



Symposium Presenters

Industry Spotlight Presenters



Tim Boarini

Assistant General Counsel, Head of Transactions
Eli Lilly

Tim Boarini is Assistant General Counsel and Head of Transactions at Eli Lilly, where he leads the business development transactions team. He is a corporate transactional attorney with more than 20 years of experience advising on M&A, licensing, and complex commercial transactions across the life sciences sector. Tim has deep industry expertise spanning research and development, pricing, managed care, and the full lifecycle of biopharma products. He earned his J.D. from the University of Iowa College of Law and his B.A. from Middlebury College.



Andrea DiFabio

Chief Legal Officer and Corporate Secretary
Xenon Pharmaceuticals

Andrea DiFabio is the Chief Legal Officer and Corporate Secretary at Xenon Pharmaceuticals. Andrea joined Xenon from Repertoire Immune Medicines, where, as Chief Legal & Administrative Officer and Corporate Secretary, she played a pivotal role in business development and investor relations, risk management, and intellectual property and corporate communication strategy. Her impressive career also includes serving as Chief Legal Officer and Corporate Secretary at Codiak Biosciences and Bioverativ Inc. At Bioverativ, she was instrumental in the company's spin-off from Biogen and its subsequent \$11.6 billion acquisition by Sanofi. During her extensive time at Biogen, she was involved in key strategic transactions and the successful commercial launch of numerous neurology products. Earlier in her career, she was part of the executive team and senior legal counsel at Parexel International. Andrea earned her JD degree from Northeastern University School of Law and a BA, Summa Cum Laude, from Boston University, where she also participated in the Executive MBA Program.

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Joe Franklin, JD, PhD

Chief Legal and Policy Officer
Biotechnology Innovation Organization (BIO)

Joe Franklin, JD, PhD, is the Chief Legal and Policy Officer at the Biotechnology Innovation Organization (BIO). In this role, he leads BIO's legal function and oversees key policy priorities including access and reimbursement, intellectual property, national security, and international affairs. Joe joined BIO in 2026 from Covington, where he played an active role in the firm's life sciences and artificial intelligence practices, advising clients in the biopharma and tech industries on complex FDA regulatory matters, clinical research, and the deployment of artificial intelligence. Previously, Joe was Chief Counsel for Regulatory and Strategic Affairs at Verily, Alphabet's precision health company. Over nearly a decade as an attorney and policy lead at FDA, Joe held several senior leadership positions and advised on a range of issues. Joe spent multiple periods in FDA's Office of the Chief Counsel, where he advised agency staff and leadership on biologics and biosimilars, emergency use authorizations, user fees, drug compounding, and controlled substances, among other areas. Joe advised FDA on the reauthorization of the Prescription Drug User Fee Act (PDUFA VI) and Biosimilar User Fee Act (BsUFA II) and development of the commitment letters for these programs.



Peter Kolchinsky, PhD

Founder and Managing Partner
RA Capital Management

Peter Kolchinsky is a founder and Managing Partner at RA Capital Management and author of *The Great American Drug Deal*. Peter is active in both public and private investments in companies developing drugs, medical devices, diagnostics, and research tools and serves on the boards of publicly- and privately-held life science companies. Peter also leads the firm's engagement and publishing efforts, which aim to make a positive social impact and spark collaboration among healthcare stakeholders, including patients, physicians, researchers, policymakers, and industry. He served on the Board of Global Science and Technology for the National Academy of Sciences, is the author of *The Entrepreneur's Guide to a Biotech Startup*, and frequently writes and speaks on the future of biotechnology innovation. Peter founded and serves as a Director of No Patient Left Behind, a non-profit advocate for healthcare reforms that would make today's medicines affordable to patients and promote the innovation that gives all of us hope for tomorrow. He holds a BA from Cornell University and a PhD in Virology from Harvard University.

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Rakel Meir

Chief Research Development & Operations Counsel
Biogen

Rakel Meir is Senior Vice President and Chief Research Development & Operations Counsel at Biogen, where she serves as a strategic legal partner to the R&D organization, advising on clinical development programs, research collaborations, and operational matters. She leads a team of R&D counsel supporting programs, clinical contracting, and manufacturing and operations. Rakel has more than two decades of experience in health law and regulatory matters, including prior senior legal roles at Tufts Health Plan, and holds a J.D. from Boston University School of Law and a B.A. from Wellesley College.



Sean Pitt

Senior Managing Director, Biopharma
Leerink Partners

Sean Pitt is a Senior Managing Director in Investment Banking at Leerink Partners. Sean has over a decade of healthcare investment banking experience and joined Leerink Partners in 2017. He has advised a broad range of biopharma companies across equity and strategic advisory assignments and transactions, having worked on over 200 transactions during his career. He earned a B.S. from The University of Sydney.



Janet Woodcock, MD

Former Acting FDA Commissioner, FDA Principal Deputy Commissioner, and
Director of FDA's Center for Drug Evaluation and Research

Dr. Janet Woodcock recently completed a long career at FDA. She served as Director of the Center for Drug Evaluation and Research for over twenty years in several stretches. Most recently she served as Principal Deputy Commissioner and prior to that as Acting FDA Commissioner. She held multiple other senior positions at FDA including at the Center for Biologics Evaluation and Research. She was the therapeutics lead for "Operation Warp Speed" during the COVID pandemic. Her most recent effort was spearheading a major reorganization of FDA's foods program and the Office of Regulatory Affairs. Dr. Woodcock completed many major regulatory initiatives during her FDA tenure. She was instrumental in getting the biosimilars legislation enacted and worked to ensure adoption in the clinical community.

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**Krista Carver**

Partner, Washington

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Krista Carver co-chairs Covington's global Food, Drug, and Device Practice Group and the firm's Life Sciences – Pharmaceutical and Biotechnology Industry Group. Drawing on her more than 18 years of experience at the firm, she provides strategic and practical advice to clients on an array of FDA regulatory issues, including those that intersect with other areas such as healthcare. Ms. Carver also assists clients with advocacy before FDA, including formal dispute resolution and citizen petitions, and maintains an active policy practice addressing legislative issues surrounding amendments to the Federal Food, Drug, and Cosmetic Act and related laws. *Chambers USA* reports that Krista “is a brilliant lawyer with deep technical expertise that she is able to boil down clearly and succinctly,” and that she “is incredibly impressive in biosimilars issues and biologics,” per *Chambers* sources. Krista co-chairs Covington's [IRA Task Force](#).

**Grant Castle**

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Grant Castle is one of the Co-chairs of Covington's Life Sciences Industry Group and is Head of Covington's European Life Sciences Regulatory Practice. He is a partner in London, Brussels, and Dublin practicing in the areas of EU, UK, and Irish life sciences regulatory law. He supports innovative pharmaceutical, biotech, medical device and diagnostics manufacturers on regulatory, compliance, legislative, policy, market access and public law litigation matters in the EU, UK, and Irish Courts.

Grant regularly advises on EU and UK regulatory pathways to market for pharmaceuticals and medical devices, including *in vitro* diagnostics and on associated product life cycle management; Pharmaceutical GxPs, including those governing pharmacovigilance, manufacturing, the supply chain and both clinical and non-clinical research; Medical device CE and UKCA marking, quality systems, device vigilance and rules governing clinical investigations and performance evaluations of medical devices and *in vitro* diagnostics; Advertising and promotion of both pharmaceuticals and medical devices; and Pricing, reimbursement and market access for both pharmaceuticals and medical devices. Grant also handles procedural matters before EU, UK and Irish regulators and UK and Irish market access bodies, where necessary bringing judicial reviews for his life sciences clients before the EU, UK and Irish Courts.



Victoria Corke

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Victoria Corke is of counsel in Covington's Healthcare Practice Group. She is a recognized leader entrusted with the most complex, high-profile, and sensitive health care legal issues related to the Medicare Program, drug pricing and Inflation Reduction Act (IRA) implementation, and pharmacy benefit managers (PBMs). Victoria joins the firm after serving as a Supervisory Attorney-Advisor at the U.S. Department of Health and Human Services (HHS), Office of the General Counsel, Centers for Medicare & Medicaid Services (CMS) Division. There she led the team of attorneys advising CMS on implementation of the Medicare drug pricing provisions of the Inflation Reduction Act (IRA). Victoria is knowledgeable on all aspects of rulemaking under the Administrative Procedure Act and section 1871 of the Social Security Act. She spearheaded the agency's strategic response to the Supreme Court's decision in *Azar v. Allina Health Services*. Victoria was the primary HHS legal expert on Accountable Care Organizations (ACOs), with deep expertise in all Medicare ACO initiatives, including the Medicare Shared Savings Program and innovative ACO models tested by the Center for Medicare and Medicaid Innovation.



Denise Esposito

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Denise Esposito co-chairs Covington's global Life Sciences Industry Group. Denise has more than 30 years of experience in the life sciences industry, including in senior leadership roles within the U.S. Food and Drug Administration (FDA), as the General Counsel of a publicly traded biopharmaceutical company, and as a Partner in private practice. She provides strategic, policy, and regulatory advice to biopharmaceutical, medical device, and other FDA-regulated clients, with a focus on matters that involve navigation of FDA and the complex political and policy challenges faced by regulated industry. Denise's practice includes advising clients on product development, marketing authorization strategies, incentive programs, expedited approval programs, life cycle management, and the advertising and promotion of medical products. She works with clients on FDA engagement strategies, formal and informal FDA dispute resolution, FDA administrative hearings and public meetings, and crisis management around FDA actions.



TJ Garrigan

Senior Advisor, Washington

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TJ Garrigan is a senior advisor in Covington's Health Care Practice Group. He is a non-lawyer, provides strategic policy advice to life sciences companies on key issues including drug pricing and Inflation Reduction Act (IRA) implementation, pharmacy benefit managers (PBMs), and the 340B program.

TJ joined the firm after having served as Deputy Director for the Division of Policy at the Centers for Medicare & Medicaid Services (CMS). At CMS, he was responsible for policy development for the Medicare Drug Price Negotiation and Medicare Inflation Rebate programs created by the IRA. He served as a member of the leadership team for the Medicare Drug Rebate and Negotiations Group which was created after passage of the IRA. TJ oversaw the drafting, editing, briefing, and approval of policy documents for the programs, including guidances, rules, and other technical communications. He advised group leadership, agency leadership, and political policy officials on various policy recommendations and decisions. Prior to his role at CMS, TJ was Director for Policy and Regulatory Affairs at CVS Health and served as lead enterprise-wide policy staffer on a variety of issues, including drug pricing and competition, drug supply chain, health IT, privacy, value-based payments, and price transparency. Prior to CVS, TJ served as Director of Policy at the Association for Accessible Medicines (previously the Generic Pharmaceutical Association).



Megan Gates

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Megan Gates has been guiding publicly traded and late-stage private companies, primarily in the life sciences industry, through capital-raising transactions, SEC reporting compliance and corporate governance obligations, and strategic mergers and acquisitions, for over 30 years. Her clients benefit from the client-focused perspective she gained during a prior in-house counsel role with Thermo Electron Corporation, where she was responsible for securities offerings and compliance for the corporation and its 23 publicly traded subsidiaries. Prior to joining Covington, Megan served as Chair of the Corporate Section, Co-chair of the Securities & Capital Markets Practice Group, and as a former member of the Policy Committee of a Boston-based law firm. Megan frequently speaks at conferences on securities offerings, corporate governance, and compliance matters, including at Boston Bar Association panels and industry meetings. She is also active in community organizations in Boston, serving as chair-elect of the board of trustees of the Pine Street Inn, and the president of the Boston Bar Foundation.



Kristie Gurley

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Kristie Gurley is a partner in Covington's Health Care Practice Group. She advises life sciences clients on complex pricing, reimbursement, and market access issues. Kristie brings unique insight from her recent experience serving in the Office of the General Counsel of the U.S. Department of Health and Human Services (HHS), where she supported the Centers for Medicare & Medicaid Services (CMS) on drug pricing issues, including implementation of the Inflation Reduction Act (IRA). In this role, Kristie served as a lead attorney on the IRA Medicare Drug Price Negotiation Program, including with respect to policy development, operations, and the first cycle of negotiations. She also supported the Medicare Prescription Drug Inflation Rebate Program and additional IRA implementation efforts, Medicaid Drug Rebate Program rulemaking and agency determinations, and the Center for Medicare & Medicaid Innovation's development and launch of a model for cell and gene therapies. Kristie's practice involves strategic, policy, and regulatory advice supporting market access for drug and biological products. Kristie provides advice related to federal health care program coverage and reimbursement, Medicaid price reporting, agency engagement, payer contracting and formulary access, value-based contracting, and other issues under federal and state drug pricing regimes.



John Hurvitz

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John Hurvitz advises both established and emerging life sciences companies on their most important strategic transactions. For more than 25 years, John's practice has focused exclusively on meeting the specialized corporate, commercial, and transactional needs of the life sciences industry. As such, he serves as a trusted adviser to many of today's leading biotech and pharma companies, counseling his clients on all aspects of complex strategic alliances, M&A, and other transactions. John co-chairs Covington's Life Sciences-Pharma and Biotech Industry Group and heads the firm's Life Sciences Transactions Practice. John's broad experience representing both innovators and acquirers of technology across a range of transactions and technologies enables him to assist clients both in finding practical solutions to their most complex problems and in efficiently and cost-effectively handling routine corporate and commercial matters. John's clients and deal experience extend throughout the U.S., Europe, and Asia as well to emerging markets and include all segments of the industry—pharma, biotech, vaccines, medtech, diagnostics, animal health, digital health, and healthcare services. He has extensive recent experience with complex deals involving gene and cell therapies, regenerative medicine, immuno-oncology, and the central nervous system (CNS).

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Megan Keane

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Megan Keane is a partner in Covington's Litigation and Investigations Practice Group. She is a litigator, with over a decade of experience, whose practice focuses on representing life sciences clients in high-stakes patent litigation and other intellectual property matters. Megan has taken a leading role in successfully representing clients on complex matters from case inception through trial and appeal. She is an experienced trial litigator and has handled complex witness examinations and oral arguments, including in some of the national's leading patent jurisdictions. Megan specializes in matters concerning small molecules, biologics, and medical devices.



Michael Labson

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Mike Labson co-chairs Covington's global Life Sciences Industry Group and has been a trusted advisor to pharmaceutical and biotechnology clients for over 25 years. He draws on his wide range of regulatory expertise to provide strategic and compliance advice, and address FDA and other health care law issues in litigation, investigations, and transactions. He previously served in a number of firm leadership positions, including as a member of the firm's Management Committee and Executive Committee and as co-chair of the Diversity Committee.

**Henry Liu**

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Henry Liu is co-chair of Covington's global Antitrust and Competition Law Practice Group, and a nationally recognized antitrust lawyer with a distinguished background in both government and private practice. He offers clients a unique perspective shaped by senior agency leadership and success in high-stakes competition matters. His practice spans the full range of civil antitrust issues, including merger and conduct investigations, litigation, compliance, and strategic counseling. Henry returned to Covington after serving as Director of the Bureau of Competition at the Federal Trade Commission (FTC), where he led the agency's antitrust enforcement during a period of heightened scrutiny. Under his leadership, the Bureau brought nearly 20 merger and conduct challenges, issued over 40 second requests, and managed hundreds of investigations. He played a key role in merger litigation involving billions in deal value, with the FTC prevailing in matters such as *Kroger/Albertsons*, *Tapestry/Capri*, *IQVIA/Propel Media*, and *Novant/CHS*. His tenure was marked by a focus on litigation strategy, a series of high-profile wins, and strengthened coordination with global and state enforcers.

**Arun Venkataraman**

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Arun Venkataraman is a partner in Covington's International Trade Practice Group. He leverages 20 plus years of government and private sector experience to provide legal, policy, and strategic advice to clients on a range of international trade matters. Arun joined the firm after serving in senior roles at the U.S. Department of Commerce. Most recently, he served as the Senate-confirmed Assistant Secretary of Commerce for Global Markets and Director General of the U.S. and Foreign Commercial Service at the International Trade Administration (ITA) from 2022-2025. Arun led the federal government's efforts to expand commercial opportunities for U.S. firms overseas and foreign firms in the United States, including by facilitating deals between U.S. and foreign companies, improving commercial policy environments, resolving barriers to trade and investment, and negotiating governmental agreements to promote commercial partnerships. He also served as Counselor to the Secretary of Commerce, advising the Secretary on all aspects of foreign economic policy within the Department. In this role, Arun led negotiations with foreign governments on technology policy, as well as Section 232 steel and aluminum tariffs. Before joining the Biden Administration, Arun was Senior Director, Global Government Engagement, at Visa. He developed and executed engagement strategy, in advocacy before the U.S. and foreign governments, as well as with trade associations, international organizations, and other stakeholder groups on a range of international policy issues including digital economy, trade, tax, and sanctions.