





ELA BOCHENEK

Vice President and Associate General Counsel NPS PHARMACEUTICALS

Ela Bochenek is Vice President and Associate General Counsel at NPS Pharmaceuticals, Inc., a global biotech orphan drug pharmaceutical company, where she is in charge of the international law department. Prior to joining NPS, Ms. Bochenek was Associate General Counsel - International for C.R. Bard, Inc., a New Jersey-based multinational medical device company, where she was responsible for providing legal oversight and counsel to all of Bard's international operations on a variety of commercial and compliance matters.

Before joining Bard, Ms. Bochenek was a member of the International Legal Departments of Schering-Plough and Bristol-Myers Squibb Company, where she provided general legal support to the companies' pharmaceutical operations worldwide. Prior to that, she practiced at two Philadelphia law firms, Morgan, Lewis & Bockius and Pepper, Hamilton & Sheetz, as a general corporate attorney with a concentration in international business transactions.

After graduating from law school, Ms. Bochenek spent a year working for the World Bank in Warsaw, Poland. Her law degree is from the University of Pennsylvania Law School, where she was a member of the Law Review. In 2009, Ms. Bochenek won the Global Counsel Award 2009 in the Best Individual Commercial Lawyer category; the award is sponsored by the International Law Office and the Association of Corporate Counsel.

REGINA CAVALIERE

Vice President and Chief Compliance Officer
OTSUKA AMERICA PHARMACEUTICAL

LAURA CONWAY

Manager, Regulatory and Compliance Services; Counsel PORZIO LIFE SCIENCES AND PORZIO BROMBERG & NEWMAN



Laura C. Conway is a Manager of Regulatory and Compliance Services with Porzio Life Sciences, LLC. Ms. Conway collaborates with the company's directors, managers, and regulatory professionals to provide regulatory guidance to customers and to maintain the content of our products and services.

She shares responsibility for support of Porzio AggregateSpendID, the organization's automated tool for the collation and aggregation of marketing expenses. On this team, Ms. Conway serves

as a contact for new customers and assists in system implementation and maintenance.

Ms. Conway is also a Counsel of Porzio, Bromberg & Newman P.C. and a member of the firm's Life Sciences Compliance, Commercialization and Regulatory Counseling Department. In her capacity with the law firm, she counsels pharmaceutical, medical device, and biotechnology organizations on compliance issues, including: healthcare compliance audits; comprehensive compliance programs; FDA and state law issues; off-label issues;

compliance with PhRMA and AdvaMed codes and OIG Guidance; implementation of aggregate spend solutions; state and federal transparency and disclosure laws; PDMA; healthcare consultant contracts; and clinical trial agreements.

Ms. Conway received a J.D. from Georgetown University Law Center and her B.A., *magna cum laude*, from Boston College. Ms. Conway is AV rated by *Martindale-Hubbell*. She proudly serves on the Board of the New Jersey Women Lawyers Association.

PAUL CURTIN Head of Global Research & Development Compliance ACTAVIS

Paul Curtin is currently the Head of Global Research & Development Compliance for Actavis, plc after having served as the International Compliance Officer & Deputy Compliance Officer for Forest Laboratories, Inc. prior to its acquisition by Actavis earlier this year.

Mr. Curtin has been a Compliance professional in the pharmaceutical and life sciences industry since 2001, and has established and managed compliance programs in domestic and international markets. Prior to his career in the pharmaceutical industry, Mr. Curtin was a healthcare and regulatory attorney in private practice.

GREGORY FIORE, MD Chief Medical Officer, Founder SSI STRATEGY

Dr. Fiore was class valedictorian at New York Medical College. He trained in Internal Medicine at Harvard Medical School's Brigham and Women's Hospital, and underwent clinical training in Pulmonary and Critical Care Medicine in the Harvard Pulmonary Fellowship Program. Dr. Fiore then joined McKinsey and Company, where he worked in a variety of industries, including life sciences.

From McKinsey, Dr. Fiore joined Abbott Laboratories before becoming the Head of Global Drug Safety at The Medicines Company, where he also was Head of Alliance Management and global leader for a Phase II development program. He later served as Chief Medical Officer of The Medicines Company.

From there, Dr. Fiore became Regional Head of Pharmacovigilance at Schering-Plough, and later assumed responsibility for Clinical Risk Management for approximately half the combined Merck/Schering-Plough portfolio, spanning multiple therapy areas.

Dr. Fiore then founded a Pharmacovigilance and Medical Affairs management consulting firm called SSI Strategy and is currently Chief Medical Officer of the firm. In 2014, he also founded Fiore Healthcare Advisors to provide medically-oriented consulting and services to emerging biotech and pharmaceutical companies.

JODIE GILLON Head, External Interface Office ASTRAZENECA



Jodie Gillon serves as the Head of the External Interface Office of AstraZeneca. She manages the Global Payment Transparency and Global Conference and Meeting Teams. In addition, she oversees the Chief Medical Office, Corporate Governance and is responsible for Crisis Management for the organization.

For nine years prior to joining AstraZeneca, Ms. Gillon served as the Director, External Medical Communications with Pfizer. In addition to overseeing Communications for the Specialty Care and Emerging Markets Business units, she led an External Collaborations Alliance focused on

academic centers, publishing companies, societies, and thought leaders. As part of Pfizer's Transparency team, she played a pivotal role in implementing the PhRMA/EFPIA Principles and integrating vendors and systems after the Wyeth merger.

Prior to Pfizer, Ms. Gillon was a Global Communications lead at Novartis and led a Phase IV/IIR review board. She served as the Director of Medical Education for Oridion Medical and as a Health Economist with the Israeli Center for Disease Control and Ministry of Health. She has held additional roles in academia, advocacy, and the White House. Ms. Gillon holds a Master's of Public Health with a dual degree in Health Economics and Epidemiology and a BSFS from Georgetown's School of Foreign Service.

SANDRA GONZÁLEZ

Manager, Regulatory and Compliance Services; Associate PORZIO LIFE SCIENCES AND PORZIO BROMBERG & NEWMAN



Sandra González is a Manager, Regulatory and Compliance Services with Porzio Life Sciences, LLC. In her role, Ms. González collaborates on the creation of new products and services and the management of existing offerings. As a member of the team responsible for Porzio AggregateSpendID, the company's automated tool for the aggregation of marketing expenses, Ms. González serves as a contact for new customers and assists in system implementation and maintenance.

Ms. González is also an associate of Porzio, Bromberg & Newman, P.C. and a member of the firm's Life Sciences Compliance, Commercialization and Regulatory Counseling Department. In her capacity with the law firm, Ms. González assists in the development of compliance programs for companies governing the sale and marketing of drugs and devices and the distribution of samples under federal and state law.

Ms. González received a J.D. from Rutgers School of Law – Newark, where she was Symposium Editor of the Rutgers Race and the Law Review and a Legal Research and Writing Teaching Associate. She earned her B.A. in Political Science from SUNY New Paltz and is fluent in Spanish.

SIMONE HANDLER-HUTCHINSON

Executive Director, Center for Health & Pharmaceutical Law & Policy SETON HALL LAW SCHOOL



Simone Handler-Hutchinson specializes in the legal, regulatory, and policy issues facing the healthcare, pharmaceutical, and medical device industries. She develops educational programs and events for various components of the health care industry and oversees the Center's research and scholarship. She has numerous publications to her credit, and has served as an adjunct professor, teaching various health law courses at Seton Hall Law. Ms. Handler-

Hutchinson came to Seton Hall Law in 2007.

Ms. Handler-Hutchinson began her health law career as an associate in Brach Eichler's health law practice group in Roseland, New Jersey. She then served as the Executive Editor at Brownstone Publishers in New York City, which published several national legal newsletters. In 2004, Ms. Handler- Hutchinson joined the health law group of Schenck, Price, Smith & King, LLP in Morristown, New Jersey.

Ms. Handler-Hutchinson received her B.A. from Emory University and her J.D. from Seton Hall Law School. After law school graduation, she served as law clerk to Judge Arthur D'Italia, Assignment Judge for the Superior Court of New Jersey.

TOBY ANN HOLETZ

Global Head, Global Aggregate Spend Reporting Team QUINTILES



Toby Ann Holetz graduated with a degree in Business Management and is currently employed by Quintiles Inc. based in the Research Triangle Park, North Carolina. Ms. Holetz has been with Quintiles for more than 15 years, and has experience in CRM system implementation, balanced scorecards, strategy map creation, and communications. She is currently the Sarbanes-Oxley Control owner for all global Clinical Revenue and is the Global Head of Quintiles' Payment Transparency Program.

Within her role as the head of the transparency program, Ms. Holetz is responsible for working directly with customers to deliver on requirements, managing internal resources and systems, developing processes to accurately document and capture data for reporting, and managing the communication and training plans.

JOHN JACOBI Faculty Director, Center for Health & Pharmaceutical Law & Policy SETON HALL LAW SCHOOL



Professor Jacobi received B.A., summa cum laude, from the State University College of New York at Buffalo and his J.D., magna cum laude, from Harvard Law School. He teaches in the areas of Health Law, Health Finance, Disability Law, Public Health Law, Mental Health Law, and Torts. Professor Jacobi spent five years working for the New Jersey Department of the Public Advocate as Special Assistant to the Commissioner, where he worked on health, civil rights, and disability issues through litigation and advocacy in the legislature and regulatory agencies. He then became a Gibbons Fellow at the Gibbons firm, where he pursued health, prisoners' rights, and

disability issues. During 2007-2008, he was on leave from the law school, serving as Senior Associate Counsel to N.J. Governor Jon S. Corzine on Health, Human Services, and Children's Issues. He serves on the Board of the Greater Newark Healthcare Coalition, and the North Jersey Community Research Initiative, an HIV service organization.

Professor Jacobi writes and speaks on issues including disability rights, health access and finance, public health, and mental health. His recent and current scholarly projects include the application of the health reform law to the poor and people with disabilities, state implementation of Medicaid and private health insurance reform, the improvement of chronic care in health systems, the funding and structure of services for children with disabilities, the obligations of government to provide services to people with serious mental illness, and the clash of disability rights and public health interests. He served on the Governor's Task Force on Mental Health, the Board of Advisors of the New Jersey Office of Child Advocacy, the New Jersey Olmstead Advisory Council on disability rights, and on other government and non-profit boards and committees. He is Faculty Director of the Seton Hall Health & Pharmaceutical Law & Policy Program.

HOLLY KRAMEN

Vice President; Principal
PORZIO LIFE SCIENCES AND PORZIO BROMBERG & NEWMAN

Holly K. Kramen is a Vice President of Porzio Life Sciences, LLC (PorzioLS). As a former in-house counsel, compliance officer and commercial business leader, Ms. Kramen has substantial hands-on experience in creative solutions for commercial success in the life sciences industry. She has lived the challenges and best practices of building compliance programs in life sciences companies of all sizes, where she has designed, led, and implemented a spectrum of initiatives. Those initiatives included assessment, remediation, policy creation and revision, training, procedures, and monitoring across the corporate enterprise, as well as building and implementing aggregate spend systems for reporting under federal and state laws. Ms. Kramen joins the team in overseeing PorzioLS personnel, quality assurance, and marketing efforts.

Ms. Kramen is also a principal of Porzio, Bromberg & Newman P.C. and a member of the firm's Life Sciences Compliance, Commercialization and Regulatory Counseling Department. Her legal practice is focused on counseling diagnostic, medical device, biotech, and pharmaceutical clients on regulatory and compliance issues related to sales, marketing, and medical affairs in all types of matters ranging from promotion to privacy to structuring corporate spending and developing efficient and effective operations and training.

Prior to joining PorzioLS, Ms. Kramen was General Counsel, Americas and U.S. Compliance Officer & Privacy Officer for a midsize medical device company specializing in GI diagnostics, where she was responsible for building, leading, and executing all legal and compliance functions and operations for the Americas. Ms. Kramen's experience includes leadership positions in sales and marketing operations at Pfizer, where she played key roles on multiple product launches and sales force initiatives and was the creator and co-author of the first pharmaceutical compliance manual (the Pfizer "Orange Book") and aggregate spend system. She later held the position of Senior Director of Global Compliance at Gilead Sciences and spent several years in multiple consulting roles.

Ms. Kramen received her J.D. from Quinnipiac University in Connecticut and her B.A. from Barnard College in New York.

JOHN LAROCCA Vice President, Deputy General Counsel ACTAVIS



John LaRocca currently serves as Vice President, Deputy General Counsel for Actavis, plc. in Parsippany, N.J. Actavis is a global specialty pharmaceutical company with operations in over 60 countries and with over 17,000 employees world-wide, and over \$16B in revenues and a market cap in excess of \$60B (ACT/NYSX).

Mr. LaRocca directly manages all legal support and staff in the United States, Canada, and Latin America in support of Actavis' businesses in both branded and generic pharmaceuticals. He

assumed this role in November of 2012, after the acquisition of Actavis Group hf by Watson Pharmaceuticals, Inc. Mr. LaRocca at that time was the Chief Legal Officer of Actavis Inc., then a subsidiary of Actavis Group hf, a role he had since 2005.

Mr. LaRocca is responsible for all commercial, M&A, transactional, and regulatory legal support for the business. He also manages a portfolio of commercial litigation, including product liability law suits, pharmaceutical pricing litigations, antitrust class actions, and various other commercial and employment disputes. Since October 2012, Mr. LaRocca has been part of a team of senior Actavis executives responsible for completing approximately \$35B of corporate acquisitions that dramatically altered the composition of the company. In June 2011, Mr. LaRocca managed the team representing Actavis' subsidiary Actavis Elizabeth LLC (formerly Purepac Pharmaceuticals) as one of the two generic manufacturers arguing in the U.S. Supreme Court case *Pliva v. Mensing*, which resulted in a 5-4 decision for the generic pharmaceutical industry shielding those manufacturers from liability for failure to warn claims based upon the content of pharmaceutical labeling.

Mr. LaRocca established and chaired the Actavis's Compliance Committee to monitor and manage the business' compliance with various regulatory issues in the United States, and he implemented systems for the management of contracting processes in compliance with Sarbanes Oxley requirements. He also implemented company-wide training on corporate ethics, harassment, compliance with applicable laws, and other areas of legal risk.

Prior to his work in the pharmaceutical industry, Mr. LaRocca worked as a mergers and acquisitions and corporate finance attorney in New York City for Parker Duryee Rosoff & Haft. While there, he represented publicly traded and privately held companies in a variety of industries including pharmaceuticals, retail, advertising and branding, gaming and resorts, software development, sports and entertainment, and manufacturing.

Mr. LaRocca attended law school at Columbia University, and earned a bachelor's degree at Columbia College. He was admitted to the New York Bar in 1990 and is a member of the American Bar Association as well as the Bar Association of the City of New York.

CHRISTINE MIKAIL

Senior Vice President, Legal Affairs, General Counsel, and Secretary NPS PHARMACEUTICALS



Christine Mikail joined NPS Pharmaceuticals in March 2014, with extensive experience in public company representation, business development, and pharmaceutical law. In her role, she is responsible for overseeing all global legal and compliance matters. Before joining NPS Pharmaceuticals, Ms. Mikail was executive vice president, corporate development, as well as general counsel, chief compliance officer and corporate secretary at Dendreon Corporation. While at Dendreon, she built and led a bi-coastal legal and compliance team, as well as a business development team.

Previously, she held senior corporate development and legal positions with Savient Pharmaceuticals, ImClone Systems and Eli Lilly. Ms. Mikail began her legal career working at several prominent law firms, where she counseled on corporate and securities law, regulatory, licensing, financings, and M&A activities on behalf of public and private companies.

She received her bachelor's degree, *cum laude*, from Rutgers University and her J.D. from Fordham University School of Law.

JOHN OROHO

Executive Vice President, Chief Strategy Officer; Principal Porzio Life Sciences and Porzio Bromberg & Newman



John Patrick Oroho, Executive Vice President and Chief Strategy Officer of Porzio Life Sciences, LLC, meets regularly with companies to identify sales and marketing issues and to propose solutions that streamline their practices in meeting compliance requirements of all 50 states and the District of Columbia.

Mr. Oroho is also a principal of the law firm, Porzio, Bromberg & Newman P.C., and practices in the Life Sciences Compliance and Commercialization Department. He concentrates his law

practice in regulatory compliance with respect to the Prescription Drug Marketing Act (PDMA), Anti-kickback statute, False Claim Act, and Medicare and Medicaid fraud and abuse.

Mr. Oroho previously served as Senior Vice President and General Counsel for the PDMA Alliance, a national trade association focused on sample distribution and pharmaceutical marketing and sales compliance.

Mr. Oroho has an extensive pharmaceutical regulatory and compliance background. He spent three years as General Counsel for Integrated Pharma Technologies and Computer Systems Services & Consulting, Inc.

Mr. Oroho received a J.D. from the University of Notre Dame School of Law in 1985 and a B.S. from the United States Merchant Marine Academy, where he graduated, with honors, in 1978.

JENNIFER A. ROMANSKI

Vice President and Chief Privacy Officer; Principal PORZIO LIFE SCIENCES and PORZIO BROMBERG & NEWMAN



Jennifer A. Romanski is Vice President and Chief Privacy Officer of Porzio Life Sciences, LLC. In collaboration with the other Directors of Regulatory and Compliance Services, Ms. Romanski is responsible for ensuring that all products are relevant to the needs of the industry and working with other personnel to create new products.

Ms. Romanski is also a principal of Porzio, Bromberg & Newman P.C. and a member of the firm's Life Sciences Compliance and Commercialization team. Ms. Romanski counsels

pharmaceutical and device manufacturers on federal and state fraud and abuse laws, sampling compliance, and state disclosure and prohibition laws. She develops policies and procedures and conducts training programs for clients, in connection with their comprehensive compliance programs. She evaluates grants and contributions, drug and device advertising and promotion, and marketing activities directed to healthcare professionals. Additionally, Ms. Romanski provides general business counseling on contractual issues.

Ms. Romanski received a J.D. from University of Pennsylvania Law School in 1997. She earned her B.A. in Biological Basis of Behavior, *cum laude*, from University of Pennsylvania in 1994.

BRIAN SHARKEY

Director of Regulatory and Compliance Services; Counsel Porzio Life Sciences and Porzio Bromberg & Newman



Brian P. Sharkey is a Director of Regulatory and Compliance Services with Porzio Life Sciences, LLC. Mr. Sharkey collaborates with company directors, managers, and regulatory professionals to maintain the content of our products and services.

Mr. Sharkey focuses on international transparency laws, codes, and regulations affecting the life sciences industry. Specifically, he analyzes the reporting obligations that companies have under governmental regulatory schemes or industry self-regulation in countries outside the United

States, and counsels clients on how to comply with them. Mr. Sharkey has also been involved in the development of Porzio's International Life Sciences Transparency Database, and has written and spoken extensively on the topic of international transparency.

Mr. Sharkey is also a Counsel of Porzio, Bromberg & Newman PC, and a member of the firm's Life Sciences Compliance and Commercialization Department, is co-chair of the Appellate Practice Group, and serves as Director of Compliance and Legal Affairs for Porzio Governmental Affairs, LLC. In his capacity with the law firm, he concentrates his practice on product liability, mass tort, and governmental affairs.

Mr. Sharkey received his J.D. from Seton Hall University School of Law, *magna cum laude*, and his B.A. from The College of New Jersey. Mr. Sharkey is recognized on the New Jersey Super Lawyers "Rising Stars" List, 2007, 2009 - 2013. He is also a co-author on, "Getting the Deal Through - Life Sciences 2013," United States Chapter, published by Getting the Deal Through, 2013.

PHILIP YACHMETZ

Former Co-President, Chief Business Officer & General Counsel SAVIENT PHARMACEUTICALS



Philip K. Yachmetz has served in senior level legal and compliance positions with both large pharmaceuticals and early commercial stage biopharmaceutical companies for more than 33 years, most recently serving as Co-President, Chief Business Officer & General Counsel at Savient Pharmaceuticals, Inc., where his responsibilities included legal, intellectual property, SEC, and pharma compliance and risk management, as well as certain business functions. While at Savient, he directed the development of policies, collaterals, and training programs for the company's pharmaceuticals compliance program as it moved from development to commercial stage.

Mr. Yachmetz previously held senior positions with Hoffmann-La Roche, Inc., CytoTherapeutics, Inc. (StemCells, Inc.) and Progenics Pharmaceuticals, Inc.