PORZIO LifeSciences

SETON HALL | LAW

PORZIO BROMBERG&NEWMAN P.C. ATTORNEYS AT LAW

Compliance Monitoring and Risk Mitigation – Speaker Biographies
Friday, February 10, 2017

SERGIO ALEGRE

Vice President, Global Compliance
Osmotica Pharmaceutical | Vertical Pharmaceuticals | Trigen Laboratories

Sergio is Vice President, Global Compliance for Osmotica Pharmaceutical and its subsidiaries. He is responsible for all aspects of Global Compliance, ensuring that the Company continues to build and enhance its Compliance Program and complies with all federal and state regulations. Sergio also serves as a member of the Company's Executive Committee. Sergio has over 15 years of corporate legal and compliance experience acquired in various business and legal organizations, including private and publicly traded companies, as well as at a Wall Street law firm.

KATHLEEN BOOZANG

Dean and Professor of Law
SETON HALL LAW SCHOOL

Kathleen Boozang has been Dean of Seton Hall Law since July 2015. She has served in multiple administrative capacities during her tenure at Seton Hall, including Associate Dean for Academic Affairs for eight years and Vice Provost for two years.

Dean Boozang came to Seton Hall in 1990 as the founder of the Law School's now top-ranked Center for Health & Pharmaceutical Law & Policy. Prior to becoming Dean, she also established the Law School's graduate degrees, Division of Online Learning and global life sciences compliance training programs.

Dean Boozang teaches a variety of health law courses in person and online including the survey health law course, a course on health care fraud and corruption, and death and dying. In her scholarship, Dean Boozang has dedicated much of her career to nonprofit governance issues with a special focus on religiously sponsored hospitals. In the last several years, however, she has expanded her research and teaching to explore the legal and policy issues related to corporate compliance, with a particular focus on the global life sciences industry.

Throughout her legal career, Dean Boozang has been active in public service. She has served on numerous advisory boards and committees for healthcare providers and for the states of New Jersey and New York, including serving as an advisor to the New Jersey Attorney General Task Force on Physician Compensation by Pharmaceutical Companies, which resulted in the promulgation of proposed regulation. She is a former member of the New York State Task Force on Life and the Law, an interdisciplinary commission with a mandate to develop public policy on bioethical issues.

Dean Boozang currently serves on the Board of Trustees of the St. Joseph Healthcare System in New Jersey. In 2013, the ASLME conferred upon Dean Boozang the Jay Healy Health Law Teacher Award. She was named the Seton Hall University Woman of the Year in 2006 and the Washington University Law School's Young Alum of the Year in 2004.

She received her B.S. from Boston College and her J.D. from Washington University School of Law in St. Louis, Missouri, where she was inducted into the Order of the Coif and served as the managing editor of Law Quarterly. She received her LL.M. from Yale Law School in 1990.

Christine N. Bradshaw

Vice President; Principal

PORZIO LIFE SCIENCES AND PORZIO BROMBERG & NEWMAN

Christine Bradshaw is a Vice President with Porzio Life Sciences, LLC. In her role, Ms. Bradshaw oversees the development, implementation and support of Porzio AggregateSpendID, the company's automated tool for the collection and reporting of payments to healthcare professionals (HCPs) and healthcare organizations (HCOs).

She serves as a primary point of contact for new customers, analyzes customer reporting requirements, and directs system design and implementations. Further, in collaboration with the other Regulatory and Compliance Services Managers and Directors, Ms. Bradshaw is responsible for ensuring that all products are accurate, current and relevant to the needs of the industry. She strives to provide our customers with practical guidance and strategies for managing compliance and regulatory challenges.

Ms. Bradshaw is also a principal with Porzio, Bromberg & Newman P.C. and a member of the firm's Life Sciences Compliance and Regulatory Counseling Department. She served as a judicial clerk for the Honorable Gail L. Menyuk of the New Jersey Tax Court during the 2006-2007 term.

Ms. Bradshaw received her J.D., cum laude, from American University's Washington College of Law, where she was the Publications Editor of the American University Journal of Gender, Social Policy & the Law. She earned her B.A. in Environmental Sciences and Policy from Duke University.

ED CROWE

Vice President

PORZIO LIFE SCIENCES

Ed Crowe is a Vice President with Porzio Life Sciences.. He began his career in the medical device and pharmaceutical industries in 1985. Since that time, he has held senior positions in diverse businesses related to the life sciences field, including spine, total joint and trauma surgery, diagnostics, pharmaceuticals and advertising.

Mr. Crowe's specific responsibilities have spanned many functions critical to a successful enterprise and they include: marketing, sales, medical education, R&D

portfolio planning, thought leader/medical society interactions, healthcare compliance, licensing and acquisitions, and study group management.

Mr. Crowe has served on the management boards of both small and large market share companies, developing clear strategies and executing focused tactics to achieve growth. Experienced in driving the development and implementation of compliance programs, Mr. Crowe utilizes his knowledge of compliance and understanding of commercial activities to strengthen clients' operations. Specifically, he consults on healthcare compliance topics, including: anti-kickback; on-label promotion; medical/scientific communications; FCPA; aggregate spend/transparency reporting; sampling; Fair Market Value; anti-trust; conflicts of interest; and industry codes of ethics. He assists businesses in all stages of commercialization in creating compliance structures and programs appropriate for a business's current activities and scalable as the company grows. He also develops procedures aligned with business operations, thereby allowing compliance to credibly and efficiently gain buy-in throughout an organization.

Additionally, Mr. Crowe writes and edits policies, codes of ethics, HCP consulting contract templates, Business Need Assessments, and other healthcare compliance documents and forms. He works on-site to manage the implementation of healthcare compliance initiatives; performs risk assessments; audits existing compliance programs and recommends practical corrective actions and improvements; establishes metrics to measure the on-going effectiveness of compliance programs; investigates allegations of individual and organizational wrongdoing; and trains clients' employees, boards of directors, 3rd party distributors and vendors with an emphasis on the points most relevant to each person's job. Mr. Crowe holds a B.A. in history and philosophy from Boston College and an MBA from the Rutgers Graduate Business School. In 2011, he was certified in Healthcare Compliance (CHC) by the Health Care Compliance Association.

CHARLENE E. DAVIS

Head of Healthcare Compliance, North America
Sun Pharmaceutical Industries, Inc.

Charlene Davis leads the development and maintenance of the U.S. comprehensive compliance program for Sun's U.S. branded commercial businesses.

Prior to her current role, Ms. Davis was Senior Compliance Counsel for U.S. affiliates of a Japanese pharmaceutical/medical device company, spending several years providing healthcare law guidance for devices, digital, and neuroscience drug products, development and maintenance of a centralized North American contact center to support the handling of medical and pharmacovigilance inquiries, development of sales force automation systems integrating compliance requirements, federal and state law reporting regarding prescription drug samples, assistance with investigations, and drafting policies and procedures on a variety of healthcare law topics. Her experience also includes supporting regulatory inspections related to pharmacovigilance compliance.

Prior to her experiences as in-house counsel for pharmaceutical companies, Ms. Davis practiced corporate defense litigation in Pennsylvania and New Jersey. Her case portfolio included matters related to healthcare, products liability, commercial disputes, white collar crime, and insurance disputes.

Ms. Davis has received various recognitions including the New Jersey Law Journal's 50 under 40 New Leaders to the Bar Award. She has accomplished both publications and speaking engagements including being the featured radio and television guest for station WIMG's program, *"Healthcare & Ethics in a Technologically Advanced Age."*

Ms. Davis is a graduate of Temple University Beasley School of Law, having received the Barrister's Award for Trial Advocacy, and Cornell University, where she received induction into the National Society of Collegiate Scholars, Cornell Chapter.

RICHARD F. ESCHLE

Corporate Ethics & Compliance
EISAI INC.

Richard Eschle is a registered pharmacist and an attorney at law. He has worked in the pharmaceutical industry for more than 15 years, and has experience implementing Corporate Integrity Agreements, state disclosure laws and federal Sunshine reporting, Fair Market Value methodology, and anti-bribery and anti-corruption policies and processes in the U.S., Mexico, and South America.

Mr. Eschle received a B.S. in Pharmacy and a Doctor of Pharmacy degree from Rutgers University College of Pharmacy, and his J.D. from Seton Hall Law School. He resides with his family in Bound Book, New Jersey, where he serves as a member of the Borough Board of Health.

LESLIE GLADSTONE RESTAINO

General Counsel
Validus Pharmaceuticals LLC

Leslie Gladstone Restaino is a life sciences attorney and compliance professional with a diverse background in all aspects of drug and medical device development, approval, commercialization, compliance, intellectual property and commercial transactions. She has been a partner with several international law firms and currently serves as General Counsel to Validus Pharmaceuticals. In this capacity, Ms. Restaino works with her executive team on all legal matters relating to acquiring, manufacturing and selling pharmaceutical products including product launch, commercialization, complex licensing arrangements, joint ventures and clinical development. She is responsible for all legal support for corporate matters, healthcare law and regulatory compliance, sales and marketing, intellectual property and commercial transactions.

Ms. Restaino also serves as Lead Compliance Counsel with direct responsibility for developing, implementing and monitoring business-wide business, ethics and regulatory compliance programs including Codes of Conduct and Ethics and policies, systems and processes to reduce risk of Anti-kickback, FCA and related healthcare law violations.

JILL FALLOWS MACALUSO

Chief Compliance Officer and Vice President
NOVO NORDISK INC.

As Chief Compliance Officer and Vice President for Novo Nordisk Inc., Jill Fallows Macaluso Esq., RN, is charged with developing, operating, and overseeing an effective healthcare compliance program within the United States.

Utilizing 15 years of industry experience, Ms. Fallows Macaluso has been instrumental in driving the evolution of Novo Nordisk's compliance program to support industry leading business practices. By serving as a corporate compliance partner, she has spearheaded efforts focused on rebranding and operational efficiency, as well as, strengthening global partnerships. As an Executive Team member, she chairs the Executive Compliance Committee and plays an active role ensuring compliance is incorporated into company decision-making processes.

Ms. Fallows Macaluso began assuming leadership responsibilities when she joined the Compliance Department as Senior Director in 2012. Prior to joining the Compliance Department, she was Senior Corporate Counsel in the Novo Nordisk Inc. Legal Department for nine years where she held several key positions.

Previously, Ms. Fallows Macaluso was with the General Corporate and Healthcare practice of Day Pitney, LLP. She holds a Bachelor of Science in Nursing from the University of Pennsylvania and a Juris Doctorate from Rutgers University School of Law.

Raegan A. McClain

Pernix Therapeutics, LLC
VP, Compliance & Legal

Raegan McClain has over 16 years of legal and compliance experience working in large and specialty global pharmaceutical and medical device organizations. In her current role as VP, Compliance & Legal at Pernix Therapeutics, a specialty pharmaceutical company focusing in the pain and neurology space, Raegan is responsible for implementing and overseeing Pernix's compliance program and supporting various legal and compliance initiatives for the organization.

Prior to joining Pernix, Ms. McClain was responsible for implementing the compliance program at Novocure, LLC, a global oncology device company where she partnered with senior leadership across all business functions. Ms. McClain began her legal career at DLA, a large international law firm, where she focused on corporate, healthcare and pharmaceutical transactional work, and also previously held in-house senior positions at Sanofi-Aventis, Eurand Pharmaceuticals and Aptalis Pharma where she supported various business teams including pharmaceutical development, clinical, clinical operations, alliances & partnerships, strategic pipelines, medical affairs, project management, regulatory, pharmacovigilance, clinical quality assurance, sales, marketing, trade, managed care and commercial operations.

Prior to entering the workforce, Ms. McClain earned a Bachelor of Science Degree from the Pennsylvania State University, her Juris Doctorate from the University of Pittsburgh and her Masters in Law in Health Law at Loyola University in Chicago. She is also a Certified Compliance & Ethics Professional.

Bill McKenzie

Group Leader, Health Care Compliance
JOHNSON & JOHNSON

Bill McKenzie is a Group Leader, Health Care Compliance for Johnson & Johnson's Medical Device business in North America. He oversees the HCC function for DePuy Synthes US, Ethicon US, and J&J Medical Devices in Canada, and he sits on the US Leadership Team for DePuy Synthes.

In this capacity Mr. McKenzie oversees all aspects of the HCC program for the North America commercial organizations, ensuring the appropriate policies and procedures are in place; that all associates are trained on the relevant policies; appropriate testing and monitoring of transactions is conducted; instances of potential noncompliance are communicated to and investigated by HCC; and that corrective action is taken when necessary.

Mr. McKenzie is a member of the AdvaMed Device & Diagnostics Compliance Group and has spoken at various compliance conferences throughout the US.

Prior to joining DePuy's Health Care Compliance department, Mr. McKenzie served as Financial Controller for the DePuy companies in Massachusetts and spent ten years in the Finance organization in a variety of roles. Before joining Johnson & Johnson, Bill was an audit manager in the Boston and Providence offices of KPMG. He audited health care providers, financial institutions, and not-for-profit organizations.

Mr.McKenzie holds a master's degree in business administration from Bryant University and a bachelor's degree in accounting from the University of Massachusetts. He is a Certified Compliance and Ethics Professional and holds an HCC certification from Seton Hall University Law School. He is a certified public accountant and resides in Massachusetts.

JOHN P. OROHO

Executive Vice President, Chief Strategy Officer; Principal
PORZIO LIFE SCIENCES AND PORZIO BROMBERG & NEWMAN

John Oroho 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 Regulatory Counseling Department. He concentrates his law practice in regulatory compliance with

respect to the Prescription Drug Marketing Act (PDMA), Antikickback statute, False Claims 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. He has an extensive pharmaceutical regulatory and compliance background. He also spent three years as General Counsel for Integrated Pharma Technologies and Computer Systems Services & Consulting, Inc.

Mr. Oroho was recognized by *Who's Who Legal: Life Sciences* in 2015 and by *Who's Who Legal: Life Sciences – Regulatory* in 2016. He received his B.S., *with honors*, from the United States Merchant Marine Academy, and his J.D. from the University of Notre Dame School of Law.

LARRY PLATKIN

Vice President Head, U.S. Office of Compliance
BAYER CORPORATION

Larry Platkin is currently Vice President and Head, U.S. Office of Compliance for Bayer Corporation. Mr. Platkin was named Vice President and Compliance Officer of Bayer HealthCare in June, 2008, responsible for the implementation of its 2008 Corporate Integrity Agreement, as well as compliance strategy, development of policies and procedures, investigations, communications and training.

Prior to that, Mr. Platkin held positions of increasing responsibility in the Bayer Law, Patents and Compliance Department, counseling the pharmaceuticals business (and its predecessor, Berlex Laboratories, Inc.). Prior to that, he held positions in the Legal Departments of Ciba-Geigy Corporation and American Home Products Corp. Mr. Platkin began his legal career in private practice in Newark, NJ.

Mr. Platkin is a graduate of Rutgers College, New Brunswick, NJ and Rutgers University School of Law, Newark, NJ.

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 Regulatory Counseling 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 P. SHARKEY

Vice President; Principal

PORZIO LIFE SCIENCES AND PORZIO BROMBERG & NEWMAN

Brian P. Sharkey is a Vice President 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 Principal of Porzio, Bromberg & Newman PC and a member of the firm's Life Sciences Compliance and Regulatory Counseling Department.

Mr. Sharkey received a J.D. from Seton Hall University School of Law, magna cum laude, and his B.A. from The College of New Jersey.

ALEXIS STROUD

Director, Ethics & Compliance

Purdue Pharma L.P.

Alexis Stroud is the Director, Corporate Compliance at Purdue Pharma where she leads the company's ethics and compliance program. Ms. Stroud is responsible for the design, implementation, and continuous improvement of Purdue's compliance program, with primary responsibility for compliance auditing and monitoring, fair market value analysis, developing and implementing compliance reporting systems, and including supervision and development of compliance professionals with responsibilities in these areas.

Ms. Stroud's career has included serving as Validation Scientist for CSSC, conducting computerized system validation, regulatory training, 21 CFR Part 11 assessments, equipment qualification, quality system development, and auditing for over 30 life science companies. Ms. Stroud directed the Quality and Compliance Department for QPharma, Inc., offering a wide range of regulatory and compliance solutions. Ms. Stroud is a member of the American Society for Quality, the Regulatory Affairs Professionals Society, and the Healthcare Businesswomen's Association. Ms. Stroud is also an ASQ Certified Quality Auditor.