Symposium Presenters

Industry Spotlight Presenters

Amy Abernethy

Cofounder
Highlander Health

Amy Abernethy, M.D., Ph.D., is cofounder of Highlander Health, an organization focused on advancing evidence generation for the new era of medical innovation. As an oncologist, serial entrepreneur, and standard setter, Dr. Abernethy is a champion for speeding the pace at which safe and effective treatments reach patients, and for progressive and responsible use of healthcare system's data. She is the former principal deputy commissioner of the U.S. Food and Drug Administration. While there, Dr. Abernethy led initiatives in advancing clinical evidence generation and personalized healthcare and also served as the agency's acting chief information officer.

Dr. Bryan Czyzewski

Managing Director, Healthcare Investment Banking
Jefferies

Bryan Czyzewski, PhD, is the Managing Director in Healthcare Investment Banking at Jefferies. Prior to Jefferies, Bryan was Assistant Vice President of Equity Research at Barclays, after starting in equity analysis at JMP Group. Before JMP, Bryan was in the Molecular Oncology group at Kadmon Corporation. Bryan received his Ph.D. in Cell Biology from NYU School of Medicine, where he worked on ion channel and membrane protein structural biology, and studied oncogenes and tumor suppressors at Memorial Sloan-Kettering Cancer Center.

Matthew Schumaker

Vice President and Head of Federal Government Affairs
Vertex Pharmaceuticals

Matthew Schumaker is the Vice President and Head of Federal Government Affairs at Vertex Pharmaceuticals in Washington, DC. He previously served as the Executive Director at Vertex Pharmaceuticals, Senior Director at Celgene, and Managing Director at the Biotechnology Industry Organization. He also worked with the Democratic Congressional Campaign Committee and the New Democrat Coalition in the U.S. House of Representatives. He holds a Bachelor of Arts in Political Science and Government from Baylor University and is skilled in politics, the pharmaceutical industry, and public speaking.

Wendell Taylor

Chief Corporation Counsel
Biogen

Wendell Taylor is the Chief Corporation Counsel at Biogen, where he manages the legal representation for Biogen's securities and disclosure functions, board of directors, business development, finance and tax, corporate affairs and information technology. Previously, he served as Chief Business Officer at Q-State Biosciences and Vice President of Business Development at Vertex Pharmaceuticals. At Vertex Pharmaceuticals, he led teams that out-licensed a multi-billion-dollar oncology franchise, acquired and in-licensed assets in the CF space and completed a broad range of acquisitions and collaborations across therapeutic areas and stages of development. Wendell holds a Juris Doctor from Boston University School of Law and a Bachelor of Science in Biology and History from The College of William and Mary.

Robin Walker

Chief Legal Officer and Corporate Secretary
Areteia Therapeutics

Robin Walker is the Chief Legal Officer and Corporate Secretary at Areteia Therapeutics. Previously, she served as Chief Legal Officer and Chief Compliance Officer at Goldfinch Bio, and as Senior Vice President, Head of Legal at Casebia Therapeutics. She holds a Juris Doctor from Boston University School of Law and a Bachelor of Arts in History from Vassar College.

Covington Presenters

Krista Carver
Partner, Washington
+1 202 662 5197
kcarver@cov.com

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. Krista 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.

Steven Fagell
Partner, Washington
+1 202 662 5293
sfagell@cov.com

Steve Fagell co-chairs Covington’s white collar defense and investigations practice, and he is widely recognized as one of the nation's leading white collar practitioners. As a former senior official in the Criminal Division at the U.S. Department of Justice, Steve represents multinational companies and senior executives in criminal and civil investigations by the Justice Department, the U.S. Securities and Exchange Commission, and other U.S. regulators. Steve is a two-time *Law360* "White Collar MVP" winner (in 2023 and 2020), an award that recognizes the most outstanding practitioners in the field each year nationwide. *Law360* has highlighted the “big wins,” which include five corporate declinations from DOJ or the SEC in a single year, and “impressive, relatively painless resolutions” that Steve has obtained for “prominent corporate clients.*"* *Chambers USA* has long ranked him as a leading white collar lawyer in Washington, DC and as a nationwide FCPA expert.

Joe Franklin
Special Counsel, Washington
+1 202 662 5553
jfranklin@cov.com

Joe Franklin is special counsel in Covington's Food, Drug and Device Practice Group. His practice includes emerging medical technologies, research uses of real world and clinical trial data, and the deployment of artificial intelligence in healthcare and biopharma. He brings experience in both government and the health tech sector to advise clients on the unique challenges and opportunities posed by evolving regulatory frameworks for novel technologies. Joe was at Verily, Alphabet's precision health company, from 2021-2024, where his roles included Chief Counsel for Regulatory and Strategic Affairs. During his years of federal service, Joe held several senior policy roles at FDA, including as policy director for FDA Principal Deputy Commissioner Amy Abernethy. At FDA, Joe played a central role in the Agency's technology and data modernization strategy and had responsibilities for a broad portfolio of regulatory and scientific programs. While in FDA's Center for Drug Evaluation and Research (CDER), Joe built and led the biosimilars policy staff in the Office of New Drugs (OND). Joe was FDA's Deputy Chief of Staff in 2015.

Sarah Griffiths
Of Counsel, Boston
+1 617 603 8815
sgriffiths@cov.com

Sarah Griffiths is of counsel in Covington's Securities and Capital Markets Practice Group. She counsels clients on a broad range of capital markets transactions and advisory matters, with particular experience in the life sciences, technology, and financial services industries. Sarah regularly represents domestic and foreign private issuers, ranging from development stage to large public companies, and investment banks in initial public offerings, follow-on equity offerings, pre-IPO financings, investment-grade and convertible debt offerings, and private placements. She also regularly advises public companies with SEC reporting, securities, and stock exchange compliance matters and on a variety of corporate governance matters, including board and committee composition and procedures, environmental, social and governance (ESG) issues, and internal and disclosure controls.

Kristie Gurley
Partner, Washington
+1 202 662 5704
kgurley@cov.com

Kristie Gurley is a partner in Covington's Health Care Practice Group where 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.

Julienne Hearn
Of Counsel, Boston
+1 617 603 8888
jhearn@cov.com

Julienne Hearn is of counsel in Covington's Life Sciences Transactions Practice Group where she advises clients in the life sciences industry on their key strategic transactions. Her practice includes structuring, negotiating and documenting a broad array of agreements, including complex collaborations, licenses, R&D collaborations, co-promotion and co-commercialization agreements, supply and distribution arrangements and other commercial agreements. Julienne has represented multinational pharmaceutical companies, early stage biotechnology companies and academic institutions in transactions across a wide range of modalities, therapeutic areas and stages of the product lifecycle, in both domestic and cross-border contexts. She has also represented financial institutions, academic institutions and companies in financing-driven transactions, such as royalty monetizations and development funding arrangements.

John Hurvitz
Partner, Washington
+1 202 662 5319
jhurvitz@cov.com

John Hurvitz co-chairs Covington's Life Sciences-Pharma and Biotech Industry Group and heads the firm's Life Sciences Transactions Practice Group. John 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'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.

Robert Kelner
Partner, Washington
+1 202 662 5503
rkelner@cov.com

Robert Kelner is the chair of Covington's nationally recognized Election and Political Law Practice Group. He counsels clients on the full range of political law compliance matters, and defends clients in civil and criminal law enforcement investigations concerning political activity. He also leads the firm's prominent congressional investigations practice. Rob's political law compliance practice covers federal and state campaign finance, lobbying disclosure, pay to play, and government ethics laws. His expertise includes the Federal Election Campaign Act, Lobbying Disclosure Act, Ethics in Government Act, Foreign Agents Registration Act, and Foreign Corrupt Practices Act. He is also a leading authority on the arcane rules governing political contributions and marketing activities by registered investment advisers and municipal securities dealers.

Amy Leiser
Special Counsel, San Francisco
+1 415 591 7069
aleiser@cov.com

Amy Leiser is special counsel in Covington's Food, Drug, and Device Practice Group, where she assists medical device, clinical laboratory, pharmaceutical, and biotechnology clients to operate within a complex, highly regulated area in a way that supports achieving their business goals while minimizing regulatory and litigation risks. With a focus on medical device, digital health, and diagnostic products and laboratory services, Amy regularly advises clients on a variety of regulatory, legislative, and compliance matters, including under the Federal Food, Drug & Cosmetic Act (FDCA), Clinical Laboratory Improvement Amendments (CLIA), and state clinical laboratory laws. In her work with both new and established companies, Amy regularly counsels clients on development and marketing pathways for new products and services, including considerations relating to the scope of FDA's medical device jurisdiction as it relates to digital health tools and laboratory testing services; issues surrounding classification, clearance, and approval of new devices; and issues uniquely impacting combination products.

Gerald Masoudi
Partner, Washington
+1 202 662 5975
gmasoudi@cov.com

Gerald (Jerry) Masoudi is a partner in Covington's Food, Drug and Device Practice Group and has more than 25 years of broad experience in the life sciences industry. He served as Chief Counsel of the U.S. Food and Drug Administration (FDA) from 2007 to 2009. Jerry also has held positions in the Antitrust Division at the US Department of Justice; as the general counsel of two large, highly regulated companies; and as a partner in private practice. He provides strategic legal, policy, and regulatory advice to life sciences clients, with a focus on FDA enforcement of manufacturing and promotional rules. His practice will focus on guiding clients through significant corporate transactions, litigation, shifting regulatory expectations, and intensive crisis management activities.

Matt O'Connor
Partner, Boston and Washington
+1 617 603 8800
moconnor@cov.com

Matthew O'Connor is co-chair of the Life Sciences Litigation and Investigations Practice Group. Matt has extensive experience in all aspects of the white collar defense practice, with a particular emphasis representing life sciences companies and executives in broad-ranging federal and state civil and criminal investigations, follow-on consumer protection actions, and congressional investigations. Matt also has an active litigation practice in defending False Claims Act, RICO, and other follow-on litigation arising from governmental investigations. Matt also conducts internal investigations for a broad range of clients and advises life sciences companies on compliance practices.

Claire O'Rourke
Associate, Washington
+1 202 662 5269
corourke@cov.com

Claire O'Rourke is an associate in Covington's Data Privacy and Cybersecurity Practice Group. Working with emerging, national, and multinational companies and non-profits, Claire handles matters involving a range of data privacy and cybersecurity issues. Claire works with clients in the technology, financial services, life sciences, and healthcare industries, among others. She provides strategic advice on preparation for, response to, and legal obligations and risk mitigation after a cybersecurity incident. Claire also counsels clients on compliance with generally applicable and sector-specific federal and state privacy laws. She has assisted clients in drafting and reviewing privacy policies and terms of service, designing new products and services to comply with applicable privacy laws, and reviewing contract or other agreements for potential privacy issues. Prior to practicing law, Claire was a congressional staffer and worked for a trade association that assists small businesses.

Mona Patel
Partner, Boston
+1 617 603 8804
mpatel@cov.com

Mona Patel is a partner in Covington's White Collar Defense & Investigations Practice Group. She has extensive experience representing clients in large scale federal and state investigations brought by enforcement authorities, related qui tam or follow-on consumer protection litigation, internal investigations and compliance matters. She advises clients in the life sciences, defense, technology and manufacturing industries on a wide variety of white collar matters. As a partner in the White Collar Defense & Investigations practice, Mona advises clients on a broad range of compliance issues arising under federal and state healthcare laws and regulations and under the Foreign Corrupt Practices Act and other anti-bribery laws. She provides counsel and tailored training to companies developing, evaluating or strengthening their anti-corruption compliance programs and controls and investigations protocols, and routinely provides strategic due diligence advice on proposed corporate transactions, joint ventures and other engagements.

Caleb Skeath
Partner, Washington
+1 202 662 5119
cskeath@cov.com

Caleb Skeath is a partner in Covington's Data Privacy and Cybersecurity Practice Group. He advises clients on a broad range of cybersecurity and privacy issues, including cybersecurity incident response, cybersecurity and privacy compliance obligations, internal investigations, regulatory inquiries, and defending against class-action litigation. Caleb holds a Certified Information Systems Security Professional (CISSP) certification. Caleb specializes in assisting clients in responding to a wide variety of cybersecurity incidents, ranging from advanced persistent threats to theft or misuse of personal information or attacks utilizing destructive malware. Such assistance may include protecting the response to, and investigation of an incident under the attorney-client privilege, supervising response or investigation activities and interfacing with IT or information security personnel, and advising on engagement with internal stakeholders, vendors, and other third parties to maximize privilege protections, including the negotiation of appropriate contractual terms. Caleb has also advised numerous clients on assessing post-incident notification obligations under applicable state and federal law, developing communications strategies for internal and external stakeholders, and assessing and protecting against potential litigation or regulatory risk following an incident. In addition, he has advised several clients on responding to post-incident regulatory inquiries, including inquiries from the Federal Trade Commission and state Attorneys General.

Nicholas Xenakis
Of Counsel, Washington
+1 202 662 5846
nxenakis@cov.com

Nick Xenakis is of counsel in Covington's Public Policy Practice Group. He draws on his Capitol Hill and legal experience to provide public policy and crisis management counsel to clients in a range of industries. Nick assists clients in developing and implementing policy solutions to litigation and regulatory matters, including on issues involving antitrust, artificial intelligence, bankruptcy, criminal justice, financial services, immigration, intellectual property, life sciences, national security, and technology. He also represents companies and individuals in investigations before U.S. Senate and House Committees. Nick previously served as General Counsel for the U.S. Senate Judiciary Committee, where he managed committee staff and directed legislative efforts. He also participated in key judicial and Cabinet confirmations, including of Attorneys General and Supreme Court Justices. Before his time on Capitol Hill, Nick served as an attorney with the Federal Public Defender's Office for the Eastern District of Virginia.