PRESENTER BIOS

EDWARD JOHN ALLERA

Co-head, Life Sciences Practice
Buchanan Ingersoll & Rooney

Edward John Allera, co-chair of the firm's FDA group, counsels clients on new product development and business opportunities in the areas of pharmaceuticals, hi-tech products, medical devices, food and cosmetics. Ed has devoted his entire career to health care, as both a pharmacist and an attorney. He began his career at the Food and Drug Administration (FDA), where he served as associate chief counsel. Because of his ability to integrate science and the law, Ed has become highly-respected by clients in the pharma/biotech industry as the person to call in a "make-or-break" situation.

BARBARA BINZAK BLUMENFELD, PH.D.

Shareholder, Life Sciences
Buchanan Ingersoll & Rooney

Barbara A. Binzak Blumenfeld, Ph.D., helps clients make and execute on strategic decisions about FDA-regulated product approvals. She leverages her unique background, integrating science and biomedical ethics into her legal practice to create true value for her clients. For example, Barbara works closely with Buchanan's IP attorneys to create a holistic IP/FDA strategy that takes into account the company's patent portfolio, FDA Orange Book listings, and FDA-granted regulatory exclusivity. Barbara assists clients with FDA regulatory matters arising before, during, and after product approval and marketing. She has worked with clients on virtually all types of FDA-regulated products, including drugs (human and veterinary), biologics, regenerative medicine (cell and gene therapies), medical devices, foods (human and veterinary), and combination products.

MICHAEL DALEY, PH.D.

Principal Consultant
Cognate Consultants LLC

Michael after receiving his B.A. degree in Biology from Northeastern University started his graduate education at Washington University School of Medicine, and later at the University of New Mexico School of Medicine in the Pathology Departments, receiving a M.S. and Ph.D. respectively. He became motivated to conduct research on mechanisms of disease and immunooncolgy. He then continued his training as a post-doctoral fellow, and later as an Instructor on the faculty of the Department of Biology at M.I.T. Starting his industry career in R&D at the former American Cyanamid, now Pfizer, he then went on to found OrthogenRx, Inc. in 2013. OrthogenRx business model was to in-license ex-U.S. products for the U.S., specifically for the treatment of osteoarthritis knee pain. He obtained two FDA product approvals by 2017 and transitioned the Company from an early-stage development to a fully integrated commercial company with 26 employees and sales exceeding $80MM by 2021 with a rich pipeline of products in development. OrthogenRx mission was to preserve highest ethical standards and patient care, while building greater transparency and partnerships to facilitate access to affordable healthcare products. In January 2022, he successfully negotiated the sale of OrthogenRx to Avanos (annual global sales of $750MM) for a deal valued with earnouts of over $200MM. Presently, Dr. Daley is active in consulting and investing in the regional biopharma and medtech ecosystem, and maintains affiliations with the Medical Device Manufacturers Association, Bio New Jersey, Tech United New Jersey, Philadelphia Alliance for Capital and Technology, Philly BIO, Life Sciences Collaborative and Pharmaceutical Consulting Consortium International. Dr. Daley was the 2021 PACT CEO of the Year, 2019 Innovative Company of the Year from Bio New Jersey, 2018 ECHO top 50 Irish Owned Companies, twice recipient of the Entrepreneur of the Year from the Pennsylvania Biotechnology Center (2018 & 2020), and recipient of the Scientific Achievement Award from American Cyanamid.

KATE EISENMANN

Director, Corporate Counsel
Otsuka America Pharmaceutical, Inc.

Kate serves as Director, Corporate Counsel to Otsuka America Pharmaceutical, Inc. Prior to going in-house, Kate practiced labor and employment law for over ten years, including most recently at Ogletree Deakins. Kate has extensive experience representing employers in litigation and providing routine advice and counseling in a wide-range of employment issues including launching DE&I initiatives.

A native of New Jersey, Kate attended Rutgers New Brunswick where she earned her B.A. in Communication and History, magna cum laude, and her J.D. from Rutgers School of Law - Camden.

BRIAN ELLMAN

Principal
Analysis Group

Brian J. Ellman, a principal in Analysis Group's Washington DC office, specializes in the application of microeconomics, statistics, and financial analysis to complex commercial litigation matters and government investigations. He has worked on behalf of the US Department of Justice and Federal Trade Commission, and has consulted to law firms in litigation matters involving antitrust and competition, intellectual property, data breaches, and general commercial damages issues. Mr. Ellman has conducted market analyses and assessments of competitive effects in major antitrust matters, as well as for proposed and executed mergers. He has also conducted statistical analysis, market research, and other economic analyses to evaluate the appropriateness of class certification in antitrust and commercial disputes, and to assess liability and damages. Mr. Ellman's expertise in matters involving the pharmaceutical and medical device industries includes analyzing therapeutic markets and competitive dynamics and assessing evidence of causal associations in product liability suits. He has published articles on a wide range of topics, including the economics of biosimilar drugs. Mr. Ellman received his M.B.A. from the Yale School of Management and his B.A. in international affairs from George Washington University.

TOM EVEGAN

Principal, Strategy & Management Consulting
RSM

Tom Evegan is a Principal at RSM, leading the Revenue Contract Management services division for life sciences. Tom has 20 years of experience in the life sciences industry with a proven record supporting companies varying in size and business model. His expertise includes market access, patient services, government pricing, commercial and government contracting, trade and reimbursement, commercial analytics and gross to net. Serving in several leadership roles, he most recently was the founder and president of a firm specializing in life science advisory, managed service operations, professional management and M&A consulting.

MATTHEW FEDOWITZ

Shareholder, Intellectual Property
Buchanan Ingersoll & Rooney

Matthew is a life sciences industry lawyer who focuses his practice on achieving the business goals of clients. This includes patent portfolio development and strategic patent prosecution; counseling with regard to FDA regulatory issues and their intersection with intellectual property; litigation in federal district court; and inter partes proceedings before the Patent Trial and Appeal Board.

Matthew has a particular expertise in the pharmaceutical, life science and medical device fields. He draws on this experience to assist clients in the identification of products as business development opportunities and to obtain and maneuver through intellectual property hurdles by coordinating due diligence, preparing patent validity, freedom-to-operate and non-infringement opinions, and resolving disputes in Federal District Court and before the U.S. Patent and Trademark Office.

LLOYD FREEMAN

Chief Diversity & Inclusion Officer
Buchanan Ingersoll & Rooney

Lloyd Freeman is responsible for advancing and expanding diversity throughout the firm and across the legal industry as a whole. Lloyd develops and drives the firm's diversity initiatives related to attorney hiring, retention and advancement. He oversees the firm's Diversity & Inclusion Council and promotes equitable policies, mentorship and sponsorship as key retention initiatives. Through the use of data & analytics, Lloyd identifies potential risk areas and centers intentionality and accountability to drive meaningful impact. Lloyd also works to ensure that the firm continues to be a driver of diversity and inclusion in the communities in which it serves. Some of these initiatives include the firm's supplier diversity program, corporate share program as well as key partnerships with local nonprofits dedicated to promoting all dimensions of diversity. Additionally, he collaborates with Buchanan's clients to meet and advance their diversity and inclusion goals and coordinates partnerships for mutually-beneficial programs such as internships, thought leadership, speaking engagements and more. Lloyd is also involved in nurturing key partnerships to drive strategic diversity and inclusion marketing, as well as business development initiatives. Lloyd has been a champion of diversity and inclusion in the legal profession throughout his career, including in his roles as a litigation partner and a Chief Diversity Officer at his previous firm. He is a sought-after speaker and has published articles on various diversity-related topics, including the impact of stigma and discrimination, best practices for inclusive workplaces, implicit bias, allyship and imposter syndrome, among others.

LAURIE LEVIN GOODSTINE

Senior Counsel, US Commercial Legal
AbbVie

Laurie Levin Goodstine leads legal support for the company's Eye Care business unit. Prior to working for AbbVie, Laurie spent 10 years working as an independent commercial legal and compliance consultant to various pharmaceutical companies. Laurie began her legal career as an IP, Commercial, and White-Collar Criminal Defense litigator at Goodwin in NY, before joining Warner Chilcott as in-house counsel. Prior to becoming an attorney, Laurie was a corporate educational software executive. Laurie holds a JD from Northwestern, an MBA from Kellogg, and a BA from the University of Pennsylvania.

JONATHAN JANOW

Shareholder, Litigation
Buchanan Ingersoll & Rooney

Jon is an experienced litigator specializing in commercial, antitrust, administrative, complex civil litigation, consumer protection, class actions and appeals. He has represented and counseled clients in a wide range of industries, with a particular expertise in pharmaceuticals and life sciences. Jon has extensive experience in federal and state antitrust and consumer protection, and provides clients with strategic counseling and insight to mitigate issues before they develop into potential liabilities. Jon also maintains an active pro bono practice, with a significant focus on voting rights litigation and representing unaccompanied immigrant children in state and federal court. He was named as Kids In Need of Defense's (KIND) Pro Bono Attorney of the Month in January 2012. He has also served as counsel to the League of Women Voters in several high-profile voting rights litigations.

SANDY LOREAUX

US President
Covis Pharma

Sandy Loreaux has over 25 years of experience in the Pharmaceutical Industry. She currently leads Covis Pharma's U.S. Operations in her role as U.S. President. Sandy joined Covis in November 2021 after previously serving as Senior Vice President & General Manager, U.S. Critical Care for Mallinckrodt Pharmaceuticals. She has led multiple Market Access Organizations in her roles as SVP, Head of Market Access at Mallinckrodt Pharmaceuticals and SVP, Head of Market Access and Commercial Operations at Bausch Health. Prior to that Sandy spent the first 18 years of her career at Sanofi and its legacy companies in various roles of increasing responsibility across, Medical Affairs, Sales, Marketing, and Market Access. Sandy is a Pharmacist by training and has a degree from Temple University School of Pharmacy from Philadelphia, PA.

JILL FALLOWS MACALUSO, ESQ., RN,

Corporate Vice President and Chief of Ethics, Compliance & Privacy Officer
Novo Nordisk, Inc.

Jill Fallows Macaluso Esq., RN, is the Corporate Vice President and Chief Ethics, Compliance & Privacy Officer for Novo Nordisk Inc. She has led the US Compliance Program since being appointed Chief Compliance Officer in September 2015, and her role has since expanded to include responsibility for the company's privacy program. Ms. Fallows Macaluso is responsible for leading a modern and effective Ethics, Compliance & Privacy Program that enables business success and meets evolving government expectations.

With 20 years of industry experience, Ms. Fallows Macaluso has evolved the Ethics, Compliance & Privacy Program to focus on proactive business partnership. She firmly believes that culture is critical to an organization's success and is committed to fostering a shared commitment to ethics, integrity, and trust throughout Novo Nordisk.

Ms. Fallows Macaluso joined Novo Nordisk in 2003. 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.

MYTHILI MARKOWSKI, PH.D.

Counsel, Intellectual Property
Buchanan Ingersoll & Rooney

Dr. Markowski focuses her practice on intellectual property law, specifically patent prosecution and litigation for clients in the pharmaceutical and biotechnology industries. For more than 16 years, she has assisted a range of clients from single inventors to large corporations to help secure, protect, or litigate their intellectual property. In her IP litigation practice, she has been associated with a number of inter partes review and patent interference matters before the Patent Trial and Appeal Board on behalf of Petitioners and Patent Owners. A number of these inter partes review proceedings were co-pending with district court action. Mythili's inter partes review experience includes involvement in all phases of the review proceedings.

JASON R. PARISH

Shareholder, Litigation
Buchanan Ingersoll & Rooney

Jason focuses his practice on complex litigation and government investigations. He has appeared before federal and state courts across the country and has taken numerous cases to trial. Jason has significant experience with issues facing the healthcare and life sciences industries and is the co-head of Buchanan's life sciences group. For the last several years, Jason has represented several generic drug companies in the nationwide Average Wholesale Price litigation. He coordinated the defense of dozens of lawsuits in federal and state courts across the country, including qui tam actions under the federal False Claims Act and civil enforcement actions by state attorneys general under state consumer protection, false claims, and false advertising statutes.

JAMES PETKUN

Director, Corporate Counsel
Sun Pharmaceuticals, Inc.; Taro Pharmaceutical Industries, Ltd.

James is Corporate Counsel and Director at Sun Pharma and its affiliate, Taro Pharmaceuticals, where he advises both global businesses on matters involving litigation, gov't affairs, disputes, antitrust/competition law, regulatory, transactions, Business Development/M&A, ethics & compliance, and corporate governance. James joined Sun and Taro from private practice where, as a partner at Klehr Harrison LLP, he represented companies in government investigations, regulatory enforcement matters, white collar criminal matters and related litigation. James previously served for 8 years as a federal prosecutor at the U.S. Attorney's Offices in Washington, D.C. and Philadelphia, within the U.S. Department of Justice, where he prosecuted complex economic crimes, led hundreds of investigations, and tried over 60 trials to verdict. He began his career as a litigation associate at Morgan Lewis & Bockius prior to serving as a law clerk to U.S. District Judge Michael Baylson in the Eastern District of Pennsylvania.

MANOJ K. RAGHUNANDANAN

President Global Self Care and Consumer Experience Organization (CxO)
Johnson & Johnson Consumer Health

Manoj Raghunandanan is President, Global Self Care and Consumer Experience Organization (CxO), and serves on the Consumer Health Leadership Team.

An inspirational, people-first leader, Manoj leads the $5B global Self Care organization and is responsible for setting a clear strategy and building the pipeline so the franchise continues its growth as a Consumer Health stronghold, with iconic brands including TYLENOL®, ZYRTEC® and NICORETTE®. With a servant leadership mindset, Manoj is adept at identifying the right marketing, commercialization and innovation solutions to grow in lead markets.

In addition, Manoj oversees an organization of subject matter experts across data sciences, insights and marketing – the Consumer Experience Organization (CxO). With Manoj's leadership, this team harnesses the power of our Consumer Health expertise and data-driven insights to unlock meaningful consumer experiences and advance capabilities that will accelerate growth and effectiveness around the world. The team's focus is insights and analytics, marketing capabilities, technology platforms, partnerships and connected commerce.

Manoj is highly respected for his ability to create team dynamics where individuals feel heard and valued. He was an architect of Consumer Health's transformation, where his business acumen and emotional intelligence were essential in creating new ways of working with new operating plans that employees understood and embraced, and that have led to continuous growth. Building on that success, he is now leading the sector's transformation into a digital-first organization.

Manoj joined J&J Consumer Health in 2007, through the Pfizer Consumer acquisition. He has since held various marketing roles in the Consumer Health and Medical Device sectors with increasing responsibility for driving iconic brands, including: LISTERINE®, TYLENOL®, ACUVUE®, NICORETTE® and ZYRTEC®.

Manoj is a vocal advocate for diversity, equity and inclusion at work, across the industry and in his personal life. With this passion, he co-founded J&J's Diversity Marketing Team and sits on a number of boards including: ANA's Alliance for Inclusive and Multicultural Marketing, Google's Health Marketing and Advertising Board, and the Global Self Care Federation executive board. He is also a proud member of the Phi Beta Sigma Fraternity, Inc., and Jack and Jill Father's Auxiliary.

Manoj earned his MBA at the Fox School of Business at Temple University and speaks regularly on DE&I, leadership and marketing at industry forums and at academic institutions.

LINDA PISSOTT REIG

Co-Head, FDA & Biotechnology
Buchanan Ingersoll & Rooney

Linda Pissott Reig focuses her practice on the life sciences industry. She has extensive experience with the laws and industry standards that apply to the marketing and sale of pharmaceuticals, medical devices, biologics, dietary supplements and medical foods.

Linda co-chairs the firm's FDA Section. She joined Buchanan Ingersoll & Rooney after having previously served as a principal for a New Jersey–based law firm, and Vice President, Compliance Services of its pharmaceutical services subsidiary.

DAVID SANDOVAL

Chief Legal Officer,
Chief Compliance Officer
Leadiant Biosciences

David Sandoval is Chief Legal Officer and Chief Compliance Officer at Leadiant Biosciences Inc., a small, entrepreneurial biopharma company exclusively focused on rare diseases. When David took on leadership of the Legal function at Leadiant in 2010, he was the youngest General Counsel/legal head in the industry. For over 12 years, David has led the in-house Legal and Compliance Departments, and has played a key strategic role on the Executive team. David also serves on the Governance Committee of the Board of Directors. David has also served as interim head of Human Resources, head of Quality Assurance, and been a lead in the Government Affairs function.

Prior to Leadiant, David served as Assistant General Counsel for Enzon Pharmaceuticals, having participated in a major divestiture of its commercial, manufacturing, and R&D business. David began working as an in-house counsel for Eisai, Inc., supporting its neurology and oncology product portfolios. David started out at the "big law" firm of O'Melveny & Myers in New York City and at the law firm of Porzio, Bromberg, and Newman, where he developed a specialty in Life Sciences law.

David holds an A.B. from Cornell University with a double major in English and Philosophy and a concentration (minor) in Law & Society, a J.D. from NYU School of Law, and a Certificate of Business Administration from Georgetown University.

SHARON SMALL

Director, Pharma Counsel, Market Access
Novartis

Sharon counsels clients on regulatory and compliance issues related to the sale and reimbursement of pharmaceutical products. Prior to joining Novartis, Sharon was Counsel in the Life Science Practices Group at Porzio, Bromberg & Newman, P.C., in Morristown, New Jersey where she counselled pharmaceutical companies on Market Access and Compliance matters. She also worked as in-house counsel at Celgene (seconded) and Merck providing legal support in R&D and Commercial transactions. Sharon earned her J.D. from the University of Pennsylvania Law School and her Bachelor of Science Degree, magna cum laude, from Fairleigh Dickinson University, New Jersey. Sharon also earned a Certificate in Health Care Compliance from Seton Hall University Law School.

Sharon has served on several committees at professional organizations, including Vice Chair, Membership for the Life Sciences Practice Group of the American Health Lawyers Association, the Scholarship Committee for the Garden State Bar Association and the Health Law Section of the National Bar Association. She regularly speaks on Compliance and Market Access topics in the Life Sciences industry and mentors Law Students and young lawyers. Committed to pro bono and community service, she serves as a member of the board of Legal Services of Northwest Jersey and volunteers her time in their Tenancy Program. She has two wonderful children and enjoys reading, sports and travel.

MICHAEL P. STRAZZELLA

Senior Principal, Government Relations
Administrative Head, Washington, D.C. Office
Practice Group Leader, Federal Government Relations
Buchanan Ingersoll & Rooney

Michael has deep experience in federal government relations, legislative strategy, grassroots advocacy, political action committees, political campaigns and coalition building. He focuses his practice on the health industry (providers and payors) and works in various industries, including pharmaceutical, hospital and health systems, health plans and retail and compounding pharmacy industries. Adept at navigating relationships, Michael works closely with Congress and the Executive Branch, including the Department of Health and Human Services; Centers for Medicare and Medicaid Services; the Food and Drug Administration; U.S. Customs; and the Drug Enforcement Administration to create effective lobbying strategies as they apply to the health care sector.

JOEL C. TROTTER

Assistant General Counsel
GSK

Joel provides legal counsel and support to GSK's global and US vaccines businesses including product sales, marketing and promotion; trade strategy, pricing and contracting; market access and policy; early-stage commercialization; and global supply chain. Joel is a member of the Diversity, Equity and Inclusion Committee within GSK Legal and is a past US co-lead of Mosaic, GSK's Black employee resource group. Prior to joining GSK, Joel was transaction counsel for Ricoh USA and an associate at Stradley Ronon.

Outside of office hours, Joel serves as President of the Board of Trustees for Richard Allen Preparatory Charter School in Southwest Philadelphia, coaches a youth track and field team, and struggles to improve his golf game.