

Health & Pharmaceutical Law & Policy

Law, Science Technology

SETON HALL LAW



About the Seton Hall Law Center for Health & Pharmaceutical Law & Policy

The Center for Health & Pharmaceutical Law & Policy, established in 2007, advances scholarship and recommendations for policy on the varied and complex issues that emerge within pharmaceutical and health law. The Center fosters informed dialogue among policymakers, consumer advocates, the medical profession and industry in the search for solutions to the ethical, legal and social questions presented in the health and pharmaceutical arena. Additionally, the Center is a leader in providing compliance training on the wide-ranging state, national and international mandates that apply to the safety and promotion of drugs and devices.

About the Gibbons Institute of Law, Science & Technology

The Gibbons Institute of Law, Science & Technology was established in 2007 thanks to a \$1 million endowment from Gibbons P.C. The Institute is a forum for lawyers, judges, scientists and government officials to discuss the legal, political and social problems that will continue to arise as scientific and technological changes challenge existing laws and institutions. The Institute aims to educate and train the next generation of attorneys and professionals for the complex issues they will face in the 21st century, while also providing resources and support to the technology and scientific communities through its faculty scholarship, publications, symposia and events.

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Dear Friends,

Thanks to our faculty, students, and our many partners and professional colleagues in the health and life sciences, technology, and telecommunications arenas the world over, the Seton Hall Law Center for Health & Pharmaceutical Law & Policy and the Gibbons Institute of Law, Science & Technology experienced another year of unprecedented growth and accomplishment in 2010-11.

This was a year of expansion for our Health Law and Intellectual Property Law curricula to benefit our J.D., LL.M. and M.S.J. degree candidates, as well as our online certificate program participants. In addition, both the Center and the Gibbons Institute offered an unprecedented array of opportunities for professional development for practicing attorneys both in the United States and in Geneva, Switzerland. Visiting faculty from esteemed universities, representatives from non-government organizations, government agencies, law firms and corporations

participated in the dialogue, proposing new ideas and enhanced policies that address the emerging issues of our changing society and business environment. The discussions took place in conferences and symposia, webinars, colloquia and online through our blog, HealthReformWatch.com.

In this issue of *Health Law/Intellectual Property Law Highlights* we invite you to learn more about this past year's accomplishments – Seton Hall Law-sponsored events, new and innovative academic programs, and the unique achievements of alumni and students who are pursuing excellence in the areas of health law and intellectual property law. These stories may spark your thinking about new and enhanced partnerships with Seton Hall Law that can improve and enhance how we live and how we do business.

Warm regards,

Lank Cillant

Vice Dean and Professor of Law

RECENT & UPCOMING Events

FALL 2011

Gibbons Institute of Law, Science & Technology Intellectual Property Roundtables

Law.shu.edu/GibbonsInstitute

SEPTEMBER 21, 2011

Distinguished Guest Practitioner Healthcare Enforcement Trends: HIPAA & Beyond Mark J. Swearingen, J.D. '98 Hall, Render, Killian, Heath & Lyman, P.C.

OCTOBER 3, 2011

Gibbons Institute Federal Circuit Year in Review

The Honorable Garrett E. Brown, Jr., *Chief Judge*

The Honorable Jerome B. Simandle, *District Judge*

U.S. District Court for the District of New Jersey

NJ/NY CLE credits provided law.shu.edu/GibbonsInstitute

OCTOBER 10-13, 2011

U.S. Healthcare Compliance Certification Program law.shu.edu/Compliance

OCTOBER 14, 2011

2011 Healthcare Compliance Forum

Porzio Pharmaceutical Services, LLC law.shu.edu/CenterforHealth

OCTOBER 25, 2011

Gibbons Institute/NJIPLA Ninth Annual Fall Lecture Series

The Honorable Joel Pisano, J.D. '74, U.S. District Court for the District of New Jersey

NJ/NY CLE credits provided law.shu.edu/GibbonsInstitute

OCTOBER 28, 2011

Law Review Symposium: Implementing the Affordable Care Act: What Roll for Accountable Care Organizations? Iaw.shu.edu/lawreviewsymposium

NOVEMBER 14-18, 2011

European Healthcare Compliance Certification Program Paris, France law.shu.edu/Paris

SPRING 2012

Gibbons Institute Roundtables law.shu.edu/GibbonsInstitute

FEBRUARY 2012

Distinguished Visiting Scholar Gian Luca Burci Legal Counsel, World Health Organization law.shu.edu/CenterforHealth

MARCH 5-9, 2012

European Healthcare Compliance Certification Program Paris, France law.shu.edu/Paris

MARCH 19-23, 2012

Distinguished Visiting Scholar Ani Satz

Associate Professor Emory University School of Law law.shu.edu/CenterforHealth

MARCH 26-27, 2012

Distinguished Visiting ScholarJerry Menikoff

Director, Office for Human Research Protections, Office of the Secretary, U.S. Department of Health and Human Services law.shu.edu/CenterforHealth

MARCH 26-27, 2012

Is For-Profit Catholic Health Care a Viable Alternative for Ministry? law.shu.edu/Ministry

JUNE 11-14, 2012

U.S. Healthcare Compliance Certification Program law.shu.edu/Compliance

JUNE - JULY 2012

The Leuven-Geneva Program in Health, Intellectual Property & International Law Leuven, Belgium and Geneva, Switzerland law.shu.edu/Geneva



Center Analyzes Health Care on Federal, State and Local Levels

This year, the Center for Health & Pharmaceutical Law & Policy's research has focused on examining the impact that national health care reform will have on New Jersey law, and on pursuing ways to improve the delivery of health care services in Newark, a traditionally underserved area.

Center Study Examines ACA's Impact on New Jersey Health Insurance Law

In early 2011, the Center for Health & Pharmaceutical Law & Policy began efforts on a seven-month research study, "New Jersey Law Reform in Response to the Patient Protection & Affordable Care Act," in collaboration with the Rutgers Center for State Health Policy. Seton Hall Law's research will address the interplay between the Patient Protection and Affordable Care Act (ACA) and state health insurance law, regulation and practice.

Professor John Jacobi, Research Fellow & Lecturer in Law Kate Greenwood (pictured), and several law students are reviewing the legislative and regulatory changes that the ACA requires and permits New Jersey to make. They will develop a "cross-walk" between current law and law that is fully compliant with the ACA. They will also relate the provisions of the ACA to current New Jersey practice, and describe options available to the state as it implements the new act. Seton Hall and Rutgers researchers will produce interim research briefs and a final paper incorporating legal, economic and public policy analyses. The study is administered by the Rutgers Center for State Health Policy and is funded by a grant from the Robert Wood Johnson Foundation. The briefs and papers may be found at www.cshp.rutgers.edu.

Greater Newark Healthcare Coalition: Improving Care through Collaboration

The Greater Newark Healthcare Coalition, now in its second year, continues to pursue cooperative projects to improve health care for

the most vulnerable in the Greater Newark area. Professor Jacobi serves as the Coalition's board chair. Other members represent a range of health care providers, consumer groups and government agencies. Coalition projects include:

- Case management of frequent utilizers of hospital emergency departments. These fragile patients will benefit from a sophisticated evaluation of their needs and referral to appropriate community placements. Professor Jacobi and Ms. Greenwood are working with clinicians on this project, and will produce analysis supporting a reconfiguration of health care funding to improve care and reduce costs.
- Improved prenatal care. The Newark area has a disproportionate number of mothers with poor access to prenatal care. The Coalition is working to bring together various organizations to improve prenatal care.
- Preparing physicians for new practice models. Accountable care
 organizations and patient-centered medical homes require the
 increased adoption of technology and physician practice patterns
 that mesh with demands for quality and efficiency. The Coalition
 will conduct training sessions for area physicians.

The Center's faculty and students are engaged and committed to lending expert support to the Coalition through legislative and regulatory advocacy and policy development. The Center believes that the fruits of health reform will reach the most vulnerable only if providers, advocates and regulators work together in cities like Newark.

Gibbons Institute Introduces Cybersecurity

Law Project

In 2010, the Gibbons Institute launched a new program in the emerging area of cybersecurity law, thanks to a grant from the Bergen County Prosecutor's Office, awarded jointly to Seton Hall Law and Rutgers School of Law-Newark.

Cybersecurity law seeks to address the technological, social and legal controls implemented by government and private entities to secure electronic communications and data networks from manipulation, theft and attack by enemies of the state, terrorists, hackers, competitors and other adversaries.

Professor David W. Opderbeck, Director of the Gibbons Institute and the Cybersecurity Law Project, commented, "Cybercrime today is considered a major threat to business, individual safety and national

security. A U.S. Senate Committee report estimates that the executive branch agencies and Congress alone are now under cyber-attack an average of 1.8 billion times per month. Many corporations hesitate to report the crime or prosecute as they fear they will lose the confidence of their customers and tarnish their brands. We estimate the cost of cybercrime on our national economy runs billions of dollars annually."

He continued, "Every area of legal practice can be affected by issues related to cybersecurity. Seton Hall Law is pleased to partner with the Bergen County Prosecutor's Office and Rutgers Law to prepare our students for these challenges that await them as they enter the legal profession."

Components of the Cybersecurity Law Project

The Cybersecurity Law Project is a multifaceted program, designed to teach and train students in a variety of legal areas. It also provides complimentary training for assistant prosecutors who were invited to audit new cybersecurity courses in Fall 2010, and attend a June 2011 conference.

The intellectual property curriculum has been expanded to include two new courses, both of which were made available to New Jersey prosecutors and representatives from the State of New Jersey Office of Homeland Security and Preparedness to audit, free of charge. Cybersecurity Law focuses on the national and global information grids, transportation, energy networks and other vulnerable information infrastructures. Students explore the current regulatory framework in the United States, European Union and China.



A full-day conference was part of the Cybersecurity Law Project, a collaborative effort involving Seton Hall University School of Law, Rutgers School of Law-Newark and the Bergen County Prosecutor's Office. Pictured from left to right, Vice Dean Erik Lillquist; Professor David W. Opderbeck; John L. Molinelli, Bergen County Prosecutor; Melissa Hathaway, Senior Advisor of Project Minerva at the Belfer Center for Science and International Affairs, Harvard University; Patrick E. Hobbs, Dean of Seton Hall Law; and John J. Farmer, Jr., Dean of Rutgers School of Law-Newark.

Drawing on the expertise of detectives and other cybercrime experts, the Cybersecurity Crimes and Practice course covers the skills necessary to prosecute and defend cybercrime cases.

This past summer, county prosecutors' offices accepted summer interns and postgraduate fellows from Seton Hall Law. Six students and alumni participated in the inaugural Cybersecurity Internship/ Fellowship Program, serving in prosecutors' offices in Bergen, Essex, Somerset and Union Counties, as well as the U.S. Attorney's Office.

The Cybersecurity Law Project included a day-long conference on June 8, 2011, at Seton Hall Law, "Cybersecurity Law and Policy: Changing Paradigms and New Challenges." The program brought together federal, state and local law enforcement as well as industry experts and academics to address the growing threat of cybercrime and terrorism. Funded by the Bergen County Prosecutor's Office, the full-day program was free of charge to the legal community, and offered CLE credits.

Melissa Hathaway, Senior Advisor of Project Minerva at the Belfer Center for Science and International Affairs, Harvard University, and former Acting Senior Director for Cyberspace at the National Security Council under President George W. Bush and President Barack Obama, served as keynote speaker.

Professor Opderbeck concluded, "Our collective mission for the Cybersecurity Law Project is to become a resource of information, expertise and learning to support law students, information technology professionals, academics and the greater legal community."

2010-11 Events



Pay for Delay: Views from the FTC, Industry and Legal Economists on Reverse Payment Settlements in Hatch-Waxman Patent Litigation

June 17, 2010

The Gibbons Institute presented a panel discussion on "Pay for Delay" Hatch-Waxman patent litigation, featuring Mark J. Woodward, Attorney Advisor to Commissioner Julie Brill of the Federal Trade Commission; Charles A. Gaglia, Jr., Counsel, Intellectual Property, Gibbons P.C.; Anastasia Winslow, Assistant General Counsel, Bristol-Myers Squibb (*pictured*); and Professor David Opderbeck. The event was co-sponsored by the New Jersey Intellectual Property Law Association.

Webinar: Understanding the Supreme Court's Bilski Decision

July 1, 2010

On June 28, 2010, the U.S. Supreme Court decided *Bilski v. Kappos*, addressing limitations in the patentability of business methods. In response, on July 1, the Gibbons Institute hosted a live webinar featuring a distinguished panel of experts, including Vice Dean Erik Lillquist, Robert E. Rudnick, Director, Intellectual Property, Gibbons P.C. and Professor David Opderbeck. The panelists reviewed, analyzed and discussed the implications of this decision on patent practice and the patent landscape in particular industries.

Why Prosecuting Health Care Fraud is a Top Priority in New Jersey

September 23, 2010

Paul J. Fishman, U.S. Attorney for the District of New Jersey (pictured), provided insight into his office's approach to prosecuting health care fraud. Mr. Fishman's talk, "Why Prosecuting Health Care Fraud is a Top Priority in New Jersey," drew a diverse crowd of professors, law students and representatives from industry and government. Mr. Fishman noted that the Department of Justice (DOJ) and the Department of Health and Human Services are working more closely than ever to combat health care fraud. Mr. Fishman indicated that over the next few years the number of cases being prosecuted will rise, including both criminal and civil fraud prosecutions. Mr. Fishman also noted that the DOJ is cash-flow positive, citing research finding that the DOJ collects four dollars for every dollar spent on health care fraud investigations and prosecutions, but underscored that deterrence was his guiding principle, with the ultimate goal being the wholesale prevention of health care fraud.



The Eighth Annual Gibbons Institute/NJIPLA Fall Lecture Series

October 5, 2010



In conjunction with the New Jersey Intellectual Property Law Association (NJIPLA), Seton Hall University School of Law and the Gibbons Institute presented the Eighth Annual Gibbons Institute/NJIPLA lecture series featuring the Honorable Paul R. Michel, former Chief Judge of the U.S. Court of Appeals for the Federal Circuit (pictured). Chief Judge Michel spoke on "The Impact of a Malfunctioning Patent System," after which a panel of distinguished attorneys, in-house counsel and faculty offered their expertise and insight on the state of the patent system in the United States. Panelists included John Parish, Senior Counsel and Managing Attorney, Roche; Caren K. Koo, Assistant General Counsel, IP Litigation, Verizon; Daniel Schulman, Chief Intellectual Property Counsel, Pactiv Corporation; and Professor David Opderbeck. The event, held at the Newark Club, attracted more than 75 guests, including judges, alumni, attorneys and students.

Judge Michel was appointed to the U.S. Court of Appeals for the Federal Circuit in March 1988. He served as Chief Judge from December 2004 until his retirement from the bench in May 2010. During his 22-year tenure on the bench, Judge Michel adjudicated thousands of appeals and wrote over 800 opinions, approximately one-third of which were in patent cases.

Aggregate Spend Forum: Solving the Aggregate Spend Puzzle

October 15, 2010

Together with Porzio Pharmaceutical Services, Seton Hall Law held an all-day workshop on the federal and state aggregate-spend reporting requirements for drug and device companies. The workshop helped prepare companies to meet the challenges of the sunshine provisions of the Patient Protection and Affordable Care Act and the various state laws requiring aggregate-spend reporting. Program faculty included, among others, John Patrick Oroho, Executive Vice President of Porzio Pharmaceutical Services (pictured, left); Michael D. Bell, Founder and President of R-Squared Services and Solutions, Inc.; Cynthia Cetani, Vice President, Ethics & Compliance and Chief Compliance Officer, Novartis Pharmaceuticals Corporation; and Audrey F. Eschbacher, Senior Regulatory Analyst, Porzio Pharmaceutical Services (pictured, right).





Students from Seton Hall Law and law schools throughout the country attended the ASLME conference on October 22, 2010.

American Society of Law, Medicine and Ethics Annual Student Health Law Conference

October 22, 2010

For the second consecutive year, Seton Hall Law hosted the Annual Student Health Law Conference, "Taking the Health Law Career Path," an event co-sponsored by the American Society for Law, Medicine & Ethics (ASLME). Over 200 students from law schools across the country attended the event, which explored the spectrum of opportunities within the field of health and life sciences law. In the plenary session, Peter Liebold, Executive Vice President and Chief Executive Officer of the American Health Lawyers Association, identified hot hiring areas in health law and advised students how to assess their personal and professional skills in order to better position themselves for a successful career in health law.

Follow-On Biologics: Implementation Challenges and Opportunities

October 29, 2010

The Gibbons Institute and the Center hosted this day-long invitational roundtable. Led by Seton Hall Law Professor Jordan Paradise, the roundtable brought together experts from academia, government, industry and private law practice to explore a number of topics, including the scientific and regulatory distinctions between the established generic drug approval processes and the Patient Protection and Affordable Care Act's expedited approval process for follow-on biologics, with a focus on the differences between traditional drugs and biologics. Henry Grabowski, Ph.D., Professor of Economics and Director of the Program in Pharmaceuticals and Health Economics at Duke University, provided the keynote address, "Implementation of the Biosimilars Pathway." Falk Ehmann, M.D., Ph.D., M.Sc., Scientific Secretariat of the European Medicines Agency's Biosimilar Working Party, Safety & Efficacy of Medicines Sector, Human Medicines Development and Evaluation Unit; and Suzanne Drennon Munck, Counsel for Intellectual Property for the Federal Trade Commission (FTC), also presented. Resulting articles from the roundtable, plus a foreword by Professor Paradise, were published in the SETON HALL LAW REVIEW.

Pictured, front row, from left: Chris Holman, Ph.D., Associate Professor of Law at the University of Missouri-Kansas City School of Law; William M. Egan, Ph.D., Vice President of PharmaNet Consulting; Professor David Opderbeck; Donna Gitter, Associate Professor of Law at Baruch College, The City University of New York; and Jill Deal, Partner at Venable LLP. Back row from left: Dr. Falk Ehmann; Dr. Henry Grabowski; Suzanne Drennon Munck; Reza Green, Ph.D., Chief Intellectual Property Counsel of Novo Nordisk; Professor Jordan Paradise; Vice Dean Erik Lillquist; Phil Katz, Partner and Practice Area Leader of Pharmaceuticals & Biotechnology at the law firm Hogan Lovells; and Nathan Cortez, Assistant Professor of Law at Southern Methodist University, Dedman School of Law.



2010-11 Events



Whistling While You Work

November 3, 2010

Visiting Professor Steven Willborn (pictured) provided a unique perspective on the laws that protect employees from retaliation, known as "whistleblower" laws. In his public lecture, "Whistling at Work: Why Employers Undervalue Whistleblower Protections," Professor Willborn acknowledged that whistleblower protection is a rare growth area in employment law and one where, unusually, workers have enjoyed both legislative and judicial success. He also addressed the current state of legal protections for whistleblowers, explaining why employers often undervalue these protections, and proposed an alternative framework through which to view whistleblowing.

The District of New Jersey's Local Patent Rules: A Year in Review, and Where We Go From Here

November 15, 2010

This panel discussion, hosted by the Gibbons Institute, featured the Honorable Garrett E. Brown, Jr., Chief Judge, U.S. District Court for the District of New Jersey and the Honorable Tonianne J. Bongiovanni, Federal Magistrate Judge, U.S. District Court for the District of New Jersey. In 2008, Chief Judge Brown appointed a special Local Patent Rules Committee to review and evaluate the need for the creation of separate local rules governing patent cases in the district, one of the most active patent venues in the country. The committee, comprised of district judges, magistrate judges and attorneys, recommended that a standard protocol for patent cases would be useful to the Court, and submitted local patent rules. The new rules took effect on January 1, 2009. Chief Judge Brown and



Pictured, from left: Arnold Calmann, William Mentlik, Judge Brown, Judge Bongiovanni, David DeLorenzi and Stephen Buckingham.

Magistrate Judge Bongiovanni, along with a distinguished panel of practitioners, considered potential amendments and practical tips for dealing with patent litigation in New Jersey. Serving on the panel and sharing their experience with the district's new rules were Stephen R. Buckingham, Lowenstein Sandler PC; Arnold B. Calmann, Saiber, LLC; and William L. Mentlik, Lerner David Littenberg Krumolz & Mentlik, LLP. The event attracted more than 100 guests.



The Future of America's Innovation Economy: Progress and Challenges at the United States Patent and Trademark Office (USTPO)

February 23, 2011

The Gibbons Institute, together with the New Jersey Intellectual Property Law Association, hosted this discussion featuring David Kappos, Under Secretary of Commerce for Intellectual Property and Director, USPTO (pictured) and Q. Todd Dickinson, Former Director, USPTO and current Executive Director, American Intellectual Property Association. The standing-room only event attracted attorneys, practitioners and students from the tri-state area.

Strategies for Compliance Professionals: Honing Your Decision-Making Skills

March 10, 2011

This single-day advanced level training workshop was attended by health care compliance professionals and lawyers wishing to strengthen their analytic and communication skills and foster decision-making capacity. Participants were presented with detailed factual scenarios and were tasked with identifying and analyzing various business and legal risks. They presented their recommendations for corrective action to a mock corporate management team comprised of recognized health care compliance leaders from Siemens, Johnson & Johnson, Eisai and Merck, among others.



Panelist Howard L. Dorfman, Vice President and General Counsel, Ferring Pharmaceuticals

Managing Medical Bills on the Brink of Bankruptcy

March 30, 2011

During a week-long visit to Seton Hall Law in March, Melissa B. Jacoby, the George R. Ward Professor of Law at the University of North Carolina at Chapel Hill, lectured in health law classes, presented to faculty and met with students. In a public lecture, "Managing Medical Bills on the Brink of Bankruptcy," she addressed how financially distressed patients manage out-of-pocket medical costs, highlighted findings from two empirical studies, and discussed the implications for bankruptcy filings, health care finance, consumer credit regulation and bankruptcy law.



Pictured, from left: Simone Handler-Hutchinson, Executive Director, Center for Health & Pharmaceutical Law & Policy; Professor Carl H. Coleman; Professor Melissa B. Jacoby; and Professor John V. Jacobi.



Pictured, from left: Vice Dean Erik Lillquist, Henry Hadad, Colleen Tracy, Professor David Opderbeck, George Johnston and Frank Bruno.

The Business of Intellectual Property: Trends and Predictions

April 6, 2011

Sponsored by the Gibbons Institute of Law, Science & Technology and the Intellectual Property Law Association (IPLA), "The Business of Intellectual Property: Trends and Predictions" featured Gibbons Institute Advisory Board Members George Johnston, Chief Patent Counsel, Roche; Colleen Tracy '96, Managing Partner, Fitzpatrick, Cella, Harper & Scinto; Henry Hadad, Vice President & Deputy General Counsel, Bristol-Myers Squibb; Frank Bruno, Director, Intellectual Property, Gibbons P.C.; and Professor David Opderbeck. The panelists examined the state of intellectual property practice in challenging economic times, tackling such issues as trends in billing arrangements, hot and not-so-hot practice areas, new models for protecting and monetizing intellectual property, and emerging ethics issues for intellectual property practice.

The Annual IPLA Meet & Greet Reception followed the panel. This gathering provides an opportunity for Seton Hall Law students to meet and network with attorneys and practitioners in intellectual property.

Managing Financial Conflicts of Interest in Pharmaceutical and Medical Device Research

April 13, 2011

This program examined the types of financial conflicts of interest that arise in research involving pharmaceuticals and medical devices, strategies for managing these conflicts, and applicable federal and state laws and policies. Program faculty included (pictured, from left) Professor Kathleen Boozang, Professor Carl Coleman and Research Fellow & Lecturer in Law Kate Greenwood, whose presentations drew on the Center's two most recent white papers, "Conflicts of Interest in Clinical Trial Recruitment & Enrollment" and "The Limits of Disclosure as a Response to Financial Conflicts of Interest in Clinical Research."



HEALTHCARE COMPLIANCE Program Update

Attendance at U.S. and European Healthcare Compliance Certification Programs Climbs



Pictured, from left: James Sheehan, former New York Medicaid Inspector General, and John Krayniak, Assistant Attorney General, Senior Counsel, New Jersey Medicaid Fraud Section

Seton Hall Law's U.S. and
European Healthcare Compliance
Certification Programs have a
well-deserved reputation among
compliance and legal professionals
in the pharmaceutical and medical
device compliance arena.

Chris Zalesky Johnson & Johnson



Dominique Laymand, Vice President Compliance & Ethics EMEA, Bristol-Myers Squibb

Strong attendance by legal and compliance professionals is the key factor supporting the continued growth of Seton Hall Law's Healthcare Compliance Certification Programs. In the United States, the most recent programs held at the Law School campus in Newark were sold out with record registration for June and October 2011. Similarly, the European Healthcare Compliance Certification Program, co-hosted by Seton Hall Law and Sciences Po and offered in Paris, has been filled three times since its launch in 2010. Attendees of the European Program now represent over 25 countries and 40 multinational life sciences companies and government agencies.

"Seton Hall Law's U.S. and European Healthcare Compliance Certification Programs have a well-deserved reputation among compliance and legal professionals in the pharmaceutical and medical device compliance arena," notes Chris Zalesky, Vice President, Global Policy & Guidance, Johnson & Johnson, Office of Health Care Compliance & Privacy, and a member of the program faculty. "It is interesting to see that the programs of the past few years have been selling out at an ever faster pace. That suggests a growing need for the sort of in-depth, rigorous training these programs offer." The programs also have garnered strong support from international industry associations including IFPMA, EFPIA, AdvaMed, EucoMed, MecoMed and AESGP.

To meet the growing demand, each program is offered twice each year. "While the U.S. and European programs are built upon the same multi-day immersion model, the laws, regulations, industry codes and enforcement regimes that apply to life sciences companies operating in the two regions vary immensely. As a result, each program boasts its own curriculum and faculty," explains Simone Handler-Hutchinson, Executive Director of the Center for Health & Pharmaceutical Law & Policy. Program faculty include health care experts from business, law, academia and government, including Dominique Laymand of Bristol-Myers Squibb, Dirk Brinckman of Johnson & Johnson, Gabor Danielfy of Sanofi, Ted Acosta of Ernst & Young, Lynn Shapiro Snyder of Epstein Becker, Kirk Ogrosky of Arnold & Porter, and James Sheehan, former New York Medicaid Inspector General, as well as Seton Hall Law's own health law professors.

Upcoming Programs

The European Healthcare Compliance Certification Program will next be offered November 14-18, 2011 and March 5-9, 2012. The next U.S. Healthcare Compliance Certification Program will be offered October 10-13, 2011 and June 11-14, 2012. For more information on these programs, please visit *law.shu.edu/compliance*.



HCCP Scholarship Award Winners, 2011

Two promising health law students received scholarships to attend Seton Hall Law's U.S. Healthcare Compliance Certification Program in June. Awarded annually since 2009, these scholarships are given to current law students based on a competitive application process, including an endorsement from their law school. Pictured with Simone Handler-Hutchinson (*left*) are 2011 scholarship award winners Jenna Smith, a third-year student at Loyola University Chicago School of Law, and Abraham Gitterman, a third-year student at the University of Maryland School of Law. For more information, please visit *law.shu.edu/compliance*.

ACADEMIC Program Update & New Programs

New And Expanded Opportunities for Learning at All Levels

Online Graduate Certificate Programs

Following the successful launch of its online Graduate Certificate in Health & Hospital Law in 2010, Seton Hall Law School's Center for Health & Pharmaceutical Law & Policy now offers a second online Graduate Certificate in Pharmaceutical & Medical Device Law & Compliance.

The Graduate Certificate in Pharmaceutical & Medical Device Law & Compliance is a non-degree program designed for individuals who seek in-depth knowledge about legal, regulatory and ethical issues related to the pharmaceutical and medical device industries. Taught exclusively online, the program offers students nationwide a targeted immersion in key substantive issues along with the practical skills necessary to research and communicate effectively about the law.

"The demand for online professional education in the health care field is unquestionably growing," says Helen A. Cummings, Director of Graduate Programs & Online Learning. "With its top-ranked Health Law Program, Seton Hall Law is in a unique position to meet that demand."

Both graduate certificates are offered at multiple times throughout the year. The intensive programs are geared to busy professionals who want to cover a significant amount of material in a relatively short period of time. Applications for these programs are being accepted now. Additional information is available at *law.shu.edu/onlinecertificate*.



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With its top-ranked health law program, Seton Hall Law is in a unique position to meet that demand.

Helen Cummings Seton Hall Law School



Study Abroad Program in Health, Intellectual Property, and International Law

The Center for Health & Pharmaceutical Law & Policy and the Gibbons Institute have completed the second year of their exciting study abroad course in Health, Intellectual Property, and International Law, part of Seton Hall Law's International Program offerings. Law students began the Program with two weeks in Leuven, Belgium, where they studied the European Union (EU) and met with experts from EU institutions. They then spent three weeks in Geneva, Switzerland, exploring issues in intellectual property law, pharmaceutical development and global public health.

A significant component of the Program includes briefings at Geneva-based international organizations involved in health and intellectual property law issues, including the World Health Organization, the World Trade Organization, the World Intellectual Property Organization and the Joint United Nations Program on HIV/AIDS. For more information regarding the Program, visit law.shu.edu/geneva.

CENTER News



Center Welcomes Tara Adams Ragone, Research Fellow & Lecturer in Law

The Center is pleased to welcome Tara Adams Ragone. As a Research Fellow & Lecturer in Law, Ms. Ragone focuses on the implementation of health care reform, accountable care organizations, bioethics, health care access, and issues related to the representation of health care professionals. She is also advising the Health Law Moot Court Team.

Ms. Ragone previously served as Deputy Attorney General for the State of New Jersey, Office of the Attorney General, Division of Law, where she handled the prosecution of licensing actions before the State's medical and other health-related professional boards and the Office of Administrative Law. Prior to her work with the Attorney General of New Jersey, Ms. Ragone served as clerk to the Honorable

Robert A. Katzmann, U.S. Court of Appeals for the Second Circuit. Ms. Ragone graduated *magna cum laude* from New York University School of Law in 2001, where she was a Root-Tilden-Kern Public Service Scholar, was elected to the Order of the Coif, and served as Senior Articles Editor for the NYU ANNUAL SURVEY OF AMERICAN LAW. At graduation, she received the prestigious Vanderbilt Medal and the Samuel A. Levy Memorial Award.

Health Reform Watch – A Finger on the Pulse of U.S. Health Policy

Health Reform Watch is the Center's official web log, managed by Professor Frank Pasquale and Seton Hall Law students. It provides an open forum for academics, medical professionals, policymakers, journalists, lawyers, students and concerned citizens who monitor the progress of health care reform in the United States.

HealthReformWatch.com has received a half-million visits since its launch in 2009 and has been cited by, among others, *The New York Times, Washington Post, L.A. Times,* NPR, *New England Journal of Medicine* and Harvard's Nieman Foundation for Journalism.

Twitter "followers" of the blog include Senator Chuck Grassley, *USA Today Health, USA Today Medical*, Robert Wood Johnson Foundation, PhRMA, Boston University Public Health, Johns Hopkins CHDS, KevinMD, Hal Luft, the Heritage Foundation, Medical Progress Today, the Public Health Foundation and a number of other industry, legal and medical providers.

In addition to Seton Hall Law professors and students, Health Reform Watch contributors hail from law schools across the country and have included Professors Thomas "Tim" Greaney of St. Louis University School of Law; Timothy S. Jost of Washington and Lee University School of Law; Nathan Cortez of the Dedman School of Law at Southern Methodist University; Mark A. Hall, Wake Forest School of Law: Carl F. Schneider, University of Michigan School of Law; and Dr. L. James Rol

Wake Forest School of Law; Carl E. Schneider, University of Michigan School of Law; and Dr. J. James Rohack, 2010 President of the American Medical Association.





A Class in Health Care Fraud

In April 2011, during one of his classes in Health Law, Adjunct Professor Christopher Zalesky, Vice President, Global Policy & Guidance, Johnson & Johnson, Office of Health Care Compliance & Privacy, moderated an in-depth discussion between a federal prosecutor and defense counsel regarding their respective approaches to prosecuting and defending health care fraud cases.

Pictured, from left: Bruce A. Levy, Director, Criminal Defense Department, Gibbons P.C.; Maureen A. Ruane, Chief, Health Care & Government Fraud Unit, U.S. Attorney's Office for the District of New Jersey; and Adjunct Professor Chris Zalesky.

GIBBONS INSTITUTE News

Advisory Board member: Loria Baskerville Yeadon, J.D. '94 Executive Vice President, Intellectual Ventures, Bellevue, Washington

As the Executive Vice President of the Invention Investment Fund for Intellectual Ventures (IV), Loria Yeadon manages a team of 170 senior leaders, engineers, patent attorneys and others in the business of invention. "Ideas are valuable, and at IV, we are building an efficient marketplace where companies can access invention rights they need for their products," says Yeadon. She is responsible for the fund's strategy, investments, returns and day-to-day business operations. "I am excited to be in a position to help define what invention will mean for the world for generations to come," she says. It's a role that perfectly complements her expertise in both IP law and engineering.

As a child growing up in rural Kenbridge, Virginia, Yeadon was never exposed to what it meant to be an engineer. When high school graduation approached, she was advised to attend a junior college to pursue liberal arts. However, her chemistry teacher, Helen Potts, wouldn't hear of it. "She told me that I was extremely good in math and science and was adamant that I should go into engineering," Yeadon says. "She saw my potential, talent and work ethic and planted the seed."

While attending the University of Virginia, Yeadon was invited by Bellcore, now known as Telcordia, to work as an engineering intern in a program for rising college seniors. After graduation, Yeadon joined Bellcore full-time, where she took advantage of every opportunity she could. She was placed into a program that sent her back to school to earn her master's degree in electrical engineering. Five years later when Bellcore was looking for two engineers to groom into patent attorneys, she was once again presented the opportunity to go back to

school at night while working during the day as a patent attorney trainee.

"Both times, I hadn't considered getting my master's or law degree," she recalls. "But the opportunities were there, and I took them."

Seton Hall Law's evening program was a perfect fit for Yeadon. She recalls, "It

was such a rich environment. I was learning along with other working professionals: nurses, doctors, politicians and CEOs. It was fantastic not only to learn about the law, but also to be exposed to the diverse perspectives of my fellow students."

When asked to name the best things about Seton Hall Law, Yeadon recalls the support, advice and encouragement she received from the Seton Hall Law staff and community. "My criminal law professor, Lawrence Bershad, saw how much the Rodney King incident upset and impacted me, so he challenged me to host a seminar to discuss it. We invited law enforcement, judicial government, law professors and students," she says. "It was so important to me to see the community come together to speak out against injustice but at the same time respect the way our system works."

Today, Yeadon serves on the Advisory Board of Seton Hall Law's Gibbons Institute of Law, Science & Technology. "I was honored to be asked to serve because I am grateful to have the opportunity to give back the support I received as a student," she says.

VISITING Scholars



Professor Melissa B. Jacoby, the George P. Ward Professor of Law at the University of North Carolina at Chapel Hill, visited Seton Hall Law in March 2011. Her research takes multidisciplinary approaches to exploring bankruptcy, debtor-creditor and commercial law problems, including issues relating to medical debt, fertility and adoption lending, and the reorganization of corporations. Professor Jacoby is a co-principal investigator of the 2007 Consumer Bankruptcy Project, a nationally representative dataset on families in bankruptcy, as well as a member of the faculty seminar on Rethinking Regulation at Duke University's Kenan Institute for Ethics. She is also an elected member of the American Law Institute and the National Bankruptcy Conference, through which she remains actively involved in law reform projects.



Professor Steven L. Willborn was a Visiting Professor at Seton Hall Law during the Fall term of 2010, coming from the University of Nebraska College of Law, where he has been on the faculty since 1979 and served as Dean from 2001 to 2009. Professor Willborn's research and scholarship focuses on the areas of labor law, employment law, employment discrimination and employee benefits law. He currently chairs the United States Branch of the International Society for Labor and Social Security Law. His most recent scholarship focuses on international labor law; specifically, on the fate of labor regulation in the global environment, important developments in the labor law of the European Community and the effectiveness of international labor standards.

ALUMNI Profiles



Sheilah O'Halloran, J.D. '83

Assistant General Counsel, Atlantic Health System, Morristown, New Jersey

While teaching at the University of Montreal and working as a French translator, **Sheilah O'Halloran** never imagined that a successful career in health care law was in her future.

After returning to the United States, she realized it might be difficult to earn a living as a translator, so she began to explore other career options. "I come from a family of lawyers – my father, James O'Halloran, was both a prosecutor and a judge, and my sister and one of my brothers are lawyers – so

going to law school seemed a natural progression for me," she says.

O'Halloran chose to attend Seton Hall Law in part because it offered an evening J.D. program, which allowed her to continue to work full-time as a translator. "Seton Hall Law was an easy choice for me, as it was one of the few schools that offered an evening program. Plus, I worked in New York City at the time and the location was so convenient." Another factor that influenced her decision was her family history with the school. "My dad was a member of Seton Hall Law's very first graduating class," she says. "And like me, he was an evening student."

Reflecting on her time at the Law School, O'Halloran says, "I got a great education at Seton Hall Law. The business-related courses were particularly strong. I was also fortunate that my work schedule allowed me to participate in both Moot Court and the SETON HALL LAW REVIEW."

After earning her J.D., O'Halloran worked at Morristown's Schenck, Price, Smith & King, LLP for 27 years. "There was no health care law concentration when I was at Seton Hall Law and I don't have traditional health care experience – I was really a business lawyer with a large health care client," she recalls. "My firm had served as outside counsel to Morristown Memorial Hospital since the 1940s and I worked on hospital matters for much of my time at the firm." Morristown eventually expanded and merged with other hospitals and together formed Atlantic Health System. "Gradually, my work for Atlantic Health grew to the point where I was essentially functioning as in-house counsel, even though I was still a partner at the firm. So when they asked me to come in-house, it just made sense."

Today, as Assistant General Counsel for Atlantic Health, O'Halloran is responsible for all legal aspects of its business operation, from physician contracting to bond financing to real estate matters. "Health and hospital work is interesting and challenging, particularly in today's rapidly changing and increasingly complex health care environment," she says. "As a health care system, we are faced with many of the same issues that any big corporation is, and each day brings something different."



Paul Matri, J.D. '08

Manager of Patent Prosecution, New Jersey Institute of Technology, Newark, New Jersey

One year after graduating Seton Hall Law, Paul Matri was back on campus – this time not as a student, but as the leader of an Intellectual Property Roundtable sponsored by the Gibbons Institute of Law, Science & Technology and the student organization, the Intellectual Property Law Association.

"Professor Opderbeck invited me back to lead a discussion on the intellectual property issues faced by research universities," Matri

explained. "In academia, it can be a real balancing act between trying to protect your patentable discoveries while still being able to present your findings to the scientific community and not jeopardize your publication schedules."

As the Manager of Patent Prosecution for the New Jersey Institute of Technology (NJIT), Matri manages this issue every day. "My job is to advise faculty on every step of the IP protection process, from the moment they create something in the lab all the way to the full patent and licensing process. I educate the faculty about the steps, from disclosing an invention, to looking at its patent potential, to patenting the idea, and finally, to exploring licensing opportunities," he says.

Matri's relationship with NJIT began while he was still a student. "I heard about an internship they were offering, through the Seton Hall Law Office of Career Services," he says. "I worked at NJIT about 18 months while I was still a student, and after graduation they asked me to stay on."

A "science and technology person at heart," Matri's interest in this field stems all the way back to when he attended the Academy for the Advancement of Science and Technology – a magnet high school in Bergen County. While earning an undergraduate degree in Biology with a Business Administration minor from the University of Richmond, Matri started thinking about attending law school to focus on intellectual property issues.

"I chose Seton Hall because of its strong IP program," he says. A class in patent law taught by Professor Dworetsky confirmed his decision to head in that direction. "The class was interesting and it was taught in an engaging fashion," he recalls, "It really ignited my excitement about the industry."

"When I look back at my Seton Hall experience, and I talk to colleagues who attended other law schools, I realized that I was exposed to a much greater variety of classes and opportunities than if I had gone elsewhere," he says. "When I graduated, I was able to hit the ground running because I had a strong theoretical background combined with practical experience."

Today, Matri continues to maintain a strong relationship with Seton Hall Law by giving back to the school. In addition to his participation in the roundtable seminar, Matri has founded an externship program between Seton Hall Law and NJIT. "Students now have a chance to gain valuable work experience at NJIT and earn credit while doing it," he says. "Since we started the program about two years ago, about 15 students have already taken advantage of this great opportunity."

Susan E. Volkert, LL.M. '99, Health Law

Partner, DeCotiis, FitzPatrick & Cole, LLP, Teaneck, New Jersey

Susan Volkert sees every day as a new opportunity to learn. "You're never 'done' being a lawyer," she explains. "The world and the laws are continuously changing. You can't stop learning about it." It's a philosophy that has been key to her success throughout her career.

After many years working in both the U.S. Department of Justice and the U.S. Attorney's office, Volkert decided to expand her focus on health law as an executive and Deputy General Counsel to the pharmaceutical company that is now Sanofi. Her main priority was to manage litigation, create and implement compliance programs and practice preventative law.

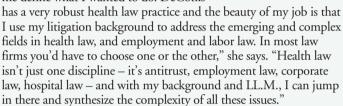
"The management team I worked for was comprised of real visionaries," she says. "My directive was to create programs that not only kept the company in total legal and regulatory compliance with the law but above compliance. This was all before Sarbanes-Oxley changed the industry. We were ahead of the curve and helped set the bar for others on how to be compliant," she says. "I learned so much — it was truly a career-shaping time for me."

When her company evolved to focus solely on life sciences, Volkert saw another opportunity to learn more. "I approached my boss and told him I could do more for the company if I had my LL.M. degree," she says. "I chose Seton Hall Law because of the reputation of the school and because of Professor Kathleen Boozang. She is brilliant and a prolific writer. I was excited about the chance to study under her."

"I was a member of the very first LL.M. class – there were only five of us," she recalls. "One of the best things about the program was

that the professors had such diverse and pragmatic experience. Not only were they distinguished scholars but they also had experience out in the working world addressing real problems. It was such a broadening experience."

Today, as a partner at DeCotiis, Fitzpatrick & Cole, LLP, Volkert concentrates her practice on employment law and health law issues. "The LL.M. program really helped me define what I wanted to do. DeCotiis



Volkert has successfully represented health care entities and professionals, including major medical centers and health providers, in a variety of matters ranging from investigations and compliance audits to suits brought by a physician or preparing the defense for suits brought against a provider. As a member of the firm, she participates in the Medical Society of New Jersey's legal defense benefit program, and has represented physicians before the U.S. Attorney's Office, the New Jersey Attorney General's office and the New Jersey State Board of Medical Examiners.



John Martin, LL.M. '10, Intellectual Property

Press Officer, U.S. Environmental Protection Agency, New York, New York

While John Martin doesn't currently practice law, he still relies on his law school education in his role as Press Officer for the U.S. Environmental Protection Agency (EPA). In addition to fielding press inquiries and writing press releases, Martin serves as the EPA spokesperson on programs regulated under environmental laws. "If we take action against someone who is not in compliance with EPA regulations, it's my job to review the complaint and find a way to communicate the information to the press and the public in a way that is easily understood," he explains. "Having my legal background definitely helps. Other people in my position may have a hard time translating all the legal terminology but for me it's second nature."

In addition to his job with the EPA, Martin also serves as President of Mainland Media, Inc., a business he founded in 2009 with a high school friend to promote and celebrate the Bronx – their beloved hometown. With both a J.D. and an LL.M. degree under his belt, Martin is able to manage both the legal and marketing sides of the business. "Mainland Media is the largest creator of Bronx-themed souvenirs and apparel. We commission artists to create original material for our company. Having a background in copyright law gives me the confidence to know what I can and can't have my artists do as we create and reproduce artwork," he says.

Martin's interest in the law was sparked by his long-standing love of politics and public policy. After earning both an undergraduate and

a master's degree in political science, he spent the next few years in various political jobs in Washington D.C. and New York City. Viewing law school as the next logical step in his career, he attended St. John's University School of Law.

During law school, Martin, who is currently a reservist in the U.S. Navy, was activated and sent to Afghanistan for one year. "That put my law school education on hold for awhile,"

he says. "But it was quite an experience and one I'll never forget."

After his graduation from St. John's, Martin found himself looking for work in a difficult job market. "I realized that I needed a differentiator to make me stand out," he says. "I was interested in IP law and heard about Seton Hall Law's program and knew that I would be more marketable with an LL.M. degree."

Martin cites the close relationships he formed with his professors as the highlight of his time as Seton Hall Law. "Frank Politano was my copyright professor and not only was he a great teacher, he was extremely helpful and generous with his time," he recalls. "Even after graduation he took the time to discuss career strategies with me. I definitely made the right decision to attend Seton Hall Law, and look forward to coming back to support and promote the University."



ALUMNI Profiles



Neal Sailer, M.S.J. '06, Health Law and Intellectual Property

Senior Director, Sanofi, Bridgewater, New Jersey

As a senior director responsible for life cycle management at Sanofi, Neal Sailer has a keen understanding of how one little difference can have a big impact.

"Getting my M.S.J. really helped me learn how to think like a lawyer," he says. "When working on projects, even when the facts and circumstances are similar, there are

always subtle differences that I've learned to look for that can put my company in a better position."

Sailer began his pharmaceutical career in sales and marketing, working his way up in a number of positions in both the branded and generics side of the business. It was this experience that led Novartis, in 1997, to choose him to join their newly formed life cycle management group. "A key responsibility at Novartis was to work on the latter, pre- and post- generic stages of their major brands, which gave me a lot of exposure to the legal side of the business, since we often worked so closely together," he says.

It was this exposure that led Sailer to consider pursuing an M.S.J. degree. "I understood the business, and could speak with lawyers and patent attorneys, but what I lacked were the credentials," he recalls. "I attended Seton Hall Law's open house for the M.S.J.

program and I thought, this is exactly what I need. And I was thrilled they offered a dual concentration in Health Law and IP Law because both are so important to what I do."

Sailer credits the M.S.J. program with giving him a much broader understanding of the life sciences industry. "It was incredibly interesting to read about cases that involved my company or the drugs I managed. It was a thrill applying my real-life experience to situations that were playing out in the legal arena," he recalls. "I remember being part of the debate about a biologic pathway before it was created. I work in biologics now and can truly say that I've been involved since the beginning thanks to my M.S.J."

"My experience at Seton Hall Law exceeded my expectations," he continues. "I'm more confident now, and having legal experience means I bring more value to my job. Very often the commercial side of my business views the legal department as a roadblock. By understanding both sides, I can act as a go-between and help both sides accomplish their goals."

His advice to those who are considering a graduate degree? Once again, it's all about having that one little difference. "Today, it seems that everyone has an M.B.A. It's the M.S.J. on your resume that's going to make you stand out and give you that key differentiator," he says. "There are so many things you can do with an M.S.J. and there is no better place than Seton Hall Law to get it."



Milky Florent, M.S.J. '10, Health Law

Regulatory Affairs Associate, Pfizer, Inc., New York, New York

As a child, Milky Florent already knew she wanted to work in the health field. "When I was very young, I would read the nutrition facts on food packaging, always wanting to know more about what they really meant," she says. This early interest led her to pursue and excel in both biology and chemistry, setting her on the path to her current career. A native of Venezuela, Florent studied pharmaceutical science at the Universidad

Central de Venezuela and majored in toxicology. This specialty led her to a position in pharmacovigilance with the Venezuelan division of Wyeth in 2007. With her solid understanding of the scientific, medical and commercial sides of Wyeth's Latin American pharmaceutical business, coupled with her strong fluency in English, Florent soon became the link between Wyeth's Latin American operations and its world headquarters in Collegeville, Pennsylvania. Many of her colleagues recognized Florent's talents in the commercial and regulatory compliance arena and encouraged her to consider law school. A friend who had attended Seton Hall Law's U.S. Healthcare Compliance Certification Program recommended the school to her. "I went online to check out the certification program, discovered the M.S.J. program instead, and thought, this is perfect for me," she recalls.

The timing however, was not so perfect. "Pfizer was in the midst of negotiations to buy Wyeth and everything was in flux," she explains. "Rather than wait around for things to settle down, I decided to quit my job, move to the United States, and enroll in Seton Hall Law's M.S.J. program full-time. It was a risky decision at the time – but totally worth it."

"My two favorite classes were Law and Genetics, and Medical Malpractice. The professors were fantastic," she recalls. "I also loved Professor Helen Cummings' legal writing class. That class really set the foundation for the entire M.S.J. program, and I use the skills I learned in that class every day."

Today, Florent is a Regulatory Affairs Associate for Pfizer in New York City. "Having my M.S.J. has made me much more efficient at my job and changed the way I view and approach a problem. Because I better understand the U.S. market, I now have a broader and more global perspective," she says. "I also made new contacts and forged valuable relationships in the pharmaceutical industry that are incredibly important to me now."

This fall, Florent will begin taking classes as a Ph.D. candidate in Health Science at Seton Hall University. "The M.S.J. program opened my eyes to all the possibilities out there," she says. "Getting my M.S.J. was just the beginning."

FACULTY SCHOLARSHIP AND PRESENTATIONS

Gaia Bernstein

Professor of Law and Margaret Gilhooley Research Fellow

Scholarship

Over-Parenting, 44 U.C. DAVIS L. REV. 1221 (2011) (with Zvi Triger)

In the Shadow of Innovation, 31 CARDOZO L. REV. 2257 (2010) (with Empirical Appendix) (selected to the Stanford-Yale Junior Faculty Forum)

Regulating the Technologies of Reproduction: Timing, Uncertainty and Donor Anonymity, 90 B. U. L. REV. 1189 (2010)

Direct-to-Consumer Genetic Testing: Gatekeeping the Production of Genetic Information, 79(2) UMKC L. REV. 283 (2010) (Symposium)

Presentations

2011 Intellectual Property Scholars Conference, Plenary Panel Presentation, *Patent Law, Technological Dissemination and the* Forgotten Non-Creative User (August 2011)

American Society of Law, Medicine & Ethics 34th Annual Health Law Professors Conference, Loyola University Chicago School of Law, *The Impact of Prohibitions on Gamete Donor Anonymity on the* Diffusion of Artificial Reproductive Technologies (June 2011)

Colloquium on Health Law and Society, Haifa University School of Law, *The Impact of Prohibitions on Gamete Donor Anonymity on the Diffusion of Artificial Reproductive Technologies* (May 2011)

Privacy Law Scholars Conference, Commentator, University of California, Berkeley Center for Law & Technology (June 2011)

Emerging Family Law Scholars Conference, UC-Hastings College of the Law, *The Impact of Prohibitions on Gamete Donor Anonymity on the Diffusion of Artificial Reproductive Technologies* (June 2011)

Symposium, Disseminating Technology: The Laws of Technology and the Technology of Law, Griffith University School of Law, Australia, *When is Timing Important in the Regulation of New Technologies?* (May 2011)

Symposium on Privacy, Autonomy and Personal Genetic Information in the Digital Age, Harvard University, American Academy of Arts and Sciences, National

Academy of Engineering, and Institute of Medicine, Roundtable Discussant (April 2011)

Intellectual Property Colloquium, Brooklyn Law School, Disseminating Technology (April 2011)

Work in Progress in Intellectual Property Conference, *Disseminating Technology*, Boston University School of Law (February 2011)

Association of American Law Schools Annual Meeting, San Francisco, California, *Genetic Testing* (January 2011)

Symposium on Genetics and Assisted Reproductive Technology, Albany Law School, *The Impact of Prohibiting Donor Anonymity on the Diffusion of ART* (October 2010)

International Bar Association Annual Meeting, Vancouver, Canada, *Direct to Consumer DNA Kits* (October 2010)

FDA Meeting on Oversight of Laboratory Developed Tests, Maryland, *Direct to Consumer Genetic Testing* (July 2010)

Other News

Elected to the Executive Board of the Privacy Section by the Association of American Law Schools (AALS)

Kathleen M. Boozang

Vice Provost, Seton Hall University and Professor of Law

Scholarship

An Argument against Embedding Conflicts of Interest Disclosures in Informed Consent, 4 J. HEALTH & LIFE SCI. L. 230 (June 2011) (with Carl H. Coleman and Kate Greenwood)

The Limits of Disclosure as a Response to Financial Conflicts of Interest in Clinical Research (2010) (A White Paper by the Center for Health & Pharmaceutical Law & Policy, Seton Hall University School of Law) (with Carl H. Coleman & Kate Greenwood)

A New Pathway to Market for Biosimilars, 4 J. HEALTH & LIFE SCI. L. 121 (2010) (with Judith Toffenetti)

Presentations

Saint Barnabas Medical Center, Annual Flora Barlotta Lecture, End of Life Care (Spring 2011) Seton Hall Law School, Managing Financial Conflicts of Interest in Pharmaceutical and Medical Device Research (April 2011) (with Carl H. Coleman & Kate Greenwood)

European Healthcare Compliance Ethics & Regulation Program, co-sponsored by Seton Hall Law School and Sciences Po, Paris, France, Lessons Learned from U.S. Healthcare Fraud and Abuse Enforcement and Compli-

ance Programs (February 2011) (with Carl H. Coleman)

American Society of Law, Medicine & Ethics 33rd Annual Health Law Professors Conference, University of Texas, *Update on Nonprofit and Tax Exemption Law* (June 2010)



FACULTY SCHOLARSHIP AND PRESENTATIONS



Carl H. Coleman

Professor of Law and Director of Global Initiatives

Scholarship

Legal Approaches to End-of-Life Decision-Making in the United States, in Self-Determination, Dignity and End-Of-Life Care: Regulating Advance Directives in International and Comparative Perspective (Stefania Negri, ed., forthcoming 2012)

World Health Organization,

GUIDANCE ON ETHICS OF TUBERCULOSIS PREVENTION, CARE, AND CONTROL (2011) (primary author of report based on two-year deliberations of international task force)

An Argument against Embedding Conflicts of Interest Disclosures in Informed Consent, 4 J. Health & Life Sci. L. 230 (June 2011) (with Kathleen M. Boozang & Kate Greenwood)

Do Physicians' Legal Duties to Patients Conflict with Public Health Values? The Case of Antibiotic Overprescription, in Infectious Disease Ethics: Limiting Liberty in Contexts Of Contagion (Michael J. Selgelid, et. al., eds. 2011)

The Limits of Disclosure as a Response to Financial Conflicts of Interest in Clinical Research (2010) (A White Paper by the Center for Health & Pharmaceutical Law & Policy, Seton Hall University School of Law) (with Kathleen M. Boozang & Kate Greenwood)

Presentations

WHO Workshop on the Ethics of Tuberculosis Prevention, Care, and Control, Beijing, China, *Ethical and Legal Aspects of Public Health Measures in TB Control* (June 2011)

Graduate Institute of International & Development Studies, Geneva, Switzerland, *Ethics in Global Public Health* (May 2011) WHO expert meeting, Integrated Response to Cholera Outbreaks in Large Humanitarian Crises, *Ethical Considerations* on Oral Cholera Vaccine Use During Crisis, Geneva, Switzerland (May 2011)

Seton Hall Law School, *Managing Financial Conflicts of Interest in Pharmaceutical and Medical Device Research* (April 2011) (with Kathleen M. Boozang & Kate Greenwood)

Graduate Institute of International & Development Studies, Geneva, Switzerland, *Ethical Issues in Global Public Health* (March 2011)

European Healthcare Compliance Ethics & Regulation Program, co-sponsored by Seton Hall Law School and Sciences Po, Paris, France, Lessons Learned from U.S. Healthcare Fraud and Abuse Enforcement and Compliance Programs (February 2011) (with Kathleen M. Boozang)

Forum for Ethical Review Committees in Asia and the Western Pacific, Shanghai, China, *Developing a Conceptual Model for Assessing the Outcomes of Research Ethics Review* (November 2010)

University of Heidelberg Institute of Public Health, Heidelberg, Germany, *Ethics and Global Public Health* (September 2010)

Other News

Co-director, Executive Course in Intellectual Property, Diplomacy, and Global Public Health, Graduate Institute of International and Developmental Studies, Geneva, Switzerland (2011)

Consultant to World Health Organization on Pan African Clinical Trials Initiative, revision of *Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants*, and development of international clinical trials legislation course (2011)



Margaret Gilhooley

Professor Emerita

Scholarship

Commercial Speech, Drugs, Promotion and a Tailored Advertisement Moratorium, 21 HEALTH MATRIX 97 (2011) Commercial Speech and Off-Label Drug Uses: What Role for Wide Acceptance, General Recognition and Research Incentives?, 37 Am. J. Law, Med. & Ethics 258 (2011) Drug Safety and Commercial Speech: Television Advertisements and Reprints on Off-Label Uses, 47 SAN DIEGO L. REV. 845 (2010)

Presentations

American Journal of Law and Medicine Symposium, Boston University School of Law, Commercial Speech and Off-Label Drug Uses: What Role for Wide Acceptance, General Recognition and Research Incentives? (February 2011)

Kate Greenwood

Research Fellow & Lecturer in Law

Scholarship

The Ban on "Off-Label" Pharmaceutical Promotion: Constitutionally Permissible Prophylaxis against False or Misleading Commercial Speech?, 37 Am. J. L. & Med. 278 (2011) (Symposium)

An Argument Against Embedding Conflicts of Interest Disclosures in Informed Consent, 4 J. Health & Life Sci. L. 230 (June 2011) (with Kathleen M. Boozang & Carl H. Coleman)

The Mysteries of Pregnancy: The Role of Law in Solving the Problem of Unknown but Knowable Maternal-Fetal Medication Risk, 79 U. CIN. L. REV. 267 (2010)

The Limits of Disclosure as a Response to Financial Conflicts of Interest in Clinical Research (2010) (A White Paper by the Center for Health & Pharmaceutical Law & Policy, Seton Hall University School of Law) (with Kathleen M. Boozang & Carl H. Coleman)

Presentations

American Society of Law, Medicine & Ethics 34th Annual Health Law Professors Conference, Junior Faculty Workshop, Loyola University Chicago School of Law, *Taking the Measure of Medication: Moral Hazard(s), Mitigation, and the Children's Supplemental Security Income Program* (June 2011)



Seton Hall Law School, *Managing Financial Conflicts of Interest in Pharmaceutical and Medical Device Research* (April 2011)(with Kathleen M. Boozang & Carl H. Coleman)

American Journal of Law and Medicine Symposium, Boston University School of Law, *Preventive Medicine: A Constitutional Defense of the FDA's Wholesale Regulation of Prescription Drug Promotion* (February 2011)

Center for Business Intelligence, Clinical R&D Compliance Forum, Recommendations for Reform of the Financing and Oversight of Clinical Research (June 2010)

John V. Jacobi

Faculty Director of the Center for Health & Pharmaceutical Law & Policy and Dorothea Dix Professor of Health Law & Policy

Scholarship

High Utilizers of ED Services: Lessons for System Reform, 20 Annals of Health Law ____ (forthcoming 2011)

Implementing Health Reform at the State Level: Access and Care for Vulnerable Populations, 39 J. LAW, MEDICINE & ETHICS 69 (2011) (with Sidney D. Watson & Robert Restuccia)

Chronic Care and Prevention: Evolution in Practice and Finance, 12 MARQUETTE ELDER ADVISORS J. 33 (2010)

Presentations

American Health Lawyers Association Annual Meeting, Boston, Massachusetts, *The Mental Health Conundrum* (June 2011)

American Society of Law, Medicine & Ethics 34th Annual Health Law Professors Conference, Loyola University of Chicago Law School, *High Utilizers of Emergency Department Services and Lessons* for System Reform (June 2011)

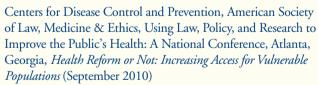
Rutgers Institute for Health, Health Care Policy and Aging Research, Rutgers University, Accountable Care Organizations and Medical Homes: Improving Care while Bending the Cost Curve, or Providing New Tools for Market Dominance? (March 2011)

Public Health Law and Science: A Seminar for Judges, New York Judicial Institute, *New Jersey Public Health Law* (February 2011)

Grand Rounds, Department of Psychiatry, University of Medicine & Dentistry of New Jersey-New Jersey Medical School, *Reforming Physical Health Care for the Seriously Mentally Ill* (December 2010)

New Jersey Office of Legislative Services and Rutgers Center on State Heath Policy, *State Implementation Tasks Under the ACA: Medicaid and Exchanges* (November 2010)

Annual Conference of American College of Obstetricians and Gynecologists of New Jersey, *Health Reform and Medicaid: The Interface of Law and Medicine* (November 2010)



2011 Governor's Conference on Housing and Community Development, Olmstead and Health Reform: The Role of Expanded Care Management and Self-Direction in Furthering Social Autonomy for People with Disabilities (September 2010)

American Society of Law, Medicine & Ethics 33rd Annual Health Law Professors Conference, University of Texas, *Mental Health Courts: Accommodation and Subordination* (June 2010)

Other News

Named Chair of the Greater Newark Healthcare Coalition, a non-profit cooperative among hospitals, behavioral health providers, nursing organizations, physicians, government agencies, and community advocates in Newark, New Jersey



FACULTY SCHOLARSHIP AND PRESENTATIONS



David W. Opderbeck

Academic Director of the Gibbons Institute of Law, Science & Technology and Professor of Law

Scholarship

Rational Antitrust Policy and Reverse Payment Patent Settlements Under the Hatch-Waxman Act, 98 GEORGETOWN L.J. 1303 (2010)

Presentations

Centre of Theology and Philosophy, "What is Life" conference, Krakow, Poland, *Law, Neurobiology and the Soul* (June 2011)

Internet Law Scholars Conference, Santa Clara Law School, *Cybersecurity and Executive Power* (March 2011)

Brooklyn Law School Intellectual Property Colloquium, *Cybersecurity and Executive Power* (February 2011)

Other News

Principal Organizer, Cybersecurity Law and Policy: Changing Paradigms and New Directions, Seton Hall University School of Law (June 2011)(law.shu.edu/cybersecurityconference)



Jordan Paradise

Associate Professor of Law

Scholarship

Claiming Nanotechnology: Improving USPTO Efforts at Classification of Emerging Nano-Enabled Pharmaceutical Technologies 10 Nw. J. TECH. & INTELL. PROP. ____ (forthcoming 2011)

Reassessing 'Safety' for Nanotechnology Combination Products: What Do 'Bistipulars'

Add to Regulatory Challenges for the FDA?, 56 St. Louis U. L.J. ____ (forthcoming 2011)

The Devil is in the Details: Health Care Reform, Biosimilars, and Implementation Challenges for the Food and Drug Administration, 51 JURIMETRICS J. 279 (2011)

Follow-On Biologics: Implementation Challenges and Opportunities, 41 Seton Hall L. Rev. 501 (2011)

Recommendations for Oversight of Nanobiotechnology: Dynamic Oversight for Complex and Convergent Technologies, 13 (4) JOURNAL OF NANOPARTICLE RESEARCH 1345 (April 2011) (with Gurumurthy Ramachandran, Susan M. Wolf, Jennifer Kuzma, Ralph Hall, Efrosini Kokkoli & Leili Fatehi)

Presentations

Third Annual Pharmaceutical Reimbursement & Market Access Conference, Philadelphia, Pennsylvania, *The ACA, Biosimilars, and FDA Implementation* (October 2011)

Food & Drug Law Institute, 54th Annual Conference, Washington, D.C., *Sottera v. FDA: Electronic Cigarettes and the Tobacco Control Act of 2009* (April 2011)

The Association of American Law Schools Annual Meeting, Biolaw Section, *Synthetic Biology Meets the Law* (January 2011)

Follow-On Biologics: Implementation Challenges and Opportunities Roundtable, Seton Hall University School of Law, *The Biologics Price Competition and Innovation Act: FDA and Biosimilars* (October 2010)

Nanotechnology & Society: Emerging Organizations, Oversight, and Public Policy Systems Conference, University of Massachusetts, *Developing Oversight for Nanobiotechnology: Human Drugs and Medical Devices* (September 2010)

American Society of Law, Medicine & Ethics 33rd Annual Health Law Professors Conferences, University of Texas, *Current Legal Status of Follow-On Biologics* (June 2010)

Other News

Elected Executive Board Member of the newly-created American Association of Law Schools (AALS) Biolaw Section

Elected Vice Chair of the Food and Drug Law Institute's Academic Committee

Frank Pasquale

Associate Director of the Center for Health & Pharmaceutical Law & Policy and Schering-Plough Professor in Health Care Regulation and Enforcement

Scholarship

The Affordable Care Act on Endless Trial, 6 F.I.U. L. Rev. (forthcoming 2011) (invited piece, Symposium)

Network Accountability for the Domestic Intelligence Apparatus, 61 HASTINGS L.J. (forthcoming 2011) (with Danielle Keats Citron)

Openness and Auditing as Fair Data Practices, 9 J. TELECOMM. & HIGH TECH. L. 235 (2011) (invited piece, Silicon/Flatirons Conference of 2010)

Beyond Competition and Innovation: The Need for Qualified Transparency in Internet Intermediaries, 104 Nw. U. L. REV. 105 (2010)

Ending the Specialty Hospital Wars: A Plea for Pilot Programs as Information-Forcing Regulatory Design, in Our Fragmented Health Care System: Causes and Solutions (Einer Elhauge, ed., Oxford Univ. Press, 2010)

Data and Power: From Individual Consent to Societal Transparency, Kaufman Foundation/Yale ISP Thought Piece For Symposium On Privacy And Innovation (2010) (shorter version will appear in NCURA Magazine, a publication of the National Council of University Research Administrators)

Search, Speech, and Secrecy: The Inversion of Network Neutrality, 1 YALE L. & POL'Y REV. INTER ALIA (2010) (invited piece, Yale Law School Symposium)

Reproducible Research, 12 (5) COMPUTING SCIENCE & ENGINEERING, 8 (September/October 2010, doi: 10.1109/MCSE.2010.113) (contributing author)

Reputation Regulation: Disclosure and the Challenge of Clandestinely Commensurating Computing, in PRIVACY, FREE SPEECH, AND THE INTERNET (Martha Nussbaum and Saul Levmore, eds., Harvard University Press, 2010)

The Troubling Trend Toward Trade Secrecy in Rankings and Ratings, in THE LAW AND

THEORY OF TRADE SECRECY: A HANDBOOK OF CONTEMPORARY RESEARCH (Rochelle C. Dreyfuss and Katherine J. Strandburg, eds., Edward Elgar Publishing, 2010)

Cognition-Enhancing Drugs: Can We Say No?, 30 (1) BULLETIN OF SCIENCE, TECHNOLOGY AND SOCIETY 9 (2010) (doi: 10.1177/0270467609358113)

Presentations

TechFreedom, Search Engine Regulation: A Solution in Search of a Problem? Capitol Hill, Washington, D.C., Fairness and Accountability for Search Engines (June 2011)

Seton Hall University School of Law, Healthcare Compliance Certification Program, *Pharma in the Hot Seat: New Challenges* for Compliance (June 2011)

The National Academy of Sciences, Committee on Science, Technology, and Law, Washington, D.C., *Civil Liberties and Sensor Networks* (May 2010)

Other News

Elected to the Executive Board of the Health Section by the Association of American Law Schools (AALS)

Of Note



David W. Barnes

Professor of Law

Free Riders and Trademark Law's First Sale Rule, 27 Santa Clara Computer & High Tech. L. J. 457 (2011)

The Incentives/Access Tradeoff, 9 Nw. J. Tech. & Intell. Prop. 96 (2010)

Tara Adams Ragone Research Fellow & Lecturer in Law

New Jersey Attorney General's Advocacy Institute, Exploring Defenses to Section 1983 Litigation: Absolute/Qualified Immunity and Beyond (June 2011)



Keeping Up With Students & Alumni

William C. Baton, J.D. '02 became a Partner with Saul Ewing LLP in Newark, New Jersey and is the co-author of a chapter in The Food and Drug Law Institute's *Top 20 Cases of 2010*.

Colleen Brennan, J.D. '91 is Vice President for Legal Affairs at Horizon Blue Cross Blue Shield of New Jersey.

Benjamin Chacko, J.D. '07 serves as Regulatory Counsel, FDA Center for Biologics Evaluation and Research in Rockville, Maryland.



Jordan Cohen, J.D. '11 is an Associate with Brach, Eichler L.L.C. in its Health Law practice located in Roseland, New Jersey.

Tamara R. Coley, J.D. '10 is an Associate with Kenyon & Kenyon and a member of the Life Sciences group in New York City. Her practice focuses primarily on pharmaceutical patent litigation.



Javier Diaz '12 co-authored an article, "Introducing the Director of the Medicaid Fraud Division and the Fraud Division's Audit Functions," in the July/August 2011 issue of *Garden State Focus*, the magazine published by the New Jersey chapter of the Healthcare Financial Management Association.

Nancy Shore Dilella, J.D. '93 is Associate General Counsel at Genentech, a biotech/pharmaceutical company located in South San Francisco. She is responsible for managing the company's Health Law Group, which supports the commercial and development organizations at Genentech.

Eric Welsh Gross, J.D. '05 is Associate Counsel for Saint Joseph's Healthcare System, located in Paterson, New Jersey.

Christina M. Hage, J.D. '09 is an Associate with Murtha Collina LLP, Health Care and Long Term Care practice groups, located in New Haven, Connecticut.



James Hlavenka, J.D. '10 has joined Buchanan Ingersoll & Rooney, PC in Newark as an Associate in the FDA/Biotechnology group. He recently completed a clerkship with New Jersey Superior Court, Appellate Division, for the Honorable Clarkson S. Fisher, Jr., J.A.D.

John P. Inglesino, J.D. '90 became the Founding & Managing Partner of Inglesino, Pearlman, Wyciskala & Taylor LLC.

Constantina Koulosousas, J.D. '10 is an Associate with Mandelbaum Salsburg, PC in West Orange, New Jersey. She specializes in health care law and elder law.

Mark Manigan, J.D. '97 a Member of Brach Eichler L.L.C.'s Health Law Practice Group, was named one of *New Jersey Law Journal*'s "40 Under 40."

Katherine Freed Matos, J.D. '11 has joined the General Counsel's Office of the Office of Inspector General for the U.S. Department of Health and Human Services in Washington, D.C.

Fabio Mattiasich, J.D. '06 is a Compliance Officer in the U.S. Food and Drug Administration's Division of Compliance Management and Operations in Jamaica, New York.

Mark J. Swearingen, J.D. '98 is in the health care group of Hall Render, LLP located in Indianapolis, and specializes in HIPAA, health information systems, regulatory compliance and patient care issues.

Brad X. Terry, J.D. '97 is an attorney with the U.S. Department of Health and Human Services, Office of General Counsel, Centers for Medicare and Medicaid Services Division in Washington, D.C.

Peter Tu, J.D. '94 is Vice President, Legal and Chief IP Counsel for Moksha8 Pharmaceuticals in Wayne, Pennsylvania.

Andrew C. White, J.D. '00 is Senior Counsel in the Law Department of Johnson & Johnson in New Brunswick, New Jersey, and is responsible for global product liability litigation.

Kalison, McBride, Jackson & Robertson Health Law Scholarship Recipient: Melody Hsiou '13

Each year, Kalison, McBride, Jackson & Robertson, P.C. awards \$5,000 to a first-year student who demonstrates promise as an attorney in the health law field. The recipient of the 2010-11 Kalison, McBride, Jackson & Robertson Health Law Award is **Melody Hsiou '13** of Los Angeles, California.

After graduating from University of California-Los Angeles in 2008 with a degree in physiological science and a minor in public health, Hsiou went

on to earn a Masters in Public Health from Columbia University, concentrating in sociomedical sciences with an emphasis in health promotion. "While working on a project to design a public health program I realized that the most effective programs are those backed by law. That's when I decided to go to law school," she says.

For her master's thesis, Hsiou completed a policy review of the Genetic Information Non-Discrimination Act of 2008. "Through that project, I became very interested in how privacy laws and health laws all intersect, especially with the emergence of new technology," she explains. Hsiou chose Seton Hall Law because of its strong Health Law and Intellectual Property Law programs and student networking opportunities. "I greatly appreciate the Kalison, McBride, Jackson & Robertson scholarship. The work they do in the health law field is impressive and I am excited to be working in such an interesting area of law."

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