. students to principles of contract and tort law necessary to provide a background to health law and intellectual property courses. The course also continues to hone the skills that students learned in *The Legal System Research & Writing I*. *3 credits*

HLTH 7400 Business Law Survey

This course introduces M.S.J. students to principles of contract and corporate law necessary to provide appropriate background to the nonlawyer. The course includes a writing component that focuses on drafting skills. *3 credits*

HLTH 7402 Constitutional Law Survey

This course provides a general overview of the constitutional law doctrines that are most relevant to nonlawyers working in heavily regulated industries. Particular attention is paid to separation of powers, privacy and reproductive rights, and the First Amendment as they relate to government regulation of health care and intellectual property. The course also considers constitutional and other issues raised by the role of administrative agencies and the implementation of legislation in the health care and intellectual property systems. *3 credits*

[Note: Students in the Health Law Track may substitute Intellectual Property Law for this class. Students in the Intellectual Property Track may substitute Health Law for MSJs I for this class.]

HLTH 8504 Advanced Topics in Health, Science, & Technology Law

This course is limited to MSJ students in their final semester. It is designed to help students synthesize and apply the material learned in previous courses through an in-depth examination of current legal issues related to health law and intellectual property. The course will be team-taught by professors from the Health Law & Policy Program and the Institute of Law, Science, & Technology, and will include guest lectures by distinguished practitioners in the field. *3 credits*

Health Law Track Core Courses

HLTH 7515 Health Law for MSJs I

This course will examine the means by which patients gain access to health care and through which sponsors of health coverage organize and compensate health care providers. It will include study of private and public means of health insurance and different types of third party payors, including Medicare, Medicaid and managed care organizations. The class will also survey the organization of hospitals and other health entities and introduce students to the issues, laws regulations and accreditation standards essential to understanding the structure and permitted functions of health care entities. This course

will introduce students to the physician-patient relationship, which includes studying the confidentiality of medical information, informed consent, and the standards to care used for malpractice actions. *3 credits*

HLTH 7516 Health Law for MSJs II

This course will examine the major legal and ethical issues surrounding patients' rights and varied approaches to medical practice and research. Topics will include medical decisions at the end of life, procreative rights and parenting issues, and the use of human subjects in medical research and drug development. This course will also examine alternative medicine and the means by which medicine is regulated. The class will also introduce students to a variety of public health issues. *3 credits*

Health Law Track Electives

PUBG 7801 Administrative Law

This course introduces students to the theory of administrative actions, administrative process, agency organization, determination and promulgation of the administrative regulations, right to notice and hearing, enforcement, judicial review, standing, and the Administrative Procedure Act. *3 credits*

HLTH 9501 Current Issues in Food & Drug Law

This seminar is an in-depth study of current issues that shape federal and state regulation of food and drug products, with a special emphasis on the treatment of pharmaceuticals. It considers changing areas of the law and examines options available to meet public concerns. Topics covered include legislative reform proposals and the impact of managed care on pharmaceutical regulations. In addition, the course examines product liability law as it relates to drugs, including the impact of liability standards and the debate about changing standards. *3 credits*

HLTH 9508 Drug Innovation, Regulation, & Cost

This seminar will examine the process and rationale for FDA regulation of drugs and medical devices, the impact of regulation on the ability to develop innovative products, and emerging issues about drug costs. The prospects for legislative change will be considered, since Congress will be revisiting FDA regulatory issues in conjunction with the need to re-authorize "user fees" for drugs. Topics to be examined include whether speeding up or changing the approval process will increase safety risks, whether reform is needed in the ability to market generic drugs while patent challenges are pending, whether direct-to-consumer advertising of prescription drugs increases costs or has other detriments, and whether there is a need for comparative efficacy testing for drugs. While the seminar will have a focus on regulatory policy issues, it will also explore the effort to control prescription drug costs through managed care programs and in legislative proposals, and the impact of these measures on innovation and health. Policies affecting the costs of AIDS and other life-saving drugs in developing countries will be considered. *2 credits*

HLTH 7512 Drugs & Devices: Law & Current Issues

This course will cover the basic legal requirements for both prescription drugs and over-the-counter drugs as well as devices for marketability in U.S. commerce. We will discuss the governmental bodies that have jurisdiction over these products and the enforcement tools they have to assure safe and efficacious

drugs and devices in the U.S. In addition, we will examine some of the constitutional limits on the FDA regulations, particularly the application of the First Amendment to restrictions on advertising and other forms of information dissemination by drug companies. *2 credits*

HLTH 8500 Food, Drugs, & Biotechnology

This course focuses on the federal legislative and administrative regulation of foods, pharmaceuticals, and medical devices. The class discussion examines the statutory aims, the nature of the legal requirements, and the effects of different types of regulatory schemes. Consideration is given to basic issues, such as the regulation of carcinogens in foods and the impact of the new drug requirements. Students also gain insight into the procedures and regulatory philosophy of the Food and Drug Administration. *2 credits*

HLTH 8505 Health Care Fraud & Abuse

The complex business of health care finance and delivery is increasingly structured by reference to an array of federal regulatory and statutory requirements. Attorneys reviewing relationships among providers and between providers and payors must be familiar with the anti-kickback laws, the False Claims Act, Stark I & II, and RICO. This course examines the application of those laws in the context of commercial relationships, regulatory reviews, and criminal investigation and prosecutions. It also examines the burgeoning area of corporate compliance programs. *2 credits*

HLTH 9515 Health Employment Issues

This seminar covers the special issues involving health care professionals that arise in the health care delivery system. The organization will follow the three ways that health care professionals are employed by hospitals and other health care delivery organizations: First, the classic independent contractor relationship of medical staff to a hospital involves issues of the application of staff by-laws and legal controls of those by-laws. Second, the formation of professional corporations by medical professionals that contract with health care delivery organizations studies the three-party relationships among health care professionals, the professional corporation, and the health care delivery system. Third, the direct employment of health care professionals by health care delivery organizations raises special legal questions of employment law. *2 credits*

HLTH 9525 HIPAA & Health Privacy

This seminar provides a comprehensive analysis of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) health privacy provisions, which pose substantial technology and privacy requirements for health plans, health care clearinghouses, and many health care providers. Topics include HIPAA's administrative simplification provisions, the Privacy Rule, the Transaction Rule, and an overview of electronic data interchange concepts as applied to health information. Students also will explore New Jersey statutory requirements for health privacy, as well as the developing body of case law in this area. Practical experience will be offered in drafting and negotiating HIPAA business associate contracts as well as in developing privacy policies and procedures. *2 credits*

HLTH 9509 The Law of Death & Dying

This seminar engages the student in an extensive study and analysis of empirical data, current statutes and cases, as well as proposed changes to the law dealing with issues related to death and dying. Class topics include alternative definitions of death, organ donation, withholding and withdrawal of death-prolonging and life-sustaining treatment, advance directives, patient demands for futile treatment, the cost of end-of-life care, wrongful living, and physician-assisted death. *3 credits*

HLTH 8508 Medical Malpractice

This seminar focuses on the principles underlying the traditional medical malpractice liability regime and proposals to reform or supplant that system. The seminar begins with a review of empirical studies on the propensity of patients to sue providers, the disposition of medical malpractice claims, and the impact of the traditional tort system on the cost and quality of medical care. The balance of the seminar concentrates on the various attempts to create a fairer, less costly, and more efficient system that will provide full compensation for victims of medical malpractice and reduce the incidents of malpractice. *2 credits*

HLTH 7511 Mental Health Law

This seminar focuses on the use of governmental authority to restrict or deprive individuals with mental disorders of liberty or property in a variety of civil contexts. These interventions are intended to either prevent future harm to self/others or to prevent individuals from making "incompetent" choices. The civil commitment, both inpatient and outpatient, of individuals with major mental illnesses is the main context studied. The commitment of sex offenders, the right to refuse psychiatric medication, the duty to warn, and competency determinations will also be examined. To provide a foundation for the legal analysis, the nature and treatment of mental disorders will be explored. A variety of mental health professionals and advocates will participate in the seminar to enhance understanding of the issues and provide diverse perspectives. *2 credits*

HLTH 9519 Nonprofit Organizations

This seminar examines state corporate law and the state and federal laws governing the taxation of non-profit health care organizations. It addresses issues of public charity, unrelated business income and private foundation status as they relate to corporate restructuring, financing, and joint ventures. *2 credits*

HLTH 9515 Public Health Law

This seminar examines the structure of public health law, with emphasis on government responsibility and power, individual rights, and the relationship between the law concerning population and individual health. Topics will include responses to threats of terrorism, infectious disease, environmental threats such as tobacco and lead, and privacy concerns. *3 credits*

HLTH 9517 Regulating Research with Human Subjects

This seminar examines the legal, ethical, and public policy issues surrounding the use of human subjects in biomedical research, focusing on current controversies and efforts to reform the existing regulatory structure. The seminar begins with a historical examination of human subject research, but the bulk of the semester is devoted to critical analysis of the current system for overseeing human subject research.

Throughout the seminar, we will consider how the regulatory system should take into account the changing relationship between academia, industry, and government. *3 credits*

Intellectual Property Track Core Courses**INDL 7301 Intellectual Property**

This course is a survey of the law of patent, copyright, and trademark. It serves as an introduction to the scope of protection of ideas and creation of legal monopolies, and provides a foundation in the area for those who intend to undertake further training in more specialized areas of proprietary rights. *3 credits*

INDL 8301 Copyright Law

This course covers all phases of common law and statutory copyright including works subject to protection; securing protection; rights of copyright holder and succession to those rights by agreement and inheritance; international problems; and fair use and infringement questions. *2 credits*

INDL 8303 Patent Law & Practice

This course undertakes an intensive examination of the nature of patents and questions of patent validity and procurement. It includes: nature of patent property; problems in the procurement of patents; international practice and problems; patent office practice; problems of validity, including novelty, utility and non-obviousness; and transfers of property rights in patents. *2 credits*

INDL 8302 Trademark Law

This course treats common law and statutory protection of trademarks and trade names, including: acquisition, loss, registration and licensing of all forms of trademarks; problems of infringement; dilution; and antitrust effects of trademark protection. *2 credits*

Intellectual Property Track Electives**INDL 9319 Biotechnology & the Law**

Counseling new or small businesses on intellectual property issues is challenging. They have limited resources, and often have personnel who are not familiar with the intricacies of intellectual property laws. However, without effective counsel, they will fail to maximize the value of their own intellectual property and run the risk of being shut down because they violate someone else's rights. Using a hypothetical biotechnology company, this course will navigate a series of complex intellectual property issues that counsel for a start-up company will likely confront. For each of the topics, students will review the current state of the law and explore ways to respond to the concerns and questions of employees of the hypothetical company. *2 credits*

INDL 7310 Communications Law & Policy

This seminar provides an intensive study of the law and public policy relating to communications, with special emphasis on telecommunications. Students will study the history and structure of the telecommunications industry in the United States and recent developments toward creating competition in formerly monopolized markets. Students also will review the sources of communications law and policy (federal and state agencies and courts), explore a layman's understanding of the

technical network fundamentals, and evaluate content issues. Students will discuss practical client concerns as they evaluate entry into new lines of business and defending existing lines of business from competitive threat. *2 credits*

INDL 7307 Electronic Commerce

This course will consider how developments in information technology affect commercial transactions. The course will consider issues related to information (including rules for protecting information, intellectual property and privacy), and various types of transactions in the electronic contexts (sales between businesses and/or consumers, Web site issues, and payments), as well as cross-border dispute-resolution issues. Particular emphasis will be placed on the social, political, and economic issues underlying those legal doctrines. *3 credits*

INDL 9324 Information Privacy Law

We live in an Information Age shaped by data and technology. As the collection and use of information in today's world escalates, privacy has become an issue of paramount importance. This course will provide an in depth analysis of information privacy law, which involves a variety of different types of law (constitutional, tort, contract, property, statutory) that have developed to address emerging threats to privacy in our information society. Some of the many topics covered include: (1) privacy and the media (reputation, media disclosures of private facts, paparazzi, private lives of public figures, and conflicts between privacy and free speech); (2) health and genetic privacy (medical records, HIPAA, confidentiality of physician-patient relationships, genetic data, and DNA databases); (3) privacy and law enforcement (wiretapping, police records, surveillance, computer searches, monitoring of e-mail, and Megan's law); (4) privacy at home, work, and school (drug testing, searches, surveillance, e-mail, telephone, and Internet use); (5) privacy and computers (databases, record systems, Internet monitoring, and profiling). Since this course focuses on information privacy, it will not include matters protected by the constitutional "right to privacy" such as abortion and contraception. *3 credits*

INDL 8310 Intellectual Property Aspects of Pharmaceutical & Biotech Businesses

This seminar focuses on the recent case law, relevant legislation, and underlying policies, related to intellectual property protection in the pharmaceutical and biotech industry. Students study key patent cases from the Court of Appeals for the Federal Circuit and the U.S. Supreme Court, and aspects of the FDA law that form the basis for IP protection in these industries. Recent patent cases, including those on enablement, written description, inherent anticipation, infringement under the doctrine of equivalents, inequitable conduct, and research tools, will be reviewed. Students also will analyze the Hatch-Waxman Act and competition law that impact both the innovative and generic drug industries, and proposed legislation that is currently being considered by Congress that could dramatically affect these industries. *2 credits*

INDL 9315 Intellectual Property Licensing

The seminar will provide a comprehensive study of all aspects of intellectual property licensing and related issues. Students will analyze and draft various trademark, copyright, music, software, patent and technology licenses, and develop related

negotiation skills and litigation strategies. The focus will be practical and will show how value can be unleashed in intellectual property assets through licensing. *2 credits*

INDL 8309 Internet Law

This course surveys legal issues related to the use and misuse of global electronic networks including the Internet. Topics to be discussed include: regulation of digital content; privacy and control of personal data; legal and constitutional implications of public key infrastructure; and regulation of electronic commerce. *3 credits*

INDL 9320 Law & the Computer

This course is a survey of computer law covering patent, copyright and trade secret protection of software, and software piracy. It discusses the acquisition process, including requests for proposal, requests for quotes, and requests for information. It studies negotiation and drafting of computer contracts for hardware, software, and services, and the resolution of computer disputes including theories of liability, vendor defenses and litigation strategy. Technical knowledge of computers is not required. *2 credits*

INDL 8302 Trademark Registration

Federal registration provides important benefits to trademark owners. Registration work is a staple of many law firm and in-house intellectual property practices. This class will cover the basics of trademark registration practice, from selection of a mark and initial screening through opposition proceedings. Assignments will include hands-on drafting of opinion letters, registration papers, and pleadings drawn from real-world examples. M.S.J. students need the approval of the Director of Graduate Programs in order to enroll in this course. *2 credits*

INDL 9310 United States Patent Application Preparation and Prosecution

This seminar develops the writing and analytical skills required to draft applications for U.S. patents. Patent claim drafting skills are not undertaken in this course. Patent prosecution techniques, however, including evaluation of Patent and Trademark Office Official Actions and preparation of responses to these Official Actions, are studied. There also is practice in drafting appellate briefs for submission to the Board of Patent Appeals and Interferences. *2 credits*

Administrative Law

See Above for Description

Current Issues in Food & Drug Law

See Above for Description

Drug Innovation, Regulation, & Cost

See Above for Description

Drugs & Devices: Law & Current Issues

See Above for Description

Food, Drugs, & Biotechnology

See Above for Description