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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*): Jordan Cohen '11, Associate at Brach, Eichler L.L.C., who served as a panelist at a health law career event for students; the skyline of Prague, Czechoslovakia, where a new installment of the Healthcare Compliance Certification Program was held in June 2014; Professor Gaia Bernstein, one of three professors in the nation chosen to present a paper at the inaugural American Bar Association – Intellectual Property Law Scholarship Symposium in April 2014; Robert L. Baechtold '66, Of Counsel at intellectual property law firm Fitzpatrick, Cella, Harper & Scinto and a member of the Advisory Board of the Gibbons Institute of Law, Science & Technology; Professor Jordan Paradise, named the Schering-Plough Professor in Health Care Regulation and Enforcement; and the team leaders for The Sentinel Project, monitoring the effectiveness of the provision of health care services in New Jersey under the Affordable Care Act: Renee Steinhagen, New Jersey Appleseed Executive Director; Seton Hall Law Professor John V. Jacobi, and Researchers & Lecturers in Law Kate Greenwood and Tara Adams Ragone.



Dear Friends,

This marks another year of strong partnerships, student success and stellar scholarship for both the Center for Health & Pharmaceutical Law & Policy and the Gibbons Institute of Law, Science & Technology.

This year, the Center for Health & Pharmaceutical Law & Policy is helping to assess how effectively New Jerseyans are receiving healthcare via the state's implementation of the Affordable Care Act. The program, called The Sentinel Project, is made possible by the Robert Wood Johnson Foundation and is conducted in partnership with the New Jersey Appleseed Public Interest Law Center.

The Center for Health is also helping to meet the growing international demand for knowledgeable compliance professionals through its M.S.J. degree program, Graduate Certificates and its Healthcare Compliance Certification Programs, now celebrating its tenth anniversary. Compliance programs were held in San Francisco and Prague in addition to Newark, Paris and Singapore. This summer, four students received paid fellowships from leading healthcare and life sciences companies to explore careers in compliance. Not surprisingly, they found their experiences to be uncommonly rewarding. The Gibbons Institute continues to serve as a unique forum for business leaders, legal practitioners, members of the judiciary and scholars, to convene and discuss developments in intellectual property (IP) law that influence innovation and shape commerce. Seminars exploring rulings by the Federal Circuit, and lessons learned from the enactment of the America Invents Act, provided vital educational opportunities for all who attended. The Gibbons Institute also maintained its focus on the rapidly evolving area of cybersecurity law through scholarship and educational events.

As the academy and legal profession seek common ground in IP law, we congratulate Professor Gaia Bernstein, who made a valuable contribution to this effort. Her paper, *The Rise of the End User in Patent Litigation*, was one of only three selected for presentation at the inaugural ABA-IP Law Section Scholarship Symposium in April.

We are pleased to share this issue of *Highlights* with you, putting the focus on our many vital partnerships. Please consider this an invitation, as always, to reach out to explore opportunities for discussion and collaboration.

Warm Regards,

IM John V. Jacob

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

David W. Opderbeck Professor of Law Faculty Director of the Gibbons Institute of Law, Science & Technology



SETON HALL UNIVERSITY SCHOOL OF LAW is pleased to announce the appointment of Jordan Paradise

as the Schering-Plough Professor in Health Care Regulation and Enforcement

Professor Jordan Paradise researches and publishes on the legal, ethical and societal implications of emerging science and technologies such as genetics and nanotechnology. A member of the Seton Hall Law faculty since 2009, she teaches classes on food and drug law, biotechnology, law and genetics, and emerging technologies. She received her B.S. from the University of Michigan in

Ann Arbor and her J.D. from Chicago-Kent College of Law with a certificate in Intellectual Property Law.

As the Schering-Plough Professor in Health Care Regulation and Enforcement, Professor Paradise will contribute scholarship on and public policy analysis of issues related to administrative law, the regulatory and enforcement concerns of providers and patients, FDA law, and drug and device innovation.

This Professorship was made possible by a \$2.5 million endowment from the former Schering-Plough Corporation and the Schering-Plough Foundation. The Schering-Plough Foundation supported the advancement of health, education, public policy and community initiatives.

Center for Health & Pharmaceutical Law & Policy

Center's Grant-Funded Research Examines Health Reform Efforts

The Sentinel Project

In January 2014, the Seton Hall Law Center for Health & Pharmaceutical Law & Policy launched The Sentinel Project to assess how effectively health insurers in New Jersey are delivering essential health benefits to consumers, as required by the Affordable Care Act (ACA). The Project, which is supported by a grant from the Robert Wood Johnson Foundation, will use individual advocacy and broad-based information gathering and analysis to develop recommendations to improve meaningful access to appropriate medical care in New Jersey. Seton Hall Law Professor John V. Jacobi and Research Fellows & Lecturers in Law Kate Greenwood and Tara Adams Ragone will gather and analyze data from individuals, federal and state insurance regulators, community-based organizations, health providers and insurers. By creating a feedback loop between consumers and stakeholders, the Project will identify problems that need attention and highlight best practices.

Under the guidance of Renee Steinhagen of New Jersey Appleseed Public Interest Law Center, Seton Hall Law students will assist consumers who enroll in individual or small group health insurance plans but are not able to get the healthcare they need due to barriers such as outright denial of insurance claims or an inadequate network of providers.



Pictured, from left: Renee Steinhagen, Executive Director, New Jersey Appleseed Public Interest Law Center; Professor John V. Jacobi; and Research Fellows & Lecturers in Law Kate Greenwood and Tara Adams Ragone

Individuals may contact The Sentinel Project by phone at 973-991-1190 or via email at *contact@njsentinelproject.org*. For more information, please visit the Project's website: *www.njsentinelproject.org*.

New Jersey Medicaid Accountable Care Organizations

In 2013 and 2014, the Center was engaged by the New Jersey Healthcare Quality Institute (NJHCQI) to analyze legal issues and logistical hurdles confronting New Jersey's Medicaid accountable care organizations (ACOs). New Jersey's Medicaid ACOs will be community-based, non-profit organizations that will work to coordinate and improve the quality of care provided to Medicaid beneficiaries, while containing costs.

In December 2013 Professors Jacobi, Greenwood, and Ragone published a report, *New Jersey's Medicaid ACO Pilot Program, Past and Future: A Baseline Report,* which discussed the antitrust, fraud and abuse, and common law liability issues that community groups hope to establish Medicaid ACOs must consider. In February 2014, Professor Ragone presented the report to the NJHCQI's Affiliated Accountable Care Organizations, a network of nascent Medicaid ACOs.

In July 2014, Professor Jacobi published a second report, *New Jersey's Medicaid ACO Pilot Program: Moving Forward*, in which he argued that New Jersey's Medicaid managed care organizations (MCOs) can and should partner with the State's Medicaid ACOs. Professor Jacobi writes, "The missions of Medicaid ACOs and MCOs, their economic incentives, and their obligations under regulation and contract support close and fruitful coordination for the benefit of Medicaid beneficiaries."

Professors Jacobi, Greenwood and Ragone remain involved in efforts to improve the health status of vulnerable Medicaid beneficiaries. Professor Jacobi serves as the Vice Chair of the Board of Directors of the Greater Newark Healthcare Coalition, which submitted an application for certification as a Medicaid ACO. In addition, Professors Jacobi, Greenwood and Ragone serve on the legal committee of the Good Care Collaborative, a statewide coalition advocating for a more efficient, higher-quality Medicaid system.

Publications may be viewed at law.shu.edu/healthlawpublications.

Gibbons Institute Advisory Board Member Profile:

Chemistry was Bob Baechtold's passion as a child. Growing up in North Bergen, he graduated from high school at the age of 16 and enrolled in the chemistry program at Rutgers University.

After earning his B.S. in Chemistry, Bob obtained a position with American Cyanamid, working in polymer research. Soon he was tasked with invention development and partnered with an attorney to help draft the requisite patents on his own inventions. "The attorney complimented me on my writing and suggested I should become a lawyer," he explained. "When I learned more about his job and the opportunities a law degree would offer me, I decided he was right."

Bob decided to attend law school at night, and with his job and family both in New Jersey, he enrolled in Seton Hall Law's evening program, which was unique at the time. He found that his chemistry background served him well. Many of his fellow evening law students had scientific backgrounds and were planning careers in patent law. "People in scientific and engineering backgrounds were successful because law is an analytical discipline," Bob said. "It was fun learning to use the scientific principles that you gain by working as a scientist to study law and analyze law, as they are compatible." Not surprisingly, Bob graduated at the top of his class.

While attending Seton Hall Law, Bob joined the patent department of a small chemical company, where he obtained experience in writing and obtaining chemical patents – "I thought I'd do that forever" – but the curriculum and professors at Seton Hall Law also exposed him to courses such as Civil Procedure and Evidence, and opened his eyes to litigation as a career path.

A year before he graduated, he joined the law firm from which he and five other partners would later leave to establish Fitzpatrick, Cella, Harper & Scinto in 1971. Today,



Robert L. Baechtold '66 Of Counsel, Fitzpatrick, Cella, Harper & Scinto New York, New York

the firm is a *National Law Journal* 250 firm, with 150 attorneys in three different cities, and one of the nation's leading Intellectual Property (IP) firms in the U.S. Earlier this year, *Managing Intellectual Property* magazine named Fitzpatrick, Cella "Firm of the Year" for Pharmaceutical IP Litigation, the fifth time in six years the firm has won the award. Seton Hall Law honored Bob as Distinguished Graduate in 2009 for his leadership in the legal profession and for his dedication to the Gibbons Institute, on which he serves as a founding member of its Advisory Board.

Bob litigates in the fields of pharmaceuticals, biotechnology, chemistry and polymeric materials. He has represented international corporations including Bristol-Myers Squibb, Warner-Lambert, Merck, SC Johnson & Son and E.I. du Pont. Many of his cases have made national news business pages. *Managing Intellectual Property* magazine named Bob an "IP Star" this year, and for the past decade, *Chambers USA* has declared him "dean of pharmaceuticals." He was also named Patent Lawyer of the Year – New York City Litigation by Best Lawyers in America.

In the last 30 years, Bob has seen IP law emerge as one of the top areas of legal practice. He became an expert in the seminal Hatch-Waxman Act passed in 1984, but notes the biggest change in patent law came in 1982, when the government created the Court of Appeals for the Federal Circuit. "There was a huge news flash when the Third Circuit Court of Appeals actually upheld a patent for the first time ever," he says, looking back on that period. "At the time, that was the climate: patents were worthless because courts would not sustain them. Having this new court that recognized the value of patents sparked the burgeoning of patent law. Finally, patent owners had a good chance of winning and damage awards could be very substantial. So law firms' IP practice went from emphasizing getting patents to emphasizing enforcing them."

As an avid supporter of Seton Hall Law School, he was honored to be invited to join the Gibbons Institute Advisory Board. "The Gibbons Institute is a timely concept. With so many companies in New Jersey involved in technology – and they were even when I went to law school – today those companies know the importance of IP law in their business. It's a great region for this kind of work, and I'm pleased that the Law School is interested in becoming a center of excellence for IP law."

Despite his decades outside the lab, Bob remains a chemist at heart. "That's one of the great things about this field," he said. "I get to work in pharmaceuticals and biochemistry, biotech and the medical field, so I'm constantly using chemistry and learning more chemistry as I go along. I just don't get to play with test tubes anymore."

2013-14 Events

Federal Circuit Year In Review

September 10, 2013

The Gibbons Institute of Law, Science & Technology and the Seton Hall Law Student Intellectual Property Law Association presented a session to review key intellectual property issues that were decided by the Federal Circuit in 2012-13, including *Gunn v. Minton*, 568 U.S.

(2013); *FTC v. Actavis*, 570 U.S. (2013) and *Fresenius USA v. Baxter*, 721 F.3d. 1330 (Fed. Cir. 2013). Panelists included Ralph A. Dengler, Former Director, Gibbons P.C.; Erik Lillquist, Vice Dean & Professor of Law; and Professor David Opderbeck. The Honorable Faith Hochberg, District Judge, U.S. District Court

for the District of New Jersey, provided a special commentary.

Justice at Stake?



Patent and Other Complex Litigation: The Adverse Effects of Sequestration, Budget Cuts and Federal Judicial Vacancies October 8, 2013

The Gibbons Institute and the New Jersey Intellectual Property Law Association conducted their eleventh annual Fall Lecture Series, which provides a forum to discuss the legal, political and social problems that continue to arise as scientific and technological changes challenge existing law and legal institutions. This year's event addressed sequestration and the related financial restraints and burdens on the federal judiciary. Panelists included the Honorable Theodore A. McKee, Chief Judge, U.S. Court of Appeals for the Third Circuit; the Honorable Gregory M. Sleet, Chief Judge, U.S. District Court for the District of Delaware; the Honorable Garrett E. Brown (Ret.), Chief Judge, U.S. District Court for the District of New Jersey; and Jack O'Brien, Chief Deputy Clerk, U.S. District Court for the District of New Jersey.

Small- and Mid-Sized Life Sciences Companies Still Face Big Issues – Minimizing the Risks October 18, 2013

Together with Porzio Life Sciences, Seton Hall Law held an all-day forum on how small- to mid-sized life sciences companies can minimize the risks they continue to face in the highly regulated drug and device arena. The forum addressed topics including how to engage



healthcare professionals both in the U.S. and internationally, as well as methods best suited for monitoring these professionals, the promotional review process, and anti-bribery and sales force compliance. Program

faculty included, among others, John Patrick Oroho, Executive Vice President and Chief Strategy Officer of Porzio Life Sciences; Jeffrey Klimaski, Vice President and Corporate Ethics and Compliance Officer of BTG International; Daniel Zavodnick, Counsel at Bayer Healthcare; and Brian Sharkey, Director of Regulatory and Compliance Services at Porzio Life Sciences.

Health Law Forum: Alumni Career Panel

November 4, 2013

In November, the Health Law Forum, a student organization, presented its Fall Alumni Career Panel featuring a panel of distinguished alumni who practice in the fields of healthcare and life sciences law. Panelists included Jordan Cohen '11 *(pictured, right)*, Associate at Brach Eichler L.L.C.; John Deno '99, Senior Counsel at Bristol-Myers Squibb; Mary Deno '99, Vice President of Human Resources at Barnabas Health; Daniel Levy '04, Associate at Epstein



Becker & Green, P.C. and Bryn Whittle '98, Senior Staff Attorney at Community Health Law Project. The discussion was moderated by Dean Kathleen M. Boozang.

Who Owns My Ink? The Fight for Copyright Ownership in the Realm of Tattoos November 7, 2013

This program addressed a unique and fascinating area of intellectual property law: the ownership issues that arise in the realm of "ink" – tattoos. The guest speaker was Marisa Kakoulas, Esq., who writes for the blog, Needles and Sins, and for *Tattoo Artist* magazine.

Corporate Governance & Risk Management: The Importance of Incentives January 28, 2014



Seton Hall Law hosted a public lecture featuring Jill Fisch, Perry Golkin Professor of Law and Co-Director of the Institute for Law & Economics at the University of Pennsylvania Law School, addressing corporate governance and risk management. For the past two decades, some of the hottest topics in corporate governance have been shareholder empowerment and executive compensation reform, as well as the issue of whether corporations are making

increasingly risky business decisions. The discussion explored the question of whether corporations are structuring incentives that are at odds with optimal risk management in our increased efforts to impose greater accountability. The event was part of the Harvey Washington Wiley Chaired Professorship in Corporate Governance & Business Ethics lecture series, which reflects Seton Hall Law's and Bristol-Myers Squibb's commitment to advancing ethical business practices in corporate law and the health law arena.

Life Sciences College: U.S. Pharmaceutical, Biotechnology and Medical Device Regulatory, Compliance and Corporate Update April 3, 2014



For the second year, Seton Hall Law and Sidley Austin LLP co-hosted Life Sciences College in New York City. Co-chaired

of Strategic Projects in

the Office of the Chief

son & Johnson; Claire

Charge Auditor in the

Revenue Management

Initiatives Department

at NYU's Langone Medical Center;

Clifford Javier '12,

Strategic Account

Manager for Novartis;

and Michelle Sturchio

'09, Manager of Legal

Hughes '14, Clinical

Medical Officer at John-

by Jim Stansel, Co-Head of the Global Life Sciences Practice at Sidley Austin, and Simone Handler-Hutchinson, Executive Director of the Center for Health & Pharmaceutical Law & Policy, the all-day seminar addressed key updates on a variety of regulatory and compliance topics for an audience of lawyers and compliance officers working within the life sciences industry. Seminar topics included, among others, the role of policy and governmental affairs in developing legal strategies, ethics for lawyers in FDA-regulated industries, SEC compliance and comparative effectiveness research. Speakers at the seminar included Seton Hall Law Dean Kathleen M. Boozang and Professors Timothy P. Glynn and Jordan Paradise; Jacob T. Elberg, Chief, Health Care and Government Fraud, U.S. Attorney's Office for the District of New Jersey; Paul Kaufman, Chief, Civil Health Care Fraud, U.S. Attorney's Office for the Eastern District of New York; Freddy Jimenez, Assistant General Counsel, Johnson & Johnson; William McConagha, Partner, Sidley Austin LLP; and several others.

M.S.J. Alumni Career Panel Discussion & Networking Reception

April 7, 2014

Seton Hall Law hosted a unique networking opportunity for both its M.S.J. degree alumni and current M.S.J. students. The evening began with a tour of the law school, followed by a moderated panel discussion of alumni currently working in a variety of healthcare positions. The panel discussion featured Karla Childers '12, Director



Pictured are Maritza Hodavance, M.S.J. '12 and Alok Vedvyas M.S.J. '11, who reconnected at the reception.

Services and Privacy Officer at Summit Medical Group. Panelists shared their respective professional backgrounds and highlighted how the M.S.J. program helped them advance their careers. The panel was followed by a networking reception.

The Washington, D.C. Experience: Exploring Careers in the Federal Government & D.C. Firms April 7, 2014

Seton Hall Law hosted a health law career panel featuring Seton Hall Law J.D. alumni working in the health care field in Washington, D.C. Panelists shared their personal and professional experiences with current law students interested in pursuing health law as a career. Co-sponsored by the Center for Health & Pharmaceutical Law & Policy and the Office of Career Services, the event highlighted the variety of health law opportunities that exist in our nation's capital. The event featured David C. Gibbons '12, Associate in the Health Care and Life Sciences



practice at Epstein, Becker & Green, P.C.; Lauren N. Haley '02; and Katherine Matos '11 *(pictured, above)*, Associate Counsel at the U.S. Department of Health and Human Services, Office of the Inspector General. The discussion was moderated by Seton Hall Law Professors Jordan Paradise and Tara Adams Ragone.

USPTO Patent Post-Issuance Proceedings Under the America Invents Act (AIA) – Considerations Impacting the Healthcare and Technology Sectors

May 6, 2014

This program, sponsored by the Gibbons Institute, examined lessons learned since the first petitions for patent postissuance proceedings were filed in the U.S. Patent and Trade Office (USPTO) in September 2012. The program emphasized emerging strategies and other considerations impacting the healthcare and technology sectors. The panel discussion



included representatives of IBM, Johnson & Johnson, Pfizer and Alcatel-Lucent along with the Honorable Rama Elluru, Administrative Judge of the USPTO.

CENTER News

Healthcare Compliance Program Celebrates Tenth Anniversary

Now offered in Newark, Paris, Prague, San Francisco and Singapore

This year marks the tenth anniversary of Seton Hall Law's U.S. Healthcare Compliance Certification Program (HCCP). Seton Hall Law started down this road because it was a unique and intellectually intriguing opportunity to expand its educational offerings in an area that complemented the activities of what is now named the Center for Health & Pharmaceutical Law & Policy. Today, Seton Hall Law's compliance activities comprise a core part of its mission to contribute to the global fight against corruption, through education and training, as well as publications and appearances by health law faculty. Compliance education includes live intensive training throughout the world, published materials for entry-level compliance professionals, online graduate certificates that provide a "deep-dive" on particular topics and a graduate degree specifically



designed for compliance professionals. Seton Hall Law health law faculty frequently publish on issues related to conflicts of interest, bribery and corruption and often present at conferences.

Launched in 2004 and offered twice each year, the U.S. HCCP boasts more than 1,700 alumni, including participants from more than 130 multinational drug, device, biotech and diagnostics companies, consulting firms, government and other organizations. Alumni include 43 international participants from Europe, Asia and South America. Seton Hall Law's international programs, the European Healthcare Compliance Program held in Paris and Prague, and the Asia-Pacific Healthcare Compliance Program in Singapore, have also grown. Program participants have come from over 50 countries and



represent more than 75 life sciences companies, law and consulting firms and other organizations.

In September, Seton Hall Law launched the inaugural Life Sciences Compliance Program in San Francisco. "Seton Hall designed this new program to address the unique challenges faced by smaller life sciences companies, start-ups and those with few, if any, FDA-approved products," said Simone Handler-Hutchinson, Executive Director of the Center for Health & Pharmaceutical Law & Policy (*pictured, above*). "The challenge that many of these companies face is to build a corporate compliance program from the ground up with very limited resources."

Seton Hall Law continues to offer a number of compliance program scholarships for professionals who might not otherwise be able to attend. Scholarships are available to employees of government agencies and nonprofit organizations, professionals who have a demonstrated financial need, and promising health law students from around the nation nominated by their law school professors for the Seton Hall Law certification. This year, in collaboration with Sciences



Po and ETHICS (International Society of Healthcare Ethics and Compliance Professionals), Seton Hall conferred for the first time the Gabor Danielfy Scholarship for Healthcare Compliance and Ethics. Inspired by Gabor Danielfy *(pictured, left)*, a respected leader and visionary in the global healthcare compliance and ethics movement, this scholarship will

be offered twice each year to a deserving professional who wishes to attend the European Healthcare Compliance Program. For more information about our programs, please visit *law.shu.edu/compliance*.

Compliance Fellowships Open a New Door for Law Students

This year, Seton Hall Law established a compliance track within its Health Law concentration for J.D. students. Students desiring to complete the compliance track must fulfill 15 credits of health law survey courses to satisfy the concentration requirements, and then complete additional compliance-related coursework including Compliance Skills and the Healthcare Compliance Certification Program. While some graduates enter the compliance profession immediately following graduation, all students benefit from hands-on experience during law school to enable them to understand the difference between compliance and law as they embark on their professional lives. Seton Hall Law has collaborated with several companies to establish paid summer fellowships in their compliance departments. Ideally, students will experience compliance in their first-year summer and spend their second summer in a law firm summer associate program so they can compare the two experiences. In actuality, most companies expose students to both the legal and compliance departments during their fellowship summer, giving them insight into the in-house perspective of both departments.

This past summer, Horizon BlueCross BlueShield of New Jersey, Johnson & Johnson, Novartis and Otsuka each hosted a compliance fellow (*pictured, to the right*). Fellows participated in salesperson "ride-alongs" to physician offices, observed employee interviews as part of the internal investigatory process, attended advertising and promotional review meetings, assessed innovative training and assessment tools, and were steeped in the federal



Pictured, from left: Elizabeth Lautenbach '15 participated in a fellowship at Horizon BlueCross & BlueShield of NJ, Christine O'Neill '16, at Johnson & Johnson and Nina Schuman '15 at Novartis. Not pictured: Chauyin (Becky) Hsu '15, who participated in a fellowship at Otsuka.

Open Payments reporting requirements. The fellowships also afforded students the opportunity to interact with corporate executives including general counsel and vice presidents of compliance. They return to their second year able to bring real-world experience to their health law classes and with a unique perspective of clients' needs as they interview for their summer associate positions. In the meantime, as companies are increasingly challenged to identify well-prepared professionals who desire a career in compliance, the fellowships offer a potential pipeline of dedicated professionals.

2014 Healthcare Compliance Certification Program Law Student Scholarship Winners



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 nationwide application process, including an endorsement from the students' law schools. The awards recognize students with an aptitude for and a commitment to a career in health law. Pictured with Amy Cattafi, HCCP Director (*right*) are 2014 scholarship winners Srishti Miglani (*left*), a second-year student at Saint Louis University School of Law, and Yesenia Perez, a second-year student at DePaul University College of Law.

Professor Gaia Bernstein Presents Paper at Groundbreaking ABA Symposium

Professor Gaia Bernstein authored a paper, *The Rise of the End User in Patent Litigation*, which was selected for presentation at the American Bar Association – Intellectual Property (IP) Law section's first IP Scholarship Symposium on April 2, 2014. The Symposium reflects the ABA's effort to bridge the gap between scholars and practitioners. A committee of scholars selected one paper from each area of IP – copyright, trademark and patent – for presentation.

Professor Bernstein's paper highlights the emergence of "end users" in patent litigation – those who do not produce or sell patented technology but use it for their business or personal consumption. End users occupy a growing role in the patent system and, Professor Bernstein argues, lack the basic procedural tools that can place them on equal footing with other players. Her paper demonstrates that the America Invents Act failed to predict and is largely ill-equipped to address the new role of end users in commerce.



FACULTY Highlights



Gaia Bernstein

Professor of Law and Margaret Gilhooley Research Fellow

Gaia Bernstein's research investigates the interrelations among technology, law and society, examining the dissemination processes of new technologies. During the 2013-14 academic year, Professor Bernstein's main research project focused on the role of end users in patent litigation. Her article, *The Rise of the End User in Patent Litigation*, which is forthcoming in the BOSTON COLLEGE LAW REVIEW, describes the emergence

of end users as players in many areas of patent litigation, shows that the new patent legislation – the America Invents Act – failed to predict and address this phenomenon, and argues for the need to consider end user status in any reform regarding fee shifting in patent litigation. This article was selected to represent patent law scholarship at the inaugural Intellectual Property Scholarship Symposium at the 29th Annual ABA Intellectual Property Section Conference. Professor Bernstein also presented this paper at the Patcon4 conference at the University of San Diego School of Law, the Intellectual Property and Information Law Colloquium at Cardozo Law School, the Tri-State Region Intellectual Property Colloquium at New York University School of Law, and at the Haifa University Faculty of Law Technology and Law Colloquium. The article was also featured on the PatentlyO and IPWatchdog blogs.

Another article, *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. Professor Bernstein presented this paper 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. She is currently working on another article that examines end users' standing to sue in patent litigation.

A second project explores 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, *Unintended Consequences: Prohibitions on Gamete Donor Anonymity and the Fragile Practice of Surrogacy,* was published as a symposium piece in the INDIANA HEALTH LAW REVIEW. Professor Bernstein 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 the Sandra Day O'Connor College of Law.

This year, Professor Bernstein chaired the Section on Privacy and Defamation of the Association of American Law Schools (AALS). At the AALS annual meeting she organized and moderated a panel on the privacy rights of children against their parents.



Kathleen M. Boozang

Associate Dean for Academic Advancement and Professor of Law

Kathleen Boozang's current primary scholarly focus is a compliance casebook, tentatively titled *Healthcare Compliance: Avoiding Corruption*, to be published by Carolina Press. The book focuses on global and domestic laws as well as professional codes directed at eliminating corporate corruption in the health and life sciences sectors. Seton Hall Law's

continued curricular expansion in compliance education enables the school to be a prime breeding ground for the development of classroom materials in the area. As part of the compliance track of Seton Hall Law's J.D. Health Law concentration, Dean Boozang taught a class in compliance skills in Spring 2014, demonstrating the skills that comprise the "7 Elements" of compliance, including auditing, monitoring, internal investigation, policy development and training. The students enjoyed using the vast trove of "Bridgegate" documents available online to plan internal investigation strategies on behalf of the multiple state and federal government investigations. Also popular were their audits of each law school department to determine the departments' knowledge of and compliance with Seton Hall University's record retention policy. Dean Boozang's new book enterprise will also benefit from the Center for Health's expansion of its healthcare compliance training programs into Eastern Europe (Prague), Asia (Singapore), and the U.S. (San Francisco). Unlike the Newark, New Jersey-based training, which views compliance through the lens of larger multinational pharmaceutical and medical device companies, the Life Sciences Compliance Certificate Program launched this September in San Francisco focuses on issues confronting small companies, which may not yet have an approved product, or may have only one product. Many of these innovative life sciences companies are backed by venture capital or private equity, and have significantly fewer resources available for healthcare compliance than larger companies.

Otherwise, Dean Boozang has devoted her time to growing the Law School's Division of Online Learning, which offers graduate degrees and certificates in health and hospital law and compliance, labor and employment law, life sciences law and compliance, intellectual property law, and soon, cybersecurity law. Dean Boozang also co-chaired a subcommittee of the Law School's overall strategic planning committee, which focused on new strategic initiatives for the Law School over the next several years.

Carl H. Coleman

Professor of Law and Academic Director, Division of Online Learning

Carl Coleman specializes in the legal, ethical and public policy implications of medical treatment, research and public health. Over the past year, he published an article on improving the quality of host country ethical oversight of international research in DEVELOPING WORLD BIOETHICS, a chapter on international issues in drug and device law in the *American Health Lawyers Association's Fundamentals of Life Sciences Law* (2d ed.) (with Simone Handler-Hutchinson), and a comment on the Second Circuit's decision in U.S. ex rel. *Fair Laboratory Practices Associates v. Quest Diagnostics* for the REVUE INTERNATIONALE DE LA COMPLIANCE ET DE L'ETHIQUE DES AFFAIRES. His chapter on The Common Rule is forthcoming in the *International Encyclopedia of Social and Behavioral Sciences (2d ed.).*

Professor Coleman works regularly as a consultant to the World Health Organization (WHO) on projects related to ethics and public health. Ongoing projects include the development of international guidelines on ethical issues in public health surveillance and on medical criteria for the determination of death, a global survey of national systems for the emergency use of unapproved drugs, the development and testing of indicators to assess the quality of research ethics systems, and the creation of English and Frenchlanguage training programs on clinical trials legislation. In addition, over the



past year he presented at a WHO consultation on the harmonization of clinical trials oversight (Entebbe, August 2014), the European Healthcare Compliance Certification Program (Prague, June 2014 and Paris, November 2013), the TB Union Ethics Advisory Meeting (Paris, October 2013), and the International Society of Healthcare Ethics and Compliance Professionals (London, September 2013). During the Fall 2013 semester he taught a graduate seminar on Compliance in Healthcare at the Université de Cergy-Pontoise in Cergy-Pontoise, France.

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.

In the past year, Professor Greenwood published an article, *Physician Conflicts of Interest in Court: Beyond the "Independent Physician" Litigation Heuristic*, in the GEORGIA STATE UNIVERSITY LAW REVIEW, and an essay, *From "Recycled Molecule" to Orphan Drug: Lessons from Makena*, in the book, *New and Enduring Challenges for FDA: Selected Essays on the Future of the Agency and its Regulation of Drugs and New Technologies*, which is forthcoming from the Columbia University Press. She co-authored two policy briefs, *The Sentinel Project: The ACA's Marketplace Reforms and Access to Care* and *New Jersey's Medicaid ACO Pilot Program, Past and Future: A Baseline Report*, with colleagues from Seton Hall Law, and she co-authored a chapter on medical science liaisons for the 2014 edition of the Food and Drug Law Institute's book, *Off-Label Communications: A Guide To Sales & Marketing Compliance*, with Deborah L. Shuff.

Since September 2013, Professor Greenwood has served as Faculty Editor of Seton Hall Law's Health Reform Watch blog, and she

is also a regular contributor. In December 2013, her blog post *The Co-Pay Coupon Controversy: Time for Détente?* was quoted in a Southern District of New York decision, AFSCME Dist. Council 37 v. Bristol-Myers Squibb. Her post Kaiser v. Pfizer and the Question of Who Pays When Fraudulent Pharmaceutical Promotion Has



Its Intended Effect led to invitations to present at a webinar in February 2014 sponsored by the American Bar Association's Antitrust Section and at a webinar in June 2014 sponsored by the Association of Corporate Counsel. Professor Greenwood also presented *The First Amendment and the Life Sciences Industry* at the SETON HALL CIRCUIT REVIEW'S Symposium on Emerging Important Issues in the Circuit Courts and *New Jersey Medicaid's Accountable Care Demonstration Project: Blueprint for Success* at the 2014 ASLME Health Law Professors conference held at University of California, Hastings College of Law.

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 access, health finance, disability and mental health law. Over the past year, Professor Jacobi published an article, titled *Medicaid Evolution for the 21st Century*, in a symposium issue of the KENTUCKY LAW JOURNAL. He also issued a report, coauthored by Professors

Kate Greenwood and Tara Adams Ragone, *The Sentinel Project: The ACA's Marketplace Reforms and Access to Care*, as part of a multi-year project funded by the Robert Wood Johnson Foundation. In addition, he published two briefs analyzing the future of Medicaid accountable care organizations in New Jersey as part of a project funded by the New Jersey Health Care Quality Institute. The briefs were *New Jersey's Medicaid ACO Pilot Program: Moving Forward* and *New Jersey's Medicaid ACO Pilot Program: Moving Forward* and *New Jersey's Medicaid ACO Pilot Program: Moving Forward* and *New Jersey's Medicaid ACO Pilot Program, Past and Future: A Baseline Report*, the latter co-authored with Professors Greenwood and Ragone.

This year, Professor Jacobi participated in a panel discussion on Moving from Enrollment to Access at a program of Health Care NJ examining the implementation of the Affordable Care Act. He also presented on The Mental Health Conundrum Revisited at the annual meeting of the American Health Lawyers' Association in New York, and participated as a panelist on inducements to beneficiaries of public programs at a Convener Session of the American Health Lawyers' Association in Washington, D.C. He participated in a panel discussion on Big Data and Privacy at the Woodrow Wilson School of Princeton University and on HCP Vaccine Mandates: Solutions, Options, and Challenges Ahead at the NYU Langone Medical Center in New York. He presented several times on New Jersey's Medicaid Accountable Care Organizations Pilot. Professor Jacobi also continues to serve as the Vice Chair of the Board of Directors of the Greater Newark Healthcare Coalition, a non-profit organization dedicated to improving healthcare for poor residents of the Newark region, and as Vice 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. His 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 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,* 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 Faculty Director of the Gibbons Institute of Law, Science & Technology

David Opderbeck focuses on the regulation of access to scientific and technological information. His most recent published work includes two articles on social relations theory and intellectual property, *Social Network Analysis of Trade Secrets and Patents as Social Relations*, 41 AIPLQ 355 (2013), and *Beyond Bits, Memes and Utility Machines: A Theology of* Intellectual Property as Social Relations, 10 U. ST. THOMAS L.J. 738 (2013); a paper on neuroscience, law, and the philosophy of mind, *The Problem With NeuroLaw*, 58 ST. LOUIS U. L.J. 497 (2014); and a paper on special courts to evaluate targeted drone strikes, *Drone Courts*, 44 RUTGERS L.J. 413 (2014). Professor Opderbeck has also been active in public lectures and continuing education programs on cybersecurity law, including programs with the Practicing Law Institute, the New Jersey Prosecutor's College and the New Jersey Attorney General's In-Service Training.

Jordan Paradise

Schering-Plough Professor in Health Care Regulation and Enforcement

Over the 2013-14 academic year, Jordan Paradise taught Food and Drug Law, Administrative Law, and a Law and Genetics advanced writing seminar. Professor Paradise published several pieces in various science, technology, public health, and law venues including No Sisyphean Task: The FDA Can Utilize the Tobacco Control Act to Regulate Electronic Cigarettes, 13 YALE J. HEALTH POL'Y, L. & Ethics 326 (2013); Electronic Cigarettes: Smoke-Free Laws, Sales Restrictions, and the Public Health, 104 AM. J. PUB. HEALTH e17 (2014); Introduction to Biologics, Chapter 3 in The Fundamentals of Life Sciences Law: Drugs, Devices, and Biotech (American Health Lawyers Association, 2014); and Return of Research Results, in Encyclopedia of Bioethics, 4TH ED., Bruce Jennings, Ed. (Macmillan, 2014). She was also a regular contributor to Seton Hall's Health Reform Watch blog on topics such as electronic cigarettes, federal preemption and the FDA's proposed changes to CBE-0 regulations, state substitution laws for biosimilar biologics, the BRAIN Initiative, the new OpenFDA database, and the Supreme Court's June 2014 decision in Alice Corp. v. CLS Bank.

Among her speaking engagements this past year, Professor Paradise

presented Is One of These Things Not Like the Other?: Biosimilar Naming and Substitution Challenges at the 37th Annual American Society of Law, Medicine and Ethics Health Law Professors conference held at University of California, Hastings College of Law in San Francisco; FDA Hot Topics, at Sidley Austin's Life Science College in



New York; *Nanotechnology Law & Policy* at Earthjustice in New York; and *The BRAIN Initiative: Law, Policy, & Ethics* at several undergraduate institutions including the New Jersey Institute of Technology, Lafayette College and Lehigh University.

Professor Paradise served as a member of the Association of American Law Schools' Biotech Law section, the American Bar Association's Science and Technology Law section, and as a member of the Food & Drug Law Institute. She was also promoted to full professor with tenure and awarded the Schering-Plough Professorship.

Tara Adams Ragone

Research Fellow & Lecturer in Law

Tara Adams Ragone writes on a variety of health law topics including implementation of health care reform, accountable care organizations, and prescription drug abuse. She is the project manager of two grant-funded projects for the Center for Health. First, she is working with Professors John Jacobi and Kate Greenwood as well as Renee Steinhagen, Executive Director of New Jersey Appleseed Public Interest Law Center on The Sentinel Project, a project funded by the Robert Wood Johnson Foundation, to assess New Jersey health plans' compliance with the essential health benefits requirement. Second, she managed a project evaluating the sustainability of New Jersey's Medicaid Accountable Care demonstration project for the New Jersey Healthcare Quality Institute, with funding from the Nicholson Foundation.

Professor Ragone also shared her expertise with various government and non-profit entities. She led a session concerning the legal and policy challenges presented by prescription drug monitoring programs for the National Attorneys General Training & Research Institute's Public Health Law Fellows. Professor Ragone also taught a health law legal ethics session for the New Jersey Division of Law. She is a member of the legal committee of the Good Care Collaborative, a coalition working to propose sensible Medicaid reform in New Jersey. In her scholarship, Professor Ragone explores various health law issues. Her article with Professor Frank Pasquale, *Protecting Health Privacy in an Era of Big Data Processing and Cloud Computing*, was accepted for publication in the STANFORD TECHNOLOGY LAW REVIEW. She also issued two reports coauthored by Professors Jacobi and Greenwood,



entitled The Sentinel Project: The ACA's Marketplace Reforms and Access to Care and New Jersey's Medicaid ACO Pilot Program, Past and Future: A Baseline Report.

Professor Ragone also continues to build strong relationships with Seton Hall Law's students. In addition to teaching a health law skills class, Professor Ragone worked closely with two student teams, one that won the National Health Law Moot Court Competition, and one that won the University of Maryland Law School's Health Care Regulatory and Compliance Competition. Professor Ragone is working with Professor Paradise to launch a Washington, D.C. health law externship program in Spring 2015.

Students & Alumni On the Move

Julia Belton, JD '15 completed a summer internship in Regulatory Advertising & Promotion and Risk Management with Novartis in East Hanover, New Jersey.

Michael Briganti, JD '08 joined Ernst & Young as Manager -Fraud Investigation & Dispute Services in Iselin, New Jersey.

Jason Cetel, JD '12 was awarded the 2013 Larry M. Simonsmeier Writing Award by the American Society for Pharmaceutical Law for his paper, "Disease-Branding and Drug-Mongering: Could Pharmaceutical Industry Promotional Practices Result in Tort Liability?"

Tamara Coley, JD '10 (*pictured, right*) was named to the Lawyers of Color's Second Annual Hot List, which recognizes early-to mid-career attorneys excelling in the legal profession.



Michellene Davis, JD '95 was named Executive Vice President, Corporate Affairs for Barnabas Health in Livingston, New Jersey.



Phillip DeFedele, JD '15 (*pictured, left*) is a legal intern at The Medicines Company in Parsippany, New Jersey.

David A. DeSimone, JD '95 was named Senior Vice President, Organizational Transformation and Chief Legal Officer with CentraState Healthcare System in Freehold, New Jersey.

Joseph P. Farano, JD '07 became General Counsel to MetTel, a telecommunications services company in New York.

Constantina Koulosousas, JD '10 was recognized as one of 2014 New Leaders of the Bar by the *New Jersey Law Journal*.

David C. Gibbons, JD '12 joined Hyman, Phelps & McNamara, P.C. as an Associate in Washington, D.C.

Eric Welsh Gross, JD '05 became Vice President, Legal and Compliance at Vitals.com in Lyndhurst, New Jersey.

Maritza Hodavance, MSJ '12 is Director, Medical Staff Affairs, CarePoint Health at Hoboken University Medical Center in Hoboken, New Jersey.

Samantha Lansdowne, MSJ '10 is Manager (I&I), Scientific Education for Celgene in Summit, New Jersey.

Kerrie L. (Cozic) Nagrod, MSJ '10 became Associate Director, Regulatory Affairs at Daiichi Sankyo in Edison, New Jersey.

Mollie K. O'Brien, JD '94 (*pictured, right*) is a Member of the Firm in the Health Care and Life Sciences practice of Epstein Becker Green, P.C. in Newark, New Jersey.



Blair Palmisano, JD '13 is an Associate in the healthcare group of Archer & Greiner in Princeton.

Angie Sim, MSJ '15 is Regional Director for Asia-Pacific and has been seconded to the Corporate Internal Audit Department for Johnson & Johnson Pharmaceutical Research & Development in Singapore.

Jean Sposaro, MSJ '15 has accepted an R&D Science Policy Preceptorship at Sanofi. She is Global R&D Process Project Manager, Quality Process Optimization, Clinical Sciences & Operations, Quality & Continuous Improvement at sanofi in Bridgewater, New Jersey.

Leslie Strohmeyer, MSJ '11 is Manager, Contract Specialist at Janssen R&D in New Jersey.

Colleen Tracy James, JD '96 joined Mayer Brown LLP as a Partner in the Intellectual Property Law practice in New York.

Seton Hall Law Teams Take First Place in Key Health Law Competitions



Seton Hall Law students emerged victorious in two prestigious health law competitions in the 2013-14 academic year.

In November 2013, Seton Hall Law School's Interscholastic Moot Court Board took First Place at the National Health Law Moot Court Competition, held at the Southern Illinois University School of Law in Carbondale. Alex Silagi '14 was awarded both Best Preliminary Round Oralist and Best Overall Oralist in the competition, and the team won Second Best Brief.

In February 2014, Seton Hall Law captured first place in the 3rd Annual University of Maryland Law School's Health Law Regulatory and Compliance competition. Team members included Lindsay Borgeson '14, Joyce Crawford '14, Phillip DeFedele '15 *(pictured, from left)* and alternate Cynthia Frumanek '14.

"The competition as a whole was an excellent experience," DeFedele said of the Regulatory and Compliance competition. "The professors, staff and student volunteers were personable and helpful. Most importantly, being able to prove ourselves to professionals, and to have them acknowledge the work we did, was incredible. I highly recommend students with a passion for health law and compliance to try out for this competition next year."

The teams were coached by health law Professors Carl Coleman, Jordan Paradise and Tara Ragone, with support from Moot Court Director Jodi Hudson and John Barry '13 .

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 Garfunkel Wild, P.C.

Janice Chapin Deputy Director Central Jersey Legal Services

Frank Ciesla Shareholder Giordano, Halleran & Ciesla, P.C.

Patrick DeDeo Director of External Relations William Paterson University-Hobart Manor

Joseph Fennelly, M.D. Internist

Alice Guttler Former Sr. Vice President & Corporate Counsel CentraState Healthcare System Gary Herschman Member Sills Cummis & Gross P.C.

Michael Kalison Of Counsel McElroy, Deutsch, Mulvaney & Carpenter, LLP

George Kendall Partner Drinker Biddle

Vivian Sanks King '85 Attorney-at-Law Law Offices of Vivian Sanks King

Edward Kornreich Partner Proskauer Rose LLP

Gary J. Lesneski Senior Executive Vice President/General Counsel The Cooper Health System

Michael B. McCulley Distinguished Practictioner-in-Residence Seton Hall University School of Law

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

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 W. 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 The Medicines Company

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

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

Gaia Bernstein Professor of Law and Margaret Gilhooley 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 DiGiorgio Vice President, Intellectual Property Comcast Elaine Drager Law Vice President, Intellectual Property Alcatel-Lucent

Patrick C. Dunican Jr. '91 Chairman & Managing Director Gibbons P.C.

Gregory Ferraro Senior Patent Attorney Novartis Pharmaceuticals Corporation

Henry Hadad Vice President and Deputy General Counsel Bristol-Myers Squibb

Patrick E. Hobbs Dean and Professor of Law Seton Hall University School of Law

George W. Johnston, Jr. Counsel, Intellectual Property Gibbons P.C. Former Vice President and Chief Patent Counsel 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 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 Member Saìber Attorneys at Law

Michael F. Schaff Shareholder Wilentz, Goldman & Spitzer P.A.

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

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

Jordan Paradise Schering-Plough Professor in Health Care Regulation and Enforcement Seton Hall University School of Law

Henry J. 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 James '96 Partner Mayer Brown LLP

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 Professor Kate Greenwood, Editor, at kate.greenwood@shu.edu or call 973-642-8277.



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UPCOMING Events 2014 – 15

OCTOBER 7, 2014 Gibbons Institute and NJIPLA's 12th Annual Fall Lecture Series: Views from the Bench featuring The Honorable Grace Obermann, Lead Administrative Patent Judge, USPTO, Patent Trial and Appeal Board law.shu.edu/GibbonsInstitute

OCTOBER 13-16, 2014 U.S. Healthcare Compliance Certification Program Newark, NJ law.shu.edu/Compliance

OCTOBER 23, 2014 Celebration of Women in IP Law Sponsored by the Gibbons Institute and Gibbons P.C. law.shu.edu/GibbonsInstitute

OCTOBER 30, 2014 Porzio Annual Compliance Forum: Uncharted Compliance Waters Newark, NJ RSVP: 973-642-8871

NOVEMBER 13, 2014 Cybersecurity CLE with the **U.S. Attorney General's Office** law.shu.edu/GibbonsInstitute

NOVEMBER 17-20, 2014 European Healthcare Compliance Certification Program Paris. France law.shu.edu/Compliance

DECEMBER 2. 2014 Cybersecurity CLE with the law.shu.edu/GibbonsInstitute

JANUARY 22, 2015 Compliance Professionals Networking Reception RSVP: 973-642-8871

JANUARY 27, 2015

Annual Federal Circuit Year in Review CLE law.shu.edu/GibbonsInstitute MARCH 9-12, 2015 **Asia-Pacific Healthcare Compliance Certification Program** Singapore law.shu.edu/Compliance

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JUNE 1-4, 2015 **European Healthcare Compliance Certification Program** Paris. France law.shu.edu/Compliance

JUNE 8-11, 2015 **U.S. Healthcare Compliance Certification Program** law.shu.edu/Compliance

SEPTEMBER 2015

Life Sciences Compliance Program West Coast Immersion San Francisco, CA law.shu.edu/Compliance