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HEALTH/LIFE SCIENCES/INTELLECTUAL PROPERTY

highlights



SETON HALL | LAW
Center for Health &
Pharmaceutical Law & Policy



SETON HALL UNIVERSITY SCHOOL OF LAW



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

The Center for Health & Pharmaceutical Law & Policy 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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FROM THE COVER (left to right): **Katelyn Mineo, J.D. '15**, the inaugural Johnson & Johnson Compliance Fellow; **Professor Ruqaiyah Yearby**, Case Western Reserve University School of Law and **Professor Seema Mohapatra**, Dwayne O. Andreas School of Law, Barry University, who attended the 36th Annual American Society of Law, Medicine & Ethics (ASLME) Health Law Professors Conference hosted at Seton Hall Law; **Theodore J. Shatynski J.D. '92**, Assistant General Counsel, Patents, at Johnson & Johnson in New Brunswick, New Jersey, and a member of the Gibbons Institute of Law, Science & Technology Advisory Board; the **Honorable Kathleen O'Malley**, U.S. Court of Appeals for the Federal Circuit, who spoke at an annual lecture series co-hosted by the Gibbons Institute and the New Jersey Intellectual Property Law Association; **Dean Patrick E. Hobbs**, Seton Hall Law and **Professor Nicole Huberfeld, J.D. '98**, University of Kentucky School of Law; and Peter Leibold, Executive Vice President and Chief Executive Officer of the American Health Lawyers Association, who spoke at the ASLME Health Law Professors Conference.



Dear Health and IP Law Alumni and Friends,

This year was extraordinarily productive for both the Center for Health & Pharmaceutical Law & Policy and the Gibbons Institute of Law, Science & Technology.

The year's highlight for the Center for Health was unquestionably our hosting of the 36th Annual American Society of Law, Medicine & Ethics (ASLME) Health Law Professors Conference, which boasted record attendance despite the simultaneous arrival of a tropical storm. In addition, the Center for Health produced a number of publications that reflect the broad spectrum of its mission: a Microsoft-funded white paper on HIPAA in the cloud; a monograph on for-profit Catholic healthcare; a series of papers with the Rutgers Center for State Health Policy on the implementation of the Affordable Care Act in New Jersey; and a Pharmaceutical and Medical Device Compliance Manual co-published with the Food and Drug Law Institute and the American Health Lawyers Association.

Our degree programs, online graduate certificates and compliance programs continue to flourish. We launched our Healthcare Compliance Program in Singapore and added a compliance track to the J.D. health law concentration. We expanded our online graduate certificate offerings, including a new online option for M.S.J. students. In May, 30 J.D. students graduated with a concentration in Health Law—more than double the number of students who graduated with the concentration just five years ago. Among our many legal education events held this year, in February the Center for Health co-sponsored the Life Sciences College in Manhattan, with the law firm of Sidley Austin. Seton Hall Law and Sidley Austin also sponsored a program on the Supreme Court's decision in *Federal Trade Commission v. Actavis, Inc., et al.*

Among its many events held for legal professionals, policy-makers and academicians, the Gibbons Institute hosted the Works in Progress in Intellectual Property (WIPIP) for intellectual property (IP) scholars from across the country, as well as a remarkable number of conferences on myriad topics

including biosimilars, counterfeiting issues in the pharmaceutical industry and patent post-issuance proceedings under the America Invents Act. The keynote speaker at the Tenth Annual Fall Lecture Series was the Honorable Kathleen O'Malley from the U.S. Court of Appeals for the Federal Circuit. The number of students pursuing their studies in IP continues to grow as the M.S.J. in IP law launches an online alternative. In May, 29 J.D. students graduated with a concentration in IP Law, continuing our long tradition as one of the premier law schools for the training of future IP lawyers.

Academic year 2013-14 promises to be as productive as we all react to a record number of Supreme Court cases in health, pharmaceutical and IP law as well as continued implementation of the Affordable Care Act with its concomitant need for analysis and recommendations for implementation and improvement.

We wish all of our colleagues a productive new year, and look forward to opportunities for collaboration.

Warm regards,

Kathleen M. Boozang
Associate Dean for Academic Advancement
Professor of Law

SAVE THE DATE!

The Seton Hall Law Center for
Health & Pharmaceutical Law & Policy
faculty invite you to join us at our
American Association of Law Schools Reception

Friday, January 3, 2014
6:30 p.m.
New York City

Seton Hall Law Hosts 36th Annual ASLME Health Law Professors Conference



Pictured, left, from left: Professor John V. Jacobi and Dean Kathleen M. Boozang of Seton Hall Law School with Ted Hutchinson, ASLME Executive Director and Publications Director. Professor Jacobi presented Dean Boozang with the Jay Healey Distinguished Health Law Teacher Award.

Pictured below, from left: ASLME 2013 Health Law Scholars Associate Professor Diane R.H. Winters, Indiana University Robert H. McKinney School of Law; Assistant Professor Katherine T. Vukadin, Thurgood Marshall School of Law; and Assistant Professor Zack Buck, Mercer University School of Law.

For the third time in the conference's 36-year history, Seton Hall Law was honored to host the Annual American Society of Law, Medicine & Ethics (ASLME) Health Law Professors Conference held in June 2013. The 175 health law professors and scholars, who attended from schools of law, medicine and public health around the nation, were apparently undeterred by the simultaneous arrival of an uninvited guest, Tropical Storm Andrea.

Despite the rain, the three-day conference agenda was bursting with over 30 substantive sessions that highlighted issues at the forefront of law and medicine, and provided essential updates on recent changes to the law, including health care reform and health data protection. The plenary session on healthcare reform included a presentation by Vicki L. Robinson, Senior Counselor for Policy, Office of Inspector General, U.S. Department of Health & Human Services. Keynotes were given by Peter Leibold, Executive Vice President and Chief Executive Officer, American Health Lawyers Association; and Dr. Lynn Hallarman, Director of Palliative Medicine and Associate Professor, Stony Brook Medicine.

One of the highlights of the annual conference is the presentation of the Jay Healey Distinguished Health Law Teacher Award. This year's Jay Healey Award was presented to our very own Professor Kathleen Boozang for her outstanding contributions to health law. The prestigious award is the only academic health law award in existence, and is given to professors who have devoted a signifi-



cant portion of their career to health law teaching and who honor Healey's legacy through their passion for teaching health law and their mentoring of students and/or other faculty.

In addition, each year four junior faculty are selected to participate in the Health Law Scholars Workshop--a collegial forum in which junior faculty who are new to health law and bioethics scholarship present works-in-progress and receive in-depth advice from experienced scholars and teachers in the field of health law and bioethics. The 2013 Health Law Scholars are Assistant Professor Zack Buck, Mercer University School of Law; Assistant Professor Anna B. Laakmann, Lewis and Clark Law School; Assistant Professor Katherine T. Vukadin, Thurgood Marshall School of Law; and Associate Professor Diane R.H. Winters, Indiana University Robert H. McKinney School of Law.



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Pictured, clockwise from left: (1) Professor Thomas (Tim) Greaney, St. Louis University School of Law; Professor Timothy Jost, Washington and Lee University School of Law (2) Peter Leibold, Executive Vice President and Chief Executive Officer, American Health Lawyers Association (3) Professor Kathy Cerminara, Shepard Broad Law Center, Nova Southeastern University; Professor Lawrence Singer, Loyola University Chicago School of Law; Professor David Orentlicher, Robert H. McKinney School of Law, Indiana University (4) Professor Efthimios Parasidis, Moritz College of Law, The Ohio State University (5) Professor Jennifer Herbst, Quinnipiac University School of Law.



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Pictured, clockwise from left: (1) Professor Sara Rosenbaum, School of Public Health and Health Services, The George Washington University (2) Professor Karen Shaw, Loyola University Chicago School of Law; Professor JoNel Newman, University of Miami School of Law, Professor Diane Hoffmann, Frances King Carey School of Law, University of Maryland; Professor James Hodge, Sandra Day O'Connor College of Law, Arizona State University; Professor Sidney Watson, St. Louis University School of Law (3) Professor Erin Fuse Brown, Georgia State University School of Law; Professor Jessica Mantel, University of Houston Law Center (4) Professor Brietta Clark, Loyola Law School, Los Angeles; Professor Glenn Cohen, Harvard Law School (5) Dean Patrick E. Hobbs, Seton Hall Law School; Professor Nicole Huberfeld, J.D. '98, University of Kentucky School of Law (6) A conference session (7) Professor Leslie Meltzer Henry, Frances King Carey School of Law, University of Maryland; Professor Melissa Goldstein, School of Public Health and Health Services, The George Washington University; Professor Jessica Berg, Case Western Reserve University School of Law (8) Professor Ruqaiijah Yearby, Case Western Reserve University School of Law; Professor Seema Mohapatra, Dwayne O. Andreas School of Law, Barry University (9) Professor Barry Furrow, Earle Mack School of Law, Drexel University.



GIBBONS Institute

Gibbons Institute Professors File U.S. Supreme Court *Amicus* Brief

Vice Dean Erik Lillquist (*pictured, top left*) and Professor David Opderbeck (*pictured, bottom left*) of the Gibbons Institute submitted an *amicus* brief to the U.S. Supreme Court in the case of *Federal Trade Commission v. Actavis, Inc., et al.*, on the insufficiency of the FTC's proposed "quick-look" approach for evaluation of reverse payment or "pay-for-delay" settlements in the pharmaceutical patent context in what is often referred to as "Hatch-Waxman patent litigation." David De Lorenzi (*pictured, top right*) and Jillian Centanni of Gibbons P.C. served as counsel on the brief.

In pay-for-delay settlements under Hatch-Waxman, the owner of a patented drug pays a generic manufacturer for delayed entry of generic products that would compete with the patented drug.

At stake in *Actavis* was the FTC's quick-look proposal for evaluating reverse settlement agreements, largely stemming from a decision by the U.S. Court of Appeals for the Third Circuit (*In re: K-Dur Antitrust Litig.*), in which it rejected the "scope of the patent test" and held that reverse-payment settlements should instead be subject to quick-look rule of reason antitrust scrutiny—and that payment from a patent holder to a generic manufacturer should be treated, presumptively, as an unreasonable restraint of trade.

In their *amicus* brief to the Supreme Court, Professor Opderbeck and Vice Dean Lillquist noted the absence in this proposed approach of any consideration of product market definition and argue, "Product Market Definition is an indispensable step in the antitrust evaluation of reverse payment settlements."

The brief concluded that, "The FTC's proposed presumptive illegality approach to evaluating reverse payment settlements should be rejected because it fails to consider the importance of product market definition."



Works in Progress in Intellectual Property

On February 22 and 23, 2013, the Gibbons Institute hosted the annual Works in Progress in Intellectual Property (WIPIP) conference. WIPIP is the second largest national intellectual property scholars' conference. Seton Hall Law is one of the few schools to have hosted the conference twice, previously in 2009. The two-day conference, organized by Professor Gaia Bernstein, provided fellow scholars with a forum to present their works in progress and receive early feedback from their colleagues. This year's conference attracted more than 90 intellectual prop law scholars from across the country and internationally.

Scholars presented their works on important and timely topics covering a broad range of intellectual property (IP) fields including patent law, copyright law, trademark law and related fields such as cyberspace law and privacy law. Vice Dean Lillquist, in welcoming the scholars, said, "Seton Hall Law School and the Gibbons Institute, our IP center of excellence, are pleased to once again host this prestigious conference and serve as a forum where faculty can present their scholarship and receive candid critique from their peers."

Professor Bernstein was pleased with the turnout of the scholars and the quality and reach of their scholarship. "At this year's WIPIP, we were fortunate to have not only most of the major law schools and centers of intellectual property represented, but some of the best IP minds, as well," she said. "We were honored that they chose to attend the forum at Seton Hall Law."

The next WIPIP conference is scheduled for February 2014 and will be held at Santa Clara Law School.



Gibbons Advisory Board Member Profile:



Theodore J. Shatynski '92

*Assistant General Counsel, Patents
Johnson & Johnson, New Brunswick, New Jersey*

Ted Shatynski '92, a patent attorney with Johnson & Johnson's Legal Department, often sounds as if he could be a member of the global organization's research and development team. As he talks about his career experience, it is clear he appreciates the actual process of invention and innovation as deeply as he understands how to safeguard the intellectual property those inventions represent, while bringing innovative approaches and devices to patients in need.

In fact, had Shatynski chosen a different career path, he could have easily been a member of J&J's cadre of engineers and scientists. He explains, "I had four siblings and all but one of us became engineers. My father, John, who earned a B.S. in Chemistry from Seton Hall University in 1941, was a chemist, and he always encouraged us to get an education that we can apply directly to a career." Taking that advice to heart, Shatynski attended New Jersey Institute of Technology and majored in chemical engineering. Soon after, he earned a Masters degree in chemical engineering in the evening.

His first job out of college was as a process design engineer, developing plants that separated air into oxygen and nitrogen and other rare gases in the atmosphere. Looking back, he says, "What was really fulfilling was to go out to the field and actually start up the designs I'd worked on. I could see if any issues occurred and refine my plans."

Shatynski worked alongside Nanette Semrau Thomas '88, who had been pursuing an M.B.A. but she then chose to pursue a law degree at Seton Hall to practice intellectual property (IP) law. He says, "She planted the seed for my becoming an IP attorney. It took two years for it to sink in, but I realized it was

a way to advance my career while supporting my interest in technology."

He decided to attend Seton Hall Law full-time, "taking every IP class I could get my hands on." "Even then, Seton Hall Law had a wide array of IP courses available," he explains. "Besides basic trademark, copyright and patent law courses, I took a class in entertainment law because it was fun to read copyright cases involving artists. But there were also practical skills courses, such as Patent Claims Drafting. There, we learned the checks and balances of the IP law process and the basic mechanics of getting a patent approved."

Shatynski first combined his engineering and IP law expertise for Exxon Chemical, and then for a New Jersey-based company that worked with chemical catalysts. Two years later, however, Shatynski accepted a position with global healthcare leader Johnson & Johnson in its centralized Legal Department, which serves the company's three primary sectors: pharmaceuticals, medical devices and consumer products, reflecting a myriad of subsidiaries and business divisions that comprise the entire organization.

Shatynski's relationship with the Gibbons Institute began with an invitation from Dean Boozang to join the Advisory Board soon after the Institute's launch in 2007. She appreciated Shatynski's ties to one of the world's leading innovators, and he welcomed the opportunity to give back to the law school and to talk with other practicing attorneys in similar industries.

As he sees it, the role of the Board is to ensure Seton Hall Law students are well-positioned for legal practice in the area of IP, and to continue to advance the economy of this geographic region, which Shatynski calls "the medicine cabinet of the nation," as a hub of

innovation in healthcare, life sciences and other industries.

For IP law students, the Advisory Board routinely conducts a curriculum review to ensure that courses continually reflect developments in technology and in IP law practice. Shatynski also values the Institute's dedication to continuing education for practicing attorneys. He singles out the ongoing Cybersecurity project as particularly innovative. Developed in conjunction with the Bergen County Prosecutor's Office, the Project offers Continuing Legal Education programs as well as fellowships for law students in prosecutors' offices across the state. "This is an area that needs attention because it's affecting all industries," he says. "I see these efforts as attacking the seed of a problem that has far-reaching implications from consumer credit information protection to healthcare privacy."

Shatynski believes that dedicated law students can reap the rewards of their legal education by combining their personal interests with a specialty in the law. He observes, "Whatever your college major, or if there is a passion you found in a post-college job or in grad school, you can probably find a way to extend that curve into the law. There is a niche in legal practice that can lead to great career satisfaction for years to come."

Looking back on his own career path, he reflects, "Like all engineers, I want to solve problems. I can meet with inventors and understand their processes, examine what's been done in the past in that area, and then tease out what's 'novel' and 'not obvious' – both, IP terms, and facilitate these advances to patients in need. That puts me on the leading edge of new technology and innovation. Having that full array of experience is a culmination of what I've done."

2012-13 Events

Inaugural Lecture in Corporate Governance & Business Ethics

October 2, 2012



Professor Stephen Lubben, who holds the Harvey Washington Wiley Chaired Professorship in Corporate Governance & Business Ethics, gave the inaugural lecture in this new annual series. The Wiley

Chair reflects the commitment of Bristol-Myers Squibb Company and Seton Hall Law School to advancing ethical business practices in corporate law generally and in the health law arena in particular. The annual lecture series was established through a generous contribution from Bristol-Myers Squibb. Professor Lubben's speech, "Separation and Dependence: Explaining Modern Corporate Governance," will be published by the SETON HALL LAW REVIEW, and may be found on Professor Lubben's Social Science Research Network (SSRN) web page.

Tenth Annual Fall Lecture Series

October 16, 2012



The Gibbons Institute and the New Jersey Intellectual Property Law Association (NJIPLA) hosted its Annual Fall Lecture Series featuring the Honorable Kathleen O'Malley (*pictured left*) of the U.S. Court of Appeals for the Federal Circuit. Judge O'Malley offered "Views from the Bench" on crucial intellectual property cases and issues.

Emerging Careers in Health Law

October 24, 2012

In a lively panel discussion, Seton Hall Law students were introduced to the myriad career opportunities available in the field of health and life sciences law. Seton Hall Law alumni Brad Davidsen '09, Senior Global Agreements Specialist, Merck; David DeSimone '95, Vice President and General Counsel, AtlantiCare Health System; Scott Liebman '05, Principal, Porzio, Bromberg & Newman and Vice President, Porzio Life Sciences; and Kara McCarthy Perry '98, Assistant General Counsel, Sanofi, S.A., described their roles and responsibilities, shared their views on the skills that attorneys most need to succeed and how to pursue a position or internship in a particular health law field.

Navigating the Biosimilars Landscape

February 19, 2013

This timely program, sponsored by the Gibbons Institute, offered key insights into the rapidly evolving biosimilars landscape. Topics included litigation under the Biologics Price Competition and Innovation Act, the patentability of monoclonal antibodies and the impact of the America Invents Act, and the Food and Drug Administration's regulation of biosimilars. Panelists included Reza Green, Vice President, Intellectual Property, Novo Nordisk, Inc.; Jordan Paradise, Associate Professor of Law, Seton Hall Law; George Gould, Counsel, Intellectual Property, Gibbons P.C. and former Chief Patent Counsel, Hoffman-LaRoche; Lisa Wang, Director, Intellectual Property, Gibbons P.C.; and Estelle J. Tsevdos, Director, Intellectual Property, Gibbons P.C. and former Patent Counsel and Manager, Biotechnology Section, American Cynamid.

Life Sciences College: Pharmaceutical and Compliance Fundamentals with Sidley Austin

February 26, 2013

This event was co-sponsored by the Center for Health & Pharmaceutical Law & Policy and held at Sidley Austin's Manhattan offices. The program addressed key legal and business challenges facing pharmaceutical companies, and included updates on recent regulatory and industry developments. Expert faculty included, among others, Seton Hall Law Professors Kathleen Boozang and Jordan Paradise; Sidley Austin Partners Jim Stansel, Paul Kalb, William Sarraile and Anna Spencer; government prosecutors Maureen Ruane from the U.S. Attorney's Office for the District of New Jersey and Heidi Wendel from the U.S. Attorney's Office for the Southern District of New York; and industry experts Frank Bigley, Chief Compliance Officer, Novo Nordisk; LaDonna Steiner, Associate General Counsel, Purdue Pharma; and Freddy Jimenez, Assistant General Counsel, Johnson & Johnson.

Asia-Pacific Healthcare Compliance Certificate Program

March 4-7, 2013

Seton Hall Law has once again expanded its compliance program offerings. The inaugural Asia-Pacific Healthcare Compliance Program was hosted in Singapore in March 2013. Program participants hailed from 11 different countries including Australia, China, India, Japan, Malaysia, South Korea and Vietnam. Taught by regional faculty, in-house compliance officers and legal experts, the curriculum tackled legal and compliance cross-border issues such as anti-corruption law, competition law, data privacy and industry codes of conduct. These issues, combined with varied enforcement regimes and cultural differences, make the Asia-Pacific region a unique and challenging environment in which to do business. Seton Hall plans on offering this program again, March 3-6, 2014, in Singapore.

For more information, visit law.shu.edu/asiapacific.



Advising the White House on Bioethics Policy: The Bush Years

March 13, 2013

The Center for Health & Pharmaceutical Law & Policy hosted a public lecture by Professor O. Carter Snead, who recounted his experience as General Counsel to the President's Council on Bioethics under President George W. Bush. Professor Snead discussed the Council's research and recommendations regarding the regulation of new biotechnologies and their effects on assisted reproduction, stem cell research and genetics. Professor Snead is a recognized legal scholar in bioethics and has served as the U.S. delegation's leader and chief negotiator for the Universal Declaration on Bioethics and Human Rights, and the U.S. government's Permanent Observer to the Council of Europe's Steering Committee on Bioethics. He is currently a member of UNESCO's International Bioethics Committee.



HIPAA, HITECH & Beyond: Protecting Healthcare Data in our Cyber World

April 19, 2013

This day-long program provided an in-depth examination of the many challenges, enforcement trends and complex regulations facing healthcare data privacy professionals who counsel physicians, hospitals and other healthcare facilities on protecting the privacy and security of healthcare data. Speakers included Professor Frank Pasquale;

Helen Oscislawski, Founder, Oscislawski, LLC; Anna Spencer, Partner, Sidley Austin LLP; Mark Swearingen '98, Hall, Render, Killian, Heath & Lyman, P.C.; Joy Pritts (pictured, left), Chief Privacy Officer, Office of the National Coordinator for Health, Information Technology, U.S. Department of Health & Human Services; and Jaime S. Pego '05, Director, Healthcare Advisory Services, KPMG LLP.



USPTO Patent Post-Issuance Proceedings Under the America Invents Act — a New Frontier

April 23, 2013

This Gibbons Institute program addressed post-grant proceedings under the America Invents Act, from the perspective of both the patent owner and the challenger, as well as discovery and other new rules of practice before the Patent Trial and Appeal Board. Featured speakers included Robert E. Rudnick and Thomas J. Bean, Directors in the Gibbons P.C. Intellectual Property Department; Kenneth Corsello, IP Law Site Counsel, IBM; Heather C. Brady, Senior Patent Counsel, Johnson & Johnson; and Mark Schildkraut, Senior IP Counsel, Becton, Dickinson and Company.

Advanced Complex Litigation Series

May 30, 2013

The Gibbons Institute co-sponsored the Federal Circuit Bar Association's Complex Litigation Series focusing on the American Invents Act; Case Management in Complex IP Litigation; Predictive Coding, TAR and E-Discovery; Hatch-Waxman Patent Litigation in the District of New Jersey; and Evolving Damages. Panelists included the Honorable Faith S. Hochberg, U.S. District Court Judge, District of New Jersey; the Honorable Randall R. Radar, Chief Judge, U.S. Court of Appeals for the Federal Circuit; the Honorable Mark Falk, U.S. Magistrate Judge, District of New Jersey; the Honorable John M. Facciola, U.S. Magistrate Judge, District of Washington, D.C.; the Honorable Stanley R. Chesler, U.S. District Court Judge, District of New Jersey; the Honorable Douglas E. Arpert, U.S. District Court Judge, District of New Jersey; John R. Kenny, Partner, Kenyon & Kenyon; Adam B. Landa, Chair, eDiscovery & Retention Practice, Greenberg Traurig, LLP; Joe Looby, founder and former Senior Managing Director of FTI Technology Practice; Arnold B. Calmann, Member, Saiber LLC; Edgar H. Haug, Partner, Frommer, Lawrence & Haug LLP; Richard C. Pettus, Shareholder, Greenberg Traurig, LLP; Nicholas Groombridge, Partner, Paul Weiss, Rifkind, Wharton & Garrison; Lisa A. Jakob, Legal Director, IP Litigation, Merck & Co.; Richard Rainey, Executive Counsel, IP Litigation, General Electric Corporation; and William E. Solander, Partner, Fitzpatrick, Cella, Harper & Scinto.



Managing Counterfeiting Issues in the Pharmaceutical Industry

June 18, 2013

The Gibbons Institute hosted a panel discussion among attorneys and academicians focused on pharmaceutical counterfeiting, a global problem which poses a deadly threat to consumers and harms the reputation and financial condition of pharmaceutical companies. Guest speakers addressed practical, anti-counterfeiting strategies and discussed how companies can develop and implement tailored "best practices" to deter and combat counterfeiting. Specialists included Owen McKeon, Director, Intellectual Property, Gibbons P.C.; David Opderbeck, Professor of Law and Faculty Director, Gibbons Institute; Catherine Begley, Regional Director for the North America Region, Merck; Kathleen Dooley, Partner, McGuire Woods, LLP; and Kristina Montanaro, Associate Counsel and Director of Special Events, International Anti-Counterfeiting Coalition.



CENTER News

The Center for Health Welcomes Michael B. McCulley as Practitioner-in-Residence

Seton Hall University School of Law has appointed Michael B. McCulley, Esq. as Distinguished Practitioner-in-Residence for the Center for Health & Pharmaceutical Law & Policy. As one of the original architects of Seton Hall Law's acclaimed Healthcare Compliance Certification Program, he will advise on the continued development of the program to benefit law students and will also consult on the Center's legal policy work. In addition, Mr. McCulley will mentor students interested in pursuing careers in health law and healthcare compliance.

Mr. McCulley is former Assistant General Counsel to Johnson & Johnson, and joins Seton Hall Law after 30 years of in-house health law experience with J&J. He joined the company in 1982 and became its first specialized medical device lawyer, helping to build the global regulatory practice for the Medical Device and Diagnostics business.

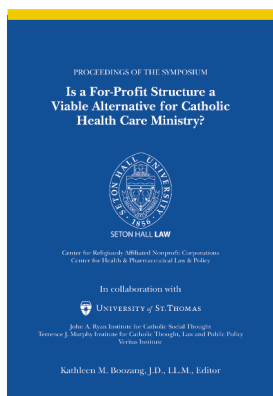
Early on, Mr. McCulley developed an expertise in analyzing

the federal Anti-Kickback Statute and its "safe harbor" regulations which led his shift to global healthcare compliance. He built and shaped the Health Care Compliance Program, serving as primary legal counsel to J&J's Chief Compliance Officer and to the Health Care Compliance organization. He also directed and led the company's production of Guidance Documents in Health Care Compliance, while offering legal support for related elements of the program.

Mr. McCulley said, "I am excited about being a part of the Center's significant legal policy work, and exceedingly pleased to have the chance to instruct both law students and life science professionals in compliance. The need has never been greater, and the opportunity to help train the next generation of health lawyers and compliance professionals is deeply gratifying."



Seton Hall Law Publishes Monograph on For-Profit Catholic Healthcare



In March 2012, Seton Hall Law hosted a groundbreaking forum, "Is a For-Profit Structure a Viable Alternative for Catholic Health Care Ministry?" The two-day conference, comprising a series of panel presentations, provided a unique forum for dialogue among practitioners, academics and scholars in law, finance, theology and Catholic social teaching to

"drill down" to specific legal, financial and operational issues

relevant to an objective examination of the relationship of the for-profit legal and financial structure to the Catholic tradition of healthcare ministry.

Earlier this year Seton Hall Law published a comprehensive monograph, edited by Dean Kathleen Boozang, reflecting the presentations given during the two-day event.

For a copy of the Symposium proceedings, please contact Catherine Finizio, Center for Health Administrator, at catherine.finizio@shu.edu, or call 973-642-8382.

2013 Healthcare Compliance Certification Program Scholarship Winners

Two outstanding health law students received scholarships to attend Seton Hall Law's U.S. Healthcare Compliance Certification Program in June 2013. Pictured with Sara Simon, HCCP Director (*center*), are scholarship recipients Kimberly Reese (*left*), a third-year law student from Washington University School of Law, and Dennis Vann, a third-year law student from the University of Georgia School of Law. Competing against students from top law schools around the country, Reese and Vann demonstrated a genuine interest in the field of health law and proven success in their health law classes. *For more information about this annual student scholarship program, please visit law.shu.edu/compliance or call 973-642-8871.*



Pharmaceutical and Medical Device Compliance Manual Published

The Center for Health, the American Health Lawyers Association (AHLA) and the Food and Drug Law Institute (FDLI) released the first edition of the *Pharmaceutical and Medical Device Compliance Manual*. The manual is a guide to deciphering the intricate web of federal and state laws and the practices of regulatory and enforcement authorities within the healthcare and life sciences arena, while also providing the practical skills needed to implement an effective compliance program.

Designed to aid health law attorneys, compliance professionals and others in the pharmaceutical and medical device field, the manual explains the law in layman's terms in addition to providing advice and guidelines on creating, managing, monitoring and auditing an effective compliance program, in essence, marrying legal expecta-

tions with the operational demands of business units.

The book was co-edited by Dean Kathleen Boozang and Simone Handler-Hutchinson, J.D. '93, Executive Director of the Center for Health.

The *Pharmaceutical and Medical Device Compliance Manual* is available as a soft-bound book and in a variety of eBook formats; to order a copy, visit law.shu.edu/compliancemanual.



Seton Hall Law Expands Online Learning Offerings

Dean Boozang calls professionals working in regulated industries “lifelong learners.” Through its Division of Online Learning, Seton Hall Law offers career development opportunities for attorneys and other professionals who seek a deeper understanding of the legal, regulatory and ethical issues within the healthcare, pharmaceutical and medical device industries to help them become lifelong learners and, in the process, advance their careers.

Over the past year, Seton Hall Law added an online option for its M.S.J. degree students, giving them the opportunity to attend classes in person, online, or both. Graduate Certificate programs are

conducted 100 percent online and are offered several times throughout the year. Certificate programs are available in Health & Hospital Law, Intellectual Property Law, Life Sciences Law and Human Resources Law. The full course list appears at left.

The Division of Online Learning has added two new certificates: Core Legal Issues for the Human Resources Professional; and Conducting Legal Investigations in the Modern Workplace. These courses are designed to immerse human resources professionals in key substantive issues and to develop the practical skills necessary for them to communicate effectively about human resources law at their organizations.

Professionals who have completed the certificates have found the online learning experience to be both rewarding and ideal. Shauna Richardson, Medical Staff Office/Clinical Education Coordinator for Kit Carson County, Colorado Health Service District and an alumna of the Graduate Certificate in Health and Hospital Law, says, “I have referenced my materials many times since the course. I thank [the professor] and Seton Hall for letting me be a part of this rewarding experience.”

If you are interested in learning more about our M.S.J. degree or Online Graduate Certificate programs, or would like to apply for the next session, visit law.shu.edu/onlinelearning or contact lawonline@shu.edu or 973-642-8871.

Online Graduate Certificate Courses – Starting in Fall 2013 law.shu.edu/onlinelearning

- Compliance Issues in the Life Sciences
- The Law of Patient Care
- Compliance Issues for Healthcare Providers
- Clinical Research & the Law
- The Law Protecting Whistleblowers
- FDA Regulation & Liability
- Patent & Trade Secret Law
- Trademark & Unfair Competition Law
- Copyright Law

SETON HALL | LAW

The First and Last Stop in Compliance Training

“I had the pleasure of participating in [Seton Hall Law’s] Healthcare Compliance Certificate Program and the Graduate Certificate Program in Pharmaceutical & Medical Device Law & Compliance. I am convinced that the caliber of thoughtful leadership and focus on both domestic and international healthcare compliance issues gave me a world-class educational experience.”

— Jari Peters, Esq, Senior Compliance Officer
Robert Wood Johnson Medical School, New Brunswick, New Jersey

FACULTY Highlights



Gaia Bernstein

Professor of Law and Margaret Gilhooley Research Fellow

Gaia Bernstein's research focuses on the interrelations among technology, law and society, examining the dissemination processes of new technologies.

During the 2012-2013 academic year, Professor Bernstein's research centered on three projects. One ongoing project examined the role of the user in patent law. An article titled, "Incentivizing the Ordinary User," which is forthcoming

in the *FLORIDA LAW REVIEW*, discusses the need for legal regulation to address user resistance to the adoption of new technologies. She is currently working on another article which highlights the rise of end users as central players in patent litigation. This year, Professor Bernstein presented these papers at the First Annual Conference on Governance of Emerging Technologies: Law, Policy and Ethics at the Sandra Day O'Connor College of Law at Arizona State University and at the PatCon3 Conference at Chicago-Kent College of Law.

A second project looks at the impact of prohibitions on gamete donor anonymity on supplies of egg and sperm and the potential effect on the practice of surrogacy. An article on this topic is forth-

coming as a symposium piece in the *INDIANA HEALTH LAW REVIEW*. Professor Bernstein has presented this article at the Baby Markets Roundtable at Indiana University's Maurer School of Law, the Mid-Atlantic Law and Society Association Conference at Drexel Law School, the Reproductive Technologies Roundtable at the Southeastern Association of Law Schools Conference, and the Health Law Professors Conference at Arizona State University's Sandra Day O'Connor College of Law. The third project Professor Bernstein is working on looks at parental monitoring of social networks as part of the trend of intensive parenting and examines the implications for children's privacy. She has presented this paper at the International Society of Family Law's North American Regional Conference at Brooklyn Law School and at the Family, Privacy, Secrets & the Law Roundtable at the University of Maryland School of Law.

This year, Professor Bernstein organized the Work-in-Progress Intellectual Property (WIPIP) Colloquium, which was hosted by Seton Hall Law. In addition, she is the Chair of the Section on Privacy and Defamation and has served on the Executive Board of the Section on Intellectual Property of the Association of American Law Schools.



Kathleen M. Boozang

Associate Dean for Academic Advancement and Professor of Law

Kathleen Boozang published several pieces in 2012 and 2013, including an article on France's new Physician Sunshine Act, an article on the Responsible Corporate Officer Doctrine that urged its application to the owner-managers of the New England Compounding Center, an article analyzing the ethical rules

implicated by in-house counsel or compliance officers who are also attorneys becoming *qui tam* relators, and an article co-authored with Carl Coleman and Kate Greenwood on physician conflicts of interest. Dean Boozang also completed two major editing projects: the proceedings of a 2012 symposium held at Seton Hall Law titled, "Is a For-Profit Structure a Viable Alternative for Catholic Health Care Ministry?" and, together with Simone Handler-Hutchinson, a manual on pharmaceutical and medical device compliance that was co-published by the American Health Lawyers Association (AHLA), the Food and Drug Law Institute and Seton Hall Law.

Dean Boozang devoted much of her time in 2012 and 2013 to Seton Hall Law's burgeoning Division of Online Learning,

which now offers online graduate degrees and certificates in health and hospital law, human resources law, life sciences law and intellectual property law. She also served on the faculty of the law school's Healthcare Compliance Certification Programs, which are now held in Paris and Singapore as well as in Newark. Among other speaking engagements, Dean Boozang participated in a panel discussion sponsored by Harvard Law School's Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics on "Compliance with and Enforcement of U.S. Healthcare Laws: Evolution of Modern Life Sciences Compliance Programs." Representing academia alongside leading experts from the government, the life sciences industry and the private bar, she urged the development of standards to measure the effectiveness of corporate compliance programs.

This year brought to a conclusion Dean Boozang's service as an AHLA board member. She now serves on the board of an urban healthcare system and as a member of the recently-created New Jersey Crisis Standards of Care Committee. She also continues service on the boards of two journals, *LIFE SCIENCE COMPLIANCE*, which is dedicated to international life science compliance issues, and the AHLA's *JOURNAL OF HEALTH & LIFE SCIENCES LAW*.

Carl H. Coleman

Professor of Law and Director of Global Initiatives

Carl Coleman specializes in the legal, ethical and public policy implications of medical treatment, research and public health. Over the past year, he published the 2005-2012 cumulative update to his textbook, *The Ethics and Regulation of Research with Human Subjects* (Lexis 2012) (with Jerry Menikoff, Jesse Goldner, and Nancy Dubler), and an article on conflicts of interest training for physician-investigators in a symposium issue of the JOURNAL OF LAW, MEDICINE & ETHICS (with Kate Greenwood and Kathleen Boozang). He also led the drafting team for the World Health Organization (WHO) report, ETHICAL ISSUES IN PATIENT SAFETY RESEARCH (2013). His most recent article, "Improving the Quality of Host Country Ethical Oversight of International Research," is currently undergoing peer review.

In July 2013, Professor Coleman led a WHO consultation in Toronto on "Developing Quality Indicators for Research Ethics Systems," which will form the basis of a forthcoming WHO

report. He presented on the role of indicators in evaluating Institutional Review Board effectiveness at the 36th Annual ASLME Health Law Professors Conference, held at Seton Hall in June 2013. Over the past year, he has also presented at the International Pharmaceutical Compliance Congress and Best Practices Forum (Madrid, May 2013), the Executive Course on Intellectual Property, Diplomacy and Global Public Health (Geneva, February 2013), the European Healthcare Compliance Certification Program (Paris, November 2012), and the International Society of Healthcare Ethics and Compliance Professionals (Paris, September 2012).

Professor Coleman recently completed a three-year appointment as a member of the Secretary's Advisory Committee on Human Research Protections, U.S. Department of Health & Human Services.



Kate Greenwood

Research Fellow & Lecturer in Law

Kate Greenwood researches and writes on a variety of health and pharmaceutical law topics, including conflicts of interest in medical treatment and clinical research, prescription drug regulation, and the role of law in incentivizing and governing biomedical research.

Over the past year, she co-authored a symposium issue of the JOURNAL OF LAW, MEDICINE & ETHICS; a chapter co-authored with Bruce D. Armon on medical science liaisons in the Food and Drug Law Institute's book, *Off-Label Communications: A Guide To Sales & Marketing Compliance*; and three policy briefs, one co-authored with John Jacobi and Tara Ragone, on the implementation of the Patient Protection and Affordable Care Act in New Jersey. Ms. Greenwood's most recent article, "Litigant Regulation" of Physician Conflicts of Interest, is forthcoming in 2014 in the GEORGIA STATE UNIVERSITY LAW REVIEW.

In May 2013, Ms. Greenwood presented her work-in-progress, "Calibrated Incentives for Orphan Drug Development: Time to Experiment?," at a conference on the future of the Food and Drug Administration, sponsored by Harvard Law School's Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics. Ms. Greenwood also blogged and provided legal commentary to a number of media outlets over the past year, including CNNMoney, Contract Pharma, Seton Hall Law's Health Reform Watch, Inside Counsel, NJ BIZ, Pharmaceutical Compliance Monitor, Pharmedica, and the television show, "American Law Journal," which airs on the Philadelphia-area CNN affiliate.



FACULTY Highlights



John V. Jacobi

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

John Jacobi teaches, speaks, and publishes in the areas of health finance, disability and mental health law.

Over the past year, Professor Jacobi published an article, titled “High Utilizers of ED Services: Lessons for System Reform,” in the *ANNALS OF HEALTH LAW*. A second article, “Medicaid Evolution for the 21st

Century,” will be published in an upcoming symposium issue of the *KENTUCKY LAW JOURNAL*. He also issued two substantial policy briefs, “Active or Passive: The Role of a New Jersey Health Insurance Exchange and “Implementing the Essential Health Benefits Requirement in New Jersey: Decision Points and Policy Issues,” the latter co-authored with Kate Greenwood and Tara Adams Ragone. The briefs were the result of a multi-year, interdisciplinary collaboration with the Rutgers University Center for State Health Policy which

was supported by the Robert Wood Johnson Foundation and the U.S. Department of Health & Human Services. In addition, Professor Jacobi published three feature op-eds in *The Record* newspaper, and was featured in an article in *NJ Spotlight*, all addressing health reform implementation in New Jersey.

This year, Professor Jacobi participated in a panel discussion on “NJ’s Health Insurance Exchange: Ready to Launch?,” at the Council on State Public Affairs-sponsored conference, New Jersey: State of Health 2013. He also presented at the Medicaid Matters workshop at the University of Kentucky College of Law, at the State Health Reform conference at Suffolk University Law School, and at the Health Care Reform: State of the States Roundtable at the University of Maryland Law School. Professor Jacobi also served and continues to serve as the Vice Chair of the Board of Directors of the Greater Newark Healthcare Coalition and the Chair of the Board of Trustees of the North Jersey Community Research Initiative, a community-based organization serving individuals with HIV and AIDs.



Erik Lillquist

Vice Dean, Professor of Law and Co-Chair of the Gibbons Institute of Law, Science & Technology

Erik Lillquist teaches in the areas of Intellectual Property, Evidence and Criminal Law and Procedure.

Dean Lillquist’s research explores the interaction of theories of human-decision making and the legal process, as well as the implications of biology, medicine and psychology for law. Most recently, he has published on

the effects of government regulation on networked technologies. In 2013, Dean Lillquist and Professor David Opderbeck filed an

amicus brief in the Supreme Court case *Federal Trade Commission v. Actavis, Inc., et.al.*, arguing that the complexity of pharmaceutical product markets made the Federal Trade Commission’s proposed “quick-look” approach to antitrust analysis inadequate.

Dean Lillquist is active in efforts to improve the operation of the criminal justice system, writing extensively on the topic. In 2012, his article, “The Puzzling Return of Jury Sentencing: Misgivings About Apprendi,” was cited by both the majority and the dissent in the U.S. Supreme Court’s decision in *Southern Union Company v. United States*. Dean Lillquist currently serves as Chair of the Section on Evidence of the Association of American Law Schools.



David W. Opderbeck

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

Professor Opderbeck, Co-Director of the Gibbons Institute, focuses on the regulation of access to scientific and technological information. His published work has employed the tools of game theory, classical microeconomics, and statistical analysis to address issues such as settlements in Hatch-Waxman litigation, cybersecurity policy, intellectual property restrictions

on essential medicines in developing countries, open source biotechnology, patent damages reform, and the interaction of law and social norms concerning music file sharing.

Professor Opderbeck’s interest in cybersecurity law and policy included a multi-year grant-funded project sponsored by the Bergen County, New Jersey Prosecutor’s Office, which included new courses, continuing legal education programs, and the creation of a governmental working group on cybersecurity and cybercrime. Professor Opderbeck frequently lectures to law enforcement agencies and other groups on cybercrime, cyberterrorism, and civil liberties.

In addition to his traditional legal scholarship, Professor Opderbeck is interested in the philosophical and moral foundations of information policy and other aspects of the law. He has written on ethical, philosophical and theological issues in law and jurisprudence, and currently is completing a doctorate in philosophical theology regarding the intersection of neuroscience and the law.

Jordan Paradise

Associate Professor of Law

Jordan Paradise taught Food and Drug Law, Administrative Law and an advanced writing seminar focused on Law and Genetics, this past academic year. She also advised a number of student law review comments addressing health law and intellectual property law issues for the SETON HALL LAW REVIEW and SETON HALL CIRCUIT REVIEW.

Professor Paradise published several law review articles on a variety of topics at the intersection of law, science and technology in the past year: “No Sisyphean Task: How the FDA Can Regulate Electronic Cigarettes,” in the YALE JOURNAL OF HEALTH POLICY, LAW & ETHICS; “Synthetic Biology: Does Re-writing Nature Require Re-writing Regulation?,” in the PENNSYLVANIA STATE LAW REVIEW, with Ethan Fitzpatrick J.D. ’13; “Reassessing ‘Safety’ for Nanotechnology Combination Products: What Do ‘Biosimilars’ Add to Regulatory Challenges for the FDA?” in the ST. LOUIS UNIVERSITY LAW JOURNAL; and, “Claiming Nanotechnology: Improving USPTO Efforts at Classification of Emerging Nano-Enabled Pharmaceutical Technologies,” in the NORTHWESTERN JOURNAL OF TECHNOLOGY & INTELLECTUAL PROPERTY. She also contributed an entry for the forthcoming 4th Edition of the

Encyclopedia of Bioethics on return of research results in genetics research and a chapter on biologics regulation or the American Health Lawyers Association’s *The Fundamentals of Life Sciences Law: Drugs, Devices, and Biotech*.

Among her speaking engagements this past year, Professor Paradise spoke at the Arizona State University Sandra Day O’Connor School of Law’s First Annual Conference on Governance of Emerging Technologies: Law, Policy, and Ethics; the New Voices in Administrative Law session at the Association of American Law Schools’ Annual Meeting; the Food and Drug Law Institute’s Annual Conference; Sidley Austin’s Life Sciences College; and a Gibbons Institute of Law, Science & Technology event, “Navigating the Biosimilars Landscape.” She also concluded her term as the Chair of the Food and Drug Law Institute’s Academic Committee.



Tara Adams Ragone

Research Fellow & Lecturer in Law

Tara Adams Ragone researches and writes on a variety of health law topics, including implementation of health care reform, accountable care organizations, prescription drug abuse, and issues related to the representation of health care professionals. In 2012, she published an article in a symposium issue of the SETON HALL LAW REVIEW in which she analyzed how to structure New Jersey’s Medicaid Accountable Care Organizations (ACOs) to assuage antitrust concerns. Building on this expertise, she was asked to convene a panel regarding the legal hurdles of Medicaid ACO implementation for a statewide conference.

With funding provided by a grant from the U.S. Department of Health and Human Services, Ms. Ragone authored two policy briefs for the New Jersey Department of Banking and Insurance (DOBI) in 2012, one concerning medical loss ratios and the other concerning insurance rating factors and rate bands. Based on her comprehensive comparison of federal and New Jersey regulation of medical loss ratios, DOBI invited Ms. Ragone to present at its annual rate review forum in April 2013. Also in 2012, Ms. Ragone, Professor Jacobi and Ms. Greenwood co-authored a Robert Wood Johnson Foundation-funded policy brief on the Affordable Care

Act’s essential health benefits requirement. In 2013, she and Professor Frank Pasquale co-authored a Microsoft-funded white paper on HIPAA’s application to cloud computing.

In Spring 2013, Ms. Ragone developed and taught an innovative health law skills course in which students gained invaluable practical skills by working with practitioners from three health law settings, government prosecution, public policy advocacy, and in-house counsel at an insurance company. Ms. Ragone also continued as a regular contributor to Seton Hall Law’s Health Reform Watch blog, on issues such as prescription drug monitoring programs and state health insurance exchanges, and her scholarship was cited by academics at the Concurring Opinions and Antitrust and Competition Policy blogs. She provided legal analysis to several media outlets as well, including *Modern Healthcare*, the *Star-Ledger*, *NJ Spotlight*, and *NJ BIZ*.



Keeping Up With Students & Alumni

Christopher Alworth, J.D. '06 is Associate Counsel at Blue Cross Blue Shield Association in Washington D.C.

Kathe Balinski, M.S.J. '05 is Vice President of the Early Phase Clinical Project Management at ImClone Systems in Bridgewater, New Jersey.

Susan A. Blair, M.S.J. '02 is Chief Privacy Officer for the University of Florida, which includes campuses in Gainesville, Jacksonville, and St. Petersburg, Florida.

Matthew D'Ambrosio, J.D. '01 is Senior Vice President, Chief Compliance and Ethics Officer at Sunovion Pharmaceuticals Inc. in Marlborough, Massachusetts.

Lauren Devlin, M.S.J. '07 is Associate Director, Policy & Risk Management, Ethics & Compliance at Novartis Pharmaceuticals Corporation.

Diana M. Fratto, J.D. '12 is an associate in the healthcare practice group at Sills Cummis & Gross in Newark, New Jersey.

Shane Freedman, J.D. '98 is Vice President at McNeil Consumer Healthcare in Fort Washington, Pennsylvania.



Clarissa Gomez, J.D. '14 was selected to participate in the Diversity and Inclusion Internship program at Bristol-Myers Squibb this past summer where she worked for the U.S. Regulatory and Commercialization and Litigation departments.

Christina Hage, J.D. '09 is General Counsel at HealthyCT in Wallingford, Connecticut.

James Hlavenka, J.D. '10 joined UCB, Inc. in Atlanta, Georgia as Counsel in the Legal Affairs Department. He was previously at Buchanan Ingersoll & Rooney in the FDA/Biotechnology group.



Matthew P. Jacobs, J.D. '05 is an Associate at Fox Rothschild LLP in Princeton, New Jersey.

Winston Kirton, J.D. '03 is Senior Corporate Counsel, Regulatory and Commercial at Bristol-Myers Squibb in Princeton, New Jersey.

Kristina LaGrasso, M.S.J. '09 is a contract manager, U.S. Contract Strategy and Management at Pfizer Pharmaceuticals in New York City, New York.

Stephanie Macholtz, J.D. '05 is Associate Director, Compliance, R&D at Eisai in Woodcliff Lake, New Jersey.

Steven McRae, M.S.J. '03 is a National Account Director – Government Payors – Managed Care – DX Sequenom CMM (Center for Molecular Medicine) in San Diego, California.

Matt McKennan, J.D. '11 is the Senior Planner at Yale New Haven Health in New Haven, Connecticut. He was formerly in the health care practice group at Sills Cummis & Gross.

Mollie O'Brien, J.D. '94 is General Counsel & Senior Vice President at Emergency Medical Associates (EMA) in Parsippany, New Jersey.

Kenneth Peist, J.D. '98 is Vice President of Legal & Intellectual Property at Amicus Therapeutics, Inc. in Cranbury, New Jersey.

Martine Pflieger, J.D. '99 is Senior Counsel, Commercial Contracting at Express Scripts in Franklin Lakes, New Jersey.

Sunitha Ramamurthy, J.D. '96 is the Executive Director, Office of Ethics and Compliance at Boehringer Ingelheim Pharmaceuticals in Ridgefield, Connecticut.

Cari Reed, M.S.J. '05 is the Chief Integrity Officer at Loyola University Medical Center in Maywood, Illinois.



Cornelius Sailer, M.S.J. '06 is Global Head, Product Patrimony Management Renal & Biosurgery, at sanofi-aventis in Cambridge, Massachusetts.

Isai Senthil, J.D. '05 is Associate General Counsel at Summit Medical Group in Summit, New Jersey. She was formerly part of the health law practice group at Brach Eichler.

Ami E. Simunovich, J.D. '07 is Assistant General Counsel at Catalent Pharma Solutions in Somerset, New Jersey.

Sameer Singh, J.D. '14 participated as a legal intern in the general counsel's office of the Advanced Medical Technology Association (AdvaMed). Located in Washington, D.C., AdvaMed is a trade association representing 80 percent of medical technology firms in the United States.

Danielle Steele, J.D. '13 is an associate in the health law practice group of Epstein Becker & Green in Washington, D.C.



Peter St. Phillip, Jr., J.D. '93 is a partner at Lowey Dannenberg Cohen & Hart, P.C. in White Plains, New York. He recently successfully argued Aetna's appeal before the U.S. Court of Appeals for the First Circuit in *In re Neurontin Marketing & Sales Practices Litigation*, a landmark RICO decision holding drug manufacturers accountable to health insurers for damages related to off-label marketing.

Johnson & Johnson Establishes Compliance Fellowship Program

Recognizing that a growing number of law students are interested in pursuing careers in the compliance field, Johnson & Johnson generously funded the establishment of a Compliance Fellowship Program for Seton Hall Law students. The Compliance Fellowship Program provides a stipend to a student working in a 10-week summer fellowship in the Compliance and Legal Departments at Johnson & Johnson.



"This fellowship has been an exceptional learning experience and fundamental in shaping my career path in health law."

— Katelyn Mineo '15

This year's Fellowship was awarded to Katelyn Mineo '15. Katelyn was selected based on a highly competitive application process that included an evaluation of the student's qualifications including law school and undergraduate academic performance, motivation to accept a compliance position for the summer, and intention to ultimately pursue a career in the compliance and/or health law field. The three finalists also underwent an interview.

Advisory Boards

Center for Health & Pharmaceutical Law & Policy

Michael Bell '97
Founder & President
R-Squared

Todd Brower
Partner
McCarter & English

Jeffrey Brown '82
Partner/Director
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Seton Hall University School of Law

Mary Anne McDonald '81
Chief of Legal Affairs and Compliance
Visiting Nurse Association Health Group

Sheilah O'Halloran '83
Assistant General Counsel
Atlantic Health System

Honorable Stewart Pollock
Of Counsel
Riker, Danzig, Scherer, Hyland & Perretti

Elizabeth Ryan '85
President and CEO
New Jersey Hospital Association

Agnes Rymer
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David E. Swee, M.D.
Associate Dean for Education
University of Medicine and Dentistry
of New Jersey-Robert Wood Johnson
Medical School

The Honorable Mara Zazzali-Hogan '98
Superior Court, Family Division
Monmouth County, New Jersey

Gibbons Institute of Law, Science & Technology

David E. De Lorenzi, Co-Chair
Chair, Intellectual Property
Gibbons P.C.

Erik Lillquist, Co-Chair
Vice Dean and Professor of Law
Seton Hall University School of Law

David Opderbeck '91, Director
Professor of Law
Seton Hall University School of Law

Rosa M. Alves
Assistant Dean
Seton Hall University School of Law

Paul M. Antinori
Senior Vice President & General Counsel
The Medicines Company

Robert L. Baechtold '66
Partner
Fitzpatrick, Cella, Harper & Scinto

Marc Began
Corporate IP Counsel
Legal, Government and Quality Affairs
Novo Nordisk

Gaia Bernstein
Professor of Law and
Margaret Gilhooly Research Fellow
Seton Hall University School of Law

The Honorable Garrett E. Brown, Jr. (Ret.)
Former Chief Judge, U.S. District Court
for the District of New Jersey
Mediator and Arbitrator
JAMS, The Resolution Experts

James DeGiorgio
Vice President, Intellectual Property
Comcast

Elaine Drager
Law Vice President, Intellectual Property
and Standards
Alcatel-Lucent

Patrick C. Dunican Jr. '91
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Gregory Ferraro
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Novartis Pharmaceuticals Corporation

Henry Hadad
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Bristol-Myers Squibb

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Seton Hall University School of Law

George Johnston, Jr.
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Roche

Stephen B. Judlowe '65
Of Counsel
McElroy, Deutsch, Mulvaney & Carpenter, LLP

Cherylyn Esoy Mizzo '03
Principal
Fish & Richardson P.C.

James Murtha
Associate Chief Intellectual Property Counsel
Becton Dickinson & Company

The Honorable Pauline Newman
U.S. Court of Appeals for the Federal Circuit

Keith Nowak '76
Partner
Carter Ledyard & Millburn

Leonard T. Nuara '84
Co-Founder, President & COO
TeraExchange

Jordan Paradise
Associate Professor of Law
Seton Hall University School of Law

Henry Sacco, Jr.
Vice President & Chief Legal Officer
Brother International Corporation

Theodore Shatynski '92
Assistant General Counsel - Patents
Johnson & Johnson

Stephen Tang
President & Chief Executive Officer
University City Science Center

Michele K. Thomas
Senior Corporate Counsel – State Regulatory
T-Mobile USA, Inc.

Colleen Tracy '96
Managing Partner
Fitzpatrick, Cella, Harper & Scinto

Roy F. Waldron
Senior Vice President and Chief Intellectual
Property Counsel
Pfizer, Inc.

Loria B. Yeadon '94
Executive Vice President, Invention
Investment Fund
Intellectual Ventures



Seton Hall University School of Law
The Center for Health & Pharmaceutical Law & Policy
The Gibbons Institute of Law, Science & Technology
One Newark Center
Newark, NJ 07102-5210
law.shu.edu

VISIT *HealthReformWatch.com*

Seton Hall Law's authoritative blog on the trends and issues affecting healthcare policy.

Interested in contributing? **Please contact Kate Greenwood, Editor, at kate.greenwood@shu.edu or call 973-642-8277.**



UPCOMING Events 2013 – 14

OCTOBER 8, 2013

Gibbons Institute and NJIPLA's 11th Annual Fall Lecture Series:
Hon. Theodore A. McKee, Chief Judge
Hon. Gregory M. Sleet, Chief Judge
Hon. Garrett E. Brown (Ret.), Chief Judge
John O'Brien, Chief Deputy Clerk
law.shu.edu/GibbonsInstitute

OCTOBER 14-17, 2013

U.S. Healthcare Compliance Certification Program
Newark, NJ
law.shu.edu/Compliance

NOVEMBER 18-22, 2013

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

JANUARY 2014

Annual Lecture in Corporate Governance & Business Ethics
Professor Jill E. Fisch
University of Pennsylvania Law School
law.shu.edu/CenterforHealth
973-642-8871

JANUARY 3, 2014

Center For Health Reception at AALS
6:30 p.m.
New York City, NY

MARCH 3-6, 2014

Asia-Pacific Healthcare Compliance Certification Program
Singapore
law.shu.edu/AsiaPacific

JUNE 2014

European Healthcare Compliance Certification Program
Prague, Czech Republic
law.shu.edu/Compliance

JUNE 9-12, 2014

U.S. Healthcare Compliance Certification Program
Newark, NJ
law.shu.edu/Compliance

COMING SOON

West Coast Healthcare Compliance Certification Program
San Francisco, CA
law.shu.edu/Compliance